



Albert Einstein College of Medicine

International Research Procedure

I. Purpose

The purpose of this procedure is to ensure that the international human research in which Albert Einstein College of Medicine (“Einstein”) or Montefiore Medical Center (“MMC”) is engaged is consistent with the ethical principles set forth in its Human Research Protection Program (“HRPP”) and meets equivalent levels of participant protection as research conducted within the United States. International human research must also comply with relevant local laws and take into account the relevant cultural context.

II. Scope

This procedure applies to when Albert Einstein College of Medicine (“Einstein”) or Montefiore Medical Center (“MMC”) is engaged in human research, including exempt human research, outside of the United States

III. Definitions

None.

IV. Procedure

1. For protocols to which this procedure applies, the International Research Protocol Addendum must be submitted to the Office of Human Research Affairs (“OHRA”) in addition to the standard application materials required for research conducted within the United States.
 - On the basis of the information provided in the International Research Protocol Addendum, the Einstein IRB will assess whether the international Human Subject Research Activities comply with relevant local laws and meet equivalent levels of participant protection as research conducted within the United States.
 - The Einstein IRB will use the information in the addendum to assess the qualifications of the research staff for conducting research in the country of interest, and to ensure recruitment, consent, and study materials consider local customs, laws, and cultural context.
 - The International Research Protocol Addendum and/or protocol must describe local site monitoring and handling of subject complaints, noncompliance, and unanticipated problems involving risk to subjects or others.

- The International Research Protocol Addendum must specify who is responsible for such monitoring and reporting.
- If deemed necessary the Chair, a designee, or the OHRA Director, the IRB will seek consultation by legal or cultural experts for its review.

2. Exempt and Expedited Review Procedure

- IRB staff will confirm the inclusion of the International Research Protocol Addendum in the submission.
- IRB staff will assign the submission to a member of the Global Research Committee (“GRC”) for a consultant review.
- If the GRC consultant reviewer finds the proposed research to be acceptable, IRB staff will assign the submission to an IRB member following the same procedure as that for non-international exempt or expedited studies. The submission will include the comments and any recommended changes from the GRC consultant reviewer.

2..1. Any changes recommended by the GRC consultant reviewer will be communicated to the investigator alongside changes required by the IRB member in the determination letter following IRB review.

- If the GRC consultant review does not find the proposed research to be acceptable, it may require changes and re-evaluation before the research is reviewed by an IRB member.

3. Full Board Review Procedure

- IRB staff will confirm the inclusion of the International Research Protocol Addendum in the submission.
- IRB staff will schedule a meeting of the Global Research Committee (GRC) to review the submission.
- Review by the GRC must be completed before IRB review at a convened IRB meeting.
- The GRC is composed of at least one ethicist, one physician, and one researcher with experience conducting international research.
- The GRC is an advisory committee that does not formally approve or dis-approve proposed research. There must be at least 2 members present to meet quorum.
- The GRC will review the protocol, International Research Protocol Addendum, and the consent form(s). The committee may request additional documents if deemed necessary.
- If the GRC finds the proposed research to be acceptable, IRB staff will forward the committee’s comments and any recommended changes to the reviewing IRB.

3..1. Any changes recommended by the GRC will be communicated to the investigator alongside changes required by the IRB in the determination letter following IRB review.

- If the GRC does not find the proposed research to be acceptable, it may require changes and re-evaluation by the committee before the research is reviewed by the IRB.

- 3..1. If the GRC requires changes and re-evaluation, IRB staff will communicate the committee's comments and required changes directly to the investigator.
4. If applicable, approval from the local IRB or equivalent institution is required before research activities can commence at the local site. A copy of the local approval letter must be submitted to Einstein IRB, along with any updated protocols or study documents.
 - If no local IRB is available, a letter from the local community or collaborator attesting to acceptability of proposed research, or consultation by an expert who is independent of the research team and is familiar with the local site's culture and norms, may be acceptable depending on the level of risk. Such documentation should be included as part of initial submission.
 - It is the responsibility of the affiliated investigators (or collaborating investigators at the local site) to be familiar with the local culture, laws, and regulations and to provide Einstein IRB with the necessary information for review and approval.

V. Effective Date

Effective as of: August 14, 2020

(Implementation Period: Six months from the effective date)

Revised as of: September 7, 2023

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.