Participant Information Leaflets and Consent Forms – Guidance for Researchers

Informed consent is a key issue in the conduct of ethical research. In order for consent to be informed, participants should be given comprehensive information regarding the nature, purpose and consequences of the research project. Where possible this should be done by providing an information leaflet about the research and requiring participants to sign a statement of informed consent.

General Guidance

Care should be taken to ensure that the participant information leaflet and consent form is phrased in a way appropriate to the intended audience (if necessary, in lay terms) and in a suitable format (e.g. large print if appropriate).

A copy of the participant information leaflet and consent form should be retained by each participant. Copies of each signed consent form should be retained by the researcher.

Please note that the headings and the level of detail required will depend upon the context of the study and the intended participants.

Guidance on producing a participant information leaflet:

Title of the proposed study

A brief and descriptive title for the proposed study should be given.

Description of the proposed study

The main features of the study should be outlined, including its purpose and value. If it is not appropriate to disclose the purpose of the study at this stage as it will influence the data, participants should be fully debriefed immediately following the study.

Invitation to participate and explanation of what participation entails

An invitation should be issued to participate in the study, clearly stating that participation is voluntary, and that the participant is free to withdraw at any time. Ideally, participants should be informed why and how they have been selected.

The participant should be told succinctly what will be required of them during the study (including the anticipated time commitment), how the proposed study may affect them (either positively or negatively) and what they can expect to experience during the study. Participants should be advised to seek further clarification from the researcher if there is anything which they do not understand prior to participating.

Participants should be clearly informed if they will be recorded in any way during the research.

The consent form also requires a "fair processing" Notice. See below for an example.

Reward/reimbursement/expenses

Any reward/reimbursement/expenses which will be paid to the participant should be stated, as should the arrangements for payment.

Confidentiality/anonymity and data security

If appropriate, participants should be informed that their data will be treated as anonymous and/or confidential.

Participants should be told who will have access to their data and for what the data will be used. Data storage and disposal arrangements may also be mentioned.

Results of the study

Information should be provided about the intended use and dissemination of the results arising from study, and about any feedback that will be provided to participants.

Who is funding the study

If appropriate, the funder of the study should be stated.

Contact details

Contact details for the researcher (including name and position) should be given to allow the participant to seek further clarification if required.

Guidance on producing a consent form:

Title of the proposed study

The title should be both descriptive of the proposed study.

Fair Processing Statement

A sample fair processing statement is included below. Please note that this may need to be adapted to accurately reflect the data processing arrangements in place for specific projects. For example, if data is to be placed in a data archive (such as the Economic and Social Data Service) at the end of the project, this should be clearly stated.

This information is being collected as part of a research project concerned with (objective of the research) by the Department of (Name) in the University of Birmingham (in collaboration with……..). The information which you supply and that which may be collected as part of the research project will be entered into a filing system or database and will only be accessed by authorised personnel involved in the project. The information will be retained by the University of Birmingham and will only be used for the purpose of research, and statistical and audit purposes. By supplying this information you are consenting to the University storing your information for the purposes stated above. The information will be processed by the University of Birmingham in accordance with the provisions of the Data Protection Act 1998. No identifiable personal data will be published.

Statements of understanding/consent

As appropriate to the study, for example these may include:

- I confirm that I have read and understand the participant information leaflet for this study. I have had the opportunity to ask questions if necessary 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. If I withdraw my data will be removed from the study and will be destroyed.

- I understand that my personal data will be processed for the purposes detailed above, in accordance with the Data Protection Act 1998.

- Based upon the above, I agree to take part in this study.

Name, signature and date

Name of participant…… Date…… Signature……..

Name of researcher/
individual obtaining consent……... Date…… Signature……..

A copy of the signed and dated consent form and the participant information leaflet should be given to the participant and retained by the researcher to be kept securely on file.