Fully met Partially met Missing and/or inadequate *Further details

UREC-SOP-002 Guidance for Reviewers

Please refer to the full SOP-002 for the Guidance for Reviewers

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.				

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Participants	• Give details of the population targeted (including numbers of potential participants) or from which a sample will be obtained and how this 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 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).				

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	• 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. • (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.				

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	• 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. ● 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	• Researchers should give a brief review of the existing literature or previous research.				

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review	• 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?				
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				

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	• Have participants been given accurate information and given appropriate consent for the research data to be reused and/or published? • 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? • 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.				

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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.