**Informed Consent**

**Purpose of the Informed Consent**

The purpose of the informed consent is to guarantee that humans participating in research activities do so voluntarily and free from coercion. Moreover, participants must fully understand how their personal data will be processed and stored. EU legislation defines “personal data” as any information relating to an identified or identifiable natural person.[[1]](#footnote-1)

The informed consent document must protect the participants’ autonomy. Thus, it must allow them to freely decide the extent to which they want to contribute to the research.

**Informed Consent: Information Sheet and Informed Consent Form**

The informed consent form includes an information section or **information sheet**, which must be handed out to participants, and a section requesting agreement to participate or **informed consent form**, which has to be signed by the participant and kept by the researcher.

The **information sheet** must include (at least) all these aspects:

* Title of the research project
* Name and contact information of the principal investigator
* Name of the university
* Funding body or bodies (if any)
* Objectives and duration of the project
* Research methodology and information about the participant’s role (interviews, tests…). It must contain a detailed description of the number and duration of sessions, their content and development, the location where they will take place, and the equipment that will be used (if any).
* Inclusion criteria. The criteria for participation (including age, if applicable) must be described.
* Privacy. Personal data processing will be carried out according to applicable legislation, indicating what type of data will be collected, how they will be protected, if they will be pseudonymized to avoid participant identification,[[2]](#footnote-2) who will have access to them, and if they may be reused or anonymized and published in an open repository at the project’s conclusion.[[3]](#footnote-3)
* Compensation (if applicable)
* Risks and benefits
* Voluntary nature of participation and the right to withdraw from participation without explanation and to have their data deleted (this only applies if the data has not been anonymized).
* Contact information (different from the principal investigator’s)

The **informed consent form** must include at least:

* Title of the research project
* Name of the principal investigator
* Name of the university
* Reference to the information sheet (to be included as an annex)
* Participant’s confirmation that they have read the information sheet, have been able to pose questions about its content, and have received all necessary information on the research project including their participation in it
* Participant’s confirmation that they meet the inclusion criteria, including the age criterion if applicable
* Expression of consent to participate in the project on the basis of the information provided
* In some special cases, expression of explicit consent (please include those that apply):
	+ recording of participants’ voice or image,
	+ processing of special categories of personal data (i.e., those revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or a natural person’s sex life or sexual orientation),
	+ reuse of personal data for other projects by the same UPF research group,
	+ personal data transmission for projects in the same field carried out by different research groups,
	+ personal data transfer to countries outside the European Economic Area,
	+ publication of identifying data (such as a person’s image or voice at a conference or in a scientific article),

In these cases, explicit consent has to be obtained. Thus, participants need to check those types of processing they consent to (see template). If the participant does not consent to one or more of these types of processing, their decision has to be respected.

* For research projects involving personal data processing, an information note has to be included in the information sheet and in the informed consent form (see template).

**Information and Basic Rights that Need to Be Included in the Forms**

As mentioned before, the information sheet must provide detailed information on the **benefits** and **potential risks** for participants. It should also state clearly that participants have the **right to withdraw** from or opt out of the study at any time without justifying their decision.

**Formal Aspects of the Forms**

The information sheet and informed consent form must be clearly written and understandable to participants. Moreover, it should be translated into their language or into a language that they fully understand.

**Special Cases or Exceptions**

* If the research project involves the participation of **minors or** **legally disqualified persons**,[[4]](#footnote-4) two sets of information sheet and informed consent form will be necessary:
1. a set addressed to parents or legal guardians. The informed consent form needs to request the signature of both legal guardians in cases of joint custody;
2. another set adapted to the participants’ reading skills.

According to data protection legislation, for persons 14 or older, only the participant’s consent is necessary to process their personal data. However, due to ethical considerations, it is necessary to obtain the parents’ or legal guardians’ signature in order for minors to participate in a research study. This consent may become obligatory in order to comply with other regulations (e.g., if researchers plan to publish creative work by the minor online).

* Exceptionally, when participants cannot consent in writing (e.g., illiterate participants), consent can be given orally if duly documented. Oral consent can also be used if written consent may place the participants at risk of being retaliated against by third parties.
* If consent is obtained electronically, a storage protocol is necessary. Options include:
1. Setting an automatic response to the participant thanking them for consenting to take part in the study and including the information sheet and consent form. The researcher should be cc’d on the email and save all the confirmation emails.
2. Saving the log file of the server that hosts the website where participants recorded their consent. It must be a log file specific for this function (the general server log file is not enough) and it has to contain at least the following information: date, time, IP address, and, if applicable, user ID. The file has to be saved for future reference.
1. In order to determine if a person can be identified, the foreseeable evolution of technology as well as the potential combination of data with other sources by the researcher or third parties must be taken into account. This includes identifiable data (first and last names, home address, etc.) and any other data that (in isolation or combined with other data) can identify persons. It can be any kind of information, such as image; voice; physiological, economic, cultural, social data, etc. [↑](#footnote-ref-1)
2. Pseudonymization refers to the replacement of information that can identify a person with a pseudonym. The link between a participant’s identity and their pseudonym must be stored in a separate file (separate from the main data) and with additional security and access control measures. [↑](#footnote-ref-2)
3. Anonymization refers to the elimination of all information included in a personal data set that makes it possible to reidentify the persons to which it refers. Reidentification cannot be possible by third parties even if they use external data sources. [↑](#footnote-ref-3)
4. In Spain, minors 14 years or older can consent to their personal data being processed. This may be different in other EU countries (<https://www.betterinternetforkids.eu/web/portal/practice/awareness/detail?articleId=3017751>). [↑](#footnote-ref-4)