



## 1. Introduction

1.1 The University's Research and Impact Strategy<sup>1</sup> seeks to create a research culture which is open, inclusive, inspiring and ethical and the University Ethics Policy states that 'The University seeks to promote the highest standards of scientific, scholarly and professional integrity and to give due consideration to the ethical, social and environmental issues arising from its activities'<sup>2</sup>. A publicly available policy and framework for ethical review is required to comply effectively with, and should work alongside, the Concordat to Support Research Integrity<sup>3</sup>, the University Ethics Policy and the Code of Good Practice in the Conduct of Research<sup>4</sup>. All researchers working under the auspices of the University of Exeter<sup>5</sup> are expected to comply with the Code of Good Practice in the Conduct of Research and with all applicable laws and professional standards.

1.2 The framework provides consistent standards for the ethical review process across the University. The Framework is complementary to existing funder and professional society guidelines and aims to meet sector-wide best practice and standards.

## 2. Why is ethical review needed?

2.1 The Framework sets out the University's expectations for the ethical review of research. High quality and responsive ethical review will:

- Ensure that the safety, rights, dignity and welfare of all research participants (human and animal) are protected
- Assist researchers to develop well-designed, well-conducted and well-managed research projects which can lead to higher quality findings and outputs
- Protect researchers from the significant consequences of unethical, non-compliant or poorly conducted research
- Maintain public trust in research and in the institution. We recognise that members of the public fund and participate in research and consider the impact of damage to trust and reputation on the ability of the University to deliver this core function
- Comply with the Concordat to Support Research Integrity and provides a visible measure of standards for reporting to UK Research and Impact (UKRI) and other relevant bodies.

2.2 We recognise the professional integrity of researchers, but also the requirement for ongoing development and consideration at all stages of a research career in order to develop a culture of research integrity and ethically reflective researchers. Research ethics are always dynamic and there is a need to continually engage with researchers in meeting complex ethical challenges. It is accepted that researchers (and their supervisors where applicable) are responsible for and well placed to evaluate the ethical issues and the conduct of their research, but researchers must be accountable for the design, management and conduct of their research. Independent ethical scrutiny and review can, and should be of sufficient quality

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<sup>1</sup> Research and Impact Strategy <https://www.exeter.ac.uk/about/vision/about/>

<sup>2</sup> University Ethics Policy <http://www.exeter.ac.uk/cgr/researchethics/codesandpolicies/>

<sup>3</sup> Concordat to Support Research Integrity <https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordat-to-support-research-integrity.pdf>

<sup>4</sup> Code of Good Practice in the Conduct of Research <http://www.exeter.ac.uk/cgr/researchethics/codesandpolicies/>

<sup>5</sup> See 4.5 below

to be, useful in improving the ethical conduct of the proposed research and in ensuring that ethical standards are applied consistently.

2.3 Conducting research in an unethical manner and failure to seek ethical review where it is required could have serious consequences for participant safety, dignity and wellbeing, on public trust, the ability of other researchers to recruit participants for future research and on the reputation of the researcher and University. The failure to seek ethical review where it is required or to abide by the conditions of a review outcome, or situations where the conduct of research could be considered to be a breach of duty of care will be managed under the relevant undergraduate and postgraduate student regulations or research misconduct procedures (see the University's Code of Good Practice in the Conduct of Research<sup>6</sup>).

### 3. Ethical principles

3.1 The University recognises the following commonly accepted ethical principles:

- Autonomy and respect for persons – the participant should normally be fully aware of the purpose of the research, be free to take part without coercion or penalty and be able to withdraw at any time without giving a reason and without the threat of any adverse effect. Researchers must give careful consideration to the principle of justice in the participant groups that they are recruiting to ensure that they are not being selected for the ease of the researcher rather than for the reasons directly related to the research question, to ensure that access to potential benefits is equitable and to the recruitment of participants who may be in a potentially vulnerable situation.
- Beneficence – the research must be worthwhile in itself and have potential beneficial effects (directly for the participant or for the public good) that outweigh any risks; the potential benefits must be maximised and the methodology must be sound so that best results will be yielded.
- Non-maleficence – any possible harm must be avoided or mitigated by robust precautions. This may be particularly important if the research involves the use of animals or the participant group could be considered to be in a potentially vulnerable situation because of their location, economic, social or health status. Consideration must be given to ensuring that the burden of taking part in the research does not fall disproportionately on those who are unlikely to benefit from the results.
- Confidentiality – participant personal data should normally remain unknown to all but the research team; it must be collected, stored and destroyed appropriately. Limits to anonymity and confidentiality, for example when disclosure of risk of harm is required, must be clear and transparent to everyone involved in the research.
- Integrity – the researcher must be open about any actual or potential conflicts of interest and must conduct their research in a way that meets recognised standards of rigour, research integrity and good stewardship. The University of Exeter encourages anyone who witnesses research misconduct or poor research practice, or who experiences or witnesses discrimination, harassment or bullying to report their concerns<sup>7</sup>.

3.2 In some exceptional circumstances, researchers may wish to override these principles, for example, where a participant wishes their voice to be heard and identified, where covert research or deception would be justifiable or where there is an overriding public interest. Researchers must provide justification for this approach and approval from an appropriate Research Ethics Committee (REC) must always be given.

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<sup>6</sup> <http://www.exeter.ac.uk/cgr/researchethics/integrity/>

<sup>7</sup> <http://www.exeter.ac.uk/cgr/researchethics/codesandpolicies/> and <http://www.exeter.ac.uk/speakout/>

3.3 The University recognises and promotes the principles of the 3R's (reduction, replacement and refinement) in research involving the use of animals. Researchers carrying out any research involving the use of animals are expected to thoroughly consider the 3Rs in the design and conduct of their research, and to robustly justify the use of animals during the ethical review process.

3.4 Researchers are also expected to give consideration to the environmental, social, political, religious or economic consequences of any research undertaken, as well as legal or professional obligations and any potential reputational risks to researchers, department, Faculty or University. RECs are not always required to specifically review these aspects of research (see 4.2 below), although it is expected that committee members, ethics officers and reviewers will be able to discuss possible implications or concerns with researchers and direct them towards appropriate sources of advice and guidance. The University's Due Diligence Policy and associated processes will also be used to identify potential risks.

3.5 Researchers, and supervisors where relevant, are expected to properly consider their own safety and that of research teams. University RECs are not required to review health and safety risks or risk assessments (for example on travel, laboratory procedures or fieldwork) and cannot approve travel arrangements or give approval for research projects to start, but members are expected to raise any concerns about the safety of researchers as quickly as possible to the relevant Head of Department or Department Health & Safety Committee. Researchers must be aware of the University's Safeguarding Framework<sup>8</sup> and ensure that appropriate reporting processes are in place as relevant.

3.6 Patient and public involvement in all stages of the research process, including the co-creation of research, is strongly encouraged. Good practice in PPI is promoted by RECs and the review process will consider the level of public involvement in all stages of the project lifecycle.

#### 4. When should a research<sup>9</sup> project be reviewed?

4.1 For the purposes of the Research Ethics Framework, research that requires ethical review is defined as an attempt to generate generalizable or transferable new knowledge or practice to answer or refine questions using sound methodology. This definition includes observation of or interaction with participants in their real-life environment and attempts to obtain generalizable or transferable knowledge by using methods to obtain findings that could be shared with the scholarly community and/or applied in settings or contexts other than those in which they were tested or gathered, even where the actual generalizability or transferability of findings is not clear at the start of the work.

4.2 **All** research involving the following **must** be ethically reviewed **and receive a favourable opinion before work commences**:

- Humans (either living or deceased), including
  - research participants
  - their data or information, including secondary data analysis and material held in archives or private collections (see 4.3.2 and Appendix C)
  - their tissue, *and/or*
- animals (living vertebrates and invertebrates), *and/or*
- significant *and/or* long-lasting adverse impacts on ecology or hydrology or that may cause disruption to environmentally sensitive sites, *and/or*
- the potential for any materially negative impact on local communities

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<sup>8</sup> <https://www.exeter.ac.uk/cgr/safeguarding/>

<sup>9</sup> The University of Exeter recognises the Frascati definition of research <http://www.oecd.org/sti/inno/frascati-manual.htm>

Exemptions to this requirement are given in 4.3. Failure to seek ethical review or to abide by outcome decisions will be treated seriously and may be considered to be research misconduct, see 2.3 above.

### 4.3 Exemptions from ethical review

4.3.1 The definition of research does not include routine audit, service evaluation, quality assurance studies, performance review and literary or artistic criticism which does not engage directly with the individuals or groups making or receiving the work<sup>10</sup>. These types of activity do not require ethical review, but researchers may choose to seek review if they consider that there are significant ethical implications, or where a Research Ethics Committee requires it.

4.3.2 Research involving the deceased where the data is obtained from literature, library or archival materials which have been formally deposited and curated for public access and display, or research involving human remains or artefacts from ancient sites (evidenced to be more than 100 years old) are exempt from the review process. Care should be taken to follow all relevant professional standards, legal and ethical requirements. Researchers must respect the environment that they are working in, cultural artefacts and remains. In cases where the requirement for review is unclear, researchers should seek advice from their local Ethics Officer. See also Appendix C, Risk and Proportionate Review Checklist.

4.3.3 The activities of project advisory groups, steering committees, artistic practice or similar will not usually require research ethics review. Activities involving public and patient involvement (including a member of the public acting as part of the research team) or to demonstrate impact will not usually require ethical review, unless the research topic is about public engagement or co-creation of research, any data is being collected and processed during the activity which will form part of a research output or publication and/or the activity falls into the definition given in 4.1 and 4.2 above. Researchers are expected to follow good practice standards and ethical principles when carrying out public engagement or impact activities that do not require ethical review, and to meet all professional obligations.

4.3.4 Use of animal or human tissue (or material derived from human or animal tissue e.g. cell lines) obtained commercially or via material transfer agreement from sources outside the University will not normally require ethical review. Where the requirement for review is unclear, researchers should seek advice from the Research Ethics and Governance (RE&G) Office.

4.4 The Research Ethics Framework **applies to all researchers working under the auspices of the University of Exeter**. The definition of researcher includes those employed by the University, undergraduate and postgraduate students undertaking research activities as described in 4.1 (either as part of their degree programme or through schemes such as ‘students as change agents’, ‘students as partners’ or education incubator projects), those with honorary or associate contracts or those commissioned to undertake research for the University. This requirement for ethical review applies to all research projects, funded or unfunded, contract research and University consultancy<sup>11</sup> where they fall into the definition of research given in 4.1 above. Activities where the primary purpose is the education of students or staff will not normally require ethical review unless they fall into the definition of research given in 4.1.

## 5. Structures for ethical review

5.1 In order to ensure that research ethics review remains useful and sustainable, a balance must be achieved between managing the volume of applications and providing competent, proportionate and responsive review. Based on the distribution of applications, research fields where ethical implications are

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<sup>10</sup> Decision tools such as the following from the Health Research Authority may be helpful: <http://www.hra-decisiontools.org.uk/research/>.

<sup>11</sup> Consultancy work must be carried out within University guidelines and private consultancy is strongly discouraged <http://www.exeter.ac.uk/research/toolkit/collaborating/industry/consultancy/>

likely to arise and groupings of reviewers with relevant expertise, the structure of RECs in the University is Faculty based, with review delegated to sub-grouped department level committees as described in the approved Standard Operating Procedures (see section 7). Outline roles and responsibilities are given below.

#### **Faculty RECs:**

- Implementation of the [Research Ethics Framework](#) within Faculty (through sub-committees for groups of departments)
  - ensuring sufficient reviewers and resource for timely and competent review
  - appointment of sub-committee Chairs
  - approval of sub-committee Terms of Reference and membership
- Approval of sub-committee Standard Operating Procedures (SOP) and associated guidance for applicants, supervisors and reviewers
- Monitor and oversee departmental review processes
- Consider issues escalated from REC sub-committees within Faculty
- Review high-risk projects escalated by sub-committees
- Adverse event and complaint management
- Annual reports to Research & Impact Executive Committee

#### **Sub-grouped departmental RECs:**

- Develop SOPs, discipline/department specific training and guidance - for applicants, supervisors and local induction for reviewers
- Research ethics review for all staff, student and associate researcher projects according to approved SOPs – may be online or in meeting according to risk profile
- Escalate high-risk reviews issues where decision cannot be reached, adverse events and complaints to Faculty REC
- Provide information to Faculty REC for annual reporting

Researchers should apply for ethical review based on their home department. This structure will be modelled within the online application system in order to ensure that applications are filtered to the relevant REC. Applications can be referred to another committee (other REC or Animal Welfare and Ethical Review Board) which may have specialist expertise in a particular topic (e.g. administration of a substance or involving fieldwork in a potentially high-risk environment). Alternatively, members of other CRECs with relevant expertise can be co-opted for specific reviews. These exchanges will be facilitated by the Research Ethics and Governance team if required. Sharing of best practice, for example by REC members attending other committee meetings as observers, is to be encouraged.

5.2 The roles of individuals involved in ethical review should be consistent across committees and be given appropriate recognition – roles include the REC Chair, REC members, Reviewers and discipline Ethics Officers. One individual may hold multiple roles, for example, a discipline Ethics Officer may review applications using the online application system and may also be a full member of a Research Ethics Committee. Roles should be allocated according to REC membership requirements (as described in appendix A) and as appropriate for the remit of the committee. Role descriptions can be found in appendices D and E. Suggested methodology for workload allocation is given in appendix F.

5.3 In-depth dual-review should be avoided where possible (for example, where projects require ethical review by a recognised research ethics committee such as an NHS REC), although the researcher is expected to provide evidence of the review and its outcome to the relevant REC who, in turn, are expected to log the decision and ensure that recognised ethical standards are met. The researcher must also ensure that evidence of the ethical review and its outcome is maintained within their own records, and amendments sought where appropriate.

5.4 Where research is being conducted by staff or students in more than one Faculty in the University, the research should be ethically reviewed by the most relevant committee, taking into account the theme and

methodology of the research, the location of the Principal Investigator and the expertise of the ethics committees.

5.5 Where research is being conducted by staff or students from the University of Exeter in collaboration with researchers from another institution, the research should be reviewed by the relevant research ethics committee at Exeter, although the committee can take reviews carried out by other Institutions into account, particularly if the Principal Investigator is from another Institution.

5.6 Where research is carried out outside the UK, researchers are expected to make best attempts to identify and seek local ethical approval from a properly constituted and independent ethics committee where possible and to comply with local ethical and regulatory standards. The RE&G office may be able to assist with identifying local requirements and have some guidance available on their webpage. Local ethical approval must be shared with the relevant REC at the University of Exeter (as in 5.3 above) to ensure that all relevant factors have been considered and researchers must provide evidence to the University REC that all necessary local approvals have been obtained. If local review is not available or appropriate, then such research must be reviewed by a relevant University of Exeter REC. Whilst all researchers must adhere to the University of Exeter's standards and principles, researchers and REC members should take local context, cultural practices and expectations into account when designing and reviewing research. Some flexibility in, for example, the approach to informed consent may be required and should be explained in the ethics application. Potential conflicts between University of Exeter standards and expectations and those in the research location must be highlighted by the researcher and considered by the REC.

5.7 Research and teaching involving the use of animals will be reviewed by the University's Animal Welfare and Ethical Review Board (AWERB) where it is regulated under the Animals (Scientific Procedures) Act 1986 and according to the related Animals in Teaching Policy<sup>12</sup>. AWERB will provide guidance on the review of non-regulated animal research for Faculty-based Research Ethics Committees, set policy and maintain oversight of non-regulated work where required. The Research Ethics and Governance team should be contacted in circumstances where it is unclear whether the research is regulated and researchers should refer to the AWERB's Policy on Research outside the UK<sup>13</sup>.

5.8 Research in some disciplines and emerging fields raise a wide range of ethical questions about the process and purpose of research. The University may convene specialist advisory groups or research ethics committees in order to give the appropriate in-depth scrutiny of proposals, to provide guidance and a forum for researchers to discuss the implications of their work, whilst maintaining confidentiality and security as required. Appendix H provides information on potential groups, their outline principles and Terms of Reference.

## **6. Operating principles for ethical review**

6.1 The aims of a research ethics committee are to facilitate research and maintain the highest ethical standards in research practice, protect the safety, dignity, welfare and wellbeing of research participants, to protect researchers from harm or unjustified criticism and to take account of legitimate interests of individuals, groups and communities and to provide reassurance to the public. The REC can consider research on behalf of the institution and provide an ethical opinion on the research – this can be used as part of the Institution's governance of research, but the REC cannot give overall 'approval' for research to take place.

6.2 The following principles should underlie ethical review arrangements, although it is recognised that they may be addressed differently according to need. Actions that should be taken to meet these principles

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<sup>12</sup> Link to be provided

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are given below. The Framework and REC Standard Operating Procedures (see section 7 below) set out how these actions are delivered at the University of Exeter.

- **Independence** – mitigating conflicts of interest and ensuring sufficient impartial scrutiny
  - Reviewers from an appropriate range of disciplines or research fields
  - Inclusion of lay or independent members with no other affiliation to the University
  - Establishing terms of reference which guarantee each REC the ability to make ethics judgements
  - Evidence of process to recognise and address potential conflicts of interest in the review process
  - Consistent standards set by an overarching committee, providing a means to manage appeals against REC decisions and to monitor performance
  
- **Competence** – ensuring that membership of committees/selection of reviewers informed by relevant expertise and that decision making is consistent, coherent and well-informed
  - Ensuring that membership contains a range of expertise across the range of research to be reviewed
  - Standard Operating Procedures in place that are regularly reviewed
  - Recognition that contributing to ethics review is accepted institutional work
  - Structuring committees to ensure that reviewers regularly consider applications and attend meetings; balancing volumes of applications so that each committee considers a sustainable number
  - Application system that provides all the information needed to make a sound and competent decision
  - Evidence of appropriate time, support and training for REC members and a sustainable commitment to competent ethical review
  - Drawing on and sharing national and international best practice
  
- **Facilitation** – recognising the role of RECs in facilitating good research and support for researchers; ethical review processes recognised as valuable by researchers
  - Administering the review process efficiently and effectively within agreed timescales, balancing detail and the burden of completing applications for ethical review
  - Balancing duties of care with enabling of research and innovation
  - Review process that recognises different levels of risk and handles them efficiently and proportionately
  - Appropriate process in place to manage expectations, concerns or difficulties at an early stage
  - Providing training for researchers at all stages of their careers in ethical issues and the review process, seeking to develop ethical decision-making skills
  - Providing opportunities for researchers to seek informal advice on ethics and integrity issues
  
- **Transparency and Accountability** – REC decisions and advice to be open to scrutiny, with responsibilities discharged consistently
  - Making a clear statement of institutional policies and processes easily and publicly available, including REC Standard Operating Procedures
  - Deliberations and decisions clearly recorded and available for scrutiny, while protecting sensitive data. This means that applicants will be provided with collated feedback on the final committee decision and individual feedback from reviewers will not routinely be made available to applicants. Information on committee deliberations and decisions may be made public (with suitable redaction) and identifiable personal or commercially sensitive data will be protected within the limits of the UK (GDPR) Data Protection Act 2018, Freedom of Information and Subject Access Request conditions.
  - Clear process for escalation of complaints/concerns

- Compliance with annual reporting process
- Open discussion between committee members and with the Faculty Ethics Committee on broader ethical issues, concerns or complaints
- Ensuring that there is a named officer of the institution who is the primary contact for research ethics and integrity matters

## 7. Procedures for ethical review

7.1 Each committee is expected to develop Terms of Reference, membership and a Standard Operating Procedure (SOP) in accordance with the Framework and using the templates provided. Templates can be found in Appendices A and B and indicate where variance is acceptable. Standard Operating Procedures (and changes to them) must be approved by the Faculty Ethics Committee before they can be implemented and they must be reviewed and re-approved by the Faculty Ethics Committee every two years.

Terms of Reference, Membership and Standard Operating Procedure documents must include information on the following:

- Membership of the REC must include guidance on the length of terms for the Chair and members.
- The application process and the provision of guidelines for researchers on completing applications using the provided online system
- Instructions on the use of University template participant information sheets and consent forms. It is expected that the templates will be used when written information is provided to participants, unless the ethics application includes a justification for not using or varying them. Research Ethics Committees will encourage and be open to alternative methods of providing information to participants (such as audio or video) where relevant.
- Description of documents which applicants must submit (as relevant) for review. This must include all participant-facing documents, recruitment materials, questionnaires, surveys and topic guides for semi-structured or open-ended interviews.
- Description of review processes which recognise differing risk levels
- Schedule of committee meetings or online review (as appropriate), including normal timelines
- Definition of opinions that could be given following review and implications of those opinions for researchers. This includes clear definitions of approved start and end dates for the active phase of the project and for longer-term retention of data and samples.
- Process for review of amended research proposals, including normal timelines
- Training and guidance provided for researchers, supervisors and committee members
- Provision of advice for grant applications
- Audit procedures
- Process for reporting adverse events, managing complaints from participants and safety measures
- End of project reporting
- Appeals and complaints procedures available to researchers, supervisors and participants

**7.2 Proportionate or expedited review** – RECs will adopt a risk adapted approach based on the checklist given in Appendix C and built in to the online application system and this will be implemented as described in their Standard Operating Procedure. The review of applications, regardless of risk, will always be managed through the online application system to ensure consistent record keeping.

It is recommended that applications identified as potentially higher risk should be reviewed by a full committee in a meeting to ensure that a robust review takes place and a comprehensive opinion is given. All applications considered to be medium risk and reviewed under a proportionate review process must be considered by at least two reviewers (this may be by a trained project supervisor and ethics committee member or by two committee members) - review by one individual is not sufficient.



Projects considered to be low risk can also be reviewed under the proportionate review process and may be lighter touch with final approval given by the REC Chair or delegate under a documented process.

**7.3 Student project review** – activities will be excluded from the requirement for review if the primary purpose is for education of the student and they do not fall into the definition given in 4.1 above (for example, classroom exercises, artistic practice or laboratory practicals). If the activity does require ethical review, the individual student, pair or student group can make an application to the relevant REC.

In some circumstances and if agreed with the REC in advance, a module convenor (e.g. for a dissertation module) can prepare an ethics application for sets of student projects within given parameters. The review will take place based on the risk factors as described above. A review can be requested for a period of up to five years with amendments requested if module parameters or participant-facing documents change within that time period. At the end of this time, or where there is a significant change to the structure of a module or programme, a new application for ethical review must be made. Module convenors must ensure that the record keeping procedures described in the REC Standard Operating Procedure are followed and these records may be subject to audit. On an annual basis, students will be provided with ethics training and will sign a declaration to confirm that work will be carried out within pre-approved parameters. Student projects should normally use the University information sheet and consent form templates (unless alternative formats are more appropriate for the participant groups or research question), adapted by the module convenor as relevant for the pre-agreed parameters. Where students wish to carry out research outside the given parameters, they should seek separate ethical review from the relevant committee and will need to justify their proposals; such applications should only be considered necessary in exceptional circumstances.

**7.4 Amendments** – researchers must seek an amendment to their ethical review if changes are made to any information provided to participants, the design, conduct, data management or dissemination of research project. Overarching applications for similar or long-term programmes of work, with amendment requests to be made in the case of changes are encouraged. Substantial amendments are defined as a change to the study design, methodology and/or to the participant pathway or experience. Minor amendments are considered to be those which do not have an impact on the study design or conduct, for example, points of clarification on participant-facing documents. The processes for review of minor and substantial amendments are given in each REC Standard Operating Procedure.

**7.5 Appeals and complaints** complaints and appeals about the ethical review process will be managed at Faculty level as described in the SOP. Faculties may refer matters to the Research Ethics and Governance team for assistance as required.

The University will not consider appeals against the decisions of external ethics committees which should provide their own appeals procedures. Broader ethical issues can be referred by Faculties to the RE&G team and, as necessary, to the Research & Impact Executive Committee (RIEC) for advice and guidance, for example, on a controversial issue or where a common University approach would be desirable. Where RECs consider that research raises a potential reputational risk (for example, because of the funding source), it should be referred to the Research Ethics and Governance Manager (or delegate) who will ensure that the risk is appropriately considered in accordance with the Due Diligence or Conflict of Interest policies.

**7.6 Complaints from research participants, adverse event reporting and safety measures** – complaints from research participants and adverse events must be managed and reported quickly, as described in the SOP and associated documents. REC members receiving complaints from participants or reports of adverse events must report these as soon as practicably possible according to the SOP. .

**7.7 Audit** – The SOP for each committee will give details of the frequency and type of audit to be carried out. It is expected that a random selection of projects will be audited as well as more targeted review primarily focusing on the highest risk projects identified during the review process. Audits will aim to ensure that consent forms are completed correctly, that record keeping meets appropriate standards and that data is being stored correctly. Audit may also be triggered as a result of a complaint or concern. Standard

templates for audit reports and 'Corrective and Preventative Actions' will be used by the RE&G team. If concerns are identified during an audit or monitoring visit, it will be managed through the corrective and preventative action, complaints, adverse events or research misconduct processes, as deemed most appropriate in the circumstances.

All researchers who have applied for ethical review will be asked to provide a short report for the REC at the end of the data collection phase of their project as one of the conditions of review, unless report of the research practice and outcomes are already being considered through University assessment procedures (e.g. BA/BSc, MA/MSc and PhD degrees). This will fulfil the audit requirement for the majority of projects. Some audit of REC decision making and record-keeping may be carried out by the RE&G office on behalf of the Faculty Ethics Committee.

**7.7 Record keeping** – RECs will be expected to keep records relating to the ethical review process using the provided online system. Researchers are expected to keep records relating to their own research and ethics applications in order to, for example, provide evidence of ethical review to publishers and to ensure that all members of a research team are aware of the ethical review. Records relating to ethical review should be retained for 6 years after the project has ended, or as required by the funder or legal agreement. Guidance provided in the University's retention schedule should be followed.

**7.8 Reporting mechanisms** – Each Faculty is responsible for making an annual report to RIEC using the template provided.

## **8. Training and guidance**

8.1 Training requirements are outlined in appendices G, H and I; this sets out what should be provided as a minimum although it is recognised that the delivery of the training will vary between departments.

The RE&G team are responsible for providing materials that can be used by those providing training in departments but can also provide training sessions directly subject to availability. The RE&G team are also responsible for providing training for ethics committee members on at least an annual basis and publicising opportunities for training and Continuing Professional Development events outside the institution. REC Chairs are responsible for ensuring that new committee members, including lay/independent members, have suitable induction and support during first year of membership. Heads of Department are responsible for ensuring that appropriate training is undertaken by all staff and PGR researchers in their department, and that time is made available to members of research ethics committees for continuing development. The Director of Education is responsible for ensuring that relevant training is provided to students within the department's programmes, drawing on centrally provided resources where needed.

8.2 Guidance for researchers on ethical review processes and ethical implications will be available on the research integrity website and accessible from committee intranet sites. New guidance on emerging topics will be provided by the RE&G team locally produced by RECs and shared between committee members. Committee members and reviewers are encouraged to highlight topics which would benefit from University-wide guidance.

## **9. Systems and support**

9.1 The RE&G team will be responsible for providing appropriate systems and ongoing support for committees as required by RIEC. This may include the provision of first line triage of applications alongside

controls built into the online application system (e.g. mandatory fields, filtering, document templates and upload) to ensure that applications received by reviewers and committees are complete and ready for review.

9.2 All committees must use the online system provided to improve to ensure consistent record keeping and response times..

## 10. Further requirements

10.1 Exclusion criteria - it is recommended, for example by the Parliamentary Committee on Women in Science, that researchers should consider the gender implications and dimensions of their research. Ethics Committees can contribute to this by asking researchers to consider this aspect in their ethical review applications and to justify their selection of participants where exclusion criteria based on e.g. gender, age, ethnicity or other protected characteristics are imposed. The use of exclusion criteria based on protected characteristics defined in the Equality Act 2010 are considered to require a high-risk review.

10.2 Good data management practice and data protection compliance is critical for ethical conduct of research. Researchers must complete the mandatory Information Governance training and are strongly encouraged to complete a data management plan even where this is not required by a research funder. A Data Protection Impact Assessment (DPIA) should be completed and maintained for projects involving the processing of personal data; this is especially critical for researchers processing sensitive personal data. Researchers using DMPOnline can complete University of Exeter-adapted data management plan templates which include DPIA questions<sup>14</sup> although a full DPIA may be required in some circumstances<sup>15</sup>. RECs are expected to promote good practice in research data management by signposting researchers to sources of guidance and support, and by strongly encouraging the use of data management plans and DPIAs which may also be used as part of the ethical review process.

10.3 The use of third parties (e.g. market research organisations or transcribers) to carry out data processing or other research activities must be supported by a legally-binding contract, signed by a recognised signatory in the University Legal Services team. The contract must specify the standards and processes for the research activities and any arrangements for data sharing and responsibilities for compliance with current data protection legislation.

## 11 Appendices

Appendix A – Model Terms of Reference and membership for ethics committees

Appendix B – Template Standard Operating Procedure for ethics committees

Appendix C – Risk and Proportionate Review Checklist

Appendix D - Role Descriptions for ethics committee chairs, members, reviewers and discipline ethics officers

Appendix E – Role description and requirements for lay/independent members of ethics committees

Appendix F – Workload allocation

Appendix G – Training requirements for University of Exeter staff, students and affiliates as applicants; for supervisors; for ethics committee chairs, members, reviewers and discipline ethics officers

Appendix H – Specialist Groups

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<sup>14</sup> <http://www.exeter.ac.uk/research/researchdatamanagement/about/rdm/>

<sup>15</sup> <https://www.exeter.ac.uk/ig/>

## **12 Related University of Exeter policies (found on the University's website)**

- University Ethics Policy
- Code of Good Practice in the Conduct of Research
- Access to Restricted Materials
- The Use of Animals in Research
- Research Involving Animals outside the UK
- Use of Animals in Teaching and Training
- Conflict of Interest Policy
- Due Diligence Policy
- Clinical Trials Transparency Policy
- Safeguarding Framework

## **13 University of Exeter guidance (found on the University's Research Ethics and Governance website)**

- Template Participant Information Sheet and Consent Forms
- GDPR for Researchers
- Guidance on the disclosure of illegal activity
- Guidance on online research and transcription
- Guidance on the use of Freedom of Information requests as a research tool
- Health and Social Care Research/Clinical Trials
- Human Tissue Act
- Export Control
- Nagoya Protocol
- Import/Export of materials (including CITES)
- Licensing for animal research

Relevant external guidance and suggestions for further reading will be provided in the 'useful links' section of the Research Ethics and Governance website, each REC Standard Operating Procedure and on REC intranet/ELE sites.

G Seymour

Updated 11<sup>th</sup> November 2022 to reflect University structure change

The following sources are gratefully acknowledged:

Association for Research Ethics (AfRE) Research Ethics Framework (2013)

UKRIO/ARMA Research Ethics Framework (2020)

ESRC Framework for Research Ethics

Health Research Authority guidance