**Ethical Approval for Non-Clinical Research Involving Human Participants**

# Reviewer Checklist for Form B: Medium/High Risk Projects

# Name of Applicant: SREC reference no:

# Name of Reviewer(s): Date reviewed:

|  |  |  |
| --- | --- | --- |
| **Information required** | **Y / N / NA** | **Detail of any insufficient information or ethical concerns & changes required** |
| Introductory information  |  |  |
| Is the title provided? |  |  |
| Is the supervisor’s name provided (if applicable)? |  |  |
|  |  |  |
| 1. Project Information |  |  |
| 1a. Are the research questions to be addressed clear? |  |  |
| 1b. Is the study justified in terms of existing knowledge and need for the work? |  |  |
| 1c. Are the research question(s) and any objectives clear? |  |  |
| 1d. Is it stated how much time the participants will give for the study?  |  |  |
| 1e. Is it stated where the study will take place? |  |  |
| 1f. Is it clear whether there is any reward or payment for taking part (if yes, details needed) |  |  |
| 1g. Has a copy of any data collection tool been included as an appendix? |  |  |
| 1h. If ‘Online surveys’ (formerly BOS) is not being used for online surveys/questionnaires is the rationale for using an alternative survey tool acceptable? |  |  |
| 1i. Is it clear exactly what data are being collected? |  |  |
| 1j. Is the format of the data clear? |  |  |
| 1k. Is there a sufficient explanation of whether the data will be anonymous or anonymised? |  |  |
| 1l. Have the data analysis plans been explained? |  |  |
| 1m. Is the duration of the study clear? |  |  |
|  |  |  |
| 2. Participants |  |  |
| 2a. Is it clear who the participants are? |  |  |
| 2b. Is there sufficient explanation of how they will be identified? |  |  |
| 2c. Is there sufficient explanation of how they will be contacted (when, where and by whom)? |  |  |
| 2d. Is there enough detail about the information they will be given (what, when, where, by whom)? |  |  |
| 2e. Is there enough information about the sample size and method? |  |  |
| 2f. Are inclusion / exclusion criteria stated (where applicable)? |  |  |
| 2g. If applicable, has appropriate permission to work with young or vulnerable individuals been obtained (e.g. Protecting Vulnerable Groups clearance from Disclosure Scotland) |  |  |
| 2h. If the research involves participants outside the UK have the implications of this been considered?  |  |  |
|  |  |  |
| 3. Informed Consent |  |  |
| 3a. Is there an adequate explanation of how participants will agree to take part (when, where, who is involved) and procedures for withdrawal? |  |  |
| 3b. Is there an adequate explanation of how consent will be taken? |  |  |
| 3c. For projects involving video- or audio-recording are procedures for obtaining informed consent adequately explained? |  |  |
| 3d. Is information about anonymity and confidentiality sufficient? |  |  |
| 3e. Are debriefing plans explained? |  |  |
| 3f. Are there any vulnerable groups involved (if yes, is this recognized and explained)? |  |  |
| 3g. If vulnerable groups are involved, is an explanation given about how consent will be obtained if participants are unable to consent themselves (e.g. children)? |  |  |
| 3h. Where consent is only being sought from children, has the rationale for not seeking consent from a parent or guardian been provided? |  |  |
| 3i. Is information about obtaining consent for the potential sharing and reuse of data sufficient? |  |  |
| 3j. Has there been adequate consideration of the implications of participants’ capacity to make their own decisions and understand the risks? |  |  |
|  |  |  |
| 4. Data Management[[1]](#footnote-1) |  |  |
| 4a. Is the lawful basis for the processing of personal data clear? |  |  |
| 4b. If applicable, is the specific condition for processing of special category data clear? |  |  |
| 4c. Is it clear that all data will be stored securely (where, who has access)? |  |  |
| 4d. Is there information about how long the data will be kept for? |  |  |
| 4e. Has the question of anonymization or pseudonymisation been adequately addressed? |  |  |
| 4f. Are arrangements for data sharing and reuse by other researchers beyond the project adequate? |  |  |
| 4g. Has the potential for re-identification of participants been adequately addressed (including explaining this to potential participants)? |  |  |
| 4h. Is there adequate description of the processes in place to erase an individual participant’s data?[[2]](#footnote-2) |  |  |
| 4i. Is there adequate description of the processes in place to stop processing an individual participant’s data? |  |  |
| 4j. Is there adequate description of the processes in place for individuals to have inaccurate personal data rectified, or completed if it is incomplete? |  |  |
| 4k. Is it clearly stated who has overall responsibility for data management for the project? Have the contact details for the senior researcher and Data Protection Officer been provided in the Participant Information Sheet? |  |  |
| 4l. Are arrangements for collection and transfer of data outside the UK adequate? |  |  |
|  |  |  |
| 5. Risks of harm to researchers and participants |  |  |
| 5a. Have any risks to participants been identified?  |  |  |
| 5b. If risks to participants have been identified, are these explained sufficiently? |  |  |
| 5c. If risks to participants have been identified are these explained sufficiently in the information sheet? |  |  |
| 5d. Are details provided of how the risks will be minimized/managed? |  |  |
| 5e. Have any risks to the researcher been identified?  |  |  |
| 5f. Are details provided of how the potential risks to the researcher will be minimized/managed (including the risks of undertaking fieldwork outside the UK)? |  |  |
| 5g. Has a risk assessment been carried out and does it adequately address the risks? |  |  |
|  |  |  |
| 6. Risk of disclosure of harm/potential harm or of criminal offences |  |  |
| 6a. Have any risks been identified (including disclosure of criminal offences; harm to participants or others)? |  |  |
| 6b. Are details provided of how the risk of potential or actual disclosure will be managed and actions which will be taken should such disclosures occur? |  |  |
| 6c. Are details provided of information which will be given to participants about the possible consequences of disclosing such information?  |  |  |
|  |  |  |
| 7. Payment of participants |  |  |
| 7a. If payment is being offered, is there an explanation of the nature of the inducement or amount of payment offered and the reason why it is necessary to offer inducements?  |  |  |
| 7b. Is there an explanation of why it is considered ethically and methodologically acceptable in the context of this study to offer such payments or other inducements? |  |  |
|  |  |  |
| 8. Voluntary participation |  |  |
| Where the participants are in particular categories which might lead an unequal relationship, is there an explanation of how the participants will be recruited and what steps will be taken to ensure that participation is genuinely voluntary? |  |  |
|  |  |  |
| 9. Other Ethical Considerations |  |  |
| If there are any other ethical considerations have they been addressed? |  |  |
|  |  |  |
| 10. Documentation[[3]](#footnote-3) |  |  |
| Has all relevant documentation been provided? |  |  |

# Decision: Approve / Return for Revision / Reject / Refer to UREC

**Optional Additional Information**

Individual SRECs may elect to add additional procedural information to the end of the checklist. An example is provided below:

# Reviewer’s Signature:

# Date response sent to SREC administrator:

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# PLEASE COMPLETE IF REVISIONS ARE REQUIRED

# Comments to applicant:

# Date comments sent:

# Date revisions received:

# Have the concerns been addressed sufficiently?:

# Reviewer’s Signature:

# Date revised response sent to SREC administrator:

1. Advice on data management can be obtained from the University’s [Data Protection Officer](https://www.dundee.ac.uk/information-governance/dataprotection/) and the [Library & Learning Centre](https://www.dundee.ac.uk/library/research/researchdatamanagement/). [↑](#footnote-ref-1)
2. Individual participants have the right to request erasure of data under the General Data Protection Regulation unless erasing the data would prejudice scientific or historical research, or archiving that is in the public interest. [↑](#footnote-ref-2)
3. In the context of the COVID-19 pandemic, researchers who are conducting face to face research should complete a [COVID-19 generic risk assessment template](https://dmail.sharepoint.com/%3Aw%3A/r/sites/ReturnToCampus/Shared%20Documents/Risk%20Assessment%20Information%20%28RAMS%29/Approved%20RAMS%20Template%202.4.docx?d=w3267708d25854a85843ab6e83ad68510&csf=1&web=1&e=33gTTO) detailing any additional control measures required to mitigate risk and submit it with their application (see: <https://www.dundee.ac.uk/research/governance-policy/ethicsprocedures/covid/>). [↑](#footnote-ref-3)