BSMS RGEC
Checklist for Applicants
Is your application ready for ethics review?

Checklist for applicants of non-clinical studies eligible for review via the BSMS Research Governance and Ethics Committee, or School Research Ethics Officer. (Clinical research involving NHS patients, their data or tissue, service users, or staff is not eligible and requires University Sponsorship **and application for** HRA Approval**).**

A. Mandatory Documents

It is expected that all submissions will include copies of the following documents:

Participant Information Sheet (PIS) for each group of participants involved in the study. The PIS should be written in accessible, user-friendly language for non-expert lay participants taking part in surveys and questionnaires, interviews, focus group discussions and interventional research.

Consent Form (CF) for each group of participants involved in the study to be signed by each participant. The CF should allow participants to indicate their understanding of, and consent to, all aspects of the project. For some research activities (e.g. where data collection is solely through online survey) it may be appropriate and practical to incorporate the consent form into research tools (e.g. as the first page embedded in an online survey). For online methods of consent to be valid, all participants should actively 'opt-in' to participate. The model of implied consent is no longer viable following introduction of the General Data Protection Regulation (GDPR) 2018, and consent 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. It is recognised that written consent forms may not be appropriate for all research scenarios or participants, and oral consent may be preferred. In such cases, researchers must explain how they will collect evidence of consent, and provide a rationale for this approach.

Recruitment materials: emails / posters / social media posts where appropriate

Summary Curriculum Vitae (CV) for non-faculty supervisors

UG and PGT Applicants

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**

B. Gatekeeper Permissions

If appropriate, the ethics application must also detail how researchers will seek consent from any organisational, institutional or participant group 'gatekeepers' prior to engagement with potential research participants. Gatekeepers should be provided with transparent, detailed information about the project (including a clear statement outlining the extent to which the organisation/institution will be anonymised, and making clear that personal data and identifiable responses from individuals will not be disclosed to the gatekeeper). Applicants to include the following documents:

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

C. 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

D. Fieldwork

For researchers 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

E. Research Conducted Overseas

Studies which are conducted overseas require additional documentation and provision of an:

Overseas Travel Safety and Security Risk Assessment (OTSSRA) Form details of the regions the student/researcher will be visiting, dates of travel, length of time in the country, public transport required, details of field supervisors where applicable, as well as the name and contact details for a contact person in the case of an emergency while in the field.

Confirmation of existing Foreign & Commonwealth Office (FCO) warnings for the locality the researcher intends to visit: https://www.gov.uk/foreign-travel-advice

Fieldwork Risk Assessment Form where there are FCO travel warnings in place, a separate Fieldwork Risk Assessment Form which details measures to safeguard the researcher while they are undertaking field work is required in support of part 2 of the OTSSRA form. Fieldwork Risk Assessment Form can be found on the University of Sussex website under 'Forms': http://www.sussex.ac.uk/hso/policies/subject_areas/transport_fieldwork

Letter of confirmation of local ethical approval where approvals have already been obtained

Overseas Research applications should:

- Clarify in the Ethical Review Application Form who the data controller will be for research projects where data transfer will occur between countries and whether a data sharing agreement is required. All professional engagements with external organisations, including collaborations on research projects involving disclosure or receipt of confidential information must be governed by an appropriate contract. A MTA (Material Transfer Agreement) or Data Sharing Agreement, may be required. Contact the Research and Enterprise Contracts Team directly contracts.instructions@sussex.ac.uk and refer to: http://www.sussex.ac.uk/staff/research/contractsandip
- Ensure that Participant Information Sheets (PIS), Consent Forms (CF), and research tools are suitable culturally and linguistically for the literacy level of the population participating in the research.

F. Imaging Research

Applications for imaging research studies should include the possibility of uncovering clinically relevant incidental findings and the protocol for responding should they be uncovered in the Participant Information Sheet (PIS) and Consent Form (CF). High risk healthy volunteer drug studies should confirm:

1. Using the MHRA algorithm whether the study is defined as a Clinical Trial of a Medicinal Product
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf

2. If you are still unsure, the study team should submit a clinical trial enquiry directly to the MHRA via clintrialhelpline@mhra.gsi.gov.uk to confirm the study does / does not meet their criteria for a Clinical Trial of an Investigational Medicinal Product (CTIMP). Evidence of informed expert opinion will be required by the University/BSMS. When applying to the BSM RGEC, the following standard operating procedures should be followed:

- High Risk Healthy Volunteer Drug Intervention Studies SOP Flow Chart v1 April 2017 [HYPERLINK]
- Risk Assessment Proforma – High Risk Healthy Volunteer Drug Intervention Studies v 1 April 2017 [HYPERLINK]
- Adverse Event Response – High Risk Healthy Volunteer Drug Intervention Studies v April 2017 [HYPERLINK]

G. Before You Submit

Solutions to errors applicants frequently commit which contribute to delays in confirming ethical approval. Have you:

- Fully answered all sections of the Application Form? (A separate protocol is not required, except for complex interventional studies, or drug studies in healthy volunteers).
- Completed the 'Roles' section? Students and all individuals providing academic and field supervision should be named. All investigators associated with the project should be listed for PGR and Staff submissions.
- Outlined a comprehensive recruitment strategy listing websites/intranet/email distribution lists/social media to be used?
- Justified your sample size? (Sample sizes should be appropriate to the analysis the research team intend to carry out). Members of Staff and PGR students undertaking large scale funded research are encouraged to seek statistical support and book attendance at a Statistics Clinic: Statistics.Clinic@bsms.ac.uk.
- 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? Researchers 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: rgoffice@sussex.ac.uk.
- 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.
- Specified a date beyond which it will no longer be possible for participants to withdraw their data?
- If you will be using video conferencing platforms to conduct online research interviews and/or focus groups please consult the following guidance: https://www.bsms.ac.uk/_pdf/research/the-use-of-video-conferencing-services-for-research-approved.pdf