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Authorization No. 7025/2018

Ana Rita Ramos Tuna notified the National Data Protection Commission (CNPD)
a processing of personal data for the purpose of carrying out a Clinical Study of
Medical Device, called Neurophysiological Study of individuals with and without
impairment of the afferent pathways of the nervous system.
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.
The information is collected directly from the holder.
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.

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.

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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.º 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 – Ana Rita Ramos Tuna

Goal -

Clinical Study of a Medical Device, called Study

neurophysiological evaluation of individuals with and without impairment of the afferent pathways of the

nervous

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

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

physical examination data; data from complementary means of diagnosis;

concomitant prior medication; quality of life data/psychological effects

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 Within the deadline maximum of 15 years for studies with implantable medical devices and 5 years for other medical devices, in accordance with the provisions of Decree-Law no. 145/2009, of June 17th.

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