



Human Research Participant Protection Program

Guidance on IRB Review of International Research

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I. Subject:

Research conducted by Cornell University investigators outside of the United States remains subject to all U.S. regulations and University policies that govern the conduct of research with human participants in the United States. However, each country has its own laws and regulations, social and economic conditions, and customs and norms, that need to be considered when conducting research with human participants outside the U.S. This document is intended to provide guidance on these matters when conducting research with human participants outside the U.S., and to outline additional information required as part of an application for IRB review.

These guidelines apply for research that involves the active collection of data from human participants outside the U.S., as well as to research that involves the analysis of existing data that were collected outside the U.S.

All investigators are strongly encouraged to **collaborate with a local organization** (e.g. hospital, research institution, university or college, academic disciplinary research group) in the country or region where research is being conducted. Often, such organizations have an established mechanism for conducting an ethical review of the research, whether it is through a registered IRB or another acceptable process.

II. International studies that pose no more than minimal risk for participants

Some research with healthy adult volunteers poses no more than minimal risk, and requires only an application for IRB review or certification of exemption, when conducted outside the U.S. The following types of studies conducted outside of the U.S. are generally considered to pose no more than minimal risk to participants:

- online surveys, and on-line minor experiments and manipulations;
- survey and interview procedures, where no sensitive, potentially embarrassing, or personally damaging information is collected;
- normal education practices in normal educational settings, and educational tests;
- observation of public behavior; and
- the study of existing data, documents or records, or human specimens, that contain private identifiable information.

Such studies generally can be reviewed by the Cornell IRB office without an ethical review by a local ethical review body. Investigators must also determine if local laws and regulations govern the research or whether any local permission is needed to conduct the research, and must comply with those requirements. [Please see the US-DHHS, OVRP, International Compilation of Human Research Standards ([current edition 2014](#)).]

If members of the research team will interact face-to-face with local study participants, research materials submitted to the IRB office will need to include information about how members of the research team are **prepared for research in the host country, including language/communication and cultural awareness** (e.g. prior experience in this country or with similar research in another country, training or expertise that demonstrates cultural competence, access to local knowledge through cultural mentors, language proficiency). Investigators should consider the cultural issues outlined in Appendix A that are relevant to their research project. Additionally, they must provide a letter of support from a local organization or community leader, or explain how they will ensure they are invited into the local community if there are no formal organizations with which they will work.

III. International studies that pose more than minimal risk for participants

Some research may pose risk to participants that they would not encounter in their ordinary daily lives, because:

- the study includes **biomedical or clinical procedures**;
- the study involves **vulnerable populations** such as children, pregnant women, individuals with limited autonomy (e.g. prisoners, women in some cultural contexts) or individuals at extreme disadvantage;
- the data collected include **sensitive, potentially embarrassing or personally damaging information** in the cultural context in which they are collected; or
- **local social, political or economic issues** may make research participation, or accidental disclosure of private information, risky.

For any study where participants outside of the U.S. may be at some risk from research participation (even if that risk is mitigated by the investigator) that they would not encounter in their normal daily lives, the Cornell IRB requires an additional review of the proposed study by a local IRB or ethical review body. Investigators should submit documentation regarding this review (application materials submitted to the local review board, approval notices and any other relevant documents) as part of their application to the Cornell IRB.

The Cornell IRB may accept the review and approval by the local review board or ask for additional protections of human participants beyond what is required by the local ethical body.

Three approaches to local ethical review are outlined below. These approaches are ranked from strongest to weakest, such that applications that receive local reviews through processes described higher on this list generally will require the submission of less additional information than will applications that receive local reviews described lower on the list.

A. Research is reviewed and approved by a local, registered IRB

If the research is reviewed and approved by an IRB in that country, with an active and valid Federalwide Assurance (FWA) with the US Office of Human Research Protections (OHRP) and registration with the local government or regulatory body, the Cornell IRB will ordinarily accept this review as indication of local acceptability of the research study.

Investigators should submit proof of approval by the local IRB, as well as the FWA # of the registered IRB, with their application to the Cornell IRB. When the local IRB requires Cornell IRB approval before granting approval, the Cornell IRB office can issue a conditional approval for the project.

B. Research is reviewed by local ethical review body that is not a registered IRB

In some cases, access to a registered IRB is not feasible. There may exist, however, local semi-formal ethics boards or committees that have been set up by local institutions or organizations. Review and approval by such local ethics boards may be acceptable in many research situations. If using this review mechanism, applications to the Cornell IRB should include a description of the credentials of this review board, a copy of the application that was approved by the board, and the letter of approval. Appendix B suggests some considerations for investigators in assessing the relevance, qualifications and credibility of the ethical body that will conduct local review of their study.

For studies that involve biomedical or clinical procedures, the local ethical review must be conducted by a body with relevant clinical expertise.

C. There is *no* established mechanism for local ethical review

If the planned study is to be conducted in an area where there is no established mechanism for local ethical review, the investigator may need to identify a group of qualified individuals to perform local ethical review. In identifying the local ethical body, investigators must assure that the members of the group are not part of the research team, and have no conflict of interest with the research project or its findings. Local community leaders (e.g. community representative in the local government), authority figures (e.g. tribal chief), non-collaborating research colleagues, or informed members of the community may comprise this group. A letter of support from this local group will be necessary for the research to take place.

IV. Data Security

Data security is a concern for all research projects. When research is conducted in foreign countries, however, some additional issues concerning data security arise. Investigators should consult the Cornell IT Security office (phone and email) or the IT support staff at their College or Department, for advice on keeping data secure from loss or breach. Some best practices are provided here:

A. General

- Take steps to protect from loss from theft or otherwise, any electronic devices or documents that might have participant data.
- Understand export and customs laws that govern computing devices and data in the country, and those of any country through which you will be passing; and take steps to manage and protect your data in compliance with those requirements.

B. To prevent the possibility of data loss of paper files, field notes, recordings, or other records:

- Transcribe and electronically store notes as quickly as possible.
- Keep a back-up copy of the electronic files either in [Cornell BOX](#) (with restricted permissions), or upload and send them via [Cornell Dropbox](#) to yourself or a research colleague. Files sent via Cornell Dropbox can be downloaded up to 21 days after they were first uploaded. Both Cornell BOX and Cornell Dropbox are accessed via Cornell NetID login, and are free to Cornell personnel.

C. To prevent exposure of data that was obtained under a promise of confidentiality:

- Collect the minimum amount of identifiable data needed
- Use systems to mask the identities of participants
- Minimize the number of local research staff members who have access to identifiable data
- Transcribe, encrypt, and electronically store notes as quickly as possible and destroy physical files if possible. Otherwise keep them secure under your control.
- Protect computers and all electronic devices, and individual files, with '[complex](#)' passwords.
- Encrypt all data (see information about [Cornell encryption methods](#))
- Do not store identifiable data in Cloud file share locations (e.g. Google docs)
- Do not transmit identifiable data via e-mail
- Store identifiable data on mobile devices only when the device is encrypted; and only as long as it takes to access a secure internet connection and upload encrypted data to [Cornell Dropbox](#)
- *Always* upload to Cornell Dropbox and erase files from mobile devices before crossing international borders

REFERENCES

University of Minnesota Institutional Review Board (2009).

- Guidance and FAQs: IRB Review of International Research
<http://www.irb.umn.edu/guidance/international.html>
- Appendix K: International Research
<http://www.research.umn.edu/irb/forms/apxK.docx>

University of Central Oklahoma in Edmond Institutional Review Board (2011).

- Research Compliance Standard Operating Procedures: SOP 505 Research at International Sites.
<http://www.uco.edu/academic-Affairs/research-compliance/sops/index.asp>
- International IRB Application
<http://www.uco.edu/academic-Affairs/research-compliance/files/documents/International%20IRB%20Application%20REV.5-12.pdf>
- International IRB Checklist
<http://www.uco.edu/academic-Affairs/research-compliance/files/documents/International-IRB-Checklist.xlsx>

Yale University Institutional Review Boards (2011).

- IRB policy 450: International Research
<http://www.yale.edu/hrpp/resources/docs/IRBPolicy450InternationalResearch5-25-11.pdf>
- 450 GD.1 International Research: Required Documents and Additional Considerations
<http://www.yale.edu/hrpp/resources/docs/450GD1Internationalresearchdraft5-25-11.pdf>
- 450 CH.1 International Research Checklist
http://www.yale.edu/hrpp/resources/docs/450CH15-13-11_001.doc

US-DHHS, Office of Human Research Protections (OHRP) (2014). International Compilation of Human Research Standards.

<http://www.hhs.gov/ohrp/international/index.html>

APPENDIX A: Cultural Relevance Topics

All of these issues will not apply to every research protocol, but the relevancy of each should be considered by the investigator. Please consider those that are relevant to your international research project.

1. Context in which the research will take place
 - How do local officials or leaders influence the population?
 - How does the economic prosperity or poverty of the area influence the prospective study population?
 - How might locally sensitive issues (e.g. race/ethnicity, gender, politics, religion, sexual orientation, union membership) affect the risk of participation in this research?
 - What relevant current events should be considered in assessing risk to participants?
2. Communication with participants is appropriate to context
 - In what language will the research be conducted, and how do you know that this language is most appropriate to the research population?
 - What is the investigator's local language proficiency, or how does the investigator plan to communicate with participants?
 - How do you know that literacy levels and language complexity of research materials are appropriate for the research population?
3. Consent procedures meet or exceed U.S. norms for autonomous decision-making
 - If there is risk of coercion in gaining consent, how will you mitigate this risk?
4. Consent procedures are consonant with local customs and norms
 - Are research participants able to give their own consent? (considering age, gender, and citizenship, for example)
 - Are there privacy laws that may interfere with informed consent assurances?
 - How appropriate is the use of written consent? (Written consent can be culturally inappropriate, intimidating, and in some contexts is considered riskier than participation in the research itself.)
 - Will the consent procedures be pre-tested?
5. Confidentiality
 - How might the local setting for data collection impact your ability to maintain privacy?
 - Are investigators required by law to report illegal activity that they discover?
 - Are there privacy laws that may interfere with confidentiality?
 - How will confidentiality be maintained?
6. Compensation is appropriate

- How do you know that compensation is provided in a locally appropriate form?
 - How do you know that the amount of compensation does not provide undue influence in the local economic context?
7. Safety of participants (and research staff)
- Are there special safety considerations for research staff in this area?
 - How do you know that travel to the research site is safe for participants?
 - Is the country or area politically stable?

APPENDIX B: Considerations in selecting a local ethical body to review your research project

1. What is the ownership structure and scope of the ethical review body?
 - Is the review body and its members independent of the research team? Do they have any conflict of interest with the research project or its findings?
 - Years of operation
 - # of committee members and their terms (do they rotate too often? Do they not rotate at all?)
 - the disciplines and community perspectives represented on the committee
2. What expertise does the ethical review body have in reviewing the proposed research?
 - Recent relevant topics/projects reviewed
3. What is the track record of the ethical review body with known investigators?
 - Prior review of research for this investigator or the advisor of a student investigator
 - Prior review of protocols for another investigator from Cornell or from another US University
4. What is the quality of review by this committee?
 - Are they considerate of the basic principle of human subject protection (autonomy, voluntary participation, fair selection, minimize risk and maximize benefit to participants)?
 - Past history of the research projects approved by this board- were they thoughtfully designed and executed?