

# Best Practice Guidance for Ethics Review of BSMS-Led Research Projects Conducted Outside the UK

## Introduction

- 1.1. The audience for this guidance is BSMS staff and Doctoral-level students submitting applications for overseas research projects eligible for ethics review via the BSMS Research Governance and Ethics Committee (RGEC). Affiliated academics, such as external collaborators undertaking or involved with funded research in connection with, or as part of, the University of Sussex also fall under the scope of this guidance.
- 1.2. This guidance is of relevance for all applications for BSMS-led collaborative research projects conducted outside the UK. (These studies may be led by research staff employed by the Medical School, or by a collaborating Investigator financed under an externally funded grant via the University of Sussex).
- 1.3. Such research varies in complexity and in its setting. It often involves multiple collaborations across organisations, national borders, interdisciplinary science and partners outside of academia.
- 1.4. This guidance is equally applicable to less complex smaller scale projects involving no more than two partners funded via smaller grants.
- 1.5. It is recognised that systems of research ethics and governance vary considerably around the world.
- 1.6. These types of applications are likely to vary in the categories of risk they pose. Some studies such as elite interviews, may touch on fewer risks, while others, such as clinical interventions and monitoring of patient populations, require the applicant to have prepared strategies for how they will minimise the risk of potential harm to participants.

## 2. Principles for international research and the requirement for local oversight

- 2.1. Any research that would require ethics review when carried out in the UK is similarly subject to appropriate ethics review when carried out overseas. Such review may be sought from the BSMS RGEC.
- 2.2. The University of Sussex expects the ethical standards set out by national and international guidelines to be adhered to, regardless of the location of the research. BSMS researchers conducting research abroad, or as part of an international collaboration (or otherwise) are expected to adhere to ethical requirements of the country where the research is being conducted and to refer to international guidelines and relevant local regulations for the country or countries where the research is taking place.

- 2.3. It is expected that the research will also comply with the University of Sussex research ethics policies and guidelines as well as other University of Sussex policies and procedures, such as relating to insurance arrangements, and travel and fieldwork risk assessment, etc.
- 2.4. These considerations are especially important in research partnerships between the UK and lower-income settings. Falling outside UK jurisdiction does not permit for “ethics dumping” as set out in the [Global Code of Conduct for Research in Resource-Poor Settings](#)<sup>1</sup>. The University expects researchers to uphold ethical principles and minimise risks in overseas research by demonstrating adherence to a number of core principles:
- 1) Expecting researchers to be sensitive to the local and cultural contexts which might not always be fully understood by a research ethics committee based in the UK. The inclusion of ethics oversight from a relevant institutional body from the location in which the research will take place can highlight social and cultural dynamics, and help UK based researchers better tailor their protocols.
  - 2) Recognise that what is perceived to be ethical or to constitute an acceptable level of risk is not universal.
  - 3) Ensure the research is relevant and responsive to local needs. The consequences of the research must not be detrimental to the communities where the research is conducted and should ideally be of benefit. What counts as a meaningful benefit can vary significantly in different contexts. For example, research outcomes published in global academic journals may be of less direct benefit than disseminating findings in more locally orientated publications/reports, forums or meetings. Judgements about benefits should ideally be informed by those who represent the interests of local stakeholders.
  - 4) Respect local systems of review and oversight of research. Ethics approval from the BSMS RGEN is conditional on approval by a relevant local Institutional Review Body (IRB). Where applicable, BSMS staff and Doctoral-level student researchers must not personally carry out fieldwork outside the UK without first obtaining a research permit from the national government of the country where the research is taking place.
  - 5) Follow local laws and regulations. Researchers should be cautious about any context in which they may inadvertently breach local legal requirements.
  - 6) Take accountability for their actions while in the field. While an institutional research ethics committee in the UK has limited means to enforce accountability, local authorities can provide better oversight by requiring appropriate monitoring, reporting and compliance with local regulations.

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<sup>1</sup> <https://www.globalcodeofconduct.org/>

### **3. Local ethics oversight from a recognised research ethics committee (REC) or Institutional Review Board (IRB)**

- 3.1. BSMS staff and Doctoral-level student researchers conducting research outside of the UK are expected to familiarise themselves with the ethics review expectations of the host country or countries where the research is being conducted.
- 3.2. To ensure a consistent approach to the ethics of research across all research disciplines at BSMS and comply with the University of Sussex research ethics policies and procedures, it is anticipated that most overseas research projects will require joint ethics approval from the BSMS RGEC and from a Research Ethics Committee (REC) or equivalent Institutional Review Board (IRB) in the country or countries in which the research will take place.
- 3.3. The order in which ethics approvals are sought and which committee is applied to first will be determined on a case-by-case basis, dependent upon a) who is leading the project, b) the nature of the activities (will they involve higher risk activities such as clinical interventions and monitoring of patients), and c) review systems in place in the host country or countries where the research is being conducted and their capacities for conducting ethics review.
- 3.4. Generally, researchers should seek primary ethics approval from the lead university which substantively employs the Principal Investigator (PI) (this will be the BSMS RGEC for staff employed by the University of Sussex), followed by local ethics review and approval from a REC or equivalent IRB in the country or countries in which the research will take place.
- 3.5. We recommend that for studies which will involve high risk activities such as clinical studies involving interventions and monitoring of patient populations, where it is practicable, ethics approval is first sought via the REC or equivalent IRB of the host country or countries where the research is being conducted. This is especially relevant for research conducted in upper-middle income settings, such as South Africa with comparable systems of oversight to the UK.
- 3.6. It is the Principal Investigator's responsibility to identify and comply with funders' conditions and any local requirements, including data protection and to keep records of all ethics approvals obtained. Some funders specify as a funding requirement dual ethics review both in the UK and overseas.
- 3.7. Where approvals have been initiated and obtained in the host country or countries where the research is being conducted first, for example, local ethics approval should be appended to the application to the BSMS RGEC to maintain oversight of the outcomes of external ethics processes on the University's behalf. Additionally:
  - All projects that take place partly overseas and partly in the UK will require dual ethics review.
  - The minimum expectation is that the BSMS RGEC should undertake ethics review for projects led by a Principal Investigator employed by the University of Sussex or collaborating Investigator financed under a grant held via the University of Sussex. However, it is recognised that in exceptional circumstances a BSMS Department may choose to require ethics approval via the BSMS RGEC for overseas research.
  - Where a research project involves human participants in more than one country then the expectation is that the appropriate ethics review procedure in each country should apply (for example a project taking place both in the UK and in two other countries would require ethics approval via the University procedure as well as ethics approval that is required in the other two countries).

- 3.8. Risk assessment is a necessary requirement for establishing responsibility for professional indemnity insurance to cover the fieldwork. BSMS staff travelling to conduct fieldwork overseas must complete a University of Sussex Overseas Travel Safety and Security Risk Assessment (OTSSRA) form which should be signed off by the appropriate line manager. Copies of the form should be retained. The form can be found here: <http://www.sussex.ac.uk/hso/specialist/hscovidpage>. Part 1 of the OTSSRA form is completed for all travel and in the event that a Foreign, Commonwealth & Development Office (FCDO) warning is against travel or against all but essential travel parts 1 and 2 need to be completed. In the event of a Foreign, Commonwealth & Development Office (FCDO) warning then the OTSSRA form should be signed by the Head of School for BSMS or their representative.
- 3.9. BSMS Doctoral-level students must adhere to the University of Brighton's procedures and complete a mandatory health & safety risk assessment for fieldwork involving face-to-face data collection conducted in the UK or overseas. The risk assessment is submitted with the supporting study documents uploaded in Sussex Direct as a part of the application to the RGEc for ethics approval for a new study. The Risk Assessment requires sign-off by a supervisor. A Word-based risk assessment form is available here: <https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/covid-19-research-update.aspx#rgec>. Further information for Doctoral students can be found via the University of Brighton's 'Research-related travel' guidance: [https://blogs.brighton.ac.uk/doctoralcollegecv19/#Research-related\\_travel](https://blogs.brighton.ac.uk/doctoralcollegecv19/#Research-related_travel)

#### 4. Local oversight when there is no research ethics committee (REC)

- 4.1. In countries where local ethics committees do not exist ethics oversight should instead be sought from the organisation(s) where the research is to be conducted, a relevant authority or other organisation (e.g. national or local ministry, government agency, embassy, NGO), or other channels (for example, many indigenous communities have well constituted Councils).
- 4.2. Establishing local collaborations is particularly important to provide research participants with accessible channels for complaints, as reporting concerns directly to the University of Sussex might be unfeasible due to language or limited means of communication.
- 4.3. Local ethics approval for the country or countries where research is to be carried out must be in place before fieldwork can commence. [The International Compilation of Human Research Standards](#) listing, compiled by the US Office for Human Research Protections, provides details of Research Ethics Committees in over 100 countries (with a focus on research involving humans). If a local ethics committee does not exist, approval from the organisation or location where the research will be conducted should be sought.

#### 5. Streamlined ethics review of BSMS-led collaborative projects conducted outside the UK

- 5.1. For BSMS-led projects which fall under a single external funding stream comprising a programme of work, projects which are led by BSMS staff and students, including individuals employed by different partner institutions but financed under a University of Sussex awarded grant, each project should be reviewed by the lead institution (i.e. by the BSMS RGEc for projects with a BSMS PI, or an overseas university if BSMS researchers are not leading the research project), and in parallel by a relevant IRB in the country of data collection.
- 5.2. Each project should submit a completed Checklist, which accompanies the application for ethics review to the BSMS RGEc, which details:

- a) Pertinent information on how the application fits in with recently submitted or previously approved projects. A short summary highlighting any features which are similar to previously approved projects.
  - b) A brief summary of how ethics approvals will be sought for the project. Whether approval will be sought primarily via the BSMS RGEC, and in parallel via relevant IRB in the country of data collection. Or, primarily via an overseas university Institutional Review Board, in cases where BSMS researchers are not leading the research project.
  - c) For every funded project: A reference to the Collaboration Agreement for the whole collaboration (available via the Research Manager for the grant).
  - d) For every funded project: Confirmation of whether appropriate data sharing agreements and confidentiality agreements are in place which cover the project (available via the Research Manager for the grant).
  - e) For every funded project: Clarification of who the data controller will be for the project, where data transfer will occur between countries, and whether a data sharing agreement is required (available via the Research Manager for the grant).
  - f) For every funded project: Confirmation of which institution will be responsible for the legal liabilities associated with the fieldwork each project (available via the Research Manager for the grant).
- 5.3. This information will be used to facilitate ethics review of each project submitted to the BSMS RGEC. It should be stressed that the responsibility for ethics oversight of each project lies with the ethics committees that have approved it.
- 5.4. For projects which carry a risk of significant harm (in particular to participants, researchers, the reputation of the University or the welfare and interests of the wider community), and where significant project development is planned prior to submission of specific activities for full ethics review, the Chair of the appropriate ethics committee should be contacted at an early stage in the research project's development. This will ensure that any concerns from an institutional standpoint about the proposals in principle can be identified and addressed.
- 5.5. Researchers working internationally with vulnerable populations or populations seen as being at higher risk of harm and exploitation or coercion should develop a framework of responsibilities in advance. The Committee may require additional information to be provided on request.

## **6. Guidance for submission of BSMS-led funded projects conducted outside the UK**

- 6.1. The Applicant Checklist Tool for Research Conducted Overseas (Appendix A) has been designed to act as a helpful prompt for researchers and reviewers submitting ethics applications for funded overseas research projects to the BSMS RGEC.
- 6.2. The security and safety of both the participants and the researcher(s) are two of the guiding ethics principles of this Checklist. RGEC will assess the scale of potential risk of harm to both participants and the researchers.
- 6.3. A copy of the Checklist should be completed by the PI and is a mandatory document for applications for funded overseas research projects submitted to the BSMS RGEC. It should be uploaded in the Supporting Documents section of the application in Sussex Direct.