

University of Dundee

Code of Practice for Research Ethics on Human Participants

What does this Code of Practice cover?

This Code of Practice covers all research on human participants carried out by staff and students at the University of Dundee, whether funded or not. If you are a lead researcher you must ensure that those responsible to you are aware of this Code and abide by it.

Why do we need a Code of Practice?

We need a Code of Practice for several reasons. In recent years ethical issues in research have become matters of public concern. Universities must ensure that they comply with several legal obligations (e.g. the Research Governance Framework from the Department of Health, the 1964 Declaration of Helsinki by the World Medical Association, European Union Directives such as Directive 95/456 on the protection of personal data and Directive 2001/20 on ethics, the Data Protection Act, the Freedom of Information Act, and the Nolan Report). Many professional bodies require a formal structure for giving ethical approval before research can begin. Most funding bodies (including Research Councils) now require proof of ethical approval and a demonstration that universities take ethical considerations very seriously. Foremost, however, the University of Dundee wishes to make clear that all of its members abide by the highest possible ethical and professional standards when carrying out research.

What is research?

For the purposes of the University Research Ethics Committee (UREC), relevant research is collecting data from and about human participants or their behaviour to further knowledge. Data can be collected experimentally, by questionnaire, by interview, observationally, by computer, telephone, over the Internet, or by any means of recording human behaviour. Some interviews with people may not count as research for this purpose. Questionnaires devised for gathering feedback on teaching performance do not need ethical approval as long as there is no intention to publish research based upon data collected in this way. If you are unsure whether what you are doing is research or not you should contact the Chair of the University Research Ethics Committee.

What are the main principles governing good research?

We expect that all staff and students of the university conduct themselves at all times in a way that does not bring the university into disrepute.

Our guiding principle is that the well being of the participants are always held paramount. The main principles governing research are hence *informed consent*, *confidentiality*, and *respect*. All participants must be treated with respect and dignity. Researchers must of course also bear in mind the safety of their participants: taking part in a study should not increase the likelihood of any participant coming to harm.

The over-arching principle is that of informed consent. All researchers must make all reasonable efforts to obtain informed consent from their participants. You must ensure that participants know who you are and understand what is involved in your study. Participants must be able to make an informed decision as to whether or not they want to take part in your study. They must be told of any factors that might reasonably influence their willingness to take part. Participants are to some extent at risk just because they do not have to be there taking part in your research, and it is essential that any likely risks to the participant must be made clear to them. Potential participants must not be coerced into taking part, and they must be able to withdraw from the study at any time without explanation or penalty. You should provide participants with an information sheet that they can keep that outlines the main principles of the research, and that provides contact information should they wish to contact you later. You must give the participants time to read the information sheet and ask you questions. Participants should then sign a consent form that you must keep.

Occasionally it might be difficult to obtain informed consent in writing. Such occasions are among the most problematic ethically. There are two examples where it might not be possible to obtain informed consent.

First, the participant population might be such that informed consent is difficult or impossible. Examples include children, people in any form of detention, people with complex communication needs, people speaking a different language, and people with Alzheimer's disease. In such cases you should endeavour to obtain consent from the participant and any legal authority. If informed consent is impossible it is essential to obtain informed consent from the nearest relative or nominated individual and the appropriate legal authority. Note that there are specific rules for obtaining consent for research on children; children should give consent (if possible) in addition to their guardians. Research involving people recruited by virtue of their being NHS patients will need to be approved by Tayside LREC (Local Research Ethics Committee). Similarly, it may not always be possible to obtain written consent (e.g. if conducting research on people with limited literacy). In such cases you must show how consent has been obtained and recorded.

Second, there are outstanding scientific reasons why some deception might be necessary. We urge all researchers to consider whether there might be alternative techniques capable of achieving the same aims. Research involving any deception will always be referred to the full University of Dundee Research Ethics Board, and it is essential to provide a full scientific rationale of the proposed work, with an explanation of why there is no

alternative to involving deceit. When there has been any kind of deceit, it is essential to provide a debriefing for the participants as soon as is reasonably possible, providing a full explanation of the aims of the study and the nature of the deception employed and why it was necessary.

There is a distinction to be made between withholding some of the details of the experimental hypotheses and deceiving participants about the nature of the study. Withholding information does not usually pose as many ethical problems as deceit. Nevertheless, it is essential that participants are fully debriefed. It is usually necessary to give participants a debriefing sheet at the end of the study in addition to the initial information sheet.

Only in some exceptional cases (e.g. telephone interviews or observational studies in public places where people expect to be observed) is written informed consent not necessary. On some occasions completing a questionnaire can be interpreted as giving consent.

Participants must have the opportunity to withdraw their data after it has been collected. This right is particularly important if the study has involved any form of deceit, or if details of the hypotheses of the study were withheld.

Your participant information sheet should explain what you intend to do with the data you collect (including video tapes). You must make sure that you keep the data you collect confidential. It is your responsibility to familiarise yourself with the current legal requirements on storage and access to personal data. In particular, you should not disclose any information about an identifiable person without that person's express consent.

Experimenters have a responsibility to monitor participants in case of any unforeseen reactions to the study. Such monitoring is particularly important when deceit has been involved. Investigators should provide some means of contact for participants should they wish to find out more about the study later or have delayed reactions to taking part in the study.

In addition, at all times we should treat our participants with *respect*. Identifiable personal information should only be conveyed to others within the legal framework and with the permission of the participant. It is essential to comply with the Data Protection Act. You must only make audio or visual recordings of participants with their permission, you must store your data securely, and you should tell the participant the reason why such data are collected. You can only show recordings to a different audience with the explicit permission of the participant. Participants must not be exposed to unnecessary risks. The research should be methodologically sound so that it does not waste people's time.

Finally, researchers must recognise that they may be seen to be in a position of authority over participants. This perceived authority must not be used to influence or coerce participants in any way.

Are there any groups of participants where ethical considerations are particularly sensitive?

Obviously any ethics committee will therefore scrutinise any research where it is difficult to obtain written informed consent. The University insurers are also concerned with particular groups of participants. Therefore the following groups are considered to be *vulnerable*: children (particularly under five years old), clinical populations, pregnant women, people with complex communication needs arising for any reason, economically or educationally disadvantaged people, people with any learning difficulty, the researcher's employees and prisoners. Note that studies involving pregnant women, children under the age of five, contraception, conception, gene therapy, and over 5000 participants also need special permission from the University insurers, and hence use of these groups must be declared on the Ethics form. If you are carrying out studies involving these groups you should contact RIS.

How long do I need to keep my consent forms?

This will vary depending on your discipline and any guidance given by your professional body. As a guideline, the American Psychological Association states that data should be kept for at least five years after publication.

What do I need to do to gain ethical approval for my research?

The University of Dundee has agreed that all research must have appropriate ethical approval before it begins.

Undergraduate and all taught postgraduate students will be told how to gain ethical approval by the Schools in which they are based. Each School will have a person responsible for dealing with ethics applications, and this person will report to a nominated person or committee at college level. The nominated college-level person will report to the University committee.

All research students and all contract and academic staff must obtain approval through one of the following routes:

Research involving non-human animals - will need approval through the Ethical Review Committee of the University of Dundee.

Research involving tissue samples - will need approval through the Tayside Local Research Ethics Committee unless using tissues samples deposited in the University's central store, in which case the research will need approval of the University of Dundee Tissue Bank, Division of Pathology and Neurosciences.

Research involving participants who are taking part by virtue of being NHS staff, patients, or their carers - will need ethical approval from the appropriate NHS Local Research Ethics Committee (usually Tayside) through the COREC (Central Office for Research Ethics Committees) system.

All others - will need ethical approval through the University of Dundee Research Ethics Committee by completing the University of Dundee Research Ethics Committee approval form.

How long does the UREC take to make a decision?

There are no set committee dates. In semester-time we aim to give a decision within three weeks (during semester time). The application form gives the details of the decision process. You must not start gathering data until you have received approval in writing. If the proposal is approved subject to conditions you must not start your research until those conditions have been satisfied and approved in writing by the Chair of the UREC.

How long does the ethical approval last, and what happens if I change the procedure?

We grant ethical approval for a specific project using a specific protocol. We expect that the project will normally be completed within three years, unless another period of time is specified. Research continuing longer than the period originally stated will need new approval.

We also grant approval for a specific research protocol. Significant deviations from this protocol will need to be approved. Normally approval for small changes can be sought simply by requesting a protocol amendment in writing or by email to the Chair of the Committee explaining how and why the protocol needs to be changed.

What happens if I carry out research without ethical approval?

Failure to follow the University's procedure, or carrying out research without ethical approval, may result in disciplinary action.

Is there a complaints procedure for participants?

Yes. If you receive any complaints concerning ethical issues in your research (e.g. a participant feels they have been misled or in any way mistreated) these must be referred to the University Research Ethics Committee. If a participant tells you that they wish to complain, they must be informed about this complaints procedure.

Is there anything else I need to take into account?

Some Colleges, Schools and professional bodies have their own codes of conduct. You must of course abide by these codes. You should also read the *University of Dundee Ethics and Research Governance Policy*.

We also expect that all researchers carry out their work to the highest standard of intellectual honesty, abiding by the University's *Code of Policy and Procedures for Investigating and Resolving Allegations of Misconduct in Research*.

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