UREC-SOP-002 Guidance for Reviewers

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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 (HRA'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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Title	• Short clear, and accurately descriptive				
Abstract	• A summary of the main points of the research or KE activity, written in terms easily understandable by a non-specialists and containing no complex technical terms.				
Investigators	• Names and institutional attachments of all persons involved in the collection and handling of data or interactions with participants, and one person named as Principal Investigator (PI). • Suitability (in terms of experience and skills) of the applicant and supporting staff. • A supervisor can include a group of students as co-investigators. • Human Tissue applicants (all investigators listed, inc. students) must provide evidence of recent HTA MRC training module completion.				
Schedule	• Has the research been adequately planned so it will be carried out in a timely manner?				
Methodology	• Outline the method or methods (in lay person language) that will be employed to collect and analyse data. Any relevant documents, such as interview or survey questions, should be sent with the completed ethics form.				
Participants	• Give details of the population targeted (including numbers of potential participants) or from which a sample will be obtained and how this				

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	sampling will be done. • Does applicant give sufficient justification to inclusion of over researched populations, vulnerable or underrepresented populations, those with protected characteristics? Has data minimisation been considered? • Information on participants (including potential number of participants) should include: a. Age b. Specific vulnerabilities c. Cultural sensitivities d. PREVENT safeguarding programme e. Safeguarding Vulnerable participants guidance f. Disclosure and Barring Service				
Recruitment procedures	• The recruitment material should clearly point the potential participant to the 'Participant Information Medium', should make clear that this is a research or KE study, and include affiliation of both the investigators and any funder. • Any recruitment materials should include the ethics application reference number and Research Ethics Committee, or other research ethics review body name, that provided the research ethics approval/favourable opinion • The recruitment plan will also be considered during ethics review, which should include how potential participants will be identified/chosen, rationale for this selection, and how they will be approached, and the process for ascertaining eligibility if appropriate. • Is there any possibility for coercion and if so, how has this been addressed? For example, are there any 'power' relationships where the participants are				

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	known to the researcher either personally or professionally? Have these relationships been recognised and steps taken to avoid or taken into account? Another example could be taking advantage of a ready-available population due to the status or location or other defining factor, i.e. prisoners in confinement or school-children at their place of study). • Have participants been informed of the time commitment expected of them and their right to decline to offer any particular information? • Have participants been given sufficient time to permit making an informed decision? • Is there fair participant selection criteria (e.g. relevant to the aims, not disadvantaging those already at a disadvantage , not including unfair or inequitable use of incentives etc.) • Are eligibility criteria clearly set out? • Is the method of collecting eligibility criteria clearly set out? • Is the eligibility criteria separate exercise from evidencing consent exercise? i.e. they must not collect eligibility criteria information on a consent form.				
Participant Information	• Is participant information media included? If not, it must be provided before any participant facing work occurs including recruitment. • Participant information can be in any suitable medium. • Different demographics require different participant facing information.				

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	• (note study and participant needs will dictate how much information is needed in the participant facing mediums): • PI name and contact details, affiliation (and funder if appropriate), title of proposal • What is the study or activity about, why is it being undertaken, why am I being approached (selection and eligibility criteria), is my participation voluntary and I have been provided clear information on when I can withdraw (without detriment or reason provided) by (and reasons for any limits by which point withdrawal would not be possible). • Any risks or benefits (direct or indirect) in participating. • Any debrief or further resources/support for contacts. • Is the Head of School or Head of College listed as point of complaints, and if so check they do not have a conflict of interest (i.e. part of the study team or KE activity team). • Is there clear information about the processing and storage of data • RECs can check the *guidance for participant facing information* via the BB module: (selection, recruitment, and valid consent section)				
Valid (and Appropriate) Consent	• Is consent form included? Consent does not always need to be written. See BB module (selection, recruitment, and valid consent section) for further advice.				

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	● In order for consent to be valid and appropriate, sufficient information needs to be provided to the potential participants. • Consent forms must not be used to collect data (including inclusion data), unless there is a regulatory requirement. • Human Tissue research – has the UoW HTA-SOP-009 Consent been used as a basis for the consent process?				
Where and when will the research be carried out and the data collected?	• Researchers should give details of where and when data will be collected with an explanation of why the research needs to be conducted in the chosen setting or location. What are the ethical implications of this setting or location, if any. Also, if it will take place on private, corporate, or institutional premises, information must be given on any approvals that have been gained/are required. However, unless there is a regulatory requirement (such as for Human Tissue or Health Research Authority) then the REC is not likely to need to see these permissions.				
Literature review	• Researchers should give a brief review of the existing literature or previous research. • They should clarify whether the proposed study replicates prior work and/or duplicates work done elsewhere and/or has an element of originality. • Is there sufficient evidence that an exhaustive literature search has been carried out to confirm that the research project is of sufficient quality, and not overly duplicating any previous work?				

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Which guidelines will be followed?	• Researchers should provide information on which guidelines will be followed. For example: BERA, BPS, BSA, SRA, MRS, SPA.				
Data protection (DP) and information security	Until the DP checklist flag in the VRE System can be introduced, all applicants that select 'yes' to *'personal and sensitive data which is identifiable or traceable'* need to be directed to the DPA Team to complete a Data Protection Impact Assessment (DPIA). That will cover the below which is not within the remit of the RECs. • Has data protection and security been addressed • adequately? • Where research involves the collection of personal information about individuals, researchers should have registered their project with the appropriate institutional data protection officer, or follow other procedures prescribed by their institution and they should confirm that this has been done. If collection of personal sensitive data is proposed appropriate safeguards should be in place. • Details of procedures and a schedule (including dates) for the storage and disposal of data to comply with the • Data Protection Act and GDPR should be included, with the earliest and latest date for the destruction of original data, where it is required. Also, any archiving arrangements that have been agreed/permitted should be included in the project schedule. Researchers should also be aware of institutional information security policy and guidance.				
Research data Management	Similar arrangements to ensure applicants have carried out RDM issues pre-ethics review will be discussed with the new RDM Manager and other data teams • Have participants been given accurate information and given appropriate consent for the research data to be reused and/or published?				

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	• If not covered elsewhere in their application or in a data management plan, researchers should give details of how their research data will be managed and published. Necessary compliance with any funding body requirements should also be described.				
Incidental disclosures and findings	• If there is a risk that disclosures raising concerns for the safety of participants or others, have relevant measures been explained? • If there is a risk that research procedures could reveal information about the health of participants, or their relatives have any responses which might be taken by the researcher been explained? This is particularly important with any research involving the collection of human tissue, DNA analysis and imaging techniques. • If there is a risk of disclosure of illegal actions and what the consequences might be.				
Debriefing	• Researchers should give details of how after data collection, information will be given/ made available to participants to inform them of the outcomes of their participation and the research more broadly. • Is the offer or breadth of the debriefing adequate? • Has the researcher offered to share findings with participants?				
Other project related risks	• If not included elsewhere, have risks been adequately addressed?				

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	• Researchers are asked how they will limit research risks by anticipating potential problems. • They are advised that where they are carrying out fieldwork in the UK or overseas, they should be aware of the institutional guidance and policies.				
Benefits and knowledge transfer	• Researchers should state how the research may be of general benefit to participants and society.				
Supporting Documents	Note: these compliance issues do not always involve the REC, unless for specific regulated research or for Class 4 research. However a complete ethics review application should have these included as part of the pre and post-ethics review compliance checks. This area will be discussed further with the relevant teams and incorporated into a pre and post ethics workflow in the VRE if possible. These should include all governance related documents: limited examples only: indemnity, funding, internal and external governance approvals/permissions, risk assessments, material transfer or similar third-party consent agreements. All listed, present, with version numbers and dates, and referenced in the ethics form.				

Human Tissue for the purposes of research:

Pre and post ethics review Human tissue governance permissions from Human Tissue Designated Individual (Prof. John Murphy, School of Life Sciences) (for all other materials you will need the Head of School or Assistant Head of School permission, please ask for the template from UREC).

Health Research Authority research:

For research falling within the ***UK Policy Framework for Health and Social Care Research*** please contact the Research and Knowledge Exchange Office. You will also be requested to gain permission from the Head of School under the University's Sponsorship requirements.

*Where a standard is partially met or missing/inadequate it is recommended the REC consider any further details here which they should provide the applicant in order for them to understand why this is information is necessary for the ethical soundness of the project.