



## UNIVERSITY TEACHING & RESEARCH ETHICS COMMITTEE

### REMIT

1. UTREC focuses on academic activity involving living human subjects, human tissues and other human samples, and also activity which may have potential adverse consequences for human welfare and wellbeing. In particular, it is concerned with
  - a) The welfare and protection of participants / subjects in research and teaching.
  - b) The ethics of research practices and modes of activity involving human subjects.
  - c) Morally inappropriate uses of the outcomes of such research.
  - d) Issues of research sponsorship where potential conflicts of interest arise.
  - e) The approval and review of individual activities of this kind.
2. UTREC will have a lead role in disseminating general information throughout the University with regard to such activities and their regulation, and will have responsibility for determining and monitoring the procedures governing the approval process.

UTREC (and the Animal Welfare and Ethics Committee [AWEC]) will report to the University Audit Committee (which in turn reports to the University Court) and to the Risk Management Task Group. Additionally, AWEC will submit annual reports (for information only) to UTREC and the Conveners of the two committees should liaise regularly.

3. UTREC will provide an overview of funders/sponsors (including firms and institutions) providing funding for research and assess whether such funding should be accepted.
4. UTREC now comes under the 'Ethical Assurance' committee, which itself comes under the 'Audit and Risk' committee which answers directly to University Court.

NOTE: All research and teaching activities in all Schools of the University that involve use of living animals (including mammals, reptiles, birds, fish, insects, etc.) will require formal approval from the AWEC, formerly the Animal Welfare Committee, in accordance with procedures to be issued by AWEC.

### Principles

1. All research and teaching activities of all staff and students in all Schools of the University that involve data collection from, interviews of, interactive investigation of, experimentation upon or demonstrations involving living human subjects, tissues and / or other samples will require formal approval from UTREC.
2. Research or teaching activities involving living human subjects, tissues and / or other samples that is undertaken by University staff outwith St Andrews also require formal review and approval by the University.

3. Where external approval of an activity is required (such as from the local Fife Research Ethics Committee):
  - a) It will never be sufficient to have external approval alone; University approval will always be required.
  - b) The granting of approval by an external agency will never be sufficient to override the refusal of approval by the University.
  - c) When external approval is required, any University approval will be conditional upon receipt of formal written approval by the relevant external body. No activity under review may commence until such notification is received by UTREC
4. When collaboration occurs with a researcher outwith the University, approval must still be sought from UTREC even if the St Andrews researcher is not the main researcher.
5. Approval of UTREC will serve to license a project in terms of the ethical implications.
6. UTREC will determine the appropriate duration for which such approval will be valid and any appropriate monitoring arrangements, but it is expected that a review and renewal of the approval will be required at least every three years.
7. All funding for research undertaken by University staff or students requires formal review and approval through UTREC.
8. There is no appeal against a decision by UTREC.
9. Membership of UTREC will include a layperson, representatives of the most commonly involved Schools, and a member of the Principal's Office. It is strongly recommended that a criterion of membership should be a record of active participation in projects involving research and teaching ethics or active involvement in pursuing issues raised by such projects. The convener of AWEC will also be an *ex officio* member on UTREC.
10. The membership of UTREC must be approved by the Principal, together with any changes to the remit and the principles (above).

## Membership of UTREC

Convener

Convener of AWEC (*ex officio* member)

Member of Principal's Office (if not otherwise represented)

Layperson(s) from outside the University (appointed by the Principal)

Nominee of Head of School of Psychology

Nominee of Head of School of Medicine

Nominee of Head of Social Anthropology

Nominee of Dean of Arts

Nominee of Dean of Science

Secretary in attendance

## **Training by UTREC for School Ethics Committee (sub-committees)**

Training will be provided for members of the SEC sub-committees on an annual basis. It is a mandatory requirement that all School Ethics Committee members attend at least one training session. Refresher sessions may be provided at alternative dates and are strongly recommended for those members who have not attended a training session in over 2 years. Training sessions will typically be organised for September each year, before the start of the new academic year in line with the appointment of new administrative responsibilities within Schools.

The UTREC Administrators will provide training for School Ethics Committee administrators/secretaries on an annual basis. It is a mandatory requirement that all SEC administrators/secretaries attend at least one training session. Refresher sessions can be offered in-house as and when required by request.

## **Procedure for gaining Ethical Approval from UTREC**

Note 1: Each School has an Ethics Committee, which is a subsection of UTREC, and generally the School Committee gives ethical approval. In certain cases the School passes the application to UTREC. In what follows, to clarify matters in that the School Committee is part of UTREC, the School Committee is known as the School Ethics Committee (SEC) and the University Teaching and Research Ethics Committee as UTREC.

Note 2: Heads of Schools are responsible for checking the ethical procedures are being followed correctly and that their SEC is operating properly.

1. When an activity is proposed that involves human subjects or tissues or samples as described above in Principles 1, the following sequence of actions will take place.
  - a) An initial, careful appraisal should be undertaken by the researcher or lecturer using the proforma (Ethical Application Form) agreed by UTREC for use in the University.
  - b) This appraisal will be reviewed by School officers appointed by the Head of School in order to determine whether any ethical implications that require further consideration by UTREC arise, following agreed protocols in relation to the use of the Ethical Application Form.
  - c) Where no ethical implications requiring consideration by UTREC arise, the Ethical Application Form should be signed by the Convener of the School Ethics Committee. The School secretary should enter the project details into the UTREC database taking note of the monthly submission dates. UTREC will view the approved applications at the monthly meetings. UTREC reserves the right to review all applications where ethical approval has been given.
  - d) Where ethical implications arise that require consideration by UTREC, the form and full details of the research must be provided, via the Secretary, to UTREC. Its consideration will normally involve the full Committee, although a subgroup may provide recommendations to the Committee. In cases where the proposal is a minor modification of an activity for which there is existing approval, the Convener may permit a fast-track process by circulation of the documentation.
  - e) No research or teaching activity requiring permission should be started by a member of the University until formal written approval is received from UTREC, and in some cases its approval will be conditional upon further approval by relevant external bodies.
  - f) Where external approval is obtained (such as from the local Fife Research Ethics Committee [LREC] or other Ethics Committees recognised by UTREC), subsequent

- approval by the School Officers, and possibly by UTREC too, is also required. Researchers should submit an internal application to the School Ethics Committee, attaching a copy of the external application and approval letter.
- g) Where collaboration occurs with a main researcher outwith the University, the St Andrews University researcher and the School Officers should satisfy themselves that ethical approval has been gained by the main researcher from an institution which has a good and effective ethics committee. The SEC convener should thereupon inform UTREC which will in turn evaluate whether or not this institution's ethics committee is satisfactory and, if it is, will add the institution's name to its list of recognised institutions. In any subsequent research where a main researcher is from that institution, approval of a project can be given by the SEC convener alone, but he/she should determine whether the project should also go before the SEC for approval. The University of St Andrews researcher should fill in the first page of the University's Ethical Application Form including the 'Rationale' and 'Ethical Considerations', submit it to the SEC convener and, once approved, the project details should be entered into the database. In cases where no approval has been sought elsewhere, and where the main researcher is from outwith the University, application for ethical approval must still come before School Officers and UTREC.
  - h) When approval is withheld by UTREC, the Committee will endeavour to provide guidance regarding how the application may be modified in order to obtain approval.
2. If an approved activity alters its methods of investigation, kinds or numbers of subjects, or in any other material way, then such activity should cease until a report of the changes has been submitted through the normal ethical approval process described above and renewed approval obtained. In many cases this can be done through the "fast-track" procedure.

### **Ethical Approval for research carried out as distance learning through another institution but with the researcher from St Andrews**

Where research is carried out as distance learning through another institution but with the researcher from St Andrews University the research proposal should always go through the ethical procedures of the Institution providing the distance learning. It should then pass through the corresponding SEC at St Andrews University. The researcher and the School Officers should satisfy themselves that external ethical approval has been gained by the researcher from an institution which has a good and effective ethics committee. The SEC convener should thereupon inform UTREC which will decide whether or not this institution's ethics committee is satisfactory and, if it is, will add the institution's name to its list of recognised institutions. In any subsequent research involving that institution, approval of a project can be given by the SEC convener alone, but he/she should determine whether the project should also go before the SEC for approval. The University of St Andrews researcher should fill in the first page of the University's Ethical Application Form including the 'Rationale' and 'Ethical Considerations', submit it to the SEC convener and, once approved, the project details should be entered into the database.

In cases where Institution providing the distance learning has no ethical procedures in place or they are not recognised by UTREC the researcher should follow St Andrews University procedures and submit a full Ethical Application Form with any additional paperwork through the corresponding SEC.

In cases where St Andrews University has no corresponding SEC a full Ethical Application Form with any additional paperwork should be submitted directly to UTREC.

## **Procedure for gaining Funding Approval through UTREC**

Anyone who has the promise or possibility of funding must go through this process. On the UTREC website, under Funding Approval, there is a list of *Current Automatically Approved Funders* – should a researcher's funder be one of these, then there is no need to complete the Funding Approval Application Form. UTREC will annually review the list of 'current automatically approved funders'. If the funder is not on the approved list, the researcher should fill in the Application form and pass it to their Head of School (HoS) for any School comments. (The research should be fully aware of any obligations specified by the body providing funding and the implications this may or may not have for their research.) The HoS will then pass the application with School comments to the UTREC Funding sub-committee who will endeavour to respond within 48 hours.. The HoS will then approve or reject the application.

Further information can be found by following the links on the UTREC webpage on <http://www.st-andrews.ac.uk/utrec/FundingApprovalApplication/> This also contains a flowchart detailing the process.

## **Timetable for approving research/teaching activities**

1. UTREC will normally meet monthly.
2. Projects should be in the hands of the Secretary by the second Monday of each month. They will be sent to UTREC for discussion on the third Wednesday of each month (or otherwise as UTREC decides).
3. Researchers/teachers will be informed within a few days of the UTREC meeting.

## **Timetable for implementation of UTREC procedures**

1. Each School, within which ethical approval may be sought, should appoint a minimum of four School Officers to ensure a quorum of three on reviewing all ethical applications. They will consider all applications from that School, preferably by meeting rather than by email. A full outline of the School Ethics Committee structure is available on our webpage.
2. These School Officers should familiarise themselves with any Guidelines, within their subject area, for minimum standards of ethical approval. Strongly recommended for all Schools are:
  - *The British Psychological Society Guidelines for Minimum Standards for Ethical Approval in Psychological Research* (this can be borrowed from the UTREC secretary),
  - The Social Anthropology Guidelines (<http://www.theasa.org/ethics.htm>),
  - The ethics series published by the Medical Research Council ([http://www.mrc.ac.uk/index.publications/publicationsethics\\_and\\_best\\_practice.htm](http://www.mrc.ac.uk/index.publications/publicationsethics_and_best_practice.htm))
  - [The Economic and Social Research Council; http://www.esrc.ac.uk](http://www.esrc.ac.uk)

3. Each application must be submitted electronically using the University Ethical Application Form with a signed copy to the SEC.
4. Each School is responsible for alerting its own staff and students to the need for ethical approval in all research and teaching activities as described above in Principles 1.
5. Any ongoing research that has not gained ethical approval procedures will require approval with immediate effect
6. Where assistance is required the Convener of UTREC is happy to be approached.
7. The UTREC webpage should contain up-to-date information

### **Approval**

1. Approval for staff and post-graduate students' research can only be given using the recognised UTREC approval letter. Approval for undergraduate projects can be given by email.
2. Research undertaken without formal approval from UTREC will not be acceptable for submission in a project or thesis. Conduct of fieldwork without ethical approval may constitute a disciplinary matter under a charge of academic misconduct.
3. Approval of funding sources can only be given using the UTREC funding approval process. Acceptance of funding or sponsorship without going through this process may constitute a disciplinary matter under a charge of academic misconduct.

### **Research/Teaching involving Risk**

For any activities that pose a real or potential danger to the demonstrator or researcher (as distinct from the human or animal subjects of research), these dangers must be pursued in relation to risk management procedures rather than ethical approval procedures.

### **Completion of Research**

On completion of research by Staff, PhD and Research Masters students a letter of completion should be submitted to the SEC and the date entered into the database.

### **Review of UTREC**

An internal review of the remit, principles and procedures will occur every two years.

**Current Membership of UTREC**

<b>Convener</b>	Dr Jamie Walker
<b>Convener of AWEC (<i>ex officio</i> member)</b>	Professor Christopher Hawkesworth
<b>Layperson from outside the University</b>	Mr Michael Wallace Mr Graeme Scott
<b>Nominee of Head of School of Psychology</b>	Dr Barbara Dritschel
<b>Nominee of Head of School of Medicine</b>	Professor Gerry Humphris
<b>Nominee of Head of Social Anthropology</b>	Professor Christina Toren
<b>Nominee of Dean of Arts</b>	Dr Ian Smith
<b>Nominee of Dean of Science</b>	Professor Robin Flowerdew
<b>Secretaries in attendance</b>	Mrs Tracy Niven Mrs Emma Hughes

**External Ethics Committees recognised by UTREC**

- NRES, MREC and LREC
- Other Universities with a UTREC or equivalents

It should be noted however that the St Andrews UTREC always reserves the right to ask questions and query a decision of an external committee

**External Funders Automatically Approved by UTREC**

Please refer to the UTREC webpage for up to date information, including information on applying for Funders Ethical Approval