Guidelines Regarding Participant Information and Consent

A Participant Information Leaflet and Consent Form must be submitted to the Research Ethics Board. If there is an external sponsor, submit the sponsor's information leaflet and their consent form. For non-sponsored projects the investigator may draw up a participant information leaflet based on the following outline. The leaflet should be written in clear non-technical English and aimed at the potential participants in the project, and not at members of the Research Ethics Committee. All the headings in the following outline should be included. For several of the headings, the recommended wording is provided in italics and should be used if appropriate for the particular study.

A sample consent form is also provided below.

1. Title of study: xxx

2. Introduction: Provide a brief description of the research project, stating the purpose of the study, the procedures involved, and the extent of the participant's involvement, e.g. time span of participation, expected number of visits to the laboratory or clinic.

3. Procedures: List the criteria for selection for participation in the study, e.g. that the participant has a particular complaint, is between certain ages, is not covered by the criteria for exclusion, and, if a woman, is not pregnant or likely to become pregnant. Then detail the nature of the participant's involvement, e.g. that the participant will undergo initial tests, will then take a course of medication, will have return visits to the doctor and subsequent examinations, etc. Note that the participant must be informed about the manner in which a drug is to be administered and whether an inactive substance (a placebo) may be administered.

4. Benefits: List any potential benefits of the study. These may include direct benefits or be related to future more general benefits as a result of knowledge gained.

5. Risks: List the material risks, discomforts and side effects involved in participating in the study. Material risks are those that a prudent person in the participant's position would regard as significant in considering whether or not to undergo the procedures in question. If the risks attaching to a treatment are unknown this should be stated.

6. Exclusion from participation: You cannot participate in this study if any of the following are true: (list the criteria excluding an individual from participating in the study).

7. Confidentiality: Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group.

8. Compensation: This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.
9. **Voluntary Participation:** You have volunteered to participate in this study. You may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.

10. **Stopping the study:** You understand that the investigators may withdraw your participation in the study at any time without your consent.

11. **Permission:** State that the trial has Research Ethics Committee approval from all institutions involved.

12. **Further information:** You can get more information or answers to your questions about the study, your participation in the study, and your rights, from ...............who can be telephoned at ............... If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.
**INFORMED CONSENT FORM - SAMPLE 1**

**Research Involving Human Participants**
(Adapt as relevant to your study)

The researcher should retain the original of the signed form in a secure file, give one copy to the participant, and send one copy to the sponsor (if appropriate).

<table>
<thead>
<tr>
<th><strong>Project title:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principal Investigators:</strong></td>
</tr>
</tbody>
</table>

**BACKGROUND:** (provide short summary of what project involves for participants, including the procedures to be carried out and the assurance of confidentiality)

<table>
<thead>
<tr>
<th><strong>Participant Declaration:</strong> (This should be written in the first person and include agreement that I (i.e. the participant):)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tick yes or no as appropriate</td>
</tr>
<tr>
<td>Have read or have had the information sheet read to me and that I understand the contents.</td>
</tr>
<tr>
<td>Have been given an opportunity to ask questions and am satisfied with answers.</td>
</tr>
<tr>
<td>Consent to take part in the study.</td>
</tr>
<tr>
<td>Understand that participation is voluntary and that I can withdraw at any time.</td>
</tr>
<tr>
<td>Understand that withdrawal will not affect my access to services or legal rights.</td>
</tr>
<tr>
<td>Consent to possible publication of results.</td>
</tr>
</tbody>
</table>

I (the participant) give my permission to:
Use the data obtained from you in other future studies without the need for additional consent.

<table>
<thead>
<tr>
<th><strong>Researcher Declaration:</strong> (This should be written in the first person and include agreement that I (i.e. the researcher):)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tick yes or no as appropriate</td>
</tr>
<tr>
<td>Have explained the study to the participant</td>
</tr>
<tr>
<td>Have answered questions put to me by the participant about the research</td>
</tr>
<tr>
<td>Believe that the participant understands and is freely giving consent</td>
</tr>
</tbody>
</table>

**Participant’s Statement:**
I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand I may withdraw from the study at any time. I have received a copy of this consent form.
Participant’s Name:  
Contact Details:  
**Participant Signature**:  
(where participant is over the age of 18)  

**Date**:  

The form needs to be signed by the consenter (or a parent or guardian in the case of the participant being unable to understand the scope, nature or significance of the study or in the case of the participant being under 18 years) and dated.  
**NAME OF CONSENTER, PARENT or GUARDIAN**:  
**SIGNATURE RELATION TO PARTICIPANT**:  
**Date**:  

**Researcher’s Statement**:  
I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.  

**Signature**:  
**Date**:  


INFORMED CONSENT FORM \(^1\) SAMPLE 2
FOR
RESEARCH PARTICIPANTS IN INTERVIEWS

The aim of this form is to facilitate informed consent by communicating with participants in language that they can understand. The material below is a sample – it does not have to be reproduced verbatim. Adapt it to fit the circumstances of your own study. Some of the sample text below assumes a study involving qualitative interview data. If that’s not your methodology, adapt the text to the approach you are using.

Information Sheet

**Purpose of the Study:** As part of the requirements for [degree] in ITT Dublin, I have to carry out a research study. The study is concerned with [keep it brief and simple – 1-2 sentences. There is no need to go into the theoretical complexities of the topic.]

**What will the study involve?** The study will involve [Indicate the procedure and time commitment, giving the simplest possible explanation and avoiding jargon and unnecessary detail.]

**Why have you been asked to take part?** You have been asked because [Because they are specifically or generally suitable to provide data for your study].

**Do you have to take part?** [The answer is no! – participation is voluntary. Explain about signing a consent form. Ideally they get to keep the information sheet and a copy of the consent form. They should be told that they have the option of withdrawing before the study commences (even if they have agreed to participate) or discontinuing after data collection has started. Where data are identifiable (e.g. from interviews yielding qualitative data), it’s useful to allow for afterthoughts by letting them withdraw within two weeks of participation and ask to have their data destroyed. Explain all this in writing.]

**Will your participation in the study be kept confidential?** [Yes! - but remember, there’s no such thing as absolute confidentiality – don’t ever make promises you may not be able to keep. Usually the relevant term is anonymity rather than confidentiality. For example:] Yes. I will ensure that no clues to your identity appear in the thesis. Any extracts from what you say that are quoted in the thesis will be entirely anonymous.

**What will happen to the information which you give?** [Kept confidential from third parties (including workers’ superiors, if relevant); will it be destroyed after a period? For example:] The data will be kept confidential for the duration of the study. On completion of the thesis, they will be retained for a further five years in a secure environment and then destroyed.

**What will happen to the results?** [For example:] The results will be presented in the thesis. They will be seen by my supervisor, a second marker and the external examiner.

\(^1\) The following draws extensively on a document produced by Dr R. Swain of UCC, and is used with permission. Copyright is vested in same and all rights therein remain with Dr Swain.
The thesis may be read by future students on the course. The study may be published in an academic journal.

**What are the possible disadvantages of taking part?** [If you think there are none, say so, but not in a black-and-white way. Before approaching this and other persons you should have discussed with your supervisor the implications of asking for the participation of this person and other like them. Upon asking them you may realise that a research question may raise issues that you are not qualified to deal with, even if you should then refer them on to other agencies. If they may feel distressed, mention the possibility and refer to the next section. For example:] I don’t envisage any negative consequences for you in taking part. It is possible that talking about your experience in this way may cause some distress.

**What if there is a problem?** [Tell them what they can do, for example:] At the end of the interview [/procedure], I will discuss with you how you found the experience and how you are feeling. If you subsequently feel distressed, you should contact...[e.g. the investigator, The Samaritans – give contact details - or their GP].

**Who has reviewed this study?** [Institute Research Ethics Committee? Local Hospital’s Ethics Committee? Both? For example:] Approval must be given by the Institute before studies like this can take place.

**Any further queries?** If you need any further information, you can contact me: [Name, mobile number, email address. Specify times and dates you will be available, be available then and reply promptly should you be unable to take the call, or reply to the e-mail, at that time. To protect your own privacy, you should delete this information from the finished thesis].

If you agree to take part in the study, please sign the consent form overleaf. [Note the formatting – it’s best not to have text dribbling on to the next page – but don’t make the font size too small, either – say, not less than size 12. Remember you can adjust the size of the margins. ]
ADDITIONAL GUIDELINES FOR A PARTICIPANT INFORMATION LETTER

Include the following points:

1. **Names of researchers**
2. **Working title of study**
3. **Description of study**
   - Aims and objectives of study (what the study is about, why this population)
   - Contribution required from participant (what the study involves, what the participant will be asked to do)
   - Possible benefits of the study
   - Possible risks to participants and after effects
   - Location of research
   - What will happen to the results of the study
4. **Confidentiality of information**
   - How information will be stored
   - How confidentiality will be ensured
5. **Compensation**
6. **Voluntary participation**
   - Not obliged to take part
   - May withdraw at any time
7. **Permission**
   - Ethical approval from X institutions
8. **Further information and how to take part**
   - Instructions on completion of consent form
   - Contact details of researcher
Guidelines for projects involving performance/abilities of school children

• Except with very young children, individual assent should be obtained from each child as well as formal consent from a parent/guardian

• Children in second level education should give written assent except for “children” age 16 or over who may give their consent

• If study data are passed to the school they should be anonymised

• If it is seen as appropriate for remedial purposes that data on a particular identifiable child are passed to the school, this must be approved in advance by the parent/guardian

• If the investigator is a student, the decision to pass information on an identifiable child to parent/guardian or school must be made by the investigator’s supervisor.