

Transnational Studies

IRB's evaluation of a researcher's plan for complying with local laws and customs when conducting transnational research

AAHRRP Element I.3

The Organization's transnational research activities are consistent with the ethical principals set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization's principal location while complying with local laws and taking into account cultural context.

HRPP 9.3

Transnational Studies Policy and Procedures

When reviewing research protocols that will be conducted at a non-MUSC foreign site, *the MUSC IRB must obtain sufficient knowledge about the local research context (local laws, customs and requirements) to ensure that adequate protections are in place for the conduct of the research in that geographic location.*

Ways To Obtain Knowledge Of Local Context

- Personal knowledge of one or more IRB members or an appropriate consultant who had direct experience with the site, its populations, and the surrounding community;
- Written materials submitted by the investigator or local site contact
 - Researchers may retain local lawyer to receive information on local laws and submit information to IRB
 - Researchers may rely on a strong collaborator to stay abreast of local details. This collaborator would be someone who has done research in the past in country or a local collaborator.
- Site visit or conversation with the local site contact or other individual identified by the investigator as being knowledgeable about the research site.

Research Protocol

- Scope and nature of the research activities to be performed at the external location/site;
- Relevance of the research to the local population's needs and interests;
- Community in which the research will take place, including any customs or practices (e.g., cultural, political, or religious) unique to the location/population;
- Characteristics of the site that may affect selection and/or privacy of participants;
- Influence of local officials on the population;

Protocol Should Include (Cont.)

- Literacy rate and language(s) understood by potential participants;
- Local legal rights of the population (including relevant sub-populations such as women in general, unmarried v. married women, children, etc.);
- Appropriateness of proposed compensation (if any) at the external location;
- Facilities/equipment at the external site relevant to research performance and protection of participants;
- Methods for maintaining confidentiality of data stored and transferred between sites;

Protocol Should Include (Cont.)

- Communication and oversight plans between MUSC and the external site;
- How complaints will be reported and to whom;
- The possibility of including officials from the area in the monitoring of the research;
- Local standards of care for relevant medical conditions;
- Applicable laws, site policies, and requirements relevant to the research and how the research team will comply with such.*

HIPAA Considerations

- The extent to which HIPAA applies to international research is currently a matter of discussion; however, once individually identifiable health information is received by MUSC (a covered entity), that information becomes protected health information (PHI).
- When a researcher sends individually identifiable health information collected internationally across a MUSC network or stores such information on a MUSC computer or server, the information becomes PHI.

Helpful Tips for IRB Reviewers

- Look for “key personnel” on the study who are local or and who have done research there before.
 - Red flag – no local personnel on a study, or no local Co-I who is trained in research.
- Did the researcher consult with Non-Governmental Organizations? These organizations are often helpful to researchers as they have great links to communities.
- Its important to get a sense of how much time the US Investigator has spent in country and how much homework has taken place on the US Investigator’s part?

Helpful Tips for IRB Reviewers (Cont.)

- Issues of participant safety are difficult to assess from afar. Routine procedures might be quite risky in some settings.
 - Find out if study procedures are new in a setting. If so, some basic write up on local safety would be useful.

COMMUNICATION

When necessary, the MUSC IRB will communicate with the host country's IRB or EC.

Questions?

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