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Genetic Information and Individual Rights

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Preface

Rainer Arnold, Roberto Cippitani, Valentina Colcelli

Genetic Information and Individual Rights

The present book is one of the outputs of the Jean Monnet Centre of Excellence "Rights and Science", established at the Department of Experimental Medicine of the University of Perugia. The Centre bring scholars from several universities who deal with legal and societal social context of the scientific research.

The work is focused on ethical and legal issues concerning the collection, the storage and other kinds of genetic data processing, especially within research and biomedical activities.

The theoretical and practical interest on these topics depends on the features of genetic information and on the potential threats to fundamental rights of the natural persons which may arise from research and therapeutic activities in genetics.

Other ethical issues also arise with respect to genetic information concerning animal and plants. This from the viewpoints of the environment protection environment and in order to avoid the illegitimate exploitation of ~~the~~ genetic resources.

Such issues should be considered within the complex and multilevel legal context, established by the European Union (with reference to the European Charter of the European Union and the EU legislation and praxis), by Members States and within international legal instruments.

The essays included in the book aim~~s~~ at showing some among the main bio-legal aspects of activities on genetic information.

The perspective of science as presented in the first part of the article by Dr. *Roland Arnold* and prof. *Rainer Arnold*. In this chapter, key aspects of genetic information are introduced. These comprise the basic molecular nature of genetic information, including the concepts of DNA, mutation and variation, as well as the implications of heredity. The stand of the art to technically read and process the genetic data are introduced. The importance of genetic information is motivated by several medical applications that rely on such data.

The perspective of science as presented in the first part of the article by Dr. Roland Arnold, Institute of Cancer and Genomic Sciences, College of Medical and Dental Sciences, University of Birmingham, is complemented by the law perspective pointed out in the second part by prof. Rainer Arnold, University of Regensburg. Data protection law as well as fundamental rights, in particular human dignity, are regarded in their multilevel (national and international) application in the field of genetic information.

Hedley Christ describes how the regulation of science, and particularly biological

science cannot be, in general, regulated by traditional legal concepts and methods alone. The complexity of science requires a subtler approach to its regulation, where regulation is needed. And it is, with medical science that such regulation is needed, and even more so when considering genetic, genomic, and proteomic information provided by patients. Such genetic, genomic and proteomic information is now being collected for medical research purposes and stored in databases which are to be made available for scientific investigation into such diseases as cancer and heart disease. These databases are also available to an international scientific community. In the first chapter, author argues that no legal system, either national or international, can provide adequate regulation for these databases, and that, far from considering more hard law we should use soft law techniques such as international regimes in which, an epistemic community may provide the principles, norms, rules, and decision-making processes. Such an epistemic community would set the principles of individuals' fundamental rights and duties; the control and access and disclosure of information, and constraints of access to the genetic information. It could also develop an understanding of what values can be put to the importance of access to data, what is the nature of ownership and intellectual property in these databases, and concepts such as custodianship. Furthermore, what governments are doing and how they are carrying out their mandated functions of providing healthcare.

Joaquín Sarrión Esteve studies the treatment or processing – including collection, recording, organisation, structuring, storage, and other uses – of personal data linked to health, under the European Union law framework (with reference to the European Charter of the European Union and EU legislation), adopting a comparative and international perspective (especially taking into account the sources of the European Council, like the Convention on Human Rights and Biomedicine). Indeed, health treatment fields face ethical and legal problems regarding the use of personal data. As we know, patients can benefit from having health or medical information available, and medical decisions can be more effective thanks to a better understanding of clinical histories, medical and health data. But at the same time, we need to guarantee privacy rights – including data protection – and confidentiality, dealing with health data treatment challenges from a fundamental rights' perspective.

Roberto Cippitani analyses the rules and principles applicable to research activities in genetic fields under the European legislation as well as within international law. The legal sources mainly provide protection for genetic information of individuals, on the grounds of legislation concerning personal data, especially in Europe by means of the new General Data Protection Regulation (EU) 2016/679, which will replace Directive 95/46/EC. The General Data Protection Regulation, besides defining sensitive genetic and personal data, provides for (more than the directive) several exceptions about protection for such data (mainly the right of access, right to rectification, right to processing restriction, right to object, and right to erase, i.e. right "to be forgotten"), for which the reference and disposition can be found in Article 89. Furthermore, as topics have arisen from European and international sources, specific provisions are applicable to the data processed for scientific purposes in respect to the specificity of the consent and the storing of data, as well as the biological materials which those data are derived from. On the other hand, privacy considerations do not cover all issues concerning experimentation, especially in

the case of genetic information, which is characterised by features such as "predictability" and "familiarity". These privacy considerations are inspired by the objective to protect research freedom recognised by national constitutions and the Charter of Fundamental Rights of the European Union. However, such freedom cannot be considered as absolute, but should take into account principles and rules set forth by constitutional legal systems. Research, besides respecting the core of other fundamental rights, and in particular the protection of people's personal sphere, has to be consistent with the fundamental principles of the European Union legal system, such as necessity, proportionality, and precaution. To achieve the correct balance between freedom of research and protection of personal data, it is advisable to revise the proprietary idea of privacy and to consider consent as an instrument that is always necessary and sufficient.

The Anglo-American and Spanish experiences on informed consent and control over the use of genetic information are considered by Francisco Miguel Bombillar Sáenz and Maurizio Borghi.

Francisco Miguel Bombillar Sáenz's paper paper is to address the legal approach of the informed consent and the donation of biological samples to a biobank for biomedical research under the Spanish regulation. It is argued that it is not possible to hide in consents full of lawless and indeterminate terms for elaborating a kind of blank cheque in order to carry out any research based on biological samples. This consent model would disobey the ethical and legal provisions ruling this sector, the right of all humans to decide on their own body integrity and on the destination of their biological samples.

Maurizio Borghi discusses the conflict between individual rights in genetic information and intellectual property rights arising from human genetic databases. It shows how Anglo-American jurisprudence has addressed the issue of individuals' control over the use genetic information, in particular when this use exceeds the scope of the initial consent given by the individual with respect to their own genetic information and other medical data. The main conflicts arise when the information has been initially released for therapeutic or research aims and then is used for commercial purposes or to develop patented inventions. Despite severe criticism by legal scholars, Anglo-American jurisprudence tends to allow secondary uses of biological material and medical information even when they are incompatible with the initial consent, on the sole condition that no harm is done to the individual's right to privacy. The chapter examines the legal mechanisms that have been adopted by government authorities to regulate the use of human genetic databases and to ensure that research on those databases is consistent with individuals' expectation and public interest.

María José Cabezudo Bajo, analyses the using the scientific DNA test in criminal and civil proceedings at an EU level. The European Legislator has made significant progress in this area, however, there are currently controversial issues that need to be further analysed in order to contribute to proposals for reform and, where appropriate, regulation. For this reason, we will first explain the state of the work in question, its justification and objectives. Next, we will identify and analyse the most controversial points of the DNA evidence in the two mentioned fields. Finally, we will present some conclusions.

The book ends with a contribution about the legal issues concerning collection of information on (per genetic resources related to plants and animals.

Valentina Colcelli analyses how, in the European legal system, Access and Benefit-sharing information are exchanged and this could help the implementation of the Nagoya Protocol and its goals, whether data flow could be controlled and whether legal consequences for infringement of rules on information exchange and storage could be more well-defined and reinforced. The flow of information available in the Access and Benefit-sharing Clearing-house platform seems to favour users more than providers, stakeholders and consumers; it also appears to kindly invite ~~the~~ users to respect the Access and Benefit-Sharing system. Providers, stakeholders and consumers, as well as the States, have the possibility to discover the illegal utilisation of genetic resources only accidentally, after products have been placed on the market. However, Art. 7(1) of Regulation (EU) n. 511/2014 makes it clear that the due diligence declaration needs to be requested by the Member States, or by the European Commission if money is provided by EU funds and the EU Offices or by the public administrations of Member States in case of request for market approval or placing products on the market. Nevertheless, the agencies in charge of Access and Benefit-Sharing control are not responsible for market approval. However, a rather ~~a~~ quite good control of the flow of information is possible in the EU legal system, if all involved public administrations or agencies check the Access and Benefit-Sharing due diligence fulfilment.

Genetics and Constitutionalism – an introductory overview

Roland Arnold and Rainer Arnold

1. *Genetics and constitutionalism*. Genetics is a highly challenging scientific field which has manifold impacts on law. Active genetic intervention is closely related to the right to health, to physical integrity, to personality rights in general, and in particular to human dignity, which has evolved as a specific constitutional category in the latest developments of constitutionalism. Moreover, as genetic data is of a highly personal character, questions of data protection, data processing, data transfer and use of data, are therefore central. A further dimension is that of research, which enlarges the problem in specific additional respects.

Before discussing some of these aspects in the second part of this article, we introduce the background and special properties of genetic information, including medical examples.

2. *Genetic information and its use in science and clinical applications – an introduction*. Genetic information comprises inherited variation as well as acquired mutations and can nowadays be read by DNA sequencing and related techniques – ultimately translating sensitive personal information into accessible data, which is open to interpretation in various ways. Whereas, until recently, the process of DNA sequencing[1] was expensive and restricted to specialised laboratories, it is now almost generally available and is set to enter the mainstream through governmental and health programs such as the 100.000 genome initiative in the UK,[2] and also through private companies offering diverse genetic testing services such as 23andMe. These novel developments make adaptation and clarification of relevant legal boundaries necessary, especially since genetic data concerns information which is related to and affects individuals, but can only be accessed and assessed by specialists. Indeed, genetic information is seen as a "special kind of personal data", by for example, the novel EU General Data Protection Regulation, which will enter into force in 2018.

a) DNA, the process of DNA sequencing, and some concepts of analysis.

Genetic information is encoded in the DNA as a sequence of 'letters', chemically nucleic acids.[3] Each cell carries a set of complete DNA. Genes comprise a sub-set of the DNA and are carrying information to encode proteins which are the active substances

1 METZKER, MICHAEL L. "Sequencing technologies – the next generation." Nature reviews genetics 11.1 (2010): 31-46.

2 CAULFIELD, M., et al., "The 100,000 Genomes project protocol", in Genomics England, 2015.

3 WATSON JAMES D., and FRANCIS HC CRICK, "Molecular structure of nucleic acids", in Nature 171.4356, 1953, pp. 737-738.

and building blocks of the cell.[4] The process of DNA sequencing enables the determination of the consecutive sequence of these letters. In reality, millions of short fragments of the DNA are read by a sequencing machine and subsequently connected computationally with or without the use of a reference genome.[5] With modern methods, a single cell can be sufficient to get a complete picture of the DNA.[6] It is also possible to restrict the sequencing to a small area of interest in the genome, for example to a gene of interest (targeted sequencing). Changes in the sequence compared to a reference that reflects the DNA sequence of a couple of individuals[7] can then be derived. These changes may be caused by mutational events, but most often reflect individual variability which is inherited.[8] Statistical and computational methods must be applied to deduce and subsequently interpret this variation, most often on the basis of previous knowledge and comparative analyses between sets of genomes. In many cases, analysis of a large exploratory set of genomes and (anonymised) patient data is necessary in order to obtain statistically significant results. Therefore, there are large scale efforts underway to sequence thousands of genomes (as in the aforementioned 100000 genomes initiative in the UK), and data is shared internationally via online accessible databases to allow re-use of the data for further research. However, different levels of data have different levels of protection, and only accredited researchers may access the most sensitive data (especially raw sequencing and clinical data) after an application process and the provision of secured infrastructure.

Knowledge derived from genetic information is inherently difficult to understand[9] due to technical limitations, limited understanding of the biological impact of mutations on the cellular system and body in general, and due to its statistical nature. This implies that clear deductions (such as health status) often cannot be made with certainty or at all: the information gained can often only provide probability ranges for a certain effect, and a large proportion of information potentially encoded in the genomic variation is still not yet interpretable. Consequently, more information could be deduced from DNA samples in the future due to the availability of improved mathematical and algorithmic methods and to a larger amount of prior knowledge and data.

b) Most genetic information is inherited and defines an individual.

The genome of a person is individual and unique, with the exception of identical twins, which can differ in the exact composition of their DNA but share most of their inherited genetic make-up. This manifests itself in many individual changes of the DNA, named genetic variation. This variation comprises, amongst others, many small changes

4 CRICK F., "Central dogma of molecular biology", in Nature 227.5258, 1970, pp. 561-563.

5 WHEELER DAVID A., et al., "The complete genome of an individual by massively parallel DNA sequencing", in Nature 452.7189, 2008, pp. 872-876.

6 GAWAD C., WINSTON K., and. QUAKE S. R., "Single-cell genome sequencing: current state of the science" in Nature Reviews Genetics 17.3, 2016, pp. 175-188.

7 Mainly, the individuals which donated DNA in the initial human genome projects.

8 KRUGLYAK L., and NICKERSON D. A., "Variation is the spice of life", in Nature genetics 27.3, 2001, pp. 234-236.

9 Especially for disease or trait related questions, where genetic fingerprint techniques and paternity tests result in clear results since they don't need to take molecular consequences of genetic variation into account.

in the actual DNA-sequence (called single nucleotide variants, SNVs) which may or may not have an effect on the genetic composition of their cells. The information in the DNA is inherited from both parents and resembles an individual mixture from both parental genomes. As a consequence, each person carries information inherited from his lineage, and also potential information on their offspring. Both the individuality and the hereditability of this information has been applied forensically in genetic fingerprinting and for parenthood determination – however, using techniques that harvest much less genetic information than modern DNA sequencing.

c) Genetic information can provide information on disease risks and acquired diseases, i.e. cancer.

Genetic information can provide information on inherited diseases - however, the genetic component and effect of mutations varies widely between different diseases.[10] The most extreme cases comprise rather rare but very severe conditions such as Huntington disease[11] which is solely caused by a genetic defect in the Huntingtin gene, leads to a severe brain damage and is always fatal, with the onset of the symptoms typically around 30-50 years of age (and as such within or towards to the end of the typical reproductive period). The probability of inheriting the mutation in case of an affected parent is 50%, which, together with the fatality of the disease, may strongly motivate genetic testing of members of affected families – which might, however, have strong psychological impact on healthy individuals.

Where this is an example of a relatively rare disease (around 7 cases per 100000 individuals in the Caucasian population), it becomes more and more apparent that frequent disorders also have a genetic component that increases disease risk and may alter prognosis and outcome. Such disorders comprise diabetes,[12] Alzheimer's,[13] a variety of mental diseases such as autism spectrum disorders,[14] and others. For these conditions, the genetic influence is typically weaker than for solely genetic disorders and may be based on different mutations and the interplay of their cellular effects. Consequently, their impact is much harder to assess and genetic information is much more difficult to interpret in their regard.

The most prominent class of diseases based on genetic alterations is cancer, where in most cases the genetic cause is acquired during one's lifetime rather than inherited. Currently, more than 200 different types and sub-types of cancer have been identified, with their only common theme being a 'disease of the genome' where an initial mutation event (referred to as 'driving' event) initiates further genetic and cellular alterations that lead to

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10 FRAZER K. A., et al. "Human genetic variation and its contribution to complex traits", in Nature Reviews Genetics 10.4, 2009, pp. 241-251.

11 WALKER F. O., "Huntington's disease", in The Lancet 369.9557, 2007, pp. 218-228.

12 MERINO J., et al. "A Decade of Genetic and Metabolomic Contributions to Type 2 Diabetes Risk Prediction", in Current diabetes reports 17.12, 2017, p. 135.

13 GATZ M. et al. "Role of genes and environments for explaining Alzheimer disease", in Archives of general psychiatry 63.2, 2006, pp. 168-174.

14 ROBINSON E. B. et al., "Genetic risk for autism spectrum disorders and neuropsychiatric variation in the general population", in Nature genetics 48.5, 2016, pp. 552-555.

uncontrolled growth of the cancer tissue.[15] [16] Due to the vast differences in the genetic and molecular make-up of cancers, novel strategies aim to selectively attack the cancer on its individual molecular make-up, a concept termed precision or personalised medicine.[17] Such approaches rely on the determination of genetic information of each individual cancer case. A prominent example for personalised medicine is the use of genetic testing to determine inherited mutations leading to a certain type of breast cancer (defects in the BRCA1 or BRCA2 gene which abolish their function in DNA repair).[18] Such defects are prevalent, depending on ethnic group, in 0.3-10% of the population and cause up to 10% of breast cancer cases in the respective ethnic groups. Defects in these genes increase the risk of breast and ovarian cancer significantly (the risk of developing breast cancer increases by approximately 5 times, whilst also increasing the risk of other cancers). 50-60% of affected women will develop breast cancer before the age of 70; this genetic defect has been linked early onset of the disease. Due to potential early onset, carriers are advised to undergo early and regular testing since an early detection increases positive results of treatment. Other preventive measures can also be applied, such as hormone therapy to induce the menopause – which reduces the risk of ovarian cancer – or by prophylactic removal of the organ (bilateral mastectomy and/or oophorectomy), reducing the risk of breast cancer by 95%. Treatment can be tailored to the special molecular setup of BRCA deficient cancers, such as by PARP[19] inhibitors which are currently at the clinical trial stage.[20] [21] Whereas for the detection of BRCA mutation a targeted approach is sufficient (only sequencing the respective genes, which does not potentially reveal other sensitive genetic information), other precision medicine approaches are based on more comprehensive determination of genetic information. A prominent example relates to immunotherapy, which constitutes one of the biggest advancements in cancer treatment within the recent years. The idea behind immunotherapy is to block the cancer's ability to evade the immune system. However, since cancer tissue is essentially derived from normal tissue, the immune system will only recognise cancer cells if they carry antigens that are sufficiently different from normal cells – which depends on their mutation load [22] and the existence of mutations that form suitable

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15 HANAHAN D., and. WEINBERG R. A., "The hallmarks of cancer", in Cell, 2000, pp. 57-70.

16 For an example pan-cancer study see: KANDOTH C., et al. "Mutational landscape and significance across 12 major cancer types", in Nature, 2013, pp. 333-339

17 DENG X., and YUSUKE N., "Cancer precision medicine: From cancer screening to drug selection and personalized immunotherapy", in Trends in pharmacological sciences, 2017, pp. 15-24.

18 JACKSON S. E., and CHESTER J. D., "Personalised cancer medicine", in International journal of cancer , 2015, pp. 262-266.

19 PARP is a protein that repairs DNA damage, as BRCA1 and BRCA2 do. If both are malfunctioning, as BRCA1 or 2 by their mutations, and PARP by chemical inhibition, the cancer cell accumulates too much damage on the DNA and dies.
http://www.nature.com/bjc/journal/v115/n10/full/bjc2016311a.html

20 NAROD S. A., "BRCA mutations in the management of breast cancer: the state of the art", in Nature Reviews Clinical Oncology , 2010, pp. 702-707.

21 TILANUS-LINTHORST M. M. A., et al., "Earlier detection of breast cancer by surveillance of women at familial risk", in European Journal of Cancer, 2000, pp. 514-519.

22 GUBIN M. M., and SCHREIBER R. D., "The odds of immunotherapy success", in Science, 2015, pp. 158-159.

antigens that can be detected by the immune system. To determine if a cancer is likely to trigger an immune response, these two aspects have to be assessed by the sequencing of large part of the genome (i.e. all coding regions in the genome) and subsequent bioinformatics analysis. As an impressive example, we want to mention the case of two siblings with a very rare but severe inherited cancer syndrome (bi-allelic mismatch repair deficiency, which leads to hyper-mutation of the genome) which induces early onset cancer, most often of the brain. Both children presented with re-current glioblastoma, which, in children, normally leads to death within 3 to 6 months. After the complete coding regions of these two children had been sequenced, it was possible to bioinformatically assess that they might profit from immune checkpoint inhibition, and they were subsequently subjected to a clinical trial for a therapy with nivolumab, an immunotherapy agent. After 9 and 5 months respectively, both "resumed normal schooling and daily activities".[23]

d) Future cures through alteration of genomic information.

As described above, the main clinical use of genetic information is of a diagnostic nature, mainly to assess disease risks and to tailor treatments. Recent developments in biotechnology may open opportunities of treatment which are not only based on genetic information but also on its manipulation. A number of such approaches are summarized under the umbrella term 'gene therapy'. The idea of gene therapy is to introduce (by altering or complementing the genome) genetic material that complements defective cellular functionality or activates novel processes, for example by specifically activating an immune response. One example is Tisagenlecleucel, a treatment which is licenced by Novartis and manipulates part of the immune system to recognize cells that play a role in certain Leukemias.[24] In the USA, the drug received FDA approval in 2017.

More recently, a new technology has begun to revolutionise genetic research, named the CRISPR-CAS9 system.[25] It allows a very targeted manipulation of genetic information, including in living organisms. Initial studies have shown success in manipulating different higher organisms, including human embryos.[26]

Importantly, these techniques could be applied to a single part of the body (such as the immune system or the actual cancer) but not to the eggs or sperms, known 'somatic gene therapy'. Alternatively, when applied to a fertilized egg or an embryo in early stage, the germline would be manipulated, and the alteration would be transferred to the offspring and future generations. Clearly, the latter would create additional ethical and legal implications. Such an alteration of the germline in humans is currently legally prohibited in many western countries.

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23 BOUFFET E., et al., "Immune checkpoint inhibition for hypermutant glioblastoma multiforme resulting from germline biallelic mismatch repair deficiency", in Journal of Clinical Oncology, 2016, pp. 2206-2211.

24 ROSENBAUM L., "Tragedy, perseverance, and chance – the story of CAR-T therapy", in New England Journal of Medicine, 2017, pp. 1313-1315.

25 DOUDNA J. A., and CHARPENTIER E., "The new frontier of genome engineering with CRISPR-Cas9", in Science, 2014, p 1258096.

26 LIANG PUPING et al., "CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes", on Protein & cell, 2015, pp. 363-372.

3. *The transnational character of constitutionalism.*

a) The term "Constitution/constitutional" is a notion with reference to basic matters which is not limited to national law.

The following reflections focus on the constitutional status of genetic data and its protection. *Constitutional* in this sense has a substantive meaning, not only a formally normative one: it connotes something fundamental, related to personality, to the inner sphere of a person which is particularly protected. This protection can be anchored in national law but is also determined by international principles and norms which have constitutional character in the aforementioned sense. The content and degree of protection must therefore be transnational and has therefore to include, at least in the coherent cultural region of Europe, not only national constitutional law but also the European Convention of Human Rights, the further instruments (in particular related to data protection and biomedicine) of the Council of Europe, as well as the principles and norms which have evolved and been created within the European Union.[27]

b) The functional relativization of the difference between strict and soft law.

In State law and, to an even greater extent, in international law, both strict and soft law co-exist. It is obvious that the importance of soft law, of resolutions, declarations, opinions, and similar non-binding expressions of convictions, orientations and intentions is underestimated. Their function can be of higher efficiency than that of binding rules. Their ideological impact can have a greater reach. The Universal Declaration of Human Rights of 1948, an emphatic appeal of the General Assembly of the then newly installed United Nations, sent out significant impulses for the worldwide dissemination of the new conviction that values related to human beings are the indispensable pillar of every legal order. This is not a result of any normative obligation but of the particular normative power inherent in the Declaration. Soft law has contributed, and continues to contribute, to the formation of new viewpoints and to the consolidation of emerging ideas which are not yet anchored in political reality. It initiates the emergence of customary law and influences the interpretation of vague terms in statutory law. Soft law often has pre-normative character and contributes to the establishment of convictions which shape general principles of law, and themselves constitute initial forms of customary law. It seems therefore adequate for the study in the field of genetics not only to focus on strict law but also to duly consider soft law.

c) Transnationality through an interfunctional three-level-constitutionalism.

Constitutionalism today has multiple dimensions. In Europe, fundamental rights are protected by national, conventional and supranational legal orders. Normatively these orders are autonomous, but functionally they are interconnected and constitute a European "constitutional unit", a *bloc de constitutionnalité européen*.[28] The relationship

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[27] ARNOLD R., "Begriff und Entwicklung des Europäischen Verfassungsrechtes", in Staat – Kirche – Verwaltung, Festschrift für Hartmut Maurer, M.-E. Geis/D. Lorenz (Hrsg.), München 2001, pp. 855 - 868.

[28] ARNOLD R., "Protección de los derechos fundamentales (en Europa)", in Mario I. Álvarez Ledesma y Roberto Cippitani (Edit by), Diccionario Analítico de Derechos Humanos e Integración Jurídica, ISEG Roma-Perugia-México, 2013, p. 555 – 565, 556-558.

between national orders and the European Convention of Human Rights is *cumulative*, while the relationship between the constitutional guarantees of the EU member States and the EU Fundamental Rights Charter is *an alternative one*, as it is expressed in article 51.1 of the Charter.

The process of Europeanization (a particularly intensive form of internationalization) continues to develop in both a formal and informal way. Formal internationalization is a consequence of the binding force of the Convention for the Council of Europe member states, a human rights instrument which is obligatory for most European countries and has over 60 years' history, largely detailed in its jurisprudence. It is obvious that the high authority of this convention has given it the leading role in European human rights constitutionalism. Moreover, the European Union's Charter of Fundamental Rights is more than half a century younger than the Convention, and for this reason its contents have been shaped by the Convention, reiterating its principles in a modern form, albeit with less authority. This development can also be explained by the fact that the evolution of fundamental rights protection in the European Communities has, since its origin, been heavily influenced by the Convention and the jurisprudence of the Strasbourg Court. The Convention therefore is, in an essential respect, the ideological mother of the Charter, the latter being influenced both by the Convention and by national constitutions which have been shaped by the Convention themselves.

The importance of the Convention results therefore from a quantitative element (the great number of signatory states), from the element of time (over 60 years of proven experience), and from the functional element that the Convention had the chance, from an early stage, to influence constitutionalism in Europe. The new democracies in Central, East and Southeast Europe have taken their main inspiration from the Convention, regarded as the real European common charter which guarantees European legitimacy and adherence to the European family of nations.[29]

The leading role of the ECHR in providing direction to many other countries' protection of human rights is also demonstrated by the fact that European legal thinking is essentially shaped by how the Convention is interpreted in Strasbourg jurisprudence. All guarantees laid down in separate documents such as national constitutions or the EU Charter are so influenced.

European three-level-constitutionalism is characterized by a vertical and horizontal inter-functionality.[30] The first type is based on normative obligation, the second on dialogue, acceptance of foreign concepts, coordination and not subordination. A vertical relationship exists for the Council of Europe member states which have to comply with the Convention, and for the EU Member States - which are integrated into the supranational order of the EU – EU law enjoys immediate effect within national orders and primacy over national law. The relationship between the EU and ECHR is horizontal,

[29] SARRIÓN ESTEVE J., "El Tribunal de justicia de Luxemburgo como garante de los Derechos fundamentales", 2013, p. 112-121 and 127-132.

[30] ARNOLD R., "Foreign influences on national Constitutional Law, in: Constitutionalism - Old Concepts, New Worlds, German contributions to the VIth World Congress of the International Association of Constitutional Law (IACL) in Santiago de Chile 2004, Eibe Riedel (Hrsg.)", Berlin 2005, pp. 37 - 54.

as is the relationship between each of the European States. This relationship is not based on normative obligations but on a voluntary approximation of law. This is essentially reinforced by the vertical relationship of these countries to the ECHR which creates parallel similarities as a basis for further horizontal dialogue. In a similar way, Strasbourg jurisprudence influences interpretations of the EU Charter, either by express provision (see article 52.3 of the Charter) or by the general influence of the Convention as the leading fundamental rights document in Europe. Furthermore, article 6.3 TEU (Treaty on the European Union) recognizes Convention rights as general principles of EU law, which confirms and reinforces its above-mentioned leading role.

In conclusion we can state that European fundamental rights constitutionalism shows a significant tendency to converge, and shows a functional interconnection in respect of the interpretation of written norms, in determination of unwritten rights and in adapting the law to major social changes. This functional interconnection is mainly realized by the constitutional judges whose task it is to understand the constitutional texts as "living instruments" which have to be interpreted in correspondence to the basic principle of freedom in a substantively and functionally efficient way, and must be brought into concordance with international perspectives. This is the real basis for the transnationalization process of constitutional values.

d) Human rights as universal rights by nature. European three-level-convergence is a specific form of intensive internationalization.

Similarly, outside Europe, national values are undergoing an internationalization process which is furthered by the existence of numerous general and specific multilateral treaties on human rights and a huge amount of international soft law. This reflects the world wide ideological orientation in favour of the protection of the individual which has been supported by the opinion that world peace is not reachable without the respect of human rights, a basic idea of the United Nations.

The importance of internationally-held values is demonstrated by the fact that collective values reflect, far more potently than individual, isolated national views, which rights are most deserving of protection. The reason for the intrinsic transnational tendency of human rights protection is that human rights are not nation-related but expressions of the international human community, because they refer to the very nature of the person. Universality is therefore inherent in human rights, of course apart from certain regional divergences. The transnational character of human rights is a direct consequence of the uniqueness and equality of human beings.

Violations of human rights as they frequently occur in many countries are not grounds on which to adopt a pessimistic attitude towards rights protection. International law is clearly aware of the indispensability and absoluteness of human rights protection and has even developed the understanding that they constitute a universal public order of values, in form of *ius cogens*, the breach of it being a breach affecting the whole universal community.[31]

[31] DE SCHUTTER O., "International Human Rights Law", Cambridge University Press, 2010, pp. 31 - 47.

4. *The basic structure of constitutionalism - a universal model.* Constitutionalism of today has its basic orientation in the human person. It is anthropocentric. The individual has gained the supreme position in law, which is mainly expressed by constitutional law. The supreme constitutional value is human dignity. The individual is recognized as a subject, a value in itself, which cannot be made an object, an instrument for another purpose. Dignity is the supreme value for state and society, is absolute and does not underlie restrictions nor relativizations by a balance with other values. Human dignity has become a constitutional category and is, written or unwritten, inherent in all democratic-liberal constitutional orders. Law ultimately exists for the benefit of man, to serve his existence, his life and the deployment of his personality in spiritual, cultural, economic and social spheres; goals shared with constitutional law. Constitutional law in this sense, as will be discussed further, is to be understood in a broader sense, as *basic law* whether on the national, supranational or even international level.

Human dignity is accompanied necessarily by a twin value: the principle of freedom of the individual. Dignity presupposes freedom and freedom does not exist without the recognition of dignity. While dignity is absolute and never under restrictions, freedom has to be shared with the community of individuals. However, dignity is a value of the individual as such, not of the community. The respect of the dignity of a person is always related to this person; the absoluteness of dignity results from the direct and exclusive relationship with the person. However, freedom is based on the relationship with the community, with all other individuals who are, each of them, holders of the right to freedom. It is evident that limitations on individual freedom result from this relationship with the community.

It is a consequence of dignity that freedom of the person is the *principle* and restriction of freedom is the *exception* which must be legitimized.

The most appropriate instrument with which to find the right balance between freedom and restriction of freedom is the principle of proportionality, which has evolved as one of the most important – perhaps even the most important - instruments in contemporary constitutionalism. Originally, it seems, emanating from Europe it has spread out all over the democratic-liberal world. This principle only allows restrictions of freedom which are really indispensable for a legitimate public interest and which are adequate in their intensity.

The principle of freedom which is the basis of specified fundamental rights must be substantively and functionally efficient. Substantive efficiency means protection from all restrictions on freedom, notwithstanding whether this protection is written in constitutions or not. The principle of freedom presupposes completeness of protection. As constitutional texts are written in a certain historical moment, they reflect the legal thinking of that moment. However, they are also living instruments which must be effective throughout their existence, often extremely long periods. It is obvious that these texts have to be adapted to the major social changes which occur, adaptation to be made either by formal reform (which is a politically difficult process) or by interpretation. In the field of rights, interpretation is the adequate instrument. Judges, in particular constitutional judges, have the task and the obligation to complete the written text by interpretation. The principle of freedom requires comprehensive, complete protection

of the individual. Therefore the judges have to formulate the unwritten aspects of fundamental rights protection. Furthermore, they have to make the protection efficient by interpreting the rights in a dynamic, *effet utile* - oriented way. Interpretation has to adapt the meaning of fundamental rights, which are regularly formulated in a general, undetermined way so as to be adaptable to the evolving convictions and orientations of society. It is obvious that interpretation is not able to and should not modify the objective regulatory intention of the constitutional provisions; it has to find the right way between normative evolution and normative conservation.

Functional efficiency of the protection of rights means the preservation of freedom against excessive restriction by the legislator through a strict observation of the principle of proportionality, as well as by a safeguard of the very essence of fundamental rights. It is commonly recognized that restrictions of freedom can only be effectuated by the legislator, not by the executive as such. Consequently, as Jean-Jacques Rousseau states, the individual is born free and therefore has to consent, as a consequence of autonomy flowing from dignity, to restrictions of freedom. Legislation is made by the representatives of the people, and therefore by individuals realizing their freedom of self-determination. They have to consent, on the basis of the majority rule expressed by legislation, to restrictions of freedom. It is therefore the prerogative of Parliament to define the limitations of freedom.[32]

The rule of law is the most important pillar of constitutionalism. In its modern form it focuses on the constitutionality, not only the legality, of public actions – it also encompasses values, and is value-oriented. The principle of freedom is therefore an integral part of rule of law, together with the respect of human dignity. Primacy of the constitution over legislation is the institutional aspect of rule of law, while values and principles are its main substantive dimension.

The rule of law, democracy and the principle of freedom as expressed by fundamental rights constitute a *functional unit* the components of which cannot exist in an isolated way. Democracy is not a formal institution based on numeric majority, is not a matter of numbers but a matter of substance, in particular of values. If democracy is not the bridge between the people and rule of law, it is no true democracy. Furthermore, democracy is political self-determination and therefore the expression of freedom. The German Federal Constitutional Court has rightly underlined that democracy is closely linked to human dignity.

This basic structure of a constitutional order exists in all democratic-liberal systems, in national orders as well as in the supranational EU, which is based on common values between the member states, and in the system of the Council of Europe, encompassing the European Convention of Human Rights and other human rights related instruments. The anthropocentric approach as the main characteristic of contemporary constitutionalism is present at all these levels, and multinational human rights guarantees can be found even in some of the less integrated areas of international law.

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[32] ARNOLD R., "Common Principles of Constitutional Law in EuropeSpeech on the Constitution Day of Lithuania 2016", in Konstitucine Jurisprudencija Lietuvos Respublikos Konstitucinio Biuletenis Nr.4 (46), 156-163, Constitutional Court of Lithuania, Vilnius 2017.

5. *Constitutionalism and its link with genetics.* In our context, it is important to stress the particularly close link between genetics and the constitutional guarantees for the individual. This link results from the specific impact of genetics on the human person. Human dignity is central for genetic intervention as well as for the protection of genetic data. National laws, supranational and international instruments are substantively of constitutional character if they define solutions for concurrent and conflicting principles. One of the most recent concretizations of constitutional principles in this context is the EU general regulation on data protection which encompasses genetic data. The constitutional principles which have to be weighed out are laid down in the EU Charter of Fundamental Rights. However, human dignity – the highest value within the EU Charter – is absolute and cannot be outweighed or restricted in favor of another constitutional value. This has already been mentioned above in relation to other constitutional documents.

Data protection is significant for a further characteristic of modern constitutionalism: in order to prevent the violation of this right, various procedural rules are regulated by ordinary legislation. Complying with these rules means efficiently preventing the infringement of the constitutional principle of privacy. Rights protection by procedure is a modern, frequently used approach to protect freedom and dignity especially in the field of new technologies.

Genetic data is closely linked to basic constitutional questions: is it permissible, from the viewpoint of human dignity and the rights of personality, to collect and analyze genetic data, to store it and to use it? These basic questions are also relevant at the supranational and international level. It can be said that even on these levels the issue is functionally constitutional although formally international. It becomes evident from the relevant multinational documents that the same problems are also recognized there in the same way.

In view of the fact that data protection is close to human dignity it is not surprising that the human being is in the center of data related argumentation. This is also reflected in international documents.[33] It is recognized for this reason that genetic data enjoys a special status, as is underlined by article 4 of the International Declaration on Human Genetic Data of 16 Oct. 2003, confirmed in recent documents such as article 9 of the EU general regulation on data protection which will come into force in 2018.

It is evident that the basic requirement is the consent of the persons concerned that their genetic data be collected; consent which can be freely revoked as an exercise of their personality-based rights and individual character.[34] The right of access to the data (article 13 of the Declaration 2003) by the person concerned is evident as long as the data exists, duration of existence being dependent upon the person's will. This individual right of disposal can only be restricted if the data (the subject of the research) has been made anonymous, no longer able to be individualized.[35] The right to access

[33] VOSSENKUHL C., "Der Schutz genetischer Daten. Unter besonderer Berücksichtigung des Gendiagnostikgesetzes", 2013.

[34] See Art. 9 of the Declaration 2003.

[35] See for details Art.14 c,d of the Declaration 2003.

this data belongs exclusively to the persons concerned, and under the protection of privacy cannot be revealed to third persons in the field of insurance, labor relations, education etc.[36]

It flows from human dignity and personality rights that the individual has a right to know as well as the right not to know his/her genetic data. These rights comprise data knowledge which has been intentionally researched as well as discovered by chance.[37]

It is not possible in this context to fully evaluate the legal details on genetic data which have been developed by strict and soft law, and at national, supranational and international levels.[38] It seems adequate to reflect on the general principles which can be drawn from the broad perspective of the legal protection of genetic data at various levels.

It is important to state that human dignity is recognized as an expression of the primacy of the individual and has developed into a normative category of prime importance. Basic normative requirements for data collection and processing are related to dignity, such as individual consent, exclusive disposal of personalized data, free decision on whether to acquire knowledge of such data, etc. However, it is commonly accepted that the individual is not an isolated person but a member of the community. To this extent, the individual's personal sphere is limited by the legitimate interests of the other individuals. Exceptions and limitations of individual disposals of genetic data must be examined for their compatibility with human dignity. This involves the question of the definition of dignity, the question where the genuine sphere of dignity ends and the sphere of freedom begins; freedom is restrictable, but only within the confines of the principle of proportionality. In order to appreciate the importance of dignity and freedom in this respect, it is necessary to apply a comprehensive perspective which takes into account not only the national but also supra- and international approaches.

[36] See Art. 14 b of the Declaration 2003.
[37] See Art. 10 of the Declaration 2003.
[38] See Vossenkuhl (note 33) and Pawel Kwiatkowski, DOI 10.4746/ppuam.2016.6.04.

Soft Law Governance in Genetic, Genomic, and Proteomic Databases. An International Regime Approach

Hedley Christ

1. *Introduction.* The concept of human rights in patient care has wide application. It includes bioethics, patients' rights, right to health, and patient safety. But beyond this there is a societal good in that, information gathered from patients may help in providing cures for specific diseases or conditions. Human rights in patient care therefore, addresses wider rights, including the benefits to other patients than the one undergoing investigation and treatment. However, this inevitably encompasses a conflict between the right of the patient and the information that they provide, particularly when the information they provide is their own genetic information.[1] The European Convention on Human Rights and Biomedicine provides a number of rights and protections to individuals who provide genetic information useful for research of however, this does not address the issues of storage and the provision of access to this information for research purposes. Furthermore, this form of information as data is significantly different from that conceived in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. We therefore, need to consider how genetic information, provided by patients, can be governed, such that, both protection is given to the patient and researchers have the opportunity to use such information in medical research. We need to consider whether soft law techniques are, in fact, more appropriate to such governance.

2. *The Nature of Genetic Information.* Since the mapping of the human genome the amount of genetic sequence information now being generated has been called a tidal wave of data. The range and type of these databases are numerous. International collaborations have provided three primary sequence databases: GenBank, maintained by the National Center for Biotechnology Information (NCBI), Nucleotide Sequence Databases, maintained by the European Molecular Biology Laboratory (EMBL), and DNA Databank of Japan. These primary sequence databases have subsidiary databases for the storage of particular types of sequence data.[2] These include: dbEST for expressed sequence tags, dbGSS for single pass genomic survey, dbSTS for sequence tagged sites,

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1 The genetic information provided is specific to the individual, and thereby may readily identify them and their health issues.

2 GOSTIN L.O. ET AL, "The Public Health Information Infrastructure: A National Review of the Law on Health Information Privacy", in Journal of the American Medical Association, 1996, 275, pp. 1921-1927.

and HTG for high-throughput genomic division used to store unfinished genomic sequences data. Two important protein sequence databases are; SWISS-POT, and TrEMBL. Beyond these there are a range of specific databases including, rDNA, tRNA, Promoter Sequences, Regulatory Elements, and Inbase, a database of inteins which are small peptides that are spliced out of some microbial protein. OMIM (Online Mendelian Inheritance in Man) is a database of human genes and genetic disorders maintained by NCBI. Incyte is a commercial database containing DNA sequences, transcripts, extensive annotations, expression data and access to cDNA for experimental studies. There are, therefore, a vast number of databases widely distributed. In addition, there are now two databases which specifically hold data on individuals' genes: UK Biobank[3] which recruited 500,000 people aged between 40-69 years in 2006-2010 from across the UK to take part in this project, and EGA which provides a service for the permanent archiving and distribution of personally identifiable genetic and phenotypic data resulting from biomedical research projects.[4]

These data are being collated and stored in genetic, genomic, and proteomic databases within a computer-assisted data management system known as bioinformatics. As more and more genetic and protein information is generated, the intention is to link these databases, both nationally and internationally, to other genetic, genomic, and proteomic databases and/or public health information systems, leading finally perhaps to a few international mega-database systems. This network of database systems will then be able to provide vast genetic and protein data and information important in the development of medicine, both in research (pure and applied) and clinical practice. However, genetic, genomic and proteomic databases contain information about individuals' and their families' health which has long been considered as sensitive information with strict confidentiality rules. Fundamental to the development of these databases will be the balance to be drawn between an individual's privacy rights and the social welfare in health that these bioinformatics systems will be able to provide. The notion of this balance is compounded by the development of intellectual property rights within these genetic, genomic, and proteomic databases. This network of national and international databases will, therefore, need to develop management and governance within an international framework.[5]

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[3] UK Biobank is a major national and international health resource, and a registered charity in its own right, with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses – including cancer, heart diseases, stroke, diabetes, arthritis, osteoporosis, eye disorders, depression and forms of dementia. Patients provided blood, urine and saliva samples for future analysis, detailed information about themselves and agreed to have their health followed. Over many years this will build into a powerful resource to help scientists discover why some people develop particular diseases and others do not.

[4] Data at EGA was collected from individuals whose consent agreements authorize data release only for specific research use to bona fide researchers. Strict protocols govern how information is managed, stored and distributed by the EGA project.

[5] ROSENAU J.N., "Towards an Ontology for Global Governance", in HEWSON, M. & SINCLAIR, T.J. (edit by), Approaches to Global Governance Theory, New York, State University of New York Press, 1999.

Such management and governance will need to develop within a legal framework. However, no such international framework exists; there is instead a collection of international human rights' agreements and certain national laws, none of which provide a coherent legal framework for the management of such databases.[6] One such approach, therefore, is to consider soft law as a means by which the management of these databases could be undertaken, for example; an international regime to enable the efficient, effective, ethical, and best use of this network system of genetic, genomic, and proteomic databases. However, there is no clear understanding of who the actors are in producing and controlling the development of bioinformatics systems, what type of databases are being produced and whether and to what extent these databases are being linked.

3. *What are Genetic, Genomic and Proteomic Databases and why are they important?* Genetic, genomic, and proteomic databases are computer-assisted data management systems that gather, and analyze genetic, genomic, and proteomic data. They store and search[7] data on gene and protein sequences,[8] structures,[9] expression profiles, and biochemical pathways. The importance of these databases is that they analyze genetic and proteomic sequences and structures, enabling an understanding of how genes and proteins influence the working of the body at a molecular level. They enable biological data to be used to understand the higher-level functions of the cell, such as biochemical pathways, regulatory networks, signal transduction pathways, and what influences the behaviour of cell, organ and organisms. They enable the modelling of target proteins' interactions with drug molecules and the way individuals are affected by the interaction between their genetic make-up and their environment or life circumstances. In 2001 the UK Parliament, House of Lords Select Committee on Science and Technology on Human Genetic Databases recognized that understanding the genome will bring substantial improvements in medicine, particularly through the use of genetic data[10] and medical histories.[11]

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6 BOVENBERG J.A. (2000) "Should Companies Set-up Databases in Europe?", in Nature Biotechnology, 2000, 18, pp. 907-909.

7 There are a range of retrieval tools which allow a text-based search within a number of linked databases. Most widely used are Entrez, DBGET, and SRS. Sequence searches can be done with BLAST or FASTA.

8 Sequences are derived from DNA, RNA, and Proteins. Genomic DNA is taken directly from the genome, e.g. its natural state and therefore contains introns, and regulatory elements. cDNA is generated by reverse transcribing of mRNA. rDNA includes the sequences of vectors (e.g. Plasmids), modified viruses and other genetic elements.

9 Structures related to proteins and nucleic acids.

10 UK Parliament, House of Lords, Select Committee on Science and Technology, Fourth report: Human Genetic Databases: Challenges and Opportunities, HMSO 2001.

11 UK Parliament (2001), House of Lords, Select Committee on Science and Technology, Fourth Report: Human Genetic Databases: Challenges and Opportunities. London: HMSP. GOSTIN,L.O.ET AL, "The Public Health Information Infrastructure: A National Review of the Law on Health Information Privacy", in Journal of the American Medical Association, 1996, 275, pp. 1921-1927.

Over the last ten years the development of genetic, genomic, and proteomic databases, along with combinational chemistry, has made a significant contribution to the understanding of disease and drug development. Both genomics and proteomics have revolutionized the way target molecules are identified and validated for drug targeting. Thousands of potential new targets can now be identified by sequences, structures, and functions. The contribution of these databases, particularly in medicine, is their ability to analyze sequences and structures, enabling an understanding of how genes and proteins influence the working of the body at a molecular level, and model target protein interactions with drug molecules *inter alia* and is being practiced worldwide by academics' groups, companies, and national and international research consortia.[12]

Genetic, genomic, and proteomic databases and their database management systems are resources, therefore, that must be managed. Data ownership[13] and the legal frameworks which regulate their control are vital in determining the availability and control of the information which is stored, manipulated, and disseminated. This is particularly important for these databases where, as the UK House of Lords noted; information about individuals and their health can be very sensitive and genetic data are particularly so. Genetic information may say something about family members as well as the individual directly concerned. The challenge, therefore, is to find ways of protecting the interests of individuals, while at the same time making essential information available to medical research. A principal concern, therefore, is that these data systems must be managed in such an efficient way as to bring social welfare benefits to the international community while at the same time respecting the informational privacy of individuals. However, set against this is the demand for open science. Organizations campaigning against any notion of ownership of biological information are working to develop a public or open licensing plan for information.[14] In contrast to open science is the issue of intellectual property (IP) in these databases and how such IP should be managed.

During February and March of 2004, the OECD held a Workshop on Human Genetic Research Databases (HGRDs) – Issues of Privacy and Security (Tokyo Workshop), recognizing that HGRDs are invaluable tools which will have immense possibilities for medicine. The Workshop felt that clear procedures must be in place for informing patients about the way that data, based on their genetics, might be used, and whether, therefore, current informed consent is sufficient to assure patients' privacy and achieve an appropriate balance with research and access. Whether or not such a balance is achieved

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12 KRASNER S.D., (edit by) "International Regimes, Ithaca and London", Cornell University Press, 1983.

13 In database systems, the data site is often termed master site (or primary site) which makes data available to slave sites (or subscribers). A master site may own the data; however, there may also be multiple sites in which ownership is invested in distinct fragments.

14 Bioinformatics.org and the Open Lab offer web hosting and project support relating to bioinformatics. The projects within the Open Lab are primarily end-user software tools for scientists looking to solve particular biological and bioinformatics problems. The Distributed Sequence Annotation systems (DAS) developed at the Cold Spring Harbor Laboratory and Ensembl are both projects intended to bring the human genome into the public domain. Cold Spring Harbor Laboratory is looking at using MP3 players as a means to sharing genetic information, peer-to-peer.

in public policy will affect how successful genetic science is as a driver for innovation products and processes and delivery of better health. The Workshop also concluded that the OECD should develop principles of best practice, that is soft law principles, for the management and governance of HGRDs, but as yet has been unable to provide such principles of best practice.

The reason for this lack of management and governance guidance of HGRDs lies in the complexity of the task-in-hand. In part the OECD acknowledges: "The protection of individuals' genetic information relies on a combination of health-related, confidentiality, and/or personal data protection laws.[15] Many countries also provide constitutional protection, human rights legislation or both. In general, however, no specific laws distinguish the processing of genetic data from other personal or sensitive information. Yet genetic data is perceived as being special because it can reveal important information about both an individual and his/her family and can have a significant impact on an individual's life, including his or her reproductive choices."

Beyond the use of genetic, genomic, and proteomic databases for personal healthcare these databases may also play a significant role in public health management.[16] As Gostin (1996) has pointed out; the development of public health information has produced a vast reservoir of information on health status giving states a means of health surveillance. Public health investigation through epidemiological research, testing and screening for disease, and now genetic and proteomic databases "enable the public health systems to identify health problems, inform the public, intervene, and influence funding decisions". However, like the OECD Gostin also recognizes: "Patients, often physically and mentally vulnerable, divulge intimate details of their lives to their physician, medicine's paternalistic traditions have long-recognized that the patient's weakened position compels strict confidentiality assurances even in the face of government demands…Law and ethics in late twentieth emphasize autonomy as a theoretical justification for privacy, patient autonomy encompasses the right to control the dissemination of person health information…Confidentiality is central to a trusting physician/patient relationship – this promotes patient's candor about health and disease risks."

This conflict between an individual's informational privacy and the disclosure and access to genetic and proteomic data is compounded by the introduction of intellectual property and the possibility of a commercial application to these databases. In the final report from the OECD Working Group on Biological Information it stated: "The actual holding of biological materials clearly leads to the control of the access to related information and, in practice, also to the control of any possible invention that could derive from those materials. In this perspective, the problem of intellectual property of

[15] In the UK, the construction of a genetic, genomic, or proteomic database has to receive ethical committee approval before it can be developed. Such approval will only allow the database to be constructed on the basis of the application for ethics approval. Any alteration, development, or linkage not in the initial application requires further ethical committee approval. These ethical committees are particularly concerned with patient consent which cannot be 'blanket' consent for any use of the database.

[16] Office of the High Commissioner for Human Rights. CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12). Adopted at the Twenty-Second Session of the Committee on Economic Social and Cultural Rights, on 11 August 2000.

biological information is also connected to this problem of ownership of media where that information is stored."

In the European Union, many EU countries have implemented the 1996 Database Directive (96/9/EC) which gives an intellectual property right in databases. As Bovenberg (2000) notes, these database rights in a DNA database would almost undoubtedly represent valuable intellectual property, especially with the uncertainty that still surrounds DNA sequence patenting. Database rights allows its holder to prevent extraction or reutilization of substantial parts of the database for fifteen years after completion of a database. In fact, the right may pertain in perpetuity given that it can be rolled over following any substantial modification to the database that requires a substantial investment. Such modifications include the routine business of DNA databases: extension, deletions, and amendments. The UK Chorley Report identified a wide range of public datasets which could have commercial application and where possible should be commercialized to recoup the development costs. Many states now recognize the potential for the commercialization and intellectual property exploitation of public research.[17]

As more and more genetic and protein information is generated with the purpose of linking this information either to other genetic, genomic, and proteomic databases or other types of databases such as clinical records, the need to manage these resources efficiently and within strict legal boundaries has become paramount. Governments and international organizations are driving greater and deeper linkages within these databases at the same time as demanding tighter controls over informational privacy and intellectual property rights. Central to this debate is the issue of ownership. The contribution that these databases can make to medicine, both in research and in clinical practice will depend on the network system that is created for it. This network system will be of an international character bringing about both economies of scale and economies of scope. Good governance should bring about economies of scale through efficiency gains in coordinating rulemaking, enforcement activities, and the acquisition of specialized skills and organizations, while reducing unnecessary regulatory disharmony. Economies of scope will bring about reductions in costs resulting from centralized access points and wider benefits to the international community.

Within this framework are international and national legal systems (developed in a pre-digital age), which were not designed for genetic, genomic and proteomic databases. In fact, these legal systems may positively inhibit the efficient management of these database systems. Furthermore, this still emerging technology requires international cooperation and an understanding between a wide range of actors (epistemic community) as to the nature of efficient database regulation. If an international regime is to be developed then it is necessary to identify the actors concerned (the epistemic community), the range of and type of genetic, genomic, and proteomic databases being produced, and identify the legal issues that will constitute the agenda setting.[18] We therefore need to consider soft

[17] UK Parliament (1987) Select Committee Report into the Handling of Geographic Information. The Chorley Report.

[18] VOGLER J.,"The Global Commons. Environment and Technology Governance", Chichester, John Willey & Sons, 2000.

law approaches to the management of these databases, rather than relying on disparate international and national legal frameworks.

Any form of soft law approach for the management of these databases will need to consider a range of issues. For example, in determining the practical goal for these databases, that is, for whom is the knowledge intended to be useful rather than patients, society, government, or industry? What is the degree of transdisciplinarity; biology, medicine, computer science, legal and policy, and ethics *inter alia.* The nature of linkage, electronically, organizationally, socially, informally, through a functioning network of communication, and the degree of flexibility. How is brokering to be achieved with individuals coming from many different institutions and organizations which are dispersed geographically. Then there is the nature of social accountability and transparency. There are therefore a range of policy responses such as networks, alliances, agreements, shared facilities, governments and business relations, and considerations such as complexity, costs, risks, and technology, which have to be considered within an international arena.[19] This cannot be achieved through legal frameworks based on regulation and control, it must be undertaken through a form of global governance.

The nature of global governance covers a range of themes and approaches. There is no single model or form of global governance, no single structure or set of structures. As the Commission for Global Governance has stated, it is a broad, dynamic, complex process of interactive decision-making that is constantly evolving and responding to changing circumstances. Implicit in this broad conception of governance are the control mechanisms necessary for the management of these databases. However, one form of global governance, or model of global governance is regime analysis.

4. *Regimes as a Means of Governing GGP Databases.* Krasner (1983) has defined an international regime as a set of implicit or explicit principles, norms, rules and decision-making procedures around which actors' expectations converge in a given area of international relations. The concept of regimes is therefore, conceived of as an issue area in which relevant actors share the principles, norms, rules and determine how decision-making processes are made and implemented.[20] However, as Rosenau (1999) notes little attention has been paid generally to the actors, other than governmental actors, who could form such a regime, despite considerable evidence that in many regimes other types of actors play a crucial role. Ruggie (1975) argued that the existing literature on technology change and international cooperation was inadequate because of its restricted focus on law and organization. "What was required was a wider view encompassing implicit understanding between a whole range of actors." More recently Vogler (2000) stated "A form of regime analysis that has been relatively neglected is the fundamental one of how agendas are set and issues arise, altered and are aggregated together. Who

[19] RUGGIE, J.G., "International Responses to Technology: Concepts and Trends", in International Organization, 1975, 29, pp. 557-583.

[20] International regimes were first defined by Krasner, S.D. (1983) as a "set of implicit or explicit principles, norms, rules, and decision-making procedures around which actors' expectations converge in a given area of international relations".

defines what this social construct- the issue area – will be? Who are the actors?"

Such views are particularly important for genetic, genomic, and proteomic databases. Throughout the international molecular biology community many genetic, genomic, and proteomic databases are being produced with an agenda to integrate these databases. The result could be a few international databases accessible by national public health systems and an international research community. However, it is not clear how many research groups are producing genetic, genomic, and proteomic databases. How many of these databases are already linked, either to other genetic, genomic, or proteomic databases or public health records such as clinical records? How many of these databases are linked nationally and/or internationally? What type of genetic, genomic, and proteomic databases are being produced, i.e. specific disease types, protein interaction drug targeting, and diagnostic testing, and for what purpose? Who has access to these databases, and who has control over the development, use, and access to these databases?

Just as important as understanding who the actors are in this developing technology are the issues that will need to be addressed by these actors as these databases become more and more linked, particularly on an international level. It is already apparent that, apart from the issues of standardization, these issues will principally surround the balance to be drawn over individual privacy rights, intellectual property rights, and social welfare. However, it is not apparent how these agenda-setting issues affect the epistemic community. What are the principal concerns the actors have in developing genetic, genomic, and proteomic databases? How do these concerns manifest themselves when these databases are linked? What do the actors believe will be the important issues that will determine whether an efficient, effective international database system will be developed, and how will an international system be managed, monitored, controlled, developed, and accessed?

The policy choices open to the international community wishing or needing to take action to manage genetic, genomic, and proteomic databases fall into a number of categories. These include regulation, persuasion (often considered as soft law), the use of property rights, the use of targeted economic instruments, and adjusting direct or indirect economic policies that do not have as their goal the efficient regulation of these databases, such as the overriding aim of commercial exploitation of these databases. Alongside these policy choices is the risk of fragmentation, that is, where policies develop on individual lines lacking the coordination that efficient regulation will require. Such soft law policy will, therefore, need to consider which policy variables are most likely to affect the efficient regulation of these databases set against the desired goals and concerns over fragmentation.[21] For example, what is the typology and linkage of the genetic, genomic, and proteomic databases, who forms the epistemic community[22] and what is the nature of

[21] Resulting from 'market failure', i.e. conflict of interest among states and conflict of interest across states, the approach of agenda setting issues must develop policy choices of cooperation, particularly within the distinct areas of database usage, privacy, and intellectual property, which will coordinate rather than contradict one another.

[22] The policy choice of who constitutes the epistemic community will have a strong influence on the nature, form, structure, and management of the genetic, genomic, and proteomic databases, i.e. certain interest groups may impose externalities on others, how interests are balanced, and how a wide epistemic community may not understand the uncertainties that actors commonly face regarding

their capacity, and what are the agenda setting issues[23] for such an international regime in these databases, what are the policy options?[24] Principal among these is the policy choices which will need be taken within the existing legal framework of the research. These policy options and choices will fundamentally determine the nature, form, structure, and overall efficient regulation of an international regime in genetic, genomic, and proteomic databases and how these databases will be used for research, clinical practice, and public health welfare regulation. Furthermore, they will determine the balance of public and private involvement of this international regime.

In considering how genetic, genomic and proteomic databases are to be managed with forms of governance in the absence of governments, or at least only partial governmental input or involvement, the nature of soft law regimes will need to sit within a corpus of legal rules related to human rights in patient care, privacy laws, database laws, intellectual property laws, *inter alia.* The generation, therefore, of soft law principles requires a foundation in hard law principles. These hard law principles should begin with the right to health set within the Universal Declaration on Human Rights. However General Comment No. 14 clearly states that in considering the right to health of an individual, that right does not exclude, in fact the right becomes dependent upon, the realization of other human rights. The legal framework in which an international regime on genetic, genomic, and proteomic databases must sit therefore, within a wider understanding of patient rights, that is, although the DNA sample is obtained from a patient, having given informed consent, the right of the patient over their sample is constrained by other rights.

The concept of human rights in patient care has wide application. It includes bioethics, patient's rights, right to health and patient safety. But beyond this there is a societal good in that information gathered from a patient may help in providing cures for specific diseases or conditions. Human rights in patient care therefore addresses wider rights including the benefits to other patients than just the one undergoing investigation and treatment. However, this inevitably encompasses a conflict between the rights of the patient undergoing treatment and the information that may come from such a patient, particularly in the area of scientific research. Such issues therefore as how can patients give informed consent to keeping and sharing information that comes from their treatment and how can the privacy and confidentiality of such information be assured to the patient when that information will be potentially important to other patients?

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the nature of the particular issues in everyday management.

23 In developing an agenda setting programme for an international regime what should constitute the substantive content governing the area of international genetic, genomic, and proteomic database regulation. This reflects not only the policy choices of form of approach taken, and elimination of fragmentation, as above, but also on the nature of the obligation it provides and on the delegation to third parties (WHO, OECD, or newly created institution).

24 Certain policy options have already been undertaken by Governments covering the subject matter of database usage, privacy, and intellectual property. These will constrain the type of options available and it may be unrealistic to expect the desired policy changes to happen at once. It might be appropriate to take a longer-term view entering into 'policy dialogue' with the epistemic community perhaps involving the exchange of information at a professional and technical level.

However, General Comment 14[25] clearly states that in considering the right to health of an individual, that right does not exclude other human rights. The legal framework in which an international regime on genetic, genomic, and proteomic databases must be set, falls within, a wider understanding of patients' rights, that is, although the DNA sample is obtained from a patient, having given informed consent, the right of the patient to that sample is constrained by other rights. General Comment 14 therefore notes, that unlike the concept of patients' rights, which provides certain specific rights to the patient, the concept of human rights in health, refers to the application of general or universal human rights to all those involved. That is, not only other patients but also all those involved in the provision of healthcare. This therefore, brings into the notion, that healthcare also involves the scientific community who bring an understanding of the nature of disease. Human rights in healthcare therefore, encompass a wider range of individuals whose human rights we also need to consider, such as the scientific community, hospitals, clinics, and other places where healthcare provision is given.

Such considerations do require a balancing of those rights. In General Comment 14 it notes that the right of the acceptability of healthcare includes the right to seek, receive, and impart information, and ideas concerning health issues. However, accessibility to information should not impair the right to have personal healthcare treated with confidentiality. This is specifically the case with genetic, genomic and proteomic databases, which require, in their management, the consideration of privacy and confidentiality set against the provisions of information for research into the various diseases and conditions. The European Convention on Human Rights and Biomedicine[26] also notes that those instruments, that is, a human rights approach, differs when we consider the patient's rights approach in that such rights applied to both the patient and healthcare providers and also that information provided by the patient may advance medical understanding.

Beyond the notion of a wider human rights approach to the sharing of genetic and protein information, concerns the requirement of governments to promote care, health, including the positions for research into disease. Under the United Nations Regime (article 12, ICESR) it obliges states with a number of duties including the implementation of effective measures for the prevention, treatment, and control of disease. However, General Comment 14 interprets this article to include freedom from human rights abuses including human dignity, privacy, the access to information. Thus, the right to privacy and confidentiality becomes an essential aspect of healthcare provision. This presumably also includes the rights to information.

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[25] General Comment No. 14 states that the right to health includes the availability of public health and healthcare facilities and that the right includes the right to privacy and access to information. However, it also states that the right to health is realized through the pursuit of numerous complementary approaches and therefore involves a range of activities which are to benefit many, not just an individual.

[26] Also note the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to Application of Biology and Medicine on the Prohibition of Cloning Human Beings, and the Additional Protocol to the Convention on Human Rights and Biomedicines Concerning Biomedical Research.

The nature of privacy is often stated as a right, and thereby an individual right. However, more recently the notion of privacy has been seen as a value rather than a right, in which the individual chooses the level of privacy which they wish to impose. But in terms of healthcare there is a distinction between the individual's privacy and the social value of that privacy. Privacy here must be understood in terms of the purposes that transcend that of the individual without denying the importance of the value of that privacy to the individual.[27] There is therefore a continuing balance to be drawn between the patients' rights. As Rahu and McKee note, it is important to recognize that the individual's right to confidentiality is circumscribed by the individual's responsibility to contribute that information to promote societal good such as, the disclosure of their health information. The balance therefore is one in which we have to ensure patient participation in the decision-making process as enshrined in the World Health Organizations' Alma-Ata Declaration which provides for the universal access and patient participation in healthcare and public health decision-making.[28] Here then patients not only have certain rights but also certain duties. Within the European Charter of Patients' Rights Article 3; individuals have rights to access all kinds of information regarding their state of health and all that scientific research and technological innovation makes available. This therefore, clearly implies that individuals have a duty to participate in the further understanding of healthcare issues. However, the European Charter of Patients' Rights also recognizes, the genetic information may be different. At Article 11 discrimination against a person on the grounds of his or her genetic heritage is prohibited. Furthermore Article 12 states that tests, which are predictive of genetic diseases and which either identify the subject as a carrier of the genetic disease or detect a genetic predisposition or susceptibility to disease may be performed only for health purposes or for scientific research linked to health purposes.

The nature of scientific research is therefore at the heart of health provision. There are clear safeguards that are required to protect patients, particularly when it is also clear that the patient has a duty to improve healthcare provisions by being subject to or of scientific research. Chapter 5 of the European Charter of Patients' Rights provides for the need of approval of the scientific research by some competent body,[29] and that the patient provides free and informed consent to being part of the research, along with being informed of their rights and safeguards prescribed by law. There are therefore, a number of human rights' provisions, both hard law and soft law, to which the management of genetic, genomic and proteomic databases can draw in producing an international regime for their management.

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27 This is specifically an issue when considering informed consent. However, as Bennett and Raab note that privacy cannot be allowed to sit in the way of the exploitation of modern technologies. However, the primacy of privacy as a basic human right and into which incursion can be made, must be justified.

28 Article 4 notes that the people have the right and duty to participate individually and collectively in the planning and implementation of their healthcare.

29 Articles 5 and 16. Article 17 also provides that the research itself should aim at contributing to the significant improvement in scientific understanding of a disease or disorder and that there is a potential to produce real and direct benefits to the patient.

Beyond the legal framework of healthcare provision, lies the issue of data processing. The Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data does provide, at Article 1, the overall protection of individuals' fundamental rights and freedoms, particularly that of the right to privacy with regard to the automatic processing of personal data. Consideration therefore, needs to be given as to how genetic information, housed within these databases, can be governed. That is, how the patient's genetic information can be safeguarded at the same time as providing the opportunity of researchers to use the genetic information. Would such databases be considered legitimate? Article 5 of the Convention gives a clear indication that such databases are legitimate in that they are obtained and processed fairly and lawfully; they are produced for a specific purpose; that the data is relevant and not excessive; the data is accurate and kept up-to-date, and that the database permits the identification of the data subject for no longer than is necessary. At the same time the European Convention on Human Rights and Biomedicine at Article 10 provides that individuals have the right to know the information collected about their health and that they have the opportunity to check that such information is accurate, adequate, and relevant. The difficulty is, that these general principles, cannot hold for patients to see information which would not be understood by them and therefore not be able to consider its accuracy, and to consider whether it is complete or not.

Of major significance for the information held in these databases is that they have, or potentially have, economic significance. The nature of how these databases are owned thus becomes an important issue. Is the genetic information held in these databases, subject to intellectual property rights; particularly if such information has a commercial potential? The notion of ownership therefore, becomes paramount. Do we conceive therefore, that the ownership of the data is one of a contractual obligation between researcher and patient. Or could we conceive of this information is being held on trust. Here the nature of the trust would be that the property, here the genetic material, is managed in trust for the patient, the researcher becoming trustee manager of the genetic information.

The management of genetic, genomic and proteomic databases cannot therefore, be undertaken by hard law alone. A better approach, therefore, may be to consider a soft law approach which can sit within a hard law legal framework. One such approach could be to consider an international regime in which the principles, norms, rules, and decision making processes, can be identified, within the hard law framework. This can provide for patient safeguarding and at the same time provide access to genetic and protein data for the furtherance of medical research. Such development of an international regime being in the hands of an epistemic community. That is, a community who has the knowledge for its development. Such an epistemic community, constituted of experts and interested groups, including patients, whose quasi-autonomous character would allow them to constitute a broad international community, setting the principles of individuals' fundamental rights and duties; the control and access and disclosure of information, by considering such issues as informed consent, and anonymizing of data, constraints of access to the genetic information, *inter alia*, which would lead into the norm building and rule making processes. It could also develop an understanding of what values can be put to the importance of access to data, depending perhaps, on the final usage of the data and

including such concepts as the freedom of information; what is the nature of ownership, and concepts such as custodianship. Furthermore, what governments are doing and how they are carrying out their mandated functions of providing healthcare. These and many other considerations could be undertaken by an international regime for the management of genetic, genomic and proteomic databases set within a hard law framework of human rights, database laws, and ownership and intellectual property laws. A system which could provide significant benefits to the understanding of disease and the furtherance of health-care provision.

Health Data Treatment. An approach to the International and EU Legal Framework

Joaquín Sarrión Esteve

1. *Motivation.* Health treatment fields face ethical and legal problems regarding the use of data. As we know, patients can benefit from having health or medical information available, and medical decisions can be more effective with a better understanding of clinical histories, medical and health data. Nevertheless, we need to guarantee privacy – including data protection rights – and confidentiality dealing with health data treatment challenges from a fundamental rights perspective.

Although the New European Union (EU) Privacy regulation has been seen as a 'property-based conception' regulation,[1] the reality is that this is a very important instrument to guarantee fair and quality use and treatment of privacy data.

The complaint about ethical and legal requirements – including constitutional ones – is particularly relevant in the use and treatment of health issues (health data) because when dealing with health we need a fundamental rights protection approach in order to identify the ethical and legal limits regarding the use of this type of sensitive data.

Moreover, in order to address this, we need to use multilevel methodology because we live immersed in a European legal space comprised of legal systems with different levels which are increasingly interconnected.[2] Therefore, we need a theoretical basis to approach it and try to study any element or reality included in these related legal systems, and dealing meanwhile with the new constitutional horizon opened in the EU after the Lisbon Treaty.[3]

First, the methodology we are going to use, the multilevel one, will be described. After that, we study the concept of health data, the uses and purposes – both for health and medical uses among others – of health data, the legal requirements of processing health data, an analysis of relevant case law and finally the actual trends on this issue in the EU.

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1 Due to the entitlement of data rights, the protection of rights even after the transfer and the existence of remedies to protect rights, and particularly because it 'treats personal data as commodity capable of changing hands'. See VICTOR, J. M., "The EU general data protection regulation: Toward a property regime for protecting data privacy", in Yale Law Journal , 2013, v. 123, 2, p. 515 and p. 527.

2 GÓMEZ SÁNCHEZ, Y., "Constitucionalismo multinivel: Derechos Fundamentales", Sanz y Torres, 2011, p. 20.

3 SARRIÓN ESTEVE, J., "El nuevo horizonte constitucional para la Unión Europea: a propósito de la entrada en vigor del Tratado de Lisboa y la Carta de Derechos Fundamentales", in CEFLegal: Revista Práctica del Derecho, p. 162.

2. *Multilevel methodology on health data treatment.* It is typical – from the Law perspective[4] – to describe the relationship between EU law and national ones in terms of a multilevel legal system, i.e., constitutional pluralism[5] or multilevel constitutionalism.[6] In both cases, we speak about theoretical constructions which try to explain the EU multilevel fundamental rights protection architecture,[7] and therefore the relationship and interaction of different legal systems or levels, particularly EU and national ones. These are becoming progressively more interconnected, because we need to approach this complex 'legal reality' as Prof. Gómez Sánchez pointed out some years before,[8] with the logic of relationships and integration.[9]

Certainly, the problem that arises is the special complexity of fundamental rights protection in this type of multilevel reality which deals with multisided systems and we need

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4 There are other approaches from Political Science, Economics, or Sociology. Regarding the interdisciplinary status of EU studies and a comparison between them and Law approaches, see MILCZAREK, D., "Theoretical Aspects of European Studies" in the book "Introduction to European Studies: A New Approach to Uniting Europe, Centre for Europe", University of Warsaw, 2012, p.13-32.

5 See for example MACCORMICK, N., "Questioning Sovereignty. Law, State and Nation in the European commonwealth", Oxford University Press, 1999; TORRES PÉREZ, A., "Conflicts of Rights in the European Union. A Theory of supranational Adjudication", Oxford Scholarship Online, 2009; JAKLIC, K., "Constitutional Pluralism in the EU", Oxford University Press, 2014. It is a way to approach EU integration that differs from the traditional sovereigntist one as pointed out by Fabbrini (See FABBRINI, F., "Fundamental Rights in Europe", Oxford University Press, 2015, p. 19). However, some authors outline differences between Legal Pluralism and Plural Constitutionalism, see CHALMERS, D., & DAVIES, G., and MONTI, G. "European Union Law", 3rd edition, Cambridge University Press, 2014, p. 219-222.

6 PERNICE, I., "Multilevel constituionalism and the Treaty of Amsterdam: European Constitution-making evisited?", in Common Market Law Review, 36, 1999; PERNICE, I., "Multilevel constitutionalism in the European Union" in European Law Review, 27; BALAGUER CALLEJÓN, F., "Constitucionalismo multinivel y derechos fundamentales en la Unión Europea" in the book "Estudios en homenaje al Profesor Gregorio Peces Barba", v. 2, 2008; FREIXES SAN JUAN, T., "Constitucionalismo multinivel e integración europea" in the book "Constitucionalismo Multinivel y relaciones entre Parlamentos: Parlamento europeo, Parlamentos nacionales, Parlamentos regionales con competencias legislativas", CEPC, 2011; GÓMEZ SÁNCHEZ, Y., "Constitucionalismo multinivel. Derechos fundamentales", 2nd edition, Sanz y Torres, 2014. Nevertheless, it is important to note that although Multilevel Constitutionalism and Constitutional Pluralism have a different origin and development in the European integration studies debate, both of them 'display significant similarities in terms of theoretical foundations' (MAYER, F. C. & WENDER, M., "Multilevel Constitutionalism and Constitutional Pluralism", in the book "Constitutional Pluralism in the European Union and Beyond", Hart Publishing, 2012, p. 151).

7 Although it is difficult to affirm the existence of a Human Rights or Fundamental Rights protection system in a strict sense, we are facing a system in construction (SARRIÓN ESTEVE, J., "El Tribunal de Justicia de Luxemburgo como garante de los derechos fundamentales", Dykinson, 2013) rationalised by scholars (TENORIO SÁNCHEZ, P. "Diálogo entre Tribunales y Protección de los Derechos Fundamentales en el ámbito europeo", in Revista General de Derecho Europeo, 31, p. 2-4).

8 GÓMEZ SÁNCHEZ, Y., "Constitucionalismo multinivel. Derechos fundamentales", cit. p. 55.

9 BILANCIA, P., "The Dyanimcs of the EU integration and the impact on the National Constitutional Law", Giuffrè, 2012, p. 84.

to take into account not only EU and national law, but also international law and obligations[10] including the European Convention on Human Rights (ECHR),[11] and other international instruments such as the Convention on Human Rights and Biomedicine (Oviedo Convention).[12]

Nevertheless, some authors usually tend to share an assumption that seems problematic, as Komárek pointed out recently[13]: the identity of fundamental rights at the different levels and systems, based on the universality of human rights. Certainly, fundamental rights are founded on universal values, but are linked to a specific legal order, and therefore to a specific constitutional and national identity (of which they are a part). The reality is that Fundamental Rights protection in the EU Legal order has its own ground and standard of protection and guarantees, which differs from national ones and even from the ECHR order. This makes it more difficult to determine the applicable level of protection and fundamental rights guarantees.

Certainly, according to article 51(1) of the EU Charter of Fundamental Rights,[14] the EU Charter provisions are addressed not only to EU institutions but also to the EU Member States when they are implementing EU law. The European Court of Justice's (ECJ) interpretation of this provision is very extensive, in the sense that it is linked to the concept of the scope of EU law. Therefore, EU Fundamental Rights protection is binding for EU member states not only when they implement EU law but in any case within the scope of EU law (*Åkerberg Fransson*, C-617/10),[15] and the application of EU Fundamental Rights standard is binding, not allowing the application of the national one unless the EU law provides a margin to do so without questioning the primacy

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10 We differentiate between external produced/approved law and internal produced law. Within the external law we can also point out a very relevant distinction between international law and supranational law, i.e., EU law is supranational law because EU law applies thanks to its own principles in Member States ex EU legal order.

11 Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, 4 Nov. 1950, better known as the *European Convention on Human Rights.*

12 Convention for the Protection of Human Rights and dignity of the Human Being with regard to the Application of Biology and Medicine, Oviedo, 4 April 1997, better known as *Convention on Human Rights and Biomedicine* or *Oviedo Convention*. Entry into force on 1.12.1999. Italy signed it (4.4.1997) but has not yet ratified it. Spain signed it and ratified it on 23.07.1999.

13 Komárek argued that the origin and bases of fundamental rights are different: Constitutional fundamental rights protection is based on a political constitutional project after World War II, and EU fundamental rights protection on the foundations of the European market integration project. See KOMÁREK, J., "Why National Constitutional Courts Should Not Embrace EU Fundamental Rights", in LSE Law, Society and Economy Working Papers, 23/2014, available on: http://www.lse.ac.uk/collections/law/wps/ , 2014, p. 8-10.

14 Charter of Fundamental Rights of the European Union, better known as EU Charter, elaborated in 2000, Niza. After that the Charter was adapted in Strasbourg in 2007 and entered into force with the Lisbon Treaty on Dec. 2009. The last version of 26.10.2012 was published in the OJEU C 326/391 and is available at: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX-:12012P/TXT&from=EN

15 CJEU, C-617/10, Åkerberg Fransson.

of EU law (*Melloni*, C-399/11[16]; and *Åkerberg Fransson*, C-617/10) challenging the multilevel system.[17]

Therefore, there is no simple answer regarding fundamental rights protection on health data treatments, but we are going to try to develop an overview on the actual legal framework of health data treatments in the EU by outlining actual challenges.

3. *Health data treatment legal framework.* Health, Biological and Biometric data are sensitive because they concern the privacy of the person (private life) in different dimensions. On the one hand, health data are personal data linked to the health of a person (derived from health care treatments), and on the other hand, biological and biometric data enable the identify of a person.[18] In both cases, we deal with sensitive and relevant data linked to privacy.

My aim in this paper is to overview the legal framework regarding the treatment or processing (including collection, recording, organisation, structuring, storage, and other uses) of health data. In other words, particularly I focus on one of these dimensions of privacy (the health one), although we think that it is also important to outline relevant related issues.[19]

3.1 Health data treatment international legal framework. At the international law level, it is important to note the Universal Declaration of Human Rights (UDHR) of 1948 as a milestone document in human rights protection adopted by the United Nations General Assembly. Although it is not a binding document, it can be an important source for the interpretation of the law. Article 12 provides for privacy:

'No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks'.

There are also other non-binding international instruments such as the Universal Declaration on Bioethics and Human Rights of 19 October 2005 (UDBHR) within UNESCO (United Nations Educational, Scientific and Cultural Organization) framework, which aims to 'provide a universal framework of principles and procedures to guide States

16 CJEU, C-399/11, Melloni.

17 Regarding the challenges of the application of the EU fundamental rights protection standard limiting the national ones, see my previous work SARRIÓN ESTEVE, J. "Actual Trends and Challenges of the Constitutional Fundamental Rights and Principles in the ECJ Case Law from the Perspective of Multilevel Constitutionalism" (September 4, 2015), available at SSRN: https://ssrn.com/abstract=2656394 or http://dx.doi.org/10.2139/ssrn.2656394

18 On biologic and biometric data linked to identify persons, I suggest the lecture of the work CABEZUDO BAJO, M. J., "Genetic Evidence" in this book "Genetic Information and Individual Rights", Universitsverlag, Regensburg, 2017.

19 In this paper, we focus particularly on the privacy of health data related to the interest and control power of the patient related to collection, storage and processing of such data. But of course, it is also important to deal with the question of confidentiality related to the respect of privacy in the relationship between the doctor and the patient.

in the formulation of their legislation, policies or other instruments in the field of bioethics' (art. 2(a) UDBHR), and emphasises the need to carry out medical research within the framework of the ethical principles that the Declaration states by respecting the dignity, human rights, and fundamental freedoms (art. 2 (d) UDBHR).

It provides for minimisation regarding applying and advancing scientific knowledge, medical practice and associated technologies; maximising direct and indirect benefits to patients and individuals (art. 4 UDBHR); respecting the autonomy of persons (art. 5 UDBHR); requires 'the prior, free and informed consent of the person concerned, based on adequate information' (art. 6(1) UDBHR) or the authorisation according to national law (art. 7 UDBHR) and the respect for privacy and confidentiality (art. 9 UDBHR); prohibition of discrimination (art. 11 UDBHR), inter alia. In particular, regarding privacy and confidentiality, article 9 UDBHR stipulates that:

'*The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or discloses for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law*'.

More importantly, due to its binding nature, the ECHR at the Council of Europe (CoE) regional system provides in article 8 that:

1. *Everyone has the right to respect for his private and family life, his home and his correspondence.*
2. *There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.*

There are other articles in the ECHR relevant for health treatments including article 2 (right to life), article 3 (prohibition of torture, rights to integrity and dignity), and particularly on health data, article 14 provides the prohibition of discrimination without any distinction, which we must interpret as including the prohibition of genetic discrimination; and article 9 related to freedom of thought, conscience and religion, which anyone can use in order to limit some of his or her health data treatments.

Certainly, the relevance of the ECHR is that any individual can ask for the protection of human rights recognised after the end of the national action. And EHRC had the opportunity to resolve questions on the issue of health data treatment under article 8 ECHR, as for example in the case *Z v. Finland* (1996) when EHRC called for a more careful scrutiny relating the disclosure of personal information from medical records without a patient's consent.[20]

[20] EHRC, 25 February 1997, Z v. Finland, Application No. 9/1996/627/811. It is interesting that in this case the disclosure of the medical file was ordered during a trial of the patient's husband for manslaughter, and in this case the EHRC considered the disclosure as necessary for the purpose of the trial, but that the publication of personal data such as the witness's name and health data (HIV status) in the subsequent appeal trial was not justified, because the limitation of privacy must be at

However, privacy rights cannot restrict or limit the right to identity also covered by art. 4 ECHR, as essential to an effective privacy right, as EHRC pointed out in the case *Bensaid v. The United Kingdom* (2001).[21] Privacy also includes the right to know the circumstances of those born and to establish the identity of the ascendants as a vital interest (*Jäggi v. Switzerland*, 2003).[22]

The consent for health treatment or medical examination is essential (a precondition) to the implementation of health or medical treatment or examination unless it is a medical emergency. Therefore, it is also essential to the subsequent health data treatments.

Regarding persons not able to consent, such as minors or adults unable to consent, it is important to obtain the parent's or legal representative's consent. In this sense, the EHRC ruled in *M.A.K. and R.K v. United Kingdom* (2010) that a medical examination of a nine-year-old girl without the required parental consent was a violation of articles 8 and 13 ECHR.[23]

Based on article 8 ECHR, the Convention for the protection of individuals with regard to the automatic processing of personal data of 1981 provides specific rules regarding the processing of personal data.[24] This instrument requires taking the necessary steps in the national legislation to apply its principles (art.4(1)), including:

1) Quality of data (art. 5): data shall be obtained and processed fairly and lawfully; stored for specified and legitimate purposes and not used in an incompatible way; adequate, relevant and not excessive in relation to the sole purposes; accurate and where necessary kept up to date; preserved in a way that permits identification no longer than is required for the storage purposes.
2) Special safeguards for special categories of data, including personal data concerning health (art. 6).
3) Appropriate security measures (art. 7).
4) Safeguard rights for the data subject including access, rectification or erasure of data (art. 8).
5) Special provisions for transborder data flows (art. 12).

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a minimum. Nevertheless, in *Colak and Tsakiridis v. Germany* (2010) protected the confidentiality principle and the doctor's decision to not inform the patient's partner on the patient's HIV status according to his request, even her risk exposure in this case (EHRC, 5 March 2009, Colak and Tsakiridis v. Germany, Application Nos 77144/01 and 35493/05)

21 EHRC 6 February 2001, Bensaid v. The United Kingdom, Application No.44599/98. Certainly, the EHRC stated that article 8 'protects a right to identity and personal development (...) The preservation of mental stability is in that context an indispensable precondition to effective enjoyment of the right to respect for private life'.

22 EHRC 3 July 2003, Jäggi v. Witzerland, Application No. 58757/00.

23 EHRC 24 March 2010, M.A.K. and R.K v. United Kingdom, Application nos. 45901/05 and 40146/06. It is an interesting case because there was a blood sample that could be used to conduct a test in order to investigate eventual sexual abuse by the parent without the parent's consent. Although the existence of medical suspects on the father, the Court ruled against UK and the medical actuation without the parent's consent.

24 Convention for the protection of individuals with regard to the automatic processing of personal data (No108), 1981.

The CoE Council of Minister adopted in 1997 the Recommendation on the protection of medical data providing for the application of privacy legislation for all medical data.[25]

Moreover, in the CoE system, there is a specific convention as we pointed out before: the *Convention on Human Rights and Biomedicine* (*Oviedo Convention*) of 1997.[26] The purpose of the Oviedo Convention is precisely to serve as an instrument for the protection of human rights in the field of biomedicine, signed and ratified by Spain. However, one of the obstacles to its implementation is that some relevant CoE States have still not signed it (such as Germany, the United Kingdom or Russia) while others that have signed it have still not ratified it (Italy, Holland or Poland).[27] Notwithstanding, there was no obstacle for the EHRC to mention the Oviedo Convention in case law affecting those countries.[28]

Furthermore, the Oviedo Convention, which is 20 years old, is now supplemented by 4 protocols: on the prohibition of human cloning (ETS No. 168), on human organ and tissue transplantation (ETS No. 186), biomedical research (ETS No. 195), and genetic tests for health purposes (ECTS No. 203).

Certainly, the Oviedo Convention focused on biomedicine, and it is important due to the specific provisions on protection of 'dignity and identity of all human beings' and 'guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine' (article 1(1) Oviedo Convention), and it is a binding instrument which compels States to partake at an internal level to give effect to the Convention provisions (art. 1(2) Oviedo Convention):

- The Primacy of the human being (art. 2 Oviedo Convention).
- Equitable access to health care (art. 3 Oviedo Convention).
- Professional standards in the health field (art. 4 Oviedo Convention)
- Free and informed consent in the health field (arts. 5-9 Oviedo Convention).
- Private life and right to information (art. 10 Oviedo Convention).
- Non-discrimination on grounds of genetics (art. 11 Oviedo Convention).

There are other provisions for other issues on scientific research, organ transplant, prohibition of financial gain which are not relevant to this paper.

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25 CoE Recommendation No. R (97) 5 on the protection of medical data.

26 Convention for the Protection of Human Rights and dignity of the Human Being with regard to the Application of Biology and Medicine, Oviedo, 4 April 1997 (ETS No. 164) better known as *Convention on Human Rights and Biomedicine* or *Oviedo Convention.*

27 Chart of signatures and ratifications of Treaty 164. Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Status as of 10/04/2017. Available at: http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=C9Qv25Dq

28 For example, EHRC 9 March 2004*,* Glass v. UK, Application no. 6187/00; 10 April 2007, *Evans v. UK* (GC), Application no. 6339/05, 23 March 2010, M.A.K. and R.K. v. UK, Application no. 45901/05 and 40146/06; 26 May 2011, *R.R. v. Poland*, Application no. 27617/04; 23 July 2015, Bataliny v. Russia, Application no. 10060/07; 27 August 2015, Parrillo v. Italy (GC), Application no. 46043/14.

Regarding the restrictions on the exercise of the rights guaranteed, article 26 stipulates that no restrictions shall be placed other than those prescribed by law necessary in a democratic society in the interest of public safety, prevention of crime, protection of public health or other's rights.

Article 27 of Oviedo Convention regulates wider protection, in the sense that none of the Oviedo Convention provisions 'shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection' regarding biology and medicine. Therefore, the Oviedo Convention provides a minimum standard regarding medicine in this field.

We shall only emphasise, as we pointed out before, the relevance of free and informed consent as a requirement to health treatment, and therefore as a previous precondition to subsequent health data treatment. The general rule for consent under the Oviedo Convention is that 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it', with previous appropriated information (to the purpose and nature of the intervention, consequences and risks), and with the right to freely withdraw consent 'at any time' (article 5 Oviedo Convention). We must interpret article 5 of the Oviedo Convention in the sense that the information must be appropriate regarding the intervention, consequences and risk, and it must be a previous information, but the article does not speak about a full information.

Regarding the protection of persons unable to consent (minors and adults without the capacity to consent) according to the national law, the intervention is only allowed if it is in their direct benefit (art. 6(1)Oviedo Convention) with the authorisation of parents or legal representatives, a person or body provided by the law (art. 6(2)and(3)) receiving a previous appropriate information (art. 6(3) Oviedo Convention), and who may withdraw authorisation at any time in the best interest of the patient (art. 6(5) Oviedo Convention).

Moreover, article 8 concerns an emergency situation when the appropriate consent cannot be obtained: 'any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned' (art. 8 Oviedo Convention). The previously expressed wishes by a patient, who at the time of the medical intervention is not in a state to express wishes shall be taken into account (art. 9 Oviedo Convention).

Private life is protected in relation to the information about health (art. 10(1) Oviedo Convention), and the patient is entitled to know any information collected about his/her health (10(2) Oviedo Convention), although this can be limited in the patient's interest (art. 10(3) Oviedo Convention). Moreover, there is no obligation to know the information as 'the wishes of individuals not to be so informed shall be observed' (art. 10(2) Oviedo Convention).

3.2 Health data treatment European Union legal framework. At the European Union Law level, we must consider the EU Charter (EUCFR), which recognises the principle of human dignity (article 1), the right to life (article 2), the right to the integrity of the person (article 3), the prohibition of torture and inhuman or degrading treatment or punishment (article 4), respect for private and family life (article 7), protection of personal data

(article 8),[29] the prohibition of all discrimination including that of genetic characteristics in an express way (article 21).

It is particularly relevant to outline article 3 EUCFR, since it recognises the right of everyone to respect his or her physical and mental integrity. Article 3(1) states that 'in the fields of medicine and biology, the following must be respected in particular' (article 3(2))[30]:

(a) the free and informed consent of the person concerned, according to the procedures laid down by law;
(b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
(c) the prohibition on making the human body and its parts as such a source of financial gain;
(d) the prohibition of the reproductive cloning of human beings.

Although the EU Charter is a very advanced human rights instrument with the inclusion of the last generation of rights, and it is assumed to provide the higher standard of protection for fundamental rights, it includes (as other human rights instruments) a safeguard clause in article 53, ruling that:

Nothing in this Charter shall be interpreted as restricting or adversely affecting human rights and fundamental freedoms as recognised, in their respective fields of application, by Union law and international law and by international agreements to which the Union or all the Member States are party, including the European Convention for the Protection of Human Rights and Fundamental Freedoms, and by the Member States' constitutions.

Nevertheless, as we pointed out before, the ECJ interpreted article 53 in a non-safeguard sense, i.e., that this provision does not allow a Member State to the application of the national fundamental rights standard (in the scope of EU law) unless the EU law provides a margin to do so without questioning the primacy of EU law (*Melloni*, C-399/11; and *Åkerberg Fransson*, C-617/10). Consequently the EU standard of protection will be binding as a general rule when we are in the scope of EU law, which is most of the time.

On the issue of privacy and data protection for health data treatment, the actual EU legislation[31] is Directive 95/46/EC on the protection of individuals with regard to the

[29] European Court of Justice developed the right to data protection including the right to be forgotten, see CJEU, C-131/12, Google Spain.

[30] From my point of view article 3 applies to the field of health, genetic and biometric data treatment or processing -including collection, recording, organisation, structuring, storage, and other uses- because we are speaking about the treatment or processing of data linked to medicine and biology.

[31] Excluding the treatment in criminal and security areas. The Data Protection Directive explicitly excluded from its scope of application data processing '*in the course of an activity which falls outside the scope of Community law, such as those provided for by Titles V and VI of the Treaty on European Union and in any case to processing operations concerning public security, defense, State security (including the economic well-being of the State when the processing operation relates to State security matters) and the activities of the State in areas of criminal law*' (art. 3(2)); and the new Data Protection Package includ-

processing of personal data and on the free movement of such data (Data Protection Directive, DPD).[32] This was in force until the application of the new Data Protection legislation[33]: the Regulation (EU) 2016/679 of EP and the Council on the protection of natural persons with regard to the processing of personal data on the free movement of such data (General Data Protection Regulation, GDPR),[34] planned for 25 May 2018.

Certainly, article 99 of GDPR stipulates the enter into force of the GDPR 'on the twentieth day following that of its publication in the Official Journal of the European Union' (99(1) and that 'It shall apply from 25 May 2018'. Therefore, it entered into force on 25 May 2017 but it shall not apply until 25 May 2018. Nowadays the current legislation consists of the DPD and the national transposition and development legislation of the Data Protection Directive.

Nevertheless, to take into account both of them we are going to focus on the new regulation, the GDPR, particularly the new provisions that may apply to health data treatments.[35]

First, it is important to note the concepts included in the GDPR:

– 'Processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (art. 4(2) GDPR).
– 'Controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by the Union or Member State law (art. 4(7) GDPR).

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ed these areas in a new Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA.

32 Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Data Protection Directive), OJ 1995 L 281.

33 Actually, the new Data Protection legislation known as Data Protection Package includes two instruments: the general Regulation in which we are interested, and a Directive on criminal and security areas. See above.

34 Regulation (EU) 2016/679 of EP and the Council on the protection of natural persons with regard to the processing of personal data on the free movement of such data (General Data Protection Regulation), OJ 4.5.2016 L 119/1.

35 There are relevant differences between the two instruments. Although the PDD was adopted by EU Member States, there are important differences in the implementation, and it did not take into account new technologies. Besides this, the new GDPR will apply to all EU member states since 28 May 2018, and it takes into account new technologies.

– 'Processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller (art. 4(8) GDPR).

The DPD and GDPR stipulate as a general rule the prohibition of the processing of data concerning health (art. 8(1) DPD, art. 9(1) GDPR) except in some situations (art. 8(2) and (3) DPD, and art. 9(2) GDPR). Nevertheless, the new GDPR introduces genetic[36] and biometric data,[37] as particular data (different from health data[38]) and provides the same protection, and permits Members States to introduce further conditions about genetic, biometric and health data.

Certainly, the processing of genetic data, biometric data and data concerning health shall be prohibited as a general rule (art. 9(1) GDPR), except art. 9(2) GDPR:

(h) processing ***is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services*** *on the basis of Union or Member State law* ***or pursuant to contract with a health professional*** *and subject to the conditions and safeguards referred to in paragraph 3;*

(i) processing ***is necessary for reasons of public interest in the area of public health****, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy; L 119/38 EN Official Journal of the European Union 4.5.2016*

(j) ***processing is necessary for archiving purposes in the public interest****,* ***scientific or historical research purposes or statistical purposes*** *in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject'*. (Emphasis added by the author)

The New General regulation provides for general principles when processing data in the same way,as the Directive, but with some innovation which we will outline. The general principles for processing data are (according to art. 5 GDPR):

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[36] 'Genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question (art. 4(13) GDPR).

[37] 'Biometric data' are defined as personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data (art. 4(14) GDPR).

[38] Defined as personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status (art. 4(15) GDPR).

1) Principle of lawfulness, fairness and transparency. Data shall be processed lawfully, fairly and in a transparent manner in relation to the data subject (art. 5.1(a) GDPR).
2) Principle of purpose limitation. Data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purpose (art.5.1(b) GDPR).
3) Principle of data minimisation. Processing shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (art. 5.1(c) GDPR).
4) Principle of accuracy. Personal data shall be accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay (art. 5.1(d) GDPR).
5) Principle of storage limitation. Data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject (art.5.1(e) GDPR).
6) Principles of integrity and confidentiality. Data shall be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures (art. 5.1(f) GDPR)
7) Principle of accountability. The controller shall be responsible for, and be able to demonstrate compliance with previous obligations, paragraph 1 art. 5 (art. 5(2) GDPR).

It is important to outline that the principle of accountability is a new principle, the controller has to prove that he or she respects the above principles (the burden of the proof is with him or her).

The processing of data will be lawful only applying one of the following principles (art. 6(1) GDPR)[39]: a) Explicit and unambiguous consent[40] or the authorisation of the

[39] Note that these are not a requirement list, i.e., the regulation allows for processing applying any of the principles covered by art. 6(1). Therefore, the consent or authorisation principle is a legitimate way to process data, but it is not the unique way to do it.

[40] The data subject has given consent to the processing of his or her personal data for one or more specific purposes (art.6(1)(a)) GDPR). The conditions for the consent are developed in art. 7 GDPR: 1) The controller shall be able to demonstrate that the data subject has consented, i.e., burden of the proof is with controller (art. 7(1) GDPR). 2) Consent must be informed in intelligible and accessible forms, using clear and plain language, any part which constitutes an infringement shall not

holder of parental responsibility[41] (art. 6.1(a) GDPR; b) the processing is necessary for the performance of a contract with the data subject (art. 6.1(b) GDPR; c) processing is necessary for compliance with a legal obligation ((art. 6.1(c) GDPR); d) processing is necessary in order to protect the vital interests of the data subject or another natural person ((art. 6.1(d) GDPR); e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority (art. 6.1(e) GDPR); f) processing is necessary for the purposes of the legitimated interests pursued by the controller or by a third party except where such interests are overridden by the interests or fundamental rights of data subject (not applicable to the authorities) (a(art. 6.1(f) GDPR).[42]

Nevertheless, as we pointed out before, health data are a special category of personal data (sensitive data), and they are included in article 9 with biological and biometric data. The general rule is that these special categories cannot be processed (art. 9(1) GDPR) with the exceptions provided in art. 9.2(h), i and j GDPR, so the processing of these data categories is based on the legitimate purposes of preventive or occupational medicine, medical diagnosis, provision of health or social care, health or social care treatment or management system (art. 9.2(h) GDPR), for reasons of public interest in the area of public health (art. 9.2(i) GPDR), and where appropriate for archiving purposes in the public interest, scientific or historical research purposes or statistical ones (art. 9.2(j) GDPR).[43]

One might ask whether in these cases consent or authorisation is needed (art. 6.1(a) GDPR) or we should not apply this provision -art. 6.1(a)-. My interpretation is that the processing of health data for these purposes can be covered by consent (art. 6.1(a) GDPR), or any other principles of art. 6(1) but we need to be covered by one of them,[44] although it is true that it seems to me easy to justify the processing of health data in the purposes of art. 9, in any of the principles ruled in art. 6(1) as the protection of the vital interests of the data subject or another person (art. 6.1(d) GDPR), legitimated interest of the medical centre or hospital (art. 6.1(f) guaranteeing fundamental rights and interests

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be binding (art. 7(2) GDPR). Therefore, the consent must be explicit and unambiguous. We can say that we need a clear affirmative act, for example although it can be written, electronic or oral, in the last case we need to record it in order to prove the consent. 3) The data subject has the right to withdraw the consent at any time (art. 7(3) GDPR).

41 In the case of minors under 16, it is necessary to have consent or authorisation by the holder of parental responsibility. Member States may provide by law for a lower age (not below 13), according to art. 8 GDPR.

42 Moreover, Member States may introduce more specific provisions in pints c and e (art. 6(2) GDPR).

43 Moreover, according to art. 9.2(e) GDPR if the health data are public because patients made their data 'manifestly public', these data are no longer protected as sensitive data. It is obvious that this concept is subject to interpretation.

44 Certainly I think that although perhaps the original aim of the GDPR is to allow the processing of health, genetic and biometric data without the consent of the data subject, the correct interpretation should be other, i.e., according to article 3(2) of EU Fundamental Rights Charter -which must be applied in the processing of data in the fields of medicine and biology- we need the consent of the data subject or in any of the other principles ruled in art. 6(1) GDPR as lawful bases for the processing of these types of data.

GDPR), for compliance with a contract (6.1 (b) GDPR) in the case for example medical or health preventive treatment under employment contracts or health insurances contracts, or a legal obligation (art. 6.1(c) covered by health or social management legislation, or for the performance of a task carried out in the public interest or in the exercise of official authority (art. 6.1(e) GDPR). Nevertheless several authors suggest that Member States must use the provision of article 9(4)-which allow EU Member States to introduce additional conditions to the processing of health, biometric and genetic data - to end interpreting doubts.[45]

At any rate, it is important to note that health data should be processed by or under the responsibility of a professional subject under the obligation of professional confidentiality under EU or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under EU or Member State law or other rules (art. 9(3) GDPR).

European Court of Justice ruled in the *Lindquist* case (ECJ C-101/01)[46] that charge of criminal violation of Swedish data protection law based in the publication on the internet of health information relating a Lindquist's colleague, particularly the fact that she [Lindquist's colleague] had injured her foot and was on medical leave, are health data and, i.e., the charge was not a disproportionate violation of the principle of freedom of expression.

On the processing of data, the patient or data subject has several rights:

1) Right to access (art. 15 and recital 63 GDPR). Access to your own personal data, including your medical record, and request a copy (the controller can charge a fee). The New General Regulation regulates remote ways to provide access to data, in this case the information shall be provided in a commonly used electronic form.
2) Right to rectification (art. 16 GDPR). Rectification of inaccurate personal data concerning him or her. Taking into account the purposes of the processing, the data subject shall have the right to have missing personal data completed, including by means of providing a supplementary statement.
3) Right to be informed (arts. 13 and 14 GDPR). Right to be provided in a concise, transparent, intelligible and clear and plain language some information as the identity and detailed contact of the controller, the purposes of the processing, the recipients of personal data, the period of storement, the existence of the rights to access, the existence of automated decision-making; and if the information has not been obtained from the data subject; the source of the data.
4) Right to erasure (including right to be forgotten) (art. 17 GDPR). Right to obtain the erasure of personal data when the personal data are no longer necessary – this provision, we think, is difficult to apply to health data, in fact we deal

[45] See BELTRAN AGUIRRE, J. L., "Tratamiento de datos personales de salud: incidencia del Reglamento General de Protección de Datos", in the book "Salud electrónica. Perspectiva y realidad", Tirant lo Blanch, Valencia, 2017, p. 121 and 122; BOMBILLAR SÁENZ, F., "Tratamiento jurídico del consentimiento informado y la donación de muestras biológicas a un biobanco para investigación biomédica: los consentimientos en blanco", in Derecho y Salud, 2017, v. 27, 1, p. 111.

[46] CJEU, C-101/01, Lindquist.

with an exception below –, have been unlawfully processed, for compliance with a legal obligation, etc.
Exceptions: the processing is necessary for legal compliance, for reasons of public interest in the area of public health, for archiving purposes in the public interest or historical research purposes or statistical purposes, for the establishment, exercise or defense of legal claims.

5) Right to portability (arts. 20 GDPR). Right to receive the personal data provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller which have been provided when the processing is based on a consent pursuant to point (a) of article 9.(2) (consent) and the processing is carried out by automated means.
Certainly, there is a clear limitation of the use of this right regarding the health data processed on other grounds, but we suppose that hospitals and medical centres may give the complete information regarding processing by reasons of effectiveness.
6) Right to object (art. 21 GDPR). Right to object to the data processing if the processing is based on public interest (art. 6.1(e), for the legitimate purpose of the controller (art. 6.1(f) GDPR), or in the context of direct marketing, or based on the ground of scientific or historical research purposes or statistical purposes unless the processing is necessary for public interest reasons.
7) Right to communication of a personal data breach (art. 34 GDPR). When the personal data breach is likely to result in a high risk to the rights and freedoms of natural persons, the controller shall communicate the personal data breach to the subject without undue delay. Moreover, there is also a provision to notify the breach to the Data Protection Authority (art. 33 GDPR).
8) Right to lodge a complaint with a supervisory authority (art. 77 GDPR). Right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement in the case of considering a processing that infringes the regulation. There is also the right to an effective judicial remedy against a supervisory authority (art. 78 GDPR).
9) Right to an effective judicial remedy against a controller or processor (art. 79 GDPR). Right to an effective judicial remedy against a controller or processor before the courts of the Member State where the controller or processor has an establishment, or alternatively before the courts of the Member State where the data subject has his or her habitual residence, unless the controller or processor is a public authority of a Member State acting in the exercise of its public powers.
10) Right to a compensation and liability (art. 82 GDPR). Right to receive compensation from the controller or processor for the damage suffered (material and non-material damage) as a result of an infringement of the GDPR.

One of the most interesting parts of the new GDPR is the binding figure of the Data Protection Officer (DPO). Certainly, the DPD allows the possibility for national law to

provide that controllers may appoint an official to act as a personal data protection officer (art. 18(2) DPD). The objective is to ensure the respect to the rights and freedoms of the data subjects in the processing operations. However, this figure was only included (as far as we know) in the German Federal Law on Data Protection.[47]

Actually, the new regulation (GDPR) introduces this interesting figure in arts. 37, 38 and 39. The controller and as far as we know, the processor shall designate a DPO in any case where:

a) The processing is carried out by a public authority or body, except for courts acting in their judicial capacity;
b) The core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or
c) The core activities of the controller or the processor consist of processing a large scale of special categories of data pursuant to art. 9 GDPR (including health data) and personal data relating to criminal convictions and offences referred to in art. 10 GDPR.

In other cases, the controller or processor or associations and other bodies representing categories of controllers or processors may or, where required by the Union or member State, shall designate a DPO. The DPO may act for such associations and other bodies representing controllers or processors (art. 37(5) GDPR).

A group of undertakings may appoint a single DPO provided that a DPO may be designated for several such authorities or bodies, taking account of their organisational structure and size (art. 37(2) GDPR).

Where the controller or the processor is a public authority or body, a single DPO may be designated for several such authorities or bodies, taking account of their organisational structure and size (art 37(3) GDPR).

The DPO shall be designated on the basis of professional qualities and, in particular, expert knowledge of data protection law and practices and the ability to fulfil the tasks of art. 39 (art. 37(5) GDPR). And may be a staff member of the controller or processor, or fulfil the tasks on the basis of a service contract (art. 37(6) GDPR).

Finally, the controller or the processor shall publish the contact details of the DPO and communicate them to the supervisory authority (art. 37(7) GDPR).

Certainly, with these provisions we guess that the DPO will be a very relevant figure in the future from the point of view of fundamental rights protection regarding the processing of data, including health ones, and it will be very important to guarantee the highest position in the structure to allow him or her to develop the assigned attributed tasks. In fact, article 38 GDPR states regarding the DPO position that the controller and proces-

[47] It is pointed out by the FRA 2014 Handbook on data protection law (pages 100-101), for example: 'In Germany, according to Section 4f, Subsection 1 of the German Federal Data Protection Act (Bundesdatenschutzgesetz), privately owned companies are required to appoint an internal personal data protection official if they permanently employ 10 or more persons in the automated processing of personal data'. See FRA 2014 Handbook on data protection law, available at: http://fra.europa.eu/en/publication/2014/handbook-european-data-protection-law (22 April 2017)

sor shall ensure that the DPO is involved, properly and in a timely manner, in all issues which relate to the protection of personal data (38.1 GDPR); shall support the DPO in performing the tasks referred to in art. 39 by providing resources necessary to carry out those tasks and access to personal data and processing operations, and to maintain his/her knowledge (art. 8(2)); shall ensure that the DPO does not receive any instructions regarding the exercise of those tasks. He or she shall not be dismissed or penalised by the controller or the processor for performing his tasks. The DPO shall directly report to the highest management level of the controller or the processor (art. 38(3) GDPR).

Data subjects may contact the DPO with regard to all issues related to processing of their personal data and to the exercise of their rights under GDPR (art. 38(4) GDPR). The DPO is bound by secrecy or confidentiality about the developed tasks according to the national law (art. 38(5) GDPR) as a way to guarantee the protection of the rights exercised. Although the DPO may fulfil other tasks and duties, the controller or processor shall ensure that any such tasks and duties do not result in a conflict of interests (38(3) GDPR). Despite this attempt to avoid conflicts of interest, we think that it would be a better option to forbid the development of other tasks by the DPO in order to guarantee effective and correctly developed data protection tasks, due to the amount and complexity, which are, according to article 39 GDPR:

(a) to inform and advise the controller or the processor and the employees who carry out processing of their GDPR obligations and national data protection provisions;
(b) to monitor compliance with GDPR, other EU and national data protection provisions, and with the policies of the controller or processor in relation to the protection of personal data, including the assignment of responsibilities, awareness-raising and training of staff involved in processing operations, and the related audits;
(c) to provide advice where requested as regards the data protection impact assessment and monitor its performance pursuant to art. 35 GDPR;
(d) to cooperate with the supervisory authority;
(e) to act as the contact point for the supervisory authority on issues relating to processing, including the prior consultation referred to in art. 36 GDPR, and to consult, where appropriate, with regard to any other matter.

The promotion of codes of conduct regarding the processing of personal data, including health ones, are included both in the Directive (art. 27 DPD) and in the GDPR (article 40). However, the GDPR goes further including the promotion, in particular at the EU level, of the establishment of data protection certification mechanisms and of data protection seals and marks for the purpose of demonstrating compliance with this Regulation (art. 42 GDPR) with a voluntary character and a transparent process.

4. *Conclusions and actual challenges regarding health data treatment.* As we pointed out at the beginning, health treatment or processing fields face ethical and legal problems regarding the use of data. As we know, patients can benefit from having health or medical information available, and medical decisions can be more effective with a better

understanding of clinical histories, medical and health data. Nevertheless, we need to guarantee privacy (including data protection rights) and confidentiality when dealing with health data treatment challenges from a fundamental rights perspective. To do so, we need to respect the legal framework: including international, EU and national, according to a multilevel perspective, because we live in a multilevel legal space.

Furthermore, new technologies face health, and particularly, health data. In fact, actual trends in processing health data include big data challenges (Bointerpretation, propensity, correlations (searching quality)), Standards and Interoperability, Data Governance and Trust, Data Expertise and Infrastructure, etc.[48] But also, as we know, Internet on Things (IoT) including m-Health (mobile-lifestyle and wellbeing apps),[49] Mobile Medicine, Cloud-computing, Electronic Patient Records (EPRs),[50] etc., and the question of health data as an economic commodity[51] are facing health data treatment. Therefore, health data treatment, as a biomedical data privacy space, is nowadays a multi-disciplinary space, crossing 'ethical, legal and technical boundaries and is specialised to the type of data and processes being supported'.[52] When addressing these challenges, we must keep in mind and apply the health data legal framework which we tried to outline in this paper.

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48 European Commission Directorate-General for Health and Consumers Unit D3 e-Health and Health Technology Assessment, *The use of Big Data in Public Health Policy and Research*, 29 August 2014, p. 8-10, available at: http://ec.europa.eu/health//sites/health/files/ehealth/docs/ev_20141118_co07b_en.pdf (22 April 2017)

49 European Data Protection Supervisor, Opinion 1/2015, *Mobile Health. Reconciling technological innovation with data protection*, 21 May 2015, available at: https://edps.europa.eu/data-protection/our-work/publications/opinions/mobile-health_en (22 April 2017).

50 Digital medical records focused on interoperability standards to allow healthcare and medical providers to exchange and share medical information. See BROWN, I., "The challenges to European data protection laws and principles" in Comparative Study on Different approaches to new privacy challenges, in particular in the light of technological developments, Working Paper 1, 20 January 2010, p. 10, available at: http://ec.europa.eu/justice/data-protection/document/studies/files/new_privacy_challenges/final_report_working_paper_1_en.pdf (22 April 2017).

51 Certainly, corporations increasingly treat personal data as a commodity, collecting, compiling and selling collections to others, VICTOR, J. M., "The EU General Data Protection Regulation: Toward a Property Regime for Protecting Data Privacy", cit. p. 517. In fact, the UK Court allowed a company to sell pharmacy data with the consent of the patient thanks to anonymisation, see 2000, R. v. Department of Health, Ex Parte Source Informatics Ltd, 48. Cited in KAPLAN, B., "Selling health data: de-identification, privacy, and speech", in IPS-BIOETHICS WORKING PAPER, ISPS 14-024, available at: http://bioethics.yale.edu/sites/default/files/files/ISPS14-024.pdf (22 April 2017).

52 MALIN, B. A., EL EMAN, K., O'KEEFE, C.M., "Biomedical data privacy: problems, perspectives, and recent advances", in J Am Med Inform Assoc, January 2013, v. 20, 1, p. 5.

Genetic research and exceptions to the protection of personal data

Roberto Cippitani

1. *Freedom of research and respect for fundamental rights*. Today one of the most powerful expressions of techno-science (i.e., scientific activities that affect the world through technology) is represented by genetic research.

Interest in genetics by scholars and the public has been growing ever since the manipulative power of techno-science has allowed it to not only gain greater meaning from genetic information[1] but also to be used for intervention in the structure of life through techniques such as cloning and genetic editing.[2]

On the other hand, the law governs individual rights and duties concerning genetic information depending on the typology of living beings and thus on the specific interests to be protected[3] (in respect to the EU and international legal instruments concerning animals and plants, see in this book V. Colcelli).

With reference to individuals, Article 1 of the Recommendation of the Committee of Ministers of the Council of Europe, No. R (97) 5 on the Protection of Medical Data (of 13 February 1997) considers genetic information to be "medical data", that is, "personal data concerning the health of an individual".

As medical data, genetic information is taken into consideration by the European Convention on Human Rights and Biomedicine (approved by the Council of Europe in 1997 in Oviedo), especially by its Chapter IV on the Human Genome and by additional protocols.[4] Within European Union law, the Charter of Fundamental Rights explicitly refers to genetic information in provisions Articles 3 and 21.

For individual nations, only some recently amended constitutions, such as those of

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1 An important milestone in the history of this sector is represented by the Human Genome Project, initiated by the US National Institutes of Health (NIH) along with a private undertaking, Celera Corporation, established and run by the biochemist Craig Venter.

2 See for example recent news (2 August 2017) concerning CRISPR, a technique that allows scientists to make changes to genomes in order to correct disease-causing mutations in human embryos. Ledford H., "CRISPR" fixes embryo error. Gene-editing experiment in human embryos pushes scientific and ethical boundaries, in Nature, 3 August 2017, Vol. 548, pp. 13–14.

3 See Janneke H. Gerards, General Issues Concerning Genetic Information, in GERANRDS J.H., HERINGA A.W., and JANSEEN H.L., Genetic Discrimination and Genetic Privacy in a Comparative Perspective, Itersentia, Oxford, 2005, 5 ff.

4 Several additional protocols refer to genetic information: Prohibition of Cloning Human Beings (1998); Human Rights and Biomedicine: Transplantation of Organs and Tissues of Human Origin (2001); Biomedical Research (2005); and Genetic Testing for Health Purposes (2008).

Switzerland (Article 24*nonies*) and Portugal (Article 26.3, para. 2), make specific reference to the protection of genetic data. More typically, legal issues concerning genetic information are regulated by legislation, such as in the legal systems of France and Austria,[5] and in other legislation.[6]

According to legal sources, there are at least two interests that are protected in the case of individuals' genetic information. First, genetic information is considered a particularly important component of personality, and therefore its use must respect the dignity[7] of individuals and in general their fundamental rights.[8] In particular, the protection of dignity is necessary to prevent or punish discrimination based on genetic characteristics (Article 11 of the Convention of Oviedo and Article 21 of the EU Charter).

Another interest taken into consideration does not concern the person but humankind: the intangibility of the human genome. The protection of the human genome is achieved from several perspectives: any alteration of human genetic patrimony (see Article 16-4 of the French Civil Code) in a transmissible manner (see the Universal Declaration on the Human Genome and Human Rights of UNESCO of 1997 and Article 13 of the Convention of Oviedo) is prohibited. This, in particular, concerns whether such modifications arise from scientific practices (see article 57 of the new Argentine Civil Code, which prohibits all scientific or therapeutic practices aiming at genetically modifying the human embryo).

Reproductive cloning of human beings is also considered unlawful under Article 3 of the EU Charter and Article 16-4 of the French Civil Code).

Furthermore, supranational sources consider it "important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings" (see recitals no. 40 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions; see also Article 6, para. 2.b of the directive).

Protection of genetic identity is considered as a safeguard of human identity.[9]

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5 In particular, French law regulates the use of genetic data through Chapter III of Title I of the Civil Code concerning "*De l'examen des caractéristiques génétiques d'une personne et de l'identification d'une personne par ses empreintes génétiques*" (examining the genetic characteristics of a person and his/her identification using genetic prints), which was introduced by laws concerning bioethics, the last one being Law 2011-267 of 14 March 2011. About the French *loi de bioétique*, see CIPPITANI R., "Principi e metodo nella revisione della normativa francese relativa alla bioetica", in Diritto di Famiglia e delle Persone, 2012, pp. 1836–1865; Id., "La nueva ley Francesa en tema de bioética en el contexto europeo", in Criminogenesis, 2011, pp. 199–214.

6 With respect to Swiss law, see the Federal Law on Human Genetic Testing, approved in 2004 and entered into force on 1 April 2007. In Germany in recent years a law concerning genetic diagnostics was approved (*Gendiagnostikgesetz* - GenDG) and entered into force on 1 February 2010. See DIURNI A., "Esperienze di regolamentazione della diagnostica genetica", in Danno e Resp., 2010, 7, 660.

7 FALCONE A., "La tutela del patrimonio genetico umano, fra Costituzione e diritti. Verso la Formazione di un Corpus Iuris sul genoma umano", Rubettino, Catanzaro, 2012, p. 17.

8 RUGGERI A., "Nuovi Diritti fondamentali e tecniche di positivizzazione", in Politica del Diritto, n. 2, 1993, p. 183.

9 ECJ, judgement of 18 October 2011, C-34/10, Oliver Brüstle/Greenpeace eV, ECLI:EU:C:2011:669, para. 33.

2. *Protection of genetic information through the discipline of privacy*. As mentioned in the previous paragraph, among the interests protected by law in respect to human genetic information, personality in its more intimate aspects is of primary importance.

Due to the ethical and legal issues concerning these kinds of interests, this chapter is focused on the legal aspects of scientific research carried out on genetic information. From that perspective, legal sources consider genetic information as "personal data" related to the health of a person. Therefore, the main legal instrument for the protection of fundamental rights associated with genetic data is represented by the discipline of privacy.

At the European level, early legal sources concerning the protection of personal data, such as the Strasbourg Convention no. 108 on the Protection of Individuals with regard to the Automatic Processing of Personal Data of 1981 of the Council of Europe (hereinafter referred to as "Convention no. 108"), as well as Directive 95/46/EC of the European Union of 24 October 1995, do not explicitly consider genetic information.

However, they include references to data that can also involve genetic data. Article 8, para. 1, of the directive, especially, takes into consideration "personal data revealing racial or ethnic origin, and (…) data concerning health". Such data are considered "sensitive" because they may reveal particularly intimate aspects of the life of a person. On these grounds, the processing of those data can be prohibited or subject to special control by authorities, in order to guarantee the reinforced protection provided by the directive (see also Article 6 of the Convention no. 108).

In any case, the qualification of genetic information as personal data has been confirmed in the literature[10] and by documents issued by supranational bodies.

The Explanatory Memorandum of Recommendation No. R (97) 5 of the Committee of Ministers of the Council of Europe on the protection of medical data states that "For the purposes of the recommendation, the drafters of the recommendation considered that most of the principles should apply to genetic data as well as to medical data" (para. 41). The appendix to that recommendation provides a definition of genetic data (among the medical ones) and affirms that the text "refers to all data on the carrying of any genetic information (genes) in an individual or genetic line relating to any aspect of health or disease, whether present as identifiable characteristics or not".

Additionally, the Working Document on Genetic Data, adopted on 17 March 2004 by the Article 29 Data Protection Working Party,[11] states that genetic information must be considered as personal data (para. III, p. 5).

Today, the new Regulation (EU) 2016/679 of 27 April 2016 of the European Parliament and of the Council (General Data Protection Regulation), which will soon replace the directive, explicitly considers genetic information as "personal data" (Article 4, 1), defining the information as "data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person" (Article 4, no. 13).

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[10] D'AMICO M., "Il trattamento pubblico dei dati sensibili: la disciplina italiana a confronto con il modello europeo", in Il diritto comunitario e degli scambi internazionali, Vol. n. 4, 2002, p. 817 ff.

[11] Available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2004/wp91_en.pdf.

Article 9, para. 2, of Regulation (EU) 2016/679 confirms the qualification of genetic data as "sensitive", establishing the prohibition of their processing if some conditions are not met.

As a consequence of the reference to the discipline of privacy, it is possible to apply to genetic information the rules concerning collection, processing, and storage of personal data, especially those that must be considered sensitive.

However, as explained in the subsequent paragraphs, the discipline of protection of personal data has deviated from the general discipline concerning privacy due to the fact that data are processed with scientific research purposes and, also, that research is carried out on genetic information.

3. *Scientific purposes*. According to Article 5, para. 1 of Regulation (EU) 2106/679, personal data must be collected lawfully (let. a) and only to achieve specific proposes, and must be processed in a way that is compatible with those purposes (so called "finality principle"). Not all purposes are acceptable.[12] Pursuant to Article 5 of the International Declaration of UNESCO on Human Genetic Data of 2003 (hereinafter referred to as "Declaration of UNESCO"), the scopes available for the use of genetic data are those concerning health and criminal investigations, that is to say, diagnosis and health care, including screening and predictive testing; and forensic medicine with regard to civil, criminal, and other legal proceedings.

Furthermore, any other purpose consistent with legal definitions and requirements is admissible if it does not violate fundamental rights (see for example Article 20 of the Recommendation CM/Rec(2015)5 of the Committee of Ministers to member states on the processing of personal data in the context of employment).

Among other purposes, research activities may represent a legitimate purpose to collect and process genetic information, as legal sources explicitly establish, at different levels. In particular, Article 5 (ii) of the Declaration of UNESCO considers "medical and scientific research", that is to say medical and other scientific research, including epidemiological research, especially population-based genetic studies, as well as anthropological or archaeological studies, to be legitimate.

Research concerning genetic information is also accepted by supranational legislation (Article 8, para. 3 of Directive 95/46/EC) and by national laws (see Article 16-10 and 16-11 of the French Civil Code; see also the Italian "*Garante per la protezione dei dati personali*", General Authorisation No. 8/2012 of 15 December 2016, para. 3).

Generally speaking, the acceptability of scientific purposes arises from the relevance assumed by science for society and legal systems. Today, national and supranational constitutions, as well as international legal agreements, consider academic activity, and especially research, as a fundamental freedom (see mainly Article 13 of the EU Charter).[13]

[12] The processing of genetic information for purposes not legally recognised may be punished by criminal law, as is the case in France for those requesting genetic testing on themselves or others, outside the cases authorized by law (see Article 226-28-1 penal code).

[13] For commentary on this disposition, see MOLINA DEL POZO F. and ARCHONTAKI C., "Libertad de artes y de Investigación Científica, Libertad de Cátedra", In ALVAREZ LEDESMA M.

This freedom is considered necessary for the benefit of humankind. As stated by Article 2 of the Universal Declaration on the Human Genome and Human Rights of UNESCO of 1997, the "benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all" (Article 2.a) and "Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole." (see letter b). According to Article 14 of that declaration, states have the obligation to grant the exercise of such freedom.

Sub-constitutional legislation also underlines the importance of research. This is particularly clear in the field of personal data and especially in the EU's General Data Protection Regulation. As in other EU directives during the last thirty years, research is considered as the fulcrum of European integration. This is explained by the institutional documents of the Lisbon strategy of 2000 and today in "Europe 2020".[14]

In particular, the General Data Protection Regulation (see recital no. 159 mentioned above) underlines the importance of the circulation of information for the building of the European Research Area (hereinafter referred to as "ERA"), as provided for by Article 179, para. 1, TFU, "in which researchers, scientific knowledge and technology circulate freely".

ERA is not only a dimension of the internal market, but also the expression of a cultural pillar on which the European integration process should be built. As a matter of fact, the regulation itself affirms that "the legitimate expectations of society for an increase of knowledge should be taken into consideration" (recital no. 113) and also points out that "To meet the specificities of processing personal data for scientific research purposes, specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific research purposes" (recital 159 as above).

Due to the above-mentioned reasons, and especially on the bases of the particularities of research activities, the European discipline concerning protection of personal data provides some specific derogations or exceptions to data use in the case of processing of personal data for scientific purposes.

4. *Scientific purposes and exceptions to the rule of consent.* On the ground of the qualification as "personal data" (see Article 4, nn. 1 and 13, Regulation (EU) 2016/679), genetic information should be under the control of the "data subject", who is entitled to give her/his "informed, free, express, specific and documented consent of the person" (Convention of Oviedo, see in particular Article 14) for processing such data (see also Article 6, letter d, Declaration of UNESCO).[15]

I. and CIPPITANI R. (coord.), Diccionario analítico de Derechos humanos e integración jurídica, ISEG, Roma-Perugia-México, 2013, pp. 361–367.

[14] Communication, Europe 2020, A strategy for smart, sustainable and inclusive growth, COM(2010) 2020 final, 3 March 2010. On the legal issues of a knowledge-based society, see CIPPITANI R. (editor), El Derecho en la Sociedad del Conocimiento, ISEG, Roma-Perugia, 2012.

[15] About informed consent to use personal genetic information, see CIPPITANI R., "Consent to the

According to the definition provided for by Article 2(iii) of the Declaration of UNESCO, consent is the "specific, informed and express permission that a person freely gives for his genetic data to be collected, processed, used and preserved" (see also Article 2 (j) of the Directive 2001/20/EC on clinical trials).[16]

Due to the qualification of genetic information as "personal health data", the subject's consent should be not only clear (see Article 4, no. 11 of the General Data Protection Regulation), but also explicit.[17] This is because legal texts state that the form of expression of consent should depend on the importance of the interests to be protected.[18]

Explicit written consent is needed in the case of the individual's participation in biomedical scientific research (see Convention of Oviedo, Article 16, v), especially when research activities are related to genetic information (see the General authorisation no. 8/2012 para. 6; see also Article 16-10 of the *Code Civil*, and also in French Law Article L. 1131-1 of the *Code Santé Publique*, hereinafter "CSP").

In particular, consent is needed when the genetic data are "stored for diagnostic and health care purposes and for medical and other scientific research purposes, unless otherwise provided for by domestic law for compelling reasons and consistent with the international law of human rights" (see Article 22).

Furthermore, Article 8, para. 2 of the EU Charter states that "Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified".

However, the individual's consent and the linked rights on personal data may be subject to several exceptions to safeguard other interests recognised by constitutional norms. Privacy should be coordinated with these other important freedoms or rights recognised by constitutional norms.

National or supranational legislation may impose limitations to some rights in order to protect personal data, for reasons such as national security; defence; public security; prevention, investigation, detection, and prosecution of criminal offences or breaches of ethics for regulated professions; important economic or financial interests; or the protection of data subjects or of the rights and freedoms of others.

Moreover, legal sources provide an important set of exceptions in case personal information is used in scientific activities.[19]

The necessity for exceptions to the right of consent arises from the features of research, the development of which depends on the availability of data. In fact, public policies

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Use of Genetic Information: Between Respect of Privacy and Protection of Other Fundamental Interests", in Diritto e Processo/Right and Remedies/Derecho y Proceso, 2014, pp. 493–532.

16 See SASSI A., "Derechos patrimonialmente neutros", in Mario ALVAREZ LEDESMA M. I. and CIPPITANI R. (edit by), Diccionario analítico de Derechos humanos e integración jurídica..., pp. 213–218.

17 See WP131 - Working Document on the processing of personal data relating to health in electronic health records (EHR).

18 See Article 29 Data Protection Working Party, *Opinion 15/2011 on the definition of consent*, Adopted on 13 July 2011, para. III.A.3; available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2011/wp187_en.pdf.

19 See Commission, *Open Innovation, Open Science, Open to the World - a vision for Europe*, Bruxelles, 2016.

limiting access to data[20] may adversely affect scientific research, especially in the case of genetics.[21] For these reasons, legislation on privacy provides some limits to the rights of data subjects.

Directive 95/46/EC established that member states can be "authorized, when justified by grounds of important public interest, to derogate from the prohibition on processing sensitive categories of data where important reasons of public interest so justify in areas such as public health and social protection (…) scientific research and government statistics" (recital no. 34 of the Preamble).

Such derogations from the general rules were possible in two cases: rights of the data subject when the information is not obtained directly by the data subject her/himself (Article 11, para. 1); and the right of access in order to know how the data are processed, as well as rights of rectification, erasure, or blocking (see Article 12, para. 1). In those cases, legislation of member states was allowed to provide derogations from the data subjects' rights when these data were used for scientific purposes. In the first case, exceptions were possible if "the provision of (…) information proves impossible or would involve a disproportionate effort or if recording or disclosure is expressly laid down by law". In the case of the rights of access, limitations of the data subjects' rights were authorised by the EU directive for processing solely for scientific research purposes (see Article 13, para. 3).

The new regulation concerning protection of personal data aims at establishing a more general framework of derogations from the rights of the data subject.

Regulation no. 2016/679 considers the same case of Article 11, para. 1, of the directive, establishing for research activities a derogation from the rights of the data subject if the data are collected from sources other than the latter (see Article 14, para. 5, Regulation 2016/679; see also recitals nn. 61 and 62). Furthermore, in a wider perspective than the directive, the regulation establishes that when "personal data are processed for scientific or historical research purposes or statistical purposes", European and national laws may provide derogations from the rights normally belonging to the data subjects such as the right of access (Article 15); right to rectification (Article 16); right to restriction of processing (Article 18), and the right to object (Article 21).

Laws may also establish a derogation from the right to erasure (the right to be forgotten), established by Article 17, para. 1, of Regulation (EU) 2016/679: "The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay".

Derogations from the rights usually recognised to data subjects are also provided for by documents of the Council of Europe's bodies. For instance, Article 8, para. 2.d, of Rec-

[20] LOWRANCE W. and COLLINS F. S., "Identifiability in Genomic Research", in Science, 3 August 2007, vol. 317, pp. 600–602.

[21] See the conclusions of GYMREK M., McGUIRE A., GOLAN D., HAPERIN E. and ERLICH Y., "Identifying Personal Genomes by Surname Inference", in Science, 18 Jan 2013, vol. 339, Issue 6117, pp. 321–324; and also the editorial in Nature concerning research on science titled "Genetic Privacy". ("The ability to identify an individual from their anonymous genome sequence, using a clever algorithm and data from public databases, threatens the principle of subject confidentiality.") Nature, 24 January 2013, vol. 493, p. 451.

ommendation R(97) states that access to medical data (including genetic data) and the right of rectification may be refused when "the data are used for statistical or for scientific research purposes where there is clearly no risk of an infringement of the privacy of the data subject, notably the possibility of using the data collected in support of decisions or measures regarding any particular individual".

Therefore, according to EU law, once genetic information is processed within scientific activities, the data subject loses her/his power over the information, as provided for on the contrary in other cases of processing of personal data.

Such limitations are justified from both subjective and objective points of view: staff dealing with genetic information must be professionally qualified (see for example para. 14 of the Declaration of Helsinki, Article 3, para., lett. a, Directive 2001/20/EC)[22] and must respect "relevant professional obligations and standards" (see Article 14 of the Convention of Oviedo); the activities carried out must be qualified as "research".

According to the latter condition, due to the favourable legal and political context, "research" and "research purposes" should be considered in a broad manner, in accordance with EU law, therefore "including for example technological development and demonstration, fundamental research, applied research and privately funded research" (recital no. 159, Regulation 2016/679).

In order to avoid any doubt, research activities must be formalised in a project (see para. 4, Authorisation no. 8 of the Italian *Garante*) that has to be drawn up in accordance with the standards of the relevant disciplinary field, in order to provide evidence that the processing of data and the use of biological samples are carried out for suitable and effective scientific purposes.

5. *Further uses*. Normally, legal sources provide a "specific consent", meaning that the data subject is entitled to give her/his authorisation for any specific use of personal data, in order to achieve a more complete safeguard of the autonomy of persons. In addition to the aforesaid dispositions of the Convention of Oviedo and of the Declaration of UNESCO, the specificity of consent is provided within EU legislation, such as by Article 8, para. 2 of the EU Charter, which states that "[personal] data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law." Article 4, no. 11 of Regulation (EU) 2016/679 provides likewise.

Therefore, the discipline of protecting personal data is based on the rules of "granularity",[23] that is to say the necessity that the consent should be given for limited aims and for specific situations.[24] When the purposes of processing or the situation of the data subject change, the person should be requested to express a new consent.

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22 Freedom of research is different from freedom of expression, because it is recognised only to qualified persons acting within academic institutions or undertakings, who have the necessary skills and instruments. See CIPPITANI R., "Academic Freedom as a Fundamental Right". In: 1st International Conference on Higher Education Advances, HEAd'15, Universitat Politècnica de València, Valencia, 24–26 June 2015, Universitat Politècnica de València, pp. 552–558.

23 See para. III.A.1 of the Advice 15/2011 *on the definition of consent*, ref.

24 *Ibidem*.

This is what emerges, for example, from the Recommendation of the Committee of Ministers of the Council of Europe Rec (2006) 4 of 15 March 2006, concerning research on biological material of human origin. Article 12, paragraph 1 required that biological material collected for purposes other than scientific research (i.e., for therapeutic purposes) could not be used without consent or authorisation. Thus, when the subsequent activity is "substantially different" as regards the authorised individual,[25] new consent should be given.

Consent should not be given without time limits. EU documents set forth that those responsible for the processing of personal data shall re-ask the person to confirm her/his consent[26] if the situation of the data subject has changed (e.g., because a child becomes a teenager).[27]

The granularity rule may constitute an obstacle for research activities. As a matter of fact, the collection of data is normally realised in the frame of other activities, such as for diagnostic analysis, and then processed for scientific purposes. Those purposes are not so specifically clear at the moment of data collection, and they can change over time. Furthermore, the same base of data may be useful for many types of research, even in different fields of research (genetic data can be processed in the medical, biological, anthropological, and sociological fields, for example). Therefore, it could be difficult to acquire a consent concerning specific programmes of research, and it can be problematic and expensive to require consent for each specific scientific activity.

This is especially true for bio-banks activities, that is to say large collections of biological samples (in particular of human origin) and associated data, such as genetic information.[28] Bio-banks are established for various reasons, such as criminal investigation, therapeutic treatments, and research activities. Public and private interests (e.g., those of pharmacological industries) need to maintain genetic information in bio-banks for many years. Many kinds of research activities with stored information could be carried out in the future, but they are not all known or at least foreseeable when data and biological material are collected. This makes it particularly difficult to require consent for a specific purpose and over the entire time that research could be undertaken with the samples and associated data.

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25 Council of Europe, *Explanatory report to the convention on human rights and biomedicine*, 1997, para. 214.

26 See also Article 29 Working Party, *Opinion 2/2010 on online behavioural advertising*, adopted on 22 June 2010, available at http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2010/wp171_en.pdf.

27 Article 29 Working Party, *Working document 1/2008 on the protection of children's personal data,* adopted on 18 February 2008. Available at http://194.242.234.211/documents/10160/10704/1531889.

28 For an overview of European, international, and national legislation relating to bio-banks, see, among others, TESÓN I. V., "Bioresearch, Biobanks and Informed Consent from Vulnerable Donors in Spanish Law", in Europa e Diritto private, 2013, p. 1069 ff.; SCAFFARDI L., "Legal Protection and Ethical Management of Genetic Databases: Challenges of the European Process of Harmonization", in European Legal Integration: The New Italian Scholarship, Jean Monnet Working Paper 19/08, New York University School of Law, New York, 2008; GODARD B., SCHMIDTKE J., CASSIMAN J.J. and AYMÉ S., "Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective", in European Journal of Human Genetics, 2003, 11, Suppl 2, S88–S122.

For those reasons, studies in the literature and praxis suggest more flexible approaches. Furthermore, from an institutional point of view, in recent years we can observe a tendency to mitigate the principle of granularity.

It is possible to find solutions that refer to enlarged or broad consent (for a range of broadly defined uses); to presumed consent (where people who do not want to be involved have to opt out voluntarily); and, in some cases, also "blanket consent", that is to say consent to whatever future use has been outlined. According to the latter, which seems the furthest removed from specific consent, the World Health Organisation, in a document of 1998, admits that "[a] blanket informed consent that would allow use of sample for genetic research in general, including future as yet unspecified projects appears to be the most efficient and economical approach, avoiding costly re-contact before each new research project".[29] It would seem that this approach should be put in place to grant protection of personal data[30]; the more widely used approach, however, is broad consent.

Therefore, the Recommendation of 2016 of the Committee of Ministers of the Council of Europe has replaced the obligation to give information concerning each research activity (as established by Article 10, para. 2 of the Recommendation of 2012) with the duty to inform the data subject about a more general "nature of any envisaged research use" (Article 10, para. 1, Recommendation of 2016).

Also, the Draft Explanatory Memorandum to the Draft Recommendation on Research on Biological Materials of Human Origin, of the Committee on Bioethics (DH-BIO) of the Council of Europe of 2015, specifies that when human biological materials or associated personal data are collected, it is good practice to obtain the consent to their use for future research, even in cases where the specific research is not known. If future research cannot be identified, the consent should not be unconditional (i.e., a blanket consent) but should be as specific as possible, given the knowledge at the time consent is obtained.[31]

At the national level, for example, the UK Ethics and Governance Framework provides explicitly that "[b]ecause it will be impossible to anticipate all future research uses, consent will be sought for research in general that is consistent with UK Biobank's stated purpose (rather than for specific research)". A "[f]urther consent will be sought for any proposed activities that do not fall within the existing consent".

Other examples of the implementation of broad consent can be found in the German

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29 World Health Organisation, Proposed international guidelines on ethical issues in medical genetics and genetic services, 1998, p. 13, available at http://www.who.int/genomics/publications/en/ethicalguidelines1998.pdf .

30 *Ibidem*.

31 See Article 12, para. 48 of the Draft Explanatory Memorandum to the Draft Recommendation on Research on Biological Materials of Human Origin of Steering Committee on Bioethics: "When biological materials of human origin and personal data are collected it is best practice to ask the sources for their consent to future use, even in cases where the specifics of the future research projects are unknown. If future research use of biological materials of human origin and personal data cannot be specifically anticipated, the consent should not be framed too broadly in order to prevent unconditional, "blanket" consent. The request for consent should be as explicit as possible in regard to the future research uses of the biological material of human origin and personal data".

Nationaler Ethikrat of 2004[32] as well as in the Code of Practice of the UK Human Tissue Authority of 2006 and in Swedish,[33] Icelandic, and Estonian laws that allow a broad description of the purposes of research. The Spanish law on biomedical research[34] provides the possibility to give consent for specific research projects even if they are carried out by other subjects.[35]

Additionally. the EU regulation concerning privacy considers the hypothesis that it is not possible to fully identify the purpose of personal data processing for scientific research at the time of data collection. In that case, data subjects should be allowed to give their consent within certain areas of scientific research, if recognised ethical standards for scientific research will be observed (recital no. 33, Regulation (EU) no. 2016/679).

On the other hand, Regulation no. 2106/679 and other European sources extend the effectiveness of consent. If the principle of purpose limitation prescribes that "the processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected" (recital no. 50), nevertheless "further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes" (Article 5, para. 1, let. b) Regulation 2016/679).[36] For these types of purposes, to be a sort of presumed consent is given.

The same approach is chosen by the Council of Europe in the draft of the Recommendation on the Protection of Health-Related Data, which will replace the above-mentioned recommendation of 1997 (see Article 4.1.b); this also seems to consider it difficult to provide detailed information to the data subject about the use of health-related data at the time of collection (see Article 11.2).

In application of the model of presumed consent, the Italian Authority of Privacy, in its General Authorisation No. 8/2014 for the Processing of Genetic Data, allows processing research for scientific purposes "directly linked" to the original one. Otherwise, processing is authorised only if samples are anonymised or in the case of a new consent, but in the absence of the latter consent can be authorised by the relevant ethics committee

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32 Nationaler Ethikrat, Biobanken für die Forschung. Stellunghame, 2004, Berlin, available at www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf.

33 The Recommendation R(2006)4 of the Council of Europe was inspired by the UK Human Tissue Act of 2004 and by the linked code of practice issued by the Human Tissue Authority of January 2006. In particular, point 106 of the Code of Practice Consent provides that "consent can be general, i.e. if someone consents to the use of tissue for research, it need not be limited to a particular project". See also para. 90 stating that "consent should be generic where appropriate".

34 Ley no. 14/2007, de *Investigación biomédica*, of 3 July 2007.

35 See Article 60, para. 1: "*El consentimiento sobre la utilización de la muestra biológica se otorgará, bien en el acto de obtención de la muestra, bien con posterioridad, de forma específica para una investigación concreta. 2. El consentimiento específico podrá prever el empleo de la muestra para otras líneas de investigación relacionadas con la inicialmente propuesta, incluidas las realizadas por terceros. Si no fuera este el caso, se solicitará al sujeto fuente que otorgue, si lo estima procedente, un nuevo consentimiento*".

36 By EU and national laws. An example of such national provisions is the Austrian Data Protection Act (*Datenschutzgesetz*), Federal Law Gazette No. 165/1999, para. 46, available in English at www.dsk.gv.at/DocView.axd?CobId=41936.

and authority. However, it may not be simple to identify either the meaning of the "link" or who has control over the compliance.

Another solution regarding research can be found in the Recommendation of 2016 of the Committee of Ministers of the Council of Europe in case of collection of biological material. In that hypothesis, the material "should only be used in a research project if the latter is within the scope of the consentor authorisation given by the person concerned" (Article 21, para. 1). However, if the proposed use will not be within the scope of prior consent or authorisation, if any, given by the person concerned, reasonable efforts should be made to contact the person concerned (para. 2.a), and the process must be subject to an independent evaluation (para. 2.b).

6. *Storage of genetic data and data retention.* Storage and retention of personal data are regulated in a special manner when they are put in place within research activities. Although the discipline of privacy does not establish a fixed term for storing data, it provides for rules that are incompatible with long-time storage, such as the above-mentioned right to be forgotten and the right to withdraw, as well as the principle of "storage limitation", according to which data must "[be] kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed" (Article 5, para. 1.e, Regulation (EU) 2016/679). Also in this case, scientific purposes allow exceptions from rules concerning data processing in general.

As explained above, it is very important for current scientific activities to have access to data and materials included in long-term collections. Regulation no. 2016/679 takes into consideration the need of science to collect information and to store it (also for historical research purposes, see recital no. 160). The reason to improve archiving is explained by recital no. 157 of the new regulation: "By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions, such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services".[37]

Public interest and the use for research are considered legitimate grounds for storing health-linked personal data, including genetic data, for a longer period (see Article 4.1.f draft Recommendation on the Protection of Health-Related Data). In respect to the rule that personal data cannot be stored longer than it is necessary, national law should lay

[37] In the case of historical research purposes, the value of the archiving is underlined by recital no. 158, where it states that "Member States should also be authorised to provide for the further processing of personal data for archiving purposes, for example with a view to providing specific information related to the political behaviour under former totalitarian state regimes, genocide, crimes against humanity, in particular the Holocaust, or war crimes".

down "more detailed provisions, including the necessary safeguards, to reconcile the interest in scientific research with the right to data protection",[38] and "Keeping data for future scientific, historical or statistical use is explicitly exempt from the principle of limited data retention."[39]

With respect to the right to erase, as mentioned above, the regulation provides a specific exception in consideration of research purposes. As a matter of fact, Article 17, para. 1.b provides the right to erase (the "right to be forgotten") "where there is no other legal ground for the processing". As stated above, scientific purposes are considered the ground for not applying the rights provided under Article 17. According to the right to withdraw, Article 7, para. 3 establishes that "The data subject shall have the right to withdraw his or her consent at any time". However, the same provision states that "The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal". Therefore, it seems that ongoing research activities at least should not be affected by the withdrawal of consent.

When biological material is collected in addition to data, Recommendation CM/Rec(2016)6 of the Committee of Ministers on research on biological materials of human origin provides for the right to withdraw "in the manner foreseen by law" (see in particular Article 13), but it also states, in regard to informing the person prior to removing the material, that "This information should also include any possible limitation on withdrawal of the consent or authorisation" (Article 10, para. 2).

It should be emphasised that the guarantee of withdrawal of consent, due to the considerable size achieved by bio-banks and the continuous exchange of materials and data among researchers, is weak and difficult to concretise, especially as far as the information dimension is concerned. In this regard, Spanish law no. 14/2007 concerning biomedical research states that, in case of withdrawal, biological samples will be destroyed. However, the data obtained in the preceding phases can be maintained.[40]

7. *Specificity of genetic information.* As research activities are carried out using genetic information, it is necessary to consider some further specific issues. Although genetic information is protected by legislation concerning personal data, the Declaration of UNESCO as well as other documents (see paragraph 2 of the Working Document on Genetic Data of 2004) recognise it as having a "particular status". Some scholars do not agree with the presumed particularity of genetic information, increasing the resistance of public opinion in respect to genetic technologies.[41]

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[38] European Union Agency for Fundamental Rights, Council of Europe, *Handbook on European data protection law*, Luxembourg: Publications Office of the European Union, 2014, p. 31.

[39] European Union Agency for Fundamental Rights, Council of Europe, *Handbook on European data protection law*, … p. 73.

[40] Article 60.3: "*El consentimiento podrá ser revocado […] en cualquier momento. Cuando la revocación se refiera a cualquier uso de la muestra, se procederá a su inmediata destrucción, sin perjuicio de la conservación de los datos resultantes de las investigaciones que se hubiesen realizado con carácter previo*".

[41] RICHARDS M. P.M., "How distinctive is genetic information?", in Studies in the History and Philosophy of Biological and Biomedical Sciences, 2001, 32, pp. 663–687.

Indeed, so-called "genetic exceptionalism" has been criticised due to the exaggerated view of the significance of genetic information in people's lives, based on an unacceptable genetic determinism and genetic reductionism.[42] Nevertheless, the special status of genetic data may be observed in relation to several cases.

As a matter of fact, genetic information is different from other types of information, due to the fact that it identifies a specific individual in a permanent way ("immutability") and it is predictive of predisposition to diseases ("predictability"). Furthermore, genetic information belongs not only to the concerned person but also to people sharing the same genetic patrimony ("familiarity").[43] For example, in regard to the use of genetic data in criminal investigations, it has been argued that "DNA samples or profiles are intrinsically 'more private' objects or their collection involves greater infringement of bodily integrity than, for example, fingerprints or photographs." [44]

DNA is akin to a "future diary" of persons (it includes information about our present and future medical conditions), and the right of protection from unwanted "readership" must be imperative in order to maintain autonomous control of personal and sensitive information.[45]

The above-mentioned features of genetic information should lead to a specific regulation, also taking into account the great risks of misuse and/or re-use for various purposes and the risks of discrimination and stigmatization that may affect the individual. Moreover, some authors underline that the discipline of privacy can cover only some aspects of the protection of genetic information and related rights.[46] At least some issues may arise from the use of genetic information especially in the context of research activities: information to be provided to the data subject, relativity of anonymisation, and the rights of other subjects.

A) Information to be provided to the data subject.

Despite the limitations of the rights of data subjects in the context of scientific activity, the fact that research is carried out on genetic information may lead to solving other problems. The special informative content of genetic data has important consequences on the right of the data subject to know or not to know the implications of such data for future health.-

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42 MURRAY T.H., "Genetic Exceptionalism and Future Diaries: Is genetic Information Different from Other Medical Information", in ROTHSTEIN M.A., Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era, Yale University Press, New Haven, 1997, pp. 60–73, in particular p. 71.

43 On the co-shared nature of genetic information, see TAYLOR M.J., "Data Protection, Shared (Genetic) Data and Genetic Discrimination", in Medical Law International, 8, 1, 2006, p. 51.

44 WILLIAMS R., JOHNSON P. and MARTIN P., "Genetic information and crime investigation: social, ethical and public policy aspects of the establishment, expansion and police use of the National DNA Database. Project Report", Durham University, School of Applied Social Sciences, Durham, 2004, para. 6.2.2, p. 78

45 ANNAS G.J., "Genetic Privacy", in LAZER D., DNA and the Criminal Justice System: The Technology of Justice, Cambridge, MA: MIT Press, 2004.

46 In particular, see TAYLOR M., "Genetic Data and the Law: A Critical Perspective on Privacy Protection", Cambridge, Cambridge University Press, 2012, *passim*.

A first problem arises if the development of a new technique may give more information in comparison with the past. With reference to biomedical research, such a hypothesis seems to be covered by Article 24 of the Additional Protocol to the Convention of Oviedo on Biomedical Research, which provides for the re-examination of a research project in the "light of scientific developments or events arising in the course of the research", when "research participants, or if applicable their representatives, need to be informed of the developments or events" (para. 2.ii). When information does not refer to the health of persons, it does not seem mandatory to inform the data subject.

Another problematic aspect is represented by so-called "unexpected findings", that is, information that was not expected to be found during research or diagnostic practices, such as information on ongoing diseases or predispositions to diseases, or information concerning biological parenthood, and so on.

For example, the general authorisation no. 8/2012 of the Italian *Garante* mandates that the individual, before any genetic testing, must also be informed on the possible results of such testing, especially "with regard to unexpected findings" (para. 5.b). This caution should not be necessary in the processing of other kinds of sensitive data (as with political opinions). It is not clear what happens if information on a health situation or other information (for example concerning filiation or paternity) arises from research activities. Probably, in these cases, the data subject has to be requested to give her or his authorisation to be informed, including about any unexpected findings. However, if such authorisation was not requested, or could not be acquired (on the ground of some above-mentioned rules), the problem remains whether researchers have an obligation to inform the concerned persons. No obligation in this regard seems to be provided for by legislation, even if the importance of health would suggest the prudence of informing the affected individuals at least on the existence of findings concerning diseases, and in particular about treatment options.

B) The problem of anonymisation.

Recital no. 26 of the General Data Protection Regulation clearly states that "This Regulation does not therefore concern the processing of such anonymous information",[47] including for statistical or research purposes. Thus, if data might not be associated with a specific person, it is outside the protection of the legislation and it can be processed without the consent of the data subject.

Personal data may be collected in a non-anonymous way and be anonymised subsequently. Data "are anonymised if all identifying elements have been eliminated from a set of personal data. No element may be left in the information which could, by exercising reasonable effort, serve to re-identify the person(s) concerned".[48]

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[47] Data are considered anonymous taking into account "means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments" (see 26th recital of Regulation (EU) 2016/679).

[48] European Union Agency for Fundamental Rights, *Handbook on European data protection law*, Luxembourg, 2014, p. 44.

In addition, Recommendation CM/Rec(2016)6 of the Committee of Ministers on research on biological materials of human origin supports the use of anonymisation. In fact, the recommendation states that "non-identifiable biological materials" (see the definition under Article 3, according to which they are "those biological materials which, alone or in combination with data, do not allow, with reasonable efforts, the identification of the persons from whom the materials have been removed") "may be used in a research project provided that such use does not violate any restrictions defined by the person concerned before the materials have been rendered non-identifiable and subject to authorisation provided for by law" (Article 21, para. 4) and "Biological materials previously removed for another purpose and already non-identifiable may be stored for future research subject to authorisation provided for by law" (Article 11, para. 3).

In respect to the specific case of genetic information, the Declaration of UNESCO states that genetic data when "collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples" (Article 14c).

Otherwise, European law considers the alternative technique of pseudonymisation (see Article 4, no. 5 Regulation (EU) no. 2106/679). This occurs when the identifiers are replaced by pseudonyms, and the data cannot be identifiable without possession of a decryption key.[49]

Tissue and Cells Directive no. 2004/23/EC obligates member states to take all necessary measures to ensure that all data, including genetic data, have been rendered anonymous so that neither donors nor recipients remain identifiable (see Article 14, para. 1).

According to the General Data Protection Regulation, anonymisation and pseudonymisation are considered ordinary measures to protect personal information in research activities (see Article 89).

Additionally, the Appendix to Recommendation R(97) of the Committee of Ministers considers that "Whenever possible, medical data used for scientific research purposes should be anonymous" and that "Professional and scientific organisations as well as public authorities should promote the development of techniques and procedures securing anonymity" (see para. 12.1).

However, the option of anonymisation, as an alternative to consent, may encounter some problems in the case of genetic information. First, anonymisation is never the better option from a scientific viewpoint. As shown by legal sources (see for example the Declaration of UNESCO on genetic data), the link to an identifiable person may be acceptable "if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law" (Article 14d) and for a period that does not exceed the time needed for achieving the purposes for which they were collected or subsequently processed (Article 14.e).

Complete anonymisation implies some serious consequences: both data subject and

[49] See Council of Europe, Explanatory Report to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, Article 42.

researcher will lose important information and will not be able to yield follow-up results,[50] often fundamental to optimal performance of a research project.

Second, anonymity is always relative because of technical reasons. The anonymisation processes are likely reversible, and in principle any anonymised genetic data can be linked to a person. *A fortiori*, the situation might also occur in the case of pseudonymisation.[51]

As underlined within the scientific community, "No responsible scientist can guarantee absolute privacy" and "Privacy and confidentiality are important principles. But being identifiable has some benefits, and being anonymous has some costs; science will be better off when it acknowledges this reality."[52]

According to some authorities, the risk of re-identification posed by genetic data would be considered low. As stated by Article 29 of the Working Party, treating the matter of pseudonymisation, "In that case, although data protection rules apply, the risks at stake for the individuals with regard to the processing of such indirectly identifiable information will most often be low, so that the application of these rules will justifiably be more flexible than if information on directly identifiable individuals were processed."[53]

However, this interpretation refers to the current state of the technique and does not take into consideration that it is possible to establish an association between the genetic information and other pieces of information, in a way leading to identification of a person. As demonstrated by a study published in *Science*,[54] it is possible, through the sequencing of genetic data without identifiers, to recover surnames of the data subjects by profiling short tandem repeats on the Y chromosome and querying genetic genealogy databases (as for example www.ysearch.org and www.smgf.org). Then, a specific person can be targeted by combining the surname with other types of metadata, such as age and state, easily and freely available in Internet resources.

Therefore, it is possible, at least, to provide practical suggestions, such as those included in para. 4.2 of Authorisation no. 8 of the Italian Privacy Authority, which states that where the genetic information arises from biological samples and the "temporary" identification of the subject is necessary, specific measures should be adopted to keep identification data separated from biological samples and genetic information at the time of collection, unless this is impossible due to the particular characteristics of the treatment or to the necessity to use manifestly disproportionate means.

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[50] MACILOTTI M., IZZO U., PASCUZZI G. and BARBARESCHI M., "La disciplina giuridica delle biobanche (The Legal Aspect of Biobanks)", in Pathologica, 2008, v. 100, pp. 86–108, particularly p. 87.

[51] Article 29, Data Protection Working Party, Opinion 4/2007 on the concept of personal data, adopted on 20th June 2007, p. 18, stating that "Retraceably pseudonymised data may be considered as information on individuals which are indirectly identifiable. Indeed, using a pseudonym means that it is possible to backtrack to the individual, so that the individual's identity can be discovered, but then only under predefined circumstances."

[52] ANGRIST M., "Genetic privacy needs a more nuanced approach", in Nature, 7 February 2013, vol. 494, p. 7.

[53] Article 29, Data Protection Working Party, Opinion 4/2007 on the concept of personal data, ref.

[54] See GYMREK M. et al., "Identifying Personal Genomes by Surname Inference", in Science, ref.

C) Rights of other subjects.

As mentioned above, genetic information belongs not only to a specific person, but it is shared among persons of the same genetic group. According to Article 14 of Regulation (EU) 2016/679, the data subject also has the right to receive information from the controller (or his/her representative) when the data have not been obtained from the aforesaid data subject. In consequence, a physician or other health professional, who found a risk of a genetic disease while examining the biological material of a person, might face the following dilemma: on the one hand he/she could be bound by the obligation of secrecy, as well as the right to not inform the individual. On the other hand, he/she could be obliged under Article 11 to provide information to the data subjects, who include relatives sharing the same genetic line.

There is not a clear answer to that question, neither within the discipline concerning privacy nor in the supranational and international legal sources. According to Article 18 of the Additional Protocol to the Convention of Oviedo on genetic testing, "Where the results of a genetic test undertaken on a person can be relevant to the health of other family members, the person tested shall be informed."

However, the consequences and conditions arising from that information are not clear. According to the above-mentioned working document on privacy, at least two scenarios may be imagined: "One is that other family members could also be considered as 'data subjects' with all the rights that follow from this. Another option is that other family members would have a right of information of a different character, based on the fact that their personal interests may be directly affected."

At the national level, legislation is focused on the protection of the personal data subject's privacy, requiring his or her consent to disclose the information to relatives.[55] Within Europe, an interesting solution is provided by French law, even if it does not directly refer to scientific activities. Before the last version of the law concerning bioethics (Law 814-2011), the legislation previously in force already established a procedure for communicating the results of genetic testing to family members (s. Article L. 1131-1, para. 5 CSP), without providing any consequence in case the person had not informed her/his relatives.[56]

Such an exclusion of liability appeared in conflict with constitutional principles.[57] Thus, the *Conseil d'Etat* in its document on the review of law concerning bioethics proposed to make explicit the responsibility to inform family members about genetic abnormalities, while respecting medical confidentiality.[58] Therefore, Article 1 of the new law

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55 GODARD B., HURLIMANN T., LETERNDRE M. and ÉGALITÉ, "INHERIT BRCAs, Guidelines for disclosing genetic information to family members: From development to use", in Familial Cancer, 2006, 5, pp. 103–116.

56 See BINET J.R., "Le nouveau droit de la bioéthique: Commentaire et analyse de la loi n° 2004-800 du 6 août 2004 relative à la bioéthique", LexisNexis, Paris, 2005, p. 30 ss.

57 See the judgement of the *Conseil constitutionnel* n. 82-144 DC of 22 October 1982, in www.conseil-constitutionnel.fr. As affirmed by the Constitutional Council, "*le droit français ne comporte, en aucune matière, de régime soustrayant à toute réparation les dommages résultant de fautes civiles imputables à des personnes physiques ou morales de droit privé, quelle que soit la gravité de ces fautes.*"

58 Conseil d'État, *La révision des lois de bioéthique*, Paris, 2009, Cap. IV "*Examen des caractéristiques génétiques: respecter la volonté des personnes et renforcer leur information.*" According to the *Conseil*,

adds Article L.1131-1-1 to the *Code de la santé publique*, which states a specific duty of the physician to inform the person of the risks for family members in cases of diagnosis of a serious disease, if they were not properly informed (para. 1).

The disposition also states the duty of the person concerned to prevent the consequences of genetic abnormalities for her/his relatives, when measures of prevention can be adopted (para. 3). The person may also decide not to be informed about the results of the diagnosis. In this case, if the persons concerned do not feel able to make the communication, the physician is requested to inform the relatives (para. 4). However, the doctor will not reveal either the name of the patient or the genetic abnormality, or the risk associated with it. Basically, the physician has to invite family members to take a genetic test, if he/she envisages the existence of a potential risk.

8. *Ethical principles and freedom of research on genetic information.* According to the legal sources quoted within the previous sub-paragraphs, processing of personal data, in particular genetic information, for scientific purposes implies an exception to the discipline of protection of personal data. This situation is due to the characteristics of the scientific activities and depends on the position of science within the legal systems.

However, as a fundamental right, freedom of research also cannot be considered as absolute, and therefore it must be subject to legislative limitations,[59] in order to protect other fundamental rights. Such limitations are provided for by national constitutions (normally those most recent or recently amended, such as Article 118b of the Swiss Constitution; Article 29 of the Constitution of Bulgaria; Article 18 of the Constitution of Slovenia; and Article 23 of the Constitution of Croatia), and by supranational fundamental legal texts.

The Declaration of UNESCO of 1997 affirms the "responsibility" of researchers and their obligation to comply with principles of primary importance (such as meticulousness, caution, intellectual honesty, and integrity in carrying out their research as well as in the presentation and utilization of their findings; see Article 13), taking into consideration particular attention to research on the human genome. On the other hand, it affirms that states "should take appropriate steps to provide the framework for the free exercise of Research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes" (Article 15).

At the continental level, the need to face the potential collision between research freedom and other fundamental rights can be found within the preambles of the EU Charter of Fundamental Rights as well as the Convention of Oviedo. Furthermore, Article 26 of the Convention of Oviedo permits restrictions to the right to consent in biomedical research, if such restrictions are provided for by law and if they constitute necessary meas-

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the Swiss approach—allowing the physician to be authorised by the public authorities to contact the relatives if the patient refuses to inform them—might affect the trust relationship between the professional and the patient.

[59] See the Italian *Corte costituzionale*, judgment 4 June 1958, n. 36.

ures, in a democratic society, for public safety, prevention of criminal offenses, protection of public health, or of the rights and freedoms of others.[60] Such limits to freedom of research have to be applicable also in case of research on genetic information.

According to Article 89 of Regulation 2016/679, both EU and national laws shall provide "safeguards" in order to implement exceptions due to "public interest, scientific or historical research purposes or statistical purposes" (see also recital no. 34 of Directive 96/46/EC). The apparently wide derogations from privacy law, justified by scientific purposes, have to be implemented on the basis of "ethics principles", which are those rules aimed at making freedom of research consistent with the protection of other fundamental interests of the society, such as the principles of necessity, proportionality, and precaution.

In application of the principle of necessity, derogation from the law concerning data privacy is acceptable only when such rights likely render impossible or seriously impair the achievement of the objectives of the processing (see Article 14, para. 5.b; 13, para. 3.d; 89, para. 2, Regulation (EU) 2016/679). More in general, processing of genetic data is allowed only when their protection is guaranteed (see recital no. 52 of Regulation no. 2016/679) and where it respects "the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject" (see Article 9, para. 2, let. j).

Article 9 of the regulation implicitly quotes Article 52s, para. 1 of the EU Charter, which, indeed, states that limitations to the exercise of the rights and freedoms recognised by the charter must be provided for by law and must be necessary. In respect to the protection of personal data, this principle is affirmed in the case law of the Court of Justice, such as in the judgement Tele2 Sverige AB (see in particular para. 100).[61]

With reference to biomedical research, necessity entails that there is no alternative to involving persons (especially vulnerable ones) in research activities (see Article 16 of the Convention of Oviedo, points iv and v). Also, the principles of necessity imply that the actual benefits have to be evident, taking into account that "the very nature of biomedical research means that it is uncertain whether an individual will benefit from research participation and any benefit to the person is not the main purpose of research."[62]

(per evitare ripetizione con "in the case" qllq riga sotto) In any case, the conditions of absence of alternatives and evidence of benefits should be applicable only in the case of

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60 ANDORNO R., "The right not to know: an autonomy based approach", in Journal of Medical Ethics, 2004,30, pp. 435–440, especially p. 437. In regard to the conditions and limitations of human rights, see also ÁLVEREZ LEDESMA M. I., "La libertad de expresión en el sistema electoral mexicano desde una perspectiva jurídica", in MONTIEL G. L. and TAMÉS MUNOZ E. (edit by), Libertad de expresión en el proceso electoral 2012, México, PNDU/ONU, 2013.

61 In that judgment the court points out that "terrorism may depend to a great extent on the use of modern investigation techniques, such an objective of general interest, however fundamental it may be, cannot in itself justify that national legislation providing for the general and indiscriminate retention of all traffic and location data should be considered to be necessary for the purposes of that fight (see, by analogy, in relation to Directive 2006/24, the Digital Rights judgment, paragraph 51)."

62 Council of Europe, Steering Committee on Bioethics, Guide for Research Ethics Committee Members, January 2012.

medical interventions,[63] due to the particular position of vulnerability of the patient. In other cases, those conditions are not essential, or their respect should be ascertained with less rigor. Furthermore, Article 52, para. 1, EU Charter allows limitation of fundamental rights, such as privacy, subject to the respect of proportionality,[64] which is another primary principle of the EU legal system.[65] This is true, in particular, when personal life must be protected, including personal data.[66]

In respect to the considered matter, the principle of proportionality imposes a minimisation of the quantity of gathered and processed data (see Article 89, para. 1, Regulation 2016/679).[67] Such data must be relevant and limited to what is necessary in relation to the purposes allowed by law (see Article 5, para. 1, c). This principle also constitutes a limitation on the length of data storage (see Article 5, para. 1, let. e).

Furthermore, an evaluation in respect to proportionality and legitimacy is necessary, taking into account the principle of precaution,[68] i.e., risks for the protection of fundamental rights and freedoms of individuals and notably whether or not the intended purpose could be achieved in a less intrusive way.

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63 Biomedical research is defined by the Additional Protocol to the Convention of Oviedo of 2005 as "research activities in the health field involving interventions on human beings", and also as research concerning genetic information. Use of genetic information for research activities not linked to medical interventions should be prohibited by the discipline of the Convention of Oviedo and its additional protocols (see Article 2, para. 2.b, Additional Protocol concerning Genetic Testing for Health Purposes). However, we can observe the tendency to mitigate the link between data and medical intervention, considering health data "all personal data concerning the physical or mental health of an individual, including the provision of healthcare services, which reveals information about this person's health" (Article 3 of the draft Recommendation on the Protection of Health-Related Data).

64 See ECJ, jud. 15 February 2016, J. N./ Staatssecretaris voor Veiligheid en Justitie, C-601/15 PPU, EU:C:2016:84, paragraph 50. In general, on principle of proportionality ECJ, judg. 9 November 2010, C-92/09 y C-93/09, *Volker und Markus Schecke y Eifert*, ECLI:EU:C:2010:662.

65 The principle of proportionality is also used by the case law of the European Court of Human Rights. See, in particular, ECHR, judg. *Gillow vs. UK*, 24 November 1986, series A nº 109, para. 55, y the ECJ, judg. 20 May 2003, Österreichischer Rundfunk and Others, C-465/00, C-138/01 and C-139/01, EU:C:2003:294, para. 83)

66 See ECJ, judg. 16 December 2008, Satakunnan Markkinapörssi and Satamedia, C-73/07, EU:C:2008:727, para. 56; Id., judg. 9 November 2010, Volker und Markus Schecke and Eifert, C-92/09 and C-93/09, EU:C:2010:662, para. 77; Id., judg. 8 April 2014, Digital Rights Ireland Ltd, joined Cases C-293/12 and C-594/1, ECLI:EU:C:2014:238, para. 52; Id., judg. 6 October 2015, Schrems, C-362/14, EU:C:2015:650, para. 92.

67 According to Authorisation no. 8 of the Italian Authority for Privacy (par. 4.1), the collection of genetic data for carrying out genetic testing and screening is limited to personal and family information which is strictly necessary for the performance of the analysis.

68 According to the principle of precaution in science and technology, see for example ANDORNO R., "The Precautionary Principle: A New Legal Standard for a Technological Age", in Journal of International Biotechnology Law, Vol 1, I, 2004, pp. 11–19; COLCELLI V., "Precautionary Principle Liability in the Food Industry: the search of a general regime in vertical and horizontal Liability", in Rainer Arnold and Valentina Colcelli, (eds), Europeanization through private law instruments, Regensburg, Universitätsverlag, 2016, pp. 249 ff.

In the specific field of research, the application of the principle of precaution implies a risk assessment and a comparison with direct or indirect benefits: As a matter of fact: "Although the anticipated overall benefits of the research project must clearly be higher than the potential risks, the research may not be considered justified if there is a particularly high risk of serious harm."[69] Research activities must also observe other principles such as "distributive justice". As stated, "In biomedical research involving human beings, this implies that the distribution of risk and burden on the one hand and benefit on the other be fair—a principle known as distributive justice". Such a principle should be applied for example to the research participants, who should be those who actually may benefit from experimentation.[70]

9. *Consent and the balance between freedom of research and rights concerning genetic information.* As mentioned above, research activity is considered as a lawful reason to deviate from privacy concerns, especially in respect to consent. Such deviations have to be implemented in compliance with ethics principles that work in order to put in equilibrium freedom of research and other interests protected by the legal system.

However, to achieve a balance between interests, the idea that privacy is an absolute value should be subjected to revision. Legislation about privacy derives from a "proprietary"[71] logic concerning the whole human body and its parts, including genetic data. As a matter of fact, propriety is at the base of the meaning of "privacy" itself, since the origin of the notion can be found in the famous work of Samuel Warren and Louis Brandeis, "The Right to Privacy", published in the *Harvard Law Review* in 1890. In that paper, the notion of privacy was drawn up within the proprietary paradigm, even if from a "spiritual" and not a "physical" viewpoint.

According to European law, we can observe the tendency to overprotect privacy in comparison with other interests. The Court of Justice may be considered as the guardian of this tendency. For example, in regard to the "right to be forgotten", in a leading case regarding Google Spain,[72] the Court of Luxemburg held that the fundamental rights recognised by Articles 7 and 8 (i.e., protection of personal data) of the EU Charter "override, as a rule, not only the economic interest of the operator of the search engine but also the interest of the general public" (para. 97 of the judgement). According to the Court of Justice, the public interest should be "preponderant" in order to overtake individual rights arising from the protection of personal data. In contrast, legislation seems to be less demanding when a deviation from the right to erase requires the existence of "public interest" (see Regulation (EU) 2016/679, recital no. 65).

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69 Guide for Research Ethics Committee Members, issued by the Steering Committee of the Council of Europe on January 2012.

70 Guide for Research Ethics Committee Members, ref.

71 See for example DE WITTE J. and TEN HAVE H., "Ownership of genetic material and information", in Social Science & Medicine, 45(1), August 1997, pp. 51–60. See also CIPPITANI R., "Property paradigm" and protection of rights concerning genetic information, in Diritto e processo/Derecho y Proceso/Right and Remedies, 2016, pp. 261–288.

72 ECJ, judg. of 13 May 2014, Google Spain SL Google Inc., C-131/12, ECLI:EU:C:2014:317.

This approach is justified by the attempt to protect persons from the great risks arising from the massive use of techno-science, and in particular of the ITC or biomedical technologies. Nevertheless, as stated "In the European Convention on Bio-medicine as well as in the Universal Declaration on Human Genome, the approach to protecting data confidentiality would appear to be based on an individualistic concept" (Working Party, Working Document on Genetic Data, p. 8). Indeed, it was also stated that "If we protect privacy effectively, we will not reduce ethics to autonomy, and autonomy to data ownership. Reducing ethics to ownership comes at a high price: ethics that care only about ownership and consented transfers are, by exclusion, indifferent to distributional justice and optimizing social outcomes."[73]

Privacy should be coordinated with other important freedoms or rights recognised by constitutional norms, such as freedom of research (see, for example, the above-mentioned Article 13 of the Charter of the Fundamental Right of the European Union).[74] The Court of Justice itself, in the above-mentioned judgement regarding Google Spain, seems to consider scientific purposes adequate *per se* to deviate from the rights of the data subject (see paras. 72 and 92 of the judgement). The features of genetic data, and the specificity of science from a legal viewpoint, have as a consequence that research on genetic information cannot be reduced to a question of privacy. In particular, as stated above, legal techniques to provide free and informed consent or anonymisation do not always represent solutions to problems arising from the processing and storage of genetic data.

The relevance of scientific activities for society—especially, but not exclusively, for therapeutic reasons—should lead to a different approach. It would be advisable, also in respect to the balance of different interests in so complex a field, to put in place various strategies and new instruments.[75]

On the one hand is the idea that consent serves only as an instrument to prevent external invasions, without taking into consideration the reasons or the interests at the base of such an intervention. As a matter of fact, "The core of both 'privacy' and 'property' involves the same abstract right: the right to exclude unwanted interference by third parties. The only real difference between the two concepts is the kind of relationship that is protected from interference: 'property' principally protects market relationships while 'privacy' protects more spiritual ones".[76]

Consent may be conceived as a set of legal instruments for participating in activities which may concern not only the interests of the "data subject", but also those of third parties and of the community. It should not be considered an instantaneous act, but rather a continuous process, useful for establishing a trusted link among data subject,

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73 TAYLOR P., "When consent gets in the way", in Nature, 6 November 2008, vol. 456, pp. 32–33.

74 See MOLINA DEL POZO F. and ARCHONTAKI C., "Libertad de artes y de Investigación Científica", Libertad de Cátedra, … ref.

75 See VILLANI L., "Biobanche e test rivelatori di informazioni genetiche: spunti di riflessione per un nuovo consenso informato", in Responsabilità civile, 2010, 2, pp. 140 ff.

76 See ACKERMAN B., "Liberating Abstraction", in University of Chicago Law Review, vol. 59, 1992, pp. 317–348, in particular p. 347.

researcher, and the institutions.[77] The consent could also include the decision to voluntarily share information as a common good.[78]

As stated above, scientific activities need a model of consent which is different from the specific one, in particular a broad-based approach. However, it would be consistent with a unilateral and asymmetric logic of consent. A bilateral approach should be elaborated, according to which, for example, consentors are constantly informed on the follow-up of the research, so that they may participate in other research and be invited to events or to participate in associations. On the other hand, the centrality of consent should not be carried to extremes. In order to achieve a balance among the different types of interests, including those related to the data subject, consent may not be considered either as a sufficient or a necessary condition. In many cases, not all personal data have the same value or importance for the individual.

The following aspects should also be stressed: the procedural aspect of the consent, the quantity and quality of information to be provided, the time to make the decision, and the kinds of decisions to be taken should be adequate to the situations.[79]

For example, the International Bioethics Committee of UNESCO, in its document Human Genetic Data: Preliminary Study by the IBC on its Collection, Processing, Storage and Use of 15 May 2002, affirms that "Many tests which reveal genetic information will not have a great deal of significance for the person tested (…). Other tests, however, will have major implications, both for the individual and for relatives. The principle stated above sets out the consent requirements. For practical reasons, it would be unrealistic and unnecessary to require that there be specific consent to the genetic component in any test unless the consequences of this are sufficiently serious enough to justify this" (para. 59 p. 15).[80] Consent, considered alone, could be not sufficient.

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77 AZZINI S., "Biobanche, consenso e fonti del diritto: un caso di eccezionale disordine?", 2010, available at http://www.biodiritto.eu/sito/images/stories/azziniforum2010papersito.pdf.

78 See the document Ethical, legal and social aspects of genetic testing: research, development and clinical applications, ref., p. 41 ff., especially p. 42.

79 See BUNNIK E.M., CECILE A., JANSSENS J.W. and SCHERMER M. H.N., "Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of a Model Between Specific and Generic Consent", in Bioethics, 2012, pp. 1–9. The paper, in respect to personal genome testing, uses a "combined tiered-layered-staged model for informed consent", which may be more suitable. This combination "is tiered to provide consumers with options, so as to enable them to choose what types of information on what (categories of) diseases they wish to receive, and especially to opt out of receiving information they do not wish to receive. Layering of information will help limit the otherwise overwhelming quantity of information offered to all consumers in the first layer of the consent process, while it also strives for an 'individual consumer-based' consent, as it offers additional information for those who need that information in order to consent. Finally, a staged set-up of the pre-test information provision process can serve educational purposes and improve the quality of consent. Moreover, subsequent renewal of consent will be required as new test outcomes become available as a result of ongoing genomics research. A combined tiered-layered-staged model for informed consent in PGT would allow for relevant information provision that is both sufficiently complete and sufficiently understandable."

80 As affirmed by the UK Human Genetics Commission, "the difficulties involved in tracing and securing re-consent for different forms of medical research may make obtaining fresh consent imprac-

When issues arising from research reach a general dimension, it would be advisable to define consent of the members of a group and techniques to involve communities and to establish a sort of "collective consent" instead of the individual one. This is the case for the establishment of the program called "deCODE Genetics", approved by the Icelandic state, to gather the genetic profile of all Icelandic citizens.[81]

Furthermore, consent is not sufficient because of the vulnerability of the individual in respect to professionals and/or institutions carrying out research or other activities concerning personal data, or because it is necessary to access the research activities in order to make them consistent with the ethical principles and with legal rules. In those cases, consent in itself is not sufficient to ensure proper protection of individual interests[82] and therefore needs further tools to integrate its effectiveness.

Another important instrument to face the ethical problems concerning the use of genetic information is the control carried out by ethics committees or other third parties. For example, documents dealing with genetic screening for the recruitment of employees recommend requiring the prior assent of the appropriate labour organisation and a specific ad hoc authorisation by an independent committee. Indeed, the person may be compelled to consent to the screening in order to be recruited by the employer.[83]

According to some legal authorities in the field of health, such as the discipline of clinical trials, the expression of consent has to be subject to independent bodies' control, through ethical committees, agencies, or other bodies that allow the evaluation of the activity (see Article 6, para 3, Directive 2001/20/EC). The role of the ethics committee is affirmed by many documents of the Council of Europe in critical situations, such as when health data cannot be anonymised for technical reasons (see para. 12.2, Appendix to Recommendation (97), mentioned above), which normally is the case for genetic data; or if it is not possible, with a reasonable effort, to contact the person who has not given her/his consent to carry out research activities concerning biological material (see Article 21.2, Recommendation (CM/Rec(2016)6). In those cases, the scientific purposes together with an external and independent evaluation carried out by an ethics committee allows for the research institution to overcome the lack of consent.

In this respect, we can also see the draft Recommendation on the Protection of Health-Related Data, which establishes that "The conditions in which health-related data are processed for scientific research must be assessed, where necessary, by the body or

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tical and would seriously limit the usefulness of large-scale population databases" (Human Genetics Commission Inside Information, May 2002).

81 See ÁRNASON V. and ÁRNASON G., "Informed Democratic Consent? The Case of the Icelandic Database", in Trames, 2004, vol. 8/12.

82 OTLOWSKI M., "Developing an appropriate Consent Model for Biobanks: In Defence of 'Broad' Consent", in KAYE J. and STRANGER M. (eds), Principles and Practice in Biobank Governance, Surrey, Ashgate Publishing Limited, 2009, Chapter 5, pp 79–92.

83 See the European Group on Ethics in Science and New Technology in its Opinion no. 18 concerning "Ethical Aspects of Genetic Testing in the Workplace" of 2003, para. 2; see also the document "Ethical, legal and social aspects of genetic testing: research, development and clinical applications" of 2004, elaborated for the General Directorate of Research Commission by a group of independent experts.

bodies designated by domestic law" (Article 16.6).[84] For example, Italian law provides for situations when consent is not necessary if research activity is established explicitly by law or when the processing is foreseen in a biomedical research programme approved on the ground of Article 12-bis Legislative Decree no. 502 of 30 December 1992 and referred to the Authority of Privacy (see Article 110, para. 1, Legislative Decree no. 196/2006).

Another possible solution to achieve a balance of interests involved could be drafting a code of conduct (see Article 40 Regulation (EU) no 2016/679),[85] as highlighted by the General Data Regulation, according to which it is necessary to "calibrate the obligations of controllers and processors, taking into account the risk likely to result from the processing for the rights and freedoms of natural persons" (see Recital no. 98).

EU discipline encourages the adoption of other instruments arising from private autonomy, although it is subject to the control of authorities, such as standard contractual clauses between controllers and processors and between processors, technical standards, and mechanisms for certification (see Recital no. 167).

Other instruments for ensuring accountability and the quality of the institutions and professionals dealing with genetic information need to be refined and developed.[86]

More generally, it is necessary that the consent process be part of a governance framework of "trust, responsibility and accountability", in which the involvement of institutional review boards would be essential.[87]

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[84] With respect to the position of independent authorities, in the judgement Tele2 Sverige AB et oth. of 21 December 2016 (in Joined Cases C-203/15 and C-698/15), the exceptions due to the justification to fight crime are admissible only where they will be reviewed by an independent administrative authority (see para. 120 and 125; see, by analogy, Directive 2006/24, the Digital Rights judgement, paragraph 62; see also, by analogy, Article 8 of the ECHR, ECtHR, 12 January 2016, Szabó and Vissy v. Hungary, CE:ECHR:2016:0112JUD003713814, §§ 77 and 80).

[85] See, for example, United Kingdom Information Commissioner's Office (2012), *Anonymisation:managing data protection risk. Code of practice*, available at www.ico.org.uk/ for_organisations/data_protection/topic_guides/anonymisation.

[86] Article 5 of the Additional Protocol to the Oviedo Convention concerning Genetic Testing for Health, adopted in Strasbourg on 27 November 2008, already stipulates that states must ensure that "a) genetic tests meet generally accepted criteria of scientific validity and clinical validity; b) a quality assurance programme is implemented in each laboratory and that laboratories are subject to regular monitoring; c) persons providing genetic services have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards."

[87] CAULFIELD T., UPSHUR R.E.G. and DAAR A., "DNA databanks and consent: A suggested policy option involving an authorization model", in BMC Medical Ethics, 2003, 4:1.

Information on Access and Benefit Sharing regarding the Utilisation of Genetic Resources under the European Union Legal Regulation

Valentina Colcelli

1. *Introduction.* The chapter aims to analyse how, in the European legal system, "Access and Benefit-Sharing information" are exchanged and this could help the implementation of the Nagoya Protocol and its goals, whether data flow could be controlled and whether legal consequences for infringement of rules on information exchange and storage would be more well-defined and reinforced. 'The EU law defines positive duties of behaviours with a focus on information'.[1] However, for genetic resources or associated traditional knowledge which have not been accessed following applicable access and benefit-sharing legislation or regulatory requirements at a national or international level, this 'is not a straightforward prohibition of utilization'.[2]

The Nagoya Protocol is an international agreement, which aims at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way.

Before the Nagoya Protocol, the Convention on Biological Diversity (CBD) was the most widely applied rules for 'Access and Benefit Sharing' (ABS). The Nagoya Protocol on access to genetic resources and traditional knowledge associated with genetic resources complies with Art. 15 of the CBD, which concerns the fair and equitable sharing of benefits (monetary and non-monetary) arising from the utilisation and commercialisation of genetic resources. Such benefits should accrue to the holders of genetic resources and traditional knowledge, particularly indigenous and local communities, from whence the genetic resources have been obtained. Emphasis is also placed on capacity building, particularly in developing countries with a priority on capacity building for women. This may also involve technology transfer. The Nagoya Protocol is therefore relevant to both the private and public sectors, in which it is incumbent upon these organisations to undertake due diligence regarding their own activities relating to genetic resources. D. A. Posey recalls that already before 1990, trading of products made by indigenous person's knowledge and in low-income countries cost around 43 million dollars.[3]

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1 GODT G., "The Multi-Level Implementation of the Nagoya Protocol in the European Union", in COOLSAET B., BATUR F., BROGGIATO A., PITSEYS J. AND DEDEURWAERDERE T., (eds.), Implementing the Nagoya Protocol Comparing Access and Benefit-sharing Regimes in Europe, Brill, 2015, Leiden Netherlands, p. 319.

2 Ibidem.

3 POSEY D.A., "Intellectual Property rights and Just Compensation for Indigenous knowledge, Amazonia and Siberia: Legal Aspects of the preservation of the Environment and Development in the Last Open Spaces", in Anthropology Today, 6, 1993, 4, p. 287.

The Multinational enterprises full use of genetic resources and associated traditional knowledge, but the local community and indigenous persons usually did not provide consent and not have a decent remuneration by Multinational beneficiaries of their knowledge. A storm of protest arose from this complex situation (see f.i. Vandana Shiva's movement): the notion of bio piracy emerged to explain - *lato sensu* - the not remunerative appropriation by the Multinational enterprises of biologic and genetic resources and the traditional knowledge mainly in the Southern hemisphere. This situation is new-colonialism economic approach in the Southern hemisphere.[4]

As a matter of fact, the approach inside the abusive exploitation of the genetic resources and associated traditional knowledge is unfair, and not ethically correct. This inequity approach is amplified by multinational firms' ability to obtain patent protection or other forms of intellectual property rights (trademark, utility model, short term patent, plant variety right) starting from genetic resources and associated traditional knowledge.[5]

The ABS measure is correlated with distributive justice and the principle of solidarity,[6] that in the specific case of the framework of the European Union, the former principle underpins the General Principles of European Union law.[7] Within the European Union (EU), the Nagoya Protocol has been spelled out in Regulation (EU) n. 2014/511 and 2015/1866 through which the mechanisms for establishing access and benefit sharing are laid down. In particular, they describe the means by which access to genetic resources and the benefit of their utilisation and commercialisation may be shared.

In the ABS system, those involved in any aspect of utilising genetic resources (including plant, animal, microbial or other origin containing functional units of heredity but excluding human genetics), the information exchanged and stored by Access and Benefit-sharing Clearing-house (ABSCH) tries to realise the legal certainty and transparency on procedures for access and benefit sharing.

Through a ABSCH may deposit information and connect users and providers of genetic resources and/or traditional knowledge. The ABSCH permits storing and transferring knowledge in which a description is provided along with the source of the genetic resource and whether there are rights and obligations regarding access and benefit sharing. A platform was created for monitoring the utilisation of genetic resources along the value chain, including the internationally recognised certificate of compliance. In the EU legal framework, through the system called Declare, the data and information are submitted to ABSCH.

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4 VEZZANI S., "Il Primo Protocollo alla Convezione europea dei diritti umani e la tutela della proprietà intellettuale di popoli indigeni e comunità locali", in Diritti Umani e Diritto Internazionale, 2007, 1, p. 305-342.

5 SANDBERG A., "Property rights and ecosystem properties", in Land Use Policy, 2007, 24, p. 613-623.

6 CIPPITANI R., La solidarietà giuridica tra pubblico e privato, Iseg srl, 2011, Roma-Perugia-Mexico.

7 COLCELLI V., "The Solidarity Principle in New EU Member States", in PERUGINI C., POMPEI F. (eds.), Inequalities during and after transition in Central and Eastern Europe, Palgrave, 2015, Basingstoke, p. 247-265.

Each Member State shall designate one or more competent authorities to be responsible for the application of EU Law implementing the Nagoya Protocol(see next paragraph 7).[8] 'The competent authorities shall transmit the information received (….) to the Access and Benefit-Sharing Clearing House, established under Art. 14(1) of the Nagoya Protocol, to the Commission and, where appropriate, to the competent national authorities referred to in Art. 13(2) of the Nagoya Protocol. The national competent authorities shall cooperate with the Access and Benefit-Sharing Clearing House to ensure the exchange of the information listed in Art. 17(2) of the Nagoya Protocol for monitoring the compliance of users'.[9]

However, despite the central function assigned by the Nagoya Protocol to the information on ABS, the system realised does not establish assured legal consequences for the user of genetic resources[10] that does not comply with the rules on information exchanging and storing. The development and implementation of ABS regulatory frameworks at the national level will need to ensure that legislative, administrative or policy measures taken are consistent and mutually supportive of other existing ABS instruments. This means that each State has rules on this matter.

In the EU framework, the ABS system is running, but at the moment it is not completely clear what can be done in the case of infringement of the rules on information exchange and storage.

The EU legal system currently does not have a working administrative point for control on information exchange and storage. There are uncertain judicial claims at the EU level and at the national level. Not all the EU Member States who signed the Nagoya Protocol have the legislative, administrative or policy measures necessary for implementing the Protocol.

Thus, to analyse how, in the European legal system, access and benefit-sharing information are exchanged and how this could help the implementation of the Nagoya Protocol, this chapter will be organised as follows: section 2 describes how the Nagoya Protocol or others International Treaty on Plant Genetic Resources for Food and Agriculture apply to genetic resources over which States exercise sovereign rights. Section 3 introduces the EU legal framework implementing the Nagoya Protocol. The meaning of Due Diligence in the contest of the EU law on "Access and Benefit Sharing" is analysed in section 4. Section 5 examines how the relationship between genetic resources and associated traditional knowledge and their utilisation could be addressed by contracts and contractual clauses. Section 6 describes the information flow for ABSCH and its function, as well as the system for storing and transmitting data according to Regulation (EU) n. 511/2014. Section 7 examines when due diligence declaration needs to be requested by national competent authorities, by the European Commission or by the public administrations of Member States in the case of request for market approval or placing products on the market, and the legal consequences for the infringement of the obligation for ABS information. Sec-

8 Art. 6 Regulation (EU) n. 511/2014.

9 Art. 7 Regulation (EU) n. 511/2014.

10 Art. 4 Regulation (EU) n. 511/2014, Point 4: 'user' means a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources.

tion 8 concludes how it is possible to have rather good control of the flow of information in the EU legal system, if all the public administrations or agencies involved check the ABS due diligence fulfilment.

2. *Benefit sharing: Multilateral international system and the Nagoya Protocol approach.* The genetic resources over which States exercise sovereign rights falls within the scope of Art. 15 of the CBD. Art. 15 of the CBD recognizes 'the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. (…) Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention (…)'.[11]

The Nagoya Protocol does not extend to the full jurisdictional scope of Art. 4 of the CBD.[12] 'In addition to the CBD itself, the Nagoya Protocol will become a binding set of norms setting detailed rules on how ABS can be implemented in national legislation'.[13] 'The fact that the CBD and the Nagoya Protocol are two different legal instruments. (…) Art. 4 of the Nagoya Protocol on the relationship between Nagoya Protocol and other instruments only applies in that context and not to the general rules provided by the CBD. Thus the relationship between the CBD and other instruments of international will not be solved directly by the new rules introduced in Art. 4 of the Nagoya Protocol'.[14]

That is why an interface between the Nagoya Protocol on ABS and the International Treaty on Plant Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization (ITPGRFA) at the international level exits. The Nagoya Protocol applies to genetic resources, over which States exercise sovereign rights. However, the Nagoya Protocol gives priority enforcement to the specialized legal instruments if they are limited and qualified. This is the case of ITGRFA, just for to the genetic resources covered and for its the purpose.[15]

Annex 1 to the ITPGRFA lists crops and forages under the multilateral system for ABS (see next paragraph n. 5). 'Plant genetic resources for food and agriculture' (PGR-

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11 Art. 15 CBD.

12 See CBD, Art. 4 Jurisdictional Scope: Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party: (a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and (b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

13 PERRON F., FREEDOM KAI PHLLIPS J. M., "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level Fridtjof Nansen Institute (FNI)", in Rep. No. FNI Report 1/2011, Fridtjof Nansen Institute, 2013, Lysaker, Norway, pp. 1-71.

14 Ibidem.

15 See Art. 4 (4) Nagoya Protocol.

FA) means any genetic material of plant origin of actual or potential value for food and agriculture. The list in Annex 1 refers to different taxonomic levels and biology is not a static science. However, 'the list in the Annex gives some legal certainty for which crops are covered, the extent to which wild relatives of cultivated crops are covered introduces a certain level of uncertainty'.[16] Nevertheless, parties to the Nagoya Protocol, in the exercise of their sovereign rights, could decide that certain PGRFA falls within the scope of ITRGFA management and control, even though they are not listed in Annex I to the ITPGRFA.

As a matter of fact, 'with few exceptions there has not been legislation which differentiates between the treatment of genetic resources for food and agriculture and those of other genetic resources'.[17] If a country realised the choice above mentioned the access to plant genetic resources will be realized according to ITGRFA Multilateral System and its Standard Material Transfer Agreement (sMTA), not according to Nagoya Protocol.

3. *Implementing the Nagoya Protocol in the EU legal system.* During 2011, the European Commission adopted the EU biodiversity strategy for 2020, to halt the loss of biodiversity and ecosystem services by 2020. This document is an integral part of the Europe 2020 strategy and the 7th Environmental Action Programme. This implements EU commitments under the CBD.

During 2014, the EU adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from the utilization in the European Union, by Regulation (EU) n. 511/2014. The Regulation (EU) n. 511/2014 rules on 'Access to Genetic Resources and the Fair and Equitable Sharing of Benefits'. It dictates how the Nagoya Protocol is enforced in the EU legal system.

Though, just in the second part of 2015, Art.s 4, 7 and 9 of the Regulation (EU) n. 511/2014 were enforced. The Art.s mentioned above respectively concern the 'Obligations of Users', 'Monitoring user compliance' and checking user compliance. 'Users,' according to Regulation (EU) n. 511/2014, include the natural/legal persons that utilise genetic resources or traditional knowledge associated with genetic resources.

Thus, the Nagoya Protocol is a freestanding legal obligation expressed in the EU legal system by Regulation (EU) n. 511/2014 and the Commission Implementing Regulation (EU) n. 2015/1866 passed on 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) n. 511/2014 regarding registering collections, monitoring user compliance and best practices. The development and implementation of ABS regulatory frameworks at the national level will need to ensure that legislative, administrative or policy measures taken are consistent and mutually supportive with other existing ABS instruments.

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[16] PERRON F., FREEDOM KAI PHLLIPS J. M., "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level Fridtjof Nansen Institute (FNI), cit.

[17] Ibidem.

As above mentioned, ITPGRFA constitutes a specialised international access and benefit-sharing instrument within the meaning of Art. 4 (4) of the Nagoya Protocol,[18] also in the EU legal system (see previous paragraph 2). As matter of fact, in the framework of the EU legal system, 'users acquiring Plant Genetic Resources for Food and Agriculture (PGRFA) in a country that is a Party to the Nagoya Protocol which has determined that PGRFA under its management and control and in the public domain, not contained in Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), will also be subject to the terms and conditions of the standard material transfer agreement (sMTA) for the purposes set out under the ITPGRFA, shall be considered to have exercised due diligence in accordance with paragraph 3 of this Art.'[19] (see next paragraph 5).

'The Multilateral international system (MLS) is highly relevant for ABS because it is the first sectorial approach to ABS, and could provide useful lessons for the implementation of ABS, including whether and if so, how, sectorial ABS can be dealt with to meet the objectives of the CBD'.[20]

4. *The due diligence in the context of ABS.* In the EU legal system, the information flow on genetic resources accessed, the time and place of access and the ways in which the resource may be used are some of the circumstances for complying with the due diligence requirements in Regulation (EU) n. 511/2014 to ascertain the genetic resources and traditional knowledge associated with them.

Due diligence can be defined as an investigation prior to signing a contract, or certain standards of care applying to an act. In tort law, the standard of care is the only degree of prudence and caution required of an individual who is under a duty of care.

In the context of ABS, due diligence means that you did your very best to establish which access and benefit-sharing conditions apply to the genetic resources you wish to access and that you have taken care to meet these conditions.[21]

The users exercise due diligence in their own activities linked with genetic resources prior to obtaining 'internationally-recognised certificates of compliance as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established for the user and the utilisation specified therein',[22] and also national authorities reckoned them. Transferring, keeping, etc. of genetic resources, also for food and agriculture not contained under Annex I of the ITPGRFA, require an internationally recognised certificate of compliance.[23]

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18 See, Point 12, Regulation (EU) n. 511/2014.

19 Art. 4 (4) Regulation (EU) n. 511/2014.

20 PERRON F., FREEDOM KAI PHLLIPS J. M., "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level Fridtjof Nansen Institute (FNI), cit.

21 Art. 3, (4), Regulation (EU) n. 511/2014.

22 Point 21 of the Regulation (EU) n. 511/2014.

23 Art. 4 Regulation (EU) n. 511/2014.

According to point 21 of Regulation (EU) n. 511/2014, 'genetic resources have been accessed by applicable legal or regulatory requirements and to ensure that, where relevant, benefits are fairly and equitably shared'.

If internationally-recognised certificates of compliance are not present, the user has to comply with the *minimum* information required by Art. 17 (4) of the Nagoya Protocol, as specified in Art. 4(3) (b) of Regulation (EU) n. 511/2014. Where no international certificate exists, documents and information have to be verified by the users.[24] Also, the regulation states that users have to declare and provide evidence that they have exercised due diligence when requested.

The requirements of the standard are closely dependent on circumstances. Users obtaining a genetic resource from a collection included in the register of collections within the EU shall be considered to have exercised their obligation of due diligence.[25] A collection that is registered under EU Regulation n. 511/2014 applies standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third parties for their utilisation in line with the CBD and the Nagoya Protocol; the collection supplies genetic resources and related information to third persons for their utilisation only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable ABS legislation or regulatory requirements and, where relevant, under mutually agreed terms. The request for inclusion of a collection or a part thereof in the register, referred to in Art. 5(2) of Regulation (EU) n. 511/2014, shall contain the information specified in Annex I to Regulation (EU) n. 1866/2015.

5. *Access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation addressed by contracts and contractual arrangements.* The relationship between genetic resources and associated traditional knowledge and their utilisation could be addressed in contracts and contractual clauses. The Nagoya Protocol uses contracts to have mutually agreed terms for sharing benefits with the provider of genetic resources or of traditional knowledge associated with genetic resources. These kinds of contracts – mainly Material Transfer agreements (MTA) – have to set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources. In the EU legal system, according to Art. 3 of Regulation (EU) n. 511/2014, they have also included further conditions and terms for such utilisation as well as subsequent applications and commercialisation.

Fundamentally, 'Material Transfer agreement (MTA) is a bailment, that is, a transfer of tangible property without transfer of title. Under such an agreement, the provider could maintain ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract, there-

[24] Art. 4 Regulation (EU) 511/2014.
[25] See Point 9, Reg. (EU) 1866/2014.

fore, governs the transfer of tangible biological materials between two or more parties. In addition to the tangible property rights being owned by the provider, the material(s) may be the subject of a patent or patent application. In this case, the MTA may need to account for the transfer of Intellectually Property rights as well as the transfer of tangible material'.[26]

The user shall share fairly and equitably the benefits arising from their utilisation of the genetic resources and traditional knowledge associated with genetic resources, its progeny or derivatives in accordance with the CBD. A non-exhaustive list of non-monetary and monetary benefits is given in the Annex to the Nagoya Protocol.

Mutually Agreed Terms (MAT) are defined also at the EU level by Regulation (EU) n. 511/2014 as 'the contractual arrangements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation'.

Regulation (EU) n. 511/2014 identifies a set of criteria using the identification of the area (country, region, etc.) from which the genetic material used for developing new varieties comes. These criteria will reflect the enforcement of legal rights, the rate of entrepreneurship, the structure of the higher education system, etc. of partner countries of the Nagoya Protocol.

Firstly, contractual arrangements (MAT) should guarantee the effectiveness of legal contracts and technology transfer agreements once the biotech research activity is completed. Second, they have to contribute to develop potential market value of new varieties.

Measurement of returns – mainly monetary – from commercialising innovation will be crucial to identify a fair price to which the new varieties could be sold with particular attention to local communities. One of these criteria is a provision for sharing benefits with the provider of the genetic resources or of traditional knowledge within the contract made for utilisation, subsequent applications and commercialisation of products derived by genetic resources or by traditional knowledge associated with them.

Competent authorities of Member States should check whether users comply with the obligations[27]: this means fair and equitable sharing of benefits arising from the utilisation of genetic resources and traditional knowledge.

Competent authorities could also refer to the Judge of the National and European Union Courts[28]: through the jurisdictional control of the contract for utilisation, subsequent applications and commercialisation of genetic resources and traditional knowledge linked with them, it will be possible to fulfil the goals of Regulation (EU) n. 511/2014. In this case and to better understand what kind of juridical control there could be over

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26 https://www.cbd.int/doc/press/2015/pr-2015-10-07-abs-en.pdf.

27 See Point 29, Regulation (EU) n. 511/2014.

28 COLCELLI V., "A Critic Lecture of the EU Two Faced Approach to Biodiversity: Equal Guaranty or Multinational Bioraid? The Importance of a Self-Reconsideration of EU Politics in Biodiversity", in CERRINA FERONI G., FROSINI L. MEZZETTI T. E, PETRILLO P. L. (eds.), Environment, Energy, Food Comparative Legal Models For Sustainable Development, Cesifim, 2016, 1, I, Roma, p. 41-53.

the contracts and mutually agreed terms, it relevant settling the nature of the remedies for not fair and equitable contractual arrangements (nullity, voidable etc.), but still now it is not so clear. This situation is intertwined and takes different contours depending on the nature of the interests to be protected. The infringement of EU rules regarding not setting out specific conditions for the fair and equitable sharing of benefits from the utilisation of genetic resources or of associated traditional knowledge in the contract could mean nullity of the MTA.[29]

6. *ABSCH: information exchange and storage for facilitating the implementation of the Nagoya Protocol.* The ABSCH is the platform for exchanging information on access and benefit sharing established by Art. 14 of the Protocol, as part of the clearing house established under Art. 18, paragraph 3 of the CBD. By hosting relevant information regarding ABS, the ABSCH offers opportunities by connecting users and providers of genetic resources and associated traditional knowledge.

On 1 October 2015, the first internationally recognised certificate of compliance was issued under the Nagoya Protocol on Access and Benefit Sharing. The permit was issued by India's National Biodiversity Authority, the competent national authority under the Nagoya Protocol. The certificate through the ABSCH serves as evidence of the decision by India to grant access to ethno-medicinal knowledge of the Siddi community from Gujarat to a researcher affiliated with the University of Kent in the United Kingdom. Thus, the researcher can demonstrate that s/he has respected the ABS requirements of India when using this knowledge.

Where an internationally recognised certificate of compliance is not available, other relevant information provided in accordance with Art. 17 (4) of the Nagoya Protocol, as specified in Art. 4(3)(b) of Regulation (EU) n. 511/2014, should be submitted by the due diligence declaration.

In the case of Art. 17(4) of the Nagoya Protocol, the researcher will need in any case provide the following information required by the treaty as a *minimum*: (a) Issuing authority; (b) Date of issuance; (c) The provider; (d) Unique identifier of the certificate; (e) The person or entity to whom prior informed consent was granted; (f) Subject-matter or genetic resources covered by the certificate; (g) Confirmation that mutually agreed terms were established; (h) Confirmation that prior informed consent was obtained; and (i) Commercial and/or non-commercial use.

According to Art. 17 mentioned above, EU Regulation 511/2014, Art. 4, paragraph 3 where no internationally-recognised certificate of compliance is available, the following information and relevant documents are required:

(i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
(ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;
(iii) the source from which the genetic resources or traditional knowledge associated

[29] Ibidem.

with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;

(iv) the presence or absence of rights and obligations relating to access and benefit sharing including rights and obligations regarding subsequent applications and commercialisation;

(v) access permits, where applicable;

(vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

However, according to the CBD, an ABS National Focal Point contains information that is relevant to all public institutes, companies and individuals using genetic resources for research and development. It shall provide basic guidance for users seeking access to genetic resources as well as background information on the relevant international agreements, and explains various terms that are often used.

6.1. Declare system and transmission data in the EU legal framework. A due diligence declaration is required (only) for genetic resources or traditional knowledge associated with genetic resources obtained from a party to the Nagoya Protocol that has established relevant access and benefit-sharing legislation or regulatory requirements pursuant to Art. 6 (1) and Art. 7 of Regulation (EU) n. 511/2014. In the EU legal framework, through the system called Declare,[30] users request access to the system, submit due diligence declarations and review submitted declarations. Thus, through the Declare system, the competent authority of the EU Member State, approves new submitting organisations, submitted declarations and transmits data to ABSCH. The declaration of due diligence is submitted to the competent authority of the Member State where the recipient of funding is established.

It is relevant to underline point 25 of Regulation (EU) n. 511/2014 which affirms that one suitable point for such a declaration is when research funds are received, and also at the final stage of utilisation. This means at the stage of final development of a product before requesting market approval for a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, or, where market approval is not required, at the stage of final development of a product before first placing it on the Union market.

Annex II and III of Regulation (EU) n. 1866/2015 are both templates for a due diligence declaration to be submitted at the stage of research funding pursuant to Art. 5(2) mentioned above. Annex II regards the declaration to be submitted at the stage of research funding pursuant to Art. 5(2). The second one (Annex III) is the template for a due diligence declaration to be submitted at the stage of final development of a product pursuant to Art. 6(1).

The time of submission of such declaration may be further specified by the national authorities.[31] Annex II shall be made after the first instalment of funding has been re-

[30] Log-in with ECAS (http://ec.europa.eu/europeaid/funding/about-grants/how-apply-grant/applicant-registration-pador/ecas-registration_en).

[31] Art. 5 of Regulation (EU) n. 1866/2015.

ceived and all the genetic resources and traditional knowledge associated with genetic resources that are utilised in the funded research have been obtained, but no later than at the time of the final report, or in absence of such report, at the project end.

A single declaration may also be made by several users jointly conducting research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources funded by one grant. In this context, a special role should be given to the project coordinator, who should be responsible for submitting the declarations on behalf of the users concerned.[32]

The due diligence declaration of Annex III shall only be made once, prior to the first of the following events occurring:

(a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;
(b) a notification required prior to placing, for the first time on the Union market, a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;
(c) placing on the Union market for the first time a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources for which no market approval, authorisation or notification is required;
(d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);
(e) the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

Under Art. 7(2) of Regulation (EU) n. 511/2014, the final stage of utilisation, meaning the stage of final development of a product, should be determined. The stage of final development of a product can be identified with legal certainty as having been completed at the time when either market approval or authorisation is sought or a notification required prior to placing for the first time on the Union market is made or, where neither market approval or authorisation nor a notification is required, at the time of placing for the first time on the Union market.

Over the non-confidential data upload in the Declare system by the genetic resource, data will be under the access from the European Commission, that overviews also of the submitting organisation.

The information provided in the due diligence declarations (that are confidential) is to be submitted by the competent authorities to the ABSCH pursuant to Art. 7(3) of Regulation (EU) n. 511/2014.

7. *Where and who performs the checking on due diligence fulfilment.* As described above, Art. 4 of Regulation (EU) 511/2014 explains which users must comply and fulfil 'due diligence' in their activities linked with genetic resources ascertained. Among them, Art. 4 describes which information users need to seek, keep and transfer to comply with the due

[32] See Point 8 Regulation (EU) n. 1866/2014.

diligence obligation. The latter includes formal documentation from the country where you acquired the genetic resources and information about the genetic resources accessed, the time and place of access and the ways in which the resource may be used. Users shall keep the information relevant to access and benefit sharing for 20 years after the end of the period of utilisation.

There are three moments for prior checking on 'due diligence' and whether or not it was fulfilled by the user: a) in the first instalment of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources, or no later than at the time of the final report, or in absence of such report, at the project end; b) in the event of a request for market approval or c) the placing on the market of products deriving from the utilisation of a genetic resource (see previous paragraph 6.1).

As a matter of fact, according to Art. 5 of Regulation (EU) n. 2015/1866, 'a recipient of funding for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources shall make the due diligence declaration requested pursuant to Art. 7(1) of Regulation (EU) n. 511/2014 to the competent authority of the Member State in which the recipient is established'. If the recipient is not established in the EU and the research is carried out in the EU, the due diligence declaration shall be made to the competent authority of the Member State in which the research is carried out.

Furthermore, many products in the EU legal system need a request of authorisation for market approval or the placing of products on the market. Anyway, f.i. for placing on the market of plant protection products an authorisation is required. The Regulation for placing Plant Protection Products on the market (1107/2009) lays down harmonised rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the EU.

Food and feed derived from genetically modified organisms are authorised and supervised by a competent authority in the relevant EU country and by the European Food and Safety Authority (EFSA). Regulation (EC) n. 1829/2003 on genetically modified food and feed, lays down rules on how genetically modified organisms (GMOs) and on how genetically modified food and animal feed are labelled. In general, also medicinal products are under a market approval or authorisation.[33] The marketing authorisation holder should submit an application to the competent authorities of each Member State and in the centralised procedure, the applicant applies to the European Agency for the Evaluation of Medicinal Products (EMEA) for marketing authorisation.

In the case for notification required prior to placing for the first time on the Union market, f. i. about food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of placing on the market by forwarding it a model of the label.[34]

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[33] See, among the others, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; Regulation (EC) n. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[34] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

A further moment for a prior checking could before European Union Intellectual Property Office, or Community Plant Variety Office or Intellectual Property offices of the EU Member States, despite a coordination between the Regulation itself and the system for the protection of plant variety rights established by European Union legislation is still not present.

Regulation (EC) n. 2100/94 of 27 July 1994 on Community plant variety rights, Regulation (EC) n. 1238/95 of 31 May 1995 that establishes rules for the application of the fees payable to the Community Plant Variety and Regulation (EC) n. 1768/95 of 24 July 1995 for implementing rules on the agricultural exemption built the system for the protection of plant variety rights established by the EU. Anyway, the compliance with EU legislative framework on ABS allows intellectual property rights, valid throughout the EU, to be granted for plant varieties. As a matter of fact, disclosure requirements mean patent (and perhaps also other forms of intellectual property rights) applicants should disclose several categories of information concerning genetic resources, such as the source or origin and evidence of prior informed consent and benefit sharing, when these genetic resources are used in developing the innovation claimed in a patent application.

Due diligence obligation and an internationally-recognised certificate for compliance, as well as full information on genetic material and resources address how to apply for a vegetable patent under the aims of Regulation (EU) n. 511/2014. Without waiting for the Commission implementation how to apply for the vegetable patent under the light of the purposes of the Regulation (EU) n. 511/2014 and Nagoya Protocol, the ABS goals could be realised whether the plant patent is granted if the due diligence is not demonstrable through documentation required for applying for vegetable plants patents.

7.1. Breaching the due diligence obligation: weighing the impacts for users and providers of the lack of ABS information and its formal documents. As a consequence of infringement of paragraphs 3 or 5, Art. 4 of Regulation (EU) 511/2014, the utilisation of genetic resources or associated traditional knowledge shall be discontinued.[35] When the information is insufficient, or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation.[36]

In the absence of prior informed consent having been obtained in a timely manner, mutually agreed terms having been established, and until an agreement is reached with the provider country concerned, no exclusive rights of any kind will be claimed by an user for any developments made via the use of genetic resources, that is determined to be, or is identified as likely to be, the causing pathogen of a present or imminent public health emergency of international concern. The meaning of health crisis falls under the scope of International Health Regulations (2005), or of a serious cross-border threat to health as defined in Decision n. 1082/2013/EU of the European Parliament and the Council.[37]

[35] Art. 4, (2) of the Regulation (EU) n. 511/2014.
[36] Art. 4, (5) (6) of the Regulation (EU) n. 511/2014.
[37] Art. 4, (8) of the Regulation (EU) n. 511/2014.

In my opinion, with a lack of information, recipients of research funding[38] and user patenting will pay the consequences, over then, of course, the disadvantage for discontinuing on the utilisation of genetic resources or associated traditional knowledge.[39] For instance, on one hand, for EU research funds, we have to take into consideration that 'Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries' is, among the others, one of the main ethical principles established by the EU legal framework related to Horizon 2020. According to Art. 34 (1) of the H2020 Grant agreement, the beneficiaries of an EU project must carry out the action in compliance with: a) ethical principles (including the highest standards of research integrity) and b) applicable international, EU and national law. Thus, non-compliance with the ethical principles, the Nagoya Protocol and Reg. 511/2014, for the grant beneficiaries, means that the grant may be reduced,[40] and the agreement or participation of the beneficiary may be terminated.[41] On the other hand, the lack of information and formal documents applying for the vegetable patent would produce a nullity of the bad patent if granted, not taking into consideration information requirements by the Regulation (EU) 511/2014.

8. *Conclusions.* Art. 7(1) of the Regulation (EU) n. 511/2014 makes it clear that a due diligence declaration needs to be requested by the Member States (competent authorities responsible for the application of EU Law implementing the Nagoya Protocol[42]), the European Commission if the money is provided by EU funds and the EU Offices or the public administrations of Member States in the case of request for market approval or placing products on the market. Nevertheless, the agencies for ABS control are not in charge of market approval.

It is possible to affirm that rather good control over the flow information is possible in the EU legal system, if all the public administrations or agencies involved check ABS due diligence fulfilment. Only a crossing flow of information and data among the public bodies involved could build a working system in the EU framework. However, not all the products stemming from research and developing by genetic resources, or associated traditional knowledge are subjected to market approval or authorisation, or they derive from research activity using EU funds.

At the moment, in which the Declare system still does not established, it seems that the providers, the owners of genetic resources and the consumers are not in a position to know who is using research and developing activities[43] before market approval or at

38 Point (25) Reg. (EU) n. 511/2014 /Art. 5 Reg. (EU) 2015/1866.

39 GODT G., "The Multi-Level Implementation of the Nagoya Protocol in the European Union", in COOLSAET B., BATUR F., BROGGIATO A., PITSEYS J. AND DEDEURWAERDERE T., (eds.), Implementing the Nagoya Protocol Comparing Access and Benefit-sharing Regimes in Europe, Brill, 2015, Leiden Netherlands, p. 319, where the author talks about "piggy-back" procedures.

40 See Art.s 34 (4) and 43 Model Grant Agreement.

41 See Art.s 34 (4) and 50 Model Grant Agreement.

42 Art. 6, 9 and 11 Regulation (EU) n. 511/2014.

43 VON KRIES C., G. WINTER G., "Defining commercial and non-commercial research and devel-

the final stage of utilisation of the product (see paragraph 6.1). As a matter of fact, the declaration is not public, as well as data that shall be transmitted by the ABS competent authorities to ABSCH.

It seems that the main mission of the ABSCH provides stronger support for users, than providers. Furthermore, Art. 14 (2) of the Nagoya Protocol describes making mandatory information available in the ABSCH platform: (a) Legislative, administrative and policy measures on access and benefit sharing; (b) Information on the national focal point and competent national authority or authorities (CNA); (c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent (PIC) and of the establishment of mutually agreed terms (MAT). Also, according to Art. 12 (2), Art. 17, (1) (a) (iii) and Art. 22 (6) of the Nagoya Protocol other information made available includes: (a) Measures to inform potential users of traditional knowledge associated with genetic resources about their obligations for access to and fair and equitable sharing of benefits arising from the utilisation of such knowledge; (b) Information provided to designated checkpoints that collect or receive, as appropriate, relevant information related to prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms, and/or the utilisation of genetic resources, including from internationally recognised certificates of compliance (IRCC), where they are available; (c) Information on capacity-building and development initiatives at national, regional and international levels that should be shared through the ABSCH with a view to promoting synergy and coordination on capacity-building and development for access and benefit sharing.

The flow of information available in the ABSCH platform seems to converse with the users more than with providers, stakeholders and consumers and appears to kindly invite the users to respect the ABS system. Providers, stakeholders and consumers, as well as the states that have the sovereign of the genetic resources used, have the possibility to discover the illegal utilisation of genetic resources only accidentally, after products are placed on the market. In this case, the only instruments for contesting the use of the illegal product will be the judicial claim. In EU legal system, thanks to the EU multilevel guaranty system,[44] a number of instances for providers, stakeholders and consumers and others private or public persons can bring 'direct action, where appropriate, before the Court of Justice, (…) not intended to create new remedies in the national courts to ensure the observance of Community law other than those already laid down by national law',[45] also if not all the members states still now have ruled the legal measure to comply with Nagoya Protocol.

As a matter of fact, with regard to the EU legal system, individual rights can be effectively protected only if they are used in actions before national courts.[46] It is for 'the legal system of each Member State to determine which court has jurisdiction to hear

opment under the Nagoya Protocol and in other context", in E. CHEGE KAMAU E., G. WINTER G., STOLL P.T., (eds.) Research and Development on Genetic Resources. Public domain approaches in implementing the Nagoya Protocol, Routledge, 2015, London-New York, pp.125-147.

44 FORSBERG T., "Normative Power Europe, Once Again: A Conceptual Analysis of an Ideal Type", in JCMS, vol. 49, n. 6, 2011, pp. 1183-1204.

45 Rewe v Hauptzollamt Kiel (C- 158/80), [1981] ECR, 1805.

46 Theresa Emmot v Minister for Social Welfare, (C-208/90) [1991] ECR, I-4269.

disputes involving individual rights derived from Community law, but at the same time the Member States are responsible for ensuring that those rights are effectively protected in each case'.[47]

When the national system of protection cannot guarantee community rights sufficiently, the equipment provided by the EU legal system comes into action. In the system, a uniform network of safeguards for community individual rights (e.g., liability of a Member State, recovery of sums paid but not due, disapplication and obligation to interpret national law in conformity with community law) is provided when the judiciary of a Member State does not safeguard the effectiveness of the protection of community rights. The system does not envision specific or special protection for individual rights but provisions by Member States for effective national legal protection.

[47] Ibidem.

Legal approach for informed consent and donation of biological samples to biobanks for biomedical research: a glance to Spain[1]

Francisco Miguel Bombillar Sáenz

1. *Biobanks and European Union Law:* in varietate concordia. This paper aims to address the legal approach for informed consent and the donation of biological samples to a biobank for biomedical research under Spanish regulation[2] – one of the most advanced and complete of the European continent. I argue that it is not possible to hide in consents full of lawless and indeterminate terms for elaborating a kind of blank cheque in order to carry out any research based on biological samples.

To date, there is no international or European regulatory framework (in other words, of supranational nature) that controls in any uniform way[3] the singular phenomenon of biobanks.[4] These are public service structures organised for science progress and innovation on health,[5] which, if mismanaged, could damage the main fundamental rights regarding people's dignity, privacy and physical integrity.

The European Union Law has been unable to answer (beyond the implementation of community regulation in terms of data protection) the challenges[6] that face European

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1 The opinions expressed here are exclusively the author's responsibility and they do not necessarily represent the majority opinion of the *Comité Coordinador de Ética de la Investigación Biomédica de Andalucía*, of which he is a member.

2 See the brilliant paper of ARIAS-DÍAZ J., MARTÍN-ARRIBAS M.C., GARCÍA DEL POZO J. and ALONSO C., "Spanish regulatory approach for Biobanking", in European Journal of Human Genetics, 2013, 21, p. 708-712.

3 This is inherent to all problems within the framework of the bioethics field. In this sense, we could think of the different legislative solutions adopted in the field of voluntary pregnancy termination, the patient's rights at the end of his/her life or gestational surrogacy or posthumous fertilisation after the death of the husband.

4 M.G. MIGLIAZZO already warned us about this in "Biobanche e diritti fondamentali: un fenomeno da diagnosticare. Italia e Spagna a confronto" in Pérez Miras A., Teruel Lozano G.M. and Raffiotta E.C. (Edit by), Desafíos para los derechos de la persona ante el siglo XXI: Vida y Ciencia, Thomson-Aranzadi, 2013, Navarra, p. 240 ff.

5 For the *Comité de Bioética de España*, biobanks are 'a fundamental institution in the exercise of research action in the field of biomedicine'. See 'Informe del Comité de Bioética de España sobre el Proyecto de Decreto por el que se regula la Autorización, Organización y Registro de los Biobancos en la Región de Murcia', 2014, p. 3.

6 See European Commission, Directorate-General for Research and Innovation, 'Biobanks for Europe. A challenge for governance'. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank, 2012.

citizens regarding this particular scientific-technical sector – that has only been briefly legally explored (although it has been present for over two decades now[7]).

In any case, after reading the regulation enacted in this regard by the different Member States of the European Economic Area[8] (the case of Estonia,[9] Iceland,[10] Norway,[11] Portugal,[12] Sweden[13] or Spain) we can characterise biobanks[14] as physical establishments[15] (usually part of a network[16]) that contain with unlimited nature[17] (or limited in time[18]) an organised collection[19] of biological samples with cession purposes to third parties (their main asset). Those samples possess associated information (description of the state of health, genealogy, genetic data and other information that could reveal the patient's identity) that require special management in terms of data protection.

Many biological samples are stored in these public service establishments in order to promote and advance biomedical research[20] (on which this paper is based), healthcare assistance [with diagnostic[21] and therapeutic purposes (highlighting blood and

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7 It is believed that was in the work of LOFT S. and POULSEN H.E., "Cancer risk and oxidate DNA damage in man", published in the Journal of Molecular Medicine, 1996, 6, where these establishments were mentioned for the first time in writing in the scientific literature.

8 See BRINCEIRO MORAIA L et al, "A comparative analysis of the requirements for the use of data in biobanks based in Finland, Germany, the Netherlands, Norway and the United Kingdom", in Medical Law International, March 2015, 14(4).

9 Human Genes Research Act (2000).

10 Act on Biobanks (2000).

11 Act relating to Biobanks (2003).

12 *Lei n.º 12/2005, de 26 de Janeiro – informação genética pessoal e informação de saúde* (*DR* no. 18, of 26th January 2005).

13 Biobanks in Medical Care Act (2002).

14 MALANDA S. R. provides a legal concept of biobank and ORFAO DE MATOS A. a technical concept, under the voice 'Biobanco', in CASABONA R. C.Mª (Edit by), Enciclopedia de Bioderecho y Bioética, Comares, 2011, Granada, vol. I, respectively, in p. 131-146 and 129-131. In line with this, see also the work of ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas con fines de investigación biomédica en el ordenamiento jurídico español", in Estudios de Deusto. Revista de la Universidad de Deusto, 2011, 59 (1), p. 183-228.

15 Portugal speaks of 'repositories'.

16 The term biobank 'it refers not only to the physical facilities of the Biobank but, above all, to the management of the samples stored under that label, and particularly to the requirements for their cession'. ARIAS-DÍAZ J. et al, "Spanish regulatory approach for Biobanking", cit., p. 709.

17 Iceland or Spain.

18 Sweden or Portugal.

19 According with the dispositions of the Committee of Ministers of the European Council's Recommendation no. 4 (2006) on research on biological materials of human origin.

20 These biobanks are a very useful tool to promote biomedical research, ensure the availability of samples, prevent illicit traffic of biological materials and centralise the management of informed consent. ROMEO MALANDA S., "Biobanco", cit., p. 142.

21 In fact, we can locate the origin of biobanks in the biological samples collections coming from diagnostic procedures (for example, biopsies or blood samples from newborns) that used to be stored in the anatomical pathology departments.

tissue banks and, specially, cord blood banks[22])], without dismissing forensic research. But, traditionally, it has been the therapeutic and forensic use, as opposed to that of biomedical research, which has found a greater normative development in the Spanish legislation.[23]

In Spain, as we will see in the following section, there is a detailed and advanced regulation, not without gaps,[24] of legal (from 2007) and implementing nature (from 2011) regarding the gathering, storage or preservation and use of biological samples of human origin in a biobank for the purposes of biomedical research. It is precisely the aim of this paper to shed some light on this normative framework. Other authors[25] already faced this challenge with great solvency.

In other countries, like Italy,[26] there is no regulatory framework of generic nature on this matter, but is only partially addressed with the decisions from the *Comitato Nazionale per la Bioetica*, the orientations of the *Società Italiana di Genetica Umana* and the doctrine in the *Garante per la protezione dei dati personali*,[27] on the authorisations issued on the application of the most important rule in terms of data protection,[28] as well as by the specific dispositions enacted in the umbilical cord stem cells[29] and the fight against terrorism and criminality fields, by creating DNA databases through the Treaty of Prüm.[30]

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22 See LARIOS RISCO D., "Donación y uso privativo de la sangre de cordón umbilical: aspectos jurídicos", in Derecho y Salud, July-December 2007, 15 (2), p. 181-215.

23 As a sample, and without entering into the regulatory development of each of these Acts, take into account the *Ley 30/1979, de 27 de octubre, sobre extracción y trasplante de órganos* (*BOE* no. 266, of 6th November 1979); the *Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida* (*BOE* no. 126, of 27th May 2006); the *Ley 29/1980, de 21 de junio, de Autopsias Clínicas* (*BOE* of 27th June 1980), as well as the *Ley de Enjuiciamiento Criminal*, in the case of forensic or judicial autopsies; or the *Ley Orgánica 10/2007, de 8 de octubre, reguladora de la base de datos policial sobre identificadores obtenidos a partir del ADN* (*BOE* no. 242, of 9th October 2007).

24 Some of these shortcomings have recently been highlighted by DE ABAJO F.J. and RODRÍGUEZ-MIGUEL A. in "Ley de Investigación Biomédica, diez años después: carencias y propuestas", in ICB digital, March 2017, online in the URL: http://se-fc.org/gestor/images/icbdigital/101aarticulo.pdf [consulted on 17th April 2017].

25 For this reason, I highlight the studies carried out in this respect from the Inter-University Chair in Law and Human Genome, by professor Romeo and other collaborators as Pilar Nicolás Jiménez or Sergio Romeo Malanda.

26 MIGLIAZZO M.G., "Biobanche e diritti fondamentali..." cit., p. 244.

27 MARRANI D, "Investigación biomédica y consentimiento informado para el tratamiento de datos genéticos", in ADORNO R. and IVONE V. (Edit by.), Casos de Bioética y Derecho, G. Giappichelli Editore-Tirant lo Blanch, 2015, Torino-Valencia, p. 117-118.

28 *Decreto legislativo 30 giugno 2003, n. 196, Codice in materia di protezione dei dati personali* (*GU Serie Generale* no. 174, of 29th July 2003. Ordinary supplement no. 123).

29 *Ordinanza del Ministro della Salute 4 Maggio 2007 n.110, Misure urgenti in materia di cellule staminali da cordone ombelicale* (*GU Serie Generale* no. 110, of 14th May 2007).

30 *Legge 30 giugno 2009, n. 85, "Adesione della Repubblica italiana al Trattato concluso il 27 maggio 2005 tra il Regno del Belgio, la Repubblica federale di Germania, il Regno di Spagna, la Repubblica francese, il Granducato di Lussemburgo, il Regno dei Paesi Bassi e la Repubblica d'Austria, relativo all'approfondimento della cooperazione transfrontaliera, in particolare allo scopo di contrastare il terrorismo, la*

It is only through regulation on data protection that the European Union Law has emerged in this domain. One more evidence of the important role that data protection regulation have in the field of health. In fact, shortly, all national legislations – also in relation to biobanks – shall adapt to the provisions of the new General Data Protection Regulation of the European Union (GDPR), as they previously did regarding the Directive of 1995.[31] The personal data regarding health, as expected, is subject to special protection by this regulation[32] (under the legal approach of Arts. 6 or 9 of GDPR), whether in healthcare assistance[33] or the biomedical research field.[34] Thus, among all health-related data mentioned here, the information obtained from tests or exams of a body part or a body substance, including the information from genetic data[35] and biological samples (recital 35 in connection with Art. 4, sections 13, 14 and 15 of GDPR) are also included.

At the European Union level, it is also relevant to view, along with other instruments and regulatory acts (specially directives[36]), the role of the Charter of Fundamental

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criminalità transfrontaliera e la migrazione illegale (Trattato di Prum). Istituzione della banca dati nazionale del DNA e del laboratorio centrale per la banca dati nazionale del DNA. Delega al Governo per l'istituzione dei ruoli tecnici del Corpo di polizia penitenziaria. Modifiche al codice di procedura penale in materia di accertamenti tecnici idonei ad incidere sulla libertà personale" (*GU* no. 160, of 13th July 2009. Ordinary supplement no. 108).

About the Treaty of Prüm, see the work of GÓMEZ SÁNCHEZ Y., "Los datos genéticos en el Tratado de Prüm", in Revista de Derecho Constitucional Europeo, 2007, 7, p. 137-166. In relation to genetics, data protection and police databases, I refer to the doctoral thesis of BOBO RUIZ J., "Intervención y gestión en la genética humana: el ámbito sanitario, la protección de datos y la investigación", Universidad de Granada, 2005.

31 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (*OJ* L 119/1, of 4th May 2016).

In this regard, it would also be appropriate to point out Article 8 of the Charter of Fundamental Rights of the European Union and the Convention for the protection of individuals with regard to automatic processing of personal data no. 108 of the Council of Europe of 28th January 1981.

32 The RGPR is analyzed by BELTRÁN AGUIRRE J.L., "Tratamiento de datos personales de salud: incidencia del Reglamento General de Protección de Datos", in Pérez Gálvez J.F. (Edit by), Salud electrónica. Perspectiva y realidad, Tirant lo Blanch, 2017, Valencia, p. 97-134; and SARRIÓN ESTEVE in his chapter on this monograph.

33 See, among others, SARRIÓN ESTEVE J. and BENLLOCH DOMÈNECH C., "Protección de los datos clínicos relativos a la propia salud", in Fernández-Coronado González A. and Pérez Alvarez S. (Edit by), La protección de la salud en tiempos de crisis: nuevos retos del bioderecho en una sociedad plural, 2014, p. 331-359.

34 The community regulation considers specific guarantees and exceptions that can be applied to personal data processing with scientific research purposes in Article 89 of GDPR.

35 I refer to the work of GÓMEZ SÁNCHEZ Y., "La protección de los datos genéticos: el derecho a la autodeterminación informativa", in Derecho y salud, 2008, 16 (1), p. 59-78; or NICOLÁS JIMÉNEZ P., "La protección jurídica de los datos genéticos de carácter personal", Comares, 2006, Granada.

36 In the fields of high technology medicinal products commercialisation, particularly those obtained through biotechnology; of the legal protection of biotechnological inventions; or of the intentional release of genetically modified organisms in the environment.

Rights,[37] whose Article 3, section 2, declares the right to integrity regarding biomedical research and, among other aspects, establishes as a premise the previous free and informed consent of the source subject, the focus of this paper, and prohibits making the human body or its parts a source of financial gain (prohibiting therefore the commercialisation of biological samples).

At the European supranational level, but out of the European Union, it is worth mentioning the works of the Council of Europe and, especially, the endorsement of the Convention on Human Rights and Biomedicine (Oviedo Convention)[38] and its additional Protocols on the Prohibition of Cloning Human Beings, on Transplantation of Organs and Tissues of Human Origin (2002), and on Biomedical Research (2004). It is also worth mentioning here the contributions of the three UNESCO declarations on aspects regarding biomedicine and human rights.[39]

And obviously I have to mention the Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin (adopted by the Committee of Ministers on 11th May 2016) and the previous one Recommendation of March 2006.

In this context, the legal system on the management of biological samples in Spain is set out in *Ley 14/2007, de 3 de julio, de Investigación biomédica*[40] (LIB, for its initials in Spanish), Title V [in particular in Chapters III ('Utilización de muestras biológicas humanas con fines de investigación biomédica') and IV ('Biobancos')], and in the *Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica*[41] (RDB, for its initials in Spanish).

In the same way, in Spain, in general we should follow the *Ley Orgánica 15/1999, de 13 del diciembre de Protección de datos de carácter personal*[42] (LOPD, for its initials in Spanish), the *Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999, de 13 del diciembre, del protección de datos de carácter personal*[43] (RDLOPD, for its initials in Spanish), the *Ley 41/2002, de 14 noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de*

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37 *OJ* L 326, of 26th October 2012.

38 Instrument of Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine), made in Oviedo on the 4th April 1997 (*BOE* no. 251, of 20th October 1990).

39 On this matter, see, among other works, the work directed by GROS ESPIELL H. and GÓMEZ SÁNCHEZ Y., "La Declaración Universal sobre Bioética y Derechos Humanos de la UNESCO", Comares, 2006, Granada.

40 BOE no. 159, of 4th July 2007 Article 3.b defines the treatment of biological samples as 'operations and procedures for the collection, conservation, use and disposal of [···] biological samples'.

41 BOE no. 290, of 2nd December 2011.

42 BOE no. 298, of 14th December 1999.

43 BOE no. 17, of 19th January 2008.

información y documentación clínica[44] (LAP, for its initials in Spanish) and the remaining related regulation at the European, national and autonomous levels.

All these regulatory instruments, as well as others ones of ethical nature that we could mention here,[45] concern biomedical research without losing sight of its close connection and implications with the ensemble of all fundamental rights. The advance of science and knowledge and health innovation should not warrant, in any case, a decrease in the exercise of fundamental rights. In sum, we cannot conceive the right to research, to freedom of creation and scientific production (GÓMEZ SÁNCHEZ),[46] as absolute; its defence cannot protect damaging dignity, autonomy of the will, intimacy or corporal integrity of a person. Contrary to what Machiavelli proposed, the end does not justify the means, no matter how laudable the objectives to be achieved.[47]

This is the core idea of this work, on which we will pay special attention to the role of consent from the source subject in the donation of biological samples to a biobank[48] and the requirements that must be met by institutions and researchers who deal with them. Specifically, this paper responds to the different scenarios that can be presented here, and in particular, the use of biological samples for purposes other than those authorised at the time by the source subject.

In the next sections, we will argue that it is not possible to hide behind lawless and in-

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44 *BOE* no. 274, of 15th November 2002. Application of a supplementary character by the second final provision of the LIB.

45 Think of the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization; the Medical Deontological Code of the Spanish Medical Colleges Organization; or the Declaration of Helsinki of the World Medical Association, whose last modification took place in the 64th General Assembly, in Fortaleza, in 2013.

46 On the legal nature of the right to research, among others, we refer to the work of GÓMEZ SÁNCHEZ Y., "La libertad de creación y producción científica: especial referencia a la Ley de Investigación Biomédica", in Revista de Derecho Político, May-December 2009, 75-76, p. 489-514.

47 Regarding the limits of the right to free scientific and technical production, the following pronouncement by the Superior Court of Justice of Galicia is very enlightening and conclusive, although in the field of clinical trials: 'This sacred right cannot be considered absolute when its exercise must be in close relation with the most sacred right to life and to the physical integrity of patients who undergo these tests. Broad, but not unlimited, must be the field of clinical research and hence its subjection to the ethical and deontological control of committees born for this purpose, given that the right to free scientific and technical production, as intended the recurrent, serious consequences could be followed for humanity by justifying the success of science all kinds of practices, even the most despicable, about the human being'. In the third legal ground *in fine* of the Judgment of the TSJ of Galicia (Contentious-Administrative Room, Section 1st), no. 251/2001 of 28th February.

48 Already in 2005, before the promulgation of the Law of Biomedical Research (of 2007), some authors had the opportunity to pronounce in this respect as CASABONA R. C.Mª, "Utilización de muestras biológicas y bancos para la investigación biomédica", in IV Congreso Mundial de Bioética. Ponencias y comunicaciones, Sociedad Internacional de Bioética, 2005, Gijón, p. 79 a 104; or MARTÍN URANGA A., MARTÍN-ARRIBAS MªC., DI DONATO J-H. and POSADA DE LA PAZ M., 'Las cuestiones ético-jurídicas más relevantes en relación con los biobancos', Instituto de Salud Carlos III-Ministerio de Sanidad y Consumo, 2005, Madrid.

determinate terms for elaborating a kind of *blank cheque* in order to carry out any research based on biological samples. This consent model would disobey the ethical and legal provisions ruling this sector. Previous consent is claimable, and not only for the inherent risks of the sample extraction itself, but mostly for the right of all humans to decide on their own body integrity and on the destination of their biological samples.

2. *Storage of biological samples in a biobank, collection and a specific research project in Spain.* After having delineated the field, let us proceed to analyse the legal regime that affects the treatment of human biological samples[49] for biomedical research purposes stored in biobanks in light of the LIB and the RDB in Spain. In accordance with the regulatory framework mentioned, the biological samples of human origin for biomedical research (Art. 22.1 RDB) could be: 1) stored in a biobank, 2) preserved for use on a specific research project, or 3) stored as a collection for biomedical research purposes in light of the organisational scope of a biobank.[50] The legal system that could be applied in every case is different depending on where it is based and the purpose that justifies the gathering and preservation of samples.

In this regard, the RDB includes the following definitions[51]:

- *Biobank with biomedical research purposes*: 'public or private non-profit establishment that holds one or several collections of biological samples of human origin with biomedical research purposes, organised as a technical unit with quality, order and destination criteria, regardless of whether or not it holds other samples with other purposes'[52] [Art. 2. b)].
- *Collection of biological samples of human origin*: 'Permanent and organised ensemble of biological samples of human origin, preserved out of the organisational scope of a biobank' [Art. 2.f)].[53]
- *Biological samples of human origin preserved for use in a research project:* 'biological samples of human origin that are preserved in light of the organisational scope of a

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[49] See the contributions of NICOLÁS JIMÉNEZ P., among others, "Donación y utilización de material biológico humano con fines de investigación biomédica", in LARIOS RISCO D., GONZÁLEZ GARCÍA L. AND DE MONTALVO JÄÄSKELÄINEN F., PALOMAR OLMEDA A. AND CANTERO MARTÍNEZ J. (Edit by), Tratado de Derecho Sanitario, vol. 2, Thomson Reuters-Aranzadi, 2013, Madrid, p. 939-967; or "El régimen legal de la utilización de muestras biológicas humanas en el marco de los bio-bancos para investigación biomédica", in Comunicaciones en propiedad industrial y derecho de la competencia, 2012, 66, p. 253-276.

[50] ARIAS-DÍAZ J. et al, "Spanish regulatory approach for Biobanking", cit., p. 708-709.

[51] I would like to remark that all the quotes collected in this paper have been unofficially translated from Spanish to English.

[52] In this regard, we could think, for example, of the biobank of the Public Health System of Andalusia. Regulated by the *Decreto 1/2013 de 8 de enero, por el que se regula la autorización para la constitución y funcionamiento de Biobancos con fines de investigación en Andalucía y se crea el Biobanco del Sistema Sanitario Público de Andalucía* (*BOJA* no. 7, of 10th January 2013).

[53] This excludes, obviously, the biological samples of human origin that are exclusively preserved for use in a specific research project, 'provided that its preservation is not extended beyond the final date of the project and they are not going to be transferred' [Art. 2.f) *in fine*].

> biobank, exclusively for use in a specific research project, provided that its preservation is not extended beyond the final date of the project and they are not going to be transferred' [Art. 2.i)].

The legal treatment of biological samples of human origin preserved for use in a research project does not present major interpretative problems *a priori*. The informed consent signed for this purpose will expressly dictate that those samples of the source subject can only be used by that specific researcher and, exclusively, within that specific investigation.

The legal treatment of the storage of these samples in a collection or in a biobank is worth more attention. The biological samples deposited in biobanks in Spain are regulated by the provisions of Articles 58 and following in Chapter III, Title V of the LIB, regarding the gathering, previous information, consent, confidentiality, cession, preservation of data and samples, access to data and right to not be informed.

The incorporation of a collection of biological samples to a biobank could imply that these samples will be at the disposal of other researchers,[54] unrelated to the one with which the source subject initially consented. The aim of cession to a third party is precisely what characterizes it. This would never be possible within a collection, since the samples –although they could be used in different research areas, in light of the signed consents – would always be in charge of the concrete researcher that the patient expressly authorised.

To this end, Article 70.2 of the LIB states that: 'the biological samples incorporated by biobanks could be used for any biomedical research, in the terms described in this law, provided that the source subject or, if applicable, his/her legal representatives, have given their consent in these terms'.

According to this rule and considering the highlighted purpose of public service advocated by biobanks, it is possible to transfer biological samples to a third party (other researchers) from these establishments, provided that this would have been duly informed to the source subject in the corresponding informed consent – although more general, but not *blank cheque* – agreed to that effect and that the samples are going to be used within the research area (they do not need to be related to a unique and specific research) authorised by the source subject. In these cases, as a consequence, it will not be necessary to request a new informed consent for every cession of biological samples that takes place in the context of the biobank and in terms of the informed consent subscribed to that effect by the subject source.

But when the cession of biological samples is used in research projects that are completely different than the research area foreseen in the original cession informed consent that was signed by the source subject, it would be necessary to grant a new specific consent (*ex* Art. 60.2 of the LIB). This provision of the LIB provides that 'specific consent

[54] It is possible that the internal regulation of the biobank foresees some kind of cession priority to researchers or groups that provide samples more actively to the biobank, particularly in the case of special interest samples or limited in quantity. Instituto de Salud Carlos III, 'Respuestas a las preguntas más comunes sobre el Real Decreto 1716 / 2011 sobre Biobancos' (Version of 15th November 2012). Answer to question no. 22, in p. 9.

may provide for the use of the sample for other lines of research related to the one initially proposed, including those made by third parties. If this were not the case [in line with Art. 58.2 LIB], the subject shall be requested to grant, if he or she deems it appropriate, new consent'.

As a result, according with the given consent, if the cession is intended for a non-authorised research area by the source subject at that moment, it would be necessary to obtain a new consent. The opposite, besides being a breach of data protection regulation, would also mean to leave without implementation the basic framework of rights that assists all persons participating in biomedical studies.

Moreover, the revocation of that initial consent is also possible here, that is, the source subject disavows that primitive assignment to third parties or other research areas. In fact, the GDPR guarantees that there is always consent that explicitly foresees the use of samples for research areas different from the original one, as well as the actual possibility that the donor rejects that 'extended cession', whether initially or later, in accordance with the consolidated ARCO (acronym of the rights of Access, Rectification, Cancellation and Opposition) rights.

I am taking for granted a univocal concept of research area and related research area.[55] Something that is not true in the Spanish legal system. I am facing with an indeterminate legal concept. It is therefore up to the Research Ethics Committees (REC) to determine when we are dealing with a research area related.[56]

Therefore, the legal approach that affects the cession of samples to a biobank seems to be more flexible – there is a thin and controversial separating line – than the one foreseen for the samples stored in a collection, where the samples are not depleted at the end of the research project that motivated their gathering but they cannot be transferred to third parties (a researcher, natural person,[57] different from the original in charge of the collection), even though the research in question has similar characteristics. This means

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[55] See SEONE J.A. and CASADO DA ROCHA A., "Consentimiento, biobancos y Ley de Investigación Biomédica", in Revista de Derecho y Genoma Humano, July-Dicember 2008, 29, p. 131-148, in esp., p. 144.

[56] See DE LECUONA I., "Los Comités de Ética como mecanismos de protección en investigación biomédica: Análisis del Régimen Jurídico Español", Thomson Reuters-Civitas, 2011, Navarra, p. 160 ff.

[57] Given the case where the collection is decided to not be incorporated into a biobank, besides the project evaluation on which they will be used by the corresponding Research Ethics Committee (REC), the main researcher is compelled to communicate its storage and use to the centre, and also to register that collection (provided that is not anonymised) in the National Registry of Biobanks, with the purpose to inform other researchers and members of RECs of the existence of this collection. *Respuestas a las preguntas más comunes sobre el Real Decreto 1716/2011 sobre Biobancos…*, *cit.* Answer to question no. 25, in p. 10. In order to register a collection in this National Registry it is necessary that a natural person appears in the application as person in charge of the collection, and under no circumstances, can this be a corporation. The definition of collection itself is linked to a specific purpose, that appears in the consent document which was given to a specific researcher (natural person), unlike biobanks, which are structured as physical establishments with cession purposes to third parties. 'Respuestas a las preguntas más comunes sobre el Real Decreto 1716/2011 sobre Biobancos…', cit. Answer to question no. 42, in p. 17.

that the source subject needs to authorise every cession to third parties, since its link is solely and exclusively with that researcher and the research areas that he or she proposed to him or her.

To many authors, this is the main difference between a biobank and a collection: the biobank's purpose is the cession to third parties, it is not a reservoir or a stationary structure, its raison d'être is the exchange of samples with other researchers. Therefore, for these authors, to require a specific informed consent to protect every cession would make biobank management a huge complex task. In ROMEO MALANDA's words, 'The truth is that the possibility to obtain a generic consent for biomedical research has been widely accepted in all fields (doctrine, public opinion, bioethics committees, legislators), and nowadays is an usual practice in most countries. The requirement to request the source subject's consent for every specific use of the sample would be economically impracticable, as it forces the biobank to keep a continuous communication with every source subject and to regularly interfere in their lives, which could be extremely annoying and even, painful'.[58]

3. *The consent for gathering, storage or preservation and use of biological samples of human origin in a biobank in Spain.* Article 4.1.I of the LIB – and Articles 45 and 60.1 of the LIB regarding the treatment of biological specimens – states that 'the free autonomy of persons who may participate in biomedical research or who may provide their biological samples will be respected, for which they must have previously given their express written consent after receiving the appropriate information', which will be detailed by the researcher not only in writing[59] but also orally to the subject who is going to participate in the research.

Thus, the gathering of samples, storage or preservation and subsequent use would require the corresponding previous written consent[60] by the source subject, indicating the purpose (or purposes) that justifies its gathering and previous information of the consequences and risks for health that could be involved in this extraction. We do not want the information provided to the source subject to be too technical or complex, which may even be counterproductive, away from the objective pursued (the protection of their rights, not the interests of the researcher), but is adequate to make him or her understand the real implications of his/her participation in the study, so that in the exercise of his/her autonomy opts for what he/she deems most appropriate in this regard.

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58 ROMEO MALANDA S., "Biobanco", cit., p. 144. Of the same opinion NICOLÁS JIMÉNEZ P., "Donación y utilización de material biológico humano con fines de investigación biomédica", cit., p. 949.

59 Obviously, if the subject of the investigation could not write or read (for example, a visual impairment), consent may be provided by any means allowed by law to allow a record of their will (Art. 4.1.IV LIB). The principles of universal accessibility and design for all included in the International Convention on the Rights of Persons with Disabilities (which in the case of the previous example would lead to the documents being drafted in *Braille*) must be taken into account here.

60 Article 6.2 Universal Declaration on Bioethics and Human Rights.

In any case, with respect to this right of self-determination, the faculty of the source subject to give his/her consent must be guaranteed for every purpose separately[61] (Art. 23.1 RDB in connection with Art. 58.1 LIB). Remember that, according to Article 60.2 of the LIB, the specific consent could foresee the use of the sample for other research lines related with the one proposed originally, including those performed by third parties. Otherwise, the consent of the source subject will be necessary provided that these samples are intended to be used for a different purpose (Art. 58.2 LIB). The consent on the use of the biological sample will be given at the moment of the sample extraction or later (when its possible use for research purposes at the time of obtaining was not foreseen), in a specific way for a given research (Art. 60.1 LIB). In the latter case, it will be the researcher's task – despite the inconveniences, also economic, that this can mean for the study – to contact these subjects again to obtain the appropriate consent.

Either because that sample is a part of the human body, and therefore, property[62] of the source subject, or because it is a personal information support, which implies processing of sensitive personal data that needs to be protected, it is always necessary to have the explicit consent of the source subject, even though it is of generic nature[63] (with the nuances that we will expose).

Furthermore, it is not possible to use only one consent to participate in the study in question and to donate the samples to the biobank. The participation in a study cannot be subject to the cession of samples to a biobank, because that could lead to understanding that the principal aim pursued is not to carry out the study but to obtain a collection of samples. The patient can always participate in the study without having to give the excess of his/her samples to a biobank. Therefore, a single consent cannot be used to participate in the specific study and to donate the samples to the biobank. We are faced with two different realities.

Moreover, for Romeo Malanda, even if both consents can be given at the same time, the consent that protects the use of a sample in research must be independent of the one that is allowed to authorise its extraction.[64]

In particular, when this request for samples takes place within the framework of a care process, further precautions should be taken to banish any hint of coercion to the source

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61 Article 22 Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.

62 In ARIAS-DÍAZ's words: 'While most countries are reluctant to grant donors property rights of the samples, in Spain, Germany, and Portugal donors maintain actual ownership of their samples. The role of a Biobank would be to act as a custodian or depositary trustee of the samples ensuring a proper use according to the will of the donor'. ARIAS-DÍAZ J. et al, "Spanish regulatory approach for Biobanking", cit., p. 711.

63 According to what CASABONA R. C.Mª pointed out in 'Utilización de muestras biológicas humanas con fines de investigación biomédica y regulación de biobancos', in SÁNCHEZ CARO J. and ABELLÁN F. (Edit by), Investigación biomédica en España: aspectos bioéticos, jurídicos y científicos, Comares, 2007, Granada; and the content of the Committee of Ministers of the European Council's Recommendation no. 3 (1992) on genetic testing and screening for healthcare purposes.

64 See ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas…", cit., p. 189.

subject for the assignment of the samples. Consequently, 'the patient must be made aware that allowing the research with his/her biological sample has nothing to do with clinical use of it'.[65] This is in line with Article 6 of the LIB, which states that a person cannot be discriminated against because of his/her refusal to 'give consent to participate in biomedical research or to donate biological materials, with the medical assistance provided to him/her'.[66]

Also, in connection with the provisions of LIB in Article 61, given the case that the samples are preserved (in compliance with the principles of necessity and sufficiency, only if they are necessary for the purposes that justified their gathering, unless the source subject has given his/her explicit consent for other subsequent uses), the source subject will be informed in writing of the preservation conditions, aims, future uses, cession to third parties and conditions for their withdrawal or to request their destruction. All of this must be considering that the identification data of the sample has not been anonymised, according with the LIB.

On a different matter, appropriately enough, this consent could be revoked completely or for certain purposes, at any time (Art. 23.5 RDB). When the revocation refers to any use of the sample, it will be immediately destroyed, without prejudice to the preservation of the resulting data from the studies that were carried out previously (Art. 60.3 LIB). The corresponding documentary evidence of all this should be kept.[67]

In the scenarios mentioned, the role assigned by the LIB to the REC plays a prominent role, as guarantors of respect for the ethical-legal framework that must prevail in biomedical research. Hence, Article 66.1 of the LIB provides for the obligation of any biobank to have an external REC,[68] which, among other things, is responsible for assessing the criteria for obtaining the samples. Accordingly, in light of Articles 12.2.e and 62,[69] prior to the collection of the samples, the RECs (where appropriate) shall report any biomedical research involving the collection and use of biological samples. Thus, a research project of this nature cannot be started without the previous and prescriptive favourable report of the corresponding REC.

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65 *Ibidem*, p. 207. This is the reason why this author pleads for obtaining in these cases the consent in two different processes and in different documents.

66 Neither is there any discrimination because of its genetic characteristics (Art. 6 *ab initio* LIB). This connects with Article 58.6 of the LIB, which states that 'in genetic diversity studies, local and ethnic traditions will always be respected, while avoiding practices of stigma and discrimination'. See ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas…", cit., p. 224 ff.

67 The document with the consent of the source subject for the gathering and use of his/her biological samples will be issued in triplicate: one for him/her, one will be kept at the centre were the sample was extracted and the third will be kept by the biobank or the person in charge of the collection or the research, as appropriate (Art. 23.4 RDB).

68 The biobank of the Public Health System of Andalusia is the *Comité Coordinador de Ética de la Investigación Biomédica de Andalucía*.

69 In this respect, it is of interest to consult the document issued by the Grupo para el uso de muestras biológicas para investigación biomédica, 'Guía práctica para la utilización de muestras biológicas en investigación biomédica', Instituto Roche, 2006, Madrid, p. 133 ff.

Informed consent is a fundamental human right (STC 37/2011),[70] consequence or explanation of the classic rights to life, physical integrity and freedom of conscience. It is not a simple formality, a mere cause of liability exoneration (although, obviously, it has logical consequences in this field[71]). It finds its foundation and support in the Spanish Constitution itself (Arts. 9.2 and 10.1), in the exaltation of the person's dignity (Art. 10.1) and in freedom (Art. 1.1), recognising the autonomy of the individual to choose according to his/her own interests and preferences (in this case, if he/she wants his/her samples to be subject to biomedical research and under what parameters).[72]

In short, the source subject's consent will always be necessary for biomedical research purposes when the biological samples were extracted for a different purpose, anonymised or not.

Therefore, I think that a kind of presumed consent, of a legal presumption by which biological samples obtained for diagnostic and therapeutic purposes can be used for the purposes of biomedical research, is not completely correct, as pointed out in Article 36.2 of Law 8/2003, of 8 April, of Castilla y León, on the rights and duties of persons in relation to health, with the following statement: 'within the framework of applicable legislation, and provided that there is no opposition on the part of the interested party, centres, services and establishments subject to this Law may retain and use biological tissues or samples for lawful purposes other than those which gave rise to biopsy or extraction'.[73]

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[70] To that effect, the Spanish Constitutional Court Judgement 37/2011 already stated that the informed consent is built 'as a guaranteed procedure or mechanism for effectiveness of the patient's will autonomy principle and, therefore, of the constitutional rules that recognise the fundamental rights that could be concerned in medical acts, and, distinctly, an implied and mandatory consequence of the guarantee of the right to physical and moral integrity, reaching in this way a constitutional relevance that determines that its neglect or defective performance could entail a damage of the fundamental right itself'.

[71] Which refers us, among others, to the system of responsibility that configures Article 18 of the LIB. For DÍAZ MARTÍNEZ, this provision 'only applies to personal injury caused by invasive procedures used to obtain biological samples assigned for those purposes. It is a rigorous regime of strict liability, with reversal of the burden of proof in relation to causal link, limited temporarily to damages suffered during the investigation and in the year following its termination, accompanied by the compulsory subscription of insurance and of the determination of those responsible (jointly and severally) in case, for different reasons, the insurance did not cover the loss'. DÍAZ MARTÍNEZ A., "Daños causados en la investigación biomédica y la realización de estudios genéticos: conductas y omisiones determinantes de responsabilidad y resarcimiento", in Diario La Ley, September 2007, 4, p. 1671-1679, in esp., p. 1677.

[72] The informed consent or the prohibition of experimentation in humans without previous and informed consent has even passed as part of the articulation of the Constitutions of countries like Hungary, Lithuania, Estonia, Poland or Bulgaria. Among others, in this respect, see the work of GÓMEZ SÁNCHEZ Y., "El derecho de autodeterminación física como derecho de cuarta generación", in Brena Sesma I. (Edit by), Panorama Internacional en Salud y Derecho, Instituto de Investigaciones Jurídicas, UNAM, 2007, México, p. 205 ff.

[73] See ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas…", cit., p. 211.

Having established this, the truth is that the LIB also considers, although as an exception, the processing of codified or identified samples with biomedical research purposes without the source subject's consent, when the acquirement of that consent is not possible or represents an unreasonable effort[74] (Art. 58.2 LIB, in connection with Art. 3.i) LIB). In these cases, whether or not the anonymisation of the samples (ex. Art. 58.2.I LIB), that is, anonymisation does not exempt this procedure (anonymisation is not a sort of *carte blanche* to circumvent ethical and legal controls, to obviate the right to self-determination of the source subject[75]), would be necessary the favourable opinion of the corresponding Research ethics committee (REC),[76] that committees should consider, at least, the following requirements:

a) That the research is of general interest.
b) That the research is carried out by the same institution (concept broader than that of 'centre') that requested the consent for the gathering of samples (which prevents it from being transferred to third parties outside the institution without the prior consent of the source subject).
c) That the research would be less effective or not possible without the identity information of the source subject.
d) That there is no explicit objection from the source subject.
e) That the confidentiality of the personal information is guaranteed.

In line with this particular scenario, another exceptional assumption that we could name here is the one that refers to obtaining biological samples from deceased persons. Our legal system[77] seems to opt for this sampling whenever there is no prior opposition from the deceased (which in practice also implies express consent in this regard to his/her relatives), there is a clear interest for biomedical research, the data are anonymised and all this is endorsed by the relevant REC. If we have questions regarding the position of the deceased or we cannot locate his/her relatives, it is recommended not to take the samples.[78]

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74 In line with the dictates of Council of Europe Recommendation no. 4 (2006) that contemplates this supposition as an exception, in Article 2.1.ii.

75 See JOLY Y., KNOPPERS B.M. and NGUYEN M.T., "Stored tissue simples: through the confidentiality maze", in The Pharmacogenomics Journal, 2005, 5, p. 4.

76 Here it would be appropriate to use a process of pseudonymisation, with reversible encryption, in line with the dispositions of the new European Regulation. This implies the exemption of the researcher for requesting the consent of the patients from who the samples come from, without preventing him/her from access to their identity information, protecting the ethical order to communicate to the patients any relevant finding, as provided in Article 4.5 of the LAP.

77 This is what we can gather from the reading of Article 48.2 of the LIB, which provides that 'samples of deceased persons may be obtained and analysed whenever it may be of interest for the protection of health, unless the deceased expressly forbade it in life and so accredited', as well as Article 13 of the Council of Europe Recommendation no. 4 (2006), on research with biological materials of human origin, and Article 5.2 of Law 30/1979, regarding the extraction of organs or other anatomical pieces of the deceased. NICOLÁS JIMÉNEZ P., "Donación y utilización de material biológico humano con fines de investigación biomédica", cit., p. 962 ff.

78 ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas…", cit., p. 195-197.

Regardless of the particularities exposed, the consent document for the gathering, storage or preservation and use of biological samples of human origin with biomedical research purposes will include, at least, according to the provisions of the second section of Article 23 of RDB (in connection with Art. 59 of the LIB and the regulation in terms of personal data protection), the following information for the source subject:

a) Description of the research project on which the sample is going to be used or the studies or research lines for which he/she gives consent.

b) Identity of the person in charge of the research, if applicable.[79]

c) Indication that the donated sample can only be used, as specified in the consent, for its storage in a biobank, for its preservation as a collection with biomedical research purposes or for its preservation for use in a specific research project.

d) Indication that the biobank and the person in charge of the collection or research project will have at the disposal of the donor all the information on the research projects on which the sample is used and that the external ethical committee of the biobank or the REC that evaluated the research project, will decide which cases will be indispensable that the information needs to be sent individually.

e) Expected benefits from the research project or the biobank (for the source subject and for society). Article 15.2.h itself states that 'any future potential use, including commercial use, of the results of the investigation[80]' shall be reported, which also implies the possibility of a patent application.[81]

f) Possible inconveniences related to the donation and gathering of the sample, including the possibility to contact the source subject in order to gather information or additional samples, to provide him/her the information foreseen in paragraph i) or other justified reasons, for this purpose, information could be requested regarding the way to do it, as well as his/her faculty to take position to that effect.

g) Place of analysis and destination of the sample at the end of the research. If these particulars are unknown at that moment, the commitment to inform about them when they are known[82] will be established.

h) Indication that the sample or part of it and its related clinical details or linked with the future of it, will be held and, if applicable, transferred to third parties with biomedical research purposes in the terms foreseen in the LIB and the RDB.

i) The possibility to obtain information regarding his/her health or from his/her relatives, originating from the genetic analysis carried out with his/her biological sample, as well as on his/her faculty to make a decision regarding its communication (in the exercise, if applicable, of the right to not know[83]).

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79 ROMEO MALANDA also includes here timely contact information so that the participants can resolve any doubts that arise. *Ibidem*, p. 201.

80 See Comité de Bioética de Cataluña, 'Problemas éticos en el almacenamiento y la utilización de muestras biológicas', 2004, Barcelona, p. 94 ff.

81 I agree to what they indicate in this sense MARTÍN URANGA A., et al in "Las cuestiones ético-jurídicas más relevantes en relación con los biobancos", cit., p. 63.

82 What is known as *two-part consent*.

83 NICOLÁS JIMÉNEZ P., "Donación y utilización de material biológico humano con fines de investigación biomédica", cit., p. 965 ff.

j) Mechanisms to guarantee the confidentiality of the information obtained, indicating the identity of the persons who will have access to the source subject's personal information that is not intended to be anonymised.
k) Right to revoke the consent, totally or partially, at any time, and its effect, including the possibility of destruction or anonymisation of the sample and that those effects will not spread to the resulting data from studies that were already carried out.[84]
l) Possibility to include some restrictions on the use of the samples.
m) Waiver of any right of economic, patrimonial or discretionary nature on the results or potential benefits that may originate, directly or indirectly, from the studies carried out with the donated sample for research purposes, in connection with Article 7 of the LIB.[85]

The possibility that volunteers receive benefits for the results or commercialisation of products originating from the mentioned biomedical research[86] –the benefit-sharing[87] – is not supported; although it is true that without the donated samples and their direct participation, the scientific process would not have been possible.[88]

However, according to Article 58.3 of the LIB, and without prejudice to what was stated in Article 7 of the LIB, 'an economic benefit could be fixed for the physical inconveniences, costs and other inconveniences that could originate from the extraction of the sample'.[89]

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84 Anonymisation does not mean destruction of the sample.

85 Article 44.4 of the LIB repeats that gratuitousness principle: 'during all the donation process, cession, storage and use of biological samples both for source subjects and for depositors, without prejudice to the compensation of costs'.

86 In the United States, the payment to voluntary subjects for their participation in studies or for the cession of biological material is envisaged. Actually, in the *Moore vs. Regents of University of California* case, the Supreme Court of California recognised the property right of a person on his/her cells. The Supreme Court revoked this Decision, but not because Moore was devoid of this right, but because in the signed consent benefit-sharing was not considered. Y. GÓMEZ SÁNCHEZ talks about all of this in "Reflexiones sobre la participación de voluntarios en la investigación", in PÉREZ MIRAS A., TERUEL LOZANO G.M. and RAFFIOTTA E.C. (Edit by), Desafíos para los derechos de la persona ante el siglo XXI: Vida y ciencia, Thomson-Aranzadi, 2013, Navarra, p. 261 ff.

87 See IBC, "Report of the IBC on the Principle of the Sharing of Benefits', 2nd October 2015. Analyzed by DE LECUONA I., "Análisis de la Declaración Universal sobre Bioética y Derechos Humanos de la UNESCO: un referente en bioética y en investigación (e innovación responsable) en seres humanos", in Revista de Derecho y Genoma Humano, 2016, 45, p. 181-209, in esp., p. 109-201.

88 Moreover, what happens when these biological samples are used to, for example, test the operation of a machine and that it can obtain the CE marking? Here we would not be talking about biomedical research properly. Can we understand this use as encompassed by the generic consent that the source subject signed in his day? Should this person be also deprived of access to any kind of economic benefit? This is another element for the debate.

89 The regulation on clinical trials is articulated in this same line. Therefore, according with Article 3.1 h) of the *Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos* (*BOE* no. 307, of 24th December 2015), 'the persons participating in trials with the possibility to receive a direct potential benefit for the research subject or his/her legal representatives,

n) In the case of minors' samples storage,[90] the guarantee of the minors to access to the information of the sample indicated in Article 32 of the RDB when they reach full legal age.[91]
o) In the event that the biobank closes or the authorisation for its constitution and operation is revoked (in the cases considered in Art. 71 of the LIB), the information on the destination of the samples will be at his/her disposal in the National Registry of Biobanks for biomedical research so he/she can express his/her agreement or disagreement with the foreseen destination of the samples, all of this without prejudice to the information that the source subject should receive in writing before giving his/her consent for the gathering and use of the sample.[92]

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could receive from the promoter the reimbursement of the extraordinary costs and productivity loss originating from the participation of that person in the trial. In special situations, the RCE could inform favourably of the compensation to trial subjects for the inconveniences originating from their participation on it, provided that the said compensation does not have an influence on the subject's decision to participate in the study'.

90 The gathering of biological samples from minors and disabled people with biomedical research purposes, is subject to the conditions included in Article 58.5 of the LIB, which are: a) The adoption of all required measures to guarantee that the risk of intervention is the minimum possible for them; b) The possibility to obtain from the research relevant knowledge on the disease or situation that is of crucial importance to understand, palliate or cure it; c) That this knowledge cannot be obtained in any other way; d) To have the authorisation of his/her legal representatives or, if applicable, there are guarantees for his/her appropriate consent, for which it would be necessary that the information is provided in an adequate format according to his/her capacity and personal circumstances (following the guidelines marked regarding persons with functional disabilities, from the universal accessibility and design principles for everyone included in the Convention on the Rights of Persons with Disabilities). NICOLÁS JIMÉNEZ P., "Donación y utilización de material biológico humano con fines de investigación biomédica", cit., p. 960 ff.
It is the researcher who is called to value, first, the ability of the subjects involved in the research. The problem arises with those elderly people who may be incapable, even temporarily (because they are in a coma or under the effects of a particular medical treatment), but are not incapacitated by a judicial sentence. About this and other issues, it is interesting to bear in mind not only the related written legislation, but also the provisions of, among others, the 'Guías Éticas de Investigación en Biomedicina' of the *Comité de Ética del Instituto de Investigación de Enfermedades Raras* of the *Instituto de Salud Carlos III*, from 2009; and ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas…", cit., p. 193-195.

91 Without prejudice to the information that the source subject should receive in writing before giving his/her consent for the gathering and use of the sample, information regarding the use of his/her sample by third parties shall be provided, unless the information has been anonymised, and particularly: a) Exact purpose of the research or studies for which the sample was used; b) Benefits expected and reached; c) Identity of the person in charge of the research; d) Genetic data duly validated and relevant for health that were obtained from the analysis of the samples donated; e) Mechanisms to guarantee the confidentiality of the information obtained; f) Identity of the persons who accessed the source subject's personal information that has not been dissociated or anonymised.

92 Article 28 of the RDB provides that the persons in charge of the sample collections for biomedical research purposes preserved out of the organisational scope of a biobank and who preserve biological samples for its use in a specific research project should communicate the date regarding the collections and samples to the establishment where they are preserved.

p) In the case of samples used in specific research projects, and of collections for biomedical research purposes preserved out of the organisational scope of a biobank, the source subject will be informed of the options, among the possible ones, regarding the destination of his/her sample at the end of the project or research.

According to the provisions of Article 23.4 of the RDB, when the samples are anonymised,[93] only the information mentioned in paragraphs a), b), c), e) and f) will be needed. Even in this case, it is also necessary to comply with six of the obligations in terms of information that Article 23 RDB points.[94]

It should be remembered, in greater detail, that this last subsection of the RDB is in accordance with the provisions of Article 58.2.1 LIB, which provides that 'The consent of the source subject will always be necessary when biological samples are to be used for biomedical research purposes, obtained for a different purpose, whether or not their anonymisation is carried out'.

The ensemble of the legal system, as well as the ethical and deontological rules applicable here, is unanimous, both in writing and in spirit, when requesting the previous consent, in the terms indicated, from the source subject for the extraction of biological samples for biomedical research. This previous consent is claimable, and not only for the inherent risks of the sample extraction itself (which may be minimal: consider, as an extreme example, those biological samples present in sanitary waste), but mostly for the right of all humans to decide on their own body integrity and on the destination of their biological samples.

As praiseworthy as the pursued aim of this research might be, it could never be justified to leave without effect and, therefore, breach the ethical and legal framework to which the biomedical research is meant to be subject to. In this respect, the Oviedo Convention already spoke about this in Article 2: 'The interests and welfare of the human being shall prevail over the sole interest of society or science' and, in this same line, Article 2.b of the LIB.

Hence, it is not acceptable to have a model of informed consent with no references to the study that it intends to serve (normally the donations to the biobanks take place

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93 When, for health reasons, the source subject or his/her family needs it, they could use the samples, provided that they are available and are not anonymised (Art. 58.4 of the LIB). This rule would not, however, apply to biological samples obtained for diagnostic purposes in order to proceed to a second diagnosis in another centre. This is clear from the jurisprudential study of NICOLÁS JIMÉNEZ P., "The rights of patients on their biological sample: different jurisprudential opinions", in Revista Derecho y Genoma Humano, 2003, 19, p. 207 ff., In relation to the SAP of Vizcaya of 21st July 2000 (Rapporteur: María de los Reyes Castresana García) and the STSJ of Cantabria of 16th May 2001 (Rapporteur: María Josefa Artaza Bilbao). It starts here from the idea, erroneous, that the subject lacks a possible property right on the sample, as we defend here.

94 In any case, with ROMEO MALANDA (although he refers to Art. 59 LIB), we should not consider this long list as a *numerus clausus*. This author indicates that the source subject is also informed in relation to the source of funding that underpins the concrete research project. ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas…", cit., p. 203.

in the context of a specific research project),[95] that does not inform the source subject of the studies to be made with his/her biological samples (not even of the possible research lines that could be carried out with them) or of the person or persons in charge of these studies (indicating, for example, if the samples are going to be transferred to researchers outside of Spain[96]). A model of informed consent of these characteristics would not be suitable for the ethical and legal parameters that govern the biomedical research in our country. That lack of information is a very serious breach of the legal-ethical framework that these studies are meant to respect. The source subject of the research must know at the moment of the donation of his/her samples to whom he/she is donating them and for what (although it is in generic terms, but never a blank cession).

I repeat, there are no informed consent documents that are completely decontextualised from the study (or studies) to which it is supposed to serve. The gathering of samples for generic use of clinical details and biological material in order to carry out future biomedical research studies are not supported under standard informed consents. It is not possible to hide behind lawless and indeterminate terms for elaborating a kind of *blank cheque* in order to carry out any research based on samples.

Knowing the interest and opportunity that a study supported by that kind of consent could have, the truth is that this consent model would disobey the provisions of the LIB and the RDB. In order that the biological samples incorporated into a biobank could be used for any biomedical research, in the terms disposed in the LIB, it is necessary that the source subject (or, if applicable, his/her legal representatives), has given his/her consent[97] in these terms, complying with the dispositions of the referred Article 23 of the RDB.

I share with Romeo Malanda and Nicolás Jiménez the opinion that generic consents (that is, specific but broad; which authorise the cession of samples to third parties to be used in different research lines) could be considered in our legal system on account of the right to self-determination (although we could also claim, as he states, that without com-

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95 Neither is it logically feasible, as we have already pointed out in this work, that the participation in a study is linked to the transfer of samples to a biobank.

96 Article 11 of the LIB states in this respect the following: 'The intra-Community and extra-Community entry and exit of biological samples of human origin for the purposes of biomedical research referred to in this Law shall be governed by the provisions established by regulation. In the case of biological samples from biobanks, the conditions of assignment and security established in Title V of this Law shall also be observed'. We have to put this in connection with the provisions of Article 16 of the Council of Europe Recommendation no. 4 (2006), which states that 'biological materials and personal data associated therewith should only be transferred to another State if that State ensures an adequate level of protection'. One problem that may arise here is that different ways of assessing the value of the informed consent of the source subject (counterposing specific consents to lax consent) can be found between the biobanks of one and the other country when proceeding with the assignment of samples between them. In greater detail, see ROMEO MALANDA S., "El régimen jurídico de la obtención y utilización de muestras biológicas humanas…", cit., p. 223; and NICOLÁS JIMÉNEZ P., "Donación y utilización de material biológico humano con fines de investigación biomédica", cit., p. 958 ff.

97 For the sake of completeness, see CAPLAN A.L, "Consent and anonymization in research involving biobanks", in embo Reports, 2006, 7.

plete information[98] it is not possible to give consent to future studies that are unknown at that moment).

However, what is important, therefore, is to know the concrete terms in which the appropriate consent was signed to authorise these assignments. The diction of this model of consent, on the other hand, will have to be validated by the competent ethical committee of investigation.

Furthermore, we conclude with Romeo Malanda that we should not discard the possibility to include some kind of restriction in these consents, meaning that there is no place for *blank cheques* or denying the possibility to establish some limits to avoid these consents from becoming too lawless. We should give the source subject the possibility to exclude any kind of research line that causes him/her ethical problems (for example, related with the beginning of life).[99] More when it is demonstrated than the European citizens (67% of the Spanish population) are reluctant to the broad consents.[100]

In short, according to Arias Díaz[101]: "Facing the issue of the extent of the donor informed consent, the Spanish approach has been to define a particular regime for biobanks, allowing a certain degree of flexibility to the possible use of the samples, without implying, however, that the informed consent has been given as a 'blank' consent. Instead, the donor gives consent for the storage of the sample in an authorized Biobank, considered to be a somewhat 'controlled' place".

In the same way, the Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin says: 'Prior to consent to or authorisation for the storage of biological materials for future research, the person concerned should be provided with comprehensible information that is as precise as possible with regard to: the nature of any envisaged research use and the possible choices that he or she could exercise; the conditions applicable to the storage of the materials, including access and possible transfer policies; and any relevant conditions governing the use of the materials, including re-contact and feedback' (Art. 10.1).

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98 In the case that a sample is transferred to a biobank with a more generic consent (including one or several research lines), the key point of the debate would be what information about those lines is required in that generic consent. For example, would it be enough to note that the sample is transferred for future studies on genomics and cancer? Or would it be necessary to amplify this information (including the line's general aims) or making it more specific (requiring the type of cancer or genetic tests)? This is a required debate that even today does not have a consensus.

99 ROMEO MALANDA S., "Biobanco", cit., p. 144.

100 In the European Commission's words: 'Interestingly, attitudes in Europe towards broad consent are also shaped by levels of information: the more people know about biobanks, the more they are ready to give broad forms of consent, whereas the less they know the less likely are they to participate'. In fact, 'Given the lack of awareness about biobanks and the concerns about privacy and data protection, the European stake-holders in biobank research need to work hard to develop efficient mechanisms for informing European citizens about biobank research, why it is there, and what it is doing'. In "Biobanks for Europe. A challenge for governance", cit., p. 27.

101 ARIAS-DÍAZ J et al, "Spanish regulatory approach for Biobanking", cit., p. 711.

On a different matter, the fact that in research healthy subjects or volunteers not affected by any kind of pathology could participate, does not lead us to lower our guard in the need to obey the guarantees indicated.[102]

4. *Special regulation of cession and gathering of biological samples of human origin with biomedical research purposes by biobanks in Spain.* Although this contribution has focused on analysing informed consent, before finalising these thoughts, I would like to outline some of the legal peculiarities of the assignment and collection of biological samples of human origin for biomedical research by biobanks.

In Spain, biobanks and persons in charge of collections could gather biological samples of human origin through cession, gathering from corpses[103] or from living subjects, always under the LIB and RDB provisions (Art. 33.1 RDB).[104]

The cession of samples or collections of samples to biobanks and persons in charge of collections should be performed through a previous written agreement[105] (Art. 22.2 RDB). This agreement shall be signed between the title holder of the biobank or the person in charge of the collection of destination, and the title holder of the biobank or the person in charge of the collection of origin of the samples.[106]

The biobank or the person responsible for a collection could transfer the samples

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[102] This matter was already addressed by Y. GÓMEZ SÁNCHEZ, in "Reflexiones sobre la participación de voluntarios en la investigación", in Desafíos para los derechos de la persona ante el siglo XXI: Vida y ciencia, cit., p. 259-274.

Currently, the Andalusian Parliament is discussing a *Proposición no de ley* regarding the creation of a registry of persons who wish to be included in clinical trials developed in Andalusia 10-16/PNLP-000053 (*BOPA*, no. 256, of 24th June 2016). The overall average is positive, but presents some problems of an ethical nature that are being taking care of actually. One of the main concerns is, for example, the inclusion of healthy volunteers. In any case, this Andalusian regulation does not intend –it could not do it anyway, because it is of European and National origin– to modify the actual legal framework that controls the clinical trials with medicinal products.

Particularly, regarding the samples field, we also have in Andalusia a Registry of Sample Donors for Biomedical Research, an initiative of the Health Department of the *Junta de Andalucía* in order to promote biomedical research among all the population that uses the Public Health System of Andalusia (SSPA for its initials in Spanish). Here, it is important to follow the provisions of the *Orden de 15 de junio de 2015, por la que se crea en el ámbito de la Consejería de Igualdad, Salud y Políticas Sociales el fichero de datos de carácter personal denominado 'Donantes de Muestras para la Investigación Biomédica en Andalucía'* (*BOJA* no. 120, of 23rd June 2015).

[103] In connection with Article 36 of the RDB.

[104] Because of its legal particularities, we will not mention here the legal system that affects the cell lines deposit in the National Bank of Cell Lines and their cession for research. Y. GÓMEZ SÁNCHEZ talks about this matter seamlessly in "El Banco Nacional de Líneas Celulares y el depósito y cesión de las IPSC", in BALAGUER CALLEJÓN F. and ARANA GARCÍA E. (Edit by), Libro homenaje al profesor Rafael Barranco Vela, vol. 2, Thomson-Civitas, 2014, Madrid, p. 1587-1608.

[105] Without prejudice to the provisions of Articles 10 and 11 of the RDB on the explicit disposal of the destination of the biobank's stored samples in closing or authorisation revocation decisions for the constitution and operation of the biobank.

[106] In those cases in which both parts agree it will not be necessary to conclude the agreement.

(in the minimum quantity needed to carry out the project[107]) to the person in charge of a research project, provided that the source subject has given his/her consent for the cession. The cession of samples will only be possible for applications coming from research projects that have been scientifically approved (Art. 34.2 RDB).

In the case of biobanks, if the consent document, as we mentioned above, does not foresee the use of the sample for the research line, in relation with the one proposed originally, that the person in charge of the research, to whom the samples are going to be transferred, intends to carry out, it would be necessary that the source subject gives a new consent (Art. 34.2 RDB), as it is necessary to prove that the cession have the approval of the source subject and does not violate his/her wishes.

As a general rule, the samples and related information will only be transferred anonymously or dissociated (Art. 34.3 RDB). In those cases where the nature of the research project requires additional clinical information regarding the source subjects, the biobank or the person in charge of the collection will coordinate the gathering of this information with the centre where the sample was obtained, provided that this has not been anonymised. In the sample request application, the specific measures to be applied in order to guarantee the confidentiality of personal data that could be attached to the cession will be detailed.

The person in charge of the research would need to file an application for the cession, which shall include the project in question and the explicit commitment to not use the requested material for a different use than the one indicated there, with the favourable opinion of the corresponding RCE attached, regarding the project for which the samples are being requested. In the case that the donor is a biobank, the cession shall be informed objectively by the scientific and ethic committees[108] and by the title holder of the scientific direction, regarding the application filed (Art. 34.3 RDB in connection with Art. 69.2 LIB).

Remember that Article 62 of the LIB indicates that, in any case, the RCE's favourable report regarding the centre, for the gathering and use of biological samples for biomedical research and biodiversity studies will be necessary, particularly when the use of biological samples coming from deceased persons or when planning the incorporation of a biological sample to a research line not related with the one for which the consent was initially obtained have been foreseen.

Moreover, the application shall be attached with a cession agreement document, signed by the person in charge of the research and the biobank or the person in charge of the collection, that should include the following (Art. 34. 5 RDB):

a) The obligation of the recipient to ensure the traceability of the sample.

b) Availability guarantee of validated and relevant genetic information for health that, if applicable, is gathered from the samples' analysis.

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[107] This remark appears repeatedly in LIB and RDB. Article 69.3 *in fine* provides that 'the quantity of sample transferred will be the minimum needed to carry out the project'.

[108] In those cases where the Research Ethics Committee is responsible for delivering the opinion regarding the project is the same ethical committee of the biobank, it will only be necessary to deliver one opinion regarding the project.

c) In the case that the donor is a biobank, the commitment to comply with the internal regulation of operation of the donor biobank on everything applicable.

d) The commitment to destroy or return to the biobank or to the person in charge of the collection the excess material once the project is completed.

The costs for gathering, preservation, manipulation, shipment and other similar costs related with the samples could be charged with the cession of every sample (Art. 69.3 LIB). That is, there is an economic consideration for these concepts in favour of the biobank.

The gathering, transport, storage, manipulation and shipment of samples will be performed under biosecurity conditions (Art. 69.4 LIB).

In the case that the donor is a biobank,[109] the cession application could be denied when any of the external committees of the biobank or the title holder of the scientific direction have given unfavourable information, or when the person in charge of the research has violated any of the commitments or obligations mentioned in previous sections regarding previous cessions of samples from the same biobank.[110] The cession dismissal shall be reasoned and notified to the applicant (Art. 34.6 RDB in connection with Art. 69.5 LIB).

In the case that the biobank is a public body (as is the case in Andalusia), the procedure for the cession or cession dismissal shall be subject to the provisions of the *Ley 39/2015, de 1 de octubre, del Procedimiento Administrativo Común de las Administraciones Públicas*, with the possibility to appeal in the terms provided on this Law.

5. *Some conclusions.* To date, we do not have an international or European regulatory framework (beyond the implementation of the community regulation in terms of data protection) that controls in any uniform way the singular phenomenon of biobanks – public service structures organised for science progress and innovation on health, which, if mismanaged, could damage the main fundamental rights.

This has forced the different Member States of the European Economic Area to dictate their own internal regulation in this respect. In Spain, we discuss the detailed and advanced regulation regarding the gathering, storage or preservation and use of biological samples of human origin in a biobank.

All the regulatory instruments, as well as others of ethical nature that we have mentioned here, concern biomedical research without losing sight of its close connection and implications with the ensemble of all fundamental rights. The advance of science and knowledge and health innovation should not warrant, in any case, a decrease in the

[109] The biobank will include in its annual report, the following provisions of Article 34.7 of the RDB, a reference to the sample cessions carried out, that shall include the identification of the persons in charge of the studies, the centres where the samples are going to be stored and the research projects.

[110] Although in the field of clinical trials, there is some connection with this assumption by the ruling of the Supreme Court of Madrid (Contentious-Administrative Room, Section 7th), no. 1188/2013, of November 7th. It is discussed here the suspension by the CEIC of the Ramón y Cajal University Hospital of Madrid of the clinical trial promoted by the recurrent investigator for not meeting the requirement of suitability, in view of their repeated previous breaches.

exercise of fundamental rights. Either because that sample is a part of the human body, and therefore, property of the source subject, or because it is support of personal information, which implies processing of sensitive personal data that needs to be protected, it is always necessary to have the explicit consent of the source subject, even though it is of generic nature.

It is not possible to hide behind lawless and indeterminate terms for elaborating a kind of *blank cheque* in order to carry out any research based on samples. Knowing the interest and opportunity that a study supported by that kind of consent could have, this consent model would disobey the ethical and legal provisions ruling this sector. This previous consent is claimable, and not only for the inherent risks of the sample extraction itself, but mostly for the right of all humans to decide on their own body integrity and on the destination of their biological samples.

Individual rights and property rights in human genetic databases: a common-law perspective

Maurizio Borghi

1. *Introduction.* Human genetic databases (HGD) are essential facilities for medical research, which attract huge public and private investment worldwide and growing attention at policy and legislative level.[1] HGD are large collections of biological samples and personal details of individuals belonging to a given regional group or sharing some genetic characteristics, aiming at covering a whole group or a significant sample of it.[2]

For public HGB projects to be successful, broad segments of the population must provide access to biological information and other medical and personal data.[3] Typically, HGB combine genotype data derived from biological samples with other personal information about individuals' medical history, such as clinical data, genealogical data, and information on the health, lifestyle and environment of the individuals.[4] They may also collect research reports, publications and data generated by the use of the database, and thus developing into "hubs" of collaborative research and investigation.

Participants in HGB projects may have expectations of collective benefits resulting from the use of the samples and information they provide access to. In this connection, particular concerns are raised by uses of the resource that are commercial in nature or that otherwise involve financial benefits. These uses are typically premised upon the issuance of patents on research outputs. [5] However, given the broad range of actual and potential uses of HGB, in which often public and private interests conflate in a tangle of shared

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1 See generally RICHARD TUTTON and OONAGH CORRIGAN (eds.), "Genetic Databases: Socio-ethical issues in the collection and use of DNA". London and New York, Routledge, 2004; MATTI HÄYRY et al., "The Ethics and Governance of Human Genetic Databases. European Perspectives". Cambridge, Cambridge University Press, 2007; BERNICE ELGER "Ethical Issues of Human Genetic Databases: A Challenge to Classical Health" (London and New York: Routledge, 2012).

2 Genetic databases are defined by the UK Human Genetic Commission as being "collections of genetic sequence information, or of human tissue from which such information might be derived that are or could be linked to named individuals" House of Lords Select Committee on Science and Technology, 2001.

3 BRENDA M. SIMON, "How to Get a Fair Share: IP Policies for Publicly Supported Biobanks", Stanford Journal of Law, Science and Policy 1 2009, p. 66.

4 Jean V McHale "Regulating genetic databases: some legal and ethical issues", *Medical Law Review* 12 (2004) 70-96, 72.

5 SIMON B., "How to Get a Fair Share", p. 68. For a comprehensive discussion on HGB in relation to open access principles, see Roberto Caso and Rossana Ducato "Intellectual Property, Open Science and Research Biobanks", Trento Law and Technology Research Group, Research Paper n. 22, October 2014.

interests, it is not always easy to define the boundaries of the legal entitlements of the various parties involved. In particular, the question arises as to the legal instruments to ensure that the use of HGB delivers collective benefits in line with the expectations of participants and the society at large. To answer this question, this chapter will focus on the tension between individual rights of participants in HGB projects and proprietary rights that arise in relation to the making and use of these resources.

HGB present a tension between individual rights and property rights at three different levels.

The first level is the material and information that constitute a HGB as such. This typically include biological samples, genotype data extracted from biological material (genetic information), medical data and other personal information. While these material and information are commonly perceived as individuals' ownerships, the current legal framework is not prepared to recognize property rights at this level. This may create tensions between participants' expectations and actual use of genetic resources.

The second level is the aggregate collection of those blocks: once collected and arranged systematically, individuals' data and information constitute a database, which is eligible for protection under either copyright law or other neighbouring rights. The property rights that the law creates at this level are a two-edges sword: they can be used to secure exclusive use over essential facilities for genomics research (including commercial research), but also to exclude, or to otherwise regulate, uses that are commercial in nature or involve financial benefits.

The third level is in fact the *use* of the database and the material and information herein contained. The use may generate new information, which in turn may be converted in products and methods derived from this use (e.g. drugs, therapies, diagnostic methods). Such new information, products and methods may be eligible to attract other intellectual property rights, in particular patents. The chapter will discuss contract-based policies recently adopted to regulate ownership at this third layer. It will be shown that these policies are a valuable tool to give effect to principles encoded in international law, which would otherwise remain dead letter in common-law jurisdictions.

2. *Background and international framework.* The completion of the Human Genome Project at the dawn of 21st Century marked the beginning of the "post-genomic era",[6] which promised to change forever the direction of bio-medicine and medical research in general. It is in this connection that, even before the sequence of human genome was completed in 2003, various initiatives were launched worldwide to create large population databases combining genetic information with other personal medical data. Given the many legal and ethical implications of the use of information that potentially affects the life of every human being, policy makers worldwide addressed possible regulatory instruments and principles. In 1997 UNESCO issued the Universal Declaration on the Human Genome and Human Rights, preceded by the "Bermuda Principles" set by the Human Genome

[6] TUTTON R. and CORRIGAN O.P., "Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA", London, Routledge, 2004, p. 1.

Organization in 1996, which declared the human genome "heritage of humanity" and set down the fundamental principles for the collection and use of genetic information, such as "free and informed consent",[7] confidentiality[8] and non-discrimination.[9] The Declaration sets down also general conditions for the exercise of scientific research[10] and, in its art. 4, provides that "The human genome in its natural state shall not give rise to financial gains."

The controversial experience of the Icelandic Biogenetic Project, launched by the Icelandic government in 1998 in collaboration with an US private company, proved the limited effect of the principles established by the Declaration and prompted for a more specific regulatory framework for the use of genetic information.[11] The debate that followed the early experience with genetic databases resulted in the adoption, in 2003, of the International Declaration on Human Genetic Data. In its art. 19, the Declaration provides that

"In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community."[12]

The provision is followed by an exemplary list of what may constitute a "benefit" for the purpose of giving effect to the norm, and this include notably the "provision of new diagnostics, facilities for new treatments or drugs stemming from the research".[13]

The tem "benefit" is construed broadly, but it is not clear whether it applies also to financial gains resulting from the exploitation of those benefits. Compared to art. 4 UDHG

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7 UDHG 1997, art. 5 (b): "In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest."

8 UDHG 1997, art. 7: "Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law."

9 UDHG 1997, art. 6: "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."

10 UDHG 1997, art. 13-16. For a critical discussion of the cultural underpinnings of the UDHG 1997 see Shawn Harmon "Ethical Rhetoric: Genomics and the Moral Content of UNESCO's 'Universal' Declarations", University of Edinburgh Working Paper Series, no. 2011/27.

11 As part of this project, the Icelandic government gave a private company, deCODE Genetics, access to medical records and genetic data of 270,000 Icelanders (plus around 700,000 deceased people) without prior informed consent, based on a Parliament Act. The case raised many controversies and was brought before the Supreme Court of Iceland, which declared the Act unconstitutional in 2003 (*Guðmundsdóttir v The State of Iceland*, No. 151/2003). The project was discontinued, but deCODE Genetics developed their proprietary database and filed a number of patents applications in the US and other jurisdictions. A search on Espacenet (the database for patent search worldwide hosted by the European Patent Office) returns 617 patents or patent applications with "deCODE Genetics" as applicant. For a critical discussion see Maria Bottis "Iceland and genetic databanks: where 'consent' to genetic research means patenting a nation's genes", paper presented at the ETHICOMP conference, Sweden, September 12-16, 2005.

12 IDHGD 2003, art. 19.

13 Ibid., art. 19(iii).

1997, which excludes "financial gains" in relation to human genome "in its natural state", art. 19 IDHGD 2003 does not rule out financial gains resulting from the use of genetic data and other genetic material. So, while the *benefits* resulting from the use of genetic data must be "shared with the society as a whole and the international community", nothing is said regarding the *financial gains* derived from the exploitation of those benefits.

It remains unclear whether, for instance, patenting a drug stemming from research on human genetic data would be compatible with art. 19 IDHGD 2003. To be sure, art. 19 cannot be interpreted as a general limitation to patentability. First of all, the Declaration is with no prejudice to international agreements, in particular the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 1992, which is recalled in the preamble. Art. 27(1) of the TRIPS Agreement requires Members countries to make patents available "for any inventions […] in all fields of technology",[14] subject to the only possible exclusions listed in the subsequent paragraphs. These may cover inventions contrary to public morality or *ordre public*,[15] methods of diagnosis, treatment and surgery,[16] biological processes (other than microbiological processes) for the production of plants and animals.[17] No other exclusions are permitted under the TRIPS Agreement. This means that art. 19 IDHGD cannot be construed as extending the scope of the permitted exclusions to patentability. In other words, a national country is not allowed to introduce in its legislation a general exclusion to patents derived from research on human genome.

On the other side, the requirement of "benefit-sharing" established in art. 19 IDHGD is clearly at odds with indiscriminate and uncontrolled "propertization" of human genetic data. Patents are the strongest legal form of protection over research findings. Whether these findings are "shared" or not, largely depends on the way in which legal entitlements over them are handled. In other words, while art. 19 IDHGD does not curb the availability of patents and other property rights over products and methods derived from the research on human genetic data, it does impose conditions on the *exercise* of those rights. These conditions will be discussed in section 4 below, after having examined the conflicts arising between individual rights and property rights at the level of individual information (section 2) and aggregation of information into databases (section 3).

3. *Rights in HGB "building blocks": biological material, information and data.* Genetic information is part of the broader spectrum of medical data,[18] and it is a well-established principles in both civil law and common law jurisdictions that "informed consent" must be given for medical data to be used for medical research lawfully.[19] The IDHGD 2003 specifies that such consent must be "free, informed and expressed" and must not be ob-

14 TRIPS Agreement 1992, art. 27(1).

15 Ibid., art. 27(2).

16 Ibid., art. 27(3)(a)

17 Ibid., art. 27(3)(b). A thorough discussion of patentability of human genetic material is outside the scope of this chapter. See generally POZO M. D., "Patenting Genes", Cheltenham, Elgar, 2017.

18 See IDHGD 2003, Preamble.

19 Deryck Beyleveld and Roger Brownsword *Consent in the Law* (Oxford and Portland, OR: Hart Publishing, 2007), 245-248.

tained by the inducement of "financial or other personal gain".[20] This standard applies to both consent in having personal information and biological material included in a genetic database *and* consent in making use of information and material for a specific research purpose. This latter requirement has proven to be very difficult, if not impossible to meet, in the case of HGB. Research in biomedicine and molecular biology evolves speedily and new potential uses of the resources included in the databases emerge continually. Hence, for instance, information and material initially collected on a small scale for clinical purposes may subsequently merge into a larger database which is used to conduct large scale epidemiological research, or it can even become a profitable resource for commercial uses by the pharmaceutical industry. Obtaining new consent for uses that were not predictable at the time the information was released might be too burdensome or even impracticable. The 2003 Declaration addresses this problem in art. 16, "Change of purpose", which provides that data "Should not be used for a different purpose that is incompatible with the original consent" *unless* the proposed new use "corresponds to an important public interest reason and is consistent with the international law of human rights",[21] or *unless* the data in question is "irretrievably unlinked to an identifiable person".[22] In the latter case, the use must only be "in accordance with domestic law" or with the procedures established by national ethics committees.[23]

The standard applied by legislators and regulatory authorities to assess new uses that are inconsistent with the original consent may vary significantly, but share some common principles. It is presumed that, once an individual has given informed consent to use their data to carry on a given research, he or she would give consent to other uses too, insofar as it fits in the same objective of promoting public health.[24] An approach that has been applied in this respect is based on the principle of social solidarity, which broader in scope than "public interest". Social solidarity means that an individual does not only have a presumptive interest, but also a *duty* to facilitate research and to provide knowledge that could be crucial for the health of others.[25] Since individuals accept the benefits that flow from medical research, they have an obligation in justice to contribute to social practices which produce them.[26] Under this approach, the use of data for research purposes is in principle lawful—even when informed consent has been obtained for a more limited purpose, such as clinical use.[27]

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20 IDHGD 2003, art. 8(a).

21 IDHGD 2003, art. 16(a).

22 IDHGD 2003, art. 16(b).

23 Ibid.

24 As the House of Lords Selected Committee on Genetic Databases puts it, "we believe that it can generally be presumed that individuals are content for data about them to be used for the common good, provided that their personal privacy is protected" (quoted in MCHALE J. "Regulating genetic databases", 82).

25 CHADWICK Ruth and BERG Kåre, "Solidarity and Equity. New Ethical Frameworks for Genetic Databases", in Nature Reviews Genetics, 2 , 2001, p. 318 and 327.

26 See HARRIS J., "Scientific Research and Moral Duty", in Journal of Medical Ethics, 31 2005, p. 242.

27 Ibid. However, this "liberal" approach is not endorsed by everyone. See McHALE J., "Regulating genetic databases", p. 81 and 82. Others base the "general consent" approach on a more fundamental obligation "flowing from the interconnection between bodies and the world from which an individu-

The doctrine of social solidarity—and associated principles—may limit significantly the individual's control over the use of their genetic information. An even more important limitation derives from the rule of "anonymization" of data. As acknowledged in art. 16(b) IDHGD, once data are "irretrievably unlinked" to an identifiable person, they fall outside the scope of individual's rights. Does this mean that those data can be processed for uses that are inconsistent or even at odds with the initial purpose? The common-law jurisprudence tends to respond to this question in the affirmative, as exemplified by the *Source Informatics* case.

3.1. *Limits on individual's control over the use of genetic information: the* Source Informatics *doctrine*. *Source Informatics* is a case on the processing of anonymized information for purposes other than those for which the information was initially collected.[28] Source Informatics Ltd. used information provided by medical doctors and pharmacists to create a database of drug prescriptions. The database comprised the doctor's and patient's name, the date of the prescription, the drug prescribed and the quantity of the dose. This was valuable information for pharmaceutical companies to analyse prescribing habits and target marketing communications to doctors. With the consent of doctors and pharmacists, but not of the patients, Source Informatics sold the database purged from the patient's personal details to the pharmaceutical industry. The Department of Health stated in a policy document that this conduct was breaching the patients' confidentiality, despite the fact that the information was anonymized. This was on the ground that "the patient would not have entrusted the information to the GP or pharmacist for it to be provided to the data company".[29] Source Informatics brought an action challenging the policy document, which was rejected at first instance. However, the decision was reversed in appeal. Here the court ruled that there is no misuse of personal data when there is no risk of breach of confidence, and therefore no risk of damage to the patients, irrespective of the fact that the patients gave their consent for a specific use only.

The decision of the Court of Appeal has been subject to criticism.[30] For the sake of our analysis, this case is important insofar as it highlights the narrow approach adopted by common-law jurisprudence with respect to individuals' control over the use of personal medical information. As Deryck Beyleveld observed, the right of individuals over medical information should not be limited to prevent uses that would be detrimental to themselves or their own interests. Rather, "individuals have the right to know what will be

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al has benefitted in the past and will benefit in the future" (HERRING J. and CHAU P-L, "My body, your body, our bodies", in Medical Law Review 15 , 2007, p. 34 and 55.), or simply on the notion of "gift": once an individual has given her permission, then she may be regarded has having "donated" her DNA and ceded control over it (McHALE J., "Regulating genetic databases", p. 80).

28 *R v Department of Health, ex parte Source Informatics Ltd* [2001] FSR 8.

29 Although "[t]he duty of confidence may in some circumstances be outweighed by the public interest in disclosure", the Department maintained that selling information to the pharmaceutical industry "could [not] be argued to be in the public interest" (quoted in *R. v Department of Health, ex parte Source Informatics Ltd* [2001] FSR 8, § 7).

30 See LAURIE G., "Genetic Privacy. A challenge to Medico-Legal Norms", Cambridge University Press, 2000, pp. 224-226.

done with personal information about themselves and to control how it is used and how it is disposed".[31] Criticizing the argument of the Court, Histed and Beyleveld remarked that "[p]atients might object to the purpose to which the information, once rendered anonymous, is to be put",[32] and conclude that it is incorrect to say that the information is no longer "theirs" since they are no longer identifiable. On the contrary, they argue, "the information has been obtained from the personal information they provided, and would not exist otherwise".[33] Under this approach, the individual's legal interest not to have their medical data used in ways that are contrary to their moral beliefs should not be exhausted with the first release of the information, nor should it be completely ruled out by the anonymization of the information. As Graeme Laurie observes, when personal information is released for a given purpose, there is a "legitimate expectation of use–why would we necessarily expect that information given for a perfectly legitimate health purpose could then be used for an entirely unrelated research or marketing purpose?"[34]

The *Source Informatics* case sets a precedent for the use of medical data in the common-law jurisprudence, which founds an obvious application to genetic information included in HGB. It can be safely concluded that common law does not preclude the use of genetic information for purposes that are *entirely unrelated* from – or even at odds with – the purpose for which the information was initially collected, insofar as the information is not linked to an identifiable person.

3.2. *Property rights in biological material and data*. It is a long established principle at common law that property rights cannot subsist in the human body or in parts thereof. The principle has been reiterated by the UK supreme court (the House of Lords) in a landmark criminal law decision in 2005.[35] The facts of the case are curious: The defendant committed a robbery pointing his index finger at the victim from inside his jacket pocket, falsely pretending he had a gun in his pocket. He was charged with robbery and with "possession of an imitation firearm" in the course of the robbery. Reversing the decision of the court of appeal, the House of Lords dismissed the second claim, on the ground that the hand or finger is not something that can be "possessed":

"One cannot possess something which is not separate and distinct from oneself. An unsevered hand or finger is part of oneself. Therefore, one cannot possess it. […] What is possessed must under the definition be a thing. A person's hand or fingers are not a thing."[36]

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31 BEYLEVELD D., "Law, Ethics and Genomics", in Business Briefing: PharmaTech, 2001, p. 30.

32 HISTED E. and BEYLEVELD D., "Betrayal of confidence in the Court of Appeal", in Medical Law International 4(3&4), 2000, 277, p. 295. The authors provide the following examples: "Roman Catholics might object to new contraceptive methods being developed from information they have provided. Those who disapprove of the policies of some pharmaceutical companies towards developing countries might object to these companies profiting from their information. The patenting of human sequence is integral to the process of the new drug development, but some consider this to be immoral" (Ibid.)

33 Ibid.

34 LAURIE G., "Genetic Privacy. A challenge to Medico-Legal Norms", p. 226.

35 *R. v Bentham*, [2005] UKHL 18.

36 Ibid., § 7 (*per* Lord Bingham).

The possession of material extracted from the body has not been yet tested by courts. Case law from the USA suggests that in biological material extracted from the human body. The first of this line of cases is *Moore v. Regents of the University of California*.[37] The plaintiff was a patient of the Medical Center of the University of California at Los Angeles who underwent a treatment for an uncommon form of leukaemia. In the course of the treatment, samples of his body fluids and other biological material where taken, which were later developed into a cell line that was patented and commercialized. In its majority opinion, the Supreme Court of California dismissed Moore's conversion claim on the patent, among other things, on the ground that the plaintiff had no property rights over removed body parts.

In *Greenberg v Miami Children's Hospital*[38] plaintiffs were a group of parents of children affected by Canavan disease, who provided the Hospital with children's tissues for research on the disease, and three non-profit organizations who aided in the identification of other affected families and helped developing a confidential database. Researchers of the Hospital isolated and patented the gene sequence and developed a genetic screening test. The court dismissed several of the plaintiffs' claims, including lack of informed consent, breach of fiduciary duty, fraudulent concealment of the patent, and misappropriation of trade secrets, but it upheld a claim of unjust enrichment made by the donors of the tissues. Interestingly, though, the claim was upheld not because the donors had a legal entitlement over the tissues, but on the ground that they invested "time and significant resources" in the collaboration with the researchers.[39]

The principle that no ownership subsists in biological material was clearly affirmed by the Court of Appeals of the Ninth Circuit in *Washington University v Catalona*.[40] Dr. Catalona was an urologist specialist in prostate cancer who was employed by Washington University. When he moved to another university he tried to take a biobank of around 100,000 biological samples with him. He sent a letter to the patients who donated the samples asking them to authorize the transfer. Washington asserted that it, not the patients, own the samples and sued to establish ownership of the biological material. Confirming the District Court's finding, the Appeals Court upheld the claim of Washington University: patients who have donated biological samples with valid consent, do not have an ownership right and cannot direct, transfer or control their use.

4. *Intellectual property rights in aggregated data: the legal protection of databases.* Under both European and US laws, collections of data attract copyright protection only when the way in which content is selected and arranged bears in itself an element of authorial originality or creativity.[41] This is normally not the case with "comprehensive" databases, namely databases that comprise, or aim at comprising, given factual information related to a

37 *Moore v. Regents of the University of California*, 51 Cal. 3d 120 (1990)

38 *Greenberg v. Miami Children's Hosp. Research Inst.*, 208 F. Supp. 2d 918 (N.D. Ill. 2002).

39 "[T]he facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing time and significant resources."

40 *Washington University v William J. Catalona*, 437 F. Supp. 2d 985 (2006).

41 Directive 96/9/EC on the legal protection of databases, art. 3(1); Feist Publications v. Rural Telephone Service Co. Inc. 499 U.S. 340 (1991).

whole class of subjects. Examples of comprehensive databases are telephone directories, where no creativity is involved in the selection and arrangement of the contents.[42] Some HGB too, like population genetic databases, can lack the necessary element of creativity in selection and arrangement to attract copyright protection.

However, under EU law, even databases that do not meet the threshold of copyright protection are eligible for a *sui generis* form of protection. The *sui generis* database right, which was introduced in 1996 by the European Database Directive, affords protection to virtually any aggregation of contents, on condition that "substantial investment" has been made "in either the obtaining, verification or presentation of the contents".[43] As we will see, the condition is not difficult to be met in HGD.

There has been extensive scholarly discussion on the effect of the database right on access to information, especially in the context of scientific research and education.[44] In the Evaluation Report on the Database Directive, issued on 2005, the European Commission acknowledges that "[t]he issue of access to 'information' is of concern to various categories of users".[45] As Reichman and Okediji straightforwardly put it, the regime of the *sui generis* database right "introduced radical new restrictions on access to and use of compilations of data that were previously unknown to any intellectual property paradigm".[46] This is because this regime brings together the proprietary features of copyright with those of the industrial property paradigm. Like copyright, the *sui generis* database right arises automatically with no need of entering an examination process or fulfilling any formalities. Like patents, however, it gives an extensive control over the "use" of the protected subject matter as such and comes with a relatively weak system of exceptions and limitations. This combination of copyright-style subsistence and patent-style scope creates a hybrid regime with strong proprietary features, is much more effective than legal entitlements of individuals as a tool to control the use of HGD.

4.1. *The "substantial investment" requirement: which genetic databases are protected?* Article 7 of the Database Directive sets forth the unique requirement in order for an aggregation of data to be eligible for protection, namely that a "substantial investment" has

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42 As in *Feist v Rural*, cit.

43 Directive 96/9/EC, art 7(1).

44 See the seminal article of Jerome REICHMAN H. and SAMUELSON P., "Intellectual Property Rights in Data?", in Vanderbilt Law Review, 50, 1997, p. 52. See also DERCLAYE E., "Legal Protection of Databases. A Comparative Analysis", Cheltenham, Elgar, 2008 and the literature herein cited.

45 First evaluation of Directive 96/9/EC on the legal protection of databases, p. 10. Examples include: "information in the public domain (eg an electoral register); information where the database constitutes the only available source of that information (e.g. a telephone directory); information pertaining to academic and scientific research and other public interest users such as consumers, the disabled, libraries; information which is 'created' independently of any other activities where the primary purpose or principal activity is the creation of a database whether using own data or data acquired from another source (e.g. an encyclopaedia); information which is generated from 'spin-off' databases (eg football fixtures lists)". (Ibid).

46 Jerome REICHMAN H. and OKEDIJI R. L., "When Copyright Law and Science Collide: Empowering Digitally Integrated Research Methods on a Global Scale", in Minnesota Law Review 96, 2012, 1362, p. 1419.

been made "in either the obtaining, verification or presentation of the contents".[47] This requirement is essentially split into two cumulative conditions, namely that the investment made is "substantial" and it is "of the right kind"—i.e. directed towards "either obtaining, verification or presentation", and not to something else. Neither of these conditions is difficult to meet. As to the "substantiality" requirement, it has been interpreted by the European Court as a *de minimis* rule which should not preclude, for instance, that databases that are mere "spin-offs" of other activities attract protection.[48] What seems to be relatively more challenging is the second condition, namely "towards what" is the investment directed. In a series of cases brought before the European Court, the requirement has been developed as implying a distinction between expenditure of resources and skills to *create* the content of the database, and investment directed towards the *collection* of pre-existing content.[49] While the latter is eligible to attract protection, the former is not. The rationale of this distinction is to exclude from protection the so-called "sole source" databases, i.e. databases that contain data or information which are not available elsewhere. Making up data not otherwise available leads inevitably to the creation of sole sources databases, and exclusive rights over these kind databases would result in a de facto monopolization of facts and information. According to the CJEU, this would be contrary to the intention of the European legislator.

In the context of HGB, this distinction in the criteria for eligibility suggests that investment in *generating* genotype data does not count towards attracting protection under *sui generis* database right. Although extraction of genotype data from biological samples may well represent the main share of investment in a HGB, it is not the only one. Substantial investment is also needed in other stages of the making of HGB, for instance at the stage of collecting data from the population or presenting the data in a workable and retrievable format. Given the relatively low threshold of "substantiality", it is out of question that most of the HGB attract protection under *sui generis* database right in Europe.

Similarly, any aggregation of content that is created in relation to the genetic information for purposes of research may be equally protected, since no new data are technically created. This could be the case of repositories of scientific resources—including articles, abstracts and data—generated through text mining techniques to cover specific genomic research fields.[50] Since the *sui generis* database regime applies, these research-oriented resources receive automatically full protection in Europe, even if they are not meant for commercial exploitation.

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47 Database Directive, Art. 7(1).

48 "[P]rotection is also possible where the obtaining was initially for the purpose of an activity other than the creation of a database. For the Directive also protects the obtaining of data where the data was not obtained for the purposes of a database" (*The British Horseracing Board Ltd and Others v William Hill Organization Ltd* (Case C-203/02), 9 November 2004 [2005] 1 C.M.L.R. 15; Stix-Hackl Advocate General, § 47). For a critique of this approach see DERCLAYE E., "Databases 'Sui Generis' Right: Should we Adopt the Spin-Off Theory?", European Intellectual Property Review, 2004, 402, pp. 407-408.

49 *Fixtures Marketing Ltd v Oy Veikkaus AB*, Case C-46/02 [2004] ECR I-10365; *Fixtures Marketing Ltd v Svenska Spel AB*, Case C-338/02 [2004] ECR I-10497; *Fixtures Marketing Ltd v Organismos Prognostikon Agonon Podosfairou (OPAP)*, Case C-444/02 [2004] ECR I-10549.

50 REICHMAN H. and OKEDIJI R. L., "When Copyright Law and Science Collide: Empowering Digitally Integrated Research Methods on a Global Scale", p.1367 and 1368.

4.2. *Scope of protection and limitations*. The *sui generis* database regime provides for the exclusive right to "prevent extraction and/or re-utilization of the whole or of a substantial part"[51] of the protected database. "Repeated and systematic extraction and/or re-utilization of insubstantial parts" is also restricted, insofar as that it implies acts "which conflict with the normal exploitation" of the database or "unreasonably prejudice the legitimate interests of the maker of the database".[52] "Extraction" is defined as the "permanent or temporary transfer of all or a substantial part of the contents of a database to another medium by any means or in any form", while "re-utilization" means the "making available to the public" of the database's content—in whole or in part—by distribution, rent, on-line or other forms of transmission.[53] In *British Horseracing Board v William Hill*, the CJEU has made clear that both the thresholds of "substantial part" and of "repeated extraction of insubstantial parts" can be reached whenever unauthorised acts of extraction or re-utilisation have the result of reconstituting "the whole or a substantial part of the contents" of the database and prejudicing the investment of the database maker—either by individual action or cumulative effect.[54] This practically means that *every* extraction from a database through automated means falls within the scope of the sui generis right. In this respect, this right can be understood as preventing automated access to a database's content. In theory, one could speculate on whether some of the 'uses' of the database's content made by search engines and knowledge discovery tool qualifies as 're-utilization', insofar as they do not make content available to the public. However, as we have seen, the *sui generis* right covers extraction per se, even absent re-utilization—as indicated by the use of the double conjunction 'and/or' in Article 7(1). This makes any examination of the purpose of the secondary use of the database's content largely speculative.

Few exceptions to extraction and re-utilization are available, and the range of permissible activities with respect to protected databases is significantly narrow compared to copyright. Practically, the only meaningful use that may be carried out on electronic databases without authorization is "limited extraction"—but not re-utilization—for the non-commercial purpose of "illustration for teaching or scientific research".[55] The exception has limited value in case of scientific research on HGB, for two reasons. First, most of the research carried out in relation to HGB – such as bio-informatics – requires use of large amount of data. Second, beneficiary of the exception may be seriously hampered in

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51 Database Directive, Art. 7(1).

52 Ibid, Art. 7(5).

53 Ibid, Art. 7(2).

54 *The British Horseracing Board Ltd and Others v William Hill Organization Ltd* (Case C-203/02), 9 November 2004 [2005] 1 CMLR 15, § 95.

55 Database Directive, Art. 9(b). The two other permitted activities are extraction for private use (but only for non-electronic databases, Art. 9(a)), and "extraction and/or re-utilization for the purposes of public security or an administrative or judicial procedure" (Art. 9(c)). In comparison, the parallel exception that applies to copyright-protected databases is broader in scope, since it permits "use" of the database for the same purpose, and accordingly it covers also activities that fall under "re-utilization". Ibid, Art. 6(2)(b). See WALTER M. M. and VON LEWINSKI S., "European Copyright Law", Oxford, Oxford University Press, 2010, 9.9.10.

publishing the results of his research, since any partial disclosure of data may amount to re-utilization of the database's content. For this reason, it seems practically very difficult if not impossible to lawfully carry out scientific research on an HGB without authorization from the owner. Relying on this strong form of protection, the database owner can set the conditions upon which research on HGB is permitted. These may include restrictions on patent filing and on the exercise of other intellectual property rights.

5. *Regulating the use of HGB by contract-based policies.* Many HGB have policies that impose specific conditions on the use of genetic information. These include rules on the use of intellectual property rights arising from research on the datasets.[56] The UK Biobank, a major charity-supported initiative that recruited 500,000 participants between 2006-2010, requires all researchers to place results in the public domain after a "reasonable period" of confidentiality.[57] Although, as stated in the governance policy, the Biobank "is not expected in itself to lead to patentable inventions that return significant income", this possibility is not excluded in principle, and commercial companies are allowed to access the database "if their proposal falls within the UK Biobank purpose and complies with the usual scientific and ethics requirements".[58]

The rules of the Genomics England Clinical Interpretation Partnership (GeCIP) issued in August 2016 are inspired by the same principles, but are much more detailed and specific, especially with respect to the management of intellectual property rights.[59]

Genomics England is the name of a government organization set up by the UK National Health Service (NHS) in 2013 to deliver the 100,000 Genomes Project, aimed at sequencing whole genomes from NHS patients with rare diseases, cancers and infectious diseases. The organization is part of the UK Department of Health and, although depending on public money, aims to attract private investments too.[60]

In order to have access to the dataset of whole genome sequences and clinical data arising out of the 100,000 Genomes Project, researchers and companies must sign the GeCIP Participation Agreement. Under the Agreement, ownership and use of research outputs and intellectual property rights are subject to special conditions. In essence, ownership is entirely transferred to Genomics England,[61] which grants back to the participant a non-exclusive licence to use the outputs for non-commercial research and a right to negotiate a "fair and reasonable licence" for the commercialization of those outputs.[62] The terms and conditions of these licences are subject to the policy on intellectual

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56 VERLINDEN V., MINSSEN T. and HUYS I. "IPRs in biobanking - risks and opportunities for translational research", in Intellectual Property Quarterly, 2015, 2, p. 106.

57 UK Biobank Ethics and Governance Framework, Version 3.0 (October 2007), p. 14.

58 Ibid., p. 18.

59 Intellectual Property Principles for 100,000 Genomes Project, August 2010.

60 RAMESH R., "Jeremy Hunt launches genomics body to oversee healthcare revolution", in The Guardian, 5 July 2013.

61 Rules of the Genomics England Clinical Interpretation Partnership (GeCIP), August 2016, § 10.3-4

62 Ibid., § 10.10.

property rights,[63] which specifies the rules for the ownership of intellectual property, the protection, management and commercialization of patents and other intellectual property rights arising from the 100,000 Genomes Project, and the basis on which access to the dataset is granted.

As already mentioned, one of the unique characteristics of GeCIP is that the all IP rights arising from the use of the dataset are transferred to the dataset owner, namely to Genomics England. The reason for this is to avoid fragmentation of IP rights, which may become a hindrance to effective collaboration,[64] and to enable the organization to have control over the use of IP so that a "socially responsible patent strategy"[65] is adopted. Hence, the "single owner" approach has both an efficiency and ethical rationale.

As a single owner of IP rights, Genomics England commits itself to a strict policy on patenting. This covers both patent filing and patent management. Filing patent applications is limited to inventions that support the primary aims of the project and "constitute a significant development".[66] No claims will be made for isolated gene sequences, or for marginal improvements, or that are overly broad or for mere hypothetical methods.[67] As to the management of patent rights, all licenses shall be approved by the Genomics England's Board of directors, and should be time limited, purpose-specific and unenforceable by third parties. Moreover, the licence shall include special conditions and preferential prices for the use of the invention by the NHS.

The "single owner" policy and the related licensing policies are based on the hypothetical scenario that the participant who is given access to the dataset carries out his research entirely within the GeCIP and without using external assets, such as data of his own property or owned by a third party. However, the policy document identifies two alternative scenarios and specifies the approaches to be adopted in these cases.

The first alternative scenario ("scenario 2") is when the research is carried out entirely within GeCIP but using substantive assets that are not owned by Genomics England.[68] The external asset might be for instance a software algorithm or a collection of genome sequences to be analysed in conjunction with the 100,000 Genomes Project dataset. In this scenario, to be evaluated on a case by case basis, the policy details the rules to allocate the rights and to avoid joint ownership of results.[69] The general principle underlying these rules seems to be the "separability" of the assets: if the external asset is logically and materially separable from the dataset, then the owner of the external asset retains

63 Genomics England Intellectual Property Policy, August 2016.

64 Ibid., § 2.1.2-3

65 Ibid., § 2.1.6.

66 Ibid., § 3.1. At the time of writing this chapter, no patent applications on behalf of Genomic England appear to have been filed at the major patent offices.

67 Ibid., § 3.2. The provisions of this section should exclude so-called "reach-through" claims (i.e. claims that seek to extend patent protection to an indefinite numbers of downstream inventions. See Reach-Through Claims in the Age of Biotechnology", in American University Law Review 51, no.4, 2002, 609, pp. 618-19.

68 Ibid., Annex, § 2.

69 Ibid., § 2.2.6.

its rights over the asset and Genomics England acquires full ownership of the results.[70] By contrast, if the external asset is inseparable, then Genomics England will retains full ownership of the results, subject to covering the costs.[71]

The principle of separability operates also to determine the allocation of ownership in scenario 3, namely when the research not only uses external assets, but is also carried out partly outside GeCIP (typically as part of a broader collaborative project). For instance, ownership can be allocated according to the technical field in which the collaborators operate,[72] or according to whether it constitutes an improvement to a parties background intellectual property.[73] Where inseparable, joint ownership of intellectual property rights will apply. The same rules apply in case of collaboration with commercial involvement, such as when a commercially entity is given access to the dataset. In this case, additional policies applies, whereby the entity is "encouraged" to adopt a "socially responsible patent strategy".[74]

6. *Conclusion.* The chapter has illustrated some of the tensions between individual rights and property rights in human genetic material and data. Common-law jurisprudence presents a paradox in this respect, insofar as property rights are recognized at all levels of the construction of a human genetic databases, *but not* at the level of its "building blocks". In other words, participants to HGB are the only subjects that do not "own" any part of the resource that they have contributed to create, and that would not exist at all without their contribution. The limits on individuals' control over biological material extracted from their body, and over information extracted from their *persona* once the information can no longer be linked to individuals, result in an almost complete loss of control over the use of such material in HGB. This loss of individuals' power can only be compensated by strong public regulation on the access and use of HGB. Such regulation cannot simply reiterate general ethical principles contained in soft-law international instruments, but must translate those principles into detailed and binding contractual conditions on the ownership of results. In this respect, the experience with highly sophisticated contract-based policies such as that of the GeCIP can set a new standard in the regulation of genomics research and its contentious relation to commercial interests.

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70 This is for instance the case when a software algorithm is used to analyse the dataset. Ibid., § 2.3.1.

71 For instance, a collection of whole genome sequences to be integrated to the dataset for the purpose of carrying out a particular analysis. Ibid., § 2.3.2.

72 "For example, in a collaboration between a pharmaceutical company and developer of inhalation devices to develop a new asthma product, the parties might agree that pharmaceutical company will own any arising intellectual property that relates primarily to pharmaceutical compound and the inhaler company will own any arising intellectual property that relates primarily to the inhaler device." § 3.2.4.

73 § 3.2.5.

74 § 4.2.

New challenges in the regulation of dna evidence at the eu level

María José Cabezudo Bajo

1. *State of the question, justification of the work and objectives.* The DNA test, given its scientific-technological nature, currently has great potential, but it also has enormous limitations. This means of evidence is used in criminal and civil matters at a European Union level. Given that DNA testing pursues different purposes for each of these two areas, it has evolved (in the legislative sphere) in different ways.

In the criminal sphere, it is a means of evidence that allows associating two or more scenarios of a crime or to identify the holder of an indeterminate DNA sample, which may contribute, in the latter case, to the determination of the author of the commission of an offense in a national criminal proceeding. Given Member States' public interest in preventing areas of impunity between themselves and tackling serious cross-border crimes (mainly organised crime and terrorism), the European Legislator has specifically and intensively regulated this means of evidence. In particular, the enforcement of the Prüm Treaty in 2005 led to the stepping up of cross-border cooperation, in particular in combating terrorism, cross-border crime and illegal migration, resulting in a turning point for European regulation. Although it is a Treaty of International Law, adopted outside the EU, it was, fortunately, incorporated three years later into the acquis communautaire through Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime. Known as the "Prüm" Decision, the content was similar to the Treaty's. In this way, the exchange of DNA profiles, fingerprints and data from the vehicle registration register was, essentially, regulated. Together with the Prüm Decision, Council Decision 2008/616/JHA on the implementation of Decision 2008/615 was adopted. Both norms, the Prüm Decision and the Decision that developed it, regulate the automated online consultation and comparison of DNA profiles. The European Legislator, aware that the effective exchange of DNA profiles between EU Member States' databases could only be achieved if the fundamental rights affected by such processing of DNA data were respected, adopted the Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed within the framework of police and judicial cooperation in criminal matters. This rule has been repealed by Directive 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data by competent authorities for the purpose of prevention, investigation, detection or prosecution of criminal offenses or the execution of criminal sanctions, and to the free movement of such data.

With the adoption of these rules on the exchange of DNA profiles and the protection of DNA data, the European institutions assumed that there were more issues regarding the effective achievement of a cross-border match at an EU level which needed to be harmonised in order to obtain evidence that was efficient from a procedural point of view. They have therefore adopted Framework Decision 2009/905/JHA of 30 November on the accreditation of forensic service providers carrying out laboratory activities, the Council Resolution of 30 November 2009 on the exchange of results of DNA analysis and, finally, Directive 2014/41, of 3 April, referring to the European order of investigation in criminal matters. Beyond the norms, in the EU interest regarding DNA testing is continuing to increase, as seen on June 9, 2016 when the Council of the European Union published its Conclusions and Action Plan on the way forward, with a view to the creation of a European Forensic Science area.[1] In short, DNA testing has been subject to progressive and intense regulation by the European Legislator since 2005, which will continue in the future, and as such we will devote greater study to this area.

In a civilian context, DNA testing provides a means of evidence that can be used to determine or challenge filiation in national civil proceedings. In the case of an inter-subjective or cross-border dispute within the EU, the European Legislator has generally ruled that a test can be obtained in one Member State (the requested State) if this is necessary to facilitate a legal ruling of a proceeding in another Member State (the requesting State). And this, aimed at realising the right to effective judicial protection or right of access, which constitutes the constitutional basis for the international legal cooperation[2] necessary for the proper functioning of the internal market. In view of the fact that this purpose is of less public interest than the interest of DNA testing in criminal matters, the European Legislator has generally limited itself to regulating the cooperation between the courts of the Member States for the taking of evidence in civil and commercial matters under Regulation 1206/2001 of 28 May, applicable since January 2004.[3] Thus, since the European Legislator has not regulated the cross-border

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1 Information on the European Forensic Science Area is available at: http://data.consilium.europa.eu/doc/document/ST-10128-2016-INIT/en/pdf.

2 VIRGOS SORIANO M. and GARCIMARTÍN ALFÉREZ F.J., "International civil procedural law. International litigation", Madrid 2007, pp. 41-45; DIAGO DIAGO, "Regulation 1206/2001 on cooperation between the courts of the Member States in obtaining evidence in civil and commercial matters: a study of their mandatory, imperative and exclusive nature. Electronic Journal of International Studies, nº 25, 2013, p. 3; GIL NIEVAS, R., "Obtaining evidence" in Cooperation on Civil Matters in the European Union: texts and comments, ed., Aranzadi, 2009, p. 455, notes that in the matter of access rights or the right to effective judicial protection, there is also a right to the test insofar as the right of defence cannot be fulfilled if the means of evidence required to achieve the conviction of the judgement in a certain sense cannot be used.

3 This rule, according to its Art. 21.1 shall take precedence over bilateral or multilateral agreements or conventions concluded by the Member States and, especially over The Hague Convention of 1 March 1954 on Civil Procedure, and over The Hague Convention of 18 March 1970 on the taking of evidence abroad in civil or commercial matters, within the framework of relations between Member States which are party to those Conventions. Specifically, DIAGO DIAGO notes "Regulation 1206/2001," relative…, op. Cit., P. 4, that in practice there are no problems of compatibility between The Hague Convention of 18 March 1970 and Regulation 1206/2001, the Report from

obtaining of DNA testing in an intense or specific way, we will devote less attention to the study of this issue.

In both fields, the fundamental rights that may be affected by the taking of this means of evidence are those related to personal and family privacy and the protection of personal data.[4] However, the fact that DNA testing pursues different purposes framed within the aims pursued in criminal or civil processes, implies that the legal requirements that must be fulfilled in its procurement vary in each field. In particular, it is true that the set of requirements that DNA testing has to meet regarding a scientific and technological nature in order to ensure it is procured in the most reliable way possible are common to both processes. However, certain conditions of a legal nature must be observed during the process of DNA testing, which will enable lawful obtainment and which differ across each field. For this reason, we will carry out a different study for each of the two fields[5] in which we will identify and analyse the most controversial points of the cross-border procurement of a DNA test (in the requested State), so that they can be used in criminal or civil proceedings (in the requesting State). We will focus on the requirements of a legal and scientific-technological nature whose compliance allows the taking of DNA evidence and for this to be as reliable as possible, respectively. This is because, with current EU regulations, there are issues that can make it difficult to comply with both types of requirements.

2. *Obtaining a cross-border dna test in criminal matters.* In order to carry out an analysis of cross-border procurement, so that the evidence can be used in a national criminal proceeding, I will first outline the methodology adopted on a general basis in analysing DNA tests in criminal matters. In accordance with this methodological approach, we will then identify any weak points, of a scientific and legal nature, in the regulation of the test, which hinder the harmonised exchange and protection of DNA data in the EU.

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the Commission to the Council, the European Parliament and the European Economic and Social Committee of 5 December 2007.

4 CIPPITANI, R. notes, "Consent to the use of genetic information: respect of privacy and protection of other fundamental interests", on which, according to the "Working Document in Genetic Data" adopted by "Article 29 on Data Protection Working Party", there is no doubt that genetic information must be considered as personal data.

5 We consider this subject to be of extraordinary interest from the perspective of the legality and reliability that the DNA test must have, and it will be the object of study in another work.
DNA evidence is also being used in the administrative field, where it can be used by the interested party and if necessary, in order to prove the filiation in a family reunification procedure. Council Directive 2003/86/EC on the right to family reunification lays out common rules on family reunification, according to which each Member State has regulated this administrative procedure in its national legislation and, in particular, has provided for the exceptional use of DNA evidence to prove the filiation. In June 2012, the European Migration Network has prepared a study on Member States' use of DNA evidence, along with other topics, entitled "Misuse of the right to family reunification": http://extranjeros.empleo.gob.es/es/redeuropeamigracion/Estudios_monograficos/ficheros/REM_Informe_de_Sintesis_Reagrupacion_familiar_ES.pdf.

2.1. Methodological approach. In order to carry out the study mentioned above, we will take the legal nature of DNA evidence as a starting point, which is to say that it is statistical scientific evidence that is progressively collected over three phases. We will then further explain this statement, discussing, firstly, what DNA evidence as statistical scientific evidence entails and, secondly, what exactly is meant by being progressively collected over three phases.

A) DNA evidence as statistical scientific evidence.

When stating that DNA evidence is statistical scientific evidence, what underlies this concept is the idea that it has extraordinary potential but it also has extraordinary limitations. According to the above, one may wonder what it means when DNA testing is said to have a scientific nature. The answer is that the DNA test is collected progressively over three stages, which includes a stage related to the collection of the DNA sample, an analysis of the profile, and the treatment of the DNA data on the police database; stages that we will explain in more detail in the next point, and that have a scientific-technological nature because it is obtained through the use of what we have called 'technologies for the forensic use of DNA'. Like all technologies, those that are used to obtain DNA evidence have limitations because such technologies are not infallible. However, even if not infallible, such technologies are very reliable and, in addition, it is possible to quantify how reliable they are thanks to probability calculations. Thus, as a consequence of its scientific nature, DNA testing is a test that can be expressed in terms of probability.[6] In short, we can claim that the DNA test is statistical scientific evidence because, being scientific, it cannot be infallible. In particular, we can identify two types of limitations of 'the technologies for the forensic use of DNA' which explain that since they are technologies, they are not or cannot be infallible.

In the first place, 'technologies for the forensic use of DNA' are not infallible because, despite its high degree of reliability, there are legal constraints that this type of evidence must overcome. Effectively, since the use of these technologies is aimed at being used as evidence, and since such evidence must be validly used in criminal proceedings, this reliability must be restricted in order to obtain licit evidence. Otherwise, among other consequences, a procedural penalty would occur, that is, such evidence could not be taken into account as it would be prohibited or unlawful evidence.[7]

Secondly, 'technologies for the forensic use of DNA' are not infallible, since no technology is. The reliability of such technologies, which include those used for sample collection, laboratory profile analysis and treatment on the police database, has limitations

6 On its nature as statistical scientific evidence, please see BUTLER, Forensic DNA Typing, 2 ed., 2005, pp. 497-517.

7 For a better understanding of what we are exposing, we provide the following example: from a scientific-technological point of view, and as hypothesis, it is possible to analyse the 'complete' profile of the DNA of an individual. If we compared an unidentified 'complete DNA profile' with an identified 'complete profile', the probability that it corresponds with the same individual 'could result in being' 100% if, and only if, we could affirm the infallibility of the DNA evidence, because the technologies used were infallible. But this would be achieved at the expense of a breach of several fundamental rights. It would reveal very important genetic information, sensitive data, fundamentally related to health, which would entail an unjustified intrusion of fundamental rights to privacy.

of a scientific and technological nature, derived from the technologies themselves or from human failures in the use of such technologies.

Therefore, according to the two types of limitations set out above, DNA testing can be obtained with the greatest possible reliability, with such reliability being the result of using the most appropriate technologies, assuming that they have their own limitations alongside any possible human error in its use, to the limit set by the requirement to obtain licit evidence. In short, the use of 'technologies for the forensic use of DNA' will enable the obtainment of a licit test as reliable as possible, and just how reliable it is can be quantified through probability calculations.

B) Progressive collection of DNA evidence.

Given that DNA testing is statistical scientific evidence, we are going to add a second element –that its production takes place progressively across three phases. These stages include the taking of samples, a stage related to a laboratory analysis of the profile, and, finally, the data processing stage on the police DNA database.

If we add these two notes, which make up the legal nature of DNA testing, we can affirm that DNA testing has to be conducted, thanks to the use of 'technologies for the forensic use of DNA', as reliably as possible and in a licit form across each of the three phases previously mentioned. And to ensure obtaining evidence that is licit and as reliable as possible, that is, evidence with a high probative value, it is necessary that this is properly regulated in the national legal order. If this is achieved, it will be the first step for the expert to be able to correctly present this evidence in terms of probability and for the judge to be able to assess it freely.

It is therefore necessary for the national legislator to regulate the requirements for the taking of evidence, firstly, as reliably as possible, during the stages of sampling, the analysis of its profile and data processing on the police DNA database; and, secondly, that it is licit, through these stages just mentioned. However, in this regulation it is necessary to achieve an adequate balance between reliability and lawfulness. In fact, each Member State differs in their definition of this middle ground, which means there are States that are more protective or defenders of fundamental rights and freedoms and States that are more vigilant regarding the security and reliability of the evidence. This is due, among other factors, to the use of a greater or lesser number of markers that are analysed to obtain a DNA profile, on the greater or lesser inclusion criteria of the profiles or the criteria related to the cancellation of profiles on the databases.

In fact, since each Member State places more emphasis on either lawfulness or on reliability, and also because European rules do not regulate many of these aspects because it refers to the national legislation of each of the EU Member States, there is no harmonisation on these issues, creating distortions that prevent or hinder the effective exchange of DNA data between Member States' databases since what is admitted in one State may not be admitted in another State in the same way.[8]

[8] On the necessary harmonisation, please see SCHNEIDER, P.M., "DNA Databases for Offender Identification in Europe : The Need for Technical, Legal and Political Harmonization" in https://www.promega.com/~/media/files/resources/conference%20proceedings/ishi%2002/oral%20pres-

Thus, according to the legal nature of DNA testing as statistical scientific evidence or scientific evidence expressed in terms of probability, that is progressively obtained, thanks to the use of what we have called the 'technologies for the forensic use of DNA', throughout the three phases referred to including the taking of the sample, analysing the profile and treating the DNA data, we have stressed the fact that regulations on this means of evidence have to enable the obtaining of a test that is as reliable and as licit as possible. And, within the EU context on which this work is focused, compliance with these two requirements, greatest possible reliability and legality across each of the three phases, should be regulated in European legislation without reference to domestic law, to the end that harmonised legislation is achieved.

2.2. Lack of legislative harmonisation in the cross-border taking of DNA evidence. In order to obtain cross-border DNA testing at an EU level, it is necessary to carry out an automated search and comparison between those profiles contained on the respective police databases of the Member States in accordance with the provisions of Arts. 3-8 of the Prüm Treaty, Arts 3-8 of the "*Prüm* Decision" 2008/615 and Arts. 3-12 of the Framework Decision 2008/616 on the Implementation of the Prüm Decision. The objective of this action is the achievement of a cross-border match between profiles, in a lawful way and as reliable as possible. In order to achieve this, it is absolutely necessary that the EU regulations make it possible, through the regulation of both conditions in a harmonised way. If such a harmonised European regulation is not envisaged, but rather refers to each country's national laws, there is a risk that, as each regulation is different across each Member State, the evidence will not be lawful and as reliable as it could be, and therefore it cannot be effectively used in the requesting State. So, this harmonisation, which, in any case, must ensure the right balance between the legality and the reliability of the evidence, is essential, ultimately between freedom and guarantees, on the one hand, and security, on the other.

In this sense, at least two conditions should be met for the European legislation to be harmonised. From a formal point of view, regulation should be binding for the Member States. From a material perspective, such regulation should include all the necessary requirements to ensure the legality and the greatest possible reliability of the DNA test. The problem, as we will see below, is that the European legislator has not followed its purpose to this end, because all the rules that regulate aspects related to a DNA test are not binding, and all the requirements necessary to obtain a cross-border test in a licit and as reliable as possible way have not been regulated at an EU level. On the contrary, essential questions such as the criteria for the inclusion of profiles, the cancellation of data, the identification of markers to be analysed, etc. have been left in the hands of the internal domestic laws of each Member State. Therefore, I will outline some of these key issues next.

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entations/11.pdf; SCAFFARDI, L., "Legal Protection and Ethical Management of Genetic Databases: Challenges of the European Process of Harmonization" in http://www.jeanmonnetprogram.org/wp-content/uploads/2014/12/081901.pdf

A) Legislative harmonisation to achieving 'licit' DNA testing.

In order to achieve cross-border DNA matches that will allow obtaining lawful DNA evidence, it is necessary, among other things, for the legislator to properly regulate different issues. Listed below are the most relevant ones.

– The analysis of the non-coding part of the DNA.
  From the point of view of the lawfulness of the evidence, the analysis of the DNA profile must be carried out with maximum respect paid to the fundamental rights of those concerned, essentially, the right to privacy. This introduces the question as to which part of the DNA sequence should be analysed by the Member States, whether it should only be the non-coding sequence, or whether it should include the coding sequence as well.
  In order to achieve the intended harmonisation on this issue, Decision 2008/615 of 23 June 2008 limits the analysis of the DNA profile to the non-coding part (Art. 2.2). However, Art. 4 of Spanish Organic Law 19/2007, of police DNA databases[9] does not expressly limit the analysis of DNA to the non-coding part, so it can be interpreted in a manner that allows the analysis of the coding part of the DNA, which is the one that also contains genetic information that reveals other sensitive data, such as those relating to the health of a subject. It is true that the preamble of said Spanish law expressly prevents the analysis of the coding part of the DNA, but that statement, although laudable, is not found in the Articles of the norms and, therefore, lacks binding value. In addition, there is no Spanish legislation detailing the markers used by the country's forensic police, as opposed to what is stated in the Council Resolution of 30 November 2009, which lists in its Annex the markers that could be used by EU Member States. The consequence of this is that in Spain we do not know which markers are used by the forensic police and even less so those that are used by 'default' from the non-coding part. On the other hand, the Italian Law of 30 June 2009 on its accession to the Prüm Treaty establishes in Art. 11.3 that the systems of analysis apply exclusively to DNA sequences that do not allow the identification of diseases that may affect the person in question and Art. 12.1 notes that DNA profiles and related samples do not contain information that allows for direct identification of the subject to which they relate.
  Therefore, if we want this issue to be harmonised at an EU level, it would be necessary for national legislations to comply with European legislation as required by Art. 36.1 of this decision when it states that Member States are to take the necessary measures to comply with the provisions of Chapter 2, where is the aforementioned Art. 2.2.

– Criteria for the inclusion of profiles on the police database.
  Another key element in achieving legislative harmonisation in the EU is for all Member States to use the same criteria to introduce DNA profiles onto the database, and

[9] Art. 4 LO 10/2007 states that only 'identifiers obtained from DNA, in the context of a criminal investigation, which provide, exclusively, genetic information revealing the identity of the person and his/her gender, shall be registered on the database'.

this, done from two points of view. In the first place, from an objective perspective, as to the seriousness of the crimes being investigated and, secondly, from a subjective perspective, regarding the degree of imputation of the investigated subject.
Unfortunately, European regulation has not harmonised the aforementioned profile inclusion criteria, leaving its regulation to each Member State, who set the point of balance between security and freedom wherever they have considered best. By way of example, Spain, in Art. 3.1 A) LO 10/2007,[10] stipulates that DNA profiles may be incorporated into the investigation of certain 'serious' crimes (which according to the Spanish penal code are those that carry a sentence exceeding 5 years) and, in any case, those that affect life, freedom, indemnity or sexual liberty, integrity of people, assets, provided that they are carried out using force or violence or intimidation against persons, as well as in cases of organised crime (as set out in Art. 282.bis 4 LECRIM). This, from an objective point of view, regards the crime that is being investigated. Regarding the subject being investigated, if it is an identified sample, Art. 3.1 a) LO 10/2007 establishes that the subject's condition must be that of 'a suspect, detainee or an accused', to which it must be added 'convicted' under LO 1/2015 Reform of the Criminal Code. The criteria for inclusion of profiles from the objective and subjective points of view are different and are set out in paragraphs 1 and 2 respectively in the Italian Law of 30 June 2009 on its accession to the Prüm Treaty.
The fact that there is no regulation at an EU-level can lead to mismatches in the necessary harmonisation. The seriousness of a criminal offense and the degree of imputation are essential requirements of the principle of proportionality that must be fulfilled in order for the limitation of a fundamental right not to be deemed unlawful and, to prevent that, as a consequence, a disproportionate restriction on a fundamental right does not lead to unlawful evidence. In conclusion, the need for a European standard to harmonise these criteria for the inclusion of profiles on the respective police DNA databases of the different Member States should be stressed.

– Criteria for the cancellation of profiles on the police database.
In order to obtain lawful evidence, the Legislative harmonisation at a European level is essential regarding the criteria for the cancellation of profiles on police DNA databases. However, European regulations in Art. 27 and 28 of the Decision 2008/615 do not establish a cancellation period that is common to all Member States, but its regulation refers to the domestic law of each Member State.[11] Thus, in Spain, Art. 9 LO 10/2007

[10] This precept has been analysed by ETXEBERRÍA GURIDI, J. F., "LO 10/2007 of October 8 regulating the police database on identifiers obtained from DNA", La Ley, nº 6901, 2008 in https://www.administraciondejusticia.gob.es/paj/publico/ciudadano/informacion_institucional/organismos/instituto_nacional_de_toxicologia_y_ciencias_forenses/cnadn/pleno/ut/p/c5jZDBCoMwEEQ_KauJ0R4jTclijVaJtV7EQ5FA1R5Kv78Rz8buHh8PZoZ0xP08fO04fOwyDy_Sko73GmSYpIGAIuMJYAzlqdB5ACx2_MF7jjLCqmaMmjMDpE0jS5UDMPjHhp0TXhvZZnu4s0VWpUqraxFlN5esERT5BSmwYLM93J_8vi6131yGfl5zP2cH_rrsyn3bHTTQapme5D0ZY1qwaMvxB5Zyq3I!/dl3/d3L2dJQSEvUUt3QS9ZQnZ3LzZfTjBFMjhCMUEwT0s2ODBJNzBQOU9TTEwUzc!/?itemId=115511

[11] On the subject of the cancellation deadlines, please see the ruling from the ECHR-Marper Case (2008).

establishes different cancellation criteria.[12] Specifically, it stipulates that the retention of profiles will not exceed the period for the statute of limitations for the offense, or the time legally provided for the cancellation of antecedents (in the case of a final judgement of conviction, or acquittal by exculpatory circumstance or a lack of impunity or guilt, unless there is a judicial decision to the contrary) or immediately (in the case of an acquittal or dismissal), or in the case of un-accused initial suspect, the period corresponding to the statute of limitations for the offense. The Italian Act of 30 June 2009 on its accession to the Prüm Treaty establishes different criteria for the cancellation of profiles in its Art. 13.

In order to gather EU cross-border lawful evidence, it would be desirable to establish cancellation periods in the European regulations, so that this requirement is harmonised and the same across all Member States.

– Protection regime for DNA data in the European Union.

The application of Directive 2016/679 on the protection of individuals with regard to the processing of personal data by the competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offenses or for the execution of criminal sanctions and on the free movement of such data[13] will be an essential step towards the harmonisation of the general regime of protection applicable to DNA data or profile included on police databases. The aim of this Directive is to approximate the legislation of the Member States in this matter, which is essential for the cross-border taking of a licit DNA test that can be used in any of the EU Member States.

Prior to this Directive, which repeals the Framework Decision 2008/977, the rules on the protection of DNA data set out in Framework Decision 2008/615 and in the not yet repealed Framework Decision 2008/977 applied only to 'DNA data exchanged or transmitted', excluding from its scope the 'national DNA data', whose protection is provided for in the laws of the Member States. As a consequence of this, there were two different schemes in the Member States, with different areas of protection, that produced negative effects:

Firstly, a cross-border protection regime, applicable to the DNA data exchanged, would have to be incorporated into the national Law of the Member States (Prüm Decision/Treaty-Arts-24-32). And, secondly, a national system for the protection of DNA data, laid out in the legislation of each Member State,[14] which in the Spanish

[12] This subject has been addressed by SARRIÓN ESTEVE, J., "The guarantee of the term of the cancellation of data in the exchange of DNA profiles in the European Union", in MJ Cabezudo Bajo (Coord), police DNA databases: Are they truly an effective tool in the fight against serious national and cross-border crime?, Dykinson, 2013, pp. 297-324.

[13] Art. 63.1 sets out that 'Member States shall adopt and publish, by 6 May 2018 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate the text of these provisions to the Commission. Those provisions shall be in force from 6 May 2018'.

[14] On the guarantee of fundamental rights in relation to DNA evidence within the multilevel system, please see SARRIÓN ESTEVE, J., "Fundamental Rights Affected in Biological Sampling for the

case is provided in Organic Laws 10/2007 and LO 15/1999 Data Protection, although unfortunately is not specifically applicable to criminal proceedings, should be amended legislatively.

The negative effects of this can be essentially summarised in three points. First, there is the difficulty in determining, at a specific time, the system, either cross-border or national, applicable to DNA data. Secondly, this double regime will lead to the increasing concurrence of different levels of data protection pertaining to many criminal records in the Member States, with some data coming from authorities from other MS and other data obtained in the home country itself. Finally, it will lead to the weakening of EU Member States in their negotiations with third States, like the USA, as it will not be able to condition the exchange of information at an adequate level with regard to internal protection.

At this time, in order to avoid these negative effects, there are two possible solutions: for the EU to adopt either a rule to try to approximate the legislation of the Member States with regard to the protection of personal data, or a rule that can be directly applicable to the Member States, establishing the same protection regime for data exchanged and national data. Finally, the chosen outcome was the former, although, from our point of view, greater harmonisation would have been achieved with the latter option.

B) Legislative harmonisation to achieve DNA testing that is as reliable as possible.

To the end of achieving a cross-border matching that makes it possible to obtain DNA evidence that is as reliable as possible, it is necessary, among other things, for the legislator to properly regulate different issues. Detailed below are the most relevant issues.

– Markers that must be analysed.

In order to obtain cross-border DNA testing with the highest possible reliability, it is necessary that the markers that are analysed in the laboratory to extract the genetic profile are the same. It is therefore necessary to harmonise this issue at a legislative level across the EU.

In this regard, the EU has adopted the Council Resolution of 30 November 2009, inviting Member State to use 12 markers, which form part of the current European standards set (ESS). This 'invitation' is not binding, which implies, once again, that each Member State may use those it deems most appropriate. In fact, each Member State analyses different markers, although there are some that are common.

In Spain, among the functions of the CNUFADN established in Royal Decree 1977/2008, which regulates the composition and functions of the National Commission for the Forensic Use of DNA, is 'the elaboration and approval of the official technical protocols on the taking, conservation and analysis of samples, including the

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obtaining of DNA evidence valid and effective from the point of view of domestic and European Union law, "Journal of Law and Human genome", no. Extraordinary, 2014, pp. 328-329; SOLETO MUÑOZ, H, "European parameters of limitation of fundamental rights in the use of DNA data in the criminal proceeding" in General Review of Procedural Law, nº 38, 2016.

determination of the homogeneous markers on which accredited laboratories are to perform the analyses' (Art. 3). In this regard, the CNUFADN has established that Spanish laboratories have to adapt to the 12 European markers. However, the use of markers other than the 12 European ones is not legally established, even though the reality is that the Spanish Scientific Police analyses others without such normative coverage.
All MS should use the same genetic markers in order to ensure that the cross-border taking of DNA evidence has a high degree of reliability, the maximum possible from this point of view.

– Method of analysis in the laboratory
Another essential element in achieving cross-border DNA testing, that is obtained as reliably as possible, is the harmonisation of the method of analysis in the laboratory at an EU level. This method should be used by all accredited laboratories in all EU Member States.
However, at an EU level, regulation of this method, which has in fact been legally established, has no binding effect on the Member States. In fact, it is the Council Resolution of 30 November 2009 which contains such a regulation, but only 'invites' MS to obtain analysis results according to tested and scientifically approved DNA techniques based on studies carried out in the ENFSI framework. This situation is also aggravated by the fact that in Spain the methods that are used are not legally established, which leads us to propose its legal provision. On the contrary, Art. 11.1 of the Italian Law of 30 June 2009 on its accession to the Prüm Treaty provides that the analysis of the biological sample for the typing of DNA analyses must be carried out in accordance with parameters for international recognition set out by the ENFSI (European Network of Forensic Science Institutes), in order to ensure uniformity (of the analysis).
It should therefore be noted that the European legislator should regulate the legally binding methods to be used by the laboratories to carry out an analysis of the genetic profile, in order to harmonise this issue among all EU Member States.

– Laboratory accreditation.
This is regulated at an EU level and is binding, and therefore we can state that there is harmonisation on a legislative level in relation to the accreditation requirements that the laboratories carrying out an analysis of genetic profiles must be met.
In this regard, Council Framework Decision 009/905 states that 'laboratory activities shall be carried out by forensic service providers accredited by a national accreditation body certifying that such activities comply with EN ISO /IEC 17025'. In Spain, according to Art. 5.2 of LO 10/2007 that refers to the 1977/2008 RD of the CNUFADN (Arts. 3 and 8), it is established that CNUFADN is responsible for carrying out 'the accreditation of laboratories and an evaluation of their compliance with EN ISO/IEC 17025, and the establishment of quality official controls to which they must submit periodically'. In this respect, the CNUFADN has reached an agreement according to which the laboratories have to pass quality control assessments recognised by ISFG,

or ENFSI by National Entity of Accreditation (according to norm EN ISO/IE 17025). Also, in Art. 11.2 of the Italian Law of 30 June 2009 on its adherence to the Prüm Treaty, it outlines that DNA profiles may only be entered onto the national DNA database if they have been analysed in laboratories certified under ISO / IEC standard.

3. *Cross-border taking of dna evidence in civil matters.* In order to analyse the cross-border taking of DNA evidence in the EU to be used in a national case, we will set out the procedure for taking DNA evidence regulated in Regulation 1206/2001 and, along the same lines, we will confine ourselves to identifying some problems that hinder the effective cross-border taking of DNA evidence in civil matters. Certainly, the methodology we have adopted to analyse legislation in the criminal sphere in the previous point would, in principle, extend to civil matters, but with the peculiarities derived from the fact that the aim pursued in civil proceedings is different from those intended in criminal proceedings, as we will indicate throughout/along this Point III. Assuming such peculiarities, we will identify, in the ruling laid out in the aforementioned Regulation, some of the problems that make it difficult to obtain a licit test which is as reliable as possible. Before this, we will justify that specific expert DNA evidence falls within its scope of application.

3.1. DNA testing and Regulation 1206/2001. In this section, we will explain why the cross-border taking of DNA evidence falls within the scope of application of Regulation 1206/2001. To do so, we refer to Art. 1 of this Regulation that establishes its scope.[15] According to such precept, there are four conditions for the application of the Regulation: 1) requests for the taking of evidence; 2) evidence intended for use in judicial proceedings, either commenced or contemplated; 3) in civil or commercial matters; 4) by the court of a Member State. It is necessary to determine whether the DNA test falls within its scope of application, specifically an explanation of how the term 'civil or commercial matters' has been interpreted.

In the Report[16] from the Commission to the Council, the European Parliament and the European Economic and Social Committee on the implementation of Regulation 1206/2001 issued in 2007, the problems were highlighted that could result from the inclusion, within the concepts of 'civil and commercial matters' and of 'evidence', the taking of DNA and blood samples, especially in the context of paternity testing. The Report also indicated that in 2005, the European Judicial Network in civil and commercial matters examined a draft for a practical guide for the implementation of the Regulation, drawn up by the Commission Services in consultation with the network.[17] This guide indicates that the notion of 'civil and commercial matters' is an autonomous concept of Community Law which is to be interpreted in light of the objectives of the Regulation

[15] On the scope of the Regulation, please see WŁOSIŃSKA, A., "Taking of evidence between EU Member States (some remarks on a substantive scope of application of the EU Evidence Regulation)" in http://blogs.sps.ed.ac.uk/sls/files/2013/08/Aleksandra-Włosińska_.pdf

[16] Available at http://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:52007DC0769&-from=EN, p. 2

[17] The guide can be found at: http://ec.europa.eu/civiljustice/evidence/evidence_ec_guide_en.pdf

and of the EC Treaty and, in particular, in accordance with Art. 65. The European Court of Justice has, on different occasions, given interpretations of it.[18] The Regulation applies to all civil and commercial proceedings whatever the nature of the court or tribunal in which they are taking place. It will, for instance, be applicable to litigation based on civil and commercial law, consumer law, employment law and even competition law as far as private proceedings are concerned. Moreover, it should be stressed that the scope of application of the Regulation includes matters which are excluded from the scope of application of the Brussels I Regulation such as in matters relating to the status or legal capacity of natural persons, rights for property arising out of a matrimonial relationship, wills and succession, bankruptcies, proceedings relating to the winding-up of insolvent companies or other legal persons, judicial arrangements, compositions and analogous proceedings.

From our point of view, it should be understood that DNA testing is included in the scope of the Regulation in accordance with the meaning and purpose of the Regulation itself and Art. 65 of the EC Treaty.

3.2. Procedures for the taking of DNA evidence: identification of problems of legality and the reliability of the test. In the event of a conflict that has a cross-border impact, upon identification of the competent court before which the filiation proceeding will take place in a given EU Member State, the taking of DNA evidence in another Member State may be required to prove the filiation. The procedure for the taking of evidence is carried out directly between the courts of the Member States (Art. 2 of the Regulation) by the most expeditious route possible, since, as previously noted, this procedure is informed by the principles of expedition, simplification and efficiency. Along this line, Art. 3 provides that each Member State shall designate a central body responsible for providing information to the courts, seeking remedies in the event of a request involving difficulties and, on an exceptional basis and at the request of a requesting court, to forward a request to said court.

Specifically, the Regulation sets out two procedures, one ordinary procedure, on the taking of evidence from the requested court, regulated in Arts. 10 to 16, and a second special procedure, for the direct taking of evidence by the requesting court, laid out in Art. 17. in the case of DNA testing, where it is established that the DNA sample may be voluntarily carried out in the requested Member State without the need to apply coercive measures (Art. 17 (2)), the requesting court can get the tests directly. On the contrary, if voluntary procurement is not laid out, then the general procedure would be applied, which will have to be processed according to this procedure, regardless of whether or not the recipient of the measure voluntarily agrees. Next, we will outline how these procedures for the cross-border obtaining of DNA evidence would be developed and, specifically, we will highlight some of the problems that could arise in reference to the legality and reliability of this evidence.

[18] See e.g. 14. October 1976, 29/76, LTU and Eurocontrol, in ECR, 1541; 16. December 1980, 814/79, Ruffler, ECR, 3807; 21 April 1993, C-172/91 Sontag, ECR, I-1963; 14. November 2002, C-271/00, Steenbergen v. Baten.

A) Ordinary procedure for obtaining evidence from the requested court.

Next, we will present this procedure, for which we have differentiated three stages referred to as the request, admission of the request and execution, and we will highlight some problems regarding the legality and reliability of the DNA evidence.

– Request.

Once the requesting court has accepted the practice of DNA testing in accordance with its lex fori,[19] it can request a test to be conducted from to the requested court. Art. 4 of the Regulation states that the request shall be submitted by means of Form A, which appears in the Annex, which shall contain the following information: 1) identification of the requesting and requested courts (Art. 4.1 a); 2) name and address of the parties and, where appropriate, of their representatives (Art. 4.1b); 3) the type of case, object of the process and brief exposition of the facts (Art. 4.1 c); 4) the description of the measures of evidence requested, in particular the DNA evidence and information on the documents or objects to be examined (Art. 4.1 d and f); 5) the information contained in Art. 10.3, on the law applicable to the taking of evidence, in Art. 10.4, on the use of technological means for the taking of evidence, in Art. 11, regarding the taking of evidence to be carried out in the presence of, and with the participants of the parties, and in Art. 12 in relation to relevant practices in the presence, and with the participation of representatives of the requesting court. With regard to this information, we are going to raise an issue regarding the legality and reliability of this test. The issue refers to the fact that the Regulation, in order to obtain a validly usable test in an open proceeding in the requesting State, has established in Art. 10.3. that the requesting court can ask that the request is executed in accordance with the procedure laid out in the law of its Member State by means of Form A. Likewise, the requested court shall also comply with this request unless the procedure is incompatible with the laws of the Member State of the requested court or that there are serious difficulties in doing so.[20] In accordance with Art. 10.3, we can deduce that the Regulation seeks evidence that is obtained under the laws of the requesting State, provided that it is respectful of the law of the requested State, so that the evidence can be effectively used in the legal proceedings held in the requesting State. We need to relate this interpretation with the peculiarities of the DNA evidence and, in particular, with the fact that, in order for the DNA evidence to be effectively used within a process, it must be obtained lawfully and in a way that means it is as reliable as possible. For this reason, we question whether Art. 10.3 can guarantee the necessary harmonisation of both requirements.

As for the lawfulness of the evidence, we understand that Art. 10.3 may include the necessary conditions for obtaining lawful evidence. Also, and in case there were any problems concerning the protection of fundamental rights, essentially data protec-

[19] GIL NIEVAS has pointed out that in "Obtaining evidence…", op. cit., p. 459, nothing prevents that form from being completed by the party proposing the testing, to be subsequently completed and assumed by the competent court (of the requesting State) in the process of admission of evidence.

[20] If the requested court does not consent to the petition on any of the grounds mentioned above, it will inform the requesting court using Form E.

tion, recital 18 of the Regulation states that any data transmitted under the Regulation are protected by European data protection legislation.[21]
However, as the DNA test is a scientific test, questions arise as to whether the issues that affect the reliability of the test are sufficiently guaranteed by Art. 10.3 of the Regulation. We understand that it is not easy to include it in the mentioned Art. 10.3 because, among other reasons, the scientific issues associated with DNA testing in the civil field are not usually regulated in the legal order of the Member States. Specifically, we refer to the conditions related to storage and the transfer to the corresponding laboratory of the DNA sample that has been taken, to the use of the same markers when analysing the DNA sample in the laboratory, to the requirements that the laboratory must meet to be accredited to carry out the function of analysing the DNA profile and the methods of analysis to be used, among other issues. Certainly, this information can be described in Form A, when it lays out a question on the inclusion of the information related to the description of the measures of inquiry sought (Art. 4.1. (d)). This would be the only way for the requested State to comply with the same scientific criteria in taking the sample and the analysis of the profile, as those used by the requesting State. But Art. 4.1 (d) does not guarantee that the requested State will in fact comply with the same scientific criteria as that of the requesting State because, among other reasons, it may use different technologies in obtaining a reliable DNA test which may not even be regulated. Therefore, whether or not the results were a match between two DNA profiles that contributed to determine or challenge the filiation, the results obtained when interpreting the coincident result in terms of probability might not be fully reliable. Consequently, even if the evidence obtained cross-border was lawful (Art. 10.3), not even under Art. 4.1 (d) of the Regulation could assurances be made that the DNA evidence is as reliable as possible. In view of this current situation, where, unlike in criminal law, such issues have been regulated at an EU level by the European legislator, it is worth asking whether it would not be convenient to seek harmonisation of such aspects with regard to the reliability of the DNA evidence in the same way that has been achieved with respect to the legality of the DNA evidence under Art. 10.3 of the Regulation.
Finally, it should be noted that neither the application nor the accompanying documents have to be authenticated nor comply with another equivalent formality (Art. 4.2). The request for, and all necessary communications shall be drawn up in the official language of the requested State (Art. 5) and shall be transmitted by the fastest route accepted by the requested State (Art. 6).

– Admission of the application.
The competent requested court shall issue an acknowledgment of receipt to the requesting court through Form B within seven days of the receipt of the request for a DNA test. There may be various situations in which the application has not been

[21] In particular, we highlight the Regulation of the European Parliament and of the Council of 27 April 2016 on the protection of individuals (with regard to the processing of personal data and on the free movement of such data) which repeals Directive 95/46/EC.

properly formulated. Firstly, it is possible that the request does not comply with the provisions set out in Art. 5 and 6 of the Regulation, referring to the language in which the application and communications are to be written and with respect to their transmission, in which case the requested court shall state as such in the acknowledgment of receipt (Art. 7.1). Secondly, if the court receiving the request was not competent, it will be forwarded to the competent authority of its Member State and this will be communicated to the requesting court using Form A (Art. 7.2). Thirdly, (this is possible) the application may be incomplete (Art. 8), either because it does not contain data as required in Art. 4, or because of the lack of provision of funds set out in Art. 18.3, cases in which the requested court will inform the requesting court using Form C so as to complete the information or make up the provision of funds.

– Execution of the request.
Once the execution of the request is agreed,[22] the requested court will execute it as soon as possible and in any case within ninety days following the receipt of the request (Art. 10) or, as the case may be, from the moment in which the requested court has received the duly completed request form (Art. 9). The Regulation provides that it may be executed in the presence, and with the participation of the parties (Art. 11) as well as representatives of the requesting court (Art. 12). The execution consists of the recipient of the measure providing a DNA sample, which at the time of the beginning of the proceeding is not known with certainty. Precisely, this uncertainty is the very thing that justifies resorting to the ordinary procedure. This uncertainty will be cleared up once the stage of the execution of the request has been met, in which the person requested to provide the sample can assume two positions: 1) voluntarily agree to providing a sample; 2) not voluntarily agree to providing a sample.
In the former case, the DNA sample would be taken according to the provisions of Art. 10.3, that is, under the law of the requesting Member State unless it is incompatible with the law of the Member State of the requested court or there are actually serious difficulties to do so. At this point, we want to bring up the previously mentioned problems regarding whether 'Member State law' has to be interpreted to include both the requirement of legality and of the reliability of the DNA test. Along with this first interpretative problem, already analysed in the previous point, it is possible to raise a second question, deriving from the fact that the DNA test is not obtained through one single action, but as we noted in relation to the criminal area, is obtained progressively over three stages. In the case of obtaining the DNA evidence within the civil field, we refer to the stages of obtaining the sample, a second one on the analysis of the profile and thirdly, since there are no databases addressing this field, to a comparison with the identified sample that is available from the beginning, in order to know whether they are or are not coincidental, in which case, we should interpret this matching result in mathematical terms of probability. Since the procurement involves three stages, it is worth considering whether, when we refer to the execution of the

[22] The grounds for the refusal of execution of the request are regulated in Art. 14 of the Regulation.

DNA test, we should interpret that, according to the Regulation, the three stages must be carried out in the requested State, which would seem the most desirable option, or whether only the first stage should be carried out. If, under the Regulation, only the first phase was carried out in the requested State, that is to say, the obtainment of the DNA sample, the sample should be transferred to the requesting State in order to carry out the following two phases. This second option would not be totally optimal in view of the added problems that may arise with regard to the non-existent regulation of a chain of custody that would have to be respected in these cases involving cross-border DNA testing.

In the second case, if the party that should provide the sample does not voluntarily agree to do so, although the Regulation provides for the possibility of carrying out coercive measures, we wonder whether this would be possible in the case of DNA testing, since the use of coercive measures to obtain a DNA sample[23] is not established in the Spanish legal system. The use of coercion would not be possible if it is not legally established by the law of the requesting and requested States. The question left unanswered regarding this centres around whether, in the future, Member State legislators should consider enforcing this measure in civil proceedings through judicial authorisation. It would be a measure restricting the fundamental right to a private personal life and, where appropriate, to the protection of personal data that a judge should decide by means of a reasoned decision in accordance with the requirements derived from the principle of proportionality.

B) Special procedure for obtaining direct evidence on behalf of the requesting court.

Regarding the application, the requesting court shall submit the request for obtaining the DNA evidence to the central body or to the competent authority of that State referred to in Art. 3 through Form I (Art. 17.1).

With respect to the admission of the request, the central body or the competent authority of the requested Member State shall inform the requesting court within 30 days of the receipt of the request as to whether it has been accepted[24] and under what conditions the taking of said evidence must be conducted in accordance with the Law of the requesting Member State, by using Form J (Art. 17.4).

Finally, the taking of DNA evidence will be carried out by a member of the judicial staff or by any other person, such as an expert, designated in accordance with the law of the Member State of the requesting court (Art. 17.3). In addition, the central body or the competent authority may designate a court from the requested Member State to take part

[23] In Spain, the process of filiation is regulated in Arts. 764-768 of the Law of Civil Procedure, in Arts. 748-755 LEC that generally apply, and in Arts. 108-141 of the Civil Code. Art. 767.2 LEC states that in filiation trials, the investigation of paternity and maternity will be admissible through all kinds of evidence, including biological ones; and, in Art. 767.4 LEC it is stated that an unjustified refusal to submit to a biological test of paternity or maternity will allow the Court to declare the filiation claimed, provided that there is other evidence of paternity or maternity, and evidence for this has not been obtained by other means.

[24] Art. 17.5 establishes the grounds on which the central body or the competent authority can refuse the direct procurement of evidence.

in the taking of evidence in order to ensure the correct application of the provisions of Art. 17 of the Regulation and of the conditions that have been established.

All of the above is with respect to whether 'Member State law' is to be interpreted as including both the lawfulness and reliability requirements of the DNA test, – together with the fact that the DNA evidence is not obtained through a single act, but throughout three stages of which it is necessary to know, which one(s), according to the Regulation, can be carried out in the requested Member State –, is transferable to this special method of taking cross-border DNA evidence.

4. *Conclusions.* In the analysis of DNA evidence, it is necessary to assume the synergy that exists between, on one side, the scientific-technological-probabilistic issues, and on another, legal issues, that conform and transfer the result of this analysis to the European legislation and to that of its Member States, which would make it possible to carry out cross-border procurement efficiently.

In the criminal sphere, European legislation regulates the cross-border procurement of DNA evidence, so that it can become an effective tool for combating serious cross-border crime, especially organised crime and terrorism. However, such a tool will not really be effective if the essential requirements for the cross-border test to be lawful and as reliable as possible are not regulated in a harmonised way by the European legislator.

In the civil and commercial sphere, DNA testing has the problem that the Regulation, which could guarantee a licit DNA test under Art. 10.3, cannot ensure the highest possible reliability of DNA evidence (according either to Art. 10.3 or to Art. 4.1 d), which leads us to wonder about the effectiveness of Regulation 1206/2001 in relation to obtaining cross-border DNA evidence to be used in a filiation proceeding.

The issues discussed in this paper have been raised in order to highlight some preliminary conclusions but remain subject to further study.