

The problem of the consent for the processing of health data, particularly for biomedical research purposes, from the perspective of fundamental rights protection in the Digital Era^{*}

El problema del consentimiento para el procesamiento de datos de salud, en particular con fines de investigación biomédica, desde la perspectiva de la protección de los derechos fundamentales en la era digital

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Resumen / Abstract: El tratamiento de los datos relativos a la salud se enfrenta a problemas éticos y legales relacionados con los derechos fundamentales. Como sabemos, los pacientes pueden beneficiarse en la era digital de tener a su disposición información médica o de salud, y asimismo las decisiones médicas pueden ser más efectivas con una mejor comprensión de historias clínicas, datos médicos y de salud gracias al desarrollo de Inteligencia Artificial, el Internet de las Cosas y otras tecnologías digitales. Sin embargo, al mismo tiempo, debemos garantizar los derechos fundamentales, incluidos los de privacidad. La preocupación sobre el cumplimiento de los requisitos éticos y legales, incluidos los constitucionales, es particularmente relevante en el tratamiento de datos de salud. Este trabajo se centra en el problema del consentimiento requerido para el tratamiento de datos de salud y las excepciones establecidas en el nuevo Reglamento General de Protección de Datos, que contempla el tratamiento de estos datos especiales con fines de investigación científica, histórica y estadística como propósitos legítimos, junto a otros. La conclusión que se obtiene es que estamos ante conceptos abiertos problemáticos tanto para la protección de los derechos vinculados a la privacidad como para la propia seguridad jurídica de la investigación. Por un lado, hay varios problemas de interpretación relacionados con el tratamiento de los datos de salud y la protección de la privacidad; éstos también afectan a los profesionales que deben llevar a cabo el tratamiento con respeto al marco legal multi-nivel aplicable y garantizar al mismo tiempo los derechos fundamentales. Por todo ello, se defiende que necesitamos un marco legal más claro para la investigación biomédica.

Health data processing fields face ethical and legal problems regarding fundamental rights. As we know, patients can benefit in the Digital Era 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 thanks to the development of Artificial Intelligence, Internet of Things and other Digital technologies. However, at the same time, we need to guarantee fundamental rights, including privacy ones. The complaint about ethical and legal requirements – including constitutional ones – is particularly relevant in the processing of health data. This paper is focused on the problem of the consent required to the processing of health data and the exceptions established in the new European Union General Data Regulation, which cover the processing of this special data -within other aims- for scientific, historical and statistical research as legitimate purposes, which include biomedical research. The conclusion is that these open concepts are problematic both for the protection of privacy rights and for the legal security/certainty

of research. On one hand there are several interpretation problems, regarding the processing of health data and the protection of information privacy. On the other hand, professionals must follow the Multilevel legal framework and to guarantee fundamental rights in the processing of health data, so there are also problems of interpretation for researchers. Therefore, we need a clearer legal framework for biomedical research.

Palabras clave / Keywords:

Datos sanitarios / Investigación biomédica / Consentimiento / Privacidad / Protección de datos / Tecnologías digitales.

Health data / Biomedical research / Consent / Privacy / Data protection / Digital technologies.

1. Motivation

Health data processing fields face ethical and legal problems regarding fundamental rights. As we know, patients can benefit in the Digital Era 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 thanks to the development of Artificial Intelligence, Internet of Things and other Digital Technologies, with a better general governance of Big Data. However, at the same time, we need to guarantee fundamental rights.

Although the new European Union (EU) Information or Data Privacy regulation has been a 'property-based conception' regulation¹, the reality is that although it is a very important instrument to guarantee fair and quality use and processing of personal data, this legal instrument opens the health data processing for very open purposes as scientific, historical and statistical research² without a clear regulation of the guarantees.

The complaint about ethical and legal requirements – including constitutional ones – is particularly relevant in the processing of health data because when dealing with health we need a fundamental rights protection

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, Jacob M., "The EU general data protection regulation: Toward a property regime for protecting data privacy", *Yale Law Journal*, No. 123, 2013, pp. 513-528. Certainly, the issue of personal data property is controversial and there has been an interesting discussion on this issue, see SCHWARTZ, Paul, "Property, Privacy, and Personal Data", *Harvard Law Review*, No. 7, Vol. 117, 2004, pp. 2055-2128; RODWIN, Marc A., "Patient Data: Property, Privacy & the Public Interest", *American Journal of Law & Medicine*, No. 36, 2010, pp. 586-618.

² Scientific research purposes include, of course, biomedical research ones.

approach to identify the ethical and legal limits regarding the use of this type of sensitive data.

In order to achieve our aims, from a methodological perspective, 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 interconnected³. 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 Treaty⁴.

In this paper, 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, and finally we focus our aim on the problem of the consent and the exceptions of scientific, historical and statistical research, which include biomedical research purposes.

2. Multilevel methodology on health data processing

It is typical – from the Law perspective⁵ – to describe the relationship between EU law and national ones in terms of a multilevel legal system, i.e., constitutional pluralism or multilevel constitutionalism. In both cases, we speak about theoretical constructions which try to explain the EU multilevel fundamental rights protection architecture⁶, and therefore the relationship and interaction of different legal systems or levels, particularly EU and national ones. These are becoming progressively more intercon-

³ GÓMEZ SÁNCHEZ, Yolanda, *Constitucionalismo multinivel: Derechos Fundamentales*, Sanz y Torres, 2011, p. 20.

⁴ SARRIÓN ESTEVE, Joaquín, "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", *CEFLegal: Revista Práctica del Derecho*, No. 162.

⁵ 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, Dariusz, "Theoretical Aspects of European Studies", *Introduction to European Studies: A New Approach to Uniting Europe*, Centre for Europe", University of Warsaw, 2012, pp.13-32.

⁶ 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, Joaquín, *El Tribunal de Justicia de Luxemburgo como garante de los derechos fundamentales*, Dykinson, Madrid, Spain, 2013) rationalised by scholars (TENORIO SÁNCHEZ, Pedro, "Diálogo entre Tribunales y Protección de los Derechos Fundamentales en el ámbito europeo", *Revista General de Derecho Europeo*, No. 31, pp. 2-4).

nected, because we need to approach this complex 'legal reality' as Prof. GÓMEZ SÁNCHEZ pointed out some years before⁷.

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 to consider not only EU and national law, but also international law and obligations⁸ including the European Convention on Human Rights (ECHR)⁹, and other international instruments such as the Convention on Human Rights and Biomedicine (Oviedo Convention)¹⁰.

Nevertheless, some authors usually tend to share an assumption that seems problematic, as KOMÁREK pointed out recently¹¹: 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.

⁷ GÓMEZ SÁNCHEZ, Yolanda, *Constitucionalismo multinivel. Derechos fundamentales*, *cit.* p. 55.

⁸ 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.

⁹ Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, 4 Nov. 1950, better known as the *European Convention on Human Rights*.

¹⁰ 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.

¹¹ 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, Jan, "Why National Constitutional Courts Should Not Embrace EU Fundamental Rights", *LSE Law, Society and Economy Working Papers*, 23/2014, available at: <http://www.lse.ac.uk/collections/law/wps/>, 2014, pp. 8-10 [Last accessed: 29 April 2018]

Certainly, according to article 51(1) of the EU Charter of Fundamental Rights¹², 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)¹³, 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 of EU law (*Melloni*, C-399/11¹⁴; and *Åkerberg Fransson*, C-617/10) challenging the multilevel system¹⁵.

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

3. Health data processing 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 person¹⁶. In both cases, we deal with sensitive and relevant data linked to privacy.

¹² 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>

¹³ CJEU, C-617/10, *Åkerberg Fransson*.

¹⁴ CJEU, C-399/11, *Melloni*.

¹⁵ Regarding the challenges of the application of the EU fundamental rights protection standard limiting the national ones, see my previous work SARRIÓN ESTEVE, Joaquín, "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> [Last accessed: 29 April 2018]

¹⁶ On biologic and biometric data linked to identify persons, I suggest CABEZUDO BAJO, María José, "Genetic Evidence", *Genetic Information and Individual Rights*, ARNOLD, R. / CIPPITANI, R. / COLCELLI, V. (Eds.), Series "Law & Science", Vol. 1, Universität Regensburg, Regensburg, Germany, 2018, pp. 134-147.

This paper is focuses on the actual trends of health data processing (including collection, recording, organisation, structuring, storage, and other uses) in the Digital Era, considering the actual legal framework of health data.

3.1. *Health data processing 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 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 disclosed 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 consent¹⁷.

However, data privacy rights cannot restrict or limit the right to identity also covered by art. 4 ECHR, as essential to and effective as information privacy rights, as EHRC pointed out in the case *Bensaid v. The United Kingdom* (2001)¹⁸. Identity also includes the right to know the circumstanc-

¹⁷ 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 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)

¹⁸ 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

es of those born and to establish the identity of the ascendants as a vital interest (*Jäggi v. Switzerland*, 2003)¹⁹.

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 ECHR²⁰.

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 data²¹. 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).

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'.

¹⁹ EHRC 3 July 2003, *Jäggi v. Switzerland*, Application No. 58757/00.

²⁰ 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.

²¹ Convention for the protection of individuals with regard to the automatic processing of personal data (No108), 1981.

5) Special provisions for transborder data flows (art. 12).

The CoE Council of Minister adopted in 1997 the Recommendation on the protection of medical data providing for the application of data privacy legislation for all medical data²².

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 1997²³. 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)²⁴. Notwithstanding, there was no obstacle for the EHRC to mention the Oviedo Convention in case law affecting those countries²⁵.

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 inter-

²² CoE Recommendation No. R (97) 5 on the protection of medical data.

²³ 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*.

²⁴ 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 29 April 2018. Available at: http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=C9Qv25Dq [Last accessed: 29 April 2018].

²⁵ 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.

nal 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.

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 considered (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 processing EU legal framework

At the European Union 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)²⁶, 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))²⁷:

(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;

²⁶ European Court of Justice developed the right to data protection including the right to be forgotten, see CJEU, C-131/12, Google Spain.

²⁷ 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.

(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*’.

The aim of this article is to protect physical and mental integrity, and although it deals basically with medical treatment rather than the processing of health data, from my point of view health data treatment is capable of impacting – in some cases- physical integrity, and therefore we cannot exclude the application of article 3(2) in the processing of health data as we will explain later.

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, but 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 processing, the precedent EU legislation²⁸ was Directive 95/46/EC on the protection of

²⁸ 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 included 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

individuals with regard to the processing of personal data and on the free movement of such data (Data Protection Directive, DPD)²⁹. This was in force until the application of the new Data Protection legislation³⁰: 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),³¹ applicable from 25 May 2018³².

The new regulation³³, the GDPR, 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):

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).

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.

²⁹ 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.

³⁰ 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.

³¹ 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.

³² 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 is applicable from 25 May 2018.

³³ 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 applies to all EU member states since 25 May 2018, and it takes into account new technologies.

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 must 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)³⁴: a) Explicit and unambiguous consent³⁵ or the

³⁴ 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.

³⁵ 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

authorisation of the holder of parental responsibility³⁶ (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)³⁷.

Nevertheless, health data are a special category of personal data (sensitive data), and they are included in article 9 with genetic³⁸ and biometric data³⁹, as particular data (different from health ones⁴⁰) with the same protection, although GDPR permits Members States to introduce further conditions about genetic, biometric and health data.

The general rule is that these special categories cannot be processed (art. 9(1) GDPR) with the exceptions provided in art. 9(2). The first one is the explicit consent of the data subject for one or more specified purposes (art. 9. (a) GDPR) but there are other which we can call lawful cases, causes, purposes or basis. The most important ones linked to the health data are, obviously, the legitimate purposes of preventive or occupational medi-

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).

³⁶ 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.

³⁷ Moreover, Member States may introduce more specific provisions in points c and e (art. 6(2) GDPR).

³⁸ '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).

³⁹ '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 dactyloscopy data (art. 4(14) GDPR).

⁴⁰ 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).

cine, 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) GDPR), and where appropriate for archiving purposes in the public interest, scientific or historical research purposes or statistical ones (art. 9.2(j) GDPR), which have been underlined before by several authors⁴¹:

'(h) processing⁴² 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)

⁴¹ See BELTRÁN AGUIRRE, Juan Luis / GARCÍA LÓPEZ, Fernando José / NAVARRO SÁNCHEZ, Carmen, "Protección de datos personales y secreto profesional en el ámbito de la salud: una propuesta normativa de adaptación al RGPD", SESPAS Report, November 2017, p. 7, available at: <http://sespas.es/2017/11/30/proteccion-de-datos-personales-y-secreto-profesional-en-el-ambito-de-la-salud-una-propuesta-normativa-de-adaptacion-al-rgpd/>; SARRIÓN ESTEVE, Joaquín, "Health Data Treatment", *Genetic Information and Individual Rights*, ARNOLD, R. / CIPPITANI, R. / COLCELLI, V. (Eds.), Universität Regensburg, Regensburg, Series "Law & Science", Vol. 1, 2018, p. 44.

⁴² '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).

However, there are other legal purposes or causes covered under art. 9(2) which can be used to processing health data in some cases (letters b, c, d, e, f)⁴³:

*'(b) processing is necessary for the purposes of carrying out the **obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law** in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject;*

*(c) **processing is necessary to protect the vital interests of the data subject** or of another natural person where the data subject is physically or legally incapable of giving consent;*

*d) processing is carried out in the course of its **legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious** or trade union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects;*

*(e) processing relates to **personal data which are manifestly made public by the data subject***⁴⁴;

*(f) processing is necessary for the **establishment, exercise or defence of legal claims** or whenever courts are acting in their judicial capacity;'*

One can imagine, for example, specific obligations or rights linked to health in the employment, social security and social protection law other than those covered letter h (art. 9.2(b) GDPR), the processing of health data which is in the vital interest of the data subject (art. 9.2(c) GDPR), a healthcare association which develops legitimate aims processing health data (art. 9.2(d) GDPR), health data which are made public by the data subject in social profiles (art. 9.2(e) GDPR), or the use of health data in legal claims (art. 9.2(f) GDPR).

⁴³ Certainly, the only case which cannot be used is, from my point of view, letter (g)- public interest- because is already covered under letter (i) public interest in the area of public health.

⁴⁴ Of course, when patients made their data 'manifestly public', these data are no longer protected as sensitive data. It is obvious that this concept -manifestly public- is subject to interpretation.

The problem is that the exceptions in these special categories use very open concept categories, you can think for example -in particular- about the open concepts of **scientific -including biomedical-, historical, or statistical research as legitimate purposes in letter j. Any scientific, historical or statistical purposes can be included?**

4. The problem of the consent for the processing of health data

Certainly, the open concepts covered by the GDR is problematic both for the protection of data privacy rights and for the security of research.

In one hand, in order to protect privacy, and particularly personal data, several authors suggested 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 about the application of consent in these cases covered by article 9(2) legal purposes⁴⁵.

One might ask whether in these cases both article 6 and 9 GDPR applies cumulatively, or the processing of health data can be covered by consent (art. 9.2(a) GDPR), or any other legal purposes provided in article 9(2), and therefore we don't need to go to article 6 GDPR for a second legitimation for special categories -including health, genetic and biometric data- because we only need a lawful base⁴⁶.

However, recital 51st GDPR indicates for data special categories that *'In addition to the specific requirements for such processing, the general*

⁴⁵ See BELTRAN AGUIRRE, José Luis, "Tratamiento de datos personales de salud: incidencia del Reglamento General de Protección de Datos", in Juan Francisco, *Salud electrónica. Perspectiva y realidad*, Tirant lo Blanch, Valencia, Spain, 2017, pp. 121 and 122; BELTRÁN AGUIRRE, Juan Luis / GARCÍA LÓPEZ, Fernando José / NAVARRO SÁNCHEZ, Carmen, "Protección de datos personales y secreto profesional en el ámbito de la salud: una propuesta normativa de adaptación al RGPD", *cit.* pp. 7 and 8; BOMBILLAR SÁENZ, Francisco, "Tratamiento jurídico del consentimiento informado y la donación de muestras biológicas a un biobanco para investigación biomédica: los consentimientos en blanco", *Derecho y Salud*, No. 1, Vol. 27, 2017, p. 111; and BOMBILLAR SÁENZ, Francisco, " Legal approach of informed consent and donation of biological samples to biobanks for biomedical research: a glance to Spain", ARNOLD, R. / CIPPITANI, R. / COLCELLI, V. (Eds.), *Genetic Information and Individual Rights*, Universität Regensburg, Regensburg, Series "Law & Science", Vol. 1, 2018, p. 99.

⁴⁶ BELTRÁN AGUIRRE, José Luis, "Tratamiento de datos personales de salud: incidencia del Reglamento General de Protección de Datos", *cit.* BOMBILLAR SÁENZ, Francisco, "Tratamiento jurídico del consentimiento informado y la donación de muestras biológicas a un biobanco para investigación biomédica: los consentimientos en blanco", *cit.* p. 111.

principles and other rules of this Regulation should apply, in particular as regards the conditions for lawful processing', maybe calling for the application of article 6 (lawfulness of processing). And Article 29 Data Protection Working Party interpreted article 6 in this way⁴⁷, i.e., a cumulative application of articles 6 and 9(2) GDPR.

Although I advocated for this interpretation before⁴⁸, I have interpretative doubts. It seems to me that the lawful basis for special or sensitive data categories -including health, biometric and genetic data- are in article 9 instead of article 6(1) GDPR, and therefore these data categories have an specific legal status.

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, guarantying the fundamental rights to research⁴⁹, but this interpretation faces several legal interpretative problems:

a) First, the constitutional (EU) problem of article 3.2(a) of EU Fundamental Rights Charter, which must be applied -from my point of view- in the processing of data in the fields of medicine and biology. In this sense, this article guarantees *'the free and informed consent of the person concerned, according to the procedures laid down by law'*.

As I pointed out before, the aim of this article is to protect physical and mental integrity, and although it deals basically with medical treatment rather than the processing of health data, in my opinion health data treatment is capable of impacting – in some cases- physical integrity, and therefore we cannot exclude the application of article 3(2) in the processing of health data.

Moreover, although it is true that this article speaks about the 'procedures laid down by law', the procedures are the ways established by law in order to give the consent, and it cannot be a base to exclude the consent of

⁴⁷ According to Article 29 Data Protection Working Party 'Controllers can only process special category personal data if they can meet one of the conditions set out in Article 9(2), as well as a condition from Article 6'. See Article 29 Data Protection Working Party, Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679, WP 251 17/EN, adopted on 3 October 2017, p. 22.

⁴⁸ See SARRIÓN ESTEVE, Joaquín, "Health Data Treatment", *cit.* pp. 48-49.

⁴⁹ Certainly, the scientific research is a right, but we cannot coceive it as an absolute right, and therefore, we need to protect dignity, autonomy of the will, intimacy, etc. See GÓMEZ SÁNCHEZ, Yolanda, "La libertad de creación y producción científica: especial referencia a la Ley de Investigación Biomédica", *Revista de Derecho Político*, No. 75-76, 2008, pp. 489-514; BOMBILLAR SAENZ, Francisco, "Legal approach for informed consent and donatios of biological samples", *cit.* p. 103.

the person concerned in a general way. Following this interpretation, it is possible to doubt about the constitutionality – under EU Fundamental Rights Charter- of the general exceptions to the requirement of the consent in art. 9 GDPR. Nevertheless, if we read this right in the light of international treaties as the Oviedo Convention which protect private life in relation to the information about health (art. 10 Oviedo Convention) it is true that there is not a right to control health data by the data subject.

b) Secondly, the constitutional (Spanish Constitutional law) and legal problem.

The GDPR is the first EU regulation which develops a fundamental Spanish Constitution right (article 18(4) Spanish Constitution) which is covered by the organic law reserve of article 81 Spanish Constitution⁵⁰. Well, from my point of view article 93 Spanish Constitution -in which is based the transfer of Spanish Sovereignty competences to EU institutions- is an enough instrument to overlap the problem of the organic law reserve in the Spanish Constitution.

Nevertheless, although -as we known- the EU regulation applies with prevalence over national one, there may be interpretative problems regarding the guarantee of consent of the subject due to its guarantee in the current Spanish legal framework⁵¹ as part of the fundamental right to data protection⁵². In fact, GDPR provides a remarkable margin to national systems in article 9(4) GDPR. This margin can be also important to apply Constitutional Fundamental Rights protection standard, due to *Melloni* and *Ackberg* ECJ doctrine: 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 of EU

⁵⁰ PIÑAR MAÑAS, José Luis, “Objeto del Reglamento”, *Reglamento General de Protección de Datos. Hacia un nuevo modelo europeo de privacidad*, PIÑAR MAÑAS, J.L., (Dir), Reus, Madrid, Spain, 2018, p. 58

⁵¹ See BELTRÁN AGUIRRE, Juan Luis / GARCÍA LÓPEZ, Fernando José / NAVARRO SÁNCHEZ, Carmen, “Protección de datos personales y secreto profesional en el ámbito de la salud: una propuesta normativa de adaptación al RGPD”, *cit.* p. 23. In fact, informed consent can be seen itself as a fundamental human right. See BOMBILLAR SÁENZ, Francisco, “Legal approach for informed consent and donations of biological samples”, *cit.* p. 110.

⁵² The right to data protection is recognised in the Spanish Constitution as a right to self-determination (article 18(4) Spanish Constitution). It is founded in the person's dignity (art.10(1) Spanish Constitution) and in the person's freedom (art. 1(1) and 17 Spanish Constitution), concepts 'dignity' and 'freedom' which are more linked in the biomedicine field, and to the person's right to decide on his/her own vital options, reality and life. See GÓMEZ SÁNCHEZ, Yolanda “Dignidad y autodeterminación física como fundamento del estatuto del paciente”, *Acta Bioethica*, No. 1, Vol. 17, 2011, p. 41.

law⁵³. Moreover, one can interpret that the current Spanish legislation is in fact applying this legislative margin provided by GDPR for national legislation, and therefore Spanish legislation is already requiring additional conditions.

c) Thirdly, the problem of the exception to the principle of purpose limitation for scientific, historical and statistical research as legitimate purposes regulated in the GDPR which can also create (legal certainty) problems. Indeed article 5(1b) GDPR⁵⁴ covers the further processing of health data - which will be always compatible with the first purpose- for these cited purposes, with pseudoanonymization (art. 89(1) GDPR). This provision opens the door to a legal presumption in favour of the processing of health data for biomedical research.

This legal presumption certainly clashes with the redaction of Recital 33,⁵⁵ and perhaps with the tradition based on the consent of the data subject and the autonomy in the biomedical research⁵⁶.

On the other hand, 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 to respect the legislation at EU and national level, and to guarantee fundamental rights protection.

⁵³ See paragraphs 2 and 3.2 in this paper.

⁵⁴ Article 5(1b) GDPR stipulates that '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 purposes** ('purpose limitation')

⁵⁵ Recital 33 GDPR: 'It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose'

⁵⁶ BOMBILLAR SÁENZ, Francisco, "Tratamiento jurídico del consentimiento informado y la donación de muestras biológicas a un biobanco para investigación biomédica: los consentimientos en blanco", *cit.* p. 111. For this reason, authors advocate for the introduction of additional national requirements -as consent or anonymization- for the further processing of health data for research purposes by the for-profit private sector. See BELTRÁN AGUIRRE, Juan Luis / GARCÍA LÓPEZ, Fernando José / NAVARRO SÁNCHEZ, Carmen, "Protección de datos personales y secreto profesional en el ámbito de la salud: una propuesta normativa de adaptación al RGPD", *cit.* p. 26.

In this sense, it will be important that the National Legislation regulates these issues to give legal security/certainty for the processing of health data⁵⁷. But the reality is that the Spanish Organic Law Project⁵⁸ -which is in the process of being approved- seems to leave out of coverage the treatment of genetic, biometric and also health data in the field of biomedical research, and there is a big concern of the Spanish Society of Public Health (Sociedad Española de Salud Pública) and the Spanish Society of Epidemiology (Society of Epidemiology) which asked recently the political parties for a specific national regulation on the processing health, genetics and biometric data processing⁵⁹.

Despite the Opinion of the Legal Office of the Spanish Agency for Data Protection (Agencia Española de Protección de Datos) which in a recent report on the incidence of the GDPR in the field of biomedical research and the Spanish Organic Law Project concluded that the law framework remains unchanged, and that we will have a more flexible interpretation of the scope that can be given to the consent given, it is no less true that it is an interpretation that raises many doubts according to the legislation.

Furthermore, new technologies face health, and particularly, health data. In fact, actual trends in processing health data include Big Data challenges (Bionterpretation, propensity, correlations (searching quality)), Standards and Interoperability, Data Governance and Trust, Data Expertise and Infrastructure, etc.⁶⁰ But also, as we know, Artificial Intelligence, Inter-

⁵⁷ SARRIÓN ESTEVE, Joaquín / BENLLOCH DOMÈNECH, Cristina, "Una necesaria reflexión sobre el marco normativo de la investigación científica biomédica (A required consideration on Biomedical scientific research legal framework)", *cit.*

⁵⁸ 121/000013 Proyecto de Ley Orgánica de Protección de Datos de Carácter Personal, available at: http://www.congreso.es/backoffice_doc/prensa/notas_prensa/57631_1518684517278.PDF [Last accessed: 29 April 2018]

⁵⁹ La Sociedad Española de Salud Pública y la Sociedad Española de Epidemiología piden a los partidos políticos una ley específica sobre datos relativos a salud, genética y datos biométricos, 1 March 2018, available at: <http://sespas.es/wp-content/uploads/2018/02/NdP-SEE-y-SESPAS-Enmiendas-Ley-Protecc-Datos.pdf> [Last accessed 29 April 2018]. See SARRIÓN ESTEVE, Joaquín / BENLLOCH DOMÈNECH, Cristina, "Una necesaria reflexión sobre el marco normativo de la investigación científica biomédica (A required consideration on Biomedical scientific research legal framework)", *Gaceta Sanitaria* (in press).

⁶⁰ 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 [Last accessed 29 April 2018]

net on Things (IoT) including m-Health (mobile-lifestyle and wellbeing apps)⁶¹ etc.

5. Conclusions: we need a clearer legal framework of processing health data for biomedical research

Health data processing faces ethical and legal problems regarding the use of data. We need to guarantee privacy (including data protection rights) and 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.

Health data, as sensitive data, are a special protected category under EU GDPR. The processing of health data can be covered on several legitimate grounds, of course the consent of the data subject, but also other legal purposes as public interest.

As we pointed in the paper the general rule is that these special categories cannot be processed (art. 9(1) GDPR) with the exceptions provided in art. 9(2) GDPR. The processing of these data categories is based particularly 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) GDPR), and where appropriate for archiving purposes in the public interest, scientific or historical research purposes or statistical ones (art. 9.2(j) GDPR). Nevertheless, the processing can be based also in other legal causes covered in article 9(2) letters b, c, d, e, and f.

In the paper we focused on the problem of the open purposes of the scientific research -which include biomedical research- as legitimate grounds for health data processing. Certainly, the open concepts covered by the GDR is problematic both for the protection of data privacy rights and for the legal security/certainty of research.

On one hand there are several interpretation problems, regarding the processing of health data and the protection of privacy, including personal data protection when there is a processing of health data without the data subject consent, taking into account the relevance of the consent as part of the right to data protection, linked to person's dignity and freedom, not only at international and EU level, but also at national one: in the Spanish legal

⁶¹ 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 [Last accessed: 29 April 2018]

framework this right is developed as a right to self-determination. I also suggest some constitutional problems from the perspective of the EU Charter of Fundamental Rights.

On the other and health data should be processed by or under the responsibility of a professional subject under the obligation to respect the EU multilevel system legislation and to guarantee fundamental rights protection, and the open concepts of scientific, historical and statistical research as legitimate purposes regulated in the GDPR create also problems for researchers from the legal certainty perspective.

Furthermore, new technologies face health, and particularly, health data in the actual Digital Era. In fact, actual trends in processing health data include Big Data challenges, Artificial Intelligence and Internet on Things (IoT), and therefore we need a better and clearer legal framework of processing health data for biomedical research at EU and national level.

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