CER
Comitè d'Ètica
de la Recerca
UVIC·UCC

Recommendations for writing the Information Sheet for participants and the Informed Consent form for research involving people or personal data

In this document, the Research Ethics Committee (CER) 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 the Informed Consent form.

The UVic-UCC CER will not only assess the format of these documents, but also the procedure for obtaining informed consent and guarantees of confidentiality for subjects taking part in research studies. This procedure will be described in the documents attached to the project assessment submission.

When a sample of people in an organisation is used, permission must be obtained from the centre management.

In general, the following points should be considered when drawing up the Information Sheet and Informed Consent form:

- There must be detailed, accurate information identifying the research project (including the name of the project, the research group, the main researcher, the centre which the project is ascribed to, and the organisation where it will be carried out).
- When more than one centre is involved in the project, data must be provided on all of them.
- There must be detailed information on the circumstances and objectives of the research, and the specific participation that is requested.
- Texts must be written in clear language that can be understood by people who are not experts on the subject.
- There should be two parts:
    - The Information Sheet for participants, written in a direct style, e.g. "You have been invited to participate...".
    - The Informed Consent form, written in the first person, e.g. "I have been invited to participate", "I have been informed of the research objectives".

  These two texts should be combined in one document, with numbered pages. A duplicate will be issued. One copy will be for the participant and one for the research team.
- The following information should be included about the project: the objectives, the form of participation, the benefits, the risks, the right to not 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 a copy of any information provided, information about the researcher and the right to ask questions.
- Mention should be made of guarantees and mechanisms to ensure the confidentiality of data processing and protection under Spanish Organic Law 3/2018, of 5 December, on

Personal Data Protection and guarantee of digital rights.

Specifically, the document should contain the following information:

- **Introduction:** details identifying the study, a short presentation of the invitation to participate, indicating that the aim of the document is to help potential participants decide.
- **Identification of the organisation:** identification of the researcher leading the project, the research group and the centre where the research will be carried out.
- **Subjects of study:** briefly, in outline.
- **Selection of participants:** specifying that participation is voluntary. Indication of exclusion and inclusion criteria.
- **Description of participation:** explaining what participation involves, including step by step the entire experience that the participant will undergo (the instrument, the kind of questions, the topics covered, the length of the participation, the number of visits, recording of interviews, or similar).
- **Recording of participation:** if participation is recorded as video or audio, authorisation of the participant must be sought, and this point must be clearly stated in the informed consent document.
- **Benefits:** an explanation of the general benefit of the study or the benefit for the participant.
- **Risks:** any discomfort or risks that the participant could suffer must be mentioned, or it should be stated that participation is risk-free, if this is the case. When necessary, the procedures to follow if any discomfort occurs should be indicated, together with a guarantee that any care required will not be charged to participants.
- **Compensation:** a statement of the kind of compensation for participating in the study, or that there is no compensation, as appropriate.
- **Confidentiality:** a statement that all information provided will be considered confidential.
    - In the case of focus groups, each participant will be requested to undertake not to reveal comments made by other people they interact with in the situation.
    - Regarding data protection, reference should be made to Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights and the General Regulation (EU) 2016/679, of 27 April, on data protection (GDPR) and other relevant regulations.
    - Regarding publication and use of images, the document should refer to Spanish Organic Law 1/1982, of 5 May, for civil protection of the right to honour, and personal and family privacy, and to one's own image.
- **Storage and safeguarding of information:** the document should indicate the place and procedure used to store information, and that the information will only be accessible to those involved in the research, throughout the period of the research study. The name of the person responsible for data storage should be given. The

research data file will be kept on a UVic-UCC server, with access restricted to researchers and their collaborators, strictly for project use. To make a complaint, contact the Data Privacy Officer (DPD) at UVic-UCC, the person in charge of this matter at the university.

- **Right to know results:** indicating how the participant can find out about the results of the study, if they wish to.
- **Right to decline to participate or withdraw:** explaining that the participant can decline to participate in any part of the study, or withdraw from the study if they wish to, without needing to give a reason.
- **Right to ask questions:** explaining that participants have the right to ask any questions they consider necessary regarding the characteristics of the study and their participation in it.
- **Contacts:** providing contact details of the lead researcher (address and email).
- **Two signed copies:** indicating that two identical copies of the document will be signed, and that a printed copy will be issued to the participant.

CER
Comitè d'Ètica
de la Recerca
UVIC·UCC

Model information sheet

Information for participants

The members of the research team [GIVE THE NAME OF THE RESEARCH TEAM], led by [NAME AND SURNAME(S) OF THE LEAD RESEARCHER], are carrying out a research project entitled [TITLE OF THE PROJECT].

The project is designed to [GIVE THE AIMS OF THE STUDY]. First, [DESCRIBE THE METHOD] and, secondly, [DESCRIBE THE METHOD IF IT HAS VARIOUS 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 STAGES AND DESCRIBE THEM].

Participants will be assigned a code, rendering it impossible to identify participants from the answers given, and fully guaranteeing confidentiality. The data obtained from participation shall not be used for any other purpose than described in this research and shall form part of a data file which will be under the responsibility of the lead researcher. This data will be protected by means of [DESCRIBE THE PROTECTION SYSTEM], and only [IDENTIFY THE PEOPLE WHO HAVE ACCESS TO IT] will have access.

The data file of the study is the responsibility of the lead researcher, who you may address at any time to exercise your rights under Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights, and the General Regulation (EU) 2016/679, of 27 April, on data protection and supplementary regulations.

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

Model informed consent form

Informed consent

I, [NAME AND SURNAME(S)], of legal age, with identification number [IDENTIFICATION NUMBER],
Acting in my own name and on my own behalf

STATE THAT:

I have received information about the project [TITLE OF THE PROJECT] in the information sheet attached to this consent form and my participation has been requested. I understand it, any 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 data protection with regard to the management of personal data in this project and the guarantees given in compliance with Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights, and the General Regulation (EU) 2016/679, of 27 April, on data protection and supplementary regulations.

My collaboration in the project is totally voluntary and I have the right to withdraw from it at any time, revoking this consent. In no circumstances will withdrawal from the project have any negative impact on me. If I withdraw from the project, I will have the right to remove my data from the data file of the study.

[WHEN APPLICABLE] Likewise, I renounce any economic, academic or other kind of benefit that could result from the project or its results.

As a result of the above,

I GIVE MY CONSENT:

1. *To participation in the project [STATE THE TITLE OF THE PROJECT]*
2. *That the research team [GROUP NAME] and Dr [NAME OF LEAD RESEARCHER] as lead researcher manage my personal data and publish information generated by the project. To measures to ensure that at all times my identity and privacy are preserved, with the guarantees established in the Spanish Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights, and the General Regulation (EU) 2016/679, of 27 April, on data protection and supplementary regulations.*
3. *That the team [GROUP NAME] retain all records made about me electronically, in line with legal guarantees and terms, if established, and in the absence of legal provisions for as long as necessary to fulfil the needs of the project for which the data has been collected.*

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

[SIGNATURE OF PARTICIPANT] *[SIGNATURE OF LEAD RESEARCHER]*