

Guidance on completing an Information Sheet

An information sheet should help a person to make an informed choice regarding whether or not to participate in a research project. Therefore, an information sheet should provide sufficient information to enable potential recruits to make an informed choice and should clearly state that participants are free to withdraw at any time.

Researchers should take the steps necessary to ensure that all participants in the research (a) understand the process in which they are to be engaged, including why their participation is necessary and (b) understand the purpose of the research and how and to whom its research findings will be reported.

It is recommended that the content of an information sheet is:

- relevant to the proposed research.
- accurate and concise.
- clear, simple and understandable from a lay person's perspective (e.g. avoids jargon).
- presented on the headed paper of the institution carrying out the research.
- appropriate for the cultural and social context in which it is being given.

It is recommended that the content of an information sheet does not include:

- any abbreviations, jargon or technical terms.
- bias or coercion or any inappropriate inducements.

How long should an information sheet be?

Information sheets should only contain relevant information that a reasonable person would want to know (i.e. in order to decide whether or not to participate in a research project). It is recommended that, where appropriate, an information sheet contains information in the order specified under the headings given overleaf.

The length and design of an information sheet should encourage a prospective participant to read it in full. A participant may take more care when reading a concise information sheet and, thereby, be better informed than if s/he has to read an information sheet that runs into several pages. However, with respect to projects that involve 'particularly vulnerable' participants and/or which require access to 'sensitive' personal data the information sheet may need to be relatively longer in order to cover more detailed information.

Note on Human Tissue:

If your research project involves access to and use of human tissue it is advised that you consult the Medical Research Council's (MRC) guidance fact-sheet 'Human tissue and biological samples for use in research': www.mrc.ac.uk/pdf-tissue_guide_fin.pdf

Please Turn Over

Model Information Sheet

1. Research Project Title:

Is the title self-explanatory to a lay person?

2. Invitation paragraph

Explains that the prospective participant is being asked to take part in a research project.

Example paragraph:

'You are being invited to take part in a research project. Before you decide 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. Ask us 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. Thank you for reading this.'

3. What is the project's purpose?

The background, aim and duration of the project should be given here.

4. Why have I been chosen?

You should explain how the participant was chosen and how many other participants will be recruited.

5. Do I have to take part?

You should explain that taking part in the research is entirely voluntary and that refusal to agree to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Example paragraph:

'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form) and you can still withdraw at any time without it affecting any benefits that you are entitled to in any way. You do not have to give a reason.'

6. What will happen to me if I take part?

You should state how long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to participate and for how long each time. You should explain if travel expenses are available.

You should explain what exactly will happen (e.g. blood tests, interviews etc.?)

Where a participant is to be interviewed the questioning style should be explained (e.g. clarify if questions will enable open as well as closed answers to be given in relation to a particular topic; e.g. clarify which aspects of the topic participants should be able to discuss in-depth and which not in-depth).

You should explain the participant's responsibilities, setting down clearly what you expect of them.

You should set out simply the research methods you intend to use.

7. What do I have to do?

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

8. What are the possible disadvantages and risks of taking part?

Any reasonably foreseeable discomforts, disadvantages and risks need to be stated. Researchers should make known to the participants any predictable detriment arising from the proposed research process. Any unexpected discomforts, disadvantages and risks to participants, which arises during the research, should be brought immediately to their attention.

9. 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.

Example opening sentence:

'Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will ...'

10. What happens if the research study stops earlier than expected?

If this is the case the reason(s) should be explained to the participant.

11. Will my taking part in this project be kept confidential?

An applicant should consult the ethics data protection for advice on what information to provide to prospective participants, available at:

<http://campus.leeds.ac.uk/dpa/>

You need to obtain the participant's permission to allow restricted access to information collected about them in the course of the project. You should state that all information collected about them will be kept strictly confidential and explain how information will be kept confidential. Example paragraph:

'All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any reports or publications'.

Where, due to the nature of the research, it may not be possible to safeguard the confidentiality of the data then the reasons for this should be stated here. Furthermore, the consequences to the participant from data not remaining confidential should be provided here.

12. What type of information will be sought from me and why is the collection of this information relevant for achieving the research project's objectives?

Please explain here.

13. 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 (i.e. when the results are likely to be published, whether they can obtain a copy of the published results) and add that they will not be identified in any report or publication.

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 (if this is the case then this should be explicit on the participant consent form).

15. Who is organising and funding the research?

You should state the organisation or company that is sponsoring or funding the research.

16. Contact for further information

You should give the participant a contact point for further information.

This can be your name, address and telephone number or that of another researcher in the project (if this is a supervised-student project, the address and telephone number of the student's Supervisor).

Finally ...

the information sheet should state that the participant will be given a copy of the information sheet and, if appropriate, a signed consent form to keep.

and remember to thank the participants taking part in the project.

Question to insert into an information sheet if the research involves producing recorded media:

Will I be recorded, and how will the recorded media be used?

You need to obtain the participants' permission to record their activities on audio or video media. You must ensure that there is a clear understanding as to how these recorded media will be used. For instance, if you record a music or theatre performance, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the performers' permission. Storage (and eventual disposal) of interview recordings which contain sensitive material can also be an issue to address.

Example paragraph:

'The audio and/or video recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.'

If you plan to use the recording in a publication or broadcast or deposit it in an archive, it will usually be best to prepare and sign a separate release form for each item used.