

 LEHIGH UNIVERSITY	Institutional Review Board (IRB)		
	Guidance: International Research		
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Background

This guidance describes the IRB's review of international research activities conducted by Lehigh University faculty, staff, and students, taking into account local laws and cultural context. The IRB applies all applicable federal regulations, guidelines, and university policies.

When researchers conduct studies in other countries or with immigrant communities in this country, the IRB must be knowledgeable about the local laws, regulations, codes, and guidance that govern such research, as well as the cultural context in which the research will be conducted. The IRB will review and determine that international research subjects are afforded the same level of protection that would otherwise be required in the researcher's domestic location. The researcher must submit the International Research Appendix with their IRB application. The appendix requires information about language, local laws, and cultural context. Please also reference the [LU IRB Guidance "Consenting Subjects Who Do Not Read, Speak, or Understand English"](#) for more information on working with non-English speaking populations.

IRB considerations when reviewing international research:

1. The application's description of the international or local immigrant research location and description of the levels of protection appropriate for the location, i.e. appropriate access and consent options.
2. The convened IRB or the designated expedited reviewer(s) may determine that equivalent levels of protections are afforded to international or local immigrant research participants that would otherwise be required in the United States.
3. The convened IRB or the designated expedited reviewer(s) may review and/or consult with university, local, or national experts to determine if the research is appropriate based on the laws and knowledge of the country or community in which the research will take place.
4. The IRB may consult the federal Office of Human Research Protections (OHRP) publication [The International Compilation of Human Research Standards](#) for in-country research information.
5. The committee will consider current events and news sources as appropriate.

Questions the IRB may ask when reviewing international research:

1. Is there a viable ethics committee in the host country that will review the protocol and how can they be contacted?
2. What is the principal investigator's relationship with the community from which research volunteers will be recruited?
3. When negotiating informed consent, how will the researcher assure that the research volunteers understand the consent?
4. Are the risks to volunteers acceptable in the social context of the host country?
5. Does anyone else in the host country know about the research?

When applicable, the IRB may also ask:

1. Does the research plan address the ethical challenges for conducting research in a developing country?
2. Is the purpose of the research responding to the health needs of the host country?
3. What exactly is the local standard of medical care?
4. What public health action will result from the findings of the research study?
5. Is capacity building an essential element of the research protocol?