

INFORMED CONSENT AND PATIENT INFORMATION DOCUMENT

Clinical Trial: …………………………………………………………………………………………, associated with the Research Project ……………………………………………………………

1) Information for the patient about the subject of the study:

(Must include Potential benefits and risks of the project (Applies to any undesirable or involuntary experience that may affect the subject during the research process). (Must be written clearly, intelligible for the patient)

2) Informed consent:

1. I have read and understood the relevant information sheet.

2. I have had the opportunity to ask questions.

3. My questions have been successfully answered.

4. I have received enough information about the trial and the tests to be run.

5. I understand that participation is voluntary and I may leave the trial at any time without having to provide an explanation and without it affecting my medical care.

6. In accordance with the provisions of European Parliament and Council Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC, as well as other regulations in force and applicable to the protection of personal data, I have been informed that my personal data, obtained by the filling in of this form as well as those resulting from my participation in the project will be treated under the responsibility of FUNDACIÓN UNIVERSITARIA SAN PABLO CEU ( hereinafter, FUSP-CEU), with the purpose of managing my participation in this research project. In addition, I have been informed of the following aspects:

a. That profiling is planned in order to analyse or predict aspects related to my health.

b. That the prescribed treatments are legitimised by the consent I have given.

c. That my personal data, obtained by the filling in of this form, as well as those resulting from my participation in the project will be kept for the time necessary for the development of this research, which is estimated to be XXXXX months, being subsequently destroyed, without it being allowed to keep them unless they have been previously anonymized. In any case, they may not be transferred without my express consent which I do not grant herein.

d. That I can contact the FUSP-CEU Data Protection Delegate, addressing my request in writing to the postal address C/ Tutor nº 35 - 28008 Madrid or to the e-mail address: dpd@ceu.es.

e. That in accordance with the rights conferred on me by the current regulations on data protection, I will be able to contact the competent Control Authority to file any complaint that I consider appropriate, as well as to exercise my rights of access, rectification, limitation of processing, suppression, portability and opposition to the processing of my personal data and to withdraw the consent given for the processing of such data, addressing my request to the lead researcher at the contact address provided in this document.

7. I agree to make my written consent and other data available for the research project in which I’m participating, as well as for the lead researcher in said project (1) ......................................., but always respecting confidentiality and ensuring that my data will not be publicly available in any way that could lead to my identification.

8. The data collected for this project will be included, along with those of other people participating in it, in a personal database at CEU University, to which only the researchers authorized for this project will have access, all of them being subject to the secrecy inherent to their profession or derived from a confidentiality agreement.

9. I sign this consent and information document voluntarily to express my desire to participate in this research project until I decide otherwise. By signing this consent I do not waive any of my rights. I will receive a copy of this document for my records and future reference.

Name and surname(s) of the patient: …

National ID/Passport: …

Signature: Date:

Name and surname(s) of the legal representative if applicable: …

National ID/Passport: …

Signature: Date:

Name and surname(s) of the student:

Signature: Date:

Name and surname(s) of the end-of-degree project/end-of-master's project (TFG/TFM) Director:

National ID

Researcher’s contact mailing address: …

E-mail:…

Phone number: …

Signature:

 (1): Lead researcher and Student’s name