**International Research**

Additional review and documentation are required from the international site and the LCU IRB when doing international research. It will be necessary for you to start the process early to allow for a complete review of your proposal. Application should be submitted 90 days in advance of departure for the international research site. It is necessary to provide adequate time for review. When determining a timeline, take into account time: for development of accurate translations, political and economic instability, communication capabilities, the need to locate translators and advocates, and how frequently regulatory bodies meet.

## ****Regulations****

All of the regulations that apply in the US and the international research site must be met when conducting international research. The research team should provide the LCU IRB with a copy of regulations for the proposed international site when submitting a proposal.

## ****Additional Regulatory**** Reviews

Documentation Required for Minimal Risk Studies **in** Countries That Do Not Require Ethics Committee Review**:** Some countries do not require a review by a local ethics committee for a minimum risk study. However, the study still must be reviewed by LCU – i.e. the absence of local evaluation does not exempt a study from IRB review. Rather, it simply indicates that this study may proceed without additional review from the host site. The research team is responsible for contacting the appropriate entity to make the determination. Two forms of documentation should be presented to the LCU IRB if review is not required.

 1. **Letter of Cultural Appropriateness:** The letter ***must*** be authored by an individual independent of the study who is highly familiar with the culture of the region where the research will be conducted. (examples: A teacher, a preacher, a doctor, or a local official)

 The letter **must**:

 a. Be dated

 b. State the title of the research protocol

 c. Describe the expertise of the individual preparing the letter

 d. Include a statement indicating the purpose of the research

 e. Include a statement indicating the methodology to be used

 f. Confirm that the planned study does not conflict with local cultural norms

 g. Include a signature from the individual writing the letter

 2. **Documentation that Local Regulations do not require Ethics Review**: Provide at least one of the following.

 Direct references to local regulations stating ethics review is not required.

 And/or

 “Letter of Acknowledgement of Unregulated Research Activities” confirming that local ethics review is not required. This document must come from an appropriate regulatory official (examples: A chairman of an IRB, a University Administrator or Government Official such as a Director of the Ministry of Health).

 The letter of Acknowledgement of Unregulated Research Activities ***must***:

 a. Be on official letterhead

 b. Be dated

 c. State the title of the research protocol

 d. Include a statement indicating the purpose of the research

 e. Include a statement indicating the methodology to be used

 f. Include a statement the study does not require regulatory oversight (explain)

 g. Include a signature from the appropriate regulatory official

### **Documentation Required for Minimal Risk Studies in Countries that Do Require Ethics Committee Review:**

 Letter of Approval from an Ethics Committee **Must**:

 a. Be on official letter head

 b. State the title of the research protocol

 c. Clearly state the research is designated Minimal Risk by the committee

 d. Clearly state the proposed research was reviewed and approved

 e. Include a signature

 f. Include a date

 The LCU IRB may accept the approval of the foreign ethics committee and form an Inter-institutional Agreement (IAA) if the international IRB has the proper registration. If not, the LCU IRB will review the proposal and possibly require additional changes. In some cases, the LCU IRB may opt to do an additional review of a minimal risk proposal that has been approved by a foreign ethics committee with proper registration instead of forming an IAA, if there are concerns about the initial approval.

Documentation Required for Studies Designated as Greater than Minimal Risk**:** Studies designated as greater than minimal risk requires a formal ethics review within the country where the research will be conducted. Not all countries have an ethics review committee, and the oversight may be addressed by the Department of Ministries or other governmental entities.

 **Letter of Approval from an Ethics CommitteeMust**:

 a. Be on official letterhead

 b. State the title of the research protocol

 c. Clearly state the proposed research was reviewed and approved

 d. Include a signature

 e. Include a date

The LCU IRB requires an additional full review of greater than minimal risk studies by the members of LCU IRB committee.

## Site Permission Letter

Site permission letters are required when research is conducted abroad. Site permission letters must come from an authorized individual at the site (ex. Headmaster of a School, Director of an Orphanage, Pastor of a Church, Director of a government organization, Community leader, ...)

The Site Permission letter **must include**:

 a. The title of the research protocol

 b. A clear statement indicating the purpose of the research

 c. A clear statement indicating the methodology to be used

 d. A statement of support for the research team

 e. An agreement to have research conducted at the site.

 f. Include a Signature

 g. Include a date

## Local Collaborator

Local collaborators are strongly recommended when conducting research overseas. Ideally, the local collaborator is someone who has spent significant time in the country in which the research will take place. A local collaborator assists in identifying research sites, navigating local norms, overcoming language barriers, building ties in the community, understanding local ethical regulations, applying US regulations, and locating an international review entity for the country in which the study is to be done. Collaborating institutions can often complete ethics reviews for the research team. Investigators conducting high-risk studies in certain countries may be required to have a local collaborator.

## Translators/Translations

Researchers conducting research with participants who speak a language other than English must translate all surveys, consent forms, assent forms, parental permission forms, guardian permission forms, recruitment flyers, recruitment scripts, and any other communications with participants into their native language. Consulting with a local collaborator will assist the research team in determining if all documents have been translated into the local dialect accurately. Translators must be proficient in English and the language spoken by the participants. Translators must be identified in the proposal along with their credentials. Translator certifications should be noted. The IRB will have the translated documents assessed by their own consultant by creating a new translation or a back translation. All translations must be accompanied by a “Letter of Certification” from the translator giving:

- The translator’s name

- The translator’s qualifications/certification numbers

- Organizational affiliation of the translator (note any conflict of interest)

- Title of the research

- The name of the PI

- A list of all documents translated

- A statement verifying that all documents have been translated accurately

Translators who administer surveys/assessments must receive training in conducting human subjects research. This can be done through CITI or the OHRP.

## Proposal Additions

In addition to the material normally included in a proposal to be conducted in the US, the following should appear in a proposal for a study to be done at an international site.

### **In the Methodology Section of the Research Application:**

1. A statement of the specific site, city, region, and country included in the study
2. A justification for conducting the research in a different country.
3. A description of the research site.
4. A statement of whether you plan to use a local collaborator for the research study, and if so, what role the will the collaborator play (ex. Connect team with a local IRB, provide introductions to community leaders, collect data, participate in all levels of research…). Clearly state if you consider the local collaborator to be a co-researcher.
5. A list of all languages spoken by potential participants
6. A discussion of participants’ ability to read and comprehend English
7. A description of how you are accounting for colloquial variants of English
8. A discussion of the research team’s ability to communicate in the local language
9. State which language is most appropriate to the research population
10. A description of how translations and translators will be used.
11. A statement of literacy levels in the region.
12. A statement of estimated literacy levels of the participants.
13. A description of the research teams’ preparation for work in the country (language, communication, and cultural awareness).

### **In the Risks Section of the Research Application:**

Describe any aspects of the local culture, gender relationships, race relations, political climate, or economic environment that might increase risk of harm for the participants or the researchers. Describe the steps the research team will take to minimize these risks.

### **In the Benefits Section of the Research Application:**

Describe the value of any form of remuneration in the community at the international site.

### **In the Confidentiality of Data Section of the Research Application:**

Describe how the US requirements and the requirements for international site will be met. Note if any local laws differ with US laws or interfere with confidentiality.

### **In the Informed Consent Process Section of the Research Application:**

1. State the age of consent in the country.
2. Discuss the social and legal status of women, children, racial minorities, religious minorities, or any other disadvantaged group included in the research.
3. Discuss whether laws or customs in the country interfere with informed consent assurances.
4. State whether the consent process will be pre-tested.
5. All consent documents must be in a language understandable to the participants.

## Contact Information

All local collaborators, site managers, and participants should have copies of the PI’s contact information.

## Data Security

International Studies can pose unique concerns related to data security. All investigators conducting research at an international site should check with the LCU technology team for advice on keeping data secure from loss or breach.