Research ethics policy

March 2020 – March 2023

Edge Hill University

Research ethics policy

Contents

Glossary of Terms

HTA	Human Tissue Authority
REC	Research ethics committee
Sponsor	whoever is responsible for the conduct of research and providing insurance
URESC	University Research Ethics Sub-committee

Purpose

The policy is the University's statement on our approach to the promotion and monitoring of ethics and integrity in the conduct of research. Its annex includes standard operating procedures for all research ethics committees in the University. The document is to support researchers to carry out their research to the highest ethical standards. This policy applies to anyone carrying out *research sponsored* by Edge Hill University, whether academic, professional services staff, students or visiting researchers.

Introduction

2.1 Research ethics refers to the principles governing the way research is designed, managed and conducted. The term 'research' is taken to mean creative work undertaken on a systematic basis in order to increase the stock of knowledge and effectively shared.

2.2 High standards of integrity and ethics are central to the quality of research and should be an integral part of the research process from design to execution.

2.3 This definition encompasses a very broad range of our activities; Edge Hill University (EHU) recognises that all research has an ethical dimension and approval processes ensure the highest standards of research ethics are applied to research whether it involves sensitive materials, human participants, human tissue or data relating to humans, sensitive research environments and artefacts.

2.4 The University Research Ethics Sub-committee (URESC) has primary responsibility for establishing the procedures and policies governing research ethics at EHU. It has produced this policy which must be followed by all members of the EHU community.

2.5 All research must undergo ethical review via the online research ethics approval system, Haplo, where all research projects will be registered. It is at this point that it is determined whether a project will undergo expedited, standard, or enhanced review:

- Expedited review for low risk projects which requires two reviewers from the committee to agree that work can commence.
- Standard review for medium risk projects which require review by the relevant SREC. In this case, researchers outside the committee may be invited to review.
- Enhanced review for high risk projects and all those relating to our policy on researching sensitive material. This review is carried out by URESC with assistance from members of the SRECs as appropriate. Reviewers external to any University REC may also be invited to participate in assessing the application.

2.6 While URESC oversees the research ethics processes, research ethics approvals are devolved to the five subject-based research ethics committees (SRECs):

- Arts & Humanities (AHREC)
- Education (EREC)
- Health-related research (HREC)
- Social Sciences (SSREC)
- Science (ScREC)

2.7 Ethical approvals are carried out close to the academics (i.e. by academics in their own broad disciplinary area rather than a central committee) to ensure that research in the University can take place effectively and efficiently. This also helps a culture of ethical conduct and deliberation to take hold at all levels of the University. URESC only provides ethical scrutiny and approval in those exceptional cases that raise complex issues or where there is particular risk: i.e. any research using sensitive materials (see our policy on Researching and Handling Sensitive Material).

2.8 No primary research such as data collection can take place without written approval from the appropriate REC. Any data collected before approval has been secured will be destroyed unless exceptional leave to use the material has been secured by URESC.

Key principles

3.1 This ethics policy should be read in conjunction with other Edge Hill University research governance and ethics documents as appropriate to the project. As a researcher, you must be familiar with the Code of Practice for the Conduct of Research. In adopting the policy, the University has been guided by key principles of autonomy, beneficence, non-maleficence, confidentiality and integrity that are widely accepted in ethics fora:

3.2 **Legal and professional concerns:** EHU and its staff are obliged to operate within applicable laws and to adhere to its insurance, indemnity and compliance

commitments. The University is obliged to operate within the guidelines and specifications set out by the regulating bodies in higher education, such as the QAA and Research England. We are obliged to recognise and respect the codes of ethical conduct of professional associations to which our staff belong and under which we practise. The University is obliged to recognise and respect contractual obligations arising from our research funded by third parties (e.g. research councils and charities).

3.3 **Responsibility and duty:** As a member of EHU, you have a duty to act ethically in all aspects of your research and to ensure that any research that requires ethical approval be submitted for scrutiny and approval secured before any primary research is conducted. Failure to secure ethical approval or the collection of data when approval has not been granted will, at the very least, entail the discarding of that data from any analysis of the research findings (ethical approval cannot be granted retrospectively unless exceptional leave to use the material has been secured by URESC). A serious breach of this policy will entail serious consequences as detailed in EHU's Code of Practice for the Conduct of Research and its Code of Practice for the Investigation of Research Misconduct. Furthermore, if you undertake research without ethical approval, EHU may not be able to protect you against any consequences, financial or otherwise. An aggrieved participant could seek legal redress and you would have a weaker defence if the research did not have the appropriate ethical approval. All researchers have a duty to consult and seek guidance to ensure appropriate ethical scrutiny when carrying out research. Researchers, and those who manage or oversee research, have a responsibility to be open and sensitive to ethical issues and should seek guidance and support where ethical questions arise that require scrutiny. URESC oversees the support provided to researchers who require assistance.

3.4 **Benefit, integrity and quality:** Your research must be worthwhile in itself and have beneficial effects that outweigh any risks. This means that your methodological approach must be sound so that positive results can be achieved. High quality ethical research is achieved when your activity reflects intellectual integrity, honesty and transparency. Any conflicts of interest, real or perceived, must be declared by any researcher involved in the project. Researchers should consult EHU's Risk Assessment Guidance regarding identifying and mitigating risk and also consult Health and Safety in Research guidance. Good practice would also include regular review of the ethical aspect of the research and for projects that last more than a year, a formal review should take place to consider whether any amendments to the original ethical approval are required.

3.5 **Sensitivity and duty of care:** As a researcher, you owe a duty of care to research subjects, fellow researchers, students and yourself. This includes ensuring such conditions as confidentiality and anonymity, informed consent, treatment with dignity, avoidance of harm or deception, and appropriate dissemination. Likewise, for those managing research or researchers, the well-being and dignity of research staff

engaged in research and knowledge exchange should be a central priority. Research relationships should be characterised, wherever possible, by mutual respect and trust, and by honest and open communication within the research team, between researchers and managers, and between researchers and research participants.

- Research participants should have the rights to withdraw from the research without penalty and/or have their data withdrawn within a clearly defined timeframe. All human research subjects, or their guardians where appropriate, should be informed of where they can access information on the University's governance and ethics standards should they have feedback or otherwise need to speak to someone outside of the research team.
- All human research participants and their guardians (where appropriate) must receive an age-appropriate participant information sheet (PIS)[1] explaining the nature of the research and the research process and provide the details of an independent person who can respond to queries regarding the study (e.g. associate dean for research or equivalent, head of department, chair of relevant SREC). In addition, all human participants must give informed consent, generally via a consent form although be verbal consent can be acceptable in some circumstances, before any data collection begins. Any additional requirements for researching with children, such as gaining assent for the research to happen, must be adhered to (see the Ethical Guidance for Undertaking Research with Children and Young People). Where interviews are being carried out via Skype or other online media, there needs to be a risk assessment carried out to identify any particular challenges and how they will be mitigated: this is particularly important for any research which involves sensitive issues which might cause distress to the participant.
- When discussing consent, you must explain how we process personal data and be able to signpost participants to the University's privacy statement.
- You must provide the appropriate aftercare guidance; particularly where research participants are likely to be asked about personal or potentially distressing issues. Details of support organisations should be provided on the PIS and, where feasible, the research team should make contact with the organisations beforehand. If research is being carried out with subjects outside the UK, you should make contact with local organisations and include their details on the PIS.
- Participants should never be deliberately misled or research carried out in a covert manner without extremely strong scientific or medical justification. Where justified, there should be strict controls and the disinterested approval of independent advisors and researchers should follow local advice where relevant (they should consult with SREC chairs

and departmental ethics leads to ensure they are familiar with all the relevant documentation). It may be impossible to carry out some research (e.g. in some psychological processes) without withholding information about the true object of the study or deliberately misleading the participants. Before conducting such a study, you have a special responsibility to:

- determine that alternative procedures avoiding concealment or deception are not available
- ensure that the participants are provided with sufficient information at the earliest stage
- consult appropriately upon the way that the withholding of information or deliberate deception will be received. Such issues should be clearly identified in the ethics application and mitigation provided.

3.6 **Independence of the researcher:** With respect to ethical considerations, ethical research is best assured if researchers retain independence in their research and research relationships. This independence involves the exercise of your intellectual freedom, including choosing who to collaborate with or whether to join research agreements, and under which terms. Within the context that all external research and knowledge exchange relationships should conform to this policy, it protects and preserves your independence. Such activities that operate or produce outputs under conditions of coercion, withholding of key access to knowledge pertinent to the research, and/or inducement to misrepresent research findings cannot be regarded as ethically informed and run contrary to this policy. In this regard, researchers should be aware of EHU's Code of Practice for the Conduct of Research and Code of Practice for the Investigation of Research Misconduct.

Research involving human tissue

4.1 The Human Tissue Act 2004 forms the legal framework for carrying out work using and storing human tissue and your research must comply with the Act.

4.2 Research involving the use or storage of human tissue is subject to special arrangements at EHU. Researchers involved in this area should consult the Quality Manual for Governance in the Acquisition, Use, Storage and Disposal of Human Tissue.

4.3 Applications for ethical approval involving the use or storage of human tissue should be reviewed by the Science Research Ethics Committee (ScREC).

4.4 Any ScREC letter of approval, amendment or extension must state when ethical approval expires. Any further amendments or extensions require additional approval from ScREC.

4.5 For approval, amendment or extension letters involving research degree students, the letter should be addressed to the principal investigator (who should be the Director of Studies) with the student copied in.

4.6 All approval, amendment or extension letters involving research that uses or stores human tissue must be communicated to the Chair of the Human Tissue Management Sub Committee.

Research involving sensitive material

5.1 The Counter-Terrorism and Security Act 2015 places a statutory duty on universities to 'prevent individuals from being drawn into terrorism' and requires universities to have policies in place in relation to access sensitive material.

5.2 Research involving access to highly sensitive material including access to the 'dark web', security-related materials, and other materials of a distressing or sensitive nature are subject to special arrangements: see the University's Policy on Researching and Handling Sensitive Material.

5.3 Such projects should undergo scrutiny at first instance by the relevant SREC but the application can only be formally approved by URESC. The referring committee should make a recommendation to URESC when referring the application.

5.4 If you wish to access materials that are prohibited by the IT Acceptable Use Policy, you must complete an application to access sensitive content [for research purposes] and this must be appended to your ethical approval application.

5.5 Any URESC letter of approval, amendment or extension must state when ethical approval expires. Any further amendments or extensions requires additional approval from URESC.

5.6 For approval, amendment or extension letters involving research degree students, the letter should be addressed to the principal investigator with the student copied in.

5.7 All approval, amendment or extension letters involving research that accesses material prohibited by our IT Acceptable Use Policy must be communicated to the University's Prevent Lead and the Director of IT Services.

Research involving genetic resources and traditional knowledge

6.1 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity is a supplementary agreement to the Convention on Biological Diversity. It places certain obligations on the researcher regarding, access and benefit-sharing with respect to the accessing data and the subsequent knowledge generated.

6.2 The Protocol also refers to using traditional knowledge which is 'the knowledge, innovations and practices of indigenous and local communities around the world. Developed from experience gained over the centuries and adapted to the local culture and environment, traditional knowledge is transmitted orally from generation to generation. It tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds. Sometimes it is referred to as an oral traditional for it is practiced, sung, danced, painted, carved, chanted and performed down through millennia. Traditional knowledge is mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, forestry and environmental management in general' (https://www.cbd.int/traditional/intro.shtml).

6.3 All countries which are signatories to the Protocol enjoy certain protections which require that contracting parties (the researchers and the owners/custodians of the genetic materials) address specifically issues related to access and benefit-sharing to help support biodiversity conservation and sustainable use. If this is relevant to your research, you should consult the University's Guidelines on Researching and Handling Genetic Resources and Traditional Knowledge.[2]

6.4 Any Edge Hill research project that may fall under the Protocol needs to undergo review by the Science Research Ethics Committee (ScREC). In the application, you need to address specifically how you are addressing the obligations of the protocol and any particular ethical issue arising from that.

6.5 Should there be any concern relating to the project, ScREC may refer the application to URESC.

6.6 Any URESC letter of approval, amendment or extension must state when ethical approval expires. Any further amendments or extensions requires additional approval from URESC.

6.7 For approval, amendment or extension letters involving research degree students, the letter should be addressed to the student with the director of studies copied in.

Approvals, extensions and amendments to research projects

7.1When any EHU ethics committee issues a letter of ethical approval, it must state the date on which such approval expires. If you require an extension to this date, or if an amendment to the approved project is required,[1] you must make an application

[1] Examples of amendments include:

- engagement with a different group of participants
- a different method for recruiting participants
- a different approach to obtaining consent, such as major changes in the information given to participants or in the consent form
- a different method of data gathering, or
- a different venue for data collection.

for the changes/extension to be approved before any research requiring such approval is undertaken.

7.2 For approval, amendment or extension letters involving research degree students, the letter should be addressed to the student with the director of studies copied in.

Review of procedures

8.1 The policy will be reviewed and approved annually at the first meeting of URESC. Minor modifications can be made throughout the year with the approval of URESC.

SREC procedures are reviewed and approved by URESC annually.

Useful links

Concordat to Support Research Integrity

UK Research Integrity Office

This list is not exhaustive and where there is doubt, you should consult with the chair of the approving REC.

Standard operating procedures for ethical approval

Research ethics policy appendix 1

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Research ethics committee: remit and terms of reference

1.1 The University Research Ethics Sub-committee (URESC) is the primary means by which EHU seeks to ensure that research activities conform to the Research Ethics Policy (REP). URESC is a sub-committee of the University Research

Committee to which it presents its minutes and decisions/recommendations. It oversees the functioning of the five subject research ethics committees (SRECs) to satisfy itself that the REP is being adhered to. The five SRECS are:

- Arts & Humanities (AHREC)
- Social Sciences (SSREC)
- Education (EREC)
- Health-related research (HREC)
- Science (ScREC)

1.2 The remit of URESC is to oversee the good ethical practice of research carried out by staff and students across the Institution. URESC's terms of reference (ToR) are:

1.3 To ensure that the subject research ethics committees (SRECs) are executing Research Ethics Policy (REP) appropriately and ensuring best practice in ethical research and knowledge exchange.

1.4 To review any case where a SREC considers the proportionality of risk to require University level scrutiny.

1.5 To act as an appeal committee for the SRECs.

1.6 To ensure that all ethical approvals are recorded and reported appropriately.

1.7 To ensure that the University is aware of external developments of best practice in relation to ethical guidance, advice, support and scrutiny and to integrate best practice into University policy and procedure.

1.8 To ensure that training in research ethics is in place as part of the researcher development programme (URESC is not responsible for the running of these sessions).

1.9 To monitor the effectiveness of the Committee on an annual basis.

1.10 To ensure that equality considerations are taken into account in the conduct of the Committee's business.

1.11 To provide an annual report for the University Research Committee on the Concordat to Support Research Integrity.

Membership and frequency of meetings

2.1 URESC aims to have a broad membership representing a range of disciplines and representative of the diversity of the staff and student body.

2.2 URESC is chaired by a University professor appointed by Research Committee. The Research Office provides secretarial support.

2.3 Ex-officio members are:

- The Director of the Research Office

- The Human Tissue Licence Designated Individual
- The chairs of the five subject research ethics committees

2.4 Appointed members: One representative from each SREC (in addition to the chair) is appointed by University Research Committee for a period of up to three years

2.5 Two external members: URESC appoints two members from local HEIs who have experience of working on ethics committees or equivalent. They are appointed for a period of up to three years (renewable for one term) to provide relevant ethics related expertise and to help ensure the independence of the committee.

2.6 Two lay members: URESC appoints two lay persons in order that the voice of the 'officious bystander' is heard and as a check to ensure our governance documents are easily understood by the non-specialist. They are appointed for a period of up to three years, renewable for one term.

2.7 The committee is quorate with one third of ex-officio and appointed members present.

2.8 URESC meets three times per year. It may conduct with routine business through e-mail between meetings and confirm its actions at its next meeting. A sub-committee of URESC can be convened to consider individual cases requiring ethical scrutiny where time is a factor, and the full committee will confirm sub-committee recommendations.

2.9 URESC may co-opt members as required to assist with the execution of its business, such as establishing working groups on specific topics

2.10 Individual SRECs have their own terms of reference, including membership and frequency of meetings, which are based on a template approved by URESC; these ToR will be reviewed at the first meeting of the academic year by URESC

2.11 Any member of an ethics committee must declare any interest, academic or personal, in the projects being reviewed.

Procedures for referral and scrutiny

3.1 URESC provides a central focus for ethical review in EHU and has responsibility for reporting and quality assurance on the effectiveness of all institutional forms of ethical scrutiny and their operation. In turn, all faculties, departments and service areas are required to follow these ethical structures and procedures for ethical scrutiny.

3.2 The operational aspects of providing ethical approval for research projects is devolved to the SRECs which attempt to provide a timely process. While all SRECs meet at least once a semester, ethical approvals will be managed via the online ethics approval system, Haplo.

3.3 All decisions and committee minutes of the SRECs are presented to URESC for review.

3.4 All research projects must be registered via Haplo and accepted as a valid research project by the relevant head of department.

3.5 Once registered, the application will be reviewed by the chair to determine whether the application requires standard, expedited or enhanced review.

3.6 Expedited review for low risk projects which requires two reviewers from the committee to agree that work can commence.

3.7 Standard review for medium risk projects which require review by the relevant SREC. Two reviewers will lead the process and report to the whole committee. In this case, researchers outside the committee may be invited to review. 50 per cent of members must agree.

3.8 Enhanced review for high risk projects and all those relating to our policy on researching sensitive material. This review is carried out by URESC with assistance from members of the SRECs as appropriate.

3.9Most projects will be reviewed by the default SREC determined by your department; however, it is the nature of the project rather than your department that determines which SREC is the most appropriate and you can over-ride the default setting. It should be noted that some SRECs have responsibility for certain projects:

3.10 All projects that require Health Research Authority (HRA) approval must be submitted to the Health Research Ethics Committee (HREC)

3.11 All projects involving human tissue must be submitted to the Science Research Ethics Committee (ScREC).

3.12The outcome of ethical review can be one of the following:

- Application is approved and the project may commence: in some cases, you will need permissions from external organisations (e.g. a hospital) before a study can commence. The SREC chair will need to see evidence of these approvals before the study may commence.
- Application is given conditional approval where amendments are required before research can commence
- The application is rejected. In such cases, the applicant may receive feedback and it is possible to resubmit the project once it addresses the concerns of the committee
- The application is referred to URESC for consideration.

3.13 Where referral of a case or issue is made to URESC, the following procedure applies:

- All referrals and submissions should be submitted in writing to the URESC Secretary. The referral should provide all the pertinent detail for deliberation

and judgement to take place including the reasons for the referral. Referring committees are reminded that even where applications are referred to URESC, URESC expects the application to have gone through full SREC scrutiny as part of the disciplinary peer review.

- The Secretary will liaise with the URESC Chair who will determine if the case or issue should be held over for the next meeting of URESC or dealt with electronically between meetings. Exceptionally, an extraordinary meeting would be called to review the matter in hand.

3.14 Whichever process is used, the matter will be dealt with at the earliest opportunity.

3.15 The decision/recommendation and the reasons for the decision/recommendation will normally be communicated in writing within ten working days of the completion of the deliberation.

3.16 On completion of its scrutiny, URESC can take the following decisions:

- That the referring committee is competent to take a decision and the application should be returned to it.
- That the application be approved.
- That the application be approved subject to mandatory revisions. In its letter of decision, URESC will explain to which committee any resubmission should be sent.
- That the application be rejected and ethical approval refused. Reasons shall be stated.

3.7 The minutes of SREC meetings are available on the ethics wiki and URESC minutes are available on the Academic Board folder on the staff directory.

Experimental protocols

4.1 Where there are a series of research projects involving experiments based on the same protocols, it is possible to have the protocol approved by ScREC and subsequent experiments would be reviewed as an amendment to ensure that the new experiment is in-keeping with the approval already given. This serves to minimise unnecessary administrative burden while ensuring high ethical and governance standards. If the chair decides that full ethical approval is required, the researcher may not proceed with the experiment until ethical approval is secured.

Ethical review of evaluations

4.2 If you are conducting a service evaluation Edge Hill University requires that the project is registered on the Haplo online ethics application system with a letter uploaded providing evidence that the commissioning organisation confirms that it takes full governance responsibility for the evaluation (i.e. EHU is not sponsoring the evaluation). When completing the Haplo submission you will be asked to identify the

most appropriate SREC (Health, Science, Education, Social Science or Arts & Humanities) to consider the registration. The SREC Chair can then confirm that this is a service evaluation not requiring ethical review if the steps detailed above have been met.

4.3 If you wish to publish from the data collected, you will need ethical approval since the project is being identified as research not just an evaluation,

4.4 It is possible to have an evaluation protocol approved and any evaluation using the same methodology would require an amendment to approve that particular project. This allows for a more rapid review and will assist staff who are asked to publish their material after the evaluation has been complete.

4.5 In extenuating circumstances, it may be possible to have a 'permission to publish' letter if no ethical review has taken place before the evaluation has commenced.

Ethical review of student projects

5.1 All postgraduate research (PGR) student projects must follow the same process of registration and ethical review as staff projects

5.2 Undergraduate and taught postgraduate research projects must be registered by the department and permission to proceed given by at least two members of staff. Where ethical approval is required (e.g. where the work involved human participants), as a minimum the project must be approved by at least two people: the module leader and the head of department/area (who may delegate the responsibility).

Provisional opinions and amendments

6.1 There are occasions where the REC will offer a provisional opinion subject to amendments.

6.2 If the amendment is minor, it can be approved by the REC chair

6.3 If the amendment is major it needs to be referred back to the committee which may accept confirmation of two members of the REC

6.4 Amendments will be made online and no work may commence until approval is confirmed via Haplo.

6.5 If a research project is amended after approval has been secured, you must ensure that this amendment is approved by the same REC which approved the original application. A SREC has the right to refer it to URESC if required.

Ethical approval with partners and organisations with separate ethical approval processes

7.1 There are some occasions when your research may be required to undergo ethical approval processes external to the University (you should clarify with the REC

chair whether external approval is appropriate). In most cases, where Edge Hill researchers are PIs, Edge Hill must provide the ethical approval *unless* it is a requirement that the external body must give ethical approval: e.g. when carrying out research with the NHS where you will normally require HRA ethical approval. In such cases, the following processes apply:

7.2 Where research is being carried out with a partner, but Edge Hill researchers are acting as principal investigator (PI):

7.3 The research has to undergo the standard ethical approval process and be presented to the appropriate committee

7.4 Evidence of the approval and the final project description should be shared with all members of the team (to be lodged with the external organisation's ethics committee if so required)

7.5 Where research is being carried out with a partner who is acting as principal investigator (PI) (e.g. a colleague at another university):

7.6 The PI will be responsible for carrying out the appropriate level of ethical scrutiny at her/his institution

7.7 Once ethical approval has been granted, you need to:

- Present evidence of the ethical approval plus a full description of the research projects with evidence of the approval from the relevant ethical committee as part of the project registration process. The project does not require approval by Edge Hill but no work can commence until it is acknowledged that the registration is complete
- Provide contact details of the PI or equivalent should any queries arise
- Identify the roles and responsibilities of each team member (including yourself)
- Where the research is high risk, a written risk assessment needs to be completed and submitted via the Haplo registration process.

7.8 Where research is led by an Edge Hill researcher but needs Health Research Authority (HRA) (or similar) ethical approval (via IRAS):

7.9 The project needs to be approved by the Health Research Ethics Committee (HREC) as part of the review process required for sponsorship of the project (sponsors generally provide insurance and indemnity).

7.10 Any changes required during the HRA review process need to be added via the amendments function in Haplo which will be reviewed by HREC

7.11 Where changes are made subsequent to HRA approval, these need to be approved by HREC before being sent as major or minor amendments for approval via the IRAS process.[2]

7.12 If you are working with partners in another country/organisation which do not have robust ethical approval processes, you *must* seek approval from Edge Hill to ensure that all insurance and indemnity issues are properly reviewed. You would also be highlighting this in your risk assessment.

Work with collaborators where Edge Hill provides a service

8.1 There are occasions where our researchers may facilitate the use of Edge Hill research equipment by other researchers – in such cases you would not benefit from the research (e.g. have access to research findings, be involved in design or execution) as this would make you a co-investigator. These are unlikely to require ethical approval if you are not directly involved in the research but there are significant insurance and indemnity considerations and a full risk assessment is required. To do this, you will need:

- A full project description
- Evidence of ethical approval from the organisation sponsoring the research
- Evidence of separate insurance and indemnity if required
- Name of PI or other contact at the sponsoring organisation.

8.2 The project details should be logged with the Research Office and no work should progress unless you have written approval to proceed.

Appeals

9.1 All researchers have the right to appeal against the judgement of the SRECs and URESC. There are two grounds for such appeal:

9.2 Where you feel that the REC has made a judgement based on erroneous assumptions about the case or issue referred or been unfair in its consideration of the case or issue;

9.3 Where there have been any irregularities in the procedures adopted by the ethical scrutiny.

9.4 Researchers seeking to appeal should note that URESC will not normally interfere with a SREC decision to require revisions to the project. Dissatisfaction with the academic judgement exercised by members of RECs is not sufficient grounds for an appeal. The Chair of URESC will notify the relevant parties whether the Committee has granted an appeal hearing.

[2] Any queries concerning amendments to projects where EHU is the sponsor should be sent to the Research Contracts and Governance Manager in the Research Office.

9.5 Appeals against SREC decisions should be referred in the first instance to the SREC's appeal process. Where the issue remains unresolved, you (and your co-investigators where appropriate) can appeal against the SREC decision to URESC on the grounds identified above. The appeal should be in writing and should contain an adequate explanation and justification of the grounds for the appeal. Failure to do so may result in a refusal to hear the appeal.

9.6 Appeals against SREC appeal processes are heard by URESC or a sub-committee convened for the purpose. Appeals against URESC are heard by Research Committee.

9.7 The appeal is heard at the next meeting of the full URESC or its sub-committee, which will review the grounds for the decision and consider the grounds of appeal presented by you as the appellant. URESC will co-opt additional members if deemed necessary.

9.8 You are also invited to attend the hearing and have the right to be accompanied by a member of the EHU community who has a sufficiently close connection to the project. If you are a PGR student this should normally be the Director of Studies. You will not normally be permitted to introduce new arguments to the panel beyond those expressed in the letter of appeal.

9.9 The URESC appeals panel will gather relevant information from the SREC Chair and any other relevant source and circulate this to panel members. The SREC Chair, or designate, will be invited to the appeals panel to explain the grounds for its decision but they will not take part in any decision making. The SREC Chair will not normally be permitted to introduce new arguments to the panel beyond those communicated to the appellant in the letter of rejection.

9.10 The URESC appeals panel will interview the appellant and the SREC Chair (the latter where necessary) separately.

9.11 URESC may:

- Uphold its original decision to refuse ethical approval
- Allow the appeal of the appellant and approve the original proposal
- Allow the appeal of the appellant subject to any required revisions
- Allow the appeal of the appellant and return the proposal to the relevant FREC
- You, and other relevant parties, will be notified in writing of the outcome within ten working days of the appeal hearing.

9.12 Following an unsuccessful appeal, and where you remain dissatisfied with the decision of URESC, you have the right to submit a final appeal to Research Committee. This appeal must be lodged through the Chair of Research Committee within ten working days of receipt of URESC's final decision. A panel of no fewer than three members of Research Committee, who have not previously been

associated with the proposal, will make a final decision which will be based solely on the procedural propriety of URESC's decision-making process. You will be notified in writing within ten working days of this hearing.

9.13 URESC shall ensure that any institutional obligations and/or relevant contractual obligations to research funding bodies and partner institutions are met, which may include notifying them of the appeal and its outcome. In this connection, researchers should be aware of the University's Code of Practice for the Conduct of Research and Code of Practice for the Investigation of Research Misconduct.

9.14 Those making use of an ethics appeal procedure are protected by the University policies on bullying and harassment and whistleblowing.

Training

10.1 As researchers you need to ensure that you receive regular ethics training and you are responsible for ensuring that you are abiding by the most up-to-date policies and procedures which are available on the University's research webpages. To support staff, the University's Researcher Development Programme includes sessions on ethics.

10.2 Committee members must undertake training when they are first appointed to a committee. Updates on policy will be communicated via the committee structure and additional training and development will be provided as required.

Endmatter

Title	Research ethics policy
Policy Owner	Director, Research Office
Approved by	Academic Board
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Date for Review	April2023 (annual review by URESC)