CNS 15/2019

Opinion in relation to the consultation of a health center on the need for consent in the case of the use of pseudonymized health data in biomedical research

A letter from a health center is submitted to the Catalan Data Protection Authority, requesting a report from this Authority on the use of pseudonymised health data in biomedical research.

The query asks if it can be considered, taking into account the personal data protection regulations, that the treatment of pseudonymized health data in the terms of letter d) of point two of the seventeenth additional provision of Organic Law 3/2018 , of December 5, of protection of personal data and guarantee of digital rights (LOPDGDD), in relation to article 9 of the General Data Protection Regulation (RGPD), is a legitimate basis for the treatment of health data for the purpose of of biomedical research, independent of the legal basis of the consent of the interested party.

If so, the query asks if the interested party's consent does not need to be obtained when pseudonymized health data are processed in the terms indicated in letter d) of point two of the seventeenth additional provision of the LOPDGDD.

Having analyzed the request, which is not accompanied by other documentation, in view of the current applicable regulations and the report of the Legal Counsel, the following is ruled.

I

(...)

II

The consultation explains that the health center aims to carry out health, socio-health and social activities at the service of citizens, as well as teachers, research and health innovation. According to the consultation, within the framework of the purpose of health research, the center promotes and develops different types of biomedical research for the realization of which it is necessary to process the personal health data of the patients of the entity itself.

In this context, the consultation asks whether, taking into account Regulation (EU) 2016/679, of April 27, general data protection (RGPD), and the seventeenth Additional Provision of Organic Law 3/2018, of December 5, protection of personal data and guarantee of digital rights (LOPDGDD):

> **"1.- We can consider that the treatment of pseudonymized health data in the terms indicated in section d) of point two of the Seventeenth Additional Provision of the LOPD becomes, in relation to what is contemplated in article 9 RGPD, a legitimating basis for the treatment of health data for the purpose of biomedical research independent of the consent of the interested party."**

2.- If so, can we interpret that when pseudonymized health data are treated in the terms indicated in section d) of point two of the Seventeenth Additional Provision of the LOPD, it is not necessary to obtain the consent of the interested party?"

Having placed the query in these terms, we start from the basis that, according to article 4.1 of the RGPD, personal data is "all information about an identified or identifiable natural person ("the interested party"); Any person whose identity can be determined, directly or indirectly, in particular by means of an identifier, such as a number, an identification number, location data, an online identifier or one or more elements of identity, shall be considered an identifiable physical person physical, physiological, genetic, psychological, economic, cultural or social of said person;

According to article 4.15 of the RGPD, it is data relating to health: "personal data relating to the physical or mental health of a natural person, including the provision of health care services, which reveal information about their state of health" .

According to article 4.13 of the RGPD, it is genetic data: "personal data relating to the inherited or acquired genetic characteristics of a natural person that provide unique information about the physiology or health of that person, obtained in particular from the analysis of a biological sample of such a person;" (we also refer to recital 34 RGPD).

The processing of data (art. 4.2 RGPD) of patients treated at the health center for purposes related to research or medical research is subject to the principles and guarantees of the personal data protection regulations (RGPD and LOPDGDD).

According to article 6.1 of the RGPD:

"1. The treatment will only be lawful if at least one of the following conditions is met: a) the interested party gives his consent for the treatment of his personal data for one or several specific purposes;

b) the treatment is necessary for the execution of a contract in which the interested party is a party or for the application at the request of this pre-contractual measures;

c) the treatment is necessary for the fulfillment of a legal obligation applicable to the person responsible for the treatment;

d) the treatment is necessary to protect the vital interests of the interested party or another natural person;

e) the treatment is necessary for the fulfillment of a mission carried out in the public interest or in the exercise of public powers conferred on the person responsible for the treatment;

f) the treatment is necessary for the satisfaction of legitimate interests pursued by the person responsible for the treatment or by a third party, provided that these interests do not prevail over the interests or fundamental rights and freedoms of the interested party that require the protection of personal data, in particular when the interested party is a child.

The provisions in letter f) of the first paragraph shall not apply to the processing carried out by public authorities in the exercise of their functions."

Thus, the processing of personal data must have, to be lawful, a legal basis that does not necessarily have to be the consent of the affected person.

Based on this premise, with regard to the processing of categories of data subject to special protection, article 9 of the RGPD regulates the general prohibition of the processing of personal data of various categories, among others, data relating to to health and genetic data (section 1). Section 2 of the same article 9 provides that this general prohibition will not apply when any of the following circumstances occur:

"a) the interested party gives his explicit consent for the treatment of said personal data with one or more of the specified purposes, except when the Law of the Union or of the Member States establishes that the prohibition mentioned in section 1 cannot be lifted by the interested party; (...) g) the treatment is necessary for reasons of an essential public interest, on the basis of the Law of the Union or of the Member States, which must be proportional to the objective pursued, respect the right to data protection in essence and establish appropriate and specific measures to protect the interests and fundamental rights of the interested party;

h) the treatment is necessary for the purposes of preventive or occupational medicine, evaluation of the labor capacity of the worker, medical diagnosis, provision of health or social care or treatment, or management of health and social care systems and services, on the basis of the Law of the Union or of the Member States, (...);

i) the treatment is necessary for reasons of public interest in the field of public health, such as protection against serious cross-border threats to health, or to guarantee high levels of quality and safety of health care and medicines or sanitary products, on the basis of the Law of the Union or of the Member States that establishes appropriate and specific measures to protect the rights and freedoms of the interested party, in particular professional secrecy,

j) the treatment is necessary for archival purposes in the public interest, scientific or historical research purposes or statistical purposes, in accordance with the article 89, section 1, on the basis of the Law of the Union or of the Member States, which must be proportional to the objective pursued, essentially respect the right to data protection and establish adequate and specific measures to protect the interests and fundamental rights of the interested party.".

It should be borne in mind that the RGPD supports the processing of data of special categories for the development of research, in particular in the health field, with some flexibility, as can be seen, among others, from recital 52, according to the which: "(...) exceptions to the prohibition to treat special categories of personal data must be authorized when established by the Law of the Union or of the Member States and provided that the appropriate guarantees are given, in order to protect personal data and other fundamental rights, when in public interest, (...)", and of recital 53, according to which: "The special categories of personal data that deserve greater protection only need to be treated with fines related to health when necessary for achieve these goals for the benefit of people

physical and of society as a whole, in particular in the context of the management of health services and systems or of social protection, including treatment (...) or for archival purposes in public interest, scientific research purposes or historical or statistical purposes, based on the Law of the Union or of the Member State that must fulfill an objective of public interest, as well as for studies carried out in public interest in the field of public health.(...).”

The fifth final provision of the LOPDGDD has added a new article 105 bis) to Law 14/1986, of April 25, general health (LGS), according to which: "The treatment of personal data in the investigation in health will be governed by the provisions of the seventeenth additional provision of the Organic Law for the Protection of Personal Data and Guarantee of Digital Rights.”

The content, uses and access to the clinical history of patients (HC) is regulated in specific regulations, specifically, in the area of Catalonia, by Law 21/2000, of 29 December, on the rights of information concerning the patient's health and autonomy, and clinical documentation, and by Law 41/2002, of November 14, basic, regulating patient autonomy and rights and obligations in matters of information and clinical documentation.

Article 16.3 of Law 41/2002, modified by the ninth final provision of the LOPDGDD, provides for access to the medical history, among others, for research purposes, in the following terms:

> "3. Access to clinical history for judicial, epidemiological, public health, research or teaching purposes is governed by the provisions of current legislation on the protection of personal data, and Law 14/1986, of 25 April, General of Health, and other rules of application in each case. Access to the clinical history for these purposes requires the preservation of the patient's personal identification data, separate from those of a clinical and healthcare nature, so that, as a general rule, anonymity is ensured, unless the patient himself has given his consent to don't separate them.
>
> The investigation cases provided for in Section 2 of the Seventeenth Additional Provision of the Organic Law on the Protection of Personal Data and Guarantee of Digital Rights are excluded.
> (…). Access to clinical history data and documents is strictly limited to the specific purposes of each case. (…)”.

Thus, Law 41/2002, which has been modified by the LOPDGDD, provides for the treatment of health data for research purposes and starts from the general rule (as already established by the patient autonomy legislation, previously in the entry into force of the RGPD and the LOPDGDD), that clinical care data and patient identification data must be treated separately, unless the patient's consent is available.

Based on this general rule, article 16.3 of Law 41/2002 itself refers to additional provision 17a, section 2, of the LOPDGDD (DA 17a), regarding the criteria applicable to the processing of health data for research purposes, to which we will refer later.

Before that, however, it should be borne in mind that, according to section 1 of DA 17a of the LOPDGDD:

> "1. Data processing related to health and

of genetic data that are regulated in the following laws and their development provisions: a) Law 14/1986, of April 25, General of Health. b) Law 31/1995, of November 8, on the Prevention of Occupational Risks. c) Law 41/2002, of November 14, basic regulation of patient autonomy and rights and obligations in the field of clinical information and documentation. d) Law 16/2003, of May 28, on cohesion and quality of the National Health System. e) Law 44/2003, of 21 November, on the organization of health professions. f) Law 14/2007, of July 3, on biomedical research. g) Law 33/2011, of October 4, General Public Health. (...).”

In other words, the processing of health data for research purposes, provided for in the regulatory framework of the State, may find coverage (they would be "protected") in different cases (art. 9.2.g), h), and) ij) RGPD), which lift the prohibition of processing data of special categories, among others, health data, and enable their processing (art. 9.1 GDPR).

This without prejudice, as we will specify below, that the same data protection regulations (RGPD and LOPDGDD), in connection with the provisions of the internal regulations, also allow the processing to be based on the consent of those affected.

Based on this premise, it is necessary to refer to the cases of data processing provided for in section 2 of DA 17a, and to the regulatory provisions on the need to obtain or not the consent of those affected.

III

According to section 2 of DA 17a of the LOPDGDD:

"2. Data processing in health research will be governed by the following criteria:

a) The interested party or, as the case may be, their legal representative may grant consent for the use of their data for the purposes of health research and, in particular, biomedicine. Such purposes may include categories related to general areas linked to a medical or research specialty.

b) The health authorities and public institutions with powers to monitor public health may carry out scientific studies without the consent of those affected in situations of exceptional relevance and seriousness for public health. c) The reuse of personal data for health and biomedical research purposes will be considered lawful and compatible when, having obtained consent for a specific purpose, the data is used for research purposes or areas related to the area in which the initial study was scientifically integrated.

In such cases, those responsible must publish the established information by article 13 of the Regulation (...).

For the treatments provided for in this letter, a favorable prior report from the research ethics committee will be required.

d) The use of pseudonymized personal data for health and, in particular, biomedical research purposes is considered lawful.

The use of pseudonymized personal data for research purposes in public and biomedical health will require: (…).”

At the outset, section 2.a) of DA 17a provides for a case in which the consent of the affected persons is the legal basis that enables the treatment of health data for research purposes (art. 6.1. a) and art. 9.2.a) RGPD).

Regarding the treatment of health data (HC data) for research purposes, the concurrence of this assumption is consistent with the patient autonomy legislation (art. 16.3 Law 41/2002), which, as has been said, it establishes as a starting point or general rule to have the consent of those affected to enable the treatment of their clinical care data together with the identification data of the HC allowing, consequently, that the affected subject be directly identifiable.

In this regard, Law 14/2007, of July 3, on biomedical research (LIB), which regulates research related to human health that involves invasive procedures, the treatment of biological samples, biobanks, the performance of genetic analyzes and the processing of personal genetic data, among others (art. 1), starts from the general rule of authorization based on the consent of those affected - the "source subjects", for the treatment of their data, although certain exceptions are allowed (art. 58.2 LIB).

In short, section 2.a) of DA 17a of the LOPDGDD, establishes that consent can be the legal basis for the treatment of health data for research purposes, in line with the provisions of the protection regulations of data (art. 6.1.a) and 9.2.a) RGPD), and sectoral regulations.

Opinion 3/2019, on "Questions and Answers on the interrelation between the regulation of clinical trials and the RGPD", of January 23, 2019, of the European Data Protection Committee (CEPD, art. 68 et seq.) is relevant . RGPD), which examines the different legal bases that can enable the processing of data in clinical trials, taking into account the specific regulations (EU Regulation 536/2014, of April 16, on clinical trials of medicinal products for human use, and Royal Decree 1090/2015, of December 4). Although the Opinion refers exclusively to clinical trials, we cannot rule out that some considerations on the possible legal bases enabling the treatment may be applicable, in more general terms, to the treatment of health data for medical or biomedical research purposes , beyond clinical trials.

In relation to consent as a legal basis for data processing (in the context of clinical trials), at the discretion of the CEPD it is necessary to start from the premise that in order to constitute a valid legal basis, the consent of those affected must be able to be given freely and must involve a real choice and control on the part of the affected subjects regarding their data (art. 4.11 RGPD). The CEPD points out that, depending on the circumstances of the trial and the participation of those affected, situations of imbalance may occur that would not allow to consider that the consent given meets the said requirements ("the participant is not in good health conditions, or belongs to economically or socially weak groups, or is in situations of hierarchical or institutional dependency"). The CEPD thus points out that in these cases consent might not be an adequate basis for the treatment, since the requirements of article 4.11 RGPD would not be correctly complied with, so it is appropriate to take into account other alternative legal bases that can enable the finger

treatment.

IV

Having said that, it must be noted that DA 17a foresees other cases in which the enabling of data processing would not be based on the consent of those affected.

Section 2.c) of DA 17a provides for the possibility of reusing personal data for health and biomedical research purposes, without the need to obtain the consent of those affected. The LOPDGDD thus enables the processing of data that would have been initially collected for a specific purpose with the consent of those affected.

The sixth transitional provision of the LOPDGDD expressly refers to this possibility of data reuse for health and biomedical research, with respect to data collected prior to the entry into force of the LOPDGDD, on the basis of consent that those affected would have provided for the initial study.

According to article 5.1.b) of the RGPD, personal data must be collected "for specific, explicit and legitimate purposes, and will not be subsequently treated in a manner incompatible with said purposes; in accordance with article 89, section 1, the further processing of personal data for archival purposes in the public interest, scientific and historical research purposes or statistical purposes will not be considered incompatible with the initial purposes ("limitation of the purpose") ;"

The authorization to be able to reuse data under the terms of DA 17a, section 2.c), is given because article 9.2.j) of the RGPD admits scientific research as a compatible purpose - in this case, the medical research-, in the terms of article 89.1 of the RGPD, without it being necessary to base the further processing of the data on the consent of those affected, as long as this is provided for by EU or State legislation .

Therefore, the assumption of section 2.c) of DA 17a, would enable "reuse", understood as a use or secondary treatment of health data for a purpose compatible with the initial purpose for which the data would have been collected, based on the provisions of article 9.2.j) of the RGPD. This, as long as those responsible inform those affected in the terms required by article 13 RGPD and section 2.c) of DA 17a, and that a favorable prior report from the corresponding ethics committee is available.

In any case, the provision of section 2.c) would be framed in the flexibility that the RGPD provides in the context of research, especially medical research (recitals 52 and 53, cited). Thus, recital 33 of the RGPD states: "It is often not possible to fully determine the purpose of the treatment of personal data for the purposes of scientific research at the time of collection. Therefore, interested parties should be allowed to give their consent for certain areas of scientific research that respect the recognized ethical standards for scientific research. Those interested must have the opportunity to give their consent only for certain areas of research or parts of research projects, to the extent that the purpose pursued allows it.

We note that the concept of "reuse" referred to in section 2.c) of DA 17a, does not seem to properly correspond to what is regulated in Law 37/2007, of November 16, on reuse of public sector information.
According to article 3.1 of Law 37/2007, reuse is understood as: "the use of documents that are in the power of public sector administrations and organizations, by natural or legal persons, with commercial or non-commercial purposes, always that said use does not constitute a public administrative activity. (...)".

According to article 3.3 of Law 37/2007, this is not applicable, among others, to:

> **"a) Documents on which there are prohibitions or limitations on the right of access pursuant to the provisions of (...) Law 19/2013, of December 9, on transparency, access to public information and good governance and the other rules that regulate the right of access or registration publicity with a specific character. b) (...) in general, documents related to actions subject to a rule of reserve, secrecy or confidentiality. c) Documents for which access requires the holder of a legitimate right or interest. (...).”**

According to article 15.1 of Law 19/2013, modified by the eleventh final provision of the LOPDGDD: "(...) If the information includes personal data that refers to racial origin, health or sexual life, includes genetic or biometric data (...), access can only be authorized if it has the express consent of the affected person or if that person is protected by a rule with the rank of law.”

Taking into account that the data of special categories (art. 9 RGPD), among others, health data (HC) and genetic data, are subject to a specific and very limited regime of access in the terms provided for in the patient autonomy legislation, the reuse of data that regulates DA 17a, will not be governed by the parameters of the reuse legislation.

Also section 2.b) of DA 17, enables the processing of data without the consent of those affected, as long as it is carried out by the health authorities and public institutions competent in public health surveillance, and only if circumstances concur of exceptional relevance and seriousness for public health.

Having said that, we note that, according to article 8.1 of the LGS: "1. It is considered a fundamental activity of the health system to carry out the necessary epidemiological studies to more effectively guide the prevention of health risks, as well as health planning and evaluation, which must be based on an organized system of health information, surveillance and epidemiologic action."

We also note that, according to article 41 of Law 33/2011, of October 4, General Public Health (LGSP):

> **"1. The health authorities in order to ensure the best protection of the health of the population may require, in the terms established in this article, reports, protocols or other documents for the purposes of health information from the health services and professionals.**
>
> **2. The Health Administrations will not need to obtain the consent of the affected persons for the treatment of personal data, related to health, as well as their transfer to other Public Health Administrations, when it is strictly necessary for the protection of the health of the population . (...).”**

In any case, this provision of the LGSP, in connection with the provision of article 16.3 of Law 41/2002, and with article 6.1.e) RGPD and article 9.2.j) RGPD, would be the legal basis that would enable the processing of health data without consent, as long as the exceptional circumstances provided for in section 2.b of DA 17a (situations of "exceptional relevance and seriousness for public health" are met) However, in those cases in which this exceptional and serious situation does not occur

understand that the studied rule does not allow to bypass the consent of those affected, in the absence of other qualification for the treatment.

v

Article 9.2, section j) of the RGPD, enables the treatment that is necessary for research purposes, in accordance with article 89.1 of the RGPD, on the basis of the Law of the Union or of the Member States .

According to article 89.1 of the RGPD:

> "1. The treatment for archival purposes in the public interest, scientific or historical research purposes or statistical purposes will be subject to adequate guarantees, in accordance with this Regulation, for the rights and liberties of the interested parties. These guarantees will require that technical and organizational measures are available, in particular to guarantee respect for the principle of minimization of personal data. Such measures may include pseudonymization, provided that in that way said ends can be achieved.
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> As long as those goals can be achieved through further processing that does not allow or no longer allows the identification of the interested parties, those goals will be achieved in that way."

Personal data must be collected for specific, explicit and legitimate purposes and cannot be subsequently processed in a manner incompatible with these purposes. The subsequent treatment is considered compatible when it has as its object archival purposes in the public interest, scientific and historical research purposes or statistical purposes, in the terms of article 89 of the RGPD on the guarantees and exceptions applicable to the treatment with those purposes, in accordance with the principle of "limitation of the purpose" (art. 5.1.b RGPD).

It is worth saying that this principle of "limitation of the purpose" links with the principle of "quality" already provided for in article 4 of the LOPD, in its aspect of the principle of purpose, which expressly established that they were not incompatible subsequent processing of data for historical, statistical or scientific purposes (art. 4.2 LOPD). In relation to this, article 89 RGPD requires compliance with the principle of minimization (art. 5.1.c) RGPD).

Therefore, the provisions mentioned in article 9.2 of the RGPD, lift the general prohibition to treat data of special categories, specifically, health data (art. 9.1 RGPD). Therefore, these provisions would enable the treatment of health data for research purposes, in the terms provided by the Law of the Union or of the Member States.

Specifically, the provision of article 9.2.j) of the RGPD enables the processing of health data for research purposes, in connection with the provisions of article 89.1 of the RGPD, not on the basis of consent of those affected, but on the basis of compliance with the provisions and measures established by the Law of the Union or of the States (DA 17a LOPDGDD).

To this it should be added that, according to recital 54 of the RGPD: "The treatment of special categories of personal data, without the consent of the interested party, may be necessary for reasons of public interest in the field of public health. This treatment must be subject to appropriate and specific measures in order to protect the rights and freedoms of individuals. (...)."

For illustrative purposes, we note that the regulatory regulations for biomedical research already provided, prior to the entry into force of the LOPDGDD, the possibility, although exceptional, of processing health data without the consent of those affected. Thus, according to article 58.2 LIB: "2. (...), exceptionally coded or identified samples may be treated for biomedical research purposes without the consent of the source subject, when obtaining said consent is not possible or represents an unreasonable effort in the sense of article 3.i) of this Law. In these cases, the favorable opinion of the corresponding Research Ethics Committee will be required (...)."

In this sense, the document "Guidelines on consent in the sense of Regulation (EU) 2016/679" (10.4.2018), of the Article 29 Working Group, analyzes among others the processing of data for the purposes of scientific research (section 7.2), and points out that:

"(...), the RGPD does not restrict the application of article 6 solely to consent in relation to the processing of data for research purposes.
As long as the adequate guarantees are present, such as the requirements contained in article 89, paragraph 1, and the treatment is fair, lawful, transparent and conforms to the rules of data minimization and individual rights, other legal bases may be available as those contemplated in article 6, section 1, letters e) of). This also applies to special categories of data in accordance with the exception contained in article 9, section 2, letter j).

According to Opinion 3/2019 of the CEPD, cited, aside from the legal basis of the treatment based on consent, other legal bases may apply that enable the processing of data in clinical trials.

On the one hand, the treatment may be lawful if it is necessary for the fulfillment of a mission carried out in the public interest, in the terms of article 6.1.e) RGPD, in connection with the provisions of article 9.2.j) of the RGPD, and in the terms established by EU or member state law (art. 6.3 RGPD). According to the CEPD: "The processing of personal data in the context of clinical trials may be considered necessary for the fulfillment of a mission carried out in the public interest, when the performance of clinical trials falls directly within the mandate, mission and tasks conferred to a public or private entity by State law".

On the other hand, for the rest of the situations in which it cannot be considered that the clinical trial is indispensible in the fulfillment of a mission carried out in the public interest by the person in charge and attributed by law, the CEPD considers that the treatment of the data could have as a legal basis the satisfaction of the legitimate interests of the person in charge or of a third party (art. 6.1.f) RGPD), in connection with article 9.2.j) of

Thus, given the applicable regulatory framework, the processing of personal data in the context of medical research may have other alternative qualifications to the legal basis of the consent of those affected which, in the context of clinical trials, Opinion 3/2019, cited, does not consider the most appropriate legal basis.

VI

Based on this, we refer below to the first question posed:

> **"1.- We can consider that the treatment of pseudonymized health data in the terms indicated in section d) of point two of the Seventeenth Additional Provision of the LOPD becomes, in relation to what is contemplated in article 9 RGPD, a base**

legitimizing the treatment of health data for the purpose of biomedical research independent of the consent of the interested party."

According to section 2.d) of DA 17a:

"d) The use of pseudonymized personal data for health and, in particular, biomedical research purposes is considered lawful.

The use of pseudonymized personal data for research purposes in public and biomedical health will require:
1.º A technical and functional separation between the research team and those who carry out the pseudonymization and keep the information that makes re-identification possible. 2.º That the pseudonymized data are only accessible to the research team when: i) There is an express commitment of confidentiality and not to carry out any

re-identification activity.
ii) Specific security measures are adopted to avoid re-identification and the access of unauthorized third parties."

It should be borne in mind that the main element that differentiates the case in section 2.d), from the other cases examined in DA 17a, is the explicit reference to the treatment of "pseudonymized" data, for health research and biomedical

At this point it is important to bear in mind that, according to Recital 26 of the RGPD:

"The principles of data protection must be applied to all information relating to an identified or identifiable natural person. Pseudonymized personal data, that could be attributed to a natural person through the use of additional information, must be considered information about an identifiable natural person. To determine whether a natural person is identifiable, all means, such as identification, that can reasonably be used by the data controller or any other person to directly or indirectly identify the natural person must be taken into account. To determine whether there is a reasonable probability that means will be used to identify a natural person, all objective factors must be taken into account, such as the costs and time required for identification, taking into account both the technology available at the time of the treatment as technological advances. Therefore, the principles of data protection should not be applied to anonymous information, that is, information that is not related to an identified or identifiable natural person, nor to data converted into anonymous data in such a way that the interested party is not identifiable, or to be Consequently, this Regulation does not affect the treatment of said anonymous information, including for statistical or research purposes."

According to article 4.5 of the RGPD, it is necessary to understand by pseudonymization: "the treatment of personal data in such a way that they can no longer be attributed to an interested party without using additional information, provided that said additional information appears separately and is subject to measures technical and organizational techniques aimed at ensuring that personal data are not attributed to an identified or identifiable natural person;"

In other words, the RGPD configures pseudonymization as an adequate guarantee for data protection (art. 6.4.e), 25.1, and 32.1.a) RGPD, among others), without excluding from the scope of the data protection regulations and pseudonymised personal information.

The principles and guarantees of data protection are fully applicable to pseudonymised data which are, for all intents and purposes, personal data. Instead, in

in relation to anonymous information - which is that which has lost all direct or indirect connection with the natural person, so that those affected are no longer identifiable - the principles and guarantees of data protection do not apply.

Section 2.d) does not make any mention of the need to have the consent of those affected, nor does it refer to another specific legal basis legitimizing the treatment (eg art. 6 and 9.2 RGPD).

However, from the moment that this regulatory provision that we are examining considers the processing of pseudonymized data lawful for health research purposes - as long as adequate guarantees are applied -, without making explicit the requirement to provide consent for part of those affected (art. 6.1.a) and 9.2.a) RGPD), in good logic, and taking into account the considerations that have been made previously, it will be necessary to understand that the legal basis that enables the treatment can, indeed, be a basis different and independent from that of consent.

Thus, as has been explained, the data protection regulations do not require that, in relation to special categories of data, the legal basis must necessarily be consent. Not only that, but, as can be seen from the aforementioned documents of the CEPD (formerly Article 29 Working Group), as long as the appropriate guarantees are applied to the treatment, in certain cases it might even be more appropriate to base the processing of health data for medical research purposes on other legal bases other than the consent of those affected.

The processing of pseudonymized data for biomedical research purposes (section 2.d) of DA 17a), may find sufficient qualification based on the provisions of article 9.2, section j), in connection with article 89.1, of the RGPD.

For all the above, article 9.2.j) of the RGPD would enable the processing of special categories of data, no longer on the basis of the consent of those affected but on the basis of the law of the Member States, specifically, DA 17a of the LOPDGDD, in relation to the treatment of health data for research purposes.

In connection with this, and regarding the second question asked:

> **2.- If so, can we interpret that when pseudonymized health data are treated in the terms indicated in section d) of point two of the Seventeenth Additional Provision of the LOPD, it is not necessary to obtain the consent of the interested party?"**

It should be borne in mind that the enabling of data processing based on article 9.2.j), in connection with article 89.1, both of the RGPD, is independent of other legal bases, specifically, the consent of the affected (art. 6.1.a) and 9.2.a) RGPD).

As has been explained, and in line with the considerations of Opinion 3/2019, the processing of data for research purposes may be lawful if it is necessary for the fulfillment of a mission carried out in the public interest or in the exercise of public powers of the controller (Article 6.1.e) RGPD), or also if it is necessary to satisfy the legitimate interests of the controller or a third party (Article 6.1.f) RGPD).

Taking this into account, in the cases where these legal bases provided for in article 6.1 of the RGPD, sections e) and f), the processing of pseudonymized data for research purposes provided for in section 2.d) of the From 17th, it will be enabled, taking into account the capabilities of article 9.2.j) of the RGPD, without it being essential to have the consent of those affected.

As a logical consequence of what has been explained, it must be concluded that in relation to the treatment of pseudonymised data for health and biomedical research purposes (section 2.d) DA 17a) LOPDGDD), given that another legal basis may apply enabler of the treatment other than the consent of those affected, in cases where this is the case it would not be essential to have the consent of those affected to carry out the treatment subject to consultation.

VII

The legality for the use of pseudonymized data for research purposes without the consent of those affected necessarily requires compliance with the measures established by the RGPD, especially article 9.2.j), in connection with article 89.1 of the 'RGPD.

The person in charge of the treatment must articulate the technical and organizational measures that are necessary in order to ensure the lawfulness of the treatment of health data, in the terms required by article 9.2.j) and 89.1 of the RGPD, taking into account recital 53 of the RGPD, according to which: "(...). The Law of the Union or Member States must establish specific and adequate measures to protect the fundamental rights and personal data of individuals. Member States must be empowered to maintain or introduce other conditions, including limitations, with respect to the treatment of genetic data, biometric data or health-related data. However, this should not be an obstacle to the free circulation of personal data within the Union when such conditions apply to the cross-border processing of those data."

Thus, even in the case that the purpose of a treatment can be considered specific to research in the field of health and that the treatment falls under the assumption of article 2.d), object of consultation, the compatibility provided for in article 89 of the RGPD does not act automatically but is subject to the adoption by the controller of the appropriate guarantees to ensure the protection of personal data.

According to recital 28 of the RGPD: "The application of pseudonymization to personal data can reduce the risks for the affected parties and help those responsible and those responsible for the treatment to fulfill their data protection obligations. So, the explicit introduction of "pseudonymization" in this Regulation does not intend to exclude any other measures related to data protection."

Since the authorization for the treatment of article 9.2j) refers to the provisions of the law of the States, the person responsible for the treatment must comply, in particular, and without prejudice to the necessary application of other measures, to the requirements which specifies DA 17a of the LOPDGDD.

Specifically, the case provided for in DA 17a, section d) of the LOPDGDD, requires the following:

"1.º A technical and functional separation between the research team and those who carry out the pseudonymization and keep the information that makes re-identification possible. 2.º That the pseudonymized data are only accessible to the research team when: i) There is an express commitment of confidentiality and not to carry out any

re-identification activity.

ii) Specific security measures are adopted to avoid re-identification and access by unauthorized third parties.

> **The re-identification of the data at its origin may be carried out, when due to an investigation that uses pseudonymized data, the existence of a real and concrete danger to the safety or health of a person or group of persons is appreciated, or a serious threat para sus derechos or necessary to guarantee adequate health care."**

In addition, special attention must be paid to section 2.f) of DA 17a of the LOPDGGD, according to which:

> **"f) When, in accordance with the provisions of article 89 of Regulation (EU) 2016/679, a treatment is carried out for the purposes of public health research and, in particular, biomedical research, it will proceed to: 1.º Carry out an evaluation of impact that determines the risks derived from the treatment in the cases provided for in article 35 of Regulation (EU) 2016/679 or in those established by the control authority. This evaluation will specifically include the risks of re-identification linked to the anonymization or pseudonymization of the data. 2. To submit scientific research to quality standards and, where applicable, to international guidelines on good clinical practice. 3.º Adopt, where appropriate, measures aimed at guaranteeing that researchers do not access identification data of the interested parties. 4. To appoint a legal representative established in the European Union, in accordance with article 74 of Regulation (EU) 536/2014, if the promoter of a clinical trial is not established in the European Union. Said legal representative may coincide with that provided for in article 27.1 of Regulation (EU) 2016/679."**

Therefore, in relation to the case of treatment provided for in section 2.d) of DA 17a, the subject of consultation, and in addition to complying with the rest of the principles and obligations of the data protection regulations, it is necessary to realizing the need to carry out an impact assessment in the terms provided for in article 35 of the RGPD, before proceeding with the pseudonymisation of the data for its treatment for biomedical research purposes, subject to consultation.

In this sense, we refer to the document of: "Guidelines on the impact evaluation relative to data protection (EIPD) and to determine if the treatment "probably entails a high risk" for the purposes of Regulation (EU) 2016/679" , of October 4, 2017, of the Article 29 Working Group.

We also agree that, in relation to the assumption of section 2.d) of DA 17a, it is necessary to take into account section g) thereof, according to which:

> **"g) The use of pseudonymized personal data for the purposes of public health and, in particular, biomedical research must be subject to the prior report of the research ethics committee provided for in the sector regulations.**
>
> **In the absence of the aforementioned Committee, the entity responsible for the investigation will require a prior report from the data protection delegate or, failing that, from an expert with previous knowledge in article 37.5 of Regulation (EU) 2016/679. "**

For all the above, in relation to the treatment of pseudonymized data for research purposes (DA 17a, section 2.d) LOPDGDD), the person in charge of the treatment must articulate the technical and organizational measures necessary to guarantee, among d others, respect for the principle of minimization of personal data and to avoid the risk of re-identification of the information in the terms provided for in the RGPD and, given the reference to the law of the States, in DA 17a, section 2,d) f) ig) of the LOPDGDD.

This, without prejudice to the other measures that are necessary based on the characteristics of the treatment. In this sense, it must be noted that the RGPD sets up a security system that is no longer based on the basic, medium and high security levels that were provided for in the Regulation for the deployment of the LOPD, approved by Royal Decree 1720/2007 , of December 21 (RLOPD), but by determining, based on the characteristics of the treatment and a prior risk analysis, which security measures are necessary in each case (recital 83 and article 32 RGPD).

In accordance with the considerations made in this opinion in relation to the query raised, the following are made,

Conclusions

The treatment of pseudonymized data for biomedical research purposes (section 2.d) of DA 17a), may find sufficient authorization in legal bases other than consent (article 6.1, sections e) and if), and article 9.2, section j), in connection with article 89.1 RGPD). When the circumstances provided for in section 2.d) of DA 17a of the LOPDGDD occur, the consent of those affected will not be essential to carry out the processing of pseudonymized health data.

The person responsible for the treatment must have the necessary technical and organizational measures, in the terms derived from the regulations (articles 9.2.j), 89.1 and 32 RGPD). Among others, it must comply with the requirements provided for in sections 2.d), f) ig) of DA 17a of the LOPDGDD.

Barcelona, May 14, 2019