

**Background**

International human research refers to research conducted outside the United States using participants from the local community. This may include partnering with an organization, such as a non-profit, that regularly works in a foreign country. Such research involving University of Arizona investigators remains subject to the review and approval of the University of Arizona Institutional Review Board (UA IRB).

Guidance

Both the U.S. and host country standards for protecting human participants must be respected during the IRB's review and approval process and the conduct of the research. When the two sets of standards present a conflict, the research must meet the higher standard. This encompasses requirements for informed consent, criteria for waivers, additional protections for vulnerable populations, post-approval monitoring, and handling of complaints, noncompliance, and unanticipated problems involving risk to participants or others.

The UA IRB may require the Principal Investigator (PI) to provide some form of local approval from each international site where the research will be conducted. Local site authorization will be required anytime research is conducted in a non-public place. Should the IRB require this approval, the PI must provide documentation of approval as part of the IRB application either from a local review body equivalent to the IRB, such as an ethics committee or, if no such body exists, from a local community leader or expert who can attest to the host country standards for human participant protection and the protocol's conformity to those standards. The UA IRB does require that there be good faith effort applied to secure local cooperation for the research and to document those efforts as part of the application. Documentation provided to the UA IRB must be translated into English.

All PIs are expected to be familiar with the research laws, regulations, and guidelines of the host country. The [Office of Human Research Protection \(OHRP\) International Program](#) provides information for many, but not all countries. Each IRB submission should document the country's standards (laws, regulations, and/or guidelines) relevant to the study, including any local scientific and/or ethical review structures that differ. If community advisory boards are involved, describe their composition and involvement in the research protocol. Special attention should be given to local customs and to local cultural and religious norms in developing the research protocol and submission materials.

Please note that additional time is required to review studies and research personnel engaged in research outside the U.S. This accounts for the various consultations, institutional approvals, and document translations that are typically required for such research.

If the study involves an Indigenous Population, an *Appendix for Native American or Indigenous Populations* is required with the IRB submission. This is to ensure that appropriate consultation with the Indigenous Population occurred, to document any specific local laws or nation/state

rules and regulations, and to understand data ownership, data destruction, project-specific community advisory board considerations, etc.

International Data Security Laws

Researchers should be aware that international data security laws continue to emerge that protect personal data. Some notable examples include:

1. **European Union:** General Data Protection Regulation (GDPR)
2. **United States:** Various state laws (e.g., California Consumer Privacy Act (CCPA))
3. **Canada:** Personal Information Protection and Electronic Documents Act (PIPEDA)
4. **Australia:** Privacy Act 1988 and the Australian Privacy Principles (APPs)
5. **Brazil:** General Data Protection Law (LGPD)
6. **China:** Personal Information Protection Law (PIPL)
7. **Russia:** Federal Law on Personal Data
8. **Japan:** Act on the Protection of Personal Information (APPI)
9. **South Korea:** Personal Information Protection Act (PIPA)
10. **South Africa:** Protection of Personal Information Act (POPIA)
11. **Nigeria:** Nigeria Data Protection Regulation (NDPR)

These laws vary in scope and enforcement but share a common goal of enhancing personal data protection and privacy. Information about how researchers will abide by national personal data protection should be articulated in the IRB application.

European Union General Data Protection Regulation Requirements

The General Data Protection Regulation (GDPR) is a broad-scale regulation designed to harmonize data privacy laws across the Europe Union (EU), to protect and empower all EU citizens' data privacy, and to reshape the way organizations across the region approach data privacy. Investigators should be aware that research involving "personal data" about individuals located in the EU and European Economic Area (EEA) must comply with the GDPR. More information about these requirements can be found in the Human Subjects Protection Program (HSPP) [guidance](#) document, *GDPR*.

Federal Guidelines for International Research

Whenever non-U.S. institutions are engaged with the University of Arizona in non-exempt human research supported or conducted by the U.S. Department of Health and Human Services (HHS), the HHS human subject protection regulations ([45 CFR part 46](#)) apply.

This means that when appropriate, the non-U.S. institution must obtain a Federalwide Assurance (FWA). For additional information see: <http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwf/fwas/fwa-protection-of-human-subject/index.html>.

**Other University Requirements**

- The University of Arizona International Travel Registry Program requires research-related travel to be registered at least 30 days prior to departing. This is required under the [UA Interim International Travel Safety and Compliance Policy](#).
- U.S. export controls and sanctions laws apply to international research activities. Export controls are those federal laws and regulations that 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. For further information, please consult UA's export controls website: <https://research.arizona.edu/compliance/export-control-program>.
- The Research Security Program works with the UA Arizona community to strengthen protections of research and development against foreign government interference and exploitation while maintaining an open environment to foster research discoveries and innovation that benefit our nation and the world. Foreign Affiliations and Foreign Interests must be disclosed in the University's official disclosure system: [eDisclosure](#).

Research Security Incidents must be reported to the Research Security Point of Contact. A Research Security Incident is an action regarding Federal science and engineering support, such as failure to disclose information that could pose financial conflicts of interest or conflicts of commitment; misappropriation of research data or knowhow; and diversion of intellectual property; among others, due to improper foreign influence. Additionally, the Research Security Program should be contacted when a contract, agreement collaboration or visiting/exchange scholar involve any of the following:

- A person or entity in China, Russia, North Korea or Iran
- Monetary deposits in a foreign country
- Shared Intellectual Property term
- A term directing credit in a publication
- Foreign talent recruitment program or other recruitment or scholar exchange term (including a foreign talent program certification)
- Requirement to provide a NetID and/or access to a UA system
- Requests to endorse or vouch for a foreign national with whom you do not have an established professional relationship

For further information, visit the UA Research Security Program website:

<https://research.arizona.edu/compliance-public/research-security>.



Resources

- OHRP International Program: <http://www.hhs.gov/ohrp/international>
- FWA for the Protection of Human Subjects: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subject/index.html>
- UA International Travel Registry Program: <https://policy.arizona.edu/research/international-travel-safety-and-compliance-policy-interim>
- UA Export Control: <https://research.arizona.edu/compliance/export-control-program>
- UA Research Security Program: <https://research.arizona.edu/compliance-public/research-security>