Esade Business School
Dean's Office for Faculty and Research
Committee on the Use of Human Subjects in Research

Advice on Participant Information Sheets and Consent Forms

Participant Information Sheets and Consent Forms are required when undertaking research involving human participants, data or materials. The participant Information Sheet has to provide potential participants with the necessary information about the study to allow them to give informed consent. A Consent Form essentially reprises this information to ensure the key points are understood and then records this understanding, usually with a signature. Consent may also be recorded electronically, for example through online forms. More than one Consent Form may be needed (for adults and children separately, for example). Consent Forms are usually in addition to Participant Information Sheets.

Participants aged under 18 years old require consent from parents or carers, and therefore the Participant Information Sheet and Consent Forms are addressed to the parents/carers in these cases. However, you might consider it appropriate to make an additional Participant Information Sheet and Assent Form for child participants using age-appropriate language.

Participant Information Sheets

The Participant Information Sheet should be a clear and simple document, on ESADE headed paper, that can be easily understood by those to whom it is aimed; for example, it should be age-appropriate. It should be a concise document so that the potential participant is able to read it completely. It can also be displayed on screen if the study is computer based.

There is no set format, however investigators may like to consider including the following guide:

Title

Use a simplified title if the original title would be too technical

Invitation paragraph

A brief introduction; for example: *Before you decide to take part in this study it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. A member of the team can be contacted if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.*

Purpose of the study

State the background and aim of the study. When will the study be completed?

Why have I been chosen?

Explain why the potential participant has been approached.

Do I have to take part?

Explain that taking part is entirely voluntary and that refusal or withdrawal will involve no penalty or loss, now or in the future.

What will happen to me if I take part?

Say where the assessments will take place, how many will there be, how long the assessments will be each time and what exactly will happen. What are the participant's responsibilities? Set down clearly what you expect of them.

What do I have to do?

Make clear if there are any lifestyle restrictions as a result of participating.

Make clear if video or audio taping will be used and if so, say when they will be destroyed. For example: *Tapes will be identified only by a code, and will not be used or made available for any purposes other than the research project. These tapes will be destroyed at the end of the study.*

Are there possible disadvantages and/or risks in taking part?

Describe any reasonably foreseeable discomforts, disadvantages and risks.

What are the possible benefits of taking part?

Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be stated clearly. It is important not to exaggerate the possible benefits to the particular participant during the course of the project. This could be seen as coercive.

Will my taking part in this project be kept confidential?

The participant's permission will be needed to allow restricted access to information collected about them in the course of the project. You should explain that all information collected about them will be kept strictly confidential and briefly described how this will ensured. For example: *All data will be identified only by a code, with personal details kept in a locked file or secure computer with access only by the immediate research team.*

Bear in mind that investigators are responsible for ensuring that when collecting or using data, they are not contravening legal or regulatory requirements.

What will happen to the results of the research project?

You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the project they were in? You might add that they will not be identified in any report or publication. For example*: Results will be presented at conferences and written up in journals. Results are normally presented in terms of groups of individuals. If any individual data are presented, the data will be totally anonymous, without any means of identifying the individuals involved.*

Depending on the nature of your proposed project, you may need to include a statement indicating that the data collected during the course of the project might be used for additional or subsequent research.

Who is organising and funding the research?

Name the organisation or company sponsoring or funding the research.

Ethical review of the study

Example text: *The project has received ethical approval from the Research Ethics Committee of ESADE.*

Contact for further information

You should give contact details of a named investigator for further information.

Consent Forms

A Consent Form should be no longer than one side of A4. It should be formatted on ESADE headed paper and clearly state the title of the study. You can use the **Consent Form Template** provided in this site.

The Consent Form provides the main points of the Participant Information Sheet phrased as statements with which potential participants can agree or disagree. You could add a space for initials or yes/no deletions.

Some example statements include:

- *I confirm that I have read and understand the Participant Information Sheet*
- *I have had the opportunity to ask questions and had them answered*
- *I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified (except as might be required by law)*
- *I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research*

- *I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.*
- *I agree to take part in this study*

Participant's signature make a space for the participant to sign, print their name and date. If parents or carers are consenting for a child, then a space to print the child's name is also needed.

Spaces for the investigator taking consent to sign, print their name and date can also be included.