Research in International Settings

When performing human subjects research in other countries, researchers remain under University purview and thus must act according to the ethical principles set forth in the UCA IRB Policy and Procedures. All protocol submissions involving international research must receive prior approval from the appropriate local authority, organization, or IRB equivalent. Where no equivalent board or group exists, investigators must obtain approval from local experts or community leaders. The UCA IRB will not approve any protocol without previously documented "local approval."

Federal regulations for oversight of international research, together with the Association for Accreditation of Human Research Protection Programs (AAHRPP) also make the following stipulations:

1. The researcher must provide the same *or equivalent* protections to human subjects in research conducted in other countries.
    a. The protections need not be identical to those provided in the U.S. but must be equal in function or effect.
    b. Subject autonomy and dignity should be respected.
    c. Protections should encompass the ethical principles of respect for person, beneficence, and justice.
2. The researcher must be familiar with and comply with local laws, regulations, political and socio-economic factors, and cultural context in all locations where the research is conducted.
3. The researcher must have sufficient knowledge of the local context, which may impact all aspects of the research design, and in particular, the protection of the rights and welfare of subjects.

The level of knowledge about the local context and local law required for approval is based on the degree of risk to potential research participants. Higher risk studies require more thorough considerations of local context and inclusion of strategies to mitigate harm than do minimal risk studies. In such cases, the IRB may request consultation with experts in the particular international setting.

All researchers should review the US Department of Health and Human Service International Compilation of Human Subjects Protections. In addition, researchers conducting biomedical research should be familiar with applicable international guidelines: e.g., The Declaration of Helsinki, the International Conference of Harmonization – Good Clinical Practice (E6) Guidelines, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects published by the Council for International Organizations for Medical Sciences (CIOMS).

Note: If you are or will be conducting research in an international setting, be sure to visit the University of Central Arkansas Study Abroad website for international travel policy that involves approval for student/faculty/staff travel to areas of high risk.

Informed Consent Process

Due to local customs, and cultural and religious norms, alternate methods of informed consent may be necessary. Surrogate consent/permission may *not* be substituted for a subject's informed consent unless the IRB has approved an alteration or waiver to the consent process. In these cases, protocol submissions must include a completed *Request for Waiver or Alteration of Informed Consent Process*, detailing the cultural norms or conditions requiring alternate methods. Researchers must pay special attention to maintaining sensitivity to local cultural norms and applicable law, including issues such as the following: disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts to be studied; differences in cultural and societal norms; differences in the role of women in society; differences in the role of family and community in the consent process; multiple local languages; and literacy level. Alternate consent procedures might include, for example: use of pictures, video, or computers, or alternate forms of documentation such as thumbprints.

Risk Assessment

Research methods that have minimal risk in the US might have greater than minimal risk when conducted at certain international sites. In preparing protocol submissions, researchers must consider the following:

1. Questions considered innocuous in the US could be offensive or more sensitive at the international location.
2. Assuring and maintaining confidentiality may be difficult in other countries.
3. Breach of confidentiality in the research locale could have potentially dangerous consequences.
4. Due to political and/or environmental factors, dangers to the researcher may exist.
5. Appropriate resources and facilities must exist to support the protocol in compliance with this policy and local law. The researcher and international site are responsible for providing evidence ensuring that the resources and facilities are appropriate for the nature of the research.

International Research Involving Children

Many research studies in the social and behavioral sciences pose no more than minimal risk to subjects and may qualify for exemption, even if conducted in an international setting. However, even in exempt research, informed consent, parental permission, and child assent may be ethically appropriate and/or required under local law.

The following should be considered when the research involves children:

1. In the locale of the research, when a child is considered an adult.
2. The relationship between parents and their children in the specific country.
3. Acceptable and effective parental permission processes.
4. If child assent is acceptable/permissible by local custom.

5. If there are laws pertaining to orphans.

Export Controls/Embargoed Countries

In some circumstances, the University may be required to obtain prior approval from a U.S. government agency before allowing foreign nationals to participate in research, collaborating with a foreign company, or sharing research results with foreign nationals. For example, 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.

HIPAA Applicability

HIPAA regulations do not apply to health information obtained and held at international sites; however, researchers must comply with all applicable local privacy laws. If identifiable health information collected at an international site is stored within a University of Central Arkansas HIPAA-covered component, it becomes subject to HIPAA regulation.

Securing Data and Enhancing Participants' Privacy

Depending on the nature of the data to be collected and its sensitivity in the local culture, the research may need to implement a range of suggested data protection measures, for example:

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 US law. As a matter of best practices under US law, researchers 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 US, researchers may wish to consider storing data by uploading encrypted data files to University of Central Arkansas servers and then securely deleting the files from the laptop on-site to avoid unlawful or unauthorized confiscation of data. Researchers should use caution in connecting through insecure connections such as Internet cafes. Please remember that US export control laws may affect the ability to travel outside the United States with US laptops and other electronic storage devices. Similarly, US Customs may control re-importation of these devices.

Local research assistants/translators: In instances where the data to be collected has the potential to cause social stigmatization, researchers 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 researcher/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: Researchers 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 researchers or the possibility of being overheard.

Change in Research Activity

University of Central Arkansas researchers must notify the UCA IRB promptly if any change in research activities occurs after the start of the project, or if the change leads to or results in the foreign site's engagement in the research (e.g., a site previously "not engaged" begins consenting subjects).

Communication with Home Institution

The researcher must make adequate provisions for communication from the international site to the University. The protocol must include descriptions of the following:

1. How communication will occur with the UCA IRB and the local site organization, host, or supervisor.
2. How ongoing review, amendments, or reporting of unanticipated problems/adverse events, or complaints will be handled and by whom.
3. Local contact information if the principal investigator or faculty adviser cannot be reached.
4. For student researchers, explain the student's knowledge of the country and how the student will communicate with their faculty adviser.

Monitoring of Approved International Research

In certain cases, the UCA IRB may require the following documentation:

1. Regular correspondence between the PI and the international institution or site;
2. Continuing IRB/Ethics Committee approval from the international institution or site;
3. Continuing cooperation from the international institution or site if the institution or site is not engaged in the research;
4. Verification from other sources than the researcher that there have not been any substantial changes in the research since the last continuing review; and/or
5. Inclusion of an independent monitor/body as part of the data safety monitoring plan.

Additional Resources

- For information on IRBs and IECs in a large number of countries, see the Harvard School of Public Health Global Research Ethics Map.
- WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI, Ethical Principles for Medical Research Involving Human Subjects.
- Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects.

Please direct all questions to: researchcompliance.edu or (501) 852-7460