University Research Ethics Policy

1.   Policy Statement

The University of Edinburgh is committed to supporting the highest standards of research integrity in all aspects of its research. Research integrity relates both to the scientific integrity of conducted research and the professional integrity of researchers. Integral to this commitment to research integrity is the implementation of a culture that promotes robust and transparent research ethical standards. The purpose of this policy is to articulate the ethical principles, procedures, and expectations that inform the conduct of research activities undertaken by University of Edinburgh staff and students. This policy seeks to harmonise processes across the University, with the aim of supporting staff and students to enact the highest standards of ethical conduct in research.

2.   Scope

This policy applies to all students and staff[1] at the University, and all research carried out at, or in the name of, the University of Edinburgh, including research at other sites and internationally.

3.   Definitions

Research is broadly conceived to include any form of disciplined inquiry undertaken by staff and students that aims to contribute to a body of knowledge or theory. Some consultancy, and knowledge exchange and impact activities, including public engagement, may also include activities that may be categorised as research.

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[1] Staff in the context of this policy includes employees of the University of Edinburgh, in addition to honorary staff, those who are visiting from other institutions and organisations, and those undertaking or supervising research at or for the University.

Researcher is broadly conceived to include those who engage in the research activities outlined above and are employed by, or registered as a student[2] at the University of Edinburgh. Researchers also include honorary staff, those who are visiting from other institutions and organisations, and those who are undertaking or supervising research at or for the University.

Research ethics involves the application of ethical principles (see section 4) to research activities. These ethical principles are applied throughout the lifetime of a research project: from conception and design, via data collection and analysis, to dissemination, archiving of research materials, and beyond. Researchers have a responsibility to undertake their research with due diligence of all relevant ethical considerations.

Research ethics review comprises the proportionate review of the ethics and trust (hereafter 'ethics') issues associated with planned research activities, and how those ethics issues will be addressed by the researchers. All researchers should explicitly self-evaluate the ethical implications of all of their research. Where the research might reasonably be considered to raise ethical questions[3], then research ethics review will be required before the research commences. Ethical consideration is not solely the preserve of research on humans and animals. Many other fields have ethical considerations (e.g., ranging from physics, the environment, energy, to the arts). It is the responsibility of the researchers to consider, and where appropriate, seek ethical review prior to instigating any project.

Where independent scrutiny is required, the review will be undertaken by a research ethics committee (or one or more members therein) at the University, or credible alternative. The purpose of the review to provide an opinion on the ethical appropriateness of the proposed research, and, if appropriate, to suggest changes to the research that would improve its ethical status. Researchers should continue to engage with their ethics review committee throughout the lifetime of a research project, including submitting proposed amendments

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[2] It is acknowledged that the required level of engagement of, and support provided to students will be proportionate to the nature and level of their studies (Appendix 3 Roles and responsibilities of student researchers in adhering to research ethics standards)

[3] Although not an exhaustive criteria, where the research involves new or existing data of any kind collected from humans or non-human animals, research ethics review will be required.

and, if appropriate, annual updates on progress.   Ordinarily, requests for retrospective ethical opinion will not be supported.

Research integrity requires complying with the ethical, legal and professional frameworks, obligations and standards required by stakeholders, including statutory and regulatory authorities, employers and funders. A favourable opinion following ethical review is an important, but insufficient, requirement on its own to enable the research to proceed and meet the highest research integrity standards. Researchers must also ensure appropriate governance procedures are adhered to prior to and throughout the lifespan of the research (see Appendix 4).

4.   Research Ethical Principles and Values

This policy enacts our wider University values to be principled, considerate and respectful, and act with integrity in our research (Strategy 2030). The policy aims to safeguard the interests and well-being of researchers, research participants (both human and non-human), the wider research community, the environment, and broader society throughout the research lifecycle, and beyond. The overarching principles informing our research are:

4.1   Beneficence and non-maleficence

Researchers seek to maximise the benefits of their research for individuals, the environment, and society, and to avoid or minimise risk of harm via appropriate robust precautions.

4.2   Integrity, openness and transparency

Researchers design and conduct research to ensure its methodological integrity, and contribution to knowledge, working within the limits of their professional competence, and/or with appropriate supervision. The aims of the research are transparent, and the full record of the research should be as open as possible, and as closed as necessary.

Researchers undertake due diligence to assess the integrity of potential research partners, maintain independence of research, and make explicit any unavoidable actual or potential

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conflicts of interest. As research partnerships evolve and develop over time, researchers will continue to monitor issues relating to integrity, independence, and conflicts of interest.

4.3 Dignity and respect

Researchers respect the rights, autonomy, privacy, interests, values, and dignity of fellow researchers and research participants, including humans, human tissue, and non-humans alike. The principle of proportionality discourages researchers from going beyond stated objectives or imposing more than is necessary on research participants. Predictable risks are clearly communicated to human research participants, allowing informed consent. Where informed consent is not possible or not appropriate, then researchers are guided by standards for best practice. Researchers ensure participants are free to participate without coercion or penalty for not taking part, and that their right to withdraw from the research is clearly communicated and delineated at any time. Throughout the lifecycle of the research and beyond, data will be managed to maintain confidentiality, security, and adherence to legal and ethical obligations by all those who have access to the data.

4.4 Responsibility and accountability

Researchers take responsibility for adhering to the ethical principles in this policy and give due consideration to them in their actions and decisions throughout the research lifecycle, and beyond. Researchers are also accountable for the actions and decisions they make, including promoting ethical conduct and guarding against research misconduct. Thus, researchers should give due consideration to the ethical implications of their research for the researchers, research participants, the wider research community, the environment, and broader society.

4.5 Equality, diversity and inclusion

Researchers consider equality, diversity and inclusion in all of their research activities, and promote a positive inclusive environment, which ensures fairness, challenges prejudice, and celebrates difference.

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It is acknowledged that researchers may also align their work with ethical principles outlined by research funders, and/or professional or disciplinary organisations, and with respect for cultural contexts. In most cases, these additional principles will be complementary to the principles articulated above. Where there is conflict, researchers should reflect on these conflicting demands, and articulate how they propose to proceed, and why they have chosen that course.

5. Procedure for Implementing the University Research Ethics Policy

The implementation of and adherence to the University Research Ethics Policy is the responsibility of all involved in undertaking research.   Appendices 1-3 outline the roles and responsibilities of the University, Staff Researchers, and Student Researchers, respectively. Independent ethical review is an integral element of achieving robust ethical standards, and Research Ethics Committees (RECs) provide this important function.   Appendix 4 outlines the existing organisational structure of RECs in the University of Edinburgh and provides guidance on the operationalising of RECs, accountability and reporting structures, managing multi-institutional projects, and the relationship between ethics and governance.   Appendix 5 outlines the roles and responsibilities of REC members.

The University is committed to supporting a community of learning on research ethics where good practice, learning, and challenges can be shared to optimise research integrity. Further, through regular training, the University will support RECs in exercising their roles and responsibilities to conduct thorough and consistent ethics scrutiny of research. Appendix 6 provides further details on training provision.

6.   Policy History and Review

Approval Date: December 2022

Approved By: University Executive

Year of Next Review: 2025

(A more detailed document control record, showing what text has changed & when it changed, will be held by REIRG.)

Links to relevant webpages listed in the document

Research misconduct

Academic misconduct

Code of student conduct

Annual Research Ethics and Integrity Reports

Institute for Academic Development

Edinburgh Research Office – Research Integrity

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Roles and responsibilities of the University in support of research ethics

As an employer and educator of researchers, the University has a responsibility to maintain a positive research environment that encourages the highest standards of research practice. The provision of adequate structures for governance and research ethics review, as well as training opportunities for both researchers and those involved in operating these structures, is vital in supporting this positive environment.

Colleges, Schools, Institutes and research units have a responsibility to recognise that contributing to ethics review and other support processes is accepted and rewarded institutional work. The preparation of ethics protocols and applications for ethics review by researchers are a fundamental part of the research process and, likewise, are regarded as an essential contribution to the work of the institution.

The University has a responsibility to provide a mechanism for applying for research ethics review that is user-friendly, fit for purpose, proportionate to the risks involved, and facilitates the review process. Where possible, template copies of information sheets, consent forms, invitation letters, recruitment materials and other routinely used documents will be made available to researchers.

The University has a responsibility to recognize and respond to emerging and complex challenges in relation to ethical practices (e.g., trusted research, international partnerships).

Roles and responsibilities of the Researcher in adhering to research ethics standards

Ethics is a cornerstone of research integrity, and the policy and procedures in place aim to support researchers in undertaking high quality research. Researchers have an individual responsibility to ensure that they have an up-to-date working knowledge of relevant ethical issues for their research area, and that they have undertaken all mandatory research training required for their role (e.g., Data Protection Training, Information Security Essentials, Health and Safety), as well as specialist training relevant to their field or methods. Additionally, research leaders and supervisors have a responsibility to support others to work ethically. Supervisors of student research have an ongoing responsibility throughout the research to make students aware of the ethical issues and requirements associated with their research.

Researchers are responsible for ensuring that all of their research activities have undergone active, proportionate and appropriate consideration of ethical issues, risk-benefit balance, and are conducted in accordance with relevant University and national policy/guidelines. Where their research is subject to research ethics review, researchers have a responsibility to engage with the ethical review process in a respectful and conscientious manner.

In applying for research ethics review, researchers are responsible for ensuring they apply in a timely manner in advance of the commencement of any research activities, with complete submissions, which include all appropriate documentation (where required). Researchers should consider if complex projects could instead be considered as individual studies or work-packages for review purposes, to facilitate sufficient scrutiny and manageable and timely review. Researchers are responsible for considering the ongoing ethical issues throughout the lifetime of the project, and (where required) providing Annual Progress Reports, and End of Project reports.

Researchers are encouraged to view the ethics review process as a collegial and constructive process that is conducted with the intention of supporting researchers to adhere to the highest ethical standards. Failure to meet research ethical obligations can

constitute research misconduct, and as such may lead to the implementation of

a research misconduct investigation, following the Research Misconduct [Policy](#).

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Roles and responsibilities of student researchers in adhering to research ethics standards

Students undertaking research as part of their UGT, PGT or PGR studies must also adhere to appropriate ethical principles and procedures, proportionate to the nature and level of their studies. The application of the ethical principles and procedures outlined in this document will be communicated and operationalised at the local level in a way that is proportionate to project risks and context. It is acknowledged that engagement with research ethics also represents a teaching and learning opportunity, and students will be supported and supervised by appropriate staff supervisors (or equivalent) to develop their ethical practice.   For students, failure to meet research ethical obligations may constitute research misconduct. This failure may lead to a referral to the relevant Academic Misconduct Officer and implementation of academic misconduct procedures, and could lead to referral of the case for disciplinary action under the Code of Student Conduct.

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The Research Ethics Review Process and the role of Research Ethics Committees (RECs)

Robust, rigorous and proportionate research ethics review is central to supporting high quality research activity.   At the University of Edinburgh, research ethics review is devolved to School (or equivalent) local research ethics committees (RECs) within the Colleges, which bring subject-specific expertise. Figure 1 illustrates the principal committees within the University with responsibility for the implementation of research ethics reviews. These committees may have a strategic function, or both strategic and review functions.

RECs may also seek more specialist expertise to support robust ethics reviews (e.g., Artificial Intelligence and Data Ethics; Global Research Advisory Groups). Proposals requiring special advisory input will have progressed through the standard ethics processes, and have been deemed by the relevant REC to present sufficiently complex or novel issues to require expert input.

For some research projects, the most appropriate and/or necessary avenue for ethical review will be via other external credible organisations (e.g., NHS ethical review process, as directed by ACCORD).

For low risk UGT and PGT research, ethics review may be cascaded to programme level procedures (see example from School of Philosophy, Psychology and Language Sciences).

The overarching principles informing the functioning of these RECs are independence, competence, facilitation, and transparency and accountability.[4] RECs are responsible for undertaking ethics reviews in a timely manner and providing constructive reviews with the intention of supporting researchers to adhere to the highest ethical standards. RECs will undertake a proportionate level of scrutiny dependent on the risks of the project, balancing duties of care to research participants, the wider research community, the

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[4] UKRIO and ARMA (2020). *Research Ethics Support and Review in Research Organisations.* Accessed from https://ukrio.org/wp-content/uploads/Research-Ethics-Support-and-Review-in-Research-Organisations-UKRIO-ARMA-2020.pdf

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Figure 1: Overview of the committees with responsibility for the implementation of research ethics procedures and reviews at the University of Edinburgh, and current specialist advisory groups (August 2022)
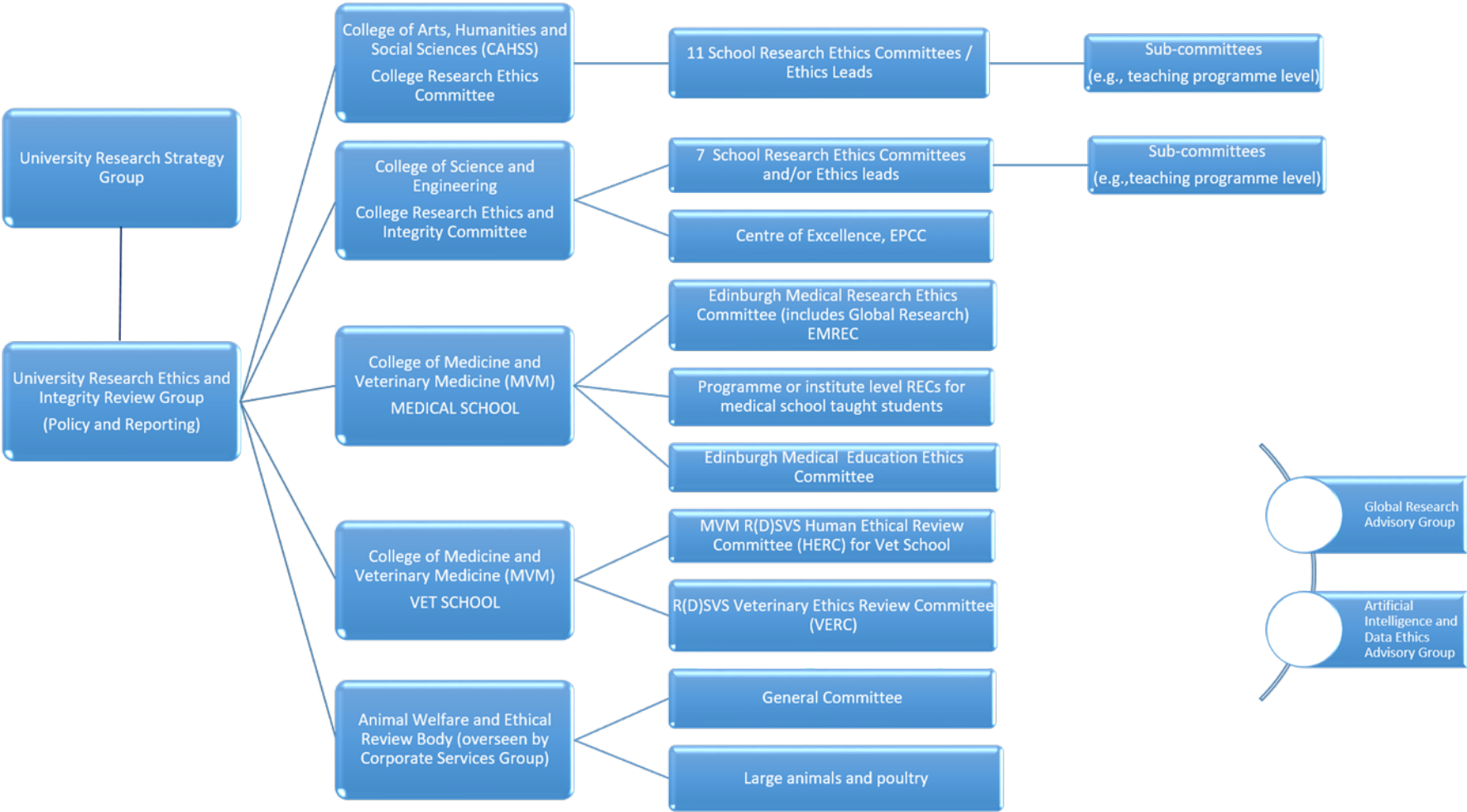
environment, and to society with the goals of enabling and supporting ethical research and innovation for public, economic and societal benefit.

Individual RECs should work towards articulating their terms of reference and make these available to all students and staff whose research falls within the scope of that REC. Terms of reference should specify the purpose and remit of the committee, the membership, responsibilities and expectations of members and designated roles, operating procedures and reporting processes. RECs are encouraged to include a member from outside the local research unit, and, where appropriate, at least one lay member external to the University. REC convenors should monitor membership and ensure an appropriate spread of discipline and methodological expertise to fulfil the remit and purpose of the committee. The EDI representativeness of the REC should be considered in line with local-level governance procedures.

The ethics application process should be transparent, clear, easily accessible, and ask no more detail than is necessary. Where possible, template copies of information sheets, consent forms, invitation letters, recruitment materials and other routinely used documents should be made available to researchers. RECs should maintain records of applications, final approved documentation, and decision letters, with an appropriate retention and disposal schedule.

Accountability, transparency and reporting of RECs

The processes used and decisions reached by RECs must be transparent and accountable through the University's research ethics governance structure. RECs will adhere to the principles and procedures outlined in this policy. RECs will communicate the remit, committee membership and training protocols to all students and staff falling within its scope through an appropriate channel.

RECs will ensure robust record keeping of applications, final approved documentation, and decision letters. On an annual basis, local RECs are required to report summary records of research ethics review and support processes to its College Research Office or College Research Ethics Committee. The Colleges will in turn report to the Research Ethics and Integrity Review

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Group (REIRG) by way of the College Annual Ethics and Integrity Reports. REIRG will review the College Annual reports on behalf of Research Strategy Group (RSG).

The Edinburgh Research Office is responsible for preparing the University's Annual Research Ethics and Integrity Report. The Annual Report provides a broad summary of the policy, processes and initiatives in place across the institution, and within the individual Colleges, for the purposes of supporting and strengthening the understanding and application of research integrity, as well as the promotion of a positive research culture.

The University Annual Ethics and Integrity Report is subject to approval by Research Strategy Group, Risk Management Committee and Audit & Risk Committee. Following approval by Risk Management Committee, and in line with the requirements of the Universities UK Concordat to Support Research Integrity, the University Annual Research Ethics and Integrity Report is published on the [University website](#).

The University's standard policies of insurance extend to the activities of members of Research Ethics Committees acting for and on behalf of the University, whether or not they are employees of the University.

Multi-Institutional Projects

In cases where research involves collaboration with external lead organisations, then the ethical review requirements should be considered by the researcher on a case-by-case basis to determine whether additional University of Edinburgh REC review is required. These considerations should be informed by the need for efficiency in avoiding duplication of effort, the level of University of Edinburgh researcher involvement in the project, and also the credibility of the external partners' review processes in terms of independence, competence, facilitation, and transparency and accountability (as per above), including consideration of potential cultural sensitivities. Researchers should also ensure that they are adhering to any requirements from the sponsor, funder, or any legal stipulations. REC processes may vary between Colleges, Schools, and Units, but it is recommended that University researchers with a substantive role in the research project apply to their local REC with a brief overview of the project, along with a copy of the application to and favourable opinion from the partner

organisation. This minimum requirement may be sufficient, or the local REC may require further scrutiny to safeguard the ethical integrity of the research.

Beyond the ethics reviews undertaken at the University and/or other collaborating organisations, it should be noted that research conducted outside of the UK may require, and/or may benefit from, ethical review in the country it concerns. Researchers should make themselves familiar with such a need where appropriate, including requirements of specific funders.

Ethics and Governance

A favourable opinion following research ethics review is an important but insufficient requirement on its own to enable the research to proceed and meet the highest research integrity standards. Prior to starting the research, researchers must also ensure that institutional approval for all relevant governance procedures are obtained from the appropriate bodies. Such governance procedures may relate to sponsorship (for health- or social-care related research), insurance, health and safety risk assessment, travel risk assessment, study design and management, data management and data protection considerations, verification of funding, and verification of adequate resource availability (e.g., facilities, staff).

The ethics review process provides a forum through which some governance requirements can be signposted.   In some RECs, members may be required to consider if governance requirements have been met (e.g., questions on data protection may be embedded in an ethics application form; data management plans may be attached).

Appendix 5

Roles and responsibilities of REC reviewers
The optimal functioning of RECs relies on the support, time and collegiality of its members. Processes for recruitment to RECs will vary at local levels. RECs may also rely on additional reviewers who are not committee members to support their remit, and the term REC reviewer is

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used inclusively. It is expected that RECs will, through its membership, fulfil the following roles and responsibilities:

a) To receive and review an ethics application in a timely fashion (adhering to locally stipulated timescales) and provide an opinion that is a) favourable of the proposed research; b) conditionally favourable, under certain defined conditions or specific requirements; or c) unfavourable[5].

b) To require the halting of research if there is evidence of substantive ethical concerns, with the research only restarting once those concerns have been fully addressed.

c) To withdraw a favourable opinion when substantive ethical issues are identified, unless these are addressed to the satisfaction of the REC.

d) To review substantive amendments to original project proposals, and provide an ethical opinion (as above).

e) To be constructive and clear in feedback provided to applicants, and provide justification for the ethical opinion given.

f) To review the applications within boundaries of competence considering the broad ethical principles detailed in the University Research Ethics Policy, and other ethical standards specific to the research project.

g) To seek advice from other colleagues when the research, ethical, governance or legal issues extend beyond boundaries of competence. This may require consultation with colleagues in other Schools (or equivalent) or Colleges.

h) To remain independent in the review process and flag any potential conflicts of interests that may compromise this independence.

i) To take up opportunities to engage in appropriate training.

j) To have a good working knowledge of the Research Governance procedures that may be relevant to the application (including, but not exhaustive, need for sponsorship, external approvals, GDPR adherence, health and safety risk assessment, and lawful processing and storage of data).

k) It is not within the remit of the REC to focus or comment on matters of methodology or design unless these raise ethical issues.

[5] The change from 'approval' to 'opinion' is a shift for some RECS, and it is expected that this change will be implemented over time as systems adapt

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l) To act as an advocate for good ethical practices in research and be available for consultation throughout the research process.

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Training and Development of the Research Ethics Community

Training in research ethics and integrity for all researchers is provided through central training opportunities curated by the Institute for Academic Development. Additional training for the ethics community is provided through training at a University, College, School or discipline level, and includes presentations from external speakers, workshops, and use of bespoke resources. Training will draw on current national and international developments in research and will support participants to develop adequate expertise to assist applicants in new and emerging research areas.

Where additional expertise is required to support substantial specialist research activities, the University may facilitate the development of committees to advise on the ethical implementation of these research activities (e.g., Ethics and AI, Global research).

For UGT and PGT students, proportionate and appropriate training in research ethical principles and procedures will be integrated at the programme level.

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