International Research with Human Subjects

Overview

International research creates unique challenges for researchers in terms of cultural appropriateness of research and local/national regulatory structures. The general guidelines for IRB review of international research remains the same as for research conducted in the US. However, some additional information will be required.

How do I complete my IRB application for work with International Populations?

1. Complete IRB Form 1 for Expedited and Full Review and all accompanying documentation (link). (If you think your project might quality for Exemption please contact the IRB chair).
2. Pay special attention to the issues and questions raised in the chart below. This chart does not replace the questions asked in the IRB Form but is merely meant to draw your attention to special considerations that frequently occur in international research, and to direct you to the section of the IRB Form where you should address these issues.
3. Complete the IRB Submission Checklist for International Research (link)

Where information should appear in IRB Form	**Additional Documentation or Explanation That May be Required of International Research**
Part II: Project Description	Evidence of background research. The Project description and literature review should provide evidence that the researcher(s) has examined the literature about the location of study, where possible including scholars local to the region of study, and is culturally informed.
Part III: Study Population	Age of Consent. Information about the age of consent should be included in the application. a. Age of majority for the country or site. b. If minors or individuals with impaired decision-making ability are participating, clarify local protections (especially if they more stringent than U.S. protections) and explain how methods will be developed to comply with such requirements. (IRB Form, Section III)
Part III: Study Population	Vulnerable populations. Does your application include vulnerable populations such as non-English speakers, economically disadvantaged populations? If so, explain how your safeguards to protect these populations are culturally appropriate including anonymity, translation of materials, etc.
Part IV: Participant Identification/ Recruitment	Culturally appropriate recruitment strategies. Your application should explain how recruitment strategies are culturally appropriate. (For example, it may be expected that you first talk to a community leader or head of household before recruiting participants for your study). If you are working with non-English speaking populations your recruitment materials/scripts

	will need to be translated after you have received IRB approval but before recruitment starts.
Part V: Methods, Materials and Procedures	Local IRB regulations. Your application should include information about IRB regulations for research with human subjects in your location of study. Are there local regulations for human subjects research that differ from US regulations and are directly relevant to your study? If there are, description of these regulations and evidence of compliance with local regulations is required. (Note: if there is a difference between local and US regulations, the more stringent regulations must be applied. For example, if the age of consent in the country you are conducting research in is 16, the IRB will still consider participants under 18 to be minors). Note: Some of this may already be addressed in earlier sections.
Part V: Methods, Materials and Procedures	For collaborations between faculty and students please identify which roles the student researcher will have and what kind of training/mentorship they will be provided either before the research commences or during the data collection.
Part V: Methods, Materials and Procedures	For research with invasive procedures and/or collection of biological specimens: a. If any invasive procedures are used (i.e., blood draws), provide assurance that individuals conducting procedures have proper training and credentials or assurances that they will have such training before the start of research. b. If any biological specimens will be transported, please provide information on the process for shipping, storing, and labeling, with clear information on local requirements and permits.
Part V: Methods, Materials and Procedures	Finding a local research assistant or translator. If your research will require you to hire a research assistant and/or translator in your location of study, describe your plans to obtain one with the appropriate qualifications.
Part VII: Risks and Benefits	Additional risks in international research. Explain how local cultural, political, or economic matters might increase the risk of harm for either local participants or researchers and explain strategies to mitigate and minimize such risks.
Part VIII: Informed Consent	Cultural considerations when obtaining consent. What are the appropriate cultural standards for obtaining consent? If consent is necessary from someone other than the research subject, the researcher should consider how they will ensure that the consent of the person participating in the study is not being coerced. (For example, if a woman's participation is dependent upon the consent of her husband, researcher should ensure that her participation is still voluntary).

Part VIII: Informed Consent	Translation of Consent Forms. If research participants are literate but not in English, you will need to have consent forms and other relevant documents translated. You should indicate the qualifications of the person doing the translation in your application. In cases where the research is of a highly sensitive nature, we may ask for a letter of certification to ensure the accuracy of the translation.
Part VIII: Informed Consent	Oral Consent. Will unwritten (oral) consent be necessary for completion of the project? (For example, oral consent is often preferred if a participant is illiterate and/or unaccustomed to dealing with forms, or when participant vulnerability makes written consent dangerous or undesirable). Justification for requiring oral consent and safeguards for research participants should be addressed.
Part IX: Outside Collaborations	Collaboration Letter. It is strongly suggested that you have a local collaborator for international research. Your application should include information about your research site including name of site and name and qualifications of your local collaborator(s) where relevant. This person/institution is not required to conduct research with you but a letter shows that you have solicited cooperation and feedback from a local institution/researcher. A collaboration letter from a local NGO, organization, or researcher is helpful in determining appropriateness of international research and is particularly relevant if you are not required to undergo local IRB. A collaboration letter may be required depending on the sensitivity of the study and the expertise of the researcher.
Additional Documentation	Approval from a local IRB. Many countries require that your application undergo their IRB process as well as ours. These are sometimes conducted through a local University or government agency and often involve a fee (that can be up to $1000). Note, conditional approval of research by our IRB can occur before local IRB approval is obtained, but no data or information may be gathered until evidence of local IRB approval is provided. If no local IRB approval is necessary, please provide evidence to this effect. (For example, you could provide a link to a website, or a letter from a scholar or government official). Please consult OHRB's database of registered IRBs (link).
Additional Documentation	Checklist. You are required to submit the IRB Submission Checklist for International Research (link).

Information and Links

The Office of Human Research Projects provides resources for human subjects research in international contexts - https://www.hhs.gov/ohrp/international/index.html. Because some countries may have specific policies for human subjects research, and these matters must be addressed in the IRB form submission, researchers should review links at OHRP to confirm that

their research will comply with both U.S. and local expectations. OHRP database of registered IRBs: https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc

Still need help? If you are new to international research protocols, or still have questions after reviewing this chart, please contact the IRB Chair at irb@csbsju.edu to schedule a meeting with a member of the IRB committee with expertise in international research.