BSMS RGEC Checklist for UG and PGT Supervisors Is a student's project ready for ethics review?

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Consider the matters below. Are they clearly addressed by the project design and supporting documents? If there is more than one possible answer, has justification been provided for the selected approach?

A. Project's Foundation

Thinking separately about the project's Research question; Objective; and selected methodology, was this suggested by previous research, the literature or a publicly recognised problem? Does the student make a clear case, based on a solid scientific rationale, for why this research should be carried out?

- Is the research question clearly stated?
- Is it clear why that question is worth asking and answering?
- Is it clear that the chosen methods are suitable to generate data to answer that question?

B. Participants

All research participation is voluntary. It is a default expectation that research with human participants must be based on the principle of meaningful, freely-given informed consent, documented by the student researcher. In line with the <u>University of</u> <u>Sussex Research Governance Standard Operating Procedure</u>, informed consent should be appropriate to the participant, the research activity and nature of the data being gathered.

Bi. Participant definition

Is it clear who will participate in the project? How will the student identify them? Does the potential participant pool include any categories of participants specified in the ethical review application form Checklist in Sussex Direct? If so, has the student explained how the vulnerabilities of those participants will be addressed? Is the pool over researched? If so, has the student provided a justification for the selection of the pool? Is involvement of the potential participant pool fair? Could participating expose them potential harm?

Bii. Recruitment

How will participants be recruited? Do the needs of the project necessitate more than one recruitment strategy? Does the recruitment method raise any privacy considerations? Will any other party be aware of the identities of persons approached about participating? Or their decision? Could the recruitment strategies expose anyone to harm?

Biii. Consent

What strategy will be used to seek and receive the consent of participants? Do the needs of the project necessitate more than one consent strategy? In accordance with the <u>University of Sussex Research Governance Standard Operating</u> <u>Procedure</u>, researchers have a duty to:

- Ensure participants give informed consent as to how their data will be stored, preserved and ultimately destroyed.
- set out clearly how confidentiality will be maintained and give sufficient thought to whether the consent that they seek will be appropriate for any later use of the data.
- Be explicit in seeking consent. Consent should be granular and specific to the information or data taken and the form
 of media being used.

Biv. Duration and needs

Does the duration of a project, its iterative nature, phases or other needs warrant seeking consent more than once?

Bv. Reconfirm consent

Is it necessary to reconfirm consent, such as for use of a direct quote in research outputs, or to contact interested participants regarding their participation in a follow-up interview?

Bvi. Online methods of consent

Will any alternatives to written consent be used? If so, will participants be required to actively 'opt-in' to participate? (Since introduction of the General Data Protection Regulation (GDPR) 2018, for consent to be valid, it must be given with a definite affirmative action to opt-in, such as clicking an 'opt-in' or 'I consent to take part in the research' button). Where written consent forms are not appropriate for the research scenario or participants, for e.g. online and telephone interviews, oral consent may be preferred. Has the student explained how they will collect evidence of consent, and provided a rationale for this approach? For projects utilising video conferencing platforms to conduct research interviews

and/or focus groups, have the University guidelines been followed: <u>https://www.bsms.ac.uk/_pdf/research/the-use-of-video-conferencing-services-for-research-approved.pdf</u>?

C. Inclusion of Mandatory Documents

It is expected that all student submissions (e.g. online surveys and questionnaires, interviews, focus group discussions and interventional research), will include copies of the following documents:

Participant Information Sheet (PIS) - are they written in accessible, user-friendly language for non-expert lay participants for each group of participants involved in the study?

Consent Form (CF) – does it allow participants to indicate their understanding of, and consent to, all aspects of the project? For online questionnaires and surveys is the consent form embedded in the first page of the online survey or provided separately, if so, how will this be circulated? See the previous section concerning online methods of consent and requirements for this approach.

Recruitment materials: emails / posters / social media posts where appropriate **Summary Curriculum Vitae (CV) for non-faculty supervisors**

Students undertaking qualitative research should also include as part of their submission:

Certificates of attendance for training modules in **conducting qualitative interviews**

Certificates of attendance for training modules in **receiving informed consent**

D. Gatekeeper Permissions

Has the student detailed how they will seek consent from any organisational, institutional or participant group 'gatekeepers' prior to engagement with potential research participants? Are the following included?

Gatekeeper letter of approach - the use of an introductory letter/email describing the research, plus information sheet Or, evidence of Gatekeeper Approval confirming willingness to endorse the project and allow access to the researchers where it has been obtained in advance of an ethics submission

E. Research Tools

Dependent on the project type, it is expected that the following study documents will also be submitted:

Validated Questionnaires and Surveys to be used as part of the study Researcher designed Questionnaires Interview Topic Guide for semi-structured and loosely structured interviews Focus Group Topic Guide Protocol for interventional studies and activities setting out the logistical details of how they will run

F. Fieldwork

For students conducting interviews remotely in an unfamiliar location, submission of a detailed protocol for the interview visits is required to assure the University of the researcher's safety and wellbeing. See the University of Sussex's Field Work Safety Policy and Risk Assessment policies:

https://www.sussex.ac.uk/webteam/gateway/file.php?name=fieldwork-safety-policy-oct-2013.pdf&site=332 http://www.sussex.ac.uk/hso/policies/subject_areas/transport_fieldwork

G. Data Management and Handling of Personal Data

Has the student detailed how research data will be stored? Data may be stored on University network servers, or University licensed BOX or OneDrive accounts, which offer GDPR compliant storage supported and protected by the University. Data should never be stored on an individual researcher's computer or peripheral device such as a USB stick. See: http://www.sussex.ac.uk/its/services/networkandstorage/filestorage.

H. Before Review by the School Research Ethics Officer (SREO)

Solutions to errors students frequently commit which contribute to delays in confirming ethical approval. Has the student:

- Fully answered all sections of the Application Form? Completed the 'Roles' section? Students and all individuals providing academic and field supervision should be named. Outlined a comprehensive recruitment strategy listing websites/intranet/email distribution lists/social media to be used?
- Justified their sample size? (Sample sizes should be appropriate to the analysis the research team intend to carry out).
 For qualitative research: clarified which approach of data analysis will be taken and whether any data analysis software will be used?
- Built in adequate time for transcription and analysis of qualitative interviews within project timescales? Supervisors and their students should bear in mind a single 2 hour interview could take up to 5 hours to transcribe.

- Checked all study documents are clear and comprehensible to a non-expert lay audience and typographical errors removed?
- Version controlled all supporting documents with the project title, version number and date in the document footer? To
 guarantee finalised versions of study documents only are issued to participants upon confirmation of ethical approval.
- Provided University contact details on all paperwork to be given to participants?
- Cited an independent complaints process participants can be directed to other than the researchers? E.g. the University
 of Sussex Research Governance Office: <u>rgoffice@sussex.ac.uk</u>.
- Specified a date beyond which it will no longer be possible for participants to withdraw their data?

With appreciation and thanks to the Australasian Human Research Ethics Consultancy Service, ahrecs.com, from whom the Checklist Tool was adapted: <u>https://ahrecs.com/human-research-ethics/a-checklist-to-assist-supervisor-to-check-a-candidates-research-ethics-review-application</u>