Requirements that the
Information Sheet and Informed Consent Sheet for Participants
must meet for research involving the collection of personal data

Obtaining consent from participating subjects is an indispensable requirement of any research involving any collection of personal data. According to Article 4 of Regulation (EU) 2016/679 of the European Parliament and of the Council 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, (hereinafter GDPR), personal data means "any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person."

The information sheet and the informed consent sheet guarantee that the subject has voluntarily expressed his/her intention to participate in a research project, after having understood the study. General forms are not valid, only the specific documents for each study and for each person.

This document is not a form. It contains indications for the drafting of the Participant Information Sheet (PIS) and Informed Consent (IC), for research projects involving the collection of personal data. The PIS and the IC must constitute a single document, with numbered pages. The participant should receive a copy after signing.

If the data is collected completely anonymously (such as answers to questionnaires in which there is no data to identify the participant), it is recommended to make a presentation with the content of the PIS, including a final sentence indicating that answering the questions implies agreement to participate. Only in this case would it not be necessary to sign the IC (which would involve the collection of personal data and meeting all the requirements explained in this document).

Participant Information Sheet (PIS)

The information sheet does not replace the individual explanation that the researcher must offer the participant; it only supports this information and allows him to have a reference point to discuss with other people his/her decision to participate or not in the study.

The information communicated to the people participating in the research must comply with the requirements set forth in Spanish legislation in the field of personal data protection. The need to comply with the ***GDPR*** must be particularly emphasized.

The information must be clear and understandable for the participating subject. It must be given in advance so that the person can reflect and decide freely, without feeling pressured.

For research involving children, a PIS and an IC will be drafted and then signed by the father/mother or legal guardian, as well as the minor, when his/her age (14 years or

older) and maturity make this possible. This document will explain that the minor has received the necessary information, adapted and complete and that he/she has been able to participate in the decision-making process to the extent possible by signing his/her assent. In the case of children under 14 years of age, if the researcher deems it appropriate, a very simple information sheet adapted to their age can be provided for their signature.

If the study takes place over a prolonged period of time (for example: cohort studies, panels, etc.), the procedure of informing the child, when he/she reaches legal age, must be considered, informing him that his/ her personal data is being used for research, and thus renewing the consent.

CONTENTS OF THE PARTICIPANT INFORMATION SHEET (PIS):

1. It should include an Invitation to participate, addressed to the participant or family member, including the Project Title and/or name that allows the identification thereof.

   It shall indicate that it is a research project, its title or a name that identifies it and that time will be given to the participant time to decide, offering him the opportunity to ask questions of both the researcher and persons not involved with the research.

   Example: "You are invited to participate in a research study called..... Please read this information carefully and ask any questions that you may have before signing the informed consent. Take your time before deciding on your participation and consult with other people if you so wish."

2. Identification of the researcher responsible for the Project; in the event that the Project is part of a Doctoral Thesis or Final Degree Project, the Director of the Thesis or Project must also be identified.

   Responsible, Position, Center/Unit and contact details

3. Research Data

   It should explain the project briefly, simply and clearly (avoiding technical terminology and taking care not to condition the responses of the subject).

   In addition, it must explain what the requested participation consists of (task to be performed, questionnaire to be completed, etc.) and the estimated time required.

   If the subject is expected to be contacted again at a later time, the subject will be alerted to the conditions of this renewed contact and consent will be obtained for this.

   If the study needs to collect specially protected data (sensitive data such as that related to ideology, union affiliation, religion, beliefs, racial origin, health, sexual

life, or commission of criminal or administrative offenses), its relevance must be justified. In addition, it shall require greater protection that must be adequately explained.

4. Personal data protection

All personal data will be processed in accordance with current data protection laws, especially Regulation (EU) 2016/679 of the European Parliament and of the Council 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, hereinafter GDPR.

The Person Responsible for the Processing of the (CUN/UN) data, in compliance with the aforementioned GDPR, informs you that, if you participate in this study, your personal data will be processed by the research team exclusively for the purposes authorized by you when signing the consent sheet. The competent authorities and members of the ethical committee may also access the data, if they consider it necessary to supervise the completion of the study.

It will not be possible to identify you by way of the communications that this study may generate.

You are responsible for the veracity and correctness of the data you provide to us and you have the power to exercise the rights of access, rectification, deletion, limitation of the processing, portability and opposition of your data in accordance with the provisions of the regulations on data protection. To exercise them, you should write to the Data Protection Officer of (UN/CUN) at the following postal address …… (CUN/UN) or the email address ……., attaching a photocopy of your national identity document or equivalent.

If you do not agree with the data processing performed or consider your rights violated, you have the right to file a complaint with the Spanish Agency for Data Protection (www.aepd.es).

5. Confidentiality

Indicate whether personal data will be used in an encrypted form and how this is done. Codification assumes that the researcher allocates a code to each subject who can then be identified by associating the code with personal data.

If the data is going to be destroyed at a certain time, inform regarding the timescale over which this will be done.

6. Other relevant aspects

Possible future use of the research results: If some personal data (images, recordings, etc.) are to be used for purposes other than research (a website, promotional materials, etc.), consent for this use must be explicitly sought and obtained.

Informed Consent (IC)

This must be offered by an individual and identified member of the research team, and communicated directly. Therefore, the document must include the names and signatures of the people who agree to it. It is not necessary to indicate the Identity number.

Here, an example is given showing informed consent. In each case, it will be assessed which statements apply to the research and which authorizations must be explicitly collected.

Example of Informed Consent:

I..... *(**subject's name)*** have received from*..... **(name of the member of the research team that has negotiated the consent)*** clear information about the study..... *(**indicate the title of the study, principal researcher and center)*** in which I willingly wish to participate.

- I declare that I have read the Participant Information Sheet about the study cited.

- I have been given a copy of the Participant Information Sheet and a copy of this Informed Consent, dated and signed.

- I have had the time and the opportunity to ask questions and raise any doubts I may have had. All questions were answered to my satisfaction.

- I have been assured that the confidentiality of my data will be maintained.

Consequently, I give my consent for participation in the proposed study.

I give my consent for the storage of my personal data in the place and conditions indicated in the PIS:

YES ☐ No ☐

I give my consent for the team to contact me again at a later date:

YES ☐ No ☐

I give my consent for the use of my personal data for purposes other than research as explained in the PIS:

YES ☐ No ☐

Signed in duplicate, having received a copy thereof.

Date:	Participant signature
Date	Signature of the researcher or the person providing the information and the consent sheet

When the participating subject is a minor (add):

"I state that I have explained the characteristics and purpose of the study to the person legally responsible for the minor, that the minor has been informed in accordance with his/her abilities and that there is no opposition on his/her part."

The legal guardian gives his consent through his/her dated signature in this document. The minor will sign his/her assent where possible if his/her age and maturity so allow.