Central University Research Ethics Committee (CUREC)

Best Practice Guidance 16_Version 1.1

Title: Ethical review of social science-based research conducted outside the UK

Contents
1. Introduction ............................................................................................................................................. 1
2. General ethics review requirements for research collaborations.......................................................... 2
3. Streamlined ethics review of large Oxford-led collaborative projects with a number of partners and complex sub-studies ........................................................................................................ 2
4. Principles for international research and the case for local oversight ................................................. 3
5. Seeking local ethics oversight from a recognised research ethics committee (REC) ......................... 4
6. Seeking local oversight when there is no research ethics committee (REC) ........................................ 5
7. Special Considerations .......................................................................................................................... 5
   Lack of local oversight capacity ........................................................................................................... 5
   Legitimacy of local oversight ................................................................................................................ 6
   Minimal risk, non-sensitive short-term research projects ....................................................................... 6
A selection of relevant literature: ............................................................................................................. 6
Appendix A: Ethics Issues Checklist for International Research ........................................................... 9

1. Introduction

The University of Oxford seeks to protect the dignity, rights and welfare of all those involved in research (whether they are participants, third parties or staff and students) and to promote high ethical standards of research. One of the guiding principles of the Central University Research Ethics Committee (CUREC) is therefore to ensure the protection of research participants, researchers and the University against harm.

What constitutes harm in research and how it should be prevented is codified in numerous international and national research ethics guidelines, of which the World Medical Association’s (WMA) Declaration of Helsinki is one of the most influential. Many of the existing guidelines, including for research in the social sciences and humanities, have adopted the Declaration’s principles, e.g. those of the Concordat to Support Research Integrity, the Economic and Social Research Council (ESRC) Framework for Research Ethics, as well as the ethics guidelines from the British Sociological Association (BSA), the British Psychological Society (BPS), and the British Educational Research Association, among others. According to the Declaration and other documents, all research involving
human participants should undergo ethical review. Research projects should adhere to the highest standards of research integrity, and consider the security and safety of researchers, fieldworkers, research participants and their data. Before applying for ethical review, researchers should consult departmental safety officers in order to ensure that adequate travel risk assessments and travel insurance are in place for University staff and students before the research project starts. Similarly, data protection issues should be considered thoroughly before applying for ethics review.

The purpose of such review is to identify and assess any potential harms that may emerge during the research against any likely benefits, while ensuring that participants are able to give free and informed consent to their participation in the research. Nowadays, most countries have strong mechanisms for the ethics oversight of research through well-constituted Research Ethics Committees (RECs); however, questions might arise about the most appropriate approaches to ethical oversight for research projects conducted in countries where this is not the case. The purpose of this guidance is to outline ethical principles and practice guidance where social science-based research will be conducted outside the United Kingdom.

2. General ethics review requirements for research collaborations

Some research projects are conducted jointly between two or more institutions – these may be subject to more than one set of ethics approval procedures. Normally, the Principal Investigator should establish whether each institution requires its own ethics approval or whether the institution is prepared to accept approval given by another. If ethical approval is required from more than one institution, adequate time needs to be left to apply to each institution and collaborators need to be prepared to respond to comments from each ethics review and amend their finalised research protocol and supporting documents where appropriate.

Where the University of Oxford is the lead institution, ethical approval from CUREC must be obtained. Compliance with CUREC policy should be prioritised in addition to accommodating the requirements of partner organisations (should multiple approvals be required). Where the University is not the lead institution, the researchers from the University of Oxford should provide the relevant Oxford committee (i.e. the SSH IDREC, OxTREC, or DREC) with the ethics application and approval notice from the lead institution, along with the appropriate application form for the Oxford ethics committee (e.g. a CUREC 1A checklist or OxTREC minimal risk form, or a CUREC 2 form or OxTREC full application (for research that raises complex ethical issues). This will then be reviewed to ensure that the approval already obtained is in accordance with the University’s policy requirements.¹

3. Streamlined ethics review of large Oxford-led collaborative projects with a number of partners and complex sub-studies

In externally funded Oxford-led projects with a large number of sub-studies led by different institutions, each sub-study should be reviewed by the local lead institution (e.g. another UK/overseas university) in the first instance, and by a relevant local research ethics committee in the country of data collection if possible. Ethics approval documents for these will need to be compiled by the Oxford coordinator/Principal Investigator, and the Oxford ethics committee asked for overarching approval of the whole project, with the proviso that the responsibility for each sub-study lies with the ethics committees that have approved this.

¹ This best practice guidance focuses on research ethics applications reviewed by the SSH IDREC and DRECs. For OxTREC requirements please see FAQ B.4 on the CUREC web pages.
Oxford as the overall lead institution (via the Oxford ethics committee) will still need to have a degree of oversight of the sub-studies and consent processes, rather than just keeping on record the relevant local ethics approval letters.

An Ethics Issues Checklist for International Research (Appendix A) may serve as a general guideline of CUREC ethics requirements for other collaborating lead institutions/local ethics boards and topics to consider in these cases. The collaborating university’s lead PI and the relevant local research ethics committee representative should complete, sign and return a copy of this Checklist to the relevant Oxford ethics committee via the lead Oxford PI, together with their ethics approval letters.

This Checklist may also be helpful for University of Oxford researchers applying to the SSH IDREC, OxTREC or DREC prior to conducting international fieldwork involving human participants or personal data, and also may be a particularly useful tool for SSH IDREC and DREC ethics reviewers. The security and safety of both the participants and the researcher(s) are two of the guiding ethical principles of this Checklist.

4. Principles for international research and the case for local oversight

The University expects that the ethical standards set out by national and international guidelines are adhered to, regardless of whether the research is undertaken within or outside the UK. Being outside UK jurisdiction does not justify “ethics dumping” as set out in the Global Code of Conduct for Research in Resource-Poor Settings. Although the University recognises the variety and complexity of situations under which research is

---

undertaken, it nonetheless expects researchers to minimise risks in international research by abiding by the following principles³:

1) Researchers should recognise that what is perceived to be ethical and what is perceived to constitute an acceptable level of risk are not universal.

2) Researchers should be sensitive to local and cultural contexts. These might not always be fully understood by their institutional RECs. Local ethics oversight by a relevant body can highlight social and cultural dynamics and help researchers tailor their protocols accordingly.

3) Research should be relevant and responsive to local needs and any ensuing outcomes should benefit the communities where the research is conducted. However, what counts as a benefit can vary significantly in different contexts. Judgements about benefits should be informed by the views of those who represent the interests of local stakeholders.

4) Researchers should recognise a country’s or community’s sovereignty over their own knowledge production priorities, strategies and processes by acknowledging local systems of oversight where these exist. Bypassing these can be construed as a sign of disrespect that disempowers local institutions. Researchers could also be inadvertently breaching local legal requirements.

5) Researchers should be accountable for their actions while in the field. Their institutional RECs have limited means to enforce accountability, whilst local authorities can provide better oversight by requiring appropriate monitoring, reporting and compliance with local regulations.

In light of the above principles, the University acknowledges the importance of local oversight of projects by a constituted REC or equivalent institution where this is possible.

5. **Seeking local ethics oversight from a recognised research ethics committee (REC)**

As mentioned above, for research projects in which the research takes place entirely overseas, researchers should generally seek, in addition to the lead university’s ethical approval, ethics review and approval from a research ethics committee in the country in which the research is to take place⁴.

Researchers should note that:

- Projects that take place both in the UK and overseas will always require appropriate ethical approval from a UK institution for those aspects of the research that takes place in the UK.
- Some funders require dual ethical review both in the UK and overseas.

It is the Principal Investigator’s responsibility to comply with funders’ conditions and any local requirements, including data protection. Local ethics approval (and the Ethics Issues Checklist for International Research (Appendix A), if applicable/required) should be appended to the application when submitting to the relevant Oxford ethics committee.


However, please also see information about informal research ethics reviews in section 6 and special considerations in section 7 below.

6. Seeking local oversight when there is no research ethics committee (REC)

In some countries local ethics committees do not exist. In these cases, oversight should ideally be sought from a relevant institution. This could be from the organisation(s) where the research is to be conducted, a relevant authority or other organisation (e.g. a national or local ministry, government agency, embassy, NGO), or a recognised local structure or other channels (for example, many indigenous communities have well constituted Councils).

While concrete guidance may be difficult, researchers should make every effort to ensure local oversight by working in partnership with local research or civil organisations (e.g. NGOs). These should be recognised and trusted gatekeepers of the communities in which the research is to take place. Local partners should act in the best interests of the participants, even if they are directly involved in the research.

They should be competent to help researchers in complying with local systems and regulations and to highlight relevant cultural norms and expectations.

Establishing local collaborations is particularly important to provide research participants with accessible channels for complaints, as complaining directly to the University of Oxford might be unfeasible due to cost, language or limited means of communication. The name of the local contact should be provided to the participant (e.g. in a participant information sheet (PIS), if appropriate). They must agree to forward all written and verbal complaints to the Principal Investigator in the first instance. If the Principal Investigator cannot resolve the issue within a reasonable timeframe, the local contact must then forward the concern or complaint to the appropriate Oxford ethics committee as soon as feasible.

7. Special Considerations

Whilst the University of Oxford requires local ethics oversight, this might be waived in light of specific local conditions. In these circumstances, the principle of “comply or explain” must be followed, i.e. researchers must provide explicit and transparent written justification in their ethics application of why local oversight has not been sought.

Circumstances in which local ethical oversight might be unfeasible or undesirable may include but are not restricted to:

**Lack of local oversight capacity**

In many countries, the infrastructure for ethics oversight might be limited, absent and/or contested. Regulatory requirements, including for ethics oversight, may not be readily accessible or easy to understand. Navigating the local bureaucracy is a common

---


challenge for external researchers who are often not totally aware of the cultural context within which they need to operate.

Local structures of oversight, when existent, may also have limited ethics expertise or enforcement capacity.

Local structures may not secure the safety of researchers or participants in their research.

**Legitimacy of local oversight**

Bearing in mind the principles articulated at section 4 (especially points 1-3) above, it may be that local structures of oversight, whether in the form of RECs or other institutions, may not always work for the benefit of the people intended to benefit from ethical oversight.

In some cases, local structures of oversight may be reluctant to approve research on sensitive issues or topics that might be controversial.

**Minimal risk, non-sensitive short-term research projects**

In some cases, gaining formal additional local ethics review may not be feasible or practical for certain low-risk, short-term research projects (e.g. students' brief non-sensitive interviews with experts/élites outside the UK).

It is important that the Principal Investigator/ the researcher’s supervisor (if applicable) and departmental CUREC signatory (i.e. head of department or nominee) are aware of and supportive of cases where local ethics review is not appropriate or may not be sought. In these cases, the signed CUREC application form should clearly explain why additional formal local ethics approval is not being sought before the project starts.

As mentioned above, alternative local ethics guidance or local permissions (e.g. through local contacts/organisations/research collaborators) should be obtained whenever possible, even for minimal risk research projects.

In these cases, applicants could refer to the **Ethics Issues Checklist for International Research** *(Appendix A)* and address the topics in this as appropriate when preparing their ethics application, in order to demonstrate their awareness of potential ethical issues in international settings. The DRECs and SSH IDREC Secretariat should consider whether this is appropriate on a case-by-case basis.

**A selection of relevant literature:**

- British Educational Research Association (BERA), *Ethics and Guidance*, [https://www.bera.ac.uk/researchers-resources/resources-for-researchers](https://www.bera.ac.uk/researchers-resources/resources-for-researchers) (accessed 6 June 2019)


- CUREC Best Practice Guidance documents, including on elite and expert research and researcher safety, https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg (accessed 6 June 2019)


APPENDIX A: ETHICS ISSUES CHECKLIST FOR INTERNATIONAL RESEARCH

The University of Oxford’s Central University Research Ethics Committee (CUREC) and its sub-committees are responsible for reviewing all research involving human participants and personal data. Important topics for the review of human participant and personal data research conducted in international settings are listed below. This Checklist does not replace the CUREC 1A or CUREC 2 ethics application forms, but may be a useful prompt of potential ethical issues to consider when completing the application forms in certain cases, to ensure that the PI/researcher has given adequate consideration to address possible areas of concern in the local research context.

In the case of collaborations involving a large number of international sub-studies (see Best Practice Guidance on ethical review of social science-based research conducted outside the UK (above), this Checklist should be helpful to demonstrate thorough ethical consideration by collaborating lead institutions and/or local ethics review boards, and should be completed and signed by their ethics committees and sent to their CUREC sub-committee, together with relevant ethics approval letters.

<table>
<thead>
<tr>
<th>Have you considered and addressed the following within your ethics application?</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cultural considerations</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Differences in cultural and societal norms and practices</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Communication, including using local language(s)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Local contact information for persons who can answer research-related questions, including local emergency contact information and participants’ rights</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Whether local ethics structures of oversight have been found and consulted (see BPG16, sections 5-7)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. The need for local permissions to conduct the research</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Political risks that your department/university should be aware of before the research begins</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>Benefits and risks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Relevance and benefits of the research to the area and to the participants, including once the project has ended</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. Awareness of differences in understanding what counts as a benefit</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9. Local legal rights of the population/potential legal issues or risks caused by the research</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. Provisions for counselling research participants prior, during and/or after the research</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Appendix A: Ethics Issues Checklist for International Research

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Have you considered and addressed the following within your ethics application?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Whether the research is likely to generate suspicion or adverse interest from local officials/ government, local security agencies, and/or any other part of the community</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12. Possibility of involving local people in the design, conduct or monitoring of the research</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13. Provisions for safety monitoring</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>14. Provisions for data monitoring</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>15. Provisions for providing support or counselling to researchers and others involved in conducting the research prior, during and/or after the research</td>
<td>☐</td>
<td>☐</td>
<td>☒</td>
</tr>
<tr>
<td>16. Whether departmental/ University travel insurance has been gained and a risk assessment completed (and, for non-Oxford fieldworkers, whether local fieldworkers will be locally insured)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>Power dynamic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Unequal relationships between researcher and participants</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>18. Additional measures for participants at risk</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>19. Provisions to ensure that participants are not being exploited (avoiding 'extractive research')</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>20. Economic prosperity of the area</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>21. Conflicts of interest (real and perceived)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>22. Influence of local officials/ government on the population</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>Consent process</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23. Whether all participants will be able to give voluntary, fully informed consent.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>24. Participants’ literacy</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>25. Whether documents/ scripts are written in lay language, tailored to the participants</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>26. A suitable approach to obtaining and recording participants’ consent</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>27. Differences in the role and status of women/ other participant groups in society/ gender issues</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>28. Differences in the role of family and community in the consent process</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>29. How complaints will be reported and to whom</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>Projects involving multiple sites</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. Nature and role of each participating/ collaborating site</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>31. For large consortiums: whether sub-studies have gained local ethics approval, and if so, whether evidence of local ethics approval will be sent to the relevant Oxford ethics committee, together with this Checklist.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Have you considered and addressed the following within your ethics application?</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>32. Whether appropriate data sharing agreements and confidentiality agreements are in place</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

For collaborations involving a large number of international sub-studies, the PI and local ethics committees should complete, sign and submit this Checklist to their CUREC sub-committee, together with relevant ethics approval letters.

__________________________
Date and Signature of Principal Investigator (Oxford)

__________________________
Date, signature and contact details of partner institution/University (if applicable)

__________________________
Date, signature and contact details of local research ethics committee in country of fieldwork (if applicable)