

**IRB GUIDANCE ON INTERNATIONAL RESEARCH INVOLVING HUMAN PARTICIPANTS**

**SCOPE:** This guidance applies to all on-going and future research studies conducted or supported by UMass Dartmouth (UMassD), faculty, staff, or students on international human participants.

**BACKGROUND:**

Research conducted by faculty, staff or students in foreign countries poses unique and complex ethical challenges. Each country has different cultures, values, and traditions which are crucial to understanding the local context. Investigators proposing to involve international communities in research are subject to the review and approval authority of the IRB. Both U.S. and host country standards for protecting human participants must be respected; where sets of standards present a conflict, the research must meet the higher standard. In addition to meeting local ethical standards for human participant protection, the IRB will maintain ethical standards, a meaningful consent process, and apply applicable protections for vulnerable populations.

**ELEMENTS FOR CONSIDERATION:**

1. **Cultural Appropriateness.** Respect for dignity and freedom in research may require different actions, protections, and attitudes when conducted outside of the U.S. Sensitivity and awareness of the local context (*ethnic, racial, and linguistic differences; cultural sensitivities [culture, traditions, and religious norms]; family structures and dynamics; community decision-making patterns; and class consciousness and socioeconomic realities;*) help identify potential barriers and ascertain the culturally acceptable process for recruitment, informed consent, and overall research conduct. A sound study design must maximize the benefits, minimize the risks, protect the participants' welfare while upholding local customs and traditions. The informed consent process must respect local/cultural norms and comport with international standards of ethical research. The IRB may consider alternative consent formats or methods, if it is culturally appropriate, or waive the documentation of informed consent to minimize the harm to research participants.
2. **Research Ethics Guidelines.** Not all countries have clear ethical guidelines for conducting domestic and/or international research and some rely on neighboring countries to assist with the ethics review. Researchers must provide approval from the international entity's ethics review body equivalent to the IRB prior to obtaining UMassD IRB approval. Where no research ethics oversight exists, researchers must rely on local experts or leaders to provide insight on the host country standards of human participant protection and attest to the protocol's conformity to the standards via letter of cultural appropriateness for each international site (*just as domestic sites external to UMassD require a letter of support to conduct research*).
3. **Vulnerable Communities.** Participants of less developed countries may be vulnerable to coercion and undue influence due to a lack of locally available services/resources, insufficient education, or knowledge of human research standards. In the absence of human participant protection programs, proposals should implement additional safeguards to ensure participation is truly voluntary and prevent against coercion and exploitation. The IRB will evaluate local context, amount, type, and/or method of compensation to determine the appropriateness of compensation offered to participants.
4. **Data laws.** While not specifically under the IRB's domain, there are restrictions on bringing identifiable data in and out of some countries. For example, the EU laws restrict what kind of identifiable information can be taken out of Europe and brought to the U.S. (*which also applies to electronic data housed on a U.S. server*). U.S. export controls and sanctions laws which govern the transfer or disclosure of goods, technology, software, services, and funds originating from the U.S. to persons or entities in foreign countries OR to foreign nationals anywhere apply to international research activities. Data export laws also affect research done in countries with which the U.S. has embargoes or trade restrictions on such as Ukraine, Cuba, Iran, North Korea, and Syria.

**OFFICE OF HUMAN RESEARCH PROTECTION (OHRP) GUIDANCE ON INTERNATIONAL HUMAN RESEARCH:**

1. **Health and Human Services (HHS) Policy for the Protection of Human Research Subjects (45CFR46):**
  - a. **46.101 (a)**, regulation "applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency outside the United States," unless waived by the HHS Secretary.
  - b. **46.101 (h)**, "When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. If a [federal] department or agency head determines that the procedures prescribed by the [foreign] institution afford protections are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or agency head."
2. **International Compilation of Human Research Standards:** The compilation enumerates laws, regulations, guidelines governing human subject protections in 131 countries and identifies key organizations and relevant ethical standard for each country. Where applicable, it includes each country's corresponding law for: general and social-behavioral research; privacy/data protection; research injury; drugs/biologics devices; clinical trial registries; biological materials collection; genetics; and embryos, stems, and cloning.

### **INVESTIGATOR RESPONSIBILITIES:**

1. Complete the IRB International Research Checklist to address relevant local context, cultural sensitivities, political differences, or other barriers which may impact the conduct and purpose of the proposed research.
2. If federally funded/sponsored, consult the funding source about special requirements which apply to conduct outside the U.S.
3. As appropriate to the local environment, obtain documentation of review and approval by a local review body equivalent to the IRB or research ethics committee. On the application, under Prior IRB Review, identify and outline the qualifications of the local review body (*e.g., source and scope of authority, location, membership*). If no local review body is available, obtain letter of cultural appropriateness from a local community expert or leader indicating the research protocol is in keeping with local social standards and expectations (*the local community leader or expert must be experienced with the culture of the target population, be independent from the conduct of research, not receive compensation or of any kind of incentive from the researcher, and cannot provide approval if the country has promulgated standards or a local review body*).
4. Within the consent form, identify local contact person for participants to contact about research related questions.
5. Provide subject facing material (*recruitment emails/flyers, consent form, and study instruments [surveys, questionnaires, interview scripts]*) in English and in the language of the host country. Include a certificate of translation to certify translations are accurate.
6. Obtain certificates of completion from all personnel engaged in research related activities of required training. Training options available are: (1) CITI Program online training or (2) a local training program, if available. If locally recruited personnel are not proficient in English, the assistance of a translator may be required. If the locally recruited personnel elect to use a local training program, documentation from the provider of that training program should be provided to the IRB as part of their review.
7. Submit to the IRB the international research checklist, proposal, application, subject facing materials (*and certified translations, as necessary*), training verification for all personnel, letter of support from the international research site, approval by a local ethics review board or equivalent (*as applicable*), and approval from institutional official at UMass Dartmouth (*if necessary*).

### **INFORMED CONSENT CRITERIA:**

Written documentation of informed consent is required from each human research participant, unless a waiver is approved by the IRB. If possible, consult with a local culture expert or leader to determine an appropriate informed consent process. If the PI, or local expert or leader, has indicated written informed consent is not standard or appropriate in the host country, then a waiver of written documentation of consent should be requested. The IRB may grant a waiver of written documentation of informed consent if:

1. The protocol meets the IRB's requirements for waiver of the documentation of informed consent.
2. The IRB application provides justification for the circumstances warranting a waiver of written documentation of informed consent (*e.g., community uses no written language or considers the signing of documents problematic*).
3. All the elements of informed consent are included within the information sheet or oral informed consent script.
4. The information sheet and/or oral informed consent script will be presented in a language, educational, and cultural level understood by international study participants.

#### Adapted with gratitude from the following references:

1. Cornell University. Research & Innovation. [IRB Policy: #14 International Human Research](#).
2. John Hopkins University. Institutional Review Board. [Guidance for Conducting Human Subjects Research in International Settings](#).
3. University of Connecticut. Office of the Vice President for Research. [Guide on Ethnographic/Naturalistic Research](#).
4. University of California, Irvine. Human Research Protection. [Policy #27: Research Conducted at International Performance Sites](#).
5. American Anthropological Association (AAA). AAA Policies. [Statement on Ethnography and Institutional Review Boards](#).