

University of Essex

Administrative Structure for Ethics Review

Introduction

The University operates a tiered approach to ethics review based on an assessment of the risks involved to research participants, both subjects and investigators. Research assessed to be of high risk must be referred to the University's Ethics Committee by an Ethics Sub-Committee (ESC). A list of such research is provided in Annex A. Research assessed to be of low risk may be reviewed and approved on behalf of the ESC by an Ethics Officer within a department. A list of such research is provided in Annex B. All other research will be reviewed by an ESC.

University's Ethics Committee

The University's Ethics Committee, a committee of Senate, undertakes the following core activities:

- 1 Development of policy and guidance;
- 2 Provision of oversight for all research-related ethical issues;
- 3 Assessment of applications for ethical approval only when referred by an ESC;
- 4 Hearing of appeals against decisions made by ESCs (an appeal against a decision made by the University's Ethics Committee when considering an application for ethical approval will be heard by a specially convened committee);
- 5 Maintenance of interaction with Health Research Authority NHS research ethics committees;
- 6 Maintenance of interaction with other external research ethics committees (for example, that of the MoD) where appropriate;
- 7 Receipt of termly reports from the ESCs;
- 8 Audit of a sample of applications processed by ESCs and on behalf of ESCs to ensure that there is consistency in ESCs working across the University and that the review process is robust;
- 9 Provision of an annual report to Senate which includes a summary of the decisions made in response to applications for ethical approval in the previous year by the Ethics Committee and all ESCs.

Membership of the Ethics Committee comprises a mix of academic staff, a representative of the students' union, lay members, a representative from Health and Safety, the Information

Assurance Manager and the Research Governance and Planning Manager. The current membership is:

Ex-officio members

Pro-Vice-Chancellor (Research): Professor Chris Greer (Chair)

Dean of Postgraduate Research and Education: Professor Shane Martin

Head of Research Governance and Planning: tba

Health and Safety Representative: Caroline Smith

Information Assurance Manager: Clare Chatfield

Vice-President (Education), Students' Union: Joe Holmes

Appointed members

Alan Cullen

Professor Tony Elston

Dr Caroline Lohmann-Hancock

Professor Wayne Martin

Professor Sabine Michalowski

James Sherrett

2 vacancies

The Chairs of the Ethics Sub-Committees attend the meetings of the University's Ethics Committee to ensure effective communication between two tiers of the ethics review process, the University's Ethics Committee and its Ethics Sub-Committees.

Ethics Sub-Committees

There are three Ethics Sub-Committees (ESC):

- ESC 1 reviewing applications from Edge Hotel School; Essex Pathways; Life Sciences; Literature, Film, and Theatre Studies; Psychology; and Sociology
- ESC 2 reviewing applications referred from Essex Business School; Health and Social Care; Mathematical, Statistical and Actuarial Sciences; Philosophical, Historical, and Interdisciplinary Studies; Psychosocial and Psychoanalytic Studies; and Sport, Rehabilitation, and Exercise Sciences
- ESC 3 reviewing applications referred from Computer Science and Electronic Engineering; East 15 Acting School; Economics; Government; Institute for Social and Economic Research; Language and Linguistics and Essex Law School

The three Faculty Deans Research act as Chairs of each of the ESCs and membership comprises the departmental Ethics Officers of the departments represented.

Each ESC assesses applications for ethical approval passed to them by departmental Ethics Officers in accordance with the procedures below. The ESC:

- 1 refers applications back to an applicant where change, clarification or additional information is required;
- 2 grants approval for applications within the departments covered by the ESC; or
- 3 refers an application to the Ethics Committee. The criteria to assist ESCs in deciding whether to refer an application to the Ethics Committee are set out in Annex A.

All application forms are authorised in the ERAMS by the Chair of the ESC.

The Chairs of the ESC share information and guidance on best practice from the Ethics Committee with members of the ESC.

Each ESC provides a termly report to the Ethics Committee summarising all decisions made in relation to applications received since the previous meeting and providing details of any other issues that have been raised. These reports are also used to assist in the compilation of the Ethics Committee's annual report to Senate.

Ethical approval at department level

Applications are assessed by the Ethics Officer of the appropriate department in the first instance. Ethical approval can be granted on behalf of the ESC by the Ethics Officer if the project only involves the procedures on the approved list provided in Annex B. Applications approved at departmental level on behalf of the ESC are authorized in ERAMS by the relevant Ethics Officer.

Ethics Officers also act as the first point of contact providing advice and support to their colleagues on issues relating to ethical approval.

A termly report to the appropriate ESC will be produced from the ERAMS summarising all decisions made by each Ethics Officer in relation to applications received during the previous term.

Records of Ethical Approval

Copies of all applications for ethical approval and the ethics review undertaken are stored in the ERAMS.

Audit

Appointed members of the University's Ethics Committee are asked to provide oversight and scrutiny of the approval process through the annual audit which involves assessing a random selection of applications reviewed and approved during the previous year.

Annex A

Guidance for ESCs about Referral to the University's Ethics Committee

Where Ethics Sub-Committees feel uncertain, or where proposed research is in a higher risk category, then the application must be sent to the University's Ethics Committee.

The following is a list of activities that must be referred.

1. Access to personal and/or confidential non-anonymised data without the identifiable participant's specific consent.
2. Administration of procedures which may be harmful to participants either during or after the research process.
3. Research that involves contact with illegal activities, or investigation of identifiable participants involved in illegal activities.
4. Collection and/or testing of gametes, embryo tissue/cells or foetal tissue/cells.
5. Administration of ionising radiation to participants.
6. Research having potential military/terrorist applications.
7. Publication of data that might allow identification of individuals.
8. Research on any activity with suspected adverse health or social consequences, funded by an organisation with a possible commercial interest in promoting that activity (e.g. research on smoking or on alcohol drinking commissioned by the tobacco or alcohol industries, or research on climate change commissioned by the airline industry or fossil fuels commissioned by the fossil fuels industry).

Note:

This does not mean that any of this research should not be conducted but that it must be referred to the University's Ethics Committee.

Annex B

Guidance for departmental Directors of Research/Ethics Officers about granting ethical approval on behalf of ESCs

Please note that research projects requiring ethical approval and funded by Research Councils will be expected to be referred to the ESC unless they have already received approval from recognised external ethics committees.

Proposals involving the following protocols and techniques, although requiring ethical approval, can be approved by a departmental Director of Research/Ethics Officer on behalf of the Ethics Sub-Committee providing they are administered appropriately, and human participants are fully informed about procedures.

Applicable across all disciplines and departments

1. Approval from recognised external ethics committee (e.g NHS, MoD, Social Care, University) already obtained.
2. Well-established, ethically non-controversial and commonly used types of test or experimental procedure aimed at investigating IQ, memory, language and verbal abilities, attitudes or personality characteristics as employed in experiments aimed at investigating cognitive processes, social interactions, and personality or attitude characteristics.
3. Secondary analysis of survey data where anonymous.
4. Questionnaires and interview schedules applied to respondents in the workplace, or low risk research involving family, friends or other students.
5. Interviewing (structured and semi-structured), ethnographic research and participant observation.
6. Routine non-invasive testing of children (minors below the age of 16 or minors lacking mental capacity above the age of 16) including photographic images and videorecording which is not shared or published outside the research team, when 'opt-in' parental consent has been obtained and providing that any researcher without a DBS check is under the active supervision of a DBS-checked researcher.
7. The presentation of visual stimuli (e.g. tachistoscopic presentations, eye movement experiments) used in experiments in visual perception.
8. The presentation of acoustic stimuli, e.g. dichotic listening tests, used in experiments in acoustic perception.
9. Think aloud tests and other forms of non-invasive psycholinguistic instrument use.

10. Experiments undertaken in the EssexLab offering monetary incentives in which: protocols do not involve deception by experimenters; participants remain anonymous to each other; incentives are not sufficiently large to create coercion (currently £15/hour with a maximum experiment length of 90 minutes) and payments are confidential; participants are at no risk of monetary loss; participants are not exposed to risk of physical, psychological or emotional harm by the experiment design.
11. Swabbing of the skin surface using sterile swabs moistened with sterile saline or water.
12. Non-invasive giving of saliva samples.
13. Collection of sub-millilitre capillary blood samples from the finger or earlobe using an 'autolet'.
14. Measurement of surface and core body temperature using skin and rectal probes.
15. Near infra-red (NIR) research. Measurement of sub cutaneous fat, blood flow and blood volume using NIR spectroscopy. This is a non-invasive technique where the measuring device is strapped to the skin over the muscle of interest, using elastic bandage. NIR light is emitted into the tissues and its reflection measured by detectors in the instrument. The device has been specifically designed and built in the USA for use with human participants.
16. Sub maximal exercise. Healthy volunteers exercise at intensities that can be sustained for longer than the duration of the test.
17. Maximal exercise. Healthy volunteers exercise at progressively higher intensities until volitional exhaustion. The point of volitional exhaustion is determined by the participant, who can terminate the exercise, without intervention of the experimenter, at any time.
18. 'Supra-maximal exercise'. Healthy volunteers exercise flat out for brief periods (30 seconds or less).
19. Dietary manipulation. Diets may be manipulated using conventional foodstuffs or approved 'over the counter' supplements (eg caffeine, creatine, vitamins). Supplements will only be administered within recommended dosage ranges.
20. Administration of 'over the counter' medicines (e.g. analgesics and/or anti-inflammatories) within recommended dosage ranges and advised by a supervising academic.
21. Measurement of body composition. Skin fold thicknesses and joint dimensions will be determined at multiple sites using callipers. Body density will be measured using underwater weighing (the participant is fully immersed for several seconds). Fat content will be estimated by bioimpedance in which skin electrodes measure the transmission of low

magnitude electrical impulses (commercially available devices are used that are battery powered. The impulses cannot be felt by the participant.).

22. Measurement of respiratory gases. The participant breathes through a mouthpiece or is fitted with a facemask. Exhaled gases are collected into a bag for analysis or gas is sampled by an automated analyser.
23. Collection of venous blood samples (up to 20 millilitres per sample; not more than 200 millilitres per participant in any 3-month period) from consenting human participants by a person who has appropriate training.
24. Electroencephalograph (EEG) recording.
25. Induction of muscle soreness in consenting individuals by downhill running or resistance exercise.
26. Transcutaneous recording of neuromuscular electrical activity (EMG).
27. MRI scans.
28. Research involving transcranial magnetic stimulation (TMS) (provided the published TMS safety guidelines are adhered to).
29. Research involving transcranial and transcutaneous electrical stimulation techniques (providing published safety guidelines are adhered to).

Applicable only to research involving animals

30. Use of an animal by-product where the death of the animal is **not** brought about for the project, e.g. waste products from commercial fishing.
31. Non-invasive observational research that does not involve a procedure. For example,
 - a. Observation of animal behaviour in the wild, e.g. birds on an estuary, or captivity, e.g. on a farm or in a zoo.
 - b. Observation of fishes, e.g. studies of behaviour in arena, growth, foraging rates, following Home Office ASPA guidance and providing a letter from the ASPA Advice Service granting permission is attached to the application.
32. Research involving invertebrates (apart from cephalopods) such as oysters, mussels, drosophila, corals
33. Research involving ringing, tagging or marking animals primarily for identification purposes which does not require an ASPA licence.

34. Practices undertaken primarily for the purposes of recognised animal husbandry as long as they comply with other animal welfare legislation or regulations.