

# Research Ethics Policy for University of East Anglia Awards 2023-24

The aim of an equality impact assessment (EIA) is to consider the equality implications of any new or amended policy, procedure, practice, project, function on different groups of staff, students and visitors to the college. This EIA tool provides a simple framework that helps evaluate whether the change may inadvertently disadvantage protected characteristics and identify ways to proactively advance and promote equality.

You will need to consider each of the equations and provide information as to consideration and any changes made in relation to Equality, diversity and inclusion.

Date EIA completed.	24/04/23
Name of person	Steve Bright
responsible for	
completing the EIA	
Role of person	Director of HE Operations
responsible for	
completing the EIA	
Who is affected by the	
policy / decision /	
change	
What's the reason for the	Update to existing policy
new policy / change in	
policy, practice, process	
etc.	

You will need to consider whether its possible that the proposed new policy / change in policy /procedure/practice etc could discriminate or unfairly discriminate or disadvantage people. You should consider:

Who gets to participate	Who does not, or who now does not due to the changes
	proposed / made.
Who is at an advantage	Who is at a disadvantage, and again has this changed?
Who will benefit	Who will not benefit (or who did and now doesn't due to the

	changes proposed in policy
Who can access the	Who cannot, or now cannot.
policy	

What	What is a potential	What action will be	Date by
degree of impact does the change have (score 1-5 with one being lowest impact and 5 being the	positive, neutral or negative impact? Include what you have considered. Are there	negative impact or remove any potential barriers identified? Note if we	when and whom will this action be taken.
1			
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	degree of impact does the change have (score 1-5 with one being lowest impact and 5 being the highest)  1 1 1 1 1 1	degree of impact does the change have (score being lowest impact and 5 being the highest)  1  1  1  1  1  1  1  1  1  1  1  1  1	degree of impact does negative impact? Include the change what you have have (score considered. Are there being lowest impact and 5 being the highest)  1  1  1  1  1  1  1  1  1  1  1  1  1

# Note:

- 1. The terms stated under protected characteristics are the terminology used in the Equality Act 2010.
- 2. As part of the policy approval process Executive Board will consider the EIA assessment and any potential barriers which we may not be able to overcome and whether the action proposed will mitigate sufficiently within legislation or whether we decide to not implement the new policy if the risk are significant. If the policy is approved the EIA is also approved.

The University Centre South Essex 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 University Centre South Essex (UCSE) students and/or staff, studying on programmes validated by the University of East Anglia (UAL) are aware of the ethical principles that the University Centre upholds, and has access to the guidance necessary to comply with those principles.

### Content

Part A. Introduction	2
Part B. Scope	3
Part C. Principles	3
Part D. Responsibilities and Procedures	6

### Part A. Introduction

- A1 The purpose of this *Research Ethics Policy* is to ensure that anyone at University Centre South Essex who is 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)* 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 <u>all</u> researchers:
  - All staff employed by South Essex College (including academic, research and support staff) carrying out research on a UEA validated programme.
  - All students undertaking research and their supervisors.
- 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 UCSE 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 UCSE other guidelines available to researchers which relate to research integrity issues, and the UCSE's Research Ethics Guidance Notes. These documents are available on Canvas.

# Part B. Scope

#### B1 The Policy:

- sets out the UCSE's core principles for undertaking ethical research;
- provides a framework for the conduct of ethical procedures within the UCSE;
- is one of a number of policies and guidelines available to researchers which relate to research integrity issues; and
- outlines the relevant responsibilities and ethics review procedures within the UCSE.

# **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 UCSE'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:
  - <u>involves human participants</u>. 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;
    - o 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);
- uses certain types of secondary data (for example organisational data this could refer to specific individuals who are identifiable within a company, or it could refer to elements such as number of employees, financial records, policies, annual reports, etc, that are for example commercially sensitive).
- <u>involves animals</u>. 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:
  - o regulated by the Animals (Scientific Procedures) Act 1986 (amended 2012);
  - o not covered by the Act, for example, fieldwork research and observational studies.

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.
- C4 Ethics review should be sought <u>before</u> 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 A UCSE ethics application must be led by a UCSE member of staff or UCSE student.
- C6 Participants in research have, at the very least, all the rights as defined by law (for example, the Human Rights Act 1998, the UK General Data Protection Regulation (UK GDPR) and Data Protection Act (DPA) 2018, the Mental Capacity Act 2005, and relevant European Directives and conventions).
- C7 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."

- C8 The Policy should also be applied to activities such as 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 to the relevant S-REC 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 UCSE'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 UCSE's stated goals and standards of integrity and ethical practice.
- C13 As a condition of their employment, all staff are required to adhere to the policies, rules and procedures of the UCSE. Researchers are individually responsible for adhering to the UCSE's *Research Ethics Policy* under the leadership of their Partnership Manager or the Director of HE Operations.

- C14 Students are governed by the UCSE's *General Terms and Conditions* which are available on the University Centre's website
- C15 The University Centre's Research Ethics Committee (REC) defines the University's *Research Ethics Policy* and operational principles, which are applied by the REC.
- C16 The UCSE recognises that it is important for REC to be able to operate independently of any influence or bias inside or outside the institution.
- C17 The Policy will be implemented by procedures determined by the Terms of Reference for REC, which are published on the Research Ethic Canvas page
- C18 Failure by a member of staff or a student to comply with the UCSE's *Research Ethics Policy* will be investigated as research misconduct.
- C21 the REC may recognise an ethics approval body within the UK as equivalent to the University's to avoid duplicating the ethics review. In this instance, the REC may ratify the ethics approval already received by the researcher using the original ethics application paperwork.
- C23 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 REC 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, the University Centre South Essex, the research funder and the academic profession.
- D4 Submission for review by the REC should be planned for in setting up the project. The chair of the REC 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 UCSE 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 the REC agrees to a retrospective review, that review will be undertaken by the REC. 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 REC a risk assessment forms part of the ethics review process. Please check the requirements of the REC you are applying to.
- D8 Ethics approval will last for the duration of the project.
- D9 For external requests for staff and students to participate in research, the Director of HE is the person to agree to research which requires access to staff as participants in the Faculty of HE. If students are required to be research participants, then the decision should be made by the relevant Programme Leader who may wish to consult the Director of HE.
- D10 When a Programme Leader is developing and setting up a **new** module, if there are any research exercises, rather than individually-chosen dissertations, whether assessed or unassessed, which will require the students to either gather knowledge from or about living individuals or groups, or use human tissues or animals, or with a potential to affect the environment or cultural objects, then the Programme Leader must seek ethics review prior to the module being offered via the REC. The same ethics approval needs to be sought if the above criteria are introduced to an **existing** teaching module.

be completed before the start of the project, outlining how the research data used and generated by the project will be managed, both during the project and after its completion. In particular, researchers should make provisions to allow the data collected during the project to be made available for re-use by other researchers and/or the public, wherever it is legally and ethically possible to do so.

- D12 Using secondary data can be a good alternative to collecting data directly from participants (primary data), removing the need for face-to-face contact. Secondary data relating to living human subjects (and in some instances, organisational data) often requires ethics approval depending on the source and nature of the data (please refer to section C3 above). Researchers should check whether secondary use of the data collected is in line with the consent originally obtained from the participants. Secondary data should be managed and acknowledged following the same principles as those for primary data.
- D13 Anyone planning a project should consider contacting the REC to identify potential issues and assist with preparing any subsequent application for ethics review.
- D14 An appeal against the decision of the REC will initially be handled by informal arbitration, and conducted by the Chair of the REC, providing there is no conflict of interest.
- D15 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 USCE is the Data Controller, they must familiarise themselves with the requirements for compliance with both the UK 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.
- D16 A researcher must ensure that they have a lawful basis for processing personal data under the UK GDPR and needs to include information about the lawful basis (or bases, if more than one applies) in their Participation information Sheet. This applies whether the researcher collects the personal data directly from the individual or collects their data from another source.
  - The UCSE will in general rely on 'public task' as a lawful basis for handling personal data in research projects. A formal definition of a university's public task does not appear to exist, however, the example given by the ICO here: <a href="https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/#different">https://ico.org.uk/for-organisations/guide-to-data-protection-regulation-gdpr/lawful-basis-for-processing of personal data. Alternatively, 'consent' can also be used as a lawful basis for processing personal data for research purposes. Further information is available at: <a href="https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/">https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/</a>.
- D17 All documentation regarding the ethics approval of a project should be retained for a period of 10 years from the end date of the project in line with the retention period for research grant documentation held in RIN and the University's Record Retention Schedule (pending review).