UNIVERSITAT DE VIC
UNIVERSITAT CENTRAL
DE CATALUNYA

Recommendations for writing the Information Sheet for participations and the Informed Consent form for research involving human or data of a personal nature

In this document, the Research Ethics Committee of the University of Vic – Central University of Catalonia aims to describe aspects that should be included in the information sheet for research project participants and in the informed consent form.

The CER UVIC-UCC shall not only assess the format of these documents, but also the procedure for obtaining the informed consent and guarantees of confidentiality from the subjects who take part in the studies. This procedure will be described in the documents attached to the request for assessment of a project.

As a general criterion, personal data will be separated from any identifying information before they are processed, so that it is not possible to directly or indirectly identify the person with whom they are associated. Security measures are not required for anonymised data.

Even when identifying data are available, the information should be processed in a disassociated way (anonymised) whenever possible. Identifying data should only be processed when necessary.

When a sample of identified or identifiable people from an institution is used, **permission must be obtained from the institution's directors.** As a general criterion, these data can only be processed with the express consent of those affected.

In general, the following points should be considered when information sheets and informed consent forms are written:

- They must contain detailed, accurate information to identify the research project (including the name of the project, the research group, the principal investigator, the centre to which the project is attached, and the institute at which it will be carried out).
- When more than one centre is involved in the project, data must be provided on all of them.
- They must contain detailed information on the circumstances and objectives of the research, and the specific participation that is requested.
- They must be written in clear language that can be understood by people who are not experts on the subject.
- They must contain two parts:
    - Information sheet: written in the second person, e.g. "You have been invited to participate".

- Informed consent form: written in the first person, e.g. “I have been invited to participate”, “I have been informed of the research objectives”.

The information sheet and the informed consent form should be put together in one document, with numbered pages. Two copies or this document should be made: one for the participant and one for the research team.

- The following information should be included about the project: the study objectives, the form of participation, the benefits, the risks, the right to refuse to participate, the right to withdraw at any time from part or all of the study without giving a reason and with no consequences, the right to know the results, procedures to ensure confidentiality, and receipt of any information provided, information about the researcher and the right to ask questions.

- The document must refer to the use of security measures that are included in data protection regulations.

Specifically, the document should contain the following information:

- **Introduction:** data identifying the study, a short presentation of the invitation to participate, indicating that the aim of the document is to help potential participants to make a decision.
- **Identification of the institution**: identification of the researcher responsible for the project, the research group and the institution at which the research will be carried out.
- **Subject of the study**: at a general level. This does not have to be very long.
- **Selection of participants:** specify that participation is voluntary. Indicate the exclusion and inclusion criteria.
- **Description of participation:** explain what participation involves, including step by step the entire experience that the participant will undergo (the instrument, the kind of questions, the topics that will be discussed, the length of the participation, the number of visits, whether interviews will be recorded or similar).
- **Recording of participation**: if participation is recorded on video or audio, the authorisation of the participant must be requested, and this point must be clearly stated in the informed consent document.
- **Benefits:** the general benefit of the study or the benefit for the participant must be explained.
- **Risks**: any discomfort or risks that the participant could suffer must be explained, or it must be stated that there are no risks, if this is the case. When necessary, the procedures to follow if any discomfort occurs should be indicated, and it should be guaranteed that any required care will not cost the participants anything.
- **Compensation:** the document will state if there is any kind of compensation for participating in the study, or that there is no compensation, if applicable.
- **Confidentiality:** the document will state that all information provided is confidential.
    - In the case of focus groups, each participant will be asked not to reveal the statements made by other people with whom they interact in the situation.
    - Regarding data protection, the document will refer to the security measures described in the Regulation that implements *Organic Law*

15/1999 of 13 December on personal data protection.

- Regarding the dissemination and use of images, the document will refer to Organic Law 1/1982, of 5 May for civil protection of the right to honour, to personal and family privacy and to their own image.

- **Storage and safeguarding of information:** the document will indicate the place and procedure used to store information, and that the information will only be accessible to those involved in the research, during the entire study period. The name of the person responsible for the data storage will be given.
- **Right to know the results:** indicate how the participant can find out the results of the study, if he or she so wishes.
- **Right to refuse or withdraw**: the document will explain that the participant can refuse to participate in some part of the study, or withdraw from the study if they wish, without having to give a reason.
- **Right to ask questions:** the document will explain that participants have the right to ask as many questions as they consider necessary regarding the characteristics of the study and their participation in it.
- **Contacts:** the contact details of the principal investigator (address and email) will be provided.
- **Signature of two copies:** indicate that two identical copies of the document will be signed, and that a printed copy will be kept by the participant.

Information sheet template

Information for participants

The members of the research team [GIVE THE NAME OF THE RESEARCH TEAM], led by [NAME AND SURNAME/S OF THE PRINCIPAL INVESTGATOR], are carrying out a research project entitled: [TITLE OF THE PROJECT].

The project is designed to [EXPLAIN THE AIMS OF THE STUDY]. First, [EXPLAIN THE METHOD] and, second, [EXPLAIN THE METHOD IF IT IS COMPRISED OF DIFFERENT STAGES].
The following research centres participate in the study: [NAME THE PARTICIPAITNG CENTRES]. In the context of this research, we request your collaboration to [EXPLAIN THE REASONS FOR PARTICIPATING] as you meet the following inclusion criteria [LIST THE CRITERIA].

This collaboration involves participating in [LIST THE NUMBER OF STAGES and describe them].

All participants will be assigned a code so that no direct link can be made between the participant and the responses that are given, as a guarantee of confidentiality. The data that are obtained during their participation will not be used for any purpose other than that explained in this research. All data will be stored safely under the direct responsibility of the principal investigator. These data will be protected by means of [EXPLAIN THE PROTECTION SYSTEM], and only [IDENTIFY THE PEOPLE WHO HAVE ACCESS TO THEM] will have access. They will be kept along with the participant's code only for as long as necessary.

[alternatively]

Participants' data will be dealt with anonymously at all times, so that they cannot be linked either directly or indirectly with the person to whom they correspond.

Please contact us if you have any questions arising from this information. You can contact us through the form on our website: [GROUP'S WEBSITE]

Model of the informed consent form

Informed consent

I, [NAME AND SURNAME/S], a person of legal age, with identification number [IDENTIFICAITON NUMBER],
Acting in my own name and on my own behalf

STATE THAT:

I have received information about the project [TITLE OF THE PROJECT] about which I have been given the information sheet attached to this consent form and in which my participation has been requested. I have understood its meaning, my doubts have been clarified, and the actions that are associated with this project have been explained to me. I have been informed of all aspects relating to confidentiality and protection of project participants' data.

My collaboration in the project is totally voluntary and I have the right to withdraw from it at any time, which will revoke this consent. Withdrawal from the project will not have any negative impact on me in any case. If I do withdraw from the project, I will have the right to remove my data from the study files.

[WHEN NECESSARY:] Likewise, I renounce any economic, academic or any other kind of benefit that could be drawn from the project or its results.

As a result of the above,

I GIVE MY CONSENT:

1. *To participate in the project [STATE THE TITLE OF THE PROJECT]*
2. *That the research team [NAME OF THE GROUP] and Dr. [NAME OF THE PI] as the principal researcher can process my data under the terms and scope required for the research. In no case will they disseminate these data in a way that could be associated with my identifying information, and the data will only be kept for as long as necessary to meet the aims of the project.*

[CITY], on [DAY/MONTH/YEAR]

[SIGNATURE OF PARTICIPANT] *[SIGNATURE OF PI]*