DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

INTERNATIONAL RESEARCH

3/24/2025

I. OVERVIEW

This policy provides requirements for conducting or participating in international research. Investigators must be aware of and follow the additional requirements that accompany such research, including those of the country in which the research is being conducted, applicable U.S. regulation, and applicable Duke policy.

II. QUALIFICATIONS TO CONDUCT INTERNATIONAL RESEARCH

Investigators proposing to conduct research internationally must be qualified to conduct such research, much the same as investigators conducting domestic research are required to be qualified. In order to demonstrate such qualifications, the following should be included in the IRB submission:

1. Document how the study will provide the same or equivalent protections to research participants in the international setting as they would if they were conducting research within Duke University Health System (DUHS), and complete all required CITI modules related to the research
2. Document an awareness of local laws and a sensitivity to local context, and commit to complying with applicable local laws
3. Provide documentation of local Institutional Review Board or Ethics Committee approval of their proposed research before they initiate the research at the international site(s), or if such a board/committee is not available to them, they must describe how they will ensure that equivalent protections are in place (such as obtaining approval from the applicable Ministry of Health representative).

Preferably the investigator(s) will have prior experience working or living in the country where the research will be conducted, and have well-established relationships with local investigators, care providers, and community leaders. The IRB will review this information as it does for investigators conducting research within the United States only.

III. LOCAL REVIEW REQUIREMENTS

International research applications submitted for DUHS IRB review should identify whether there is a local IRB, Ethics Committee (EC), or government entity that will perform review in the host country. If local review has been conducted, a copy of the approval letter/notice should be attached to the IRB application. If local review has not been initiated or is still in process, this should be made clear in the application.

Oversight by the local IRB/EC should include the following activities:

- Initial review, continuing review, and review of modifications to approved research
- Post-approval monitoring
- Review of complaints, concerns, non-compliance and unanticipated problems involving risk to subjects or others
- Review in light of local laws/regulations and cultural context to ensure that the research complies with local laws/regulations and adheres to cultural norms.

If the local IRB/EC will not perform the required review functions, the DUHS IRB must fulfill these functions.

If the research is supported by the U.S. Government, then each foreign site must hold a valid Federal Wide Assurance (FWA). If Duke is the primary grant awardee for U.S. Government funding, then sites external to the U.S. must review and conduct research in compliance with 45 CFR 46 and, if applicable, 21 CFR 50 and 56. The Duke Principal Investigator will ensure that participating sites maintain a current FWA and yearly scientific and ethical review as required with the federal regulations cited above for the duration of the study at that site.

To supplement its review, the DUHS IRB will obtain, if needed, consultation from one or more individuals familiar with the cultural background, local context, community attitudes, and laws of the country in which the research will be conducted. These individuals may not be listed on the application as key personnel or associated with the conduct of the proposed research.

IV. CONSENT REQUIREMENTS

Written consent is presumed to be required for international research. Requests for waiver of documentation of consent, or for use of an oral consent process, will be considered if the protocol with the waiver has received local IRB/EC approval. The DUHS IRB requires consent forms (or oral consent scripts) to be written at a level that will be understandable to the study population. Submission to the DUHS IRB of copies of consent documents in the local language(s) and the English template consent sent to the international site are required.

Additionally, in the IRB application, the investigator must describe who will obtain informed consent at the foreign site(s) and explain the qualifications of those persons. Refer to the Duke HRPP policy titled “Translation Requirements for Research” for requirements regarding translation of consent forms and other documents provided to participants who do speak a language other than English.

V. HIPAA CONSIDERATIONS

Based on NIH guidance, all individually identifiable health information, including individually identifiable health information of non-U.S. citizens, is protected health information (PHI) when it is held by a covered entity,

unless it is otherwise excepted from the definition of PHI at Section 164.501 of the Privacy Rule. As such, once individually identifiable health information is received by DUHS (a covered entity), that information becomes protected health information (PHI) (*nota bene*: narrow exception for overseas foreign nationals receiving health care from US agencies). When a researcher sends individually identifiable health information collected internationally across a DUHS network or stores such information on a DUHS computer or server, the information becomes PHI.

Because HIPAA concepts can be difficult to translate in international studies, researchers may request an Alteration of HIPAA Authorization, for the IRB to approve altered language or a simplified form of the required authorization language, and/or to approve an oral authorization process. Alternatively, where cultural barriers are significant, a request to the IRB to waive the requirement of HIPAA Authorization entirely may be submitted.

In such cases, the IRB must determine that the request meets all of the waiver criteria in the HIPAA Privacy Rule. The investigator(s) can avoid HIPAA considerations altogether by not transferring PHI to DUHS, but instead either transferring only coded de-identified health information or only a limited data set with an established data use agreement in place.

VI. ADDITIONAL CONSIDERATIONS

The following information, when applicable, should be included in the IRB application:

- Proposed payments to participants - The remuneration should be described in terms of both U.S. and local currency. Include a description of payment in relative terms; for example: payment equates to a day's work, hourly salary, or another local reference
- Local contact information - Include a local phone contact number on the consent form for co-investigators and/or the local IRB/EC who could answer research related questions. If the project is a clinical trial, include local emergency contact phone number(s) for participants.
- Treatment options - For treatment studies, explain if any treatment(s) will be available to participants after study completion. If a placebo arm is included in the trial, explain whether participants will be able to receive the study drug/intervention after study completion.

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