**BSMS RGEC**

**Checklist for non-UK research**

**Is your application ready for ethics review?**

**BSMS RGEC Checklist for Overseas Research, V1.0 21 April 2021**

**Checklist for applicants submitting an application for overseas research eligible for ethics review via the BSMS Research Governance and Ethics Committee. Please include a completed copy of this Checklist with your application by uploading it as a supporting document in Sussex Direct.**

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| --- | --- | --- | --- | --- | --- |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
| 1. 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. | |  |  |  |  |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
|  | **Cultural considerations** | | | | |
| 1. Differences in cultural and societal structures, norms and practices which are directly relevant to the design of the research. | | ☐ |  | ☐ | ☐ |
| 1. How communication with research participants will occur. Consider all aspects of communication, including recruitment, research activities and dissemination. Provide details of communication medium (e.g. face-to-face, social media, virtual video call, telephone call), appropriate location (e.g. where will recruitment, participant and non-participant observation or interviews take place) languages (e.g. which languages will be used, whether translators will be used and their relationship to the participants, where relevant) and personnel responsible (for communicating with research participants). | | ☐ |  | ☐ | ☐ |
| 1. Provision of local contact information for persons to answer research-related questions, including local emergency contact information and participants’ rights. (Mobile/landline telephone numbers are the preferred mode of communication rather than email). | | ☐ |  | ☐ | ☐ |
| 1. Political risks, for e.g. to the researcher, political conflicts in the region, or conflicts of interest, that the University should be aware of before the research begins. | | ☐ |  | ☐ | ☐ |
| 1. Local ethics structures (Section 5. ‘Other Ethical Clearances, Gatekeepers and Permissions required to conduct the research or to access specific populations’ in the Ethical Review Application Form). This includes specification of the relevant national/local ethical review boards and any research permits required. It also includes consideration of community and/or other institutional gatekeepers (e.g. civil society and/or recognised community-level forms of authority and decision making, local government and administration, hospital managers, other stakeholders). Details should be provided as to consultations made and permissions already obtained, as well as planned consultations and processes for seeking permissions.   Please note that the time required to obtain approvals via local review processes can often be long. Research clearance fees may also be a requirement and these can be significant for foreign research applications. | | ☐ |  | ☐ | ☐ |
|  | **Please note**: RGEC approval is **conditional** on the approval of the relevant ethical review board providing oversight in the location that the research will take place. The PI is required to provide RGEC with formal confirmation of local ethics approvals (once obtained) as well as confirmation of any changes to the study protocol or documents requested by a local ethics committee, and copies of documents which have been revised in accordance with local ethics review. | | | | |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
|  | **Benefits and risks of the research** | | | | |
| 1. Risks and benefits of the research to the local area and to the participants, including once the project has ended. Consider that there may be differences in understanding what counts as a benefit. Consideration should be given to the most meaningful channels for dissemination of findings to participants/communities/stakeholders. Will health status be provided? Acceptability of the research and research interventions by the community/participants? | | ☐ |  | ☐ | ☐ |
| 1. Material benefits of research participation (e.g. monetary compensation for time, transport reimbursement, gifts, provision of free healthcare). Balancing fairness and the needs to research against undue inducement should be given special attention. | | ☐ |  | ☐ | ☐ |
| 1. Whether research is likely to generate suspicion or adverse interest from local officials/ government, local security agencies, and/ or any other part of the community. How will you safely manage this? | | ☐ |  | ☐ | ☐ |
| 1. Provisions for safety monitoring of the research participants wellbeing, particularly if they are vulnerable populations (e.g. with a disabling and severely stigmatising Neglected Tropical Disease). This includes provision of counselling, or alternative options, if appropriate. | | ☐ |  | ☐ | ☐ |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
|  | **Researcher safety** | | | | |
| 1. Whether all members of the extended research team involved in the research, including those based overseas have been be listed in the ‘Roles’ section of the Ethical Review Application Form. The employment status and role of researchers based overseas must also be described. It must be made clear who is carrying out the research fieldwork. | | ☐ |  | ☐ | ☐ |
| 1. Whether support or counselling (if appropriate) for researchers and others involved in the research may be required prior, during and/ or after project completion | | ☐ |  | ☐ | ☐ |
| 1. University travel insurance is required for BSMS staff and students. And, for non-University of Sussex fieldworkers, confirmation of the institution responsible for their indemnification. | | ☐ |  | ☐ | ☐ |
| 1. Measures to protect the wellbeing of all researchers while carrying out research. | | ☐ |  | ☐ | ☐ |
| 1. Lone worker safety: measures to protect the health and personal security/safety of researchers working alone in urban or remote areas. | | ☐ |  | ☐ | ☐ |
|  | **Please note**: BSMS Staff (excluding Doctoral-level students) travelling to undertake fieldwork are required to completed a University of Sussex Overseas Travel Safety and Security Risk Assessment (OTSSRA) form **prior to travel.**  The OTSSRA form is divided into two parts. PART 1 should be completed by ALL staff travelling overseas on University-related business. If the [Foreign, Commonwealth & Development Office (FCDO)](https://www.gov.uk/foreign-travel-advice) has a warning against travel to this destination OR if you are aware that you will be travelling to a place that may be of higher risk, then PART 2 of the form must also be completed. In the event of an FCDO warning then OTSSRA form also requires the signature of the Head of School for BSMS or their signatory.  Forms and further information can be found on the University of Sussex website under ‘Travel on university business and off site working’:<http://www.sussex.ac.uk/hso/specialist/hscovidpage>  Up to date details of FCDO warnings can be found here: <https://www.gov.uk/foreign-travel-advice>  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).  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> | | | | |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
|  | **Recruitment** | | | | |
| 1. The recruitment process for each of the methodologies employed (for e.g. one-to-one interviews; focus groups; observations). The recruitment processes should be described in detail. Will social media platforms be used as a recruitment tool? Their appropriateness for the local context should be specified. Separate participant recruitment materials should be prepared for each methodology and type of participant, unless otherwise justified. | | ☐ |  | ☐ | ☐ |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
|  | **Power dynamics** | | | | |
| 1. Unequal relationships between researcher and participants and the effect on research participation. Include reflection on the positionality of the researcher(s) (the identities, values and power of the researcher and their institutions in relation to research participants and the social and political context of the study). Consider cultural, ethnic and or social hierarchies within those being researched and the research team – i.e. ethnic and caste politics. | | ☐ |  | ☐ | ☐ |
| 1. Whether additional supportive Safeguarding measures are required for the most vulnerable participants. Specify these where necessary. | | ☐ |  | ☐ | ☐ |
| 1. How to ensure more equitable collaboration or ‘benefit sharing’ between UK and local researchers (including, but not limited to, developing research together, opportunities for feedback/discussion, data sharing, opportunities for publications, acknowledgement and fair compensation/allocation of resources). How to ensure that participants are not exploited (by designing truly participatory research and avoiding ‘extractive research’). | | ☐ |  | ☐ | ☐ |
| 1. Conflicts of interest (real and perceived), including for local researchers. Specify management strategies. | | ☐ |  | ☐ | ☐ |
| 1. Include a reflection on the influence of local officials/government on the population and in relation to policy formulation. | | ☐ |  | ☐ | ☐ |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
|  | **Consent process** | | | | |
| 1. Whether all participants will be able to give voluntary, fully informed consent. Provide details of how this will be achieved. Consider participants’ autonomy to give consent which can differ by country context. Consider whether written or verbal consent is most appropriate for the context. Describe how consent will be recorded (e.g. signature, thumbprint, witnessed audio-recorded) and who will be receiving consent. Provide details of the consent process for **each** methodology included in the study. If informed consent will not be specifically sought from individuals (e.g. during observations in some circumstances) provide a justification and details of the alternative processes. | | ☐ |  | ☐ | ☐ |
| 1. Outline the training undertaken by the researchers who will be receiving consent to demonstrate competency to do so. | | ☐ |  | ☐ | ☐ |
| 1. Participants literacy: Participant Information Sheets, Consent Forms, and research tools should be suitable culturally and linguistically for the literacy of the population participating in the research. | | ☐ |  | ☐ | ☐ |
| 1. The language used in documents/ scripts: Technical terms such as ‘mycetoma’, ‘prevalence’ and ‘co-production’ should be described in lay terms that will be understood by research participants. Plans for translation into the appropriate local languages should be described. | | ☐ |  | ☐ | ☐ |
| 1. Differences in the role and status of women/ other participant groups in society, and their implication for the consenting process. | | ☐ |  | ☐ | ☐ |
| 1. Differences in the role of family and community in the consent process and whether approval from community leaders will be required. Make sure to describe the stages of any community consent. | | ☐ |  | ☐ | ☐ |
| 1. How complaints will be reported locally and to whom. (This includes complaints about the research process and also adverse events resulting from participation in the research). | | ☐ |  | ☐ | ☐ |
| **Projects involving multiple sites and/or collaborators. Please check that:** | | **YES** | **If YES, where?** | **NO** | **N/A** |
| 1. For every funded project: A reference to the Collaboration Agreement for the whole collaboration (available via the Research Manager for the grant). | | ☐ |  | ☐ | ☐ |
| 1. All collaborating partners and centres have been named in the Ethical Review Application Form. The nature of the involvement of each participating/ collaborating site must be described. | | ☐ |  | ☐ | ☐ |
| 1. It has been stated which institution is responsible for the legal liabilities associated with the fieldwork (available via the Research Manager for the grant). | | ☐ |  | ☐ | ☐ |
| 1. It has been stated who the data controller will be for the research project, where data transfer will occur between countries. Appropriate data sharing and confidentiality agreements must be in place which cover the project (available for every funded project via the Research Manager for the grant). | | ☐ |  | ☐ | ☐ |
|  | **Please note:** Al**l** 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 and Intellectual Property for assistance. | | | | |
| **Have you considered and addressed the following within your ethics application?** | | **YES** | **If YES, where?** | **NO** | **N/A** |
|  | **Data Management** | | | | |
| 1. Provisions for data monitoring. | | ☐ |  | ☐ | ☐ |
| 1. Data storage plans should consider practicalities such as capacity to store data and internet connectivity, which may be limited in some areas. | | ☐ |  | ☐ | ☐ |
| 1. Are informants aware of possible future uses of the research data? | | ☐ |  | ☐ | ☐ |