GUIDANCE NOTES FOR INVESTIGATORS

Informed Consent

The Ethics Review Sub-Committee has approved the following guidance for investigators regarding informed consent.

1. What is Informed Consent

Informed consent is one of the essential principles of research ethics. Its intent is that human participants can enter research freely (voluntarily) with a complete understanding about what it means for them to take part and without explicit or implicit coercion. Individuals must give consent before they enter the research. Before a person is able to participate in research activities, the investigators are responsible for obtaining that person's informed consent to participate and for documenting this consent. In order for consent to be informed the participant must understand what the research is and what they are consenting to.

There are two distinct stages to a standard consent process for competent adults:

Stage 1 (giving information): the person reflects on the information given; they are under no pressure to respond to the researcher immediately.

Stage 2 (obtaining consent): the researcher reiterates the terms of the research, often as separate bullet points or clauses; the person agrees to each term (giving explicit consent) before agreeing to take part in the project as a whole. Consent has been obtained.

The primary objective is to conduct research openly and without deception. Deception - i.e., research without consent - should only be used as a last resort when no other approach is possible.

2. Participant Information

The Participant Information Sheet is an essential component of the consent process as it ensures that the potential participants have sufficient information to make an informed decision about whether to take part in the research or not.

No matter how you recruit participants (for example, by circular emails, in person, or through posters and advertisements) they should be given an information sheet to keep. This will ensure that participants can consider their participation without pressure and have the information that they need in order to give informed consent.

It may be necessary to draft more than one information sheet if you need to communicate to participant groups with different needs (such as teachers and children) or if your project involves different types of participation (some participants asked to complete anonymous questionnaires only, while others will be interviewed and audio recorded).

If you are recruiting children under 18 years old, you must ensure the information sheet is suitable for the age of the participant. You may need several information sheets to cover the range of ages you are recruiting.

Each participant must be able to understand from an information sheet exactly what participation would involve for them.

3. How is Informed Consent Recorded

Wherever possible, and bearing in mind the nature of the research activity concerned and the research methods to be adopted, an individual's consent should be obtained in writing. Typically, you should ask research participants to sign an Informed Consent form ensuring you have a written record of their consent. This is the 'gold standard' of informed consent. Templates are available in the online ethics system, LEON. These templates are exemplars that are not intended to be prescriptive. Investigators must adapt them to be suitable for their specific study.

Online Questionnaires must include a consent section so that participants can confirm their willingness to take part in the study. Consent cannot be assumed by completion of the questionnaire or by selecting 'next' to continue the questionnaire. The consent section should list the relevant clauses, but it is not necessary for each clause to be initialled. A template for anonymous questionnaires is available through LEON. We recommend that there should be one box for participants to tick confirming their consent to take part in the study. Participants should not be asked to initial the consent section if the questionnaire is intended to be anonymous.

In some circumstances it may not be appropriate to take written consent. Documented oral consent is an acceptable alternative. Ideally oral consent should either be tape-recorded or obtained in the presence of at least one witness. An oral consent process (where researcher and participant have a conversation to give information and obtain consent) is normally used:

- where literacy is a problem,
- where there are cultural or political concerns with signing contract-like documents,
- where either the researcher and/or the participant could be put at risk by existence of a paper record,
- where time for consent is limited, eg a chance interaction between researcher and participant (although you should not use an oral process merely to correct poor planning of research).

If you will be conducting research without the informed consent of participants, you must submit a justifying statement for ethical review prior to starting your research.

4. Use of Coercion/incentives

There should be no coercion of research participants to take part in the research. In particular, there must be no claims of health benefits from taking part.

Some incentives may be construed as coercion. Adult research participants, however, may be given small monetary reimbursement for their time and expenses involved.

In some instances, it may be justified to use a free prize draw or book vouchers, to encourage responses. Respondents must not be required to do anything other than agree to participate or return a questionnaire to be eligible to a free prize draw, and incentives must not be offered that require the respondent to spend any money.

For further information see our Guidance Note on Incentives.

5. Children Under 18 Years Old

For research involving children or young people under the age of 18 years old, researchers should obtain the informed consent of both a parent or legal guardian and the assent of the child (regardless of whether or not the research is invasive or involves sensitive topics).

In the case of research in educational settings, any special school policies or procedures should be followed. Ideally, explicit, opt-in informed consent processes should be used. Opt-out consent can only be considered in low risk studies and requires review by the Sub-Committee.

There may be circumstances where seeking consent from parents could jeopardise the research (for example, in research into teenage sexuality or teenage pregnancy). In such circumstances, researchers will need to regard the potential risk to the participants of the research as a priority.

6. Vulnerable Participants

In cases where research involves potentially vulnerable groups such as older persons or adults with learning difficulties every effort should be made to secure actively given informed consent from individual participants.

If research is being conducted with detained persons (e.g. prisoners, ‘sectioned’ psychiatric patients, asylum seekers, elderly people in a residential care home) particular care should be taken over informed consent. Particular attention should be paid in these circumstances to the factors that may affect the person’s ability to give informed consent freely and voluntarily.

Research with adults (or children who are 16 years old or older) who are considered to lack mental capacity is very complex, legally and ethically. The research provisions in the Mental Capacity Act apply in England and Wales to anyone over the age of 16 years old who lacks the capacity to give or withhold their consent to participate in a study.

Fundamentally a person must be assumed to have capacity unless established otherwise. A person is unable to make a decision if s/he is unable to:

- understand the information relevant to the decision,
- retain that information,
- use, or weigh up, that information in the process of coming to a decision, or
- communicate the decision (by any means).

Studies involving participants who are 'lacking capacity' e.g. who are unable to give consent under the Mental Capacity Act 2005, require approval from the National Social Care REC. The Social Care REC is recognised by the Secretary of State as an 'appropriate body' for this purpose. University Research Ethics Committees are **not** recognised as appropriate bodies under the terms of the Act.

7. Studies Involving Deception

It may sometimes be necessary to withhold information about the true objectives of the research from the people participating in it in order to ensure the viability and validity of the research.

In this case participants should be re-consented following the study to confirm that they still agree for their participation to be included in the study. Participant's should also be provided with a de-briefing documentation explaining why this deception was necessary and reiterating their right to contact the Sub-Committee if they are not happy with the conduct of the study.

Wherever possible such research should be avoided and the Ethics Review Sub-Committee will pay particular attention to the justification for this deception.

8. Covert Research

Covert research may be undertaken when it may provide unique forms of evidence or where overt observation might alter the phenomenon being studied.

The broad principle should be that covert research must not be undertaken lightly or routinely. It is only justified if important issues are being addressed and if matters of social significance which cannot be uncovered in other ways are likely to be discovered. Normally, researchers should ensure that research participants are aware of and consent to arrangements made with regard to the management and security of data, the

preservation of anonymity, and any risk that might arise during or beyond the project itself, and how these might be minimised or avoided.

Where the research design is such that valid consent cannot be obtained from participants before data are gathered from them, ethics review of the proposal must always take place at the highest level e.g. through submission to the Ethics Review Sub-Committee.

9. Research in Public Contexts

In certain types of research obtaining consent from every individual present is neither practical nor feasible (e.g. observing behaviour in public places, attending large meetings, attending a music concert or play). Research of this kind stretches the definition of what it actually means to be a human participant in research. In research of this kind researchers should ensure the following:

- that such research is only carried out in public contexts, defined as settings which are open to public access;
- that, if relevant, approval is sought from the relevant authorities;
- that, if relevant, appropriate stakeholders are informed that the research is taking place;
- that specific individuals should not be identified, explicitly or by implication, in any reporting of the research, other than public figures acting in their public capacity (as in reporting a speech by a named individual, for example); and
- that attention is paid to local cultural values and to the possibility of being perceived as intruding upon, or invading the privacy of, people who, despite being in an open public space, may feel they are unobserved.

If individuals may be photographed or filmed as part of a research project, then the potential for people to be identifiable in the resulting materials should be considered carefully. Data protection legislation must be complied with in any case where identifiable material will be obtained.

10. Withdrawal of consent

Participants have the right to withdraw consent as well as the right not to answer particular questions.

All research should indicate the point at which data will have been anonymised and amalgamated and cannot then be excluded. If data is to be archived and shared, participants need to give specific consent to this. In some cases, it may not be appropriate to archive data.

11. Useful Links

Health Research Authority guidance on Informing participants and seeking consent