
Yale University Institutional Review Boards

450 GD.1 International Research: Required Documents and Additional Considerations

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Overview

As a supplement to IRB Policy 450: International Research, this guidance document explains the requirements for written documentation that should be prepared and submitted to the IRB by principal investigators who intend to conduct research protocols that involve human participants at sites outside the United States. In addition, guidance that addresses additional considerations for the conduct of international research, including enhanced protections for participants, is provided below.

Materials for Protocol Submission

The protocol application packet, submitted either electronically or on paper to the Yale IRB for approval, must be written in English and must include the following:

- a) The initial protocol application and associated documents (e.g., surveys, questionnaires, study information);
 - b) The proposed informed consent document(s) in English. When Yale IRB approval of the informed consent document has been given, a copy of the form, as translated into the local language, must be provided to the IRB. The consent document must be written at a level of understanding suitable for the population being recruited into the study. Translated documents should state who performed the translation services;
 - c) Evidence of approval by an IRB, Ethics Board, or Independent Ethics Committee (IEC) familiar with the local research context and local law, or a letter from the Principal Investigator stating that such review is not possible and explaining why. Note that some IRBs and Ethics Boards have fees for review. Investigators should inquire about whether there are charges, and, if so, the amount of the charge. No research that engages the local site can begin until local approval has been granted and submitted to the Yale IRB. In addition to the human research findings applicable to the IRB's or IEC's review, such documentation should state any legal issues considered by the local IRB/IEC. PIs should be aware that research that is particularly complex or presents significant risk to subjects may require consultation with Yale legal counsel to ensure that the rights of participating subjects are appropriately protected, and that the research is conducted in conformance with local law. [Note: the local Ministry of Health or a local university is often able to provide information on how to contact an appropriate IRB or IEC]; and
 - d) All foreign investigators collaborating in the research must be listed on the IRB protocol application. Whenever possible, researchers should collaborate with a research or educational institution or an investigator familiar with the local culture and research-related issues. Such collaboration helps to ensure understanding about the appropriate training of local research staff necessary to conduct the study, and facilitates other essential communications regarding the progress of the study or concerns that may need to be addressed.
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Export Controls/Embargoed Countries

The Department of Commerce's Export Administration Regulations (EAR) and the Department of State's International Traffic in Arms Regulations (ITAR) restrict the export of certain technology or technical data, such as military applications (regulated by ITAR) or commercial applications that may also have value in a

military context (regulated by EAR), overseas and to foreign nationals working in or visiting the United States.

In some circumstances, the University may be required to obtain prior approval from the appropriate agency before allowing foreign nationals to participate in research, collaborating with a foreign company, or share researching results with foreign nationals. The Treasury Department's Office of Foreign Assets Control (OFAC) regulates trade embargoes, sanctions, and travel restrictions and restricts exportation of information and research articles to embargoed entities and persons.

These regulations, which have been in place for over twenty years, carry a range of potential penalties, including imprisonment, for individuals who violate them. Yale faculty, students, and staff should recognize when the regulations may apply and when an export or OFAC license may be required in connection with research. For more information, see

<http://www.yale.edu/grants/policies/exportcontrols.html>. In case of questions, please contact the Office of Grant and Contract Administration.

Additional Considerations to Enhance Protection of Research Participants

Consideration of the following aspects will help ensure that principal investigators and other IRB-approved study personnel are better informed about the local context and local law, and will serve to enhance human research protections:

The economic prosperity of the area and the prospective study population;

The political stability of the area;

The influence of local officials or leaders on the population;

Whether the country or area allows foreign visitors;

The nature of the procedures conducted (some countries, societies, or areas may not allow invasive procedures);

The literacy rate of the area;

The legal rights of the population under local law (confer with local IRB as necessary to determine, for example, age of legal consent, disclosure and required reporting of illegal activities, and applicable privacy laws);

How complaints will be reported and to whom;

The relevance of the research to the region's health or socio-economic needs; and

The possibility of including officials from the area in the monitoring of the research.

Securing Data and Enhancing Participants' Privacy

Depending on the nature of the data to be collected and its sensitivity in the local culture, the principal investigator may need to implement a range of suggested data protection measures such as the following:

Paper files: Secure data in the research field by means of a lock box or locking file cabinets whenever possible. In some remote sites, physically securing records may be difficult and alternate approaches such as maintaining records in English in an area where English is not understood can be effective. Use notebooks interspersed with random travel notes to hinder unauthorized access to respondent data.

Electronic Data: The collection of data must comply with local law relating to data privacy and security, as well as applicable U.S. law. As a matter of best practices under U.S. law, Principal investigators (PIs) and other IRB-approved study personnel should use only password-protected computers and/or encrypted files and limit access to necessary study personnel. If the information to be collected is politically sensitive either in the country or in the U.S., PIs may wish to consider storing data by uploading encrypted data files to Yale servers and then securely deleting the files from the laptop on-site to avoid unlawful or unauthorized confiscation of data. PIs should use caution in connecting through insecure connections such as Internet cafes and should review the most recent data security best practices available at www.yale.edu/its/secure-computing/. Please remember that U.S. export control laws may affect the ability to travel outside the United States with U.S. laptops and other electronic storage devices.

Similarly, U.S. Customs may control re-importation of these devices. For further information, please refer to <http://www.yale.edu/grants/policies/electronic-devices.html>.

Local research assistants/translators: In instances where the data to be collected has the potential to cause social stigmatization, PIs and other study personnel should use care in selecting an appropriate field assistant or translator to ensure that participant confidentiality is maintained. Graduate students from a regional University are sometimes hired in this role, provided that they are sufficiently external to the community of interest to assure confidentiality. In other cases, local customs require that the translator/field assistant be drawn from the community. In this case, the PI/study personnel should train the field assistant in the confidentiality requirements of the study and train the assistant about not unduly influencing a participant to respond to questions that s/he may otherwise not wish to answer.

Location of data collection: PIs should consider the appropriateness of locations where any interactions with participants will occur, considering whether or not there may be issues related to being seen speaking to the PI or the possibility of being overheard.