

National Data Protection Commission

RESOLUTION/2022/739

I. Order

1. O Centro Hospitalar Universitário de São João, E.P.E. (CHUSJ), submitted, on June 3, 2022, the prior consultation of the National Data Protection Commission (CNPd), within the scope of the "São João Open Data Covid-19" Project, the "processing of personal data of SARS users -CoV-2 from CHUSJ collected as part of the provision of health care, with hospitalization, for the purposes of preventive medicine, medical diagnosis, provision of health care or treatments or management of health systems and services and processing necessary for the pseudonymization process for scientific research purposes, to be made available on the CHUSJ portal.

2. The CNPD issues an opinion within the scope of its attributions and powers, as the national authority for controlling the processing of personal data, in accordance with the provisions of subparagraph I) of paragraph 1 of article 57 and paragraph 2 of article 36 of Regulation (EU) 2016/679, of the European Parliament and of the Council, of 27 April 2016 (General Data Protection Regulation, RGPD), in conjunction with the provisions of article 3 and paragraph 2 of article 4 and subparagraph b) of paragraph 1 of article 6, all of Law no. internal legal system, of the GDPR).

3. The request is accompanied by the Data Protection Impact Assessment (AIPD) and the opinion of the data protection officer.

II. Analysis

i. Description of treatment

4. According to the AIPD, with the Open Data Covid-19 Project, CHUSJ intends to provide a set of data in a shared access data model based on an attribute, to respond to the high number of access requests for research purposes clinic, which continues to receive, more quickly and efficiently, thus allowing the release of human resources currently assigned to this function (information systems teams and the data protection officer) for other tasks, also ensuring the mitigation of the impact on the rights of data subjects and the improvement of data quality for research purposes (cf. pp. 5 and 6 of the AIPD).

5. For this purpose, a process of pseudonymization based on coding was designed, which, according to the analysis carried

out in the AIPD, substantially reduces the probability of arriving at the identity of the data subjects - strictly speaking, it is stated that the probability re-identification is less than 3% (cf. p. 47 of the AIPD).

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6. However, it was the decision of the person responsible for the treatment to submit the processing of personal data to the CNPD, taking into account the sensitivity of the personal data in question, the residual risk still identified and the potential for replication of the proposed methodology in view of the usefulness of the data and benefits arising from the results obtained for health research purposes.

7. The controller also admits that the analysis of the risk of re-identification must be subject to a periodic review, at least every two years, to validate that the conclusion regarding the final dataset does not contain personal data remains (see page 22 of the AIPD).

8. It also provides for the person responsible to “[submit the coding methodology to public scrutiny, thus allowing the incorporation of any unused method into the coding methodology that can contribute even more to mitigating the risks of re-identification”.

9. Finally, it is proposed to monitor research projects in a particular way in order to analyze the risk of re-identification, in order to, if necessary, improve the methodology in use.

ii. Lawfulness of data processing

10. The person responsible for the treatment identifies the purpose of scientific research as the legal basis for the processing of personal data under analysis.

11. Given that personal data relating to health are at issue, therefore, subject to a specially reinforced regime (cf. Article 9 of the RGPD), and that the collection and storage of data are legitimized by subparagraph g) of paragraph 9(2) of the GDPR, it is important here to analyze only the legal basis relating to the reuse of data for the purpose of scientific research.

12. As the person responsible for the treatment is a public entity, its attributions include the development of research activity in the area of health and the advancement and application of knowledge for the improvement of health, provided for in article 13 of Decree-Law no. 18/2017, of 10 February, and also in Decree-Law No. 61/2018, of 3 August, they fall under subparagraph e) of subparagraph 1 of article 6 and subparagraph j) of Article 9(2) of the GDPR the operations on personal data necessary to ensure the availability of data for scientific research with guarantee of the fundamental rights of the respective holders and in compliance with the principle of data minimization (cf. c) of Article 5(1) of the GDPR).

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iii. Identified risks and planned mitigating measures

13. Since the risks arising from the processing of personal data relating to health are known, not only for the privacy of the respective holders, but also, mainly because they relate to infectious diseases, discrimination and stigmatization in different contexts, the controller defined a set of security measures that mitigate such risks, by reducing the possibility of re-identifying the information to less than 3%, considering the person in charge, in the AIPD, that «[...] the technical possibility of arriving at the identity of the data subjects is practically null. In this way, we consider that the final database no longer contains personal data».

14. The measures envisaged to guarantee the rights of data subjects consist of the appropriate combination of pseudonymization and pseudonymization methods through an encoded dataset. And also security measures applied in the supporting technological platform.

15. The pseudonymization methodology is detailed and sufficiently substantiated. The various iterations and attempts to arrive at a set of generalization operations (age in 5-year intervals, aggregation of households and households and hospitalization in quartiles), suppression (removal of time) and disturbance (addition of noise) are described, ensuring a low probability of re-identification (less than 3%), maintain the usefulness of the data for research purposes.

16. To the extent that the solution found to produce a set of data encoded under these conditions ensures, with a very residual risk of re-identification, its anonymization, the processing complies with the principle of data minimization, in accordance with paragraph c) of Article 5(1) and Article 89(1), both of the GDPR, as well as with Article 31(1) of Law No. 58/2019, of the 8th of August.

17. Thus, the CNPD understands that the reuse of personal data for the purpose of scientific research under the terms described in the AIPD does not currently represent a significant risk to the rights and interests of data subjects.

18. And the three solutions of evaluation and periodic improvement take care of future technological evolutions that eventually increase the re-identification capacity in terms that the CNPD considers satisfactory.

19. Nevertheless, taking into account the relevance, in casu, of the periodic reassessment of the risk of re-identification, the CNPD stresses that it considers it essential to carry out this reassessment every two years or whenever objective knowledge of a technological development susceptible of impact the risk of the present data processing.

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iv. Rights of holders

20. With regard to the rights of data subjects, in order to implement the principle of transparency, the provision of information to data subjects in terms that the CNPD deems appropriate (cf. p. 18 of the AIPD) is ensured.

21. In this regard, it is only pointed out that the regime applicable in the specific case appears to be the one set out in Article 13 of the GDPR (and not the one set out in Article 14 of the GDPR). This is because, although it is a question of reusing personal data for the purpose of making it available to researchers, the data controller collected the data directly from the data

subject.

22. As for the other rights, the person in charge understands that there is no room for the rights of access and erasure, but he already admits the right of opposition (cf. pp. 19 to 21 of the AIPD), which, from the perspective of the CNPD, is incongruous .

23. It is important to clarify that, as this involves a set of encrypted data with a very residual risk of re-identification, it is the technical impossibility of re-identification itself that prevents the guarantee of the rights of access, rectification and erasure of data in the specific dataset presented to researchers, in accordance with Article 11 of the GDPR. It is therefore not necessary - strictly speaking, nor does it seem appropriate - to invoke the provisions of Article 89(2) of the GDPR and Article 31(2) of Law No. 58/2019 , of 8 August, nor of subparagraph d) of paragraph 3 of article 17 of the GDPR.

24. And the same goes for the right of opposition, since, given the technical impossibility of re-identification, there is no way to delimit the data of the holder who opposes the treatment. To that extent, only with regard to the future collection of health data for the immediate purpose of diagnosis and provision of health care (under Article 9(2)(h) of the GDPR) will it be possible to ensure the right to object to the reuse of data for the purpose of scientific research, as the person responsible intends to do.

III. Conclusion

25. On the grounds set out above, the CNPD considers that the processing of personal data, in the current state of technological evolution, is in accordance with the principle of legality and the principle of data minimization.

26. However, the CNPD determines the reassessment of the risk of re-identification of data every two years or whenever there is objective knowledge of a technological development likely to impact the risk of the present data processing.

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27. Regarding the rights of data subjects, the CNPD notes that:

The. the data subjects' right to information is duly guaranteed, emphasizing only that it falls under Article 13 of the GDPR;

B. in accordance with article 11 of the RGPD, the rights of access, rectification and erasure of data do not have to be guaranteed, since the data to be made available are coded in terms that do not technically allow their re-identification;

ç. at the same time, the right to object to the reuse of data for the purpose of scientific research can only be ensured with regard to the future collection of health data (collection carried out for the immediate purpose of diagnosis and provision of health care, under point h) of Article 9(2) of the GDPR).

Lisbon, July 7, 2022

Filipa Calvão (President, who reported)

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