International Research

A Brief Overview of IRB Requirements

Sara Horn, IRB Program Director

Overview of Topics

- IRB Oversight
- Applicable Human Subjects Regulations-International Research
- Training Requirements
- Delays or Setbacks in the IRB Review Process

IRB Oversight

- All human subjects research conducted by PSU Faculty, Staff, or Students of the University, regardless of where the research is happening, must receive IRB review and approval or determination.

Applicable HS Regulations

- Ethical Principles applied by reviewing IRB – Belmont Report
- HHS regulations
  - Common Rule
  - FDA- Research Involves the uses of drugs of medical devices
- Local review requirement (Ethics Committee or IRB)
  - Network with local individuals are local context, review requirements
  - Appoint local collaborator(s) to assist in site identification, review processes, infrastructure requirements, local laws/policies
  - Establish partnerships through local collaborator(s)
- Site Approval/Authorization

OHRP Resources

- OHRP International Compilation of Human Research Standards

https://www.hhs.gov/ohrp/sites/default/files/2018-International-Compilation-of-Human-Research-Standards.pdf

- OHRP Compilation of Social Behavioral Research Standards

https://www.hhs.gov/ohrp/international/social-behavioral-research-standards/index.html

- OHRP Compilation of GDPR Guidances

https://www.hhs.gov/ohrp/international/gdpr/index.html

IRB Review- Considerations of Local Context

- Local Context Expertise/Knowledge
  - Spoken Language and literacy rates
  - Knowledge/demonstration of knowledge of local laws, policies, culture
  - Political Affiliations and context
  - Religious Affiliations and context
  - Structure for approval process locally
  - Informed consent based on local context
  - Other cultural considerations
  - Risk/Benefit Assessment
  - Access to emergency medical services/care
  - Alignment of goals of community and research
  - Sharing research results

Translations

- Written Materials are to be presented in language understandable to participants
  - Require review and approval by the IRB
  - Google translate or similar automated programs likely not reliable/accurate enough- a certified professional best but generally not required
  - Complete certification of translation when submitting translated materials to the IRB
  - DON”T FORGET! All communications with local collaborators, review committees, approvals need to be translated as well
- Interpreter
  - Fluent in the language and English
  - Understanding of privacy/confidentiality concerns, research in general

General Data Protection Regulation (GDPR)

- **Went into effect May 25, 2018**, European Union/European Economic Area countries

- Applicable to studies where *personal data* from an EU subject or person located in the EU is collected, used, accessed.
  - *Sensitive data*= additional protections required
  - *Pseudo anonymized data* (e.g. coded data) considered to be personal data even if recipient of the data does not have access to key or master list that links to identifiable information
- Not applicable to truly anonymized data (does not include coded data)

- General Requirements (IRB facing)
  - Consent from subjects- Information regarding participant rights of access to, amendment, erasure of data
  - Mechanism to facilitate a participant's "right to be forgotten"
  - Appropriate safeguards for data subject to GDPR

HS Training Requirements

- Human Subjects Training- applies to those engaged in research
  - CITI Program (HS Social Science or Biomedical Courses and GCP courses available)
  - Alternative training and tracking mechanisms available for non-PSU, non-key personnel when necessary

- Qualifications of PI and Research Team (to include local collaborators)
  - Specific to local context and procedures to be performed
  - Demonstrated knowledge

Delays and Setbacks

- If the research is funded by DHHS and the foreign sites will receive funding, foreign sites are required to obtain a Federal Wide Assurance (FWA) to indicate compliance with the applicable federal regulations (FWA)
  - Requires additional time/effort
- Lack of knowledge of local context or local context information
  - Review requirements
  - Cultural competency
- Other associated requirements (not always tied to IRB Approval but may intersect)
  - Applicable PSU approvals for travel
  - Execution of agreements (MTA, DUA, etc.)
  - OGC input/help with foreign laws, requirements for conducting research in another country

PSU Resources

- Currently Available
  - HRP-103- Investigator Manual **NEW! Section on International Research**
  - IRB Analyst Consultation- Find Your IRB Analyst Here
  - HRP-304- Evaluation of Quorum and Expertise/ HRP-314- Criteria for Approval and Additional Considerations
- Currently under development: **NEW! Worksheet for the review of International Research**