UREC-SOP-002 Guidance for Reviewers

Please also refer to the Indicative Checklist for reviewers

1. Background

This Standard Operating Procedure (SOP) is to provide the University's ethics review bodies and researchers with a guide to parameters for ethics review of research and knowledge exchange activity, where it is within the University's remit to provide this.

The University has a set of **principles** developed in line with national and international guidance around research ethics review, including but not limited to ESRC's *Research Ethics Guidance*. These principles are contained within the University's *Research and Knowledge Exchange Ethics Policy* and *Research Ethics Guidance.*

This SOP also contains an indicative *checklist for reviewers*, to understand further the parameters they work within and to undertake to use these parameters when carrying out an ethics review. The checklist is based on the *Research Ethics Support and Review in Research Organisations (UKRIO/ARMA, 2020).*

The University follows the *Belmont principles* for research ethics, referred to in the UKRIO/ARMA guidance.

Although the very nature of research ethics review (diversity, multi-disciplinary, lay and experts, all with adequate and up-to-date training in ethics review) means that two different ethics review bodies, even within the same institution/following the same frameworks, may not always have exactly the same opinions on the ethical soundness of a research proposal. Nonetheless, the ethics review bodies must be consistent in their approach to review, and the principles they use and follow:

"*If a perception exists that standards of ethics review are variable or inconsistent, then this raises doubt about the whole edifice of ethics review. Without comparability, decisions reached can be perceived as arbitrary, based on differing assumptions or, worse, open to undue influence. Research participants, funders and the public need to be assured that ethics review standards are consistent. Variability is not helpful in achieving this. The same standards apply for a large complex organisation and to a small single discipline college, to work done by undergraduate students and to multi-partner international collaborations by staff… Research ethics committees must, however, operate within established standards for review to ensure that research is conducted ethically and that review determining whether research is ethical or not is based on decision making that is reached consistently and with accountability and transparently.*" *Research Ethics Support and Review in Research Organisations* (UKRIO/ARMA, 2020)

1. Scope and Purpose

This SOP is designed to ensure consistency in ethics review standards at the University, ease of use by reviewers to keep a track of a review, and to act as a starting point and prompt for reviewers. It is designed to protect participants and researchers and to facilitate and support research.

The *checklist* does not describe what should be provided in detail, merely what the reviewers are looking for, as to do otherwise would not be possible for each and every proposal.

The *checklist* is not exhaustive, and nor does every point relate to all proposals, but it should be considered where it is appropriate, by using the **principles** below.

This *checklist* is suitable for all systems of review, and reviewers should refer to the **UREC-SOP-003 Criteria and Systems for Review**, as all University systems for review must follow the same standards as review by a Full Committee.

This SOP provides transparency to researchers around the parameters for review at the University and help them prepare their proposals for ethics review (or self-assessment).

It should be noted, that whilst formal ethics review is a core function of an ethics review body, *"this should be part of, and integrated with, a broader institutional set of related functions. These might include research training, integrity policies and governance processes that provide guidance and support throughout the research cycle, from conception to dissemination and application."* *Research Ethics Support and Review in Research Organisations (UKRIO/ARMA, 2020).*

2. Process

Reviewers must refer to the:
UREC-SOP-003 Criteria and Systems for Review and **Introduction to Research Ethics Blackboard Module.**

2.1. Reviewers must use the principles below as the basis for all ethics reviews:

1. **Respect for persons** (and animals, environment, objects and sites of cultural or historical significance) and their autonomy (or integrity/protection)
2. **Beneficence** (doing and promoting good)
3. **Non-maleficence** (doing no harm)
4. Distributive **justice** (ensuring benefits and burdens are shared equitably)

2.2. An example of how these principles should be applied:

BENEFICIENCE **NON-MALEFICENCE**

AUTONOMY **JUSTICE**

- Is there a description, unambiguous research question, and purpose?
- Is the study built on what is known already?
- Will the study provide meaningful answers to the research question?
- Will the study provide valid answers to the research question?
- Are participants recruited with justifiable inclusion and exclusion criteria?
- Does the research team have the experience, skills, facilities and time to complete the study?
- Is there a fair balance of benefits and harms (risks) for all with an interest in the study?
- Will participants receive appropriate care both during and after the study?
- Is personal data handled appropriately (confidentiality)?
- Have participants been offered a fair choice through the information they are given (presented in plain English) and consent process?
- Has the research incorporated patient and participant views?
- Are there fair payments for participation and financial recompense in case of harm?
- Do participants have access to an independent complaints procedure (or advocate)?
- Will the project be registered, and results reported in the public domain?

Acknowledgments to *Association for Research Managers and Administrators (ARMA), 'Running a REC' webinar materials* (Simon Kolstoe and David Carpenter), November 2022.

2.3. Providing a supportive ethics review

Reviewers must be motivated by an endeavour to give favourable opinions to ethical research and to be supportive through the provision of advice, during the entire research life-cycle.

Reviewers must focus on the research as provided in protocols and proposals rather than the content of an application form.

However, the record within the form would ultimately be required to be correct and accurately reflect the proposal, so there is an auditable record for both the researcher and the REC/University, and any external authorities which may require access to it (i.e. funders, regulatory authorities, publishers etc.).

Some research may necessarily contain risk/high level of ethical implications, however reviewers and the University must acknowledge this and suggest how such research can be best accomplished.

Reviewers must use proportionality for the level of information and participant facing information required, in light of the type of research proposed.

Reviewers must justify opinions giving clear reasons why they are being made and to provide positive feedback as well as constructive criticism.

Ethical concerns will rarely be of sufficient magnitude to result in an unfavourable opinion. RECs should never adopt a starting position of searching for potentially limiting conditions.

The University must provide consistent and defensible frameworks for standards of review, and access to guidance for researchers (applicants).

All reviewers should have access to this SOP, when requested to undertake reviews, and the reviews should be done in line with the principles outlined above and within the *University's Code of Practice Governing the Ethical Conduct of Research.*

All reviewers must have undertaken the *Introduction to Research and Knowledge Exchange Ethics* module prior to undertaking a review on behalf of the University (via any system of review).

2.3.1. Ethical domain headings for review

Domains used by Health Research Authority (HRA) can be useful as an outline for ethics review of all disciplines:

Social Scientific Value	Recruitment arrangements, access to (patient or participant) information, fair participant selection criteria	Favourable risk/benefit ratio
Care and protection of research participants	Valid and appropriate Consent and the suitability of participant information mediums	Suitability in terms of experience and skills of the applicant and other investigators/supporting roles

2.4. An indicative checklist for Reviewers

In line with the principles described at the top of this SOP, the reviewers should use the indicative checklist as a prompt to help with the parameters of a review, noting that not all fields will be applicable and that not all applicants need to provide the level of information which may be required for work with higher or more complex ethical implications (or a combination of various ethical implications which result in higher potential risk).

The reviewers do not need to complete the *checklist* for each proposal; however, it is very important to ensure the deliberations/outcomes of an ethics review body are documented and recorded for future reference (including for amendments), record-keeping (retention policy) audit and monitoring. Therefore, the deliberations and the outcomes should be recorded in the VRE if not in formal Minutes of the meeting. The VRE acts as the audit record.

The checklist if completed is not an adequately facilitative medium for conveying information to a researcher. Instead, the review body should do that via email or verbal/video/in person communication if needed, in addition to the VRE letters/notes. Note that review bodies must always justify opinions, providing clear rationales.

Note: Ethics review for some regulated research is carried out using other arrangements, for example, such as Health Research Authority's Governance Arrangements for RECs, and the Home Office's licencing arrangements. Where that is the case, including for Human Tissue work falling within the remit of HRA, that proposal needs to go through the University's quality and governance checks and authorisations, prior to permission to submit for external ethics or governance review. See **UREC-SOP-003 Criteria and Systems for Review.**

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