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Authorization No. 7054/2018

Carla Patricia Guerreiro Gouveia notified the National Commission for the Protection of Data (CNPd) a processing of personal data for the purpose of carrying out a Clinical Study without Intervention, called MAPA - Monitor, Evaluate, Plan, Act .

The participant is identified by a code specifically created for this study, constituted in such a way as not to allow the immediate identification of the data subject; in particular, no codes are used that match the serial numbers.

identification, name initials, date of birth, telephone number, or result of a simple composition of this type of data. The encryption key is only known to the investigator(s).

The express consent of the participant or his/her legal representative is collected. Information is collected indirectly from the clinical file and from specified sources. in the notification.

Any transmission of information is carried out by reference to the code of the participant and, to that extent, anonymous to the recipient.

The CNPD has already commented in Deliberation No. 1704/2015 on the legal framework, the grounds of legitimacy, the applicable principles for the correct fulfillment of Law No. 67/98, of October 26, amended by Law No. 103/2015, of August 24, hereinafter LPD, as well as on the conditions and limits applicable to the treatment of data carried out for the purpose of clinical investigation.

In the present case, the treatment that is the subject of the notification falls within the scope of of that decision and the person in charge expressly declares that he complies with the limits and conditions applicable under the LPD and Law No. 21/2014, of 16 April, as amended by Law no. 73/2015, of June 27 – Clinical Research Law –, explained in the

Resolution No. 1704/2015.

The basis of legitimacy is the consent of the holder.

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The information processed is collected in a lawful way, for a specific purpose, explicit and legitimate and not excessive – cf. lines a), b) and c) of no. 1 of article 5 of the LPD.

Thus, under the combined provisions of paragraph 2 of article 7, paragraph a) of the paragraph 1 of article 28 and article 30 of the LPD, as well as paragraph 3 of article 1 and paragraph 9 of article 16.<sup>o</sup> both of the Clinical Investigation Law, with the conditions and limits explained in CNPD Deliberation No. 1704/2015, which are hereby given as reproduced, the present processing of personal data is authorized in the following terms:

Responsible – Carla Patricia Guerreiro Gouveia

Purpose – Clinical Study without Intervention, called MAPA - Monitor,

Evaluate, Plan, Act

Category of personal data processed – Participant code; age/date of

birth; genre; Vital signs; clinical history data; exam data data

physicist; data from complementary means of diagnosis; prior medication

concomitant

Exercise of the right of access – Through the researchers, in person

communications,

interconnections and

flows

cross-border personal data

identifiable in the recipient – There are no

Maximum data retention period – The key that produced the code that

allows the indirect identification of the data subject must be deleted 5 years after the

end of the study.

LPD and the Clinical Investigation Law, under the terms and conditions set forth herein

Authorization and developed in CNPD Deliberation No. 1704/2015, result

obligations that the person responsible has to fulfill. These must be made known to all

those involved in the processing of personal data.

Lisbon, 24-05-2018

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The president

Filipa Calvão