## UREC-SOP-002 INDICATIVE CHECKLIST FOR RESEARCH ETHICS REVIEWERS

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

| | | REC Standard | | | | |
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| | | Fully met; | Partially met; | *Inadequate/Missing; | N/A; | FURTHER DETAILS |
| **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-specialist and containing no complex technical terms. | | | | | |
| **Investigators** | Names and institutional attachments of all persons (including collaborators) involved in the collection and handling of data or interactions with participants, and one person named as Principal Investigator (PI).<br><br>Suitability (in terms of experience and skills) of the applicant and supporting staff.<br><br>Are students listed as co-investigators?<br><br>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? i.e. is there a timeline to completion. | | | | | |
| **Methodology** | Have the method/s (in lay person language) to be employed to collect and analyse data been outlined?<br><br>Any relevant documents, such as interview or survey questions, should be included. | | | | | |
| **Participants** | Gives 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.<br><br>Does applicant give sufficient justification to inclusion of over researched populations, vulnerable or underrepresented populations, those with protected characteristics?<br><br>Information on participants (including potential number of participants) should include:<br><br>a. Age<br>b. Specific vulnerabilities<br>c. Cultural sensitivities<br>d. PREVENT safeguarding programme<br>e. Safeguarding and Vulnerable participants guidance<br>f. Disclosure and Barring Service | | | | | |

| | | REC Standard<br>Fully met; Partially met; *Inadequate/Missing; N/A; Further Details | | | | |
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| **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.<br><br>Any recruitment materials should include the ethics application reference number and Research Ethics Committee that provided the research ethics approval/favourable opinion.<br><br>The recruitment plan 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.<br><br>Is there any possibility for coercion and if so, how has this been addressed?<br><br>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.)<br><br>Are eligibility criteria clearly set out?<br><br>Is the method of collecting eligibility criteria clearly set out?<br><br>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.<br><br>Participant information can be in any suitable medium.<br><br>Has the applicant used the Participant Information and Consent templates or used a similarly appropriate method to convey this information?<br><br>Has appropriate participant information been provided to different demographics e.g. children and adults. | | | | | |
| **Valid and Informed Consent** | Is a consent form (or equivalent transcript) included? Consent does not always need to be written. See BB module (selection, recruitment, and valid consent section) for further advice.<br><br>Has the applicant used the Participant Information and Consent templates or used a similarly appropriate method to convey this information? | | | | | |

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| | Is the consent and participant information culturally appropriate and in the suitable language?<br><br>Human Tissue research – has the University of Westminster 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.<br><br>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. The REC will note these only, unless there is a regulatory requirement (e.g. such as for Human Tissue or Health Research Authority). | | | | | |
| **Which guidelines will be followed?** | Researchers should provide information on which professional body, regulatory authority or Research Good Practice and Research Ethics guidelines will be followed. For example: British Psychological Society (BPS), Human Tissue Authority, Economic and Social Research Council, etc. | | | | | |
| **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). | | | | | |
| **Research data Management** | Similar arrangements to above, to ensure applicants have carried out RDM issues pre-ethics review will be discussed with the new RDM Manager and other data teams.<br><br>Is there a schedule for storage, disposal, or anonymisation of data.<br><br>Has the applicant used the Participant Information and Consent templates to outline the use of participants data or used a similarly appropriate method to convey this information? | | | | | |
| **Incidental disclosures and findings** | Are adequate measures in place to address risks of disclosures raising concerns for the safety of participants or others?<br><br>Has the applicant used the Participant Information and Consent templates to outline the use of participants data or used a similarly appropriate template to convey this information?<br><br>Has the applicant referred to the University Safeguarding Policy or other relevant Safeguarding policy? | | | | | |
| **Debriefing of participants, researchers** | Will a debriefing option be available to participants and others involved in the research? | | | | | |

| | | REC Standard<br>Fully met; Partially met; *Inadequate/Missing; N/A; Further Details | | | | |
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| **and others involved** | Will information be provided to participants about the outcome/findings of the study?<br><br>Has the applicant used the Participant Information and Consent templates to outline the use of participants data or used a similarly appropriate template to convey this information? | | | | | |
| **Other project related risks** | If not included elsewhere, have risks been adequately addressed?<br><br>Researchers are asked how they will limit research risks by anticipating potential problems. Have they adequately addressed this in their application for ethics review? | | | | | |
| **Benefits and knowledge transfer** | Researchers should state how the research may be of general benefit to participants and society.<br><br>Has the applicant used the Participant Information and Consent templates to outline the use of participants data or used a similarly appropriate method to convey this information? | | | | | |
| **Relevant research ethics documents ('VRE attachments')** | **For example, only:** Participant Information Medium, Consent medium, recruitment material or posters, indicative questions, de-brief, sensitivity protocol, investigator training evidence, safeguarding documentation, risk and benefit analysis, observation schedule.<br><br>All documents provided should include version numbers and dates and cross-referenced in the ethics form. | | | | | |
| **Supporting Documents (non-research ethics documentation)** | **These may include (examples only):** indemnity, funding, internal and external approvals or permissions, risk assessments for safety issues, material transfer or similar third-party consent agreements.<br>-All documents provided should include version numbers and dates and cross-referenced in the ethics form.<br>-The REC will only note these as part of a complete research ethics review application. The REC should note that these documents may exist elsewhere in the VRE system pages, and therefore researchers may not need to include these with the research ethics form pages, unless required for regulated research ethics review. Therefore, the REC may not be privy to the documents sitting elsewhere and may **seek advice from the RKEO if necessary.** | | | | | |

***Further information for reviewers:***

*****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.*

For regulated research and/or transfers of materials into or out of the University, including but not limited to Human Tissue Authority, Health Research Authority: reviewers must see the additional guidance note for reviewers.