RIASE
REVISTA IBERO-AMERICANA DE SAÚDE E ENVELHECIMENTO
REVISTA IBERO-AMERICANA DE SALUD Y ENVEJECIMIENTO

EDITORIAL

Lucília Nunes – Coordinating Professor, School of Health of the Polytechnic Institute of Setúbal

VOL. 4 N.º 2 AUGUST 2018

Since May 25, the General Regulation on Data Protection (RGPD – "Regulamento Geral de Proteção de Dados", in Portuguese) has entered into force, which "establishes rules on the protection of individuals regarding the processing of personal data and on the free movement of these data"[(a)]; applying to the processing of personal data wholly or partly by automated means and to the non-automated processing of personal data contained in or intended for files.

An immediate question may be regarding the impact of the RGPD on the promotion and development of health research - which compels us to compare with the framework of scientific research, specifically Law No. 21/2014 of 16 April.

The Clinical Research Law (LIC – "Lei da Investigação Clínica", in Portuguese) defined as «Clinical study or study», *"any systematic study conducted in human beings or based on individual health data, to detect or verify the distribution or effect of health factors, health status or outcomes, health or disease processes, performance and/or safety of health interventions or services, through biological, behavioral, social or organizational aspects"*[(b)]. Therefore, studies with intervention in general, clinical trials with experimental drug, studies with intervention of medical devices, without intervention... all types of studies.

LIC has established the primacy of the human person (Article 3), principles of good clinical practices (Article 4) and risk and benefit assessment (Article 5). But it considered, among the minimum conditions of protection of the participants (Article 6), the prior information ("*fully and in language appropriate to their capacity for understanding*" on the objectives, risks and drawbacks of the clinical trial), the informed consent, the right to withdraw from the clinical trial at any time, the right to moral and physical integrity as well as the right to privacy and protection of the personal data of the participants. It established the rules for the participation of underage individuals (Article 7) and those who were unable to consent (Article 8), as well as the prior requirement for an opinion[(c)] of the ethics committee responsible for clinical studies.

(a) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of these data and repealing Directive 95/46/CE (General Regulation on Data Protection). It should be mentioned that a correction to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 has been published.

(b) Law No. 21/2014, of 16 April (p), Article 2.

(c) Article 16 Opinion "1 - The carrying out of clinical studies shall be preceded by a favorable opinion from the CEC, to be issued within 30 days, without which the study cannot be carried out".

That is, the framework of the scientific research had changed between us in 2014, even if some persistence of old habits may be recognized, it is necessary for health professionals to understand that having access to people and data due to health care activities is different from being able to use data for research, being that the owner is the one who decides on the treatment of the data. In addition, it does not guarantee the right to the text without providing the means to make it effective (for example, in a consent form, it must be stated that the participant can leave the study at any time but it should not contain any contact information of the investigator for that purpose).

Looking now at the RGPD, it applies to any *"operation or a set of operations carried out on personal data or on sets of personal data, by automated or non-automated means, such as the collection, registration, organization, structuring, preservation, adaptation or alteration, retrieval, consultation, use, dissemination by transmission, dissemination or any other form of making available, the comparison or interconnection, limitation, erasure or destruction"* (Article 4).

We find the requirement of «lawfulness, loyalty and transparency» in the processing of data treatment, to be collected for specific, explicit and legitimate purposes («limitation of the purposes»), adequate, relevant and limited to what is necessary in relation to the purposes for which they are treated; kept in a way that allows the data subjects to be identified only for the period necessary for their purpose; being treated in a way that guarantees their safety.

In the case of the scientific research, the RGPD allows exceptions to the rule prohibiting the treatment of special categories of personal data – that is, the data processing for clinical research purposes is subject to the rights and freedoms of the data owner (therefore, respecting the principles of lawfulness, loyalty and transparency, limitation of purpose, minimization of data, limitation of conservation and integrity and confidentiality, as described in the RGPD), being the requirements for the processing of personal data to be performed and for the consent is given by the owner of the data and there is an obligation of professional secrecy.

In accordance with the previously existing scientific research rules on health in Portugal [including the determination of the CNPD on the *Principles applicable to the processing of personal data made in the context of Clinical Research* (No. 1704/2015), now revoked], and recognizing that there is a lack of national legislation complementing the RGPD (national implementation); probably, the impact on scientific research is to reinforce, on the one hand, the rights of the participants, including information and consent; on the other hand, raising the awareness of researchers on ethical principles and rules on the processing of personal data.

Let us emphasize, in conclusion, that if there is an objective of creating a European research area, *"treatment for archival purposes of public interest or for scientific or historical research or for statistical purposes is subject to appropriate safeguards under this Regulation for the rights and freedoms of the data owner. These guarantees ensure the adoption of technical and organizational measures in order to ensure the compliance with the principle of data minimization. Such measures may include pseudonymization, provided that the aims are achieved in that way."* (Article 89, No. 1).

Correspondence: lucilia.nunes@ess.ips.pt