Central University Research Ethics Committee (CUREC) Best Practice Guidance 16_Version 2.3 Research conducted outside the UK



Research conducted outside the UK

Contents

1.	Introduction	1
2.	Principles for international research and the case for local oversight	2
3.	Seeking local ethics oversight from a recognised research ethics committee (REC)	3
4.	Special considerations	3
a)) Lack of appropriate oversight capacity	3
b) Clear lines of accountability	4
c)	More straightforward short-term research projects	4
5.	Seeking local oversight when there is no research ethics committee (REC)	4
6.	Research collaborations	5
7.	General ethics review requirements for research collaborations	5
8.	Streamlined ethics review of large Oxford-led collaborative projects with a number of partners and complex subprojects	6
9.	References and further guidance:	7
10.	APPENDIX A: Ethics issues checklist for research conducted outside the UK	8

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. In accordance with the University's <u>Research Ethics Policy</u>, all research involving human participants must undergo ethics review. The purpose of the ethics 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. The purpose of this guidance is to outline ethical principles and practice guidance where research will be conducted outside the United Kingdom, in addition to the <u>University of Oxford's ethics review process</u>. 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 ethics review, researchers should refer to the <u>Safety Office's guidance on travel</u> <u>for University business</u> and 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. Researchers must ensure the research project has received appropriate authorisation within their Department and/ or from the Safety Office and that the project is adequately insured.

Similarly, <u>data protection issues</u> should be considered thoroughly before applying for ethics review. Data protection legislation may differ between countries, these differences should be taken into consideration when planning the collection, transfer and storage of research data, particularly if any individuals can be identified from the data. <u>Guidance on transferring data between countries</u> is available.

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

The University expects the ethical standards set out by national and international guidelines to be 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 Settings¹. 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 principles²:

- Researchers should recognise that what is perceived to be ethical and what is perceived to constitute an acceptable level of risk, are not universal. Different topics may be upsetting or cause anxiety to interviewees.
- 2) Researchers should be sensitive to local and cultural contexts. These might not always be fully understood by their institutional research ethics committees. 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. The consequences must not be detrimental to the communities where the research is conducted and should ideally be of benefit. However, what counts as a benefit can vary significantly in different contexts. For example, for a research project involving investigating and documenting the history of an area, the research team might agree to provide materials for the local museum. Judgements about benefits should be informed by the views of those who represent the interests of local stakeholders.
- 4) Researchers should recognise national and local systems of oversight. Bypassing these can be construed as a sign of disrespect that disempowers local institutions and communities.
- 5) Local laws and regulations should be followed. Researchers should be very cautious about any context in which they may inadvertently breach local legal requirements.
- 6) Researchers should be accountable for their actions while in the field. Their institutional Research Ethics Committees (RECs) have limited means to enforce accountability, whilst local authorities can provide better oversight by requiring appropriate monitoring, reporting and compliance with local regulations.

¹ Please see the <u>Global Code of Conduct for Research in Resource-Poor Settings</u>

² Taken from Cochrane, L., Boulanger, R.-F., Sheikheldin, G.-H., Song, G. (2018), 'The Case for Local Ethics Oversight in International Development Research', Canadian Journal of Bioethics, 1. 8-16., <u>https://cjb-rcb.ca/index.php/cjb-rcb/article/view/12</u>

In light of the above principles, the University acknowledges the importance of local oversight of projects by a constituted research ethics committee (REC) or equivalent institution/ body.

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

As mentioned above, for research projects in which the fieldwork takes place overseas, researchers should seek, in addition to the lead university's ethics approval, ethics review and approval from a research ethics committee or equivalent institution/ body in the country in which the research is to take place³. Exceptions to this are discussed in <u>Section 4</u> and researchers are expected to demonstrate in their application how their circumstances fit within one or more of these exceptions.

It is the Principal Investigator's responsibility to comply with funders' conditions and any local requirements, including data protection and to keep records of all ethics approvals obtained. Some funders require dual ethics review both in the UK and overseas. Local ethics approval (and the <u>Ethics</u> <u>Issues Checklist for International Research</u> (Appendix A), if applicable/ required) should be appended to the application when submitting to the relevant CUREC subcommittee. However, please also see information about informal research ethics reviews in <u>section 5</u> and special considerations in <u>section 4</u>.

4. Special considerations

Whilst researchers should seek local ethics oversight, this may be waived in light of specific local conditions. In these circumstances, the principle of "comply or explain" must be followed⁴, 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 ethics oversight might be unfeasible or undesirable may include but are not restricted to⁵:

a) Lack of appropriate oversight capacity

It is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants. In some countries, the infrastructure for ethics oversight might be limited, patchy, absent and/or contested for certain disciplines. Regulatory requirements, including for ethics oversight, may not be readily accessible.

Local structures of oversight, when existent, may also not be suitable to the research at hand or have limited ethics expertise relevant to the discipline. For instance, medically-oriented RECs might not be well placed to review some social sciences/ humanities research projects. If this is the case

http://www.globalcodeofconduct.org

³ The following guidance may be helpful: U.S. Department of Health & Human Services, Office for Human Research Protections, *International Compilation of Human Research Standards*,

https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html ⁴ Please see Global Code of Conduct for Research in Resource-Poor Settings

⁵ Please see Cochrane, L., Boulanger, R.-F., Sheikheldin, G.-H., Song, G. (2018), 'The Case for Local Ethics Oversight in International Development Research', Canadian Journal of Bioethics, 1. 8-16., <u>https://cjb-rcb.ca/index.php/cjb-rcb/article/view/12</u> for a fuller discussion of these exceptions.

the PI should provide a response from the appropriate body confirming that they are not able to carry out the ethics review.

b) Clear lines of accountability

The Principal Investigator (PI) is responsible for the intellectual leadership of the research project and for the overall management of the research. The number of people involved in conducting and supporting the research will vary but clear lines of accountability are essential⁶. It is important that everyone involved understands and agrees to what they are being asked to do, including any associated risks. The PI must consider the nature of the involvement of local parties and put measures in place to address any risks of harm to individuals connected to the research or others affected by it. CUREC's <u>Best Practice Guidance (01) on Researcher Safety</u> should be followed and risks to others involved in the research addressed through the <u>risk assessments</u>.

c) More straightforward short-term research projects

In some cases, gaining formal additional local ethics review may not be feasible or practical for more straightforward, short-term research projects (e.g. a researcher conducting a small number of interviews on subjects that are very unlikely to cause significant problems).

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.

In these cases, applicants may find it helpful to refer to the <u>Ethics Issues Checklist for International</u> <u>Research</u> (**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.

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

In some countries local ethics committees do not exist. In these cases, oversight could instead 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.

⁶ The good research conduct guidance on publication, authorship and peer review must also be followed.

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 University of Oxford ethics committee as soon as feasible.

6. Research collaborations

Against a backdrop of historic inequities between Northern and Southern scholars, "meaningful and equitable" research collaborations between Northern-based academics and partners in the Global South are identified as a marker of ethically defensible research, and indeed in many cases a nonnegotiable requirement for funding. However, despite decades-long debates about equity in international research, at the operational level achieving truly equitable collaborations remains a challenge due to the structural factors creating differentials in institutional research capacity and researchers' capabilities. Whilst it is unrealistic to expect research partnerships to address structural inequalities, it is important nonetheless to think creatively when designing collaborative projects so that opportunities are created for all parties to contribute to and benefit from the partnership. Partnerships are expected to demonstrate, through the establishment of appropriate research management processes, a commitment to co-creation and co-ownership of the research project. This may be achieved, for example, through financial arrangements to share budgetary responsibility, early and substantive engagement between partners at inception stage to co-design research aims, objectives and methodologies, or shared decision power in project execution⁷. Equity in collaborative international research is a factor that ethics committees should take into consideration when conducting the ethics review.

The recent Coronavirus pandemic has shown researchers' astounding capacity for innovation and adaptation. Many projects have successfully circumvented travel and social distancing restrictions by creatively deploying online tools and other technologies to replace face to face interactions both with partners as well as with research participants. This not only throws into question old models of fieldwork, requiring successive trips abroad, and often rightly labelled as "parachute" or "extractive" research, but it also represents an opportunity for capacity development by increasing the agency of local researchers. Whilst reliance on online communication tools can never replace face to face interaction, they should nonetheless be more extensively embedded into projects and used to distribute power among partners, allowing local researchers a greater degree of autonomy and responsibility "on the ground". On ethical as well as on environmental grounds, project plans should include, where feasible, steps to avoid unnecessary travel and maximise opportunities for local leadership and thus more equitable collaborations.

7. 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

⁷ For guidance on Fair Research Contracting see <u>https://www.cohred.org/frc</u>.

should establish whether each institution requires its own ethics approval or whether the institution is prepared to accept approval given by another. If ethics 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, ethics approval from a CUREC subcommittee 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, MS IDREC, OXTREC, or DREC) with the ethics application and approval notice from the lead institution. This will then be reviewed to ensure that the approval already obtained is in accordance with the University's <u>policy</u> requirements⁸.

8. Streamlined ethics review of large Oxford-led collaborative projects with a number of partners and complex subprojects

The <u>Ethics Issues Checklist for International Research</u> (Appendix A) may be a helpful prompt for researchers and reviewers, whether based at the University of Oxford or elsewhere. The security and safety of both the participants and the researcher(s) are two of the guiding ethical principles of this Checklist.

In externally funded Oxford-led projects with a large number of subprojects led by different institutions, each subproject should be reviewed by the local lead institution (e.g. by the appropriate CUREC subcommittee for projects with an Oxford PI, or another UK/ overseas university if Oxford researchers are not leading the research project) in the first instance, and by a relevant local research ethics committee in the country of data collection if possible.

In order to obtain overarching ethics approval from the University of Oxford for the whole collaboration or consortium, the following information will also need to be submitted to the relevant CUREC subcommittee:

- a) Basic details about the project (PI, funder, start and end dates, institutions involved, locations and information about any subprojects)
- b) Evidence of local ethics approval for each subproject, or if local ethics approval is not possible, a completed checklist for international research for each subproject (see <u>Appendix</u> <u>A</u>) The collaborating university's lead PI 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.
- c) An overview of the main ethical issues presented by each subproject and an overview of how these will be addressed.

The responsibility for ethics oversight of each subproject lies with the ethics committees that have approved it.

⁸ This best practice guidance focuses on research ethics applications reviewed by the SSH IDREC, MS IDREC and DRECs. For OxTREC requirements please see <u>FAQ B.4</u> on the CUREC web pages.

9. References and further guidance:

- British Educational Research Association (BERA), Ethics and Guidance
- British Psychological Society (BPS), <u>Code of Ethics and Conduct</u> (2018)
- British Sociological Association (BSA), Guidelines on Ethical Research
- Cochrane, L., Boulanger, R.-F., Sheikheldin, G.-H., Song, G. (2018), 'The Case for Local Ethics Oversight in International Development Research', Canadian Journal of Bioethics, 1. 8-16. 10.7202/1058307ar, <u>https://cjb-rcb.ca/index.php/cjb-rcb/article/view/12</u>
- Council on Health Research for Development: <u>Research Fairness Initiative</u>
- <u>CUREC Best Practice Guidance documents, including on elite and expert research, research</u> <u>data management and researcher safety</u>
- Economic and Social Research Council (ESRC), <u>Framework for Research Ethics</u> (2016)
- <u>Code of Conduct for Ethical Fieldwork</u> (2022)
- Gearon, L. and Parsons, S. Major (2018) 'Research Ethics in the Securitised University', Journal of Academic Ethics, DOI: 10.1007/s10805-018-9317-2, <u>https://link.springer.com/article/10.1007/s10805-018-9317-2</u>
- Global Code of Conduct for Research in Resource-Poor Settings
- Song, G. (2018). Guyana, 'How Do You Know Where to Get the Information You Need? Determining Ethics Approval Requirements in a Developing Country', Canadian Journal of Bioethics/ Revue canadienne de bioéthique, 1 (1), 17–20. <u>https://doi.org/10.7202/1058308ar</u>
- The <u>Social Sciences Division's guidance on research fieldwork</u>.
- Stefanoudis, P. & al., (2021). Turning the tide of parachute science. Current Biology, 31(4), 184-185. <u>https://doi.org/10.1016/j.cub.2021.01.029</u>
- U.S. Department of Health & Human Services, Office for Human Research Protections, International Compilation of Human Research Standards
- Universities UK, <u>The Concordat to Support Research Integrity</u>
- University of California, Berkeley, Committee for Protection of Human Subjects (CPHS), <u>International Research Checklist</u>
- University of California, Berkeley, Human Research Protection Program, <u>Human Subjects</u>
 <u>Research in an International Setting</u>
- University of Oxford, <u>GDPR checklist and guidance</u>
- University of Oxford, <u>Information Security website</u>
- Williams, C., Doing International Research: Global and Local Methods, Sage Publications (2015), <u>http://methods.sagepub.com/book/doing-international-research-global-and-local-methods</u>
- Woodall, L. C., Talma, S., Stefanoudis, P., & al., (2021). Co-development, co-production and co-dissemination of scientific research: a case study to demonstrate mutual benefits. Biology Letters, 17(4). <u>https://doi.org/10.1098/rsbl.2020.0699</u>
- World Medical Association: Declaration of Helsinki, <u>Ethical Principles for Medical Research</u> <u>Involving Human Subjects</u>

10. APPENDIX A: Ethics issues checklist for research conducted outside the UK⁹

The University of Oxford's Central University Research Ethics Committee (CUREC) is responsible for implementing the University's <u>Research Ethics Policy</u>. Important topics to consider for research conducted in international settings are listed below.

The checklist is expected for large Oxford-led collaborative projects where local ethics approval is not possible, to ensure that the PI/ researcher has considered possible areas of concern in the local research context (see <u>section 8</u> above). The CUREC subcommittee may ask to receive annual ethics monitoring reports as an alternative to reviewing the detail of the subprojects.

In all other cases, including when planning research within the UK, it is not formally expected but may be a useful prompt of potential ethical issues to consider when completing the application form.

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

This checklist does not replace the CUREC 1/ 1A or CUREC 2 ethics application forms.

⁹ Based on guidelines produced by the <u>University of California</u>, Berkeley, and excerpts from WHO/EMRO/ERC guidance. (University of California, Berkeley, Committee for Protection of Human Subjects (CPHS), International Research Checklist, <u>https://cphs.berkeley.edu/international research checklist.pdf</u> and World Health Organization, Research Ethics Review Committee (ERC), <u>guidelines on submitting research proposals for ethics review</u>.

				-
Have you considered and addressed the following within your ethics application?		YES	NO	N/A
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			
12.	Possibility of involving local people in the design, conduct or monitoring of the research			
13.	Provisions for safety monitoring			
14.	Provisions for data monitoring			
15.	Provisions for providing support or counselling to researchers and others involved in conducting the research prior, during and/ or after the research			
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)			
Ρο	wer dynamics			
17.	Unequal relationships between researcher and participants			
18.	Additional measures for participants at risk			
19.	The scope for equitable collaboration between UK and local researchers			
20.	Provisions to ensure that participants are not being exploited (avoiding 'extractive research')			
21.	Economic prosperity of the area			
22.	Conflicts of interest (real and perceived)			
23.	Influence of local officials/ government on the population			
Со	nsent process			
24.	Whether all participants will be able to give voluntary, fully informed consent.			
25.	Participants' literacy			
26.	Whether documents/ scripts are written in lay language, tailored to the participants			
27.	A suitable approach to obtaining and recording participants' consent			
28.	Differences in the role and status of women/ other participant groups in society/ gender issues			
29.	Differences in the role of family and community in the consent process			
30.	How complaints will be reported and to whom			
Pro	jects involving multiple sites		_1	<u> </u>
31.	The nature of the involvement of each participating/ collaborating site			
32.	For large consortiums: whether subprojects 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.			

Appendix A: Ethics issues checklist for research conducted outside the UK

Have you considered and addressed the following within your ethics application?	YES	NO	N/A
33. Whether appropriate data sharing agreements and confidentiality agreements are in place			

For collaborations involving a large number of international subprojects, where local ethics approval is not possible, the PI and local ethics committees should complete, sign and submit this Checklist to their CUREC subcommittee.

Date and Signature of Principal Investigator (University of Oxford)

Date, signature and contact details of collaborating university's lead PI (if applicable)