

## International Research

International research is often much more complex than similar research conducted in the US. Local collaborations, logistics, local ethical and legal requirements complicate the research process and require additional attention and effort by the investigator. Following are the key points to consider.

### Regulatory Requirements

Human subjects outside of the US who participate in research funded by HHS must receive an equal level of protection as research participants in the US (45 CFR 46.101(h)). This sets the standard for all international research, funded or not, and is guided by the [Belmont Report](#).

Review is generally required by the local country's IRB or Ethics Committee (EC). This is not just a US requirement; many countries now require local IRB/EC review, especially for biomedical research. Some countries require that their Ministry of Health review a study separately and in addition to the local IRB/EC, usually when the study is a public health study or when recruitment or data/specimen collection will occur in any Ministry of Health clinic or health outpost. Review by a Ministry of Health may add appreciably to the time to obtain approval. FDA regulations may also apply. Check the [International Compilation of Human Research Standards](#) for country-specific regulations.

The General Data Protection Regulation (GDPR) applies to research in, or with residents of, the European Economic Area (EEA). Research involving the EEA and the United Kingdom requires additional institutional review (see COMIRB's [GDPR Guidance](#)).

### Other institutional requirements

**Travel.** All students and trainees (includes residents/fellows) traveling internationally for research or any other academic or experiential purposes MUST register with the Office of Global Education. Please email [study.abroad@ucdenver.edu](mailto:study.abroad@ucdenver.edu) or call (303) 315 – 2001. UCD policy requires that faculty purchase international travel tickets through Christopherson Travel, which will automatically register you with the Office of International Affairs. There may be other important considerations when conducting international research (e.g., local contracts, Visas, safety, etc.); please contact the Office of International Affairs to discuss your plans while outside the United States.

**Import/export issues** (equipment, samples, information). Many countries have strict regulations on export of biological samples, and may need a [Material Transfer Agreement](#), FDA, or USDA approvals, and/or special customs arrangements. Consider how you will maintain security of the data and samples while in country (e.g., consent forms, biological samples, data) and how data will be transmitted to the US (e.g., secure internet connections to US, encryption for sensitive data).

### Best practice suggestions

**Local Context.** Designing culturally appropriate consent and study procedures and obtaining local IRB/ethics board approval are important steps in conducting international research. Local officials or community leaders

may be called upon to ensure that the protocol is culturally appropriate and that consent is sought from all interested parties, which may include spouses, extended family, and/or tribal or religious leaders. Investigators should plan to work closely with the local IRB in understanding what constitutes an adverse event or unanticipated problem in a particular cultural community. Ideally, the investigator has associated with or identified someone locally to advise on cultural appropriateness.

Not all countries have an [applicable IRB/EC](#) to cover your type of study (e.g., social/behavioral), and a local collaborator(s) may be affiliated with or know of an IRB/EC that can conduct a review. Also, a local NGO in a related field (not involved in the study) may review for cultural appropriateness.

**Respect the community.** Poor design, inadequate time and/or resources inconvenience and increase risk to participants. Conducting research no effort to return results or value to the community disrespects participants and likely compromises research. Work with local organizations to understand whether your research is of use to the community BEFORE you propose a study, as communities may resist research without obvious benefits to them. Lastly, plan for dissemination of results with the community when the study is complete.

**Planning.** International research is almost always more complex than US based research due to logistics, infrastructure, language, limited time, and varying priorities. If at all possible, do a preliminary trip to the research site to sort out details and/or work with faculty with international research projects. Connect with other international researchers, particularly through the Center for Global Health or COMIRB.

The COMIRB International Research Advisory Committee (IRAC) reviews all international studies and advises the COMIRB IRB reviewers on international concerns. The review will include at least one person familiar with the country/region in question. IRAC meets twice a month and the more detail provided in the submission (especially in the COMIRB application form), the more efficient the review. Build in extra time for review (minimum 2 months) to go through this process, and contact COMIRB to talk through any issues before submitting.

You may not conduct your research without a completed review, including local in-country ethics review, so make sure to plan ahead. If you plan to use local research assistants, develop a reasonable training plan and plan for oversight of the research

While in-country, if the investigator has internet access, we recommend that unanticipated problems, complaints, or adverse events be reported to COMIRB through InfoEd. If internet access is intermittent or technology fails, email COMIRB with key information.

## Resources

OHRP has helpful reference materials for [international research](#), including a searchable database for [international IRBs](#) and country specific listings of [local laws](#) related to Drugs/Devices, Privacy/Data Protection, Biological Samples, Genetic Research, and Embryo/Stem Cell research.

## VA Regulations (VHA DIRECTIVE 1200.05):

VHA policy states that permission must be obtained in writing from the [Facility Director](#) (except for Cooperative Studies Program activities which must be approved by the CRADO) prior to initiating any international research that meets the following definition:

- VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths)
- VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites
- VA-approved research that entails sending such specimens or data out of the U.S.

All international sites must hold an international Federalwide assurance, and the research must be approved by the IRB or Ethics Committee of the participating sites listed on the international Federalwide assurance.

The researcher must conduct the research in accordance with VA requirements and all other applicable federal requirements for protecting human participants, tissue banking, use of databases, federal criminal laws, and the standards of ethical conduct for employees of the executive branch.

The above definition of international research applies even if the research does not meet the definition of human subject research requiring IRB review (e.g., if the investigator receives anonymous human samples or data from an international source). NHR at the VA still requires approval and oversight by the VA R&D Committee.

- Examples
  - Sending specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site) is considered international research. Remote use of data that is maintained on VA computers within the U.S. or Puerto Rico and U.S. territories accessed via a secure connection is not considered international research.
  - International research includes multi-site trials involving non-U.S. sites where VA is the study sponsor, a VA investigator is the overall study-wide PI, VA holds the Investigational New Drug (IND), or the VA manages the data collection and the data analyses.
  - International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e., the PI for the study as a whole is not a VA investigator).
  - Research conducted at U.S. military bases, ships, or embassies is not considered international research.

**NOTE:** This policy applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including agreements, Memoranda of Understanding (MOU), Cooperative Research and Development Agreements (CRADAss), grants, or contracts. Also, all VA-approved research must be approved by the Research and Development (R&D) Committee in addition to IRAC and COMIRB review.