Informed Consent

❖ Purpose of the Informed Consent

Informed consent must guarantee that human subjects participating in research activities do so in a free of coercion, voluntary and conscious way, according to the researchers’ interests or concerns.

The Informed Consent document should therefore veil for the subject’s autonomy by enabling him/her to freely decide to which extent he/she wants to contribute to the research. The informed consent has to be handed by the researcher to the participant and he/she needs to sign it before the beginning of the research activity.

❖ Informed Consent: Information Sheet + Informed Consent Sheet

The Informed Consent is twofold as it includes information on the research as well as the subject’s consent to participate in it.

The information part or Information Sheet needs to include at least all these aspects:

- Name of the research
- Name of the supervisor/PI and name of the university
- Funding body (if applicable)
- Motivation and duration of the research
- Objectives of the research
- Research methodology and further information the participant needs to know (in case of interviews, tests... there needs to be a detailed description of the sessions’ number, duration, location, content and development, equipment that will be used, potential risks for the subject, etc...)
- Privacy (personal data will be handled according to the applicable law: What type of data will be collected? - in case of sensitive data, this will need to be clearly highlighted- How will data be protected? Will data be dissociated in order to avoid participants’ identification? Who will have access to data? Will data be published? What will be the conservation period? Will data be reused?, etc ...) (*)
- Benefit-Risk balance
- Voluntary participation
- Contact details

(*) Personal data is any kind of data which enables a person to be identified either directly or indirectly. This refers to identifying data (name, surname, address, etc. ...) and other type of data that may eventually lead to a person’s identification (for example, image, voice, physiological / financial / cultural / social data, etc.)
The Informed Consent Sheet has to include at least the following information:

- Name of the research
- Name of the supervisor / PI and name of the university
- Reference to the Information Sheet (to be included as Annex)
- Participant’s confirmation that he/she has read the Information Sheet and has been able to formulate any question about its content and that he/she has received all necessary information on the research project including his/her participation in it
- Expression of consent to participate in the project on the basis of the information provided

Special cases:

- In case of sensitive data, there should be explicit consent of its treatment
- In case of personal data transfer to other entities that collaborate in the project, specific transfer consent should be given
- In case of identifying data (such as image or voice), specific consent should be given
- In case of data reuse for future projects, there should be a specific consent including a description of the objectives and information on who exactly will have access to those data

Participant’s signature, place and date

In case of research projects where UPF is responsible for the data files, please include the following text:

The personal data provided will be stored in Universitat Pompeu Fabra file 'Projectes de recerca, desenvolupament i innovació', for the purpose of conducting research, development and innovation projects, and for managing any results of these projects. These data may be disclosed to third parties: data may be published to promote research in the media (including internet) and it may be disclosed to third parties (i.e. entities that collaborate in the development of research activities) upon receiving your previous consent. It may also be disclosed in cases provided for by law. The body responsible for the University files is the registrar (gerent). Rights to access, correct, cancel or object to data in these files may be exercised by applying in writing, including a photocopy of your identity card or equivalent to: Gerent. Universitat Pompeu Fabra. Pl. de la Mercè, 12. 08002 - Barcelona.

Information & Fundamental Rights that need to be included in the Informed Consent

As mentioned before, the Informed Consent has to give detailed information on the benefits and potential risks human subjects may be exposed to. It should also state clearly that participants have the right to withdraw or opt-out of the study at any time without necessarily justifying their decision.

Formal aspects of the Informed Consent

The Informed Consent must be clearly written and understandable to subjects. Moreover, it should be adapted/translated into the participant's language or into any language that is easily understood by the participant.
**Special cases / Exceptions:**

If the research activity implies the participation of minors or **legally disqualified persons**, the Informed Consent Sheet should be twofold: 1) a detailed consent form addressed to parents, guardians or tutors and 2) another consent form adapted to the legally disqualified person/minor so it is completely understandable by him/her. As for minors, if they are 14+ they are allowed to consent on the treatment of their personal data. Parents’, guardians’ or legal tutors’ signature is therefore not necessary (exemption: consent by parents or legal tutors is compulsory when, for example, the minor’s participation would imply creative work that needs to be published on internet).

Exceptionally, when participants aren’t able to consent in writing (illiterate participants, etc...), consent could be given orally (if duly documented).

**BASIC TEMPLATE OF AN INFORMED CONSENT SHEET**

**INFORMATION SHEET**

Name of the research:

Name of the supervisor / PI and name of the university (name, address and contact details):

Funded by:

- Research project’s objective:

- Methodology and procedures in relation to participants *(for example: your participation will consist in ... It will have an estimated duration of ...)*

- Risks and benefits *(for example: by participating in this experiment you will not have any direct benefit but you will help us ...; please specify if there will be any compensation...)*:

- Privacy *(for example: in order to protect your privacy, we will not identify you by your name but by a code that will only be known among researchers of the current project. We will store your data in a secure place under key or digitally with safe access control mechanisms so that these can only be consulted by researchers of the current project. In case of data publication, we will do it anonymously)*:

- Voluntary participation *(for example: your participation in this project is completely free and you can withdraw or opt-out of it at any time without need to justify your decision; you have the right to omit answers to any question)*:
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- Contact details (for example: Should you have any question on the research project, you may contact ..............:)

INFORMED CONSENT

Name of the research:

Name of the supervisor / PI and name of the university (name, address, contact details):

I HEREBY CONFIRM THAT:

- I have read the information sheet regarding the research project,
- I have been able to formulate any question on the project,
- I have received enough information on the project.

I UNDERSTAND that my participation is voluntary and I can withdraw or opt-out of the project/experiment at anytime without any need to justify my decision.

I GIVE MY CONSENT to participate in the current project.

Name and surnames:

Signature:

Place and date

The personal data provided will be stored in Universitat Pompeu Fabra file 'Projectes de recerca, desenvolupament i innovació', for the purpose of conducting research, development and innovation projects, and for managing any results of these projects. These data may be disclosed to third parties: data may be published to promote research in the media (including internet) and it may be disclosed to third parties (i.e. entities that collaborate in the development of research activities) upon receiving your previous consent. It may also be disclosed in cases provided for by law. The body responsible for the University files is the manager. Rights to access, correct, cancel or object to data in these files may be exercised by applying in writing, including a photocopy of your identity card or equivalent to: Gerent. Universitat Pompeu Fabra. Pl. de la Mercè, 12. 08002 - Barcelona.