



# **Guidelines for Ethical Approval of Research Involving Human Participants**

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# Introduction

1. The objectives of the Ethics Committee are to maintain ethical standards of practice in research, to protect the dignity, rights and welfare of research participants<sup>1</sup>, both subjects and investigators, and to provide reassurance to the public that this is being done. In achieving these objectives, the members of the Ethics Committee should remember that research benefits society and that they should take care not to hinder it without good cause. The Ethics Committee also protects researchers from unjustified criticism.
2. All research involving human participants, whether undertaken by the University's staff or students, must undergo an ethics review and ethical approval must be obtained before it commences. 'Human participants' are defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and fetuses, human tissue and bodily fluids, and personal data and records <sup>2</sup>(such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).
3. It is the responsibility of the person proposing to carry out a research project involving human participants to obtain the approval of the Ethics Committee. If a project is to be undertaken outside the University where a local ethics procedure exists (e.g. within an NHS organisation), the University's Committee need not necessarily be involved. However, approval of the local committee must be sought and obtained before research commences and the Research Governance and Planning Manager must be provided with all documentation relating to the approval.
4. In designing a research project involving human participants, investigators must be able to demonstrate a clear intention to benefit society and the research should be based on sound principles.
5. Investigators must ensure that there is no undeclared conflict of interest (which may be personal, academic or commercial) in their proposed work and that the relation between the sources of funding and researchers' control over results is made clear, specifically in relation to the ownership, publication and subsequent use of research data.

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<sup>1</sup> It is recognised that research investigators are research participants. However, throughout this document "participants" refers to the "subjects" of the research unless otherwise indicated.

<sup>2</sup> Research involving personal data and records which have been made available to the public will not require ethical approval. This does not include all information sourced from the social media (see "Research data and social media – some general principles") or reusing secondary data which raises additional ethical considerations (see paragraph 27).

# Protection of Participants and their Rights

6. All participants have the right not to participate in any investigation and this right must be respected. There must be no attempt to compel research participants to participate in the research. Students and others in a dependent relationship with investigators must be assured that any decision not to participate will not prejudice their academic or other progress in any way.
7. Each participant must have the right to withdraw easily from the project whenever and for whatever reason without explanation or penalty.
8. All participants and researchers have the right to expect protection from physical, psychological, social, legal and economic harm at all times during the investigation. Where there are significant risks a risk assessment will need to be undertaken. Advice on risk assessment is available from the University's Health and Safety Advisers (email [safety@essex.ac.uk](mailto:safety@essex.ac.uk); Tel 2944) and [on the University's website](#). Participants and researcher staff must be fully informed in advance of and protected against any hazardous, stressful or uncomfortable contexts and procedures. In addition, researchers should attempt to avoid harm not only to an immediate population of participants but also to their wider family, kin and community.
9. Should any adverse event occur, the researcher must report this immediately in writing to the Ethics Committee via the adverse event reporting function in ERAMS. The report should describe fully the adverse event, the action taken and the date, time and place of the event. In addition, health and safety incidents must be reported on the [University's Health and Safety Incident Report Form](#).
10. All participants have the right to expect that the information supplied by them will be treated as confidential and will be protected as such.
11. All participants have the right to expect that their identity will be protected. Participants need to be informed about circumstances that might require their identity to be disclosed.
12. Researchers must be aware of requirements with respect to personal data laid down in the Data Protection Act 2018. An information sheet [Data Protection and Research Activity](#), has been prepared by the University Records Manager which provides useful guidance.
13. Staff and students working with blood or blood products must advise the [University Biological Safety Officer](#). In addition, they should be aware of the possible hazards, in particular human blood borne viruses, and if in doubt should contact the University's Occupational Health Advisers

(email [ohquery@essex.ac.uk](mailto:ohquery@essex.ac.uk); tel 2399). The taking of human blood samples is restricted to a person who has appropriate training.

14. Participants should be advised how, when and in what form it is planned to disseminate the findings of the research.

## Informed Consent

15. Prospective participants, and their carer, parent or guardian if appropriate, should be provided with as much information as possible about the research to enable them to make an informed decision about their possible involvement. Information should be provided to participants in an accessible manner. If consent is not to be secured a statement justifying this must be provided. The primary objective is to conduct research openly and transparently without deception.

16. It should be remembered that research staff are also participants and need to be made fully aware of the proposed research and its potential risks to them.

17. Informed consent should be given on a consent form or recorded if oral consent is obtained<sup>3</sup>. It is also good practice to provide participants with a separate participant information sheet in advance.

18. Consent forms must be signed by participants **before** the start of any project indicating that they are giving their informed consent to participate in the project. However, consent should be considered as an on-going process throughout the life of a project and should be reviewed with participants on a regular basis.

19. If the participant is not capable of giving informed consent on their own behalf then consent must be obtained from a carer, parent or guardian. A person who is incapable of providing valid consent on their own behalf may nonetheless be capable of expressing their assessment (agreement) or dissent (disagreement) about participation. The assent of the participant should be obtained where possible; if a prospective participant expresses dissent, they should not be involved.

- Consent and children: Minors (under the age of 18) with sufficient understanding of the nature, purpose and potential risks of the research are able to give their consent to participate in research. The ability to understand will be heavily influenced by how the information is presented to the minor. As a matter of good practice, parental consent should also be sought, unless the minor objects to this. The researcher should think carefully about whether to include the minor as a participant should this be the case.

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<sup>3</sup> Separate guidance on written and oral consent is included in Annex 1.



Consent from a carer, parent or guardian must be obtained if the minor lacks the necessary understanding to provide valid consent.

- Adults lacking capacity: The law in England and Wales does not recognise proxy consent by a relative if an adult lacks capacity to provide informed consent. Such persons can only be included in research projects under the conditions laid out in sections 30 to 34 of the Mental Capacity Act 2005. Consulting the person's carer is required and the person cannot be included as a participant if they object or appear to object, if it contradicts an advance decision made by them which has effect, or any other previous statement that was not subsequently withdrawn<sup>4</sup>.

20. Consent should also be obtained for the sharing of research data as appropriate and for the publication of findings. Many funding bodies require that data obtained from a funded project are made available for research undertaken by others at a later date. Participants should be advised how the data that they provide will be stored, used and accessed including details of how confidentiality will be maintained. Consent for this needs to be obtained from participants before the start of the original project.

21. Participants should be provided with a copy of their signed consent form.

## **Recruitment of and Payments to Participants**

22. Advertisements or other recruiting materials seeking human participants for a research project require ethical approval. Such material should also include the name of the University and the ERAMS reference number.

23. Participants must be clearly advised, in advance, of any arrangements to reimburse them for expenses incurred or for loss of earnings.

24. Incentives, additional payments and rewards paid to participants require approval by the Departmental Director of Research / Ethics Officer, Faculty Ethics Sub-Committee or the University Ethics Committee as appropriate.

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<sup>4</sup> Such research needs to be approved by a Health Research Authority NHS Research Ethics Committee flagged to review research involving participants lacking mental capacity.

# Use of previously collected data in research ('secondary data use')

25. Use of previously collected data in research (or 'secondary data use') is defined as any use of existing data, that was previously collected from living human participants, for purposes beyond which they were originally collected. Examples include: reusing of data by the original collector of the data for a purpose different to that for which they were collected; reusing of data by other researchers. Use of previously collected data in research may require University or external ethical review depending on the source and nature of the data.
26. The following uses of existing data in research will not normally require University ethical review, unless otherwise specified by funders:
- Re-using of data which are already in the public domain (for example, published in books, journals etc).
  - Re-using of a researchers' own primary dataset for which consent for reuse for research purposes beyond which the data was originally collected was provided by the participants.
  - Re-using a third party's dataset for which consent for reuse for research purposes beyond which the data was originally collected was provided by the participants and for which all data have been fully or effectively anonymised (see point 29, Anonymity).
  - Using data obtained from a responsible repository that conducts ethical and legal checks for reuse and provides assurance regarding consent and anonymisation (e.g. UK Data Archive).
27. An ethical review will be needed if reusing of secondary data raises additional ethical considerations:
- The data can lead to re-identification of individuals.
  - The data raises concerns around the original participants' consent for future use of the data and the provenance of the data.
  - The data provider requires assurances that the project has undergone ethical review.
28. Any researcher who is unsure whether their proposed secondary data use falls under the exemptions noted in 26. must seek further advice from their departmental Ethics Officer. Queries regarding NHS ethical review of patient and service user secondary data must be directed to the REO Research Governance Team .
29. Ethical considerations when using previously collected data in research:

- **Anonymity:** Researchers should consider whether the data they intend to use are fully or effectively anonymised. Fully anonymised means all identifiers from the data have been irreversibly removed and participants are not identifiable in any way. In practice it can be impossible to assess re-identification risk with absolute certainty. Effectively anonymised means the data is in a form that does not identify individuals and where identification is not likely to take place. Although effectively anonymised data may contain some forms of identifier, it is unlikely that data subjects could be identified either directly or indirectly through its combination with other data, taking into account all the means reasonably likely to be available (see the [ICO Anonymisation: managing data protection risk code of practice](#)). If there is a risk that participants could be re-identified from datasets, the data should be considered to be pseudonymised and its use will require ethical review.
- **Consent:** Where researchers are seeking to reuse data which they did not collect themselves, and which are not in the public domain, they should: consider whether the proposed re-use of the data aligns with consent, if relevant; check whether the re-use of data aligns with the consent originally obtained from participants by seeking evidence and/or assurance from the data owner; identify the appropriate agreement that must be sought prior to accessing the secondary data, such as a data transfer agreement, and comply with the terms of the agreement.
- **Storage:** Data must be kept safe from unauthorised access, accidental loss or destruction as per the University's data protection guidance and policies.

30. Analysis of social media data sourced from the internet requires additional consideration.

Researchers who are considering the use of social media for their research should read the separate guidance: [“Research and data social media – some general principles”](#).

## Ethics Standards of External Bodies

31. In addition to University guidelines, researchers should be aware of ethics codes of the relevant professional or regulatory bodies related to their research. Such codes should be followed.

32. If research is to be conducted in an institutional setting other than the University, e.g. NHS organisations, schools, prisons, etc, researchers **must** follow any ethics standards, procedures and regulatory guidelines of that institution. This will include obtaining approval from the local ethics committee, if required, and may necessitate obtaining a Disclosure and Barring Service (DBS) check.

33. The following documents and websites may be useful:



- [British Psychological Society: Code of Conduct and Ethical Guidelines](#)
- [British Sociological Association: "Statement of Ethical Practice for the British Sociological Association"](#)
- [Economic and Social Research Council: "Framework for research ethics \(FRE\)"](#)
- [Government Office for Science: "Rigour, Respect, Responsibility: A Universal Ethical Code for Scientists"](#)
- [Human Tissue Act 2004](#)
- [Medical Research Council: Good research practice: Principles and guidelines](#)
- [Mental Capacity Act 2005](#)
- [NERC: Ethics Policy](#)
- [NHS Health Research Authority](#)
- [Ofcom Broadcasting Code](#)
- [RESPECT Code of Practice for Socio-Economic Research](#)
- [Royal College of Physicians of London: "Guidelines on the Practice of Ethics Committees in Medical Research involving Human Subjects"](#) (Fourth edition) published in September 2007
- [Social Research Association: "Ethics Guidelines"](#)
- [Society of Editors' Code of Practice](#)
- [UK Research Integrity Office](#)

# Annex 1

## Written or Oral Consent

Whether informed consent is obtained in writing through a detailed consent form, by means of an informative statement, or verbally, depends on the nature of the research, the kind of data gathered, the data format and how the data will be used.

As with many other issues in research ethics, there is debate about the best format for gaining informed consent - written or oral.

### **We recommend a pragmatic approach:**

- For detailed interviews or research where personal, sensitive or confidential data are gathered, the use of written consent forms is required to assure compliance with the Data Protection Act and with ethical requirements. Written consent documentation typically includes an information sheet and consent form signed by the participant.
- For surveys or informal interviews, where no personal data are gathered or personal identifiers are removed from the data, obtaining written consent may not be required. At a minimum an information sheet must be provided to participants detailing the nature and scope of the study, the identity of the researcher(s) and what will happen to the data collected (including any data sharing).
- If data are collected verbally through audio or video recordings, verbal consent agreements can be recorded together with the data.
- For audio-visual data where the identity of people may be disclosed from the data, it may be important that informed consent is obtained to use the data unaltered for research purposes, sharing and preservation. Voice alteration or image blurring are usually labour and cost intensive and may decrease the research potential of data.

Written consent should be gained wherever possible to ensure that information is being collected and provided in a consistent and uniform way. It may also serve to protect both researchers and participants should any form of dispute arise.

### **When to use written consent**

Some argue that written forms with check boxes for every possible scenario help make all terms and conditions explicit. Others counter argue that such formalisation represents over- bureaucratisation and confusion for the participant, and that it may violate a trust relationship with participants.

If a researcher decides against using written consent, then the next preferred option is to obtain oral consent and to audio record the participant granting consent. This approach may be used if the researcher deems that a written form is not the best way to share information and thus provide informed consent. For example, if participants have literacy limitations, if the potential participants are unusually wary of any formal documentation (e.g. refugees and asylum seekers) or in informal research settings, telephone research, etc.

Finally, it should be noted that there are circumstances (e.g. research on illegal activities, some evaluation research, covert research) where no form of consent can be obtained. These situations are exceptional and will need case-by-case review and clear arguments to satisfy the requirements of ethics review boards.

It is not surprising that there is confusion about consent in general and about the need for written consent in particular. Some guidelines and certain Research Ethics Committees, Research Governance boards or other bodies make statements indicating (or strongly implying) that written consent is required or mandatory. This is not the case in the UK. While we advocate the use of written forms, there are cases where it is not appropriate and flexibility in evaluating projects on their individual merits is essential.