LONDON METROPOLITAN UNIVERSITY

Informed Consent

Why

The principle of informed consent as applied to participation in research projects is deemed important because:

- research participants should ordinarily be able to decide whether or not they are included in a research project (this is a legally codified human right)
- participants should be free to engage and withdraw from research projects at any time
- research projects may have both foreseen and unforeseen risks and consequences for participants of which the researcher may be unaware and which the participants should be able to assess prior to participating
- participants should have access to information about the aims and objectives of any research in which they are involved, including sources of help, advice, support

When

Informed consent should be obtained whenever it is possible to do so, i.e. except when:

- the research re-uses data or materials for which informed consent has already been obtained which specifically permits this re-use;
- the research uses irrevocably anonymised data or materials;
- disclosure of the research to participants would invalidate the findings of the research;* or
- participants are ‘incompetent’**

* including some ‘observational’ studies or experiments involving deception

** legally ‘incompetent’ participants include young children, unconscious individuals and individuals with cognitive impairments – for which consent may be available from advocates or carers

Key components of informed consent

Informed consent should involve the provision or collection of information on:

- Name and contact details of researcher
- Name and contact details of participant
- Aims and objectives of the research project
- Role of the participant in the research project
- Treatment of material/information collected
- Potential risks to the participant
- Sources of advice/help/support/treatment
- Voluntary participation and freedom to withdraw
- Signature and date of researcher and participant

Written consent involves the retention of copies by researcher and participant

Different forms of (informed) consent

There are three principal forms of (informed) consent:

- Presumed consent – in which participants are presumed to have consented to participation in the research unless they indicate otherwise*
- Verbal consent – in which the researcher verbally informs participants and receives oral confirmation of consent**
- Written consent – in which the researcher provides written information regarding the research project to participants, and retains a signed copy of this 'consent form'

* presumed consent may be ethical when the participant is incompetent and when the benefits of the research outweigh any potential physical or social risks

** it may be impossible to obtain written consent in some types of studies (such as telephone interviews) but wherever possible the consent process should be recorded

Examples of informed consent forms

Examples of informed consent forms are available from a range of ethics and research organisations:

- National Institute for Health Research:
  http://rdfunding.org.uk/flowchart/ConsentForm.htm
- National Research Ethics Service
  http://www.nres.npsa.nhs.uk/rec-community/guidance/#InformedConsent
- Department of Health
  http://www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Consent/Consentgeneralinformation/index.htm
- Economic and Social Research Council
  http://www.esrc.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf