International Research

Introduction

International research requires additional review and documentation from both the international site and the Franklin University IRB. It is imperative that you start the process early and request a consultation with the IRB Office during the initial planning stages. If the Principal Investigator (PI) is a student, we recommend that both the dissertation chair and student PI meet with the IRB staff member.

Email irb@franklin.edu to request an IRB consultation.

We also recommend that you familiarize yourself with information provided by the US Department of Health and Human Services, Office for Human Research Protections (OHRP): https://www.hhs.gov/ohrp/international.

When is IRB review required?

All human subjects research conducted by Franklin University faculty, staff, or students, regardless of funding source or the location at which the research will be conducted, requires submission to the Franklin IRB.

What additional regulatory reviews are needed?

When research is conducted outside the United States, investigators must comply both with US regulations and with local policies and regulations governing the international research sites. It is important to do your homework early and, if possible, enlist a local collaborator to help you address that site's requirements and assist in identifying who to contact and what is required to obtain ethics reviews and permissions to conduct research at that international site.

To determine what laws, regulations, and guidelines on human subjects protections apply in the country where you intend to conduct research, you should consult the International Compilation of Human Research Standards list compiled by the Office for Human Research Protections: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

Definitions

Minimal risk: the probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or in routine medical, dental, or psychological examinations.

Greater than minimal risk: the research involves more than minimal risk to subjects.

Cultural appropriateness: sensitivity and awareness of how other ethnic, racial, and/or linguistic groups differ from one's own. Sensitivity can be manifested through knowledge of different languages or

manners of speech, norms, and mores, religious beliefs and practices, family structures and dynamics, community decision-making patterns, and class consciousness and socioeconomic realities.

Federal Wide Assurance (FWA): an assurance of compliance with the US federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the US Department of Health and Human Services (HHS).

Ethics committee: a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. May also be referred to as an Institutional Review Board (IRB), an Independent Ethics Committee (IEC), an Ethical Review Board (ERB) or Research Ethics Board (REB).

What is required for <u>minimal risk</u> studies?

Depending on the international site, local ethics committee review may not be required. It is the responsibility of the PI to contact the appropriate entity who will make that determination and obtain written documentation that review is not required. However, even if local ethics committee review is not required, additional documentation will be required to assess the cultural appropriateness of the proposed research and activities to be performed.

Two documents are required for studies when international regulations <u>*do not*</u> require local ethics review:

1. Memo of cultural appropriateness

This document must be authored by an individual completely independent of your study who is highly familiar with the population(s) and culture(s) of the region where the research will be conducted. This includes knowledge of the local worldview, social constructions, values, attitudes, beliefs, customs, practices, history, etc. The memo must contain the following elements:

- Reference the title of the study displayed in the IRB application
- Describe the expertise of the individual preparing the letter to address the local cultural and social norms
- Confirm they understand the intent of the research and activities to be performed
- Confirm the planned study does not conflict with local and cultural norms
- Document is signed and dated

2. Documentation that the local regulations do not require a local ethics review

The PI must provide direct references to the local regulations that state ethics review is not required, **or** a Regulatory Official (such as an IRB or ethics committee chair, a university administrator, or a government official, depending on the local research infrastructure) confirming that local ethics review is not required. This document must contain the following elements:

- Provided on the official letterhead of the signatory
- Reference the title of the study displayed in the IRB application
- Clearly state the planned research does not require local regulatory oversight
- Confirm they understand the intent of the research and activities to be performed

- Document is signed and dated

Required document for studies when international regulations *do* require local ethics review

1. Letter of approval from an ethics committee

This document must contain the following elements:

- Provided on the official letterhead of the signatory
- Reference the title of the study displayed in the IRB application
- Clearly state the research study was designated minimal risk by the committee
- Clearly state the planned research was reviewed and approved
- Document is signed and dated

What is required for greater than minimal risk studies?

Studies that are designated as greater than minimal risk **require** 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. This is why it is important to collaborate with local individuals early in the planning process so they can assist you in identifying the proper mechanism to obtain the approval.

1. Letter of approval from an ethics committee

This document must contain the following elements:

- Provided on the official letterhead of the signatory
- Reference the title of the study displayed in the IRB application
- Clearly state the planned research was reviewed and approved
- Document is signed and dated

Frequently Asked Questions (FAQs)

When are letters of support required?

When research is conducted at any site, institution, or organization outside of Franklin University, or when the investigator is otherwise relying on the cooperation of another institution or organization, an authorized individual from the proposed research site must provide written permission that the research can proceed. Please refer to the "Letters of Support" guidance on the IRB website.

If you need a visa to conduct research in your selected country, you may be required to include a local letter of support from an academic institution or other authorized organization with your application.

Why is it important to have a local collaborator and knowledge of the local culture?

Investigators are strongly encouraged to collaborate with an individual or organization with expertise in the region. This collaboration will greatly assist in identifying appropriate research sites, navigating local

regulations and policies, understanding culture and local infrastructure, overcoming language barriers, and increasing community partnership.

Based upon study location and risk level, the IRB may require a local site collaborator.

How can I provide ethics training to research assistants and other project personnel?

Human subjects training is required of anyone who assists in research; however, there are instances when it is not feasible for individuals to complete CITI training. For example, some international research is conducted in areas with limited or unreliable internet access, or on-the-ground assistants may not read or understand English. The IRB Office has prepared a Field Training Pamphlet for investigators to use when training community research assistants in international settings.

What are the additional requirements for enrolling non-English speaking participants?

When enrolling non-English speaking research subjects, investigators must have a plan to manage communications with participants during ***all phases*** of study participation. Given that participants may have questions or concerns at any time, investigators must be prepared to manage communication beyond the consent process and data collection.

Investigators should not submit translated documents that will be used with research subjects (recruitment materials, consent documents, data collection materials, etc.) until the English version of the documents have been reviewed by the IRB Office. Once the materials are approved by the Franklin IRB and the foreign ethics committee, as required, the approved documents should be submitted to a translator. The final English language documents, final translated documents, back translations, and a signed translator certification form should be uploaded to Cayuse IRB for approval.

If the PI or another listed investigator on the research team is a native speaker of the language that will be used to communicate with human participants in the research, that individual may provide the initial translation of study documents but will be required to use a certified translator for the back translation.

What additional information must I provide in my IRB application if I want to compensate participants in foreign countries?

If the laws and regulations of the foreign country permit research participants to receive monetary compensation for their time, the Franklin IRB application must describe the planned amount of compensation in both US and foreign currency. To prevent undue influence from inappropriately high levels of compensation, information regarding the average daily wage in the country must also be provided.

Why is it important to start the process early?

Now that you have a good understanding of the required review and documentation process, you can see that research in some areas of the world can require a significant amount of time to accomplish.

Investigators' most common mistake when implementing international research is not allowing a realistic amount of time for protocol development and regulatory reviews.

When developing project timelines, Investigators should consider issues such as the stability of local government and infrastructure, time differences between countries, availability of communication technology in the foreign location, responsiveness of foreign offices, cultural differences within professional organizations, and how frequently regulatory bodies convene.

Investigators should also determine if a special visa is required to travel to or conduct research in the foreign country. If so, medical testing, vaccinations, proof of insurance, police clearances, financial statements, support letters, and other documentation may be required to secure a visa or entry into the country.

Specific travel plans and the purchasing of plane tickets should **not** occur until all of the required reviews and approvals have been obtained.

Can I submit to the IRB before I have ethics approval from my international site?

You are permitted to submit to the Franklin IRB before foreign ethics approval is granted. In these cases, the Franklin IRB approval letter will state no research activities may begin until a modification is submitted to and approved by the Franklin IRB, providing documentation of foreign ethics approval.

How far in advance should I submit my international application to the IRB?

Minimal risk applications should be submitted to the Franklin IRB a minimum of two months prior to investigator approval deadlines. Submission three months prior is highly encouraged.

For **greater than minimal risk** applications, the location and topic of the research may require the Franklin IRB to employ a foreign consultant with the appropriate expertise to assist in the ethical review. Locating and enlisting the assistance of consultants may make the review process take significantly longer. It is crucial to allow a sufficient time for IRB review.

Where can I locate information on foreign research regulations for the specific country where I plan to conduct research?

Investigators can begin to educate themselves about applicable foreign research regulations, by specific country, using the resources below:

- Office of Human Research Protections (OHRP) "International Compilation of Human Research Standards": http://www.hhs.gov/ohrp/international/index.html
- Harvard School of Public Health Research Ethics Guidelines International Online Navigation Map (REGION): http://www.hsph.harvard.edu/region-map/

How can I locate a foreign ethics committee to provide review and approval of my study?
Investigators can search the OHRP "Database for Registered IORGs and IRBs, Approved FWAs and for Documents Received by OHRP in the Last 60 days" to locate a foreign oversight body:

- http://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc
- Press the "Advanced Search" link
- Select the appropriate country and search

Summary of Required Documents by Review Type

DOCUMENTATION	EXEMPT	EXPEDITED	FULL BOARD
Foreign IRB or ethics approval	If required by foreign regulation	If required by foreign regulation	Required
Memo of cultural appropriateness	Required, if foreign IRB/ethics approval is not required	Required, if foreign IRB/ethics approval is not required	Not required
Acknowledgment of unregulated research activities	Required, if foreign IRB/ethics approval is not required	Required, if foreign IRB/ethics approval is not required	Not required
Site permission	Required	Required	Required
Translated documents	Required	Required	Required
Back translations	Required	Required	Required
Translator certification	Requires a certified translator*	Requires a certified translator*	Requires a certified translator*

* Native speakers on the research team may provide the initial document translation but will need to use a certified translator for the back translation.

Modified from the University of Pittsburgh's Human Research Protection Office (HRPO).