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Strengthen the autonomy of the research subject through the protection of his/her personal data

Fortalecer la autonomía del sujeto de investigación mediante la protección de sus datos personales

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Abstract:

In research involving human subjects, it is essential for the research subject to give informed consent. Among the requirements that are considered indispensable for this figure to be considered existing, is the obligation on the part of the researcher to offer an explanation of various aspects, among which is the preservation of the confidentiality of the information related to the subject, but also the certainty that the subject will not be identified.

This document reflects on the importance of the researcher also complying with the current regulations on personal data protection, in order to be able to guarantee confidentiality in the informed consent, which, consequently, would allow a free, informed and specific decision about his/her participation in the research in question..

Keywords:

Principle of information, protection of personal data, autonomy, research subjects.

Resumen:

En la investigación en seres humanos, resulta un elemento fundamental que el sujeto de investigación otorgue su consentimiento informado. Entre los requisitos que se consideran indispensable para que esta figura se considere existente, se encuentra la obligación por parte del investigador de ofrecer una explicación de diversos aspectos, entre los que se contempla la preservación de la confidencialidad de la información relacionada con el sujeto, pero, además la certeza de que no se le identificará.

En este documento, se reflexiona acerca de la importancia que reviste que el investigador cumpla también con la norma vigente en materia de protección de datos personales, para a su vez, ser capaz de garantizar la confidencialidad en el consentimiento informado lo que, en consecuencia, permitiría decidir de forma libre, informada y específica acerca de su participación en la investigación de que se trate.

Palabras Clave:

Principle of information, protection of personal data, autonomy, research subjects.

INTRODUCTION

To start with, research on human beings, as is widely known, has been carried out for many years, not always in accordance

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with the ethical and scientific principles that should govern it.

In the popular imagination, the aberrations committed, above all, during the Second World War still survive, although we can also cite cases that occurred in the powers that fought against the Axis Tokyo-Berlin-Rome, such as the Tuskegee experiment or the one carried out in Willowbrook.

Both occurred in American locations, whose development was undoubtedly carried out through aberrant acts that violated research ethics and, more importantly, the fundamental rights of those who were research subjects, who also belonged to vulnerable groups and, in many cases, did not even consent to participate.

Although unfortunately, more examples can be cited, the present ones serve to justify the very necessary regulation of this practice not only through international treaties such as the Convention for the Protection of Human Rights and Dignity of the Human Being but also with the applications of biology and medicine (Oviedo Convention) or the Regulation of the General Health Law on Health Research, which guarantees, among other things, the right to be previously, personally and expressly informed before consenting to any participation as a research subject, respecting six fundamental rules to achieve this (NCHR):

1. Respect for the general conditions of each individual.
2. The absence of rejection on the part of the person involved.
3. Obtaining written authorization from the legal representative, if necessary.
4. Demonstrated effectiveness on other persons, and
5. The direct benefit to the person consenting to participate as a research subject.

At the same time, the obligation to respect the private life of the research subjects is established, which, together with the right to be informed to give free, specific, and informed consent, is fundamental for accepting to participate in research on human beings.

The foregoing will necessarily lead us to consider other legal norms expressly formulated to guarantee the right to protection of personal data, recognized in our country in Article 16 of the Political Constitution of the United Mexican States, which, together with its general, federal, and state laws on the subject, complement the basic legal framework to be observed to preserve the dignity of those who participate in an investigation of the aforementioned characteristics.

In this sense, the aim is to explore in general terms the rules that must be observed so that the consent of the person who is a candidate for participation in a research study is granted as required by the Regulations on the subject.

METHODOLOGY

It is important to mention that it is a retrospective and qualitative documentary research since it is an analysis of existing documents. The data will be collected through a review of the literature and current legal norms.

DEVELOPMENT

According to the Explanatory Memorandum of the Regulation of the General Health Law on Health Research (2014), this activity must comply with the requirements to guarantee the dignity and well-being of those who decide to participate in it, to promote the biomedical, medical-social, and health services areas.

Thus, its development should contribute, according to article 3 of the aforementioned regulation,

I. To the knowledge of biological and psychological processes in human beings;
II. To the knowledge of the links between the causes of disease, medical practice, and social structure;
III. To the prevention and control health problems;
IV. To the knowledge and evaluation of the harmful effects of the environment on health;
V. To the study techniques and methods to be recommended or used for the provision of health services, and
VI. To the production of inputs for health.

In this sense, the researcher must ensure compliance with the provisions of Article 14 of the previously mentioned law, to guarantee the safeguarding of respect for the dignity and protection of the rights and welfare of the person who decides to be the subject of the study.

While it is true that the cited article establishes the bases for carrying out research. For instance, it must be adapted to the ethical and scientific principles that justify carrying it out. In addition, its basis must be found in the experiments previously carried out on animals, laboratories, or other scientific facts. Moreover, it must be carried out by health professionals and only when the knowledge to be generated

cannot be generated by other means, section V stands out for our interest, which refers to obtaining the informed consent of the research subject or his/her legal representative.

Following this line of thought, the same Regulation determines that informed consent is an agreement in which, using a written document, the research subject or his/her representative declares in a free, unequivocal, and informed manner, that he/she authorizes his/her participation.

In turn, this requirement must also meet certain requirements to be considered existing following the referred Regulation, among which are Sections VIII and IX of Article 21.

The first refers to the fact that the researcher will guarantee the non-identification of the subject and the confidentiality of the information related to his/her privacy. The second is the commitment to provide the subject with updated information obtained during the procedure, even though knowing this information could affect the will already be expressed and, consequently, the subject could refuse to continue participating.

To adequately guarantee compliance with these requirements, we must take into account the regulations that contemplate the human right to the protection of personal data, which in Mexico is guaranteed in Article 16 of the Political Constitution of the United Mexican States.

The Convention for the Protection of Individuals about Automatic Processing of Personal Data was done in Strasbourg, France, on January 28, 1981 (Convention 108). As well as its additional protocol concerning the automatic processing of personal data, supervisory authorities and transborder data flows, have also been ratified. Nevertheless, the Protocol of Amendment to the Convention for the Protection of Individuals concerning Automatic Processing of Personal Data (Convention 108+) has not been ratified.

As regards the laws regulating this right, their scope of application, although it may also be territorial, depends first of all on the quality of the data controller.

On one hand, the General Law for the Protection of Personal Data in Possession of Obligated Parties (GLPPDPOS) is mandatory, according to Article 4, in the case of any authority, entity, body, and agency of the Executive, Legislative and Judicial Branches, autonomous bodies, trusts and public funds, of the federal sphere and political parties that in the exercise of their powers and functions carry out the processing of personal data of individuals, in terms of the provisions of the General Law and these General Guidelines, as well as the Institute and the guarantor bodies concerning the substantiation of appeals.

On the other hand, if the data controller is a private individual (who by exclusion does not belong to the public sector or receive public resources), it must be governed by the Federal Law for the Protection of Personal Data in Possession of Private Parties and its Regulations, no matter in which state it resides, since only the Federal Congress has the power to legislate on this particular subject.

Unlike what happens in the field of individuals, the General Law does not have a regulation that develops its content, but the National Institute for Transparency, Access to Information and Data Protection issued 2017, the General Guidelines for the Protection of Personal Data for the Public Sector.

It is worth mentioning that there are also laws on the subject applicable to regulated entities in force in each State, whose content and publication are harmonized with the General Law.

It is in this legislation on the protection of personal data that the definition of the information that mostly fills the content of the clinical records of research subjects, in other words, personal data and sensitive personal data, is established.

The first one is any information referring to a natural person, which allows us to identify him/her at this moment or make him/her identifiable in the future. The second, intrinsically related to the subject of interest, is that which refers to such intimate aspects of the person that disclosing it indistinctly may make him/her vulnerable to discriminatory behavior or a victim of the commission of a crime, for example. This category includes health, genetic and biometric data.

They are so important that, as a general rule, the processing of sensitive personal data is prohibited, unless one of the grounds of legitimacy established in the corresponding law is met, as the case may be. One of them is the consent of the owner of the data or his legal representative.

As in the case of informed consent in the field of health research, the consent granted in the field of personal data must also be free, specific, and informed to be considered validly granted.

Regarding sensitive personal data, it must be collected in writing and the obligation to demonstrate that this act was

carried out is the responsibility of the data controller, which in the case in question is the researcher.

In a non-exhaustive manner, we consider that the work carried out to guarantee that the processing of personal data is carried out following the principles of loyalty, proportionality, lawfulness, confidentiality, security, quality, consent, and responsibility, are reflected in compliance with the principle of information, whose exponent par excellence is the privacy notice, which researchers must contemplate to comply with the applicable data protection regulations.

Hence, this document must state that it is a document whose purpose is to explain the privacy policy of the researcher, as does the explanation given to the owner of the data or his/her representative as to who will process the personal data, which data are collected and differentiating those that are processed as necessary to be part of the research; for what purposes they are required, among which those that are not essential to the main activity must be clarified.

At this point, the researcher must identify which data are indispensable to carry out the study in question and that they are closely related to the purposes for which they are requested, in compliance with the principle of proportionality.

Information should also be provided if transfers are made to other data controllers, detailing which data and for what purposes they are communicated and the clause indicating whether or not the holder accepts this transfer, but also how to revoke consent for the processing of personal data, as well as how to exercise their rights of access, rectification, cancellation, opposition, and portability[*].

It is no less important to mention that the document must include the mechanisms and procedures that the data controller offers to the owner of the data to limit its use or disclosure. If it uses cookies, web beacons, or any similar or analogous technology if it is the case that it is used to treat them in a specific investigation and which are the means or procedures by which it will inform the owners about the changes in the privacy notice.

Although of paramount importance, this document is merely the crystallization of the work that, to ensure the protection of personal data, should have been carried out by the data controller, a procedure that would culminate in a dialogue in which he explains to you the contents of a document whose understanding you understand.

The amount of information and technicalities it contains can be confusing for the subscriber, vitiating his or her consent, which can happen similarly with the consent to be part of a research on human beings, which, like the latter, can be revoked at any time, although it is true that it can mean not participating in the research.

Likewise, the researcher must establish the necessary mechanisms to ensure the security of personal data and, consequently, their confidentiality. One of them is pseudo-anonymization, used mainly to conceal identities and treat personal data securely.

According to Romeo (2005, p. 34), pseudonymization is a reversible process that consists of "the disintegration or separation of the identifying data of the source subject from the rest of the data of medical-scientific interest" in which (p. 44) "a code or similar procedure is included that allows the information to be regrouped with the identifying data of the subject to which it refers".

Anonymization is a process that "shall have the effect of making it impossible to identify the subject". By applying this technique, the controller and processor can fulfill their obligations while minimizing the risks to data subjects. (Regulation 2018/1725).

For its part, GT 29 (2007: 19) differentiates between the two processes since the former is carried out in such a way "that a trace remains between the pseudonym and the identity to which it corresponds, using correspondence lists or bidirectional cryptographic algorithms". Whereas the latter uses techniques such as unidirectional cryptography to create anonymous data, which, as we shall see, are excluded from data protection regulations, unlike data resulting from traceable pseudonymization since these are considered information about indirectly identifiable natural persons.

On the contrary, a similar term is defined in the Mexican legislation on data protection. Disassociation is understood as

[*]The latter in the event that the data controller is a regulated entity as provided for in the General Law for the Protection of Data in Possession of Regulated Entities or in the harmonized legislation of the Federal Entities.

the procedure by which personal data cannot be associated with the owner or allowed, due to its structure, content, degree of disaggregation, its identification.

As can be observed, the Mexican legislation does not distinguish between levels of dissociation but is assumed as the irreversible anonymization proposed by Romeo. Its effectiveness says Maqueo (2018:44) depends on the results obtained, which should be similar or equivalent to the removal or erasure of personal data, without losing sight of the possible residual risks of re-identification in the face of available technologies.

The National Institute for Transparency, Access to Information and Protection of Personal Data (NITAIP 2016, p. 3) states that if the data is dissociated, "in such a way that it is not possible to associate it with its owner, nor allow its identification, it will cease to be considered as such" and will not enjoy the protection of the corresponding regulations. This assertion is similar to that of the corresponding European law and Romeo's approach, with all logic. Since then there is no data subject to protection, who is the real beneficiary of this type of regulatory body since the data are useful as long as they are related to a person.

It also identifies it as a mechanism to reduce the risk in the personal data processing systems in its Guide to Implementing a Personal Data Security Management System (NITAIP, 2015, p. 16). It is in this document that describes the concept under study as the isolation of data so that by themselves do not provide valuable information of a holder or the latter cannot be identifiable.

It equally identifies it as a mechanism to reduce the risk in the personal data processing systems in its Guide to Implementing a Personal Data Security Management System (NITAIP, 2015, p. 16). It is in this document that describes the concept under study as the isolation of data so that by themselves do not provide valuable information of a holder or the latter cannot be identifiable.

The same Mexican guarantor body (2015, p. 22), alludes to the fact that a correct control of dissociation allows that "data is depersonalized and thereby minimizes the risk to individuals, therefore, they are no longer identifiable. In other words, when data are isolated in such a way that they do not provide valuable information by themselves or cannot make a person identifiable, then the information is considered to be dissociated. For such a mechanism to be effective, it is necessary to have different authentications to access the different isolated data".

From the last statement, it can be deduced that this risk analysis methodology does not refer to anonymization, but pseudo-anonymization, with all the advantages and risks, that this entails. It even proposes it as enhanced security measures for access to personal data from the physical environment and highly anonymized environments.

In this regard, the SDPA (2016:1) considers that the risks of re-identification of subjects should be addressed as a residual risk to be managed and not as a breach of personal data protection security measures.

Another of the measures consists of drawing up a security document, understood as the instrument that describes in general terms the technical, physical, and administrative security measures adopted by the responsible party. Besides being necessary
to comply with the standard, it is an excellent practice to be aware of the importance of the correct safeguarding and treatment of information.

This document should include the inventory of personal data and their processing systems, the roles and obligations of those who process personal data, the risk and gap analysis, the work plan, the mechanisms for monitoring and reviewing security measures, and the general training program for the research personnel involved.

Additionally, the instrument must be modified if there are significant modifications to the processing of personal data that result in a different level of risk or if improvements are to be implemented in the personal data management system. It is also necessary to implement preventive or corrective actions in the event of a security breach, so it must be considered a living document that is constantly being modified.

Furthermore, Mexican legislation on personal data protection establishes the obligation to inform without further delay the owner of the data, as well as the National or Federal Entity Institutes. If the personal data under their custody have been subject to any violation that significantly affects the economic or moral rights of the owner of the data as soon as it is confirmed, and must adopt the necessary actions to minimize the effects suffered by the affected parties, who may initiate the corresponding legal measures to defend their rights.

CONCLUSION

To conclude, it is important to say that to fully comply with the above, the researcher should give the importance it deserves not only to the preparation of a comprehensive privacy notice but also to all the work that must support it, including the establishment of a system for the treatment of personal data and the relevant and adequate security measures, which will allow him to categorically affirm to the research subject that the conditions exist to guarantee the confidentiality of his information. In addition to providing it to him in a clear and timely manner at the time he deems necessary or when requested to do so.

To this end, we consider that the resulting document should also be reviewed by the Research Ethics Committee, with special emphasis on the representative of the affected nucleus, to overcome one of the main obstacles that prevail in the drafting of legal texts of this nature, that means to make their scope and purpose clear to any person and not only to the public with certain academic preparation.

We believe that the preparation of a clear and easy-to-read and understand the privacy notice. Besides being necessary to comply with the legislation that applies to the researcher according to its nature in terms of protection of personal data.

It is a useful tool for the researcher in that it can demonstrate that it has complied with the obligation of information and confidentiality that the Regulation of the Health Law mentioned in this document, but it would also help to plan and execute the strategy to protect the personal data of the research subjects.

For the latter, the benefit is evident, because as long as the information is clear and timely about the research, but also about the treatment to which their most sensitive information will be subjected, they will be able to decide objectively whether or not, or to what extent, they wish to participate in the proposed research, which undoubtedly reinforces not only their autonomy but also the exercise of their right to informational self-determination so that the data controller should not consider compliance as a burden.

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