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Genetic Information and Individual Rights

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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.