Tufts University Guidance: International Research with Human Subjects

Tufts University researchers often conduct biomedical and social/behavioral/educational research outside of the United States. When conducting international research, Tufts and its researchers must ensure that these activities not only meet the ethical and regulatory requirements for conducting research at Tufts, but also respect the cultural norms and research regulations in the host country.¹

This shared responsibility can be achieved by evaluating the following criteria and providing appropriate information to the Tufts Health Sciences Institutional Review Board or the Tufts Social-Behavioral-Educational Institutional Review Board (Tufts IRBs) for the review of applications for international research.

Research Oversight

Researchers who would like to conduct international research must plan in advance to obtain review of the research in the host country, in addition to fulfilling Tufts IRB review requirements. Approval from the appropriate oversight body in the host country is required for approval by the Tufts IRBs.

1. Applications for international research submitted to Tufts IRBs should indicate which local IRB, Ethics Committee, or government entity will perform review in the host country. If the study is not yet approved in the host country, clearly indicate the status of the local ethics review. If the study has been approved, provide a copy of the approval letter or notice from the host country’s ethics review (with translation into English, as needed). Provide the name and contact information/website of the ethics review body.

2. In some countries, local regulations do not require review of the research (e.g., social/behavior/educational research or use of existing data/samples) or there is no local ethics committee to review the research in the host country. In these cases, researchers must provide a letter of support from an individual in the host country who has the relevant expertise or institutional authority to review the research. The letter must support that there is no formal review process available or needed, and that the research is acceptable according to local context. This person cannot be associated with the conduct of the proposed research.

   a. This standard may apply to exempt research, depending on a variety of factors such as the country in which the research will be conducted, the PI’s and IRB’s familiarity with the country’s research regulations and local context, the nature of the research, the experience of the investigator, etc. Please contact the appropriate Tufts IRB to discuss proposals for exempt research that will be conducted internationally.

   b. If the researcher is proposing to conduct a clinical trial in a country where there is no local ethics committee to review the research, additional local oversight may be required by Tufts IRBs, such as an ad hoc review committee.

3. When non-exempt research is sponsored by a US federal agency, all domestic and international sites engaged² in the conduct of federally-funded research must hold a Federalwide Assurance³ (FWA) with

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² In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. For more information, please refer to the Guidance on Engagement of Institutions in Human Subjects Research.

³ OHRP: Federalwide Assurances
the Department of Health and Human Services (DHHS). For US federally-supported research, the international site must rely upon the approval of an IRB that is registered with DHHS and is designated on the site’s FWA. This requirement applies to all Tufts research conducted with federal funding or support. Any international research that is funded by the FDA must comply with DHHS, FDA, and any applicable local regulations.

4. Federal guidance addressing international research is periodically released by the Office for Human Research Protection (OHRP). Investigators involved in international research are strongly advised to consult federal sources, including the *International Compilation of Human Subject Research Protections* guidance document.⁴

5. If a Tufts University faculty member, employee, student, etc., becomes involved in international research after it has been initiated, approval from one of Tufts IRBs is required prior to the time of the investigator’s involvement. The PI must delineate the components of the research that he/she will be involved in, and provide documentation of prior local approval of the study.

6. Provide the name and contact information of a person not affiliated with the research who has expertise on the local context of the country or community where the research will be conducted. A member of Tufts IRB may contact this individual as an expert content reviewer or consultant.

**Local Context**

Both the Principal Investigator (PI) and Tufts IRBs must consider the local context of the host country(ies) or community(ies) to ensure that adequate provisions for protecting human subjects are in place during the conduct of international research. Cultural, economic, or political conditions of the host country/community should inform decisions about how the research is conducted, and in some circumstances may even alter the risks and/or benefits for participants.

The PI and research team members conducting international research shall include relevant local context information in their IRB applications. Local context should be evaluated for each location of the research. This includes, but is not limited to, the following:

1. Cities, regions countries where research will be conducted
2. Scientific/ethical justification for conducting the research in an international setting
3. Economic status of the country/community
4. Current events or socio-political environment in the country that may impact research conduct or alter the risks or benefits to subjects
5. Societal and cultural beliefs in the country that may impact research conduct or alter the risks or benefits to subjects
6. The role of women and children in the society, including their autonomy and legal capacity to make decisions
7. Literacy rate of the potential subject population
8. Languages and dialects of the potential subject population
9. Involvement of organizations, community leaders, or experts in engaging the subject population or conducting the research
10. Description of the research team’s knowledge of or experience in the host country
11. Relevance of the research to the area’s health, economic, educational, or other needs
12. Distribution of risks and current and future benefits

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⁴ *International Compilation of Human Subject Research Protections*
Consent Process

Researchers are expected to adhere to the federal requirements for consent, whether the research is conducted in the US or internationally. Tufts IRBs acknowledge that consent procedures typically followed in the host country/community may differ from those required by US federal regulations. Tufts IRBs may approve modifications to consent requirements if the procedures provide equivalent protection to research subjects and are approved by the local oversight body (as referenced in the Research Approval section above).

Please address any of the following informed consent topics that may apply to your research:

1. Any information presented to subjects during the course of the study must be submitted to Tufts IRBs for review and approval; the local review body may also require review and approval of this information. This includes, but is not limited to recruitment material, consent documents, educational or instructional material, hand-outs, presentation, or scripts.

2. If the research team would like to request a waiver of written consent for research in which written consent is typically required, please provide justification for the request and describe how consent will be documented. Examples may include low literacy levels within the population, the cultural significance of providing signatures, etc.

3. If minors will be enrolled in research, provide the legal age of majority and describe an appropriate assent process for the local context.

4. Consider the potential role of family and community within the consent process or issues related to autonomy (e.g. consent from community leaders or supplemental consent from male family members). Describe how the research team will address additional consent processes, if they need to occur.

5. Consider whether the research intersects with any cultural sensitivities or societal norms. If so, describe how this will be addressed in the consent process, in ICFs and other study documents (e.g. research on abortion in a country where the procedure is illegal; vaccine trials on a disease that is heavily stigmatized in the host country).

6. Informed Consent Forms (ICFs) and other study documents must be presented in language understandable to the participants.
   a. All documents provided to participants should take into account the literacy and education levels of the study population. Please ensure that all study documents are written in simple, readable language, while clearly communicating the purpose of the research.
   b. For non-exempt research, ICFs and study documents must be translated in the language/dialect of the participating subjects. Translated study documents must be submitted to the appropriate Tufts IRB, along with translator credentials or translation certifications, for review and approval prior to use with human subjects.
      i. The Tufts Health Sciences IRB requires forward- and back-translations of all study materials by 2 separate certified translators (1 forward-translator; 1 back-translator) or a forward-translation by a group of certified translators, such as a commercial service. For additional information about the document translation policy at the Tufts Health Sciences IRB, please refer to the Tufts Health Sciences IRB Policies and Operations Manual.
      ii. The Tufts Social Behavioral Educational IRB requires forward translation only of all study materials, along with the submission of a Certificate of Translation.
      iii. Tufts IRB review and approval of translated study documents is not required for Exempt research.

7. The research team must provide subjects with locally-based and US-based contact information. Researchers should select contact information that will ensure subjects have access to individuals who can answer research-related questions, even after the research team has left the host country.
**Post-Approval Responsibilities**

When developing an international research study, the PI must consider how he/she will fulfill the following responsibilities once study approval has been granted (responsibilities #1 and #2 also require documentation in the study protocol):

1. **Implementation of data and record retention plan consistent with Tufts IRB policies.** Study records such as executed consent forms, case histories, and regulatory correspondence must be accessible for inspection and copying by authorized representatives of the IRB and/or federal agencies, whether the records are maintained in the host country or in the US. Describe this plan in the study protocol.

2. **Implementation of a plan to provide Tufts IRB with reports of serious adverse events and unanticipated problems in accordance with Tufts IRB reporting timelines.** Promptly notify the IRB of non-compliance, protocol deviations, and subject complaints. Promptly submit study updates, correspondence with the local oversight body, and data and safety monitoring reports to Tufts IRBs. Describe this plan in the study protocol.

3. **Make sure that there is a well-understood line of communication with the local site.**
   a. Ensure that members of the study team and international collaborators are up-to-date with regard to the approval status of the protocol and other study documents.
   b. For student projects, there must be a well-defined plan or schedule to ensure communication and oversight between the advisor and student during the conduct of the research.

4. **Whether the Tufts PI operates domestically or in the host country, he/she must maintain oversight of the study and ensure proper conduct of the protocol and compliance with US and international regulations.** If Tufts is the primary awardee of a grant for the overall project, the PI is responsible for overseeing the research of any international collaborators. If the Tufts PI delegates responsibility for local oversight to another person, he/she ultimately remains responsible for the proper conduct of the study.

5. **Request modifications to the approved protocol from both the Tufts IRB and any local oversight bodies before initiating any changes in the research.** The only exception to the requirement of obtaining IRB approval before initiating a change in the protocol is when a change is necessary to eliminate apparent immediate hazards to a subject(s). Under such circumstances, the PI is to contact the IRB Chair, or the IRB office, within 5 days of the event.

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5 *Tufts Health Sciences IRB Unanticipated Problem and Adverse Event Reporting Policy; Tufts Social Behavioral Education IRB Adverse Event Reporting Form and Unanticipated Problem Reporting Form*