1. Applicability and Purpose of Code of Practice

This Code of Practice (‘Code’) covers all externally and internally funded research on human participants carried out by staff, both University employed and honorary, and students (‘collectively Researchers’) at the University of Dundee, unless such research involves any of the clinically-related activities listed below:

- the investigation of the safety or efficacy of a medicine, therapeutic device, foodstuff or placebo in humans
- patients, their carers, or staff of the NHS or a social care organisation
- access to anonymised collections of patient data
- use of any NHS resources including staff time, clinical support services or NHS facilities
- the collection or use of donor identifiable human biological samples
- human biological samples obtained from a tissue bank

If a proposed project will involve any of the above clinically-related activities please refer to the website of the Tayside Medical Sciences Centre (TASC) to identify the correct policy to govern the project:

http://www.tasc-research.org.uk/_page.php?id=8

The purpose of this Code is to inform Researchers of their responsibilities when undertaking non-clinical research involving human participants. Researchers must ensure that those responsible to them for the carrying out of a Research Project are aware of this Code and that they abide by it.

2. Definition of Terms

For the purposes of this Code the following terms shall have the meanings given to them below:

‘Ethics Form’ shall mean the form which is submitted by a Researcher to the School Research Ethics Committee (SREC) to seek ethical approval for a proposed research project.

‘Participant’ shall mean any individual who has consented to take part in a Research Project but excluding patients, their carers, or staff of the NHS or a social care organisation.

‘Research Project’ shall mean the collection of data from and about human participants or their behaviour in order to further knowledge. Data can be collected experimentally, by questionnaire, by interview, observationally, by computer, telephone, over the Internet, or by any other means of recording human behaviour. Data collected for the audit of administration or teaching (e.g. questionnaires designed to obtain 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. A Researcher who is unsure whether a proposed project is research or not should contact the Convener of the SREC for advice http://www.dundee.ac.uk/main/research/ethics/.

‘Researcher’ shall mean any person involved in a Research Project, regardless of whether they are specifically named in the Ethics Form.

‘Informed Consent’ shall mean the procedure by which potential participants can reach a truly informed decision about whether or not to participate in the research. In order for informed consent to be considered valid, the participant must be competent and the consent must be given voluntarily.

‘Deception’ shall mean deliberately withholding information from or providing false information to potential participants about the true nature and purpose of the research.

3. Main Principles Governing Good Research

The University expects that all Researchers conduct themselves at all times in a way that does not bring the University into disrepute. The institution’s guiding principle is that the well being of Participants in Research Projects is always held paramount. The main principles governing Research Projects are hence informed consent, confidentiality, and respect.

Informed Consent: The over-arching principle is that of informed consent. Researchers must make all reasonable efforts to obtain informed consent from their Participants who must be able to make an informed decision as to whether or not they want to take part in a study. Potential Participants must not be coerced into taking part. Researchers should recognise that they could be in a position of authority or influence over Participants who may be their students, employees or clients. This relationship must not be allowed to pressurise Participants to take part in, or remain in, a Research Project. Researchers should provide Participants with an information sheet which they can keep and which explains in terms appropriate for a lay person the main aims and methods of the Research Project. The Researcher should inform Participants of all aspects of the research that might reasonably be expected to influence their willingness to participate. It is essential that any likely risks to the Participant are made clear. Participants must be informed that they can withdraw from a Research Project at any time and without explanation or penalty. The Researcher must provide contact information should the Participant wish to contact the Researcher at a later date. Participants must be given time to read the information sheet and to ask the Researcher questions. The Researcher should, normally, explain all other aspects of the research or intervention about which the Participants enquire. Participants should then provide written consent by completing and signing a consent form which the Researcher must retain.

There are some circumstances in which it may not be possible to obtain written informed consent in the normal way. Examples include research on people with limited literacy, or people speaking a different language. In such cases the Researcher must use other methods to obtain informed consent, and should show how consent is to be obtained and recorded. There are also circumstances in which written informed consent cannot be obtained because there is no printed consent form to be signed. Examples include telephone interviews and completion of online surveys. In such cases, it is acceptable to obtain ‘consent by participation’, in which completing an interview or survey can be interpreted as having given consent.

There are cases in which it is impossible to obtain informed consent directly from Participants themselves. This may be because the Participants alone are not in a position
to give informed consent (e.g. children, people in any form of detention), or because they are unable to understand the nature of the Research Project (e.g. people with complex communication needs or learning difficulties). In these cases, it is essential to obtain informed consent from the nearest relative or nominated individual and if appropriate, any legal authority. In the case of children (i.e. younger than 18 years), informed consent must be obtained from both the parent or guardian, and the child if aged 7 years or older.

Intentional deception of Participants about the purpose and general nature of the Research Project must be avoided whenever possible. However, deception may be necessary in exceptional circumstances to preserve the integrity of the research because Participants’ behaviour could be influenced by knowledge of the true nature of the Research Project. Researchers must provide a full explanation of why there is no alternative to the deception, and should ensure that Participants will not experience undue distress when the deception is subsequently revealed. The nature of and reasons for the deception must be fully disclosed to Participants as soon as is reasonably possible, and Participants must then have the opportunity to withdraw their data if they wish.

Confidentiality: Researchers must store all data securely, and should tell Participants the reason why such data are collected. Researchers must only make audio or visual recordings of Participants with their explicit permission, and separate permission must be obtained in order to make the audio and/or video recordings available to a different audience. Participants must be informed about what the Researcher intends to do with the data collected (including audio and video recordings) and for how long the data are to be retained before they are destroyed. Researchers must ensure that all research data and its sources remain confidential unless Participants have consented to their disclosure. In this latter case, Researchers must ensure that plans have been made for storage and access to the data. Subject to the requirements of legislation, including the Data Protection Act 1998, information obtained about a Participant during an investigation is confidential unless otherwise agreed in advance. In particular, identifiable personal information should only be conveyed to others within the legal framework and with the permission of the Participant. It is the Researcher’s responsibility to familiarise himself/herself with the current legal requirements on storage and access to personal data.

Respect: All Participants must be treated with respect and dignity. Researchers must keep in mind the safety of their Participants and ensure that taking part in a study does not increase the likelihood of Participants coming to any harm, either mental or physical. At all times Participants must not be exposed to unnecessary risks. If there is any possibility that Participants might experience some distress or discomfort, then appropriate procedures for dealing with the distress or discomfort must be in place (e.g. referral to appropriate counselling services). Researchers should provide some means of contact for Participants should they have delayed reactions to taking part in the study or wish to find out more about the study later.

Researchers have a responsibility to monitor Participants in case of any unforeseen reactions to the study. Such monitoring is particularly important if deception has been involved. Arrangements must be in place to promptly review developments that could put the wellbeing of Participants at risk and to ensure that such developments are referred to the Convener of UREC. In the course of the research, a Researcher may obtain evidence of psychological or physical problems of which a Participant is, apparently, unaware. In such a case, the Researcher has a responsibility to inform the Participant if the Researcher believes that by not doing so the Participant's future well-being may be endangered. If the issue is serious and the Researcher is not qualified to offer assistance, the appropriate source of professional advice should be recommended.
Researchers have a duty to Participants to ensure that the Research Project is of the highest quality, methodologically sound and academically worthwhile so that it does not waste their time. To achieve these aims, each member of the team undertaking a Research Project must be qualified by education, training and experience to discharge his/her role in the project and must have adequate supervision, support and training. Methodologies and mechanisms must be in place to ensure that only high quality, accurate data are collected during the undertaking of a Research Project. Reports on the progress and outcomes of a Research Project required by a body providing funding to support the project, or others with legitimate interest, must be produced on time and to a high standard. The findings of a Research Project must be open to critical review through scientific and professional channels, and once established, the findings must be disseminated properly and fed back as appropriate to Participants.

4. Groups of Participants where Ethical Considerations are Particularly Sensitive

The University’s insurers are concerned with particular groups of Participants. Note that Research Projects involving children (especially under the age of five), pregnant women, Participants studied with respect to contraception or conception, people with disability (e.g. learning or communication difficulties), people engaged in illegal activities (e.g. drug taking), non-human animals, patients, or over 5000 participants may need special permission from the University insurers, and hence use of these groups must be declared on the Ethics Form.

5. Period of Retention of Data and Consent Forms

All data, consent forms and other documentation associated with a Research Project must be kept securely in paper or electronic form, as appropriate, and be available for audit. The University expects such data to be securely held for a period of ten years after the completion of a research project. It is essential to comply with the Data Protection Act 1998 (http://www.dundee.ac.uk/recordsmanagement/dataprotection/) and to ensure that arrangements are made for the appropriate archiving of data when a Research Project has finished.

6. Gaining Ethical Approval for a Research Project

The University has agreed that all Research Projects involving human participants must have appropriate ethical approval before they begin. For Research Projects governed by this Code of Practice ethical approval is sought by completing the Ethics Form and submitting this to the SREC – the Ethics Form and procedure for submission is available at: http://www.dundee.ac.uk/main/research/ethics/.

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 Committee responsible for dealing with ethics applications, and this Committee will report to UREC.

7. Duration of Ethical Approval and Process for Handling Changes in Research Projects

The SREC grants ethical approval for a specific Research Project using a specific protocol. The SREC expects that the Research Project will normally be completed within three years, unless another period of time is specified. Research Projects continuing longer than the period originally stated will need new approval. Any change to the Research Project protocol must be approved before it is implemented. Approval for a change to the protocol can be sought by requesting a protocol amendment in writing or by email to the Convener of the SREC http://www.dundee.ac.uk/main/research/ethics/ explaining how and why the protocol needs to be changed.
8. Carrying Out Research without Ethical Approval

A Researcher must not start gathering data until he/she has received approval in writing from the Convener of the SREC for a project to go ahead. If the proposal is approved subject to conditions, a Researcher must not start his/her Research Project until those conditions have been satisfied and approved in writing by the Convener of the SREC. Failure to follow the University’s procedure described within this Code of Practice, including the carrying out of a Research Project without ethical approval, may result in disciplinary action being taken by the University against a Researcher.

9. Complaints Procedure for Participants

A complaints procedure for Participants exists. If a Researcher receives any complaints concerning ethical issues during a Research Project (e.g. a Participant feels they have been misled or in any way mistreated) these must be referred to the Convener of UREC http://www.dundee.ac.uk/main/research/ethics/. If a Participant tells a Researcher that they wish to complain, they must be informed about this complaints procedure.

10. Additional Matters to take into Account

Some Schools and professional bodies have their own codes of conduct and Researchers must abide by these codes. The University also expects 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, which is available at:

http://www.dundee.ac.uk/rgp/researchmisconductwhistleblowing/

Research Governance & Policy Sub-Committee