Information and Consent

In your recruitment of participants, these two aspects, information and consent, play a crucial ethical role. It is important to ensure that consent to participate in a research project is ***fully informed*** and ***freely given*****.** These two criteria respect the basic right of people to autonomy.

The level and form of consent to participate in research should be appropriate to the research topic and design. It should recognise, in particular, the wide variety of data types, ranging from anonymised-at-source, non-sensitive data through to video recorded, identity-capturing data on sensitive topics.

The consent of every participant in research should always be sought and monitored, in a form suitable for audit and by means appropriate to the age and competence level of the participant. For children under 16 years of age and for people lacking mental capacity, where the ability to consent may be impaired, the additional consent of parents, guardians or persons in loco parentis should also be sought.

In relation to the gaining of consent from children and young people in school, where the research procedures are judged by a senior member of school staff, or appropriate professional within the school, to fall within the range of usual curriculum activities, and where a risk assessment has identified no significant risks, consent from the participants and the school could be considered sufficient. Where these criteria are not met, it will be a matter of judgement as to the extent to which the difference between the specific project and these criteria warrants the seeking of parental consent from children less than 16 years of age and young people of limited competence.

1. Fully informed consent

Fully informed consent relies on providing sufficient information to potential participants prior to the research commencing. Participant information sheets (PIS) are the basis of informed consent. Giving potential participants sufficient information about the research in an understandable form requires careful drafting. Information sheets should be provided and left with participants for their future reference. It is recommended that at least one pilot test of your draft document be carried out with a naïve person having a literacy level at the lower end of the range expected in the planned research sample.

The information sheet should normally give a clear statement of:

- the aim(s) of the project
- the type(s) of data to be collected
- the method(s) of collecting data
- confidentiality terms associated with the data
- compliance with the General Data Protection Regulation (GDPR) and Freedom of Information Acts
- the time commitment expected from participants
- the opportunity to withdraw from the study with no adverse consequences up to the specified date, usually up until data are de-identified (anonymised).
- the opportunity to have any supplied data destroyed on request (up to a specified date, again usually until data are anonymised)
- details of any risks associated with participation
- if appropriate, a statement that recompense for time and inconvenience associated with participation will be given such as the reimbursement of incurred expenses such as travel costs.
- the name and contact details of the Principal Investigator (PI)
- the name and contact details of another person, such as a research student's supervisor, who can receive enquiries about any matters which cannot be satisfactorily resolved with the Principal Investigator.
- if PI is not a research student then the name and contact details of someone not connected to the research, such as a line manager, to whom people can address any concerns
- where appropriate, evidence of insurance indemnity for the research*
- any debriefing that is planned
- how the results of the research will be made available to participants

The extent of information given under each of these headings will depend on the nature of the research.

In some circumstances the aims of the research may be compromised by giving full information prior to data collection. In such cases, it should be made clear that this is the case in the information sheet and the means by which the withheld information will be given at the conclusion of data collection should be specified. The information withheld and the delay in disclosing the withheld information should be kept to the absolute minimum necessary. The Human Research Ethics Committee (HREC) review panel will expect to see included in an application for ethical approval a justification for any withholding of information.

2. Freely given consent

It is important that participation in a research study is not coerced. Coercion can come about in many ways, not just through the offering of rewards for consenting or disincentives for not consenting. Coercion infringes the human right to autonomy and coerced participation compromises the validity of research data.

It is important that no reward, actual or implied, is offered over and above reasonable recompense for travel, other incurred costs and the time and inconvenience of participation. It is also important that participants do not misunderstand any collection of data from them as constituting any form of risk screening. Such misapprehensions might lead them to be less vigilant in relation to risks.

Potential participants, especially those from vulnerable groups such as children and persons with learning difficulties, are likely to perceive researchers as having a superior position of authority or power, and researchers should be mindful of the risks associated with dual relationships and take steps to minimise its effects on consent.

It is important that sufficient time is given for potential participants to absorb and consider the information about the research before making a decision regarding participation.

3. Consent

Consent, whether in a verbal recording, electronic or hard copy form, should include an explicit statement that it confirms that the information about the research has been given to the participant and understood.

Where hard copy, two copies of the consent form should be signed by both the researcher and the consenting participant, or their parent or other person in loco parentis. One copy should be retained by the participant and the other stored by the researcher. The copy retained by the participant should give the two sets of contact details also given in the information sheet. For certain types of research, for example where there are identifiable risks, it will also be appropriate for the consent to be witnessed and signed by an independent third party.

Renewal of consent

Where the research requires a substantial commitment of time or repeated data collection sessions, it will often be appropriate to seek renewed consent from participants. This also recognises that a fuller appreciation of the research and the nature of participation will often become clearer during participation than can be gathered from even the most carefully prepared information sheet.

*A letter from the Open University's insurers, specifying the indemnity cover for

research carried out in the University's name, is available. Please email the Human Research Ethics team to request a copy. This information only needs to be provided where there is risk.