

INTERNATIONAL RESEARCH

IRB Webinar

OBJECTIVES

- Familiarize researchers with requirements
- Review IRB considerations
- Outline steps for approval



IRB REQUIREMENTS

The Emory IRB, in reviewing Research protocols that will be conducted at a non-Emory site, must have obtained sufficient knowledge about the local research context to ensure that adequate protections are in place for the conduct of the Research in that geographic location.



INTERNATIONAL IRB/EC REVIEW

- Obtain local IRB/ethics committee approval if required. Collaborators at international site should be able to help determine requirements.
- If the study is federally funded, and a collaborating international institution is also “engaged” in research, then an OHRP-approved Federalwide Assurance (FWA) for the site may be required (*obtaining this can take extra time*)
 - To see if institution has FWA: <http://ohrp.cit.nih.gov/search/>
 - Instructions for filing FWA: <http://www.hhs.gov/ohrp/assurances/forms/fwainstructions.html>
- The international site should check OHRP FWA and IRB registrations at least annually to ensure that FWA and registration continue to be in effect.
- Guidance:
 - OHRP - <http://www.hhs.gov/ohrp/international/index.html>
 - Emory IRB - <http://www.irb.emory.edu/forms/socio.html>

DOCUMENTATION REQUIRED BY IRB

For studies which are *more than minimal risk*, local IRB/IEC review is generally required for any international sites.

Common ethical and/or regulatory codes of conduct:

- Belmont Report
- Declaration of Helsinki
- 45 CFR 46
- 21 CFR 50 (Protection of Human Subjects)
- 21 CFR 56 (Institutional Review Boards)
- International Conference on Harmonization – GCP E6

DOCUMENTATION REQUIRED BY THE IRB

For studies which are *no more than minimal risk*, local IRB/IEC review is recommended.

When the international or other non-Emory site cannot obtain IRB/IEC review:

- A letter of cooperation showing that the appropriate institutional or oversight officials are permitting the research to be conducted at the site is required (i.e. site permission or letter of invitation).
- A Cultural Context Letter is required.

CULTURAL CONTEXT LETTER GUIDANCE

If local Ethics Committee will not review, then *cultural context letter* required (upload in “Miscellaneous Documents”)

Some guidance:

- The letter cannot be written by any key personnel on the current application. Must contain contact info of the writer.
- The letter should describe the qualifications of the letter writer to provide a letter of cultural context.
- The writer must be familiar with the culture, customs and norms of the setting and able to vouch for the appropriateness of the activities and/or consenting process as well as the ability of the research team to carry out all study activities.
- The following persons would qualify if not affiliated with the current project:
 - An expert in the field at another institution
 - An Advisory Board member
 - A dissertation committee member
 - Emory University faculty member
 - The faculty advisor of the current project (not ideal, only as last resort)

OTHER FACTORS TO CONSIDER

- The extent of training in human subjects research ethics of study staff
 - Study staff includes all personnel engaged in human subjects research, even non-Emory local study staff. If local study staff are under local ethics committee oversight, then that committee's requirements take precedence, but Emory PI must ensure that some human subjects ethics training is completed
- The economic prosperity of the area in which the Research is to take place (when considering compensation in money or goods or services, re: undue influence)
- Consider visa requirements, export controls, and compensation for study team members

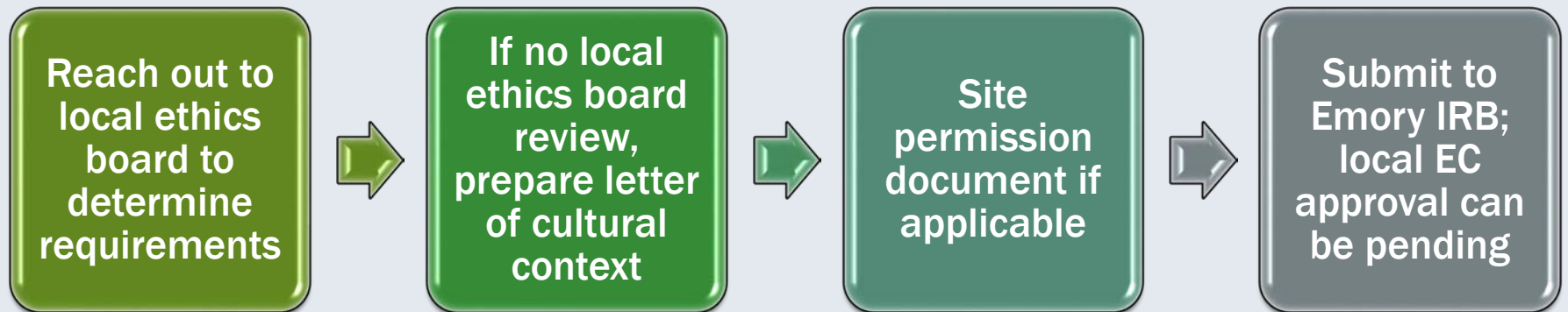
OTHER FACTORS TO CONSIDER

- The literacy rate of the area and its effect on the informed consent process – oral translation may be acceptable for low-literacy, or written translation may be required by IRB;
- The local legal rights of the population (such as legal age of consent);
- Any mandatory reporting issues, and laws relevant to sub-populations such as women (unmarried v. married women, women with children, etc., as to who can consent for themselves);
- How complaints or adverse events will be reported and to whom (both IRBs?);
- The relevance of the Research to the local population's needs and interests;
- The likelihood for the subject population to benefit from the results of the research; and
- The local standards of care for relevant medical conditions.

CONSIDERATIONS FOR INFORMED CONSENT:

- Disclosure of information to individuals who may be distrustful of people from researcher's country, or with topic of research
 - Some information may cause some people to refuse to join study, but in most cases that information needs to remain, as part of "respect for persons" – discuss with IRB if unsure
- Differences in the role of women in society
- Differences in the role of family and community in the consent process (e.g. in some cases a community leader would be the one to consent for members of the community)
- Multiple local languages
- Literacy level
- Inclusion of local (i.e. free) telephone contact
- Note: IRB can waive signature in many cases
- Please refer to the IRB policies and procedures for guidance on translation of the ICF and other study documents

THE PROCESS



HIPAA PRIVACY RULE

HIPAA is a US regulation and does not apply at international research sites; however, if protected health information is brought back to the US and analyzed here, then HIPAA will apply.

The informed consent should clearly explain the following:

- Type of research data being brought back to the US (e.g. identifiable survey data, identifiable blood samples, voice recordings, etc.)
- How the data will be protected (e.g. locked cabinet, password protected computer etc.)
- How long will data will be stored? How will data be destroyed?

Consider repatriating only fully de-identified data and samples!

Additional Guidance

Other requirements researchers should be aware of when conducting human subjects research internationally:

<http://global.emory.edu/support/>

http://global.emory.edu/support/project_planning/considerations_projects.html

<http://global.emory.edu/support/contacts/index.html>

IMPORTANT REMINDERS

- For clinical drug/device studies with an Emory investigator as “sponsor” (lead PI or IND/IDE holder), that include international sites, the Emory sponsor must provide the IRB with assurance that they are aware of international regulations and will follow them.
- The international site’s IRB/EC should provide a list of considerations and requirements regarding the use of investigational drugs along with applicable laws.
- Monitoring of the site must be considered and some countries require retention of a CRO, costs for which would be the responsibility of the sponsor-investigator.

IMPORTANT REMINDERS

- Local regulations on research vary widely from country to country. Please consult with the Office of Research Compliance and/or General Counsel's office for guidance on local legal issues.
 - In some cases, outside counsel must be retained to provide legal advice on legal requirements. In such cases, the costs for outside counsel are the responsibility of the sponsor-investigator.
- You will need to submit an amendment if you change your study design, even while abroad. The IRB is happy to assist you with this process. Please contact us by phone or email if urgent.
- For DoD and VA studies, there are special requirements. Please refer to the IRB policies and procedures on international research.

IN SUMMARY

- Before you start your project, reach out to the applicable offices and/or sites to determine what may be required. For exempt studies, touch base with the IRB to avoid unnecessary work on your part (some of the preceding rules are only for non-exempt research)
- Gather the required documentation early.
- Never hesitate to reach out to the IRB for guidance!

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THANK YOU!

Please consider taking a moment to complete our survey, link located on the webinars page of the website