CONDUCTING HUMAN SUBJECTS RESEARCH IN INTERNATIONAL SETTINGS

Guidance and Checklist for Investigators

Conducting human subjects research outside the United States requires different planning in order to satisfy legal and institutional requirements. This guidance outlines things that investigators need to prepare for prior to submitting a non-exempt human subjects research application to a JHU IRB.

Johns Hopkins University adheres to the requirements of the U.S. Common Rule (see JHU Policy on IRB Authority) for all human subjects research in which JHU personnel are "engaged", or for which funding flows through Johns Hopkins. In addition, investigators must follow foreign laws and regulations that provide protections to human subjects in addition to those that are provided by the Common Rule. **JHU investigators must be familiar with the local requirements in international research settings**, and must ensure that the terms of their funding agreements and the content of their IRB submissions are consistent with those expectations. Relying on local collaborators is important, but it is also important that the JHU investigator understand these requirements. In particular, JHU investigators should pay particular attention to the different treatment that other countries' laws and customs may give to the handling of data and biospecimen ownership and sharing.

DO NOT START YOUR STUDY UNTIL YOU HAVE APPROVAL FROM BOTH JHU IRB AND LOCAL IRB/Research Ethics Committees.

U.S. Resources

a. For federally funded studies, ensure that the subsite has an active Federal Wide Assurance ("FWA") with the Office of Human Research Protections (OHRP) if they will be engaged in non-exempt human subject research. Note that an FWA filing for the subsite is required regardless of what IRB will be serving as the IRB of record. You may search this public database to determine is a possible subsite has an active FWA (https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc).
b. Identify a local IRB or REC (Research Ethics Committee) (if federally funded, determine if the local IRB or REC is registered with OHRP and applies Common Rule standards) that will be responsible for reviewing and overseeing the human subjects research activities of the local collaborators.
c. Local approval standards for human subject research vary by country. Consult the OHRP Compilation of Human Subject Research Standards. https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html, to search for applicable, country specific information.

International Resources

CIOMS International Ethical Guidelines for Health Related Research Involving Humans: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

CIOMS International Ethical Guidelines for Epidemiological Studies: https://cioms.ch/shop/product/international-ethical-guidelines-for-epidemiological-studies/

Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

European Group on Ethics in Science and New Technologies: https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics-science-and-new-technologies-ege_en

International Conference of Harmonization (ICH) Efficacy Guidelines: https://www.ich.org/page/efficacy-guidelines

WHO: Ethical and Safety Recommendations for Intervention Research on Violence Against Women: https://www.who.int/reproductivehealth/publications/violence/intervention-research-vaw/en/

WHO: Guidelines on Ethical Issues in Public Health Surveillance: https://www.who.int/ethics/publications/public-health-surveillance/en/

WHO: Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants: https://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf;jsessionid=BC841AEF69C1DCA1D920BCDE7674A4CD?sequence=1

Investigator Checklist *Complete as part of your pre-submission planning*		
Identify Primary Funding Recipient and Subrecipients	Primary Funding Recipient	Subrecipients
List all foreign sites	Site Name, City, Country	FWA Number
Identify key collaborators, their affiliations (institutions) , and their role in the study.	Name	Affiliation and Role
Identify JHU investigators and their role in the study	Name	Role

INFORMATION REQUIRED FOR YOUR JHU IRB SUBMISSION *Think about, and check off, each item as you complete it.*	
Be aware of the human subjects research requirements at the local site.	
In your protocol, justify conducting the study at these site(s).	
In your protocol, describe community engagement activities.	
Verify qualifications of your in-country partners/study personnel to execute assigned study role(s).	
STUDY PRODUCTS	
Provide the product information (package inserts, certificates of analysis, investigational brochure) for any study products (drugs/devices, etc.) being distributed by the study, including sourcing information.	
Obtain regulatory approvals needed to conduct the study in country.	

CONSENT PROCESS AND DOCUMENTATION	
Are study languages all written (some languages are oral only)? If not, what process will you use to introduce the study?	
Will consent forms be signed? Are there any local cultural norms against signing consent forms?	
Provide translated consent documents, as needed, including a certification of the accuracy of the translation.	
Provide certificate of translation.	
Provide the rules about enrolling minors, as needed. Detail parental permission requirements, when minors may consent for themselves, etc.	
Provide any comprehension assessments you plan to use.	
Are there any extra protections you are providing participants to ensure voluntariness? In particular, address any concerns about female autonomy.	
Include information about sharing research data/specimens outside of the country, with foreign researchers.	
RISK	
Is the population vulnerable in that country because of the study topic, questions about illegal behaviors, or local cultural concerns?	
Will you be asking sensitive questions about sexual abuse or interpersonal violence?	
Are there any local mandatory reporting requirements for disease diagnosis, child abuse, or other topics?	
Are there extra resources or referrals you are providing for participants (medical care, counseling for distress, etc.) associated with information you will collect for the study?	
REPORTING	
Provide process for reporting protocol non-compliance and unanticipated problems posing risk to subjects or to others – to meet local requirements and JHU requirements.	
Provide process for handling participant complaints locally.	

DATA/BIOSPECIMEN SECURITY, MANAGEMENT, SHARING	
Review your funding agreement and its provisions about data/biospecimen requirements (sharing, ownership, de-identification, public access). Make sure all your submissions to the JHU IRB and local review committees fully disclose your proposed plans.	
In your research application, describe your data security plan, data management plan, de-identification plan, and sharing.	
If you will store biospecimens for future research, detail your plan for collection, future use, storing, sharing, including local requirements.	
If shipping biospecimens back to the U.S., obtain proper export and import permits.	
POST-STUDY PLANNING	
Prepare a plan to report study outcome back to local community.	
Address any post-study access to study interventions, continued/transitional access to care, if relevant.	
LOCAL APPROVALS	
Verify visa/licensing/ certification requirements for JHU personnel proposing to engage in clinical activities at the local site. Note that central international business office approvals for JHU personnel in country must be obtained separate from IRB approvals.	
Provide local approvals, including local ethics approval.	
Provide letters of permission from local research site(s).	