I3 GD1 Additional Requirements for International Research

Overview

As a supplement to Policy I3 Conducting Human Subjects Research Outside the United States and US Territories, this document describes the requirements for written documentation that should be prepared and submitted for review by the University of Nevada, Reno (the University) Institutional Review Board (RB) and identifies additional considerations for the conduct of international research.

Information about applicable human research protection regulations in the US and other countries may be obtained from the DHHS OHRP website under International. Basic regulatory requirements for over 100 countries may be obtained from the *International Compilation of Human Research Protections*, also available from the International pages of the USDHHS OHRP website. However, this information should only be considered preparatory to actions that result in site-specific requirements.

I3A Materials for Protocol Submission

Submit the complete protocol including attachments in English. Review the following sections for requirements.

I3A1 Required Documents, Basic

The submission must include the initial protocol application and associated documents such as the following:

- Recruitment materials (e.g., scripts, flyers, emails, electronic posts)
- Assessment and research instruments (e.g., surveys, questionnaires, data collection logs)

I3A2 Informed Consent Documents

The documents that will be used for informing subjects about the research and obtaining consent must first be provided in English. When IRB approval of the informed materials document has been given, a copy of the form translated into the local language must be provided to the IRB for review and approval.

I3A3 Evidence of External Permission and Approval for the Research

Documentation of Permission or Authorization to Conduct Research in the Targeted Country

The researcher, when applicable, may need to provide the IRB with documentation of permission to conduct research in the country. For example, authorization may be required for investigators conducting biomedical research in another country, where there are local laws about medical practice. Foreign countries may have local or regional licensing laws for practitioners. Such laws should be

addressed in the documentation of authorization for the conduct of the research. Investigators are advised to work with the local contact to determine whether such laws exist and to identify the governing bodies from which permission or authorization for the research would be obtained.

Documentation of Ethics Review Approval

Investigators must provide evidence of external 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 (PI) stating that such review is not possible and explaining why.

The external IRB's or IEC's review must address issues related to human research protection and any applicable legal concerns or considerations.

Research that is particularly complex or presents significant risk to subjects may require consultation with the Nevada System of Higher Education or the University's 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 a IRB, IEC or comparable entity.

I3A4 Identification of Foreign Investigators

All foreign investigators collaborating in the research must be listed on the IRB protocol application. Evidence of human subjects research training

To the degree 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 inform the PI about the training needs of local research staff and facilitates communications regarding the progress of the study or concerns that may need to be addressed.

I3B 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 sharing research 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. Investigators wishing to conduct international research must recognize when the regulations may apply and when an export or OFAC license may be required in connection with research. In case of questions, please contact the University's Office of Sponsored Projects.

I3C Considerations for VA Research Conducted Internationally

When following VA regulations and requirements, international research is not initiated unless permission is obtained from the chief research and development officer or designee. The chief research and development officer, or designee, will not grant permission for an international research study involving prisoners as research subjects.

I3D Additional Considerations to Enhance Protection of Research Subjects

I3D1 Understanding Local Context and Law

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

1. The economic prosperity of the area and the prospective study population;
2. The political stability of the area;
3. The influence of local officials or leaders on the population;
4. Whether the country or area allows foreign visitors;
5. The nature of the procedures conducted (some countries, societies, or areas may not allow invasive procedures);
6. The literacy rate of the area;
7. 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);
8. How complaints will be reported and to whom;
9. The relevance of the research to the region's health or socio-economic needs; and
10. The possibility of including officials from the area in the monitoring of the research.

I3D2 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 those described below.

Paper Files

Data must be secured 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.

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, PIs and all other IRB-approved study personnel should use only password-protected computers, encrypted files or both and should limit access to necessary study personnel. PIs must exercise caution if they use insecure connections such as Internet cafes.

If the information to be collected is politically sensitive either in the country in which the research is taking place or in the U.S., PIs may wish to consider storing data by uploading encrypted data files to the University's servers and then securely deleting the files from the laptop on-site. This or other safeguards must be in place to avoid unlawful or unauthorized confiscation of data.

Note: 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. Researchers are advised to visit the websites for US Immigration and Customs Enforcement for information about applicable laws and strategies for protecting data confidentiality and the FAQs available from the website of the Bureau of Industry and Security in the US Department of Commerce.

Local Research Assistants and Translator

There may be instances in which the data to be collected has the potential to cause social stigmatization. In such cases, 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 to assist the investigators or translate during research activities. PIs must insure that the students are sufficiently external to the community of interest to assure confidentiality.

There may be other situations for which local customs require that translators, field assistants, or both are drawn from the targeted community. When this is required, the researchers must train these community members to recruit and obtain consent from subjects without being unduly influential, to allow subjects to refrain from answering questions that s/he may not wish to answer, and to implement and follow the privacy and confidentiality requirements of the study.

Location of Data Collection

PIs should consider the importance of insuring subject privacy during all subject-researcher interactions when selecting locations where subjects will be recruited or enrolled in the research study and in which data will be collected. Specifically, investigators must determine if there may be issues related to a member of the community being seen speaking to the PI or the possibility of the discussion being overheard and must address such concerns before proceeding with the research.