

## Good Practice Guidelines for Information Sheets and Consent Forms

### Introduction

The aim of this document is to provide advice and guidance on the style and format of **Information Sheets and Consent Forms provided to participants**. It is not the Committee's intention to make recommendations about the ethical content of these materials or the nature of the research. Depending on the circumstances and methodological approach, different strategies for providing information and gaining consent may be necessary.

To compile this document we have used information from the National Research Ethics Service publication 'Information Sheets and Consent Forms – Guidance for Researchers & Reviewers' which can be found at <http://www.nres.npsa.nhs.uk/applications/guidance/#PIS>. For more detailed guidance we recommend that you consult this publication, adapting it for your own use as appropriate. Please note that this guidance is focused mainly on healthcare research.

### Information Sheets

#### General Comments

The NRES guidelines recommend that:

- The level of detail should be appropriate to the nature and details of the study. Studies involving minimal risk are likely to need a much shorter information sheet.
- The information sheet is best written as an invitation (the use of 'we' may help). Use the active tense and avoid the passive. Write in simple, non-technical terms that a lay person will understand easily. Use short words, sentences and paragraphs with clear subheadings to make the text manageable, and a font size for easy reading. Arial 14 is recommended by the RNIB. If you intend to recruit older subjects (or those with sensory impairments) you may need to use a large font size e.g. 16
- The first page should use the headed paper of the organisation carrying out the research with contact details (email, telephone and postal).
- All information sheets and consent forms should have a date, version number, page numbers in the header/footer.
- Details in the information sheet and consent form should be consistent.
- Copy of the information sheet and consent form to be given to participants.

## Design

The design will vary depending on the type of study and target audience. For example, if your study involves those who may lack the capacity to consent, information sheets could be very simple, utilising pictures. To help you think about your design we suggest the following sections are considered:

**Document Heading** – for example ‘Participant Information Sheet’ or ‘Information about the research’.

**Study title** – Does this explain the study in simple English?

**Invitation paragraph** – The invitation is to ask the potential participant to consider the study and then decide whether to take part. Both should be clearly explained. The following is an example:

*We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our research team will go through the information sheet with you and answer any questions you have. Ask us if there is anything that is not clear.*

**Purpose of the study** – The purpose of the study should be explained clearly and succinctly in lay language. This should be the same as the purpose described in the REC application form. If any aspect of the study is not divulged to the potential participant, the applicants will need to provide strong justification for withholding it.

**Why have I been invited?** – Briefly explain why and how the participant was chosen or recruited, and how many others will be taking part in the study.

**Do I have to take part?** – You should explain that taking part in the research is entirely voluntary. The following is an example:

*It is up to you to decide to take part in the research. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the care/support you receive.*

**What will happen to me if I take part?** – To answer this question, we suggest you try to put yourself in the participant’s shoes. Put in details of what you are asking the person to do, such as a 60 minute interview, followed by completion of a postal questionnaire 3 months later. Long-term monitoring/follow-up should be mentioned.

Participants should be informed if the research will involve video/audio-taping, filming or photography. Specific consent will be needed if published material identifies the participant. You should set out simply the research methods you intend to use.

**What will happen if I don't want to carry on with the study?** – Explain what the participant can and can't expect and what happens to the data collected up to the point they withdraw from the study.

**Will my taking part in this study be kept confidential?** – You should tell the participants what 'confidentiality' means in this context, for example, that the researcher will not tell anyone you have taken part in this study. They may repeat what you have said in their report but you will not be named. Participants should then be told how their confidentiality will be safeguarded during and after the study and any instances when confidentiality may be broken. You may wish to tell the participants how your procedures for handling, processing and storage and destruction of their data match the Caldicott principles and/or appropriate legislation. The participant should be told:

- how their data will be collected;
- that it will be stored securely, giving the custodian and how it could be linked to you (e.g. identifiable, coded, anonymised, etc.);
- what it will be used for. It must be clear if the data is to be retained for use in future studies and whether further REC approval will be sought;
- who will have access to view identifiable data (authorised persons such as researchers, sponsors etc);
- how it will be retained, when it will be disposed of, and that it will be disposed of securely;
- if appropriate, a sentence explaining when confidentiality might be broken which takes into account the nature of the group you are working with. The following, developed by the Social Care REC, is an example:

*'Everything you say/report is confidential unless you tell us something that indicates that you or someone else is at risk of harm. We would discuss this with you before telling anyone else'.*

**Expenses and payments** – You should explain if expenses (e.g. travel, meals, child-care, compensation for loss of earnings, etc.) are available and you should consider whether any vouchers, gifts, etc. which you intend to give as 'thank-you' for participation, should be detailed in the information sheet.

**Risks/benefits of taking part** - Consider if there are any risks/benefits for the participants and explain these clearly if appropriate. Try not to make exaggerated claims for the impact of the research.

**What will happen to the results of the study?** – You should tell the participants what will happen to the results of the research, whether it is intended to publish the results and how the results will be made available to participants. You should add that if the report/publication contains identifiable details they will not be identifiable unless they have given their consent.

**Who is organising and funding the research?** – The answer should include the organisation or company sponsoring the research and funding the research if these are different.

**Who has reviewed the study?** - You may like to include a statement as follows:

*This study has been reviewed and given a favourable opinion by the Social Care Research Ethics Committee. A Research Ethics Committee is a group of independent group of people who review research to protect the dignity, rights, safety and well-being of participants and researchers.*

**Further information and contact details** – The first page of the information sheet should be on headed paper with relevant contact details (postal, email and telephone). Contact details for other members of the project should also be provided as appropriate together with details of who participants should contact if they are unhappy with the study and who to complain to should they want to make a complaint.

## Consent Form

Consider carefully if a consent form is needed, it is not always appropriate to have one. For example, if your study is a postal/e-mail questionnaire a consent form may be inappropriate. If a consent form is not being used, please explain your reasons in the IRAS application form.

The following (basic) example is suitable for many types of study but may need to be altered for your study. For example, you may need to ask for consent to use audio/video-taping, photography or verbatim quotations. You may also like to give information about secure data storage. Participants may also agree that data collected up to the point they withdraw from a study may be retained and used in the analysis.

The form should be on headed paper.

## Consent Form

### Title of Project

Thank you for considering taking part in this research. If you have any questions please ask a member of the research team before you decide whether to take part. You will be given a copy of this Consent Form to keep and refer to at any time.

*Please tick*

- I confirm that I have read and understood the information sheet dated ..... (version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my care or legal rights being affected.
- I understand that if I withdraw from the study the data collected up to that point will be destroyed.
- I agree to take part in the study.

Name of Participant (please print) \_\_\_\_\_

Signed \_\_\_\_\_ Date \_\_\_\_\_

Name of Researcher (please print) \_\_\_\_\_

Signed \_\_\_\_\_ Date \_\_\_\_\_

**Reference:** National Patient Safety Agency, National Research Ethics Service, Information Sheets and Consent Forms, Guidance for Researchers and Reviewers, May 2009. A copy can be seen at <http://www.nres.npsa.nhs.uk/applications/guidance/#PIS> .