

r

NATIONAL COMMISSION

DATA PROTECTION

OPINION/2019/36

I. Order

The Research Working Group on Cells and Tissues of Human Origin, created within the Health Commission of the Assembly of the Republic, sent the National Data Protection Commission (CNPd), for consideration, the Proposal of Law No. 142/XII1 (3a), which establishes the legal regime for the collection, processing, analysis, availability and use, storage and destruction of cells and tissues of human origin for the purpose of scientific research, including stem cells.

The request made and the opinion issued now derive from the attributions and powers of the CNPD, as an independent administrative entity with powers of authority to control the processing of personal data, conferred by subparagraph c) of paragraph 1 of article 57 0 and by n. 4 of article 36 of Regulation (EU) 2016/679 of 27 April 2016 (General Regulation on Data Protection - RGPD), in conjunction with the provisions of paragraph 1 of article 21, and in paragraph 1 of article 22, both of Law no. 67/98, of 26 October, amended by Law no. 103/2015, of 24 August (Personal Data Protection Law).

II. Of Appreciation

The draft law submitted for an opinion is a revised version of two draft law proposals on the same subject, on which the CNPD commented in Opinion No. 45/2016, of December 51.

In this sense, this opinion will focus on the new solutions introduced in the Proposal, resulting either from the recommendations then made by the CNPD, or also from the fact that the legal framework regarding the protection of personal data has changed and is currently embodied in the RGPD.

In addition to establishing the legal regime for the collection, processing, analysis, availability and use, storage and destruction of cells and tissues of origin

1 Accessible at https://www.cnpd.pt/bin/decisoos/Par/40_26J2016.pdf and https://www.cnpd.pt/bin/decisoos/Par/40_45_2016.pdf, respectively.

r

for the purpose of scientific research, including stem cells, this draft law also defines the requirements for the constitution and functioning of banks of cells and tissues of human origin, for the purposes of scientific research.

According to the respective explanatory memorandum, the present proposal of law is intended to define the conditions under which the collection, processing, analysis, availability, use and storage of human cells for the purposes of scientific research, without application in human beings, is allowed. human beings, with the objective of preventing, diagnosing and treating pathologies, improving medically assisted procreation (PMA) techniques, setting up tissue and cell banks of human origin, including stem cells, and setting up projects based on research-generated knowledge.

Analyzing the current wording of the Draft Law, it is noted that a good part of the suggestions previously made by the CNPD was accepted (for example, regarding the concept of "donor", which ended up prevailing to the detriment of the concept of «donor», as well as the definition of «bank of cells and tissues of human origin» redefined to «repository», having abandoned the concept of «organisms» which the CNPD considered not to reflect the nature of these databases).

It should also be noted that new concepts were introduced in the project, without these having been defined in parallel with others, as is the case with the concept of 'destruction' (cf. Article 1(1) and Article 2 of the proposal). It is therefore recommended that they be included in the precept on definitions.

Notwithstanding the changes introduced in the Proposal, some reservations remain or new doubts arise, so, following the analysis structure of the previous opinion, the following aspects of the regime are now considered:

a) Consent for the processing of personal data

As the CNPD had the opportunity to mention in the two previous opinions, there is no doubt that operations on “cells” and “tissues” of human origin may result in the identification of their holders, so they imply the processing of personal data.

NATIONAL COMMISSION

DATA PROTECTION

However, considering that special or sensitive personal data are at stake (i.e., information relating to identified or identifiable natural persons especially protected by Article 9(1) of the GDPR), the basis for the lawfulness of their processing must be

found in the under Article 9(2) of the GDPR.

This Proposal, in particular in paragraph 2 of article 6, assumes the consent of the data subject as a basis for the lawfulness of the processing of personal data, in accordance with subparagraph a) of paragraph 2 of article 9 . of the GDPR. To that extent, this consent complies with the rules of the RGD, either in terms of its attributes (the consent is free, informed, specific and explicit), or in terms of the possibility and consequences of its revocation by the data subject - cf. Article 4(11) and Article 7 of the GDPR.

Therefore, the autonomy of this requirement in relation to consent for the purpose of collection, processing, analysis, availability and use of cells and tissues of human origin for the purposes of scientific research, provided for in article 5 of the Proposal, is welcomed. Moreover, the same Article 5, in paragraph 9, differentiates between the two types of consent, which therefore have different, albeit related, objects.

However, the CNPD considers that the information duty provided for in Article 5(3), when referring to “associated personal and health data”, may cause confusion as to its scope.

The CNPD therefore recommends that the information on the processing of personal data (which obviously covers health data and genetic data) be detached from this precept, in order to integrate it, perhaps in Article 5(9) or in Article 6 (with a specific reference to the right to information provided for in Article 13 of the GDPR).

It is only recalled, still in this regard, that the consent regarding the processing of personal data must be provided in a way that can be clearly distinguished from the other consent regarding the donation of biological material, which does not prevent them from being contained in the same document (see Article 7(2) of the GDPR).

b) Impact assessment on data protection

With regard to article 7 of the Proposal, the CNPD only suggests changing its title, since it coincides with that of article 6 - perhaps becoming 'impact assessment'.

Av. D. CARLOS I, 134 - 1o | 1200-651 LISBON | WWW.CNPD.PT | TED+351 213 928 400 | FAX: +351 213 976 832

Process PAR/2019/33 2v.

r

This provision is not essential, since the obligation to carry out an impact assessment of the processing of data resulting from this type of scientific research would already result from Article 35 of the RGD and Regulation No. 1/2018 approved by the

CNPD (published in the 2nd Series of the Diário da República on 30 November 2018)² under paragraph 4 of the same article 35 of the GDPR, a positive pedagogical effect is always recognized in its specific provision in this diploma.

It should be noted that, in the context of the specific impact study, adequate measures must be defined for the protection of personal data and for minimizing the impact of the treatment on the rights of data subjects.

c) Banks of cells and tissues of human origin for scientific research

In relation to the provision in subparagraph g) of paragraph 1 of article 18 of the Draft Law, according to which the establishment of banks of cells and tissues of human origin requires authorization from the CNPD, it is important to note that such a solution is still compatible with the RGPD, within the scope of paragraph 5 of article 36 of the RGPD, as well as the provision for prior notification of communications and transfers of personal data contained in articles 21 and 22 of the Proposal³.

Also within the scope of article 18, it is important to bring to light, once again, the fact that the wording of paragraph 3 remains unchanged, despite the observations made by the CNPD in its previous opinions. The CNPD recalls the attention to the legal imprecision of talking about “irreversible anonymization” as opposed to another “anonymization” apparently susceptible to the re-identification of the people to whom the information relates. The concept of anonymization presupposes the impossibility of re-identifying the people to whom the (anonymized) information concerns. For this reason, the CNPD reiterates the recommendation to speak of anonymization and pseudonymization in Article 18(3) (cf. Article 4(5) of the GDPR). Furthermore, it considers that the principle of minimization, provided for in subparagraph c) of paragraph 1 of article 5 of the GDPR, which justifies the option of anonymizing data, except when

² Accessible at https://www.cnpd.pt/bin/decisoos/regulamentos/regulamento__1_2018.pdf.

³ It is recalled, in this regard, that with the approval of Draft Law No. 120/XIII/3.a, which ensures the implementation of the GDPR, the regime set out in this draft law, if it enters into force after that , will assume the nature of a special regime that will prevail over the rule regime.

Process PAR/2019/33 3

NATIONAL COMMISSION

OF DATA PROTECTION

necessary to maintain the possibility of identifying the information, extends to all other data processing provided for in the

Proposal.

d) Further processing of personal data

With regard to Article 21 of the Draft Law, which is entitled "provision and transfer of samples", it appears that the intention is to transmit the samples to other entities located in national territory or in the territory of the European Union, with a view to reuse.

The first note on this article concerns the convenience, for reasons of consistency between legal regimes, of replacing the expression "transfer" with transmission, since such transfer implies the communication of personal data, but this treatment is different of sending personal data to the territory of countries outside the European Union - which, according to the GDPR, is called transfer - and which, moreover, is regulated in the following article of the Proposal.

The second note concerns the need to limit in this precept the purposes of re-use of personal data, specifying the type of purposes that may legitimize such transmission, in accordance with the purpose principle provided for in paragraph 1(b) of article 5 .° of the GDPR, always bearing in mind that the basis for this processing of personal data is the consent of the respective holder.

The third note concerns the need for the impact assessment provided for in Article 7 to be extended to any transmission of personal data referred to in Article 21 of the Proposal. In fact, involving the transfer and transmission of samples, regulated in this article, an autonomous operation of processing of special or sensitive personal data, it must be preceded by the impact assessment, under the terms of article 35 of the RGPD.

Thus, the CNPD recommends that in Article 21, an express reference be made to the need to carry out an impact assessment, possibly referring to Article 7 of the Proposal.

Finally, Article 22, concerning the transfer of samples to third countries, involves or may involve the transfer of personal data.

To that extent, it would be useful to refer

AV. D. CARLOS I, 134 - 1° [1200-651 LISBON | WWW.CNPD.pt | TeL:+351 213 928 400 | FAX: +351 213 976 832

Process PAR/2019/33 3v.

¶

expressed for chapter V of the RGPD, where specific conditions are set for such a personal data processing operation to take place, in addition to those of article 9 of the RGPD.

In any case, the CNPD insists that, in accordance with the principle of data minimization (expression of the principle of

proportionality), the samples must be transferred without it being possible to identify their donor (either because they have been anonymized, or because, having been pseudonymized, it is not possible in the country of destination to know the key that allows the re-identification of the donor). In this case, strictly speaking, the information to be transferred does not fulfill the concept of personal data and, to that extent, the transfer is not subject to the GDPR.

Thus, the CNPD recommends the provision in article 22 of the transfer of anonymized samples, whenever this is adequate and sufficient to achieve the purpose of the transfer and, when its identification is necessary, the explicit reference to the regime of chapter V of the GDPR

III. Of the Conclusions

The CNPD recognizes that the new Draft Law has accepted part of the recommendations it previously formulated, considering that there are still, however, rules that must be revised, either for reasons of legal certainty and clearer articulation between the legal regimes applicable in this matter, or for being still silent on some aspects in the regulation of the processing of personal data that it provides.

Thus, on the grounds above, the CNPD recommends:

1. The highlight or empowerment of the duty to provide information regarding the processing of personal data in relation to the duty of information regulated in article 5 of the Proposal, integrating it, perhaps, in paragraph 9 article 5 or in the Article 6 (with a specific reference to the right to information provided for in Article 13 of the GDPR);
2. Changing the heading of article 7, in accordance with its statute;
3. The differentiation, in paragraph 3 of article 18, between the data anonymization operation and the pseudonymization operation;
4. The express reference, in article 21, to the obligation to carry out an impact assessment on the transmission of personal data resulting from the transfer

Process PAR/2019/33 4

NATIONAL COMMISSION

DATA PROTECTION

or transmission of samples, possibly referring to article 7 of the Proposal;

5. The provision in Article 22 of the transfer to third countries in relation to the European Union of anonymized samples,

whenever this is appropriate and sufficient to achieve the purpose of the transfer and, when their identification is necessary, the explicit reference to the GDPR chapter V regime.

Lisbon, June 25, 2019

Filipa Calvão (President)

AV. D. CARLOS I, 134- 1o I 1200-651 LISBON | WWW.CNPD.PT | TEL: +351 213 928 400 | FAX: +351 213 976 832