GUIDE FOR DRAWING UP THE INFORMATION AND INFORMED CONSENT SHEET

With this document, the Research Ethics Committee of the Ramon Llull University (CER URL) sets out to gather together the elements to be set out in the information sheet document for participants in research projects that work with personal data, or in which people are the subject to study, and in the informed consent document.

The CER URL not only evaluates the format of these documents but also assesses the procedure for obtaining informed consent and confidentiality guarantees for the subjects taking part in the studies. This procedure will be described in the documentation attached to the request for assessment of the project.

When there are plans to use a sample of people belonging to an institution, **permission must be obtained from the management of the school or faculty.**

Overall, the following aspects must be taken into account regarding the documentation when filling in the information and informed consent sheet:

- It must contain detailed and accurate information on the data identifying the research project (name of the project, research group, principal investigator, school or faculty to which it belongs, institution where it is performed, etc).
- If more than one school/faculty is involved in the project, data must be provided on all of them.
- It must contain detailed information concerning the circumstances and objectives of the research, and the specific participation that is requested.
- It must be drafted in language that is easy to understand, avoiding the use of technical terms.
- It must comprise two parts:
    - Information sheet: drafted in the second person singular or plural "You have been invited to participate...";
    - Informed consent form: drafted in the first person "I was invited to participate..."; "I have been informed of the objectives of the research".

These two documents must comprise a single document, with numbered pages, and drawn up in duplicate. One copy will be given to the participating subject and the other to the research team.

- The following project information must be provided: the objectives of the study, type of participation, risks, benefits, right to refuse to participate, right to withdraw at any time from part or all of the study, without needing to explain any cause or reason and without consequences, right to know the results, procedures to ensure confidentiality and protection of the information provided, information on the researcher and right to ask questions.
- It must contain the guarantees and mechanisms to ensure the confidentiality of the data processed and their protection under Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

Specifically, the document as a whole must contain the following information:

- **Introduction:** data identifying the study; a short presentation of the invitation to participate, stating that the purpose of the document is to help to take a decision.
- **Institutional identification**: identify the researcher responsible, the research group and the institution conducting the research.
- **Purpose of the study**: on a general level. This should not be too long.
- **Selection of the participants:** specify that participation is voluntary. Indicate the exclusion and inclusion criteria.
- **Description of the participation:** explain what participation involves, including a step-by-step description of the entire experience that the participant will enjoy (instrument, type of questions, topics to be consulted, duration of participation, number of visits, recording of interviews or similar).
- **Recording of the participation**: if video or audio recordings are made of the participation, request authorisation from the participant, explicitly formulated in the informed consent document.
- **Risks**: mention any discomfort or risks that the participant may suffer, or explicitly mention if there are no such risks. If applicable, indicate what procedures are to be followed should participants suffer any discomfort and provide assurances that treatment will be free for participants.
- **Benefits:** explain the general benefit of the study or for the participant.
- **Compensation:** indicate whether any kind of compensation will be provided for taking part in the study, or state clearly that there will be none.
- **Confidentiality:** explain how data confidentiality will be assured. Each participant in focus groups shall be required to commit to not disclosing anything said by other people with whom they interact in the situation.
- **Data Protection.** Refer to *Organic Law 3/2018 of 5 December 2018 on Personal Data Protection and guarantee of digital rights.*
- **Storage and custody of information**: indicate the place and the procedure for storing information, ensuring that access is restricted to persons involved in the research activity, throughout the duration of the study, and mention the name of the person responsible.
- **Right to know the results:** indicate how participants may, if they so wish, know the results of the study.
- **Right to refuse or to withdraw:** explain that participants may refuse to participate in any part of the study, or withdraw from the study at any time without expressing the reasons for this.
- **Right to ask questions:** explain the right of the participants to ask any appropriate questions regarding the characteristics of the study and their participation in it.
- **Contacts:** specify the contact details of the principal investigator (address and e-mail).
- **Signature in two copies:** indicate that the document will be signed in two identical copies and that the participant will retain a printed copy.