Participant information and consent

You should supply prospective participants with as much information as possible to enable them to make an informed choice about their possible involvement. This is informed consent.

It should be clear that participation is voluntary and that any decision not to participate will have no bearing on their academic or other progress in the future. Participants must also have the right to withdraw easily from a project whenever and for whatever reason without explanation or penalty.

All participants have the right to expect that the information supplied by them will be treated as confidential and will be protected as such. They also have the right to expect that their identity will be protected.

What you need to do

It is considered good practice to provide participants with a separate participant information sheet in advance and to allow sufficient time for a decision to be made. Informed consent must be given on a consent form which must be signed by participants before the start of any project. Participants should then be provided with a copy of their signed consent form.

An exception to obtaining a signed consent form can be made for questionnaires completed online. In this case, a statement should be provided on the front page that indicates that the participant is consenting to participate in a study by completing and submitting the questionnaire. The statement should be repeated at the end of the questionnaire before submission takes place.

Although informed consent for a child to participate may have been obtained from a child's parent or guardian, it is good practice also to inform the child fully of the research in a manner appropriate to their age. Their assent to take part can then be obtained.

Information for Participants

- All documentation provided for participants must be written in plain language, free from jargon and acronyms. The length and appearance should encourage potential participants to read it in full. It may be that participants gather more information from a shorter sheet. However, the length must depend on the participants addressed and the type of information that is being collected.

- Participant information sheets should be on headed paper identifying the University as the responsible institution and the department to which the research is linked.

- The name(s) and status(es) of the researchers involved should be provided, together with details of how to contact them.

- The title of the research project should appear as it has been given on the original application for ethical approval.

- If the research is funded then the source of funding should be mentioned.
• There should be a statement about the aim of the study, i.e. the purpose and value of the study.

• Information about why potential participants are being invited to take part should be provided, e.g. inclusion/exclusion criteria. It is important that potential participants fall within the population that is to be studied.

• There should be a brief statement about what the study will entail for participants. This should include a description of any procedures/tests, the time involved both in terms of duration and frequency, and where these will take place.

• Information about whether there are any risks involved and, if so, what will be done to ensure a participant's wellbeing or safety must be provided. It is also important to advise participants of any special factors which may increase their risk if they participate, e.g. allergies, medical conditions.

• Participants should be told if there will be any benefits arising from their participation.

• Participants should be told what will happen to any information, data or samples that are collected and to whom results will be reported. Participants have a right to confidentiality and to anonymity. If their participation is to be confidential, they should be told this and how the confidentiality will be maintained. Thought should be given to how information will be stored, who will have access to it and for how long. It is possible, for example, that funders of research will expect data to be available in some form in the future for other researchers. It is important that participants are not told that only the researcher will have access to data and that it will be destroyed after a certain time if, in fact, it is necessary to deposit data in an archive. Further information about data protection and research is available from the University's Information Assurance Manager. Other helpful resources are the UK Data Service and the Health Research Authority guidance.

• There must be a clear statement that participation is voluntary and that any decision not to participate will not prejudice their academic or other progress in any way in the future.

• There must be a clear statement that participants have the right to withdraw at any time for whatever reason and without explanation or penalty. Details of how they can do this and what happens to any information that they have already provided need to be provided.

• There must be a clear statement about the legal basis for data processing and who the Data Controller is.

• Participants should be provided with details of who can be contacted if they wish to make a complaint or have a concern.

• Participants should be told that they will have an opportunity to ask any questions before agreeing to take part and how they may do this if a researcher is not present when consent is given.

Sample information sheets

The UK Data Archive provides sample information sheets.
Consent Forms

- Consent forms must be written in plain language free from jargon and acronyms.
- Consent forms must be printed on headed paper identifying the University as the responsible institution and the department to which the research is linked.
- The title of the research project should be given, together with the name of the Principal Investigator.
- The name of the participant should be given.
- There should be statements to cover the following points:
  - The participant agrees to participate in this research.
  - This agreement has been given voluntarily and without coercion.
  - The participant has been given full information about the study in the form of participant information sheet and contact details of the researcher(s).
  - The participant understands that they can withdraw from the study at any time, without giving reasons and without penalty.
  - Details relating to anonymity and confidentiality of the information provided and the participant’s understanding of these.
  - Details of what will happen to the data collected and who will have access to them
  - The participant has had the opportunity to ask any questions.

The form will vary according to the particular type of research being undertaken, and other statements may additionally be necessary.

Paperwork procedure

The form should be signed and dated by the participant or the person giving consent on their behalf and should be witnessed by the person obtaining consent, usually but not always the researcher or a member of the research team. Ideally, each of the statements should have a box which the participant can initial to indicate that they agree with or understand the statement.

A copy of the signed form should be provided for the participant and a copy should be retained by the researcher.

Sample forms

The UK Data Archive provides sample consent forms.