University of East Anglia

Title:	**Revisions to *UEA's Research Ethics Policy***
Author:	Dr Helen Brownlee (REN)
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Issue

In view of the changes in the research environment, taking into account new legislation and the requirements of funders and sponsors, Professor Nigel Norris, Chair of the University Ethics Committee (U-REC), proposed a review of the University Research Ethics Policy, which was last undertaken in 2011 and approved by Senate on 15th June 2011 (SEN10D031).

Recommendation

Recipients are invited to endorse the attached revised policy, which was approved by the University Research Exec. on 15th June 2016.

Resource Implications

Personnel to support implementation of the policy are already in post within REN who will work with U-REC members and HoSs to ensure that staff and students are aware of updates to this policy.

Risk Implications

Failure to endorse this policy may affect compliance with the terms and conditions of research funders, and hence the ability of the University to attract future funding.

Equality and Diversity

No equality and diversity issues are associated with this policy.

Timing of decisions

Approval by the Senate will allow the updated policy to take effect immediately.

Further Information

For further information contact: Dr Helen Brownlee (REN), Research Integrity Manager, ext: 3435, h.brownlee@uea.ac.uk.

Background

The revised policy states the University's position on a wider range of topics than previously. It encourages researchers to consider the ethical issues associated with the environment, cultural objects, security sensitive material and research impact as well as the more familiar and broader categories of human and animal research.

The University's fundamental principles relating to research ethics are now presented more concisely and clearly.

Documents supporting the policy will be provided separately on the Research and Enterprise Service's (REN) Research Integrity webpages. These will include:

- the Terms of Reference for the University Research Ethics Committee (U-REC), the reviewing subcommittees (S-RECs) and the Faculties' responsibilities in support of the policy, and

- specific guidance on individual topics with links to existing and internal and external guidelines, including professional codes of research conduct.

Discussion

No discussion is anticipated.

Attachment

The revised University Research Ethics Policy is attached.

Research Ethics Policy and Principles

Author: Members of the University Research Ethics Committee led by the Chair Professor Nigel Norris, the Chair Elect Ms Bridget Penhale, and the Research and Enterprise Division (RED), working from the document approved by Senate in June 2011.

Date: 07/06/2016

Version	Date	Note
0.5	07/06/16	Final draft

Review

U-REC will undertake periodic reviews of the Policy and report its findings and recommendations to the University's Research Executive, and thereafter to Senate and Council.

Foreword by the Pro Vice Chancellor (Research & Enterprise):

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 parts of its principles of Research Integrity.

This 'Research Ethics Policy and Principles' and supporting guidance incorporate good practice and local procedures in Faculties and Schools of Study, relevant legislation and the requirements of professional and funding bodies.

Its aim is not to inhibit research but to ensure that research is conducted to the highest standards.

Development of an ethical mindset is one of the University's goals for researcher development and reflects Vitae's 2010 Researcher development statement that a researcher should have 'knowledge of... ethical requirements of his/her research field... [and] the social and ethical implications of research'.

We are also guided by documents including the ESRC Framework for Research Ethics which points out that 'lack of rigorous reflection around ethics issues and failure to mitigate risks may result in liabilities, reputational damage, negative public attitudes towards research and harm to participants' and/or researchers' health and wellbeing'.

The Policy should be read in conjunction with other complementary policies, including the University's *'Guidelines on Good Research Practice'* and *'Procedures for dealing with allegations of misconduct in research'*, as well as specific ethics guidance issued by the University Research Ethics Committee and any associated sub-committees.

Professor Dave Petley
June 2016

Contents

1. Introduction

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

The significance of this for individual researchers, who can be students, faculty, research associates, or administrative staff, is that 'careful reflection and planning in relation to research ethics should not only benefit participants, but should enhance the quality of the research as a whole' (ESRC Frame work for Research Ethics, 2016). The University Research Integrity webpages provide links to guidance from a range of professional bodies and funders, emphasising the importance of these values in all fields.

The Policy recognises that it is necessary to take account of specific legislative and funding body requirements. 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 the Policy

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.

When undertaking research, it is the researcher's responsibility to consider and observe ethical principles and this Policy.

This Policy sets out conditions for establishing the ethics review requirements of research involving human participants and animals, or which may have an impact on the environment or cultural objects.

It also provides guidance on the review of projects which do not fit the definition of research but which may present ethical issues.

2. Scope

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. As such, this Policy applies to all UEA Researchers.

3. Principles

1. Research should aim to maximise benefit for individuals and society and minimise risk and harm.

2. All research that involves human participants must receive ethics review and researchers should refer to University guidance notes for clarification of research that is covered by this Policy. Ethics review is also required for research in virtual environments which involves living human participants who are potentially identifiable.

3. Before **any** animal research is undertaken by UEA staff or students (including non-vertebrate species, and field work) an assessment of the proposed research needs to be undertaken by the Animal Welfare and Ethical Review Board.

4. The rights and dignity of individuals and groups should be respected.

5. Wherever possible, participation should be voluntary and appropriately informed.

6. Independence of the research should be clear and conflicts of interest should be made explicit.

7. Participants in research have, at the very least, all the rights as defined by law (e.g. the Human Rights Act 1998, the Data Protection Act 1998, the Mental Capacity Act 2005, and relevant European Directives and conventions).

8. Researchers should take into account legislation and cultural standards relating to the country in which the research is carried out.

9. Research which may have an impact on the environment or cultural objects, whether during the project itself, or during the implementation of the outcomes of research, should be considered by the researcher for submission for ethics review.
   This also applies to the impact of research implementation on humans or animals, where there was no requirement for ethics review for the original project.

10. The nature and ethical standing of other stakeholders involved in a research project should be considered in the context of their fit with the University's mission and values.

11. Where organisations involved in research prescribe special 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.

12. 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 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.

13. Students are governed by the General Regulations for Students which are available within the annual University Calendar or on the University website.

14. The University Research Ethics Committee (U-REC) defines the University's Policy and operational principles, which are applied by U-REC and Sub-committees of the Research Ethics Committee (S-RECs).

15. U-REC is a Committee of Council and Senate, and reports to the University Research Executive, Senate and Council.

16. The University recognises that it is important for U-REC and its Sub-committees to be able to operate independently of any influence or bias inside or outside the institution, and has procedures to handle conflicts of interest.

17. The Policy will be implemented by procedures determined by the Terms of Reference for U-REC, the S-RECs and Faculties which are published on the University's Research Integrity webpages.

18. Failure by a member of staff or a student to comply with the Research Ethics Policy and Principles may constitute research misconduct, and be subject to disciplinary action under the University's Procedures for Dealing With Allegations of Misconduct in Research

19. Submission to a Research Ethics Committee should be made before the research has started, unless the requirement for review only becomes necessary during development of the project e.g. following literature review or as the findings of the research start to be implemented in practice.

4.   Definitions

Many of the ethical decisions taken at the University concern two broad areas: human participants and animal research.

Research: The 'Research Excellence Framework 2014' defines research as 'a process of investigation, leading to new insights, effectively shared'.

Human participants: Research involving human participants is defined broadly to include research that:

directly involves people in the research activities, through their physical (or virtual) participation. This may be interventional (e.g. surgery, drug trials, interviews, questionnaires of a personal nature) or non-interventional research (e.g. 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 (e.g. legal guardians of children and the psychologically or physically impaired or supervisors of people under controlled environments (e.g. prisoners, school pupils)).

Animal research: For the purposes of this Policy animal research is defined as any research involving any non-human animal. This includes research that is regulated by the Animals (Scientific Procedures) Act 1986 as amended 2012, as well as research that is not covered by the Act.

Researchers: The term Researchers is used to refer collectively to the following groups of people:

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.

5. Responsibilities and Procedures

This Policy cannot address all possible ethics issues. Researchers are expected to maintain awareness of ethics issues as they arise and seek guidance from an S-REC.

The primary responsibility for considering ethics in research lies with the lead researcher, student supervisor or equivalent. Prior to, during and following the completion of research activities, 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.

1. Submission for review by a Research Ethics Committee should be planned for in setting up the project. Chairs of S-RECs will provide informal guidance to researchers at any stage in the project lifecycle where ethical issues are apparent.

   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 body.

2. Any request for retrospective ethics review of a project which has already started, where review was needed before the research commenced, will only be considered in exceptional circumstances. Where the Chair of an S-REC agrees to retrospective review that review will be undertaken by U-REC.

3. Each Faculty should have an explicit procedure for the governance of non-research projects (e.g. service evaluation, audit, consultancy involving human tissue, enterprise and engagement activities) which may involve research methods and may have ethical issues.

4. Surveys and market research carried out within UEA by non-research staff will require ethics review and should be submitted to the Secretary of the University Research Ethics Committee.

5. 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.

6. Anyone planning a research project should consider using the relevant S-REC Research Ethics Checklist to identify potential issues.

The S-REC documents and links to a range of Guidance Documents are available from the University's Research Integrity Resources webpages. These include Terms of Reference for U-REC and the S-RECs.