

Research Ethics Policy

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Date: 25th September 2018 (*Approved by Senate 7th November 2018*)
Original - November 2005; Reviewed - 2009, June 2011, November 2016.

Version	Date	Notes
6	25/09/18	Scheduled review. Revised to: <ul style="list-style-type: none">• improve clarity on - when ethics review is required; the outcomes of retrospective ethics review; time limits on ‘umbrella’ ethics approvals; and the use of risk assessment forms.• refer to - DPA2018; GDPR; UEA’s <i>Ethics Review Appeals Procedures</i>; and UEA’s <i>Policy for Approving the Integrity of UEA Research and Innovation Related Activities and Funding</i>.• meet the UEA standard for layout.

Background

The University is committed to promoting high ethical standards in research and to safeguarding the dignity, rights and welfare of all those involved in research and the implementation of its results, as a fundamental part of its principles of research integrity.

The purpose of the *Research Ethics Policy* is to ensure that anyone engaged in research that involves the University of East Anglia is aware of the ethical principles that the University upholds, and has access to the guidance necessary to comply with those principles.

Review

This Policy will be reviewed and updated by the University Research Ethics Committee (UREC) and recommendations will be made to the University Research Executive, and thereafter to Senate before 31st July 2021.

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Part A. Introduction

- A1 The purpose of this *Research Ethics Policy* is to ensure that anyone engaged in research that involves the University of East Anglia (UEA) is aware of the ethical principles that the University upholds, and has access to the guidance necessary to comply with those principles. The *Research Excellence Framework (REF) 2021* defines research as ‘a process of investigation leading to new insights, effectively shared’. Additionally, there are forms of enquiry or investigation which may not strictly be defined as research, but which may carry risks to participants or infringe ethical principles or legal obligations, and need to be considered under the directions of this Policy.
- A2 This Policy applies to **all** researchers:
- academic, research and relevant support staff employed by the University, and other individuals carrying out research at, or on behalf of, the University;
 - all students (undergraduate, post-graduate taught, post-graduate research) undertaking research and their supervisors;
 - any persons with honorary positions conducting research within, or on behalf of, the University;
 - and the University also expects ethical oversight of research undertaken by any institution utilising UEA resources. This would/could include the University as a site for data collection.

All work carried out by the University of Suffolk postgraduate students registered with the University of East Anglia must be consistent with the principles and standards of this Policy, albeit the precise processes for ethical approval at the University of Suffolk may vary to those at the University of East Anglia.

- A3 The Policy recognises that it is necessary to take account of specific legislative and funding body requirements.
- A4 Although ethics should always be a consideration in research, this does not mean that full ethics review by the University is always required; ethics review supports good research practice and is not an end in itself.
- A5 This Policy sets out conditions for establishing the ethics review requirements of research involving human participants and animals, or with a potential to affect the environment or cultural objects.
- A6 The Policy also provides guidance on the review of projects which do not fit the definition of research but which may present ethical issues.
- A7 The Policy should be read in conjunction with the University’s other policies and guidelines available to researchers which relate to research integrity issues, and the University’s range of Research Ethics Guidance Notes. These documents are available on the Research and Innovation Services’ (RIN) Research Integrity webpages.

Part B. Scope

- B1 The University's *Guidelines for Good Practice in Research* outline what is expected of its researchers. This Policy and the associated guidance expand on this with respect to research ethics.
- B2 The Policy:
- sets out the University's core principles for undertaking ethical research;
 - provides a framework for the conduct of ethical procedures within the University;
 - is one of a number of University policies and guidelines available to researchers which relate to research integrity issues; and
 - outlines the relevant responsibilities and ethics review procedures within the University.

Part C. Principles

- C1 When undertaking research, it is the researcher's responsibility to consider and observe ethical principles and this Policy.
- C2 In line with the ESRC's *Framework for Research Ethics*, the University's core principles for ethical research are:
- research should aim to maximise benefit for individuals and society and minimise risk and harm;
 - the rights and dignity of individuals and groups should be respected;
 - wherever possible, participation should be voluntary and appropriately informed;
 - research should be conducted with integrity and transparency;
 - lines of responsibility and accountability should be clearly defined; and
 - independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.
- C3 Ethics review is required for all research that:
- involves human participants. This includes research that:
 - directly involves people in the research activities, through their physical (or virtual) participation. This may be interventional (for example surgery, drug trials, interviews, questionnaires of a personal nature) or non-interventional research (for example surveys, observational research) and may require the active or passive involvement of a person;
 - indirectly involves people in the research activities, through their provision of, or access to, information, personal data and/or tissue;
 - involves people on behalf of others (for example legal guardians of children and the psychologically or physically impaired or supervisors of people under controlled environments, for example prisoners, school pupils).
 - involves animals. For the purposes of this Policy, animal research is defined as any research involving vertebrates and protected invertebrates such as cephalopods. It includes other

invertebrates where these are registered as endangered or protected species, or involves large scale destructive sampling and/or the research is on specially protected sites. Research in this context includes research that is:

- regulated by the Animals (Scientific Procedures) Act 1986 (amended 2012);
- not covered by the Act, for example, fieldwork research and observational studies.

Ethics review of research involving animals will be undertaken by the University's Animal Welfare and Ethical Review Board (AWERB).

Research using post-mortem animal tissue such as that taken from abattoirs does not require ethics review.

- has a potential to affect the environment or cultural objects. Researchers should refer to the University's Research Ethics Guidance Notes for clarification of the ethics issues to be considered.

- C4 Ethics review should be sought **before** the research has started, unless the requirement for review only becomes necessary during development of the project, for example, following a literature review or as the findings of the research start to be implemented in practice. Research must not start unless the ethics application has been reviewed and approved.
- C5 Participants in research have, at the very least, all the rights as defined by law (for example, the Human Rights Act 1998, the General Data Protection Regulation (GDPR) and Data Protection Act (DPA) 2018, the Mental Capacity Act 2005, and relevant European Directives and conventions).
- C6 In line with the ESRC's *Framework for Research Ethics*, "Researchers should consider ethics issues throughout the lifecycle of a research project and promote a culture of ethical reflection, debate and mutual learning. The lifecycle of research includes the planning and research design stage, the period of funding for the project, and all activities that relate to the project up to - and including - the time when funding has ended. This includes knowledge exchange and impact activities, the dissemination process - including reporting and publication - and the archiving, future use, sharing and linking of data."
- C7 Ethics review is required for impact activities funded from the University's internal funding streams:
- HEIF Pro-Vice-Chancellor Impact Fund
 - ESRC Impact Accelerator Account (IAA) Funding
- C8 The Policy should also be applied to activities such as innovation, consultancy, service evaluation and audit which may have ethical issues.
- C9 Researchers should take into account legislation and cultural standards relating to the country in which the research is carried out. For research activities overseas, researchers must be able to demonstrate with documentary evidence that they are in compliance with relevant legal and ethical requirements of the host overseas country. Researchers and all partner organisations will

make sure that appropriate measures are in place to protect all involved in the research and must ensure that procedures are in place to handle any breach of Sections 2 and 6 of the DFID Supply Partner Code of Conduct, and make clear the legal ramifications of such a breach.

- C10 The nature and ethical standing of all stakeholders involved in a research project should be considered in the context of their fit with the University's mission and values.
- C11 Where organisations involved in research prescribe specific policies in this context which are not necessarily legal requirements, these should be observed, in so far as this does not conflict with ethical standards.
- C12 Specific areas of activity relating to research and innovation may require detailed consideration to ensure that they are consistent with the University's stated goals and standards of integrity and ethical practice. The University's *Policy for Approving the Integrity of UEA Research and Innovation Related Activities and Funding* sets out the procedures to be followed where there are any issues of doubt arising from these considerations, which must be followed prior to any activities starting.
- C13 As a condition of their employment, all staff are required to adhere to the policies, rules and procedures of the University. Researchers are individually responsible for adhering to the University's *Research Ethics Policy* under the leadership of their Head of School, or Dean of Faculty, who are ultimately responsible for all activities performed in the School.
- C14 Students are governed by the University's *General Regulations for Students* which are available within the annual University Calendar.
- C15 The University Research Ethics Committee (UREC) defines the University's *Research Ethics Policy* and operational principles, which are applied by UREC and its Research Ethics Subcommittees (S-RECs).
- C16 UREC is a Committee of Council and Senate, and reports to the University Research Executive, Senate and Council.
- C17 The University recognises that it is important for UREC and its Subcommittees to be able to operate independently of any influence or bias inside or outside the institution, and has procedures to handle conflicts of interest.
- C18 The Policy will be implemented by procedures determined by the Terms of Reference for UREC, the S-RECs and Faculties which are published on RIN's Research Integrity webpages.
- C19 Failure by a member of staff or a student to comply with the University's *Research Ethics Policy* will be investigated as research misconduct, and be subject to disciplinary action as appropriate under the University's *Procedures for Dealing With Allegations of Misconduct in Research*.

- C20 Certain types of research must gain approval from a NHS Research Ethics Committee (NHS-REC) before starting. This includes research involving:
- NHS patients;
 - the storage of human tissue regulated under the Human Tissue Act 2004;
 - human participants lacking capacity to provide informed consent to participation;
 - health-related-research involving prisoners;
 - clinical investigations of medical devices;
 - clinical trials of investigational medical products.

Part D. Responsibilities and Procedures

- D1 This Policy cannot address all possible ethics issues. Researchers are expected to maintain awareness of ethical issues as they arise and seek guidance from the relevant S-REC Chair in the first instance.
- D2 The primary responsibility for considering ethics in research lies with the lead researcher, student supervisor or equivalent.
- D3 Researchers are expected to consider the ethical implications of their research and, depending on its nature, the socio-cultural consequences of it for the participants involved. This should be considered in the context of a range of other potential stakeholders, including fellow researchers, their School and the University, the research funder and the academic profession.
- D4 Submission for review by a S-REC should be planned for in setting up the project. Chairs of S-RECs will provide informal guidance to researchers on request at any stage in the project lifecycle where ethical issues are apparent.
- D5 Research activities put forward for formal ethics review:
- require ethics approval prior to commencement of the research activities;
 - cannot continue if ethics approval has been withdrawn or suspended;
 - may have to request review during the course of the research if the research plan alters;
 - must comply with the conditions set by the University or other recognised bodies.
- D6 Any request for retrospective ethics review of a project which has already started, will only be considered in exceptional circumstances. Where the Chair of a S-REC agrees to a retrospective review, that review will be undertaken by the UREC. Retrospective approval is only likely to be given if there have been procedural failings. If retrospective approval is not given, the decision whether to proceed to formal research misconduct procedures will be dealt with on a case by case basis and will depend on the level of risk that was posed to the participants/researchers.
- D7 For some S-RECs a risk assessment forms part of the ethics review process. Please check the requirements of the S-REC you are applying to.

- D8 Applications for 'umbrella' ethics approval, for example the use of chick embryos, should include reasonable levels of scope and time. The S-REC, in consultation with UREC if necessary, will set the expiry date for this type of ethics approval.
- D9 Surveys and market research carried out within UEA will require ethics review. Those to be undertaken by the University's Central Services and the University's Students' Union should be emailed to the Chair and Secretary of the UREC for review and approval by the Chair. Those to be undertaken by staff and students in the Faculties and Schools of Study should be submitted to the relevant S-REC.
- D10 Research data should be managed in accordance with the University's *Research Data Management Policy*, which may require the completion of a Data Management Plan during development of the project.
- D11 Anyone planning a project should consider using the relevant S-REC's Research Ethics Checklist to identify potential issues and assist with preparing any subsequent application for ethical review.
- D12 An appeal against the decision of a S-REC will initially be handled by informal arbitration, and conducted by the Chair of the reviewing S-REC, providing there is no conflict of interest. If an informal resolution cannot be achieved, a researcher may use the University's *Ethics Review Appeals Procedures* to submit a formal appeal.
- D13 The S-REC documents are available from RIN's Research Integrity webpages.
- D14 Ethics review does not, in and of itself, ensure compliance with the data protection legislation. Where staff or students are processing personal data for which the University is the Data Controller, they must familiarise themselves with the requirements for compliance with both the GDPR and the DPA2018. This includes obligations to provide certain information to participants, and the legal requirement to undertake a Data Protection Impact Assessment (DPIA) for any processing likely to result in a high risk to individuals. The University's Data Protection Officer can provide guidance and must be consulted on any DPIA undertaken.