CNS 1/2022

Opinion in relation to the consultation of a health research foundation on the creation of a database of dependence and chronicity at county level, analysis and structuring of the data, and on the dissemination of the results with the aim of make them available to the regional business fabric

A letter from a foundation in the field of health research (hereinafter, the Foundation) is presented to the Catalan Data Protection Authority on the creation of a database of dependence and chronicity at county level , analysis and structuring of the data and dissemination of the results with the aim of making them available to the regional business fabric.

The query is accompanied by a copy of the document "Technical report..." (hereinafter, Project report), which includes information about the project, the entities involved, the work plan and the planned operations, among others.

The consultation explains that the Foundation participates in the Project (...), which sets out the characterization of the main problems and needs around dependency and the chronicity of diseases, at the level of the region.

The consultation adds that the Project is structured in a work plan that determines the carrying out of specific activities at each of the participating entities, and that the activity assigned to the Foundation is the development of a statistics laboratory and analysis of dependence and chronicity at county level.

Given that, according to the query, this entails the processing of personal data, an opinion is requested from this Authority on the legality of the processing of this data by the Foundation.

Having analyzed the request and the attached documentation, in view of the current applicable regulations, and the report of the Legal Counsel, the following is ruled.

I

(...)

II

(...).

The Report accompanying the consultation foresees the participation of different entities in the development of the Project (specified in section 4), which will carry out different operations (section 7).

The query refers exclusively to the operation that, within the Project (...), the Foundation must carry out, and not to the activities or operations that would correspond, according to the Report, to other Project participants.

(...).

According to the consultation, the activity assigned to the Foundation is the creation of a statistical laboratory and analysis of dependence and chronicity at county level, and the dissemination of the results with the aim of making them available to the fabric regional business

Specifically, the consultation asks the following questions:

> **"A)** Lawfulness of the processing of the personal data indicated for the creation of the database of dependency and chronicity (...). The ways determined to guarantee the lawfulness of the processing of personal data are considered valid (on the one hand, obtaining the consent of the interested parties and on the other the development of the database within the framework of a project biomedical research)? Is there any other legal basis other than those proposed that also allows the processing of data to be legitimized?
>
> **B)** Regarding the second phase of the Project, which consists of making available to the business fabric of the region (...) the information contained in the dependency and chronicity database in a completely anonymized and aggregated format, Is there any drawback or limitation from the point of view of the legislation on the protection of personal data? In any case, what guarantees and/or safeguards should be adopted to consider that the treatment is carried out lawfully?"

Therefore, this opinion refers to the questions raised in the consultation, in relation to the specific case being raised.

Based on the consultation in these terms, it is necessary to start from the basis that according to article 4.1 of Regulation (EU) 2016/679, of April 27, general data protection (RGPD), are personal data *"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, will be considered an identifiable natural person, como por ejemplo a number, an identification number, location data, an online identifier or one or several elements of the physical, physiological, genetic, psychological, economic, cultural or social identity of said person;*

The processing of data of identified or identifiable natural persons that is carried out in relation to the Project, and, more specifically, the processing of data that leads to term the Foundation, is subject to the principles and guarantees of the personal data protection regulations (RGPD, and Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights (LOPDGDD)).

III

At the outset, it should be noted that section 7.5 of the Report identifies the Foundation as a "responsible" for this operation, (...).

The processing of personal data must have a person in charge, who is responsible for determining the purposes and means of the processing, and who assumes a series of obligations and responsibilities regarding the processing that is carried out (art. 4.7 RGPD).

According to the query: "For the creation of the dependency and chronicity database, it will be necessary to integrate personal, health and care-related data into a single file

social, which are dealt with under the responsibility of several entities, most of them participants (in the project). (...). It is therefore personal data generated during the provision of health and/or social assistance services."

That is to say, based on the information available, the Foundation would carry out the processing of data from various entities in the field of health and social care in Catalonia.

Given the provisions of the data protection regulations, a model of responsibility cannot be ruled out through which one or several persons in charge entrust a data controller with carrying out a certain treatment (art. 4.8 RGPD).
It could be the case of the different entities that participate in the Project that, as responsible parties, could entrust, under the terms of Article 28 RGPD, the processing of data to carry out a research study to a third party (the person in charge), which in this case would be the Foundation. According to the regulations, those responsible can also establish a model of co-responsibility to carry out the treatment, which in any case would require the signing of an agreement that clearly determines the respective functions and relationships of the co-responsibles in relation to the affected (art. 26 RGPD).

In any case, given the lack of concreteness of these issues in the documentation provided, for the elaboration of this opinion it will be based on the basis that the Foundation would be responsible for the treatment on which the consultation is carried out.

IV

From the information provided it seems clear that the collection and processing of the information which will be carried out by the Foundation obeys a research purpose in the field of health and social care.

The data protection regulations establish that personal data must be treated lawfully, loyally and transparently in relation to the interested party (principle of legality, loyalty and transparency (art. 5.1.a) RGPD)).

To be lawful, the processing of personal data must have a legal basis adequate (art. 6.1 RGPD). Among others, the processing of data may be lawful if the consent of the affected is available (art. 6.1.a) RGPD), or 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).

As this Authority has agreed, among others, in Opinions CNS 15/2019 and CNS 18/2019, the RGPD supports the processing of special categories of data for the development of research, particularly in the health field , with some flexibility, as can be seen, among others, from recital 52 RGPD, which refers to "(...) archival purposes in the public interest, scientific or historical research purposes or statistical purposes, based on the Law of the Union or 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. (...)."

In this sense, according to article 5.1.b) RGPD: "the subsequent treatment of personal data for archival purposes in public interest, scientific and historical research purposes or statistical purposes will not be considered incompatible with the initial purposes".

According to article 89 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. As long as those purposes can be achieved through further processing that does not allow or no longer allows the identification of the interested parties, those purposes will be achieved in that way.

(...)."

In the case at hand, it seems clear that the legal bases provided for in article 6.1.a can be applied (in the event that the express consent of the affected persons is counted or, given the functions of the Foundation, the one provided for in article 6.1.e) (in the event that the research is part of the research mandated by a standard with the rank of law) or that provided for in article 6.1.f) given the prevalence of the legitimate interest of the Foundation in carrying out research activity for the health and social care system.

However, according to the information provided, the personal information that the Foundation would process could refer, in large part, to special category data, such as health data processed by health and social entities.

These data, as well as others relating to different aspects of the affected persons that are information of special categories, related to situations of dependency and chronicity of these persons, are subject to a special protection regime in the RGPD (art. 4.15 and art. 9.1 RGPD), and also to the patient autonomy legislation, to which we refer (Law 21/2000, of December 29, on the rights of information concerning the patient's health and autonomy , and clinical documentation, and Law 41/2002, of November 14, basic regulation of patient autonomy and rights and obligations in the field of information and clinical documentation).

For this reason, in addition to the concurrence of some of the legal bases of article 6 to which we have referred, it is necessary to comply with the provisions of article 9 of the RGPD.
According to this article, the special categories of data cannot in principle be the subject of treatment (art. 9.1 RGPD), unless one of the circumstances of article 9.2 RGPD occurs, which can enable the treatment.

The consultation considers that there are two ways that would allow the desired processing of personal data to be carried out in compliance with current regulations:

-On the one hand, with the prior and express obtaining of the consent of all interested parties in respect of whom it is intended to use their data, having received, in advance, all the information required by articles 13 and 14 RGPD.

-The other possibility that is contemplated to legitimize the processing of personal data necessary to create the database of dependence and chronicity .... is to develop this database within the framework of a biomedical research project, given that its content has an undeniable scientific value. In this framework, we consider that based on what is established in article 9.2j RGPD, (...)."

Based on the information available, the aforementioned database would be set up for the purpose of research on the dependency and chronicity situation of people cared for by health or social services in the region.

According to the RGPD, the processing of personal data for the purposes of scientific research would include "studies carried out in the public interest in the field of public health. (...)" (recital 159). Recital 54 of the RGPD adds that "The treatment of special categories of personal data, without the consent of the interested party, can be necessary for reasons of public interest in the field of public health. (…)."

Given that, as we have seen, the treatment would affect special categories of data, it is necessary to refer to two of the exceptions provided for in article 9.2 RGPD, which could enable the treatment for research purposes:

"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 Member States establishes that the prohibition mentioned in section 1 cannot be lifted by the interested party;

(…)

j) **the treatment is necessary for archival purposes in the public interest, scientific or historical research purposes or statistical purposes,** in accordance with article 89, paragraph 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 appropriate and specific measures to protect the fundamental interests and rights of the interested party.".

Given the purpose of research in the field of health, it will also be necessary to take into account article 105 bis) of Law 14/1986, of April 25, general health (LGS), according to which: "The treatment of personal data in health research will be governed by the provisions of the seventeenth additional provision of the Organic Law on the Protection of Personal Data and Guarantee of Digital Rights."

Article 16.3 of Law 41/2002, modified by the ninth final provision of the LOPDGDD, provides for access to medical records, among others, for research purposes. establish, as a general rule, it is necessary to ensure the anonymity of the information (separating the patient's identification data from the clinical care data, unless the patient himself has given his consent), and the cases provided for in section 2 of the provision additional 17a of the LOPDGDD (DA 17a).

The second section of additional provision 17a of the LOPDGDD establishes the following::

"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 cover related categories with 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 yes
scientifically integrate the initial study.

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 is considered **lawful** of research in health and, in particular, biomedical.

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

In the legal foundations that follow, the different cases provided for in this section of additional provision 17a will be analyzed, and in a special way the cases provided for in letters a) and d) to which the consultation expressly refers.

v

Section 2.a) of DA 17a provides that obtaining the consent of the affected persons, which must be explicit, can be an adequate legal basis for processing health data for research purposes, in accordance with the amended regulatory provisions (arts. 6.1.a) and 9.2.a) RGPD, in connection with art. 16.3 Law 41/2002).

In accordance with letter a) of section two of DA 17a:

"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."

Thus, as the consultation points out, the explicit consent of the affected persons could, indeed, be an authorization for the processing of data in the case examined, without prejudice to the fact that it may also be one of the other cases provided for in DA 17a of l 'LOPDGDD, which we will analyze later.

With regard to consent as a legal basis, it should be remembered that, in order to constitute a valid legal basis, it must be specific, unequivocal, informed and freely given (art. 4.11 RGPD). In addition, in the case of special categories of data, it must be explicit (art. 9.2.a)). In other words, it must involve a conscious and free choice and must allow real control by those affected with respect to their data.

Regarding this, as this Authority has agreed in Opinion CNS 15/2019 that mentions the consultation itself, the European Data Protection Committee (ECPD), examines in Opinion 3/2019 "Questions and Answers on the interrelationship between the regulation of clinical trials and the RGPD”, the different legal bases in the context of clinical trials. Although the treatment we are dealing with does not refer to a clinical trial, the CEPD's considerations on this matter may be equally applicable, since "operation 5" of the Project is also located in a context of health data treatment with research purposes in the field of health and social assistance.

In this sense, the person responsible or persons responsible for the treatment subject to consultation must to take into account, when basing the treatment on the explicit consent of the affected persons if, depending on the profile of the affected persons, and their level of participation in the Project (taking into account that the Report mentions that their active participation is intended, without further specification), they can produce -situations of imbalance that would not allow to consider that the consent fulfills with the requirements of the RGPD.

Specifically, it should be borne in mind that the processing of data and the Project focuses its attention on a specific sector of the population (dependent people, due to age, health reasons or other circumstances, as well as people suffering from chronic situations of certain diseases or vulnerabilities).

In addition, although the Project mentions the aging of the population as "the main risk factor for the appearance and development of the vast majority of chronic diseases" (for example, section 1 Report), given the information available, and taking into account that neither the chronicity of diseases nor dependence are linked solely to elderly people, we cannot rule out that it is planned to treat data from minors. In this case, it is necessary to take into account the regulatory provisions relating to the provision of consent by the minors themselves, if applicable, as this Authority has highlighted (for example, in Opinion CNS 41/2020).

In conclusion, the explicit consent of those affected can enable the treatment of the data that are necessary and suitable for the purpose provided that the consent meets the requirements of article 4.11, 7 and 9.1 RGPD. This, apart from complying with the rest of the principles and guarantees of the protection regulations data, in particular, the duty of information, to which the query refers (arts. 12 to 14 RGPD).

In addition, given that the query points out that the study could be located "within the framework of a biomedical research project", it must also be taken into account that, if it is biomedical research, it will also be necessary to take into account the forecasts established by the specific regulations for biomedical research (Law 14/2007, of July 3, on biomedical research (LIB).

In any case, and before analyzing other authorizations for data processing, it should be noted that, although the processing may be based on the consent of those affected, this must not necessarily lead to the use of personal data of the affected, which allow their direct or indirect identification without disproportionate effort. In this sense, the figure of pseudonymization (art. 4.5 RGPD), to which we will refer in detail in the following legal basis, can be an effective guarantee to reduce the risks for the people affected and for the Foundation itself and the staff involved.

Thus, from the perspective of data protection regulations, it is recommended that, even though the Foundation has the consent of those affected as a qualification to carry out the research, the possibility of carrying out the research with the pseudonymised information, in terms that guarantee its security and the impossibility of to re-identify those affected, a matter to which we will refer later. This recommendation would fall within what the RGPD defines as privacy by design (e.g. art. 25 RGPD):

"1. Taking into account the state of the art, the cost of the application and the nature, scope, context and purposes of the treatment, as well as the risks of varying probability and seriousness that the treatment entails for the rights and freedoms of people physical, the person in charge of the treatment will apply, both at the time of determining the means of treatment and at the time of the treatment itself, appropriate technical and organizational measures, such as pseudonymization, designed to effectively apply the principles of data protection, as the minimization of data, and to integrate the necessary guarantees in the treatment, in order to fulfill the requirements of this Regulation and protect the rights of those interested."

Having an authorization based on the consent of those affected, must not be incompatible with the incorporation of the pseudonymization of the personal information that will be the object of treatment, given that this mechanism supposes, per se, a greater protection and guarantee for the privacy of those affected. Especially in those cases, such as health research, in which the processing of data from special categories and vulnerable groups is envisaged, as is the case at hand.

Finally, in relation to consent as a legal basis for enabling treatment in the context of health or biomedical research, and given that the query also asks if there are other legal bases that can enable treatment, we refer to
this point in the provision of DA 17a, section 2.c) of the LOPDGDD:

"c) The reuse of personal data for health and biomedical research purposes will be considered lawful and compatible when, having obtained the consent for a specific purpose, the data are used for purposes or research areas related to the area in which the initial study was scientifically integrated."

This provision includes the possibility of reusing personal data for health and biomedical research purposes, without the need to obtain the consent of
affected persons, when it has already been obtained initially for a study or an area of research related to the study that is now to be carried out.

However, from the information available regarding the origin of the data, it seems that the initial purpose of the data processing that the Foundation will deal with would be primarily a health and social assistance purpose, and not a research purpose . Therefore, if this is the case, the treatment subject to consultation that the Foundation will carry out would not fall under the assumption referred to in section 2.c) of DA 17a) of the LOPDGDD.

Therefore, in the case described in the inquiry, the research could be based on letter a) of DA 17a) but, in principle, it does not seem that it can be based on letter c) of this same section.

VI

Apart from the possible authorization based on consent, reference should also be made to the possibility provided for in letter d) section 2 of DA 17a of the LOPDGDD, in relation to article 9.2.j) of the RGPD .

According to this letter d), "The use of pseudonymized personal data for the purposes of health and, in particular, biomedical research will be considered lawful."

In this sense, recital 26 of the RGPD expressly refers to pseudonymization in the following terms: "The principles of data protection must be applied to all information relating to an identified or identifiable natural person. Pseudonymized personal data, which could be attributed to a natural person through the use of additional information, must be considered information about an identifiable natural person. (…)."

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;"

It should be noted that the RGPD configures pseudonymization as an adequate guarantee for data protection (art. 6.4.e), 9.2.j), 89, 25.1, and 32.1.a)), understanding that the information pseudonymized remains personal information. Therefore, the principles and guarantees of data protection are fully applicable to pseudonymised data which is, for all intents and purposes, personal data.

However, the authorization provided for in this letter only operates if the treatment is carried out under certain conditions:

"The use of pseudonymized personal data for the purposes of public health and biomedical research 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 y the access of unauthorized third parties."

As has been said, the RGPD configures pseudonymization as an adequate guarantee for data protection (recital 26, art. 4.5, art. 6.4.e), 9.2.j), 89, 25.1, and 32.1. a)
RGPD), although it should be noted that pseudonymised information remains personal information. Therefore, the principles and guarantees of data protection are fully applicable to pseudonymised data which is, for all intents and purposes, personal data.

According to the consultation, the completion of the first phase of the Project, which consists in the creation of the dependency and chronicity database, "implies that for the achievement of the purpose pursued and in order to avoid duplication in the data , the database cannot be integrated directly with anonymized data, (...)."

If this is the case, that is to say, that data processing by the Foundation cannot be carried out with information previously anonymized by the entities of origin (a matter on which no further information is available), the provision of section 2.d) of DA 17a) could be sufficient authorization for the processing of data by of the Foundation.

However, given that the principles and guarantees of the data protection regulations are fully applicable to pseudonymized information, the Foundation must ensure proper compliance with the requirements of section 2.d) of DA 17, which they aim to avoid the unauthorized reversal of pseudonymisation and improper access to the information of those affected.

Therefore, for the purposes of considering applicable the authorization provided for in section 2.d) of DA 17a, of the LOPDGDD, it is necessary to determine already in the design of the project (art. 25 RGPD), how it will be carried out the pseudonymization, so that the treatment object of inquiry is adjusted to the requirements of the RGPD (principle of proactive responsibility, ex. art. 5.2 RGPD).

In application of the conditions imposed by section 2.d) of Day 17a (technical and functional separation), it is important to bear in mind that the pseudonymization process of personal information cannot be carried out by the Foundation itself, but which must have been carried out prior to the communication of information to the Foundation. In other words, the Foundation should receive the already pseudonymised personal information from the entities that have this information and are responsible for it.

It will also be necessary to articulate measures so that the people who, from the Foundation, have to process the information, cannot re-identify the affected people, and to avoid improper communications of personal information outside the intended research purpose. The systems that are used to pseudonymize the information at source, will have
to be effective enough to prevent re-identification, not only by the people who will carry out the study at the Foundation, but by any third party, even after the conclusion of the study.

It should be noted that the risk of re-identification clearly increases in the event that the pseudonymization or coding system is not sufficiently secure, or when it is reversible without disproportionate efforts to be predictable. It would be that the attribution of a code at source, which replaces the personal data of the affected person (name and surname, DNI, CIP number, etc.), does not allow the people who will carry out the research or any other third party , can identify it, at least, without disproportionate effort.

Therefore, it is advisable to use random codes without any link to any data directly or indirectly linked to the person, but which at the same time allow the traceability of information about the same individual, if applicable, to make the study viable.

Apart from this, it would be necessary to foresee commitments of confidentiality and non-re-identification on the part of the staff who will handle the pseudonymised information or, among others, the commitment of these staff to immediately communicate the cases in which it is detected that there may be a risk of identification, or any improper access, so that the appropriate measures can be taken.

Apart from this, remember that if the study is carried out under the provisions of letter d) of section 2 of DA 17, the person in charge must take into account letter g)
of this same section, which, in this case, requires the treatment of pseudonymized data for health and biomedical research purposes to be submitted to a prior report by the corresponding ethics committee or, in its absence, by the data protection delegate data of the person in charge.

Finally, and without prejudice to the considerations made in relation to the authorizations for the treatment of health data for research purposes, we note that, according to

section 7.5 of the Report, one of the first actions that must be carried out is the "Identification and definition of the **essential data to carry out the project."**

In relation to this, we agree that the personal data processed by the Foundation, coming from various entities, must be only those necessary to carry out the study to which the query refers. That is to say, without prejudice to the concurrence of sufficient authorization for the treatment to which the query refers, in the terms indicated, it must be agreed that this treatment must necessarily be adjusted to the
principle of minimization, according to which the data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (art. 5.1.c) RGPD).

VII

Without prejudice to the authorization for the processing of personal data for health or biomedical research purposes in the terms indicated from what is provided for in letters a) and) of section 2 of DA 17a, it is necessary to have taking into account that the same DA 17a, establishes a series of guarantees or common requirements that will have to be applied in both cases.

Aside from the possible effects on the rights of those affected, in accordance with what is provided for in section 2.e) DA 17a), to which we refer, letter f) requires the completion of an impact assessment on the terms of article 35 of the RGPD.

According to article 35 of the RGPD:

> *"1. When it is likely that a type of treatment, **in particular if it uses new technologies,** by its nature, scope, context or purposes, entails a high risk for the rights and freedoms of physical persons, the person responsible for the treatment will, before the treatment, an **evaluation of the impact of the processing operations on the protection of personal data.** A single evaluation may address a series of similar treatment operations that involve similar high risks.*
>
> *2. The data controller will seek the advice of the data protection officer, if appointed, when carrying out the data protection impact assessment.*
>
> *3. The impact assessment related to the protection of the data referred to section 1 will be required in particular in case of:*
>
> *(…)*
> *b) **large-scale processing of the special categories of data** referred to in article 9, paragraph 1, or of personal data relating to convictions and criminal offenses referred to in article 10, or*
> *(...)."*

Initially, the Foundation will deal with information from special categories of data (health information, among others), and information relating to natural persons who may find themselves in vulnerable situations, given their particular situation of dependency and chronicity .

In addition, according to the available information, the use of new information processing technologies is planned, specifically "big-data and data analytics techniques, development of different strategies for analyzing complex data and managing large data bases health and social data, for the development of algorithms, machine learning or artificial intelligence around health and social knowledge and impact on the territory." (section 15) Report).

The fact that it is specifically planned to use techniques such as big data or intelligence artificial in relation to the processing of personal data may pose a higher risk for those affected.

According to article 28.1 of the LOPDGDD, those responsible must assess the need to carry out an impact assessment. According to paragraph 2 of the same article 28:

> *"2. For the adoption of the measures referred to in the previous section, those responsible and responsible for the treatment will take into account, in particular, the greater risks that could occur in the following cases:*
>
> *(...)*
> *c) When the treatment is not merely incidental or accessory to them special categories of data referred to in articles 9 and 10 of Regulation (EU) 2016/679 and 9 and 10 of this organic law or data related to the commission of administrative infractions.*
> *(...)*
> *e) When data processing is carried out for groups of affected persons in a situation of special vulnerability and, in particular, for minors and persons with disabilities.*
>
> *f) When there is a massive treatment that involves a large number of affected or entails the collection of a large amount of personal data.*
> *(...)."*

On the other hand, Article 35.4 of the RGPD provides that the control authorities must publish a list of the types of processing operations that require an impact assessment related to data protection. If we follow the *"List of types of data processing that require an impact assessment related to data protection",* which is available on the website: www.apdcat.cat, it is clear that different elements are involved, in the case considered, which lead to the need to carry out an impact assessment (treatment of special categories of data, in particular, the use of genetic data - which cannot be ruled out given the available information-, data processing of vulnerable people,
treatment of a large amount of information, or use of new technologies, or an innovative use of established technologies that may pose a risk to people's rights and freedoms).

Taking into account these forecasts, and given the information available in the case at hand, it is clear that different elements concur (art. 35, sections 1 and 3 RGPD, art. 28 LOPDGDD and DA 17a) that can lead to the need to carry out an assessment of impact in the terms of article 35 RGPD.

We refer, on this, to the document *"Guidelines on 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 the Article 29 Working Group, as well as the *"Practical Guide on the impact assessment relating to data protection",* of the Authority, available on the Authority's website.

In any case remember that the obligation to make an AIPD is independent of the obligation to make a risk analysis from the point of view strictly of the security of the treatment, which also derives from the RGPD. Regarding this, remember that the RGPD sets up a security system that is based on determining, based on the characteristics of the treatment and a prior risk assessment, which security measures are necessary in each case (Recital 83 and Article 32 RGPD).

Therefore, by application of the provisions of the personal data protection regulations (articles 24 and 32 RGPD), it is required to prepare an analysis and assessment of the risks involved in the processing of data, which aims to determine the technical and organizational measures that must be applied by those responsible and in charge of the treatment (eg art. 28.3.c) RGPD).

From the point of view of information security, a risk analysis requires identifying threats (for example, unauthorized access to personal data that is necessary to process for the purpose pursued), assessing what is the probability that this occurs and the impact it would have on the people affected. The type of risk and, in short, its probability and severity, varies according to the types of treatment, the nature of the data being treated, the number of people affected, the amount and variety of treatments, the technologies used, etc. And in the case of public sector entities, as would be the case of the Foundation, the National Security Scheme (ENS) must be taken into account, in accordance with the first additional provision of the LOPDGDD.

VIII

The Foundation also asks if ***"there is any legal basis other than those proposed*** *that also allows the processing of data to be legitimized."*

At the outset, it has already been mentioned that, taking into account the type of data that, according to the query, would be the object of treatment, the authorizations of article 9.2, sections a) oj) RGPD could be applicable in relation to letters a) and) of the second section of DA 17a.

As has also been done before, the enabling of letter c) of the aforementioned second section of DA 17a, does not seem applicable in the case examined.

Apart from this, section 2.b) of DA 17a LOPDGGD, provides the following: *"b) Health authorities and public institutions with competences in monitoring public health may carry out scientific studies without the consent of those affected*
in situations of exceptional relevance and seriousness for public health."

Based on the information available, data processing would be carried out by an entity in the field of research, such as the Foundation. On the other hand, the provision of section 2.b) is applicable when the treatment is carried out by the competent public administrations in matters of public health surveillance (in the terms of Law 18/2009, of 22 October, of public health), which would not be the case.

In addition, from the information available, it does not appear that the element of exceptionality and urgency required by this regulatory provision to enable a health research study is met in the case examined.

Therefore, the provision of this section 2.b) of DA 17a, would not enable the treatment subject to consultation.

IX

In this Legal Basis we will refer to the second question posed:

"B) Regarding the second phase of the Project, which consists of making available to the business fabric of the region (...) the information contained in the database of the dependence and chronicity (...) in a completely anonymized and aggregated format, there is some inconvenience or limitation from the point of view of data protection legislation personal? In any case, what guarantees and/or safeguards should be adopted to consider that the treatment is carried out lawfully?"

As the consultation explains, this phase of the project would consist of communicating, solely, anonymised and aggregated information, which would be made available to the business fabric of the region.

Taking this into account, as recital 159 of the GDPR states:

"(...). To comply with the specifics of the processing of personal data for scientific research purposes, ***specific conditions must apply, in particular, regarding the publication or other type of communication*** *of personal data in the context of scientific research purposes. If the result of scientific research, particularly in the field of health, justifies other measures for the benefit of the interested party, the general rules of this Regulation must be applied taking these measures into account."*

By application of the principle of minimization (art. 5.1.c) RGPD), the communication of information on the results of the operation in question must be the minimum necessary to achieve the intended objective.

At the outset, if we adhere to the provisions of the aforementioned regulations regarding the treatment of health data for research purposes (art. 16.3 Law 41/2002), it is clear that the publication of medical research results, given the processed information, must not allow the identification of those affected, unless they have their consent.

The query refers to the development of the database, object of query, within the framework of a biomedical research project.

In line with the provision of article 16.3 Law 41/2002, and in the specific field of biomedical research, it must also be taken into account that the LIB establishes the need to guarantee the right to the privacy and data protection of the persons holding the information in the field of biomedical research, and to ensure its confidentiality (art. 5 LIB, to which we refer).

Specifically, and with regard to the dissemination of the results of biomedical research studies, according to article 5.5 of the LIB:

> "If it were not possible to publish the results of an investigation without identifying the person who participated in it or who provided biological samples, such results can only be published when the prior and express consent of that person has been mediated."

Therefore, unless the consent of those affected is available, the regulations do not allow the publication or dissemination of results of research in the field of health, with identification of the affected And this also includes pseudonymised data, which for all intents and purposes remains personal data.

On the other hand, 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 the protection of data This consideration may extend to aggregate information, which would not allow
nor the link with identified or identifiable natural persons.

Therefore, for the purposes of the question posed, and given the information available, in principle the communication of the results of the operation carried out by the Foundation to the business fabric of the region, specifically, of solely anonymized or aggregated information, it would not be contrary to data protection regulations.

Regarding this, we remember that, according to recital 26 of the RGPD: "(...). 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."

Now, as this Authority has done (among others, in Opinions CNS 34/2014 and CNS 20/2015, relating to the VISC + Project), from the perspective of data protection, even in the case of anonymization of the personal information subject to treatment, it is necessary to take into account the possibilities that this information may allow the identification of its owner.

This has been highlighted by the GTA 29 in its Opinion 5/2014, on anonymization techniques, in which it states the following: "(...) those responsible for the treatment must be aware that a set of anonymized data may still carry residual risks for those interested. Effectively, on the one hand, anonymization and re-identification are active research fields in which new discoveries are regularly published and, on the other hand, even anonymized data, such as statistics, can be used to enrich existing profiles of people, with the consequent creation of new data protection problems. In short, anonymization should not be seen as a sporadic procedure, and those responsible for data processing must regularly evaluate existing risks."

The risk of re-identification is inherent in any anonymization technique, so the data controller must always bear in mind that the privacy and right to data protection of those affected could be compromised.

Given the treatment potential offered by the big data environment (to which the query refers), when assessing the possibility of re-identifying a certain person, the evolution of available technology must be taken into account at all times and the information available.

Therefore, and beyond the fact that, according to the consultation, the information that would be given to the business fabric of the region is "in a completely anonymized and aggregated format", it will be necessary to apply measures to avoid re-identification by the recipients of the information, or of third parties

In accordance with the considerations made in this opinion the following are made,

Conclusions

- Question A): Given the regulatory provisions (art. 6.1.a), art. 9.2.a) RGPD, in connection with Additional Provision 17a of the LOPDGDD) the explicit consent of the affected persons could enable data processing.

The study can also be carried out with pseudonymised data, in accordance with letter d) of the aforementioned Additional Provision 17a.

In any case, it will be necessary to comply with the principles and guarantees established in the data protection regulations, among others, the principles of minimization and security and the obligation to carry out an impact assessment related to data protection, in more than the requirements that derive from the aforementioned additional provision 17a and, where appropriate, from the Biomedical Research Law.

- Question B): The communication of anonymized and aggregated information on the results of the operation carried out by the Foundation to the business fabric of the region would not be contrary to data protection regulations.

Barcelona, March 3, 2022