

## TERMS OF REFERENCE for operation of the University Research Ethics Policy and Principles

These Terms of Reference may be supplemented as required to address new legislation or funder guidelines.

### **ToR 1: Minimum Terms of Reference for the University Research Ethics Committee (U-REC)**

1. The University Research Ethics Committee (U-REC) defines the University's Research Ethics Policy and operational principles, which are applied by U-REC and its sub-committees (S-RECs which includes G-REC and the Animal Welfare and Ethical Review Body (AWERB)), and reports to Senate and Council.

2. The membership is as follows:

A Chair: appointed by Senate

A Deputy Chair

The Chair of each S-REC

The Associate Dean for Research or nominated Deputy where the Faculty has no reviewing S-REC

The University's Information Policy and Compliance Manager

At least one Lay Member

At least one male and one female member

The Secretary

Co-opted expert members as required

3. U-REC is responsible for the development and review of the Research Ethics Policy and Principles, and procedures and will take the lead on reviews of the Guidelines on Good Practice in Research, the Procedure for Dealing with Allegations of Misconduct in Research and other relevant Research Integrity documents which will be then be referred to the Research Executive.

4. U-REC identifies areas of best practice and disseminates these across the University. It is responsible for identifying and responding to strategic developments both within and outside the University. It may also instigate periodic audits of S-RECs, as routine, or where there are any causes for concern, e.g. adherence to terms of reference.

5. The Chair of U-REC provides advice to Faculties relating to the creation of new S-RECs and approves S-REC set-up.
6. U-REC coordinates the provision of research ethics training for U-REC members.
7. U-REC approves core documentation used by S-RECs for reviewing research proposals.
8. U-REC may recognize an external ethics approval body as equivalent to the University's, to avoid unnecessary duplication of reviews, and will advise S-RECs accordingly.
9. U-REC will schedule three meetings per year, with the option of cancelling two if not required, or of carrying out business virtually. U-REC will report annually to the University Research Executive and Senate.
10. U-REC may carry out any of the functions of ethics review described in the Terms of Reference for S-RECs.
11. U-REC may meet on an extraordinary basis as circumstances dictate to ensure that S-RECs are able to meet their terms of reference, including:

approval of recommendations for the recognition of external ethics review bodies;

approval of recommendations for the classification of research as low risk for the purposes of Light Touch review;

hearing appeals against decisions made by S-RECs;

undertaking the review of any submission where the Chair of an S-REC has determined that retrospective review is appropriate.

providing definitive guidance on problematic cases or interpretations of ethics review requirements;

reviewing the remit and functioning of research ethics committees in light of changing research activity profiles; and,

considering any new statutory or professional responsibility and advising the relevant Committees or Officers of the University accordingly on the implementation of that responsibility.

12. U-REC will monitor the activity of S-RECs and will carry out periodic audits of the reviews and decisions of S-RECs.

13. U-REC will carry out periodic audits of research studies approved by U-REC and S-RECs. The audit programme will be determined by the requirements of legislation and funders, the risk assessment of individual studies, and concerns raised by adverse event reports or suspicion of research misconduct.

## **ToR 2: Minimum Faculty level Responsibilities for Research Ethics Review**

1. The Associate Dean for Research, assisted by Research and Enterprise Services (REN), will have an oversight and management role for the research ethics responsibilities of the Faculty.
  
2. A Faculty may create subject or School-based sub-committees (S-RECs) to perform ethics reviews on its behalf subject to approval by the Chair of U-REC. S-REC meeting schedules, guidance and approved forms should be available on School websites and include a link to the Research and Enterprise Services (REN) Research Integrity webpages. Where research is reviewed outside the Faculty e.g. by G-REC, Schools should link to the G-REC or other website.
  
3. Research relating to health and social care, and research covered by certain legislation, requires review by a Research Ethics Committee of the Health Research Authority Research Ethics Service (an HRA REC). Where this is clearly the case, the submission is managed in Research and Enterprise Services (REN) by the relevant Project Officer, who reviews the submission for confirmation of UEA sponsorship, and records the progress of the HRA REC application.

Where it is not clear whether HRA REC review is appropriate the researcher should seek advice from their Project Officer in REN. If HRA REC decides the project is outside their remit the researcher must seek approval from a University S-REC.

4. The Faculty of Science will support the Animal Welfare and Ethical Review Body or such other committee as may be required under the terms of Home Office licensing for animal research.
  
5. Each Faculty will ensure Committee members have appropriate up-to-date training and information on ethics issues, to include:  
  
the University's Research Ethics Policy and associated guidance; and,  
  
establishment and maintenance of a web site of links to specialist sources of information on ethics, including a link to the REN Research Integrity webpages.
  
6. In addition, the Faculty will:

lead and contribute to awareness raising and staff development events

provide Research Ethics training for students

liaise with the U-REC, other RECs or specialist committees within the University or outside, e.g. the Health Research Authority Research Ethics Service

keep a record of training provided.

7. In conjunction with the U-REC, each Faculty will ensure staff and students are aware of the University's ethics approval requirements and the disciplinary consequences of non-compliance.

**ToR 3: Minimum Terms of Reference for Sub-committees of U-REC (S-RECs) including General REC (G-REC) and the Animal Welfare and Ethical Review Body (AWERB)**

1. The full membership of each S-REC (excluding AWERB) is as follows.

A Chair appointed by the relevant Head of School or Dean in consultation with the Associate Dean for Research

A Deputy Chair

At least one academic member from the research community served by the Committee. The number of members necessary will be determined by the need to provide collectively a sufficiently broad base of research experience and methodological expertise in the areas of research

At least one male and one female member

At least one member with experience of managing ethical issues

A lay member

Individuals seconded for their experience or specific methodological expertise, relevant to the research being reviewed

The AWERB will be constituted in accordance with the Animals (Scientific Procedures) Act 1986 and amendments.

The S-REC should keep a record of the names, relevant experience and training of members.

The S-REC will be responsible for providing appropriate induction of new members.

2. All members need not be involved in every review. The type of research and the form of ethical review required will determine the number of members needed, and their status, but any approval decision must include at least one member independent of the School or subject in which the research is to take place.

3. An S-REC meeting which does not include a lay member is not appropriately constituted to undertake review of ESRC funded research.

4. The Chair must stand down when the Committee reviews a submission from the Chair. For ESRC funded research, if the Deputy Chair cannot demonstrate independence from the

department in which the research is being carried out, the submission should be referred to another S-REC or its Chair.

5. The Committee may either co-opt members from other Committees or refer applications to another where a broader research experience or methodological expertise is required. Where the S-REC Chair has any doubt about the ability of the Committee to make a decision, this will be referred to the U-REC which will give definitive advice.

6. The Chair may appoint deputies to cover periods of absence or conflicts of interest. The Chair of the S-REC may not take decisions alone on cases where there is clear potential for conflict of interest or such a restriction is a condition of the funder.

7. The S-REC Chair is a member of the University Research Ethics Committee (U-REC) according to the U-REC Terms of Reference.

8. The Chair of the S-REC, or appointed deputy, will conduct an initial screening of any proposal submitted for ethical approval. The screening will determine the level of risk and complexity, which will determine which form of review will be applied. The task of screening may be delegated, but screening decisions are the ultimate responsibility of the Chair.

8. In the case of a taught student project where research projects follow a standard protocol (but not a research student project), the Chair of the Committee may delegate responsibility for assessment to the course or programme director, and this decision will be reported to the S-REC for ratification.

9. S-RECs may perform their work in a virtual environment providing papers are distributed to members in sufficient time to allow responses and discussions. A meeting of the full membership of the Committee in person will take place at least once a year.

9. The S-REC approves research as submitted, approves subject to specified conditions or rejects research proposals on the basis of the University's Research Ethics Policy and Principles, and the University's guidelines. The S-REC also provides guidance and advice on ethical issues to those undertaking research.

The S-REC does not make decisions about the quality of the research itself, which is the responsibility of the Faculty's research governance function.

10. The relevant S-REC Research Ethics Checklist should be used by researchers and S-RECs as required, to manage the process of initial application for ethical review. An exception may be made for research which clearly requires review by a Research Ethics Committee of the Health Research Authority Research Ethics Service (an HRA REC) (see point 14) providing the Faculty can demonstrate that such projects are not escaping the University REC procedures.

11. Light Touch review may be undertaken where the complexity of the case is judged to be low and the risk minimal. Initial information should be obtained from the researcher by completion of the relevant S-REC Research Ethics Checklist. The ethics approval process may be handled through Chair's Action, taking account of the potential for conflict of interest, unless legislation or funder requirements necessitate a fully constituted Committee.

12. In exceptional circumstances Expedited Review may be used outside the usual S-REC meeting schedule to provide a full review at short notice to research of importance. This may consist of a virtual or actual meeting, carried out by one or more members of the S-REC, but not by a member of the department due to carry out the research. The decision should be ratified at the next S-REC meeting.

13. For Faculties without a reviewing Ethics Committee, information about Research Ethics reviews undertaken by an S-REC should be made available to the Associate Dean for Research on request.

14. Research relating to health and social care, and research covered by certain legislation, requires review by a Research Ethics Committee of the Health Research Authority Research Ethics Service (an HRA REC). Where this is clearly the case, the submission is managed in Research and Enterprise Services (REN) by the relevant Project Officer, who reviews the submission for confirmation of UEA sponsorship, and records the progress of the HRA REC application.

Where it is not clear whether HRA REC review is appropriate the researcher should seek advice from their Project Officer in REN. If HRA REC decides the project is outside their remit the researcher must seek approval from a University S-REC.

15. Where research requiring ethical review is to be done outside the UK the researcher should provide the S-REC with evidence that ethical review has also been undertaken by an approved Institutional Review Board or Research Ethics Committee in that country in addition to review by a University S-REC.
16. Following consideration of a submission, the S-REC will issue a formal notice of review to the researcher, indicating whether or not approval has been given. This should require researchers who are given approval to provide an annual report to the S-REC including any adverse events.
17. Applications from external researchers should be referred to the Chair and Secretary of U-REC in the first instance, for initial review and referral to an S-REC if appropriate, or confirmation of approval by a recognised external body.
18. Service based research (non-academic Departments wishing to improve services or investigate problems) may require ethical review and should be discussed with the U-REC Chair.
19. Appeals against an S-REC decision will be dealt with by informal arbitration led by the S-REC Chair unless there are conflicts of interest. A final appeal may be made direct to the U-REC, which will make a definitive decision.
20. Minutes of meetings will be kept and standard documentation on decisions and guidance as approved by the U-REC will be used. Copies will be kept locally which will meet any audit or monitoring requirements, and a summary report on all ethics decisions will be supplied annually to the U-REC. No documentation should be destroyed without reference to U-REC for advice.
21. The S-REC may withdraw or suspend approval of an ongoing research project as a result of serious concerns regarding its conduct or ethical issues.
22. The S-REC should ensure that each research study proposal makes provision for handling complaints by research participants. In the case of students, the supervisor's name

and contact details should be given in the participant information. In the case of a member of staff, the Head of School's name and contact details should be given.

23. On approval by U-REC, S-RECs may recognise an external ethics approval body as equivalent to the University's to avoid unnecessary repeat reviews.

24. Each S-REC will keep a watching brief on any new statutory or professional responsibility that may affect its work and make changes as appropriate, with the relevant approval by the U-REC.

25. Each S-REC will submit the following for approval to the U-REC on an annual basis:

Committee membership, including the scope of research experience and methodological expertise within the Committee;

Details of procedures to be published on Faculty web pages, including forms, for submitting applications, Light Touch review of proposals, full review of proposals and appeals;

Frequency of meetings and deadlines for submission; and some indication of the time scale for reaching the different categories of decision;

Plans for training and awareness-raising for members, staff and students.