Introduction

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. 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.

3. This definition encompasses a very broad range of our activities and, although Edge Hill University (EHU) recognises that all research has an ethical dimension, there are particular approval processes required to ensure the highest standards of research ethics are applied to work involving sensitive material, human participants, human tissue or data relating to humans, and respect for research environments and artefacts. All research must undergo ethical scrutiny via the research project registration process. It is at this point that it is determined whether a project needs to undergo ethical approval (see diagram 1).

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.

5. Research ethics approval is a devolved responsibility and URESC is not the only ethics committee operating at EHU. Our three faculties, the Faculty of Arts and
Sciences (FAS), the Faculty of Education (FoE) and the Faculty of Health and Social Care (FHSC), have their own faculty research ethics committee (FREC): each possesses broad powers of ethical scrutiny and approval.

6. In FAS, departments have their own departmental research ethics committees (DRECs) which have the responsibility for scrutinising staff and student research projects. Ordinary DRECs have limited approval powers and generally must refer applications to the FREC for formal approval once scrutiny is complete. Currently, two departments have received devolved decision-making ethics powers: the Departments of Psychology and Sport and Physical Activity. This means that in certain prescribed circumstances, the ‘Devolved DRECs’ can issue ethics approvals. URESC maintains oversight of all RECs operating within EHU and approves all their local procedures. Researchers should consult not only the Research Ethics Policy, but also these procedures.

7. All research projects need to be registered with the University and researchers should seek to have their projects undergo ethical scrutiny and approval at the most appropriate level. This ensures that research in the University can take place effectively and efficiently and so that a culture of ethical conduct and deliberation takes 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, including:

   a. Research being carried out under the HTA license;
   b. Other work involving human tissue;
   c. Any research using sensitive material including security-sensitive material, or other research involving distressing or illegal material (e.g. child abuse; information from the ‘dark web’).

**Key principles**

This ethics policy should be read in conjunction with the **Edge Hill University research governance and ethics** documents. 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:

8. **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).
9. **Responsibility and duty:** All members of EHU have a duty to act ethically in all aspects of their 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). 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 researchers undertake research without ethical approval, EHU may not be able to protect them against any consequences, financial or otherwise. An aggrieved participant could seek legal redress and the researcher 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.

10. **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. 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.

11. **Sensitivity and duty of care:** All researchers owe a duty of care to research subjects, fellow researchers, students and themselves. 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.

  a. Research subjects 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.

b. All human research subjects and their guardians (where appropriate) must receive an age-appropriate participant information sheet (PIS) 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 FREC). In addition, all human participants must complete a consent form before any data collection begins. (There are sample PIS and consent forms available on the research wiki.) 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.

c. Researchers 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, the research team should make contact with local organisations and include their details on the PIS.

d. Participants should never be deliberately misled without extremely strong scientific or medical justification. Even then there should be strict controls and the disinterested approval of independent advisors. 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, the investigator has a special responsibility to (a) determine that alternative procedures avoiding concealment or deception are not available; (b) ensure that the participants are provided with sufficient information at the earliest stage; and (c) 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.

12. 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 their intellectual freedom, including choosing who to collaborate with or whether to join research agreements with, and under which terms. Within the context that all external research and knowledge exchange relationships should conform to the policy, it protects and preserves the independence of the researcher. Such activities that operate or produce outputs under conditions of coercion,
withholding of key access to knowledge pertinent to the research and inducement to misrepresent research findings cannot be regarded as ethically informed and run contrary to the 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**

13. 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.

14. 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.

15. Applications for ethical approval involving the use or storage of human tissue should be scrutinised at first instance by the relevant FREC or devolved DREC but the application can only be formally approved by URESC. The referring committee should make a recommendation to URESC when referring the application.

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

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

18. 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**

19. 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.

20. 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.

21. Such projects should undergo scrutiny at first instance by the relevant FREC or devolved DREC but the application can only be formally approved by URESC. The referring committee should make a recommendation to URESC when referring the application.
22. Anyone wishing to access materials that are prohibited by the IT Acceptable Use Policy must complete an Application to access sensitive content [for research purposes] and this must be appended to your ethical approval application.

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

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

25. 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

26. 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.

27. 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).

28. 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. All researchers should consult the University’s Guidelines on Researching and Handling Genetic Resources and Traditional Knowledge.¹

¹ This is currently being drafted and will be available on the Research Governance website shortly.
29. Any Edge Hill research project that may fall under the Protocol needs to undergo the relevant FREC scrutiny. In the application, the researcher needs to address specifically how s/he is addressing the obligations of the protocol and any particular ethical issue arising from that.

30. Should there be any particular concern relating to the project, the FREC may refer the application to URESC.

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

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

**Approvals, extensions and amendments to research projects**

33. When any EHU ethics committee issues a letter of ethical approval, it must state the date on which such approval expires. If the researcher requires an extension to this date, or if an amendment to the initial application is required, additional ethical approval must be secured from the approving committee before any research requiring such approval is undertaken.

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

**Review of procedures**

35. 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.

36. FREC and Devolved DREC procedures are reviewed and approved by URESC annually. Each FREC should review and approve the procedures of Devolved DRECs and Ordinary DRECs at least annually.

**Useful links**

- [Concordat to Support Research Integrity](#)
- [UK Research Integrity Office](#)

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2 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.

This list is not exhaustive and where there is doubt, the researcher should consult with the chair of the approving REC.
This policy was approved by the University Research Committee on 25 October 2017.