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| **Standard Operating Procedure****For****Research Ethics Review**  |
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SOPs should be written with regard to the University of Exeter Research Ethics Framework and appendices (currently v1.1 7th May 2021)

Guidance notes on content are given in blue and should be removed from the published document.

Text in black should be retained in the document but additional text may be added to give local guidance or information on additional procedures.

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## **Abbreviations:**

REC – Research Ethics Committee

RE&G – Research Ethics and Governance office/team

*(Others as required)*

## **Definitions:**

*(This should include a description/organogram of the REC structure within the College/Department and of the relevant roles, as well as any new terms used later in the document)*

1. **Scope:**

The Standard Operating Procedure for Research Ethics Review describes the process for ethical review as it is conducted in [College/Department]. It applies to and should be read by **all staff, students and associates carrying out research under the auspices of [College/Department] at the University of Exeter**.

The Standard Operating Procedure will be reviewed at least every two years and must be approved by the relevant College Executive Group and the University Ethics Committee.

## **Purpose and Background:**

The University of Exeter has a Research Ethics Framework which sets out the expectations for ethical review at the University and aims to provide consistent standards. The University recognises that researchers (and their supervisors where applicable) are responsible for and best placed to evaluate the ethical issues and the conduct of their research, but researchers should be accountable for the design, management and conduct of their research. Independent ethical scrutiny and review can, and should be of sufficient quality to be, useful in improving the ethical conduct of the proposed research and in ensuring that ethical standards are applied consistently. High quality and responsive ethical review will:

* Ensure that the safety, rights, dignity and welfare of all research participants 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 UKRI and other relevant bodies

## **General guidance:**

*(To be completed by each REC to reflect their own processes – the SOP must include the following sections as a minimum)*

1. The application process and the provision of guidelines for researchers on completing applications using the provided online system and associated documents which must be provided for review *(link to relevant central and REC specific guidance)*
2. Instructions on the use of University template participant information sheets and consent forms. (*It is expected that the University templates (or approved local versions adapted by Research Ethics Committees) 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.)*
3. Description of review processes which recognise differing risk levels based on Research Ethics Framework Appendix C risk categories
4. Schedule of committee meetings or online review (as appropriate), including normal timelines
5. 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.)*
6. Process for review of amended research proposals, including normal timelines
7. Training and guidance provided for researchers, supervisors and committee members
8. Provision of advice for grant applications
9. Record keeping
	* Record keeping by RECs – applications, records of review and decisions
	* REC expectations of researchers on record keeping relating to research ethics review

Records relating to review (applications, correspondence, review and decisions) will be kept for at least 6 years after the completion of the project or for as long as required by the project funder (where relevant).

Researchers should specify their retention periods in the ethics application and in their Data Management Plan.

1. Audit and monitoring procedures, including end of project reporting

Selected research projects and REC review processes will be audited each year by the Research Ethics and Governance team. The research project audit process aims 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. Annual (selected) audits of REC decision making and record-keeping will be carried out by on behalf of the University Ethics Committee.

RECs may identify projects during the review process as requiring additional mid-term reporting or audit. Where this is required, this will be noted as a condition of the favourable opinion and the PI notified.

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.

1. Process for reporting adverse events, appeals and complaints

All staff, students and associates carrying out research under the auspices of the University of Exeter and all REC members are expected to report any complaints and adverse events or incidents that they become aware of. The report must be made to the University’s Research Ethics and Governance Manager (or nominated delegate during their absence) within 24 hours of occurrence or receipt via g.m.seymour@exeter.ac.uk, 01392 726621 or 07974 206250.

Template report forms may be used to make the initial report if wished. The Research Ethics and Governance Manager will follow the University’s Research Governance SOPs on complaints and may request further information, including corrective and preventative measures taken. Depending on the nature of the complaint or adverse events, immediate measures (such as the suspension of the study) may need to be taken to protect the safety, dignity and wellbeing of participants or staff.

## Reference Documents:

1. University of Exeter Research Ethics Framework and appendices
2. University of Exeter Code of Good Practice in the Conduct of Research
3. University of Exeter Research Governance SOPs on complaints; associated report form templates

## Related Documents – suggested reading:

1. UKRIO/ARMA Research Ethics Support and Review in Organisations
2. Concordat to Support Research Integrity
3. …any relevant professional society and funder guidelines e.g. BPS, ESRC, BERA…