SOP - International Research Advisory Committee (IRAC)

Version #: 001 Effective Date: April 30, 2016 Supersedes Document: N/A

This Policy pertains to: COMIRB procedure for IRAC review and IRB review

Responsibility for executing this policy: COMIRB Director, Assistant Director, Staff, Chairs, IRAC Reviewers, Panel Members

Last Reviewed on: N/A Result: N/A

Approval Authority: Director

Approved by: Meredith Mealer Date: 04/30/2016

1. PURPOSE

The purpose of this policy is to describe the role of the International Research Advisory Committee (IRAC) and COMIRB's process on communications between IRAC review and IRB review.

2. POLICY

The IRAC is an advisory committee to IRB review at COMIRB when international research studies are submitted to COMIRB. The IRAC reviews international research studies to ensure all international issues and concerns are adequately addressed prior to IRB review. The IRAC makes recommendations to the Chair or appropriate panel assigned to conduct IRB review. The IRAC also makes recommendations to investigators conducting international research, if necessary, prior to advancing the international study to IRB review. Communication between the IRAC review and IRB review is vital in facilitating the overall review of international studies at COMIRB. The IRAC only makes recommendations and final approval rests with COMIRB.

3. SPECIFIC POLICIES

3.1 Identifying studies that require IRAC review

3.1.1 A study requires IRAC review when funding is directed to an international site and/or an affiliated investigator travels to an international site and engages in research activities such as recruiting subjects, consenting subjects, and/or collecting research data. Receiving research data/samples from international sites and analyzing such data/samples at the affiliated site do not necessarily engage the affiliated investigator in international research. When affiliated investigators receive data/samples from international sites for research purposes, it should be evaluated to determine whether the investigators are engaged in international research.

3.1.2 Not Human Subjects Research does not require IRAC review. Refer to the best practice for IRAC review of projects that are submitted by investigators as QA/QI and COMRIB determines to be research.

3.2 Process of international research studies

3.2.1 The Investigator Support (IS) team is responsible for processing international research studies, coordinating IRAC review, and facilitating communication between IRAC review and IRB review.

3.2.2 IRAC review should be completed prior to IRB review of international research studies. However, the timing of IRAC review for full-board protocols and that of expedited and exempt protocols may differ. The difference in the timing of IRAC and IRB reviews is due to the fact that full-board protocols must be reviewed and approved at weekly or bi-monthly convened IRB meetings, whereas expedited and exempt protocols can be reviewed by a Chair who is likely to have a more flexible review schedule than convened meetings.

3.2.2.1 IRAC review of full-board international studies must be completed before IRB review at convened IRB meetings.

3.2.2.2 IRAC review of exempt and expedited international studies can take place before, or concurrently with, IRB review, so long as the review process is coordinated such that IRB review incorporates IRAC recommendations prior to approval of the international studies.

3.2.2.3 All international studies must be reviewed by the IRAC and approved by COMIRB prior to commencement of research. Additionally, they generally require review and approval of the IRB/Ethics Committee (EC) in the respective country prior to commencement of research.

3.2.3 IRAC review and IRB review must be coordinated between the IS team and the appropriate panel according to the best practice in order to ensure communication between the two review committees.

3.2.4 When the IS team receives an international research study, an IRAC coordinator will create an administrative IRAC submission in the InfoEd to document IRAC review according to the best practice.

3.3 IRAC meetings and review of international research studies

3.3.1 IRAC members consist of faculty members and staff who have conducted research in international settings. Additionally, IRAC membership consists of the following: COMIRB exempt/expedited reviewers, senior COMIRB administrators, a representative from the Office of International Affairs, a representative from the Center for Global Health, and ad hoc members who have working knowledge of various international sites.

3.3.2 IRAC is an advisory committee to IRB review; it is not a voting committee. It does not require quorum in order to hold a meeting.

3.3.3 IRAC reviewers are assigned to review international research studies based on their expertise in the geographical area and/or research field.

3.3.4 The IRAC reviewer will review the protocol, Application form with Attachment B (International Research), and the consent form(s) to ensure the international study is culturally appropriate to conduct research at the requested international site and to ensure that the same human subject protections apply as would apply in the U.S. IRAC may request additional documents if deemed necessary to evaluate the adequacy of the international study.

3.3.5 COMIRB expects affiliated investigators (or collaborating investigators at the local site) to be familiar with the local culture, laws, and regulations and to provide COMIRB the necessary information for review and approval.

3.3.6 The IRAC reviewer will complete the IRAC Checklist (CF-112). The Checklist will be filed in the study file according to the SOP on Filing (CP-028).

3.3.7 The IRAC can make the following recommendations: (a) Acceptable as submitted; (b) Acceptable with recommendations; or (c) Requires changes and to be re-evaluated by IRAC prior to IRB review.

3.3.7.1 Re-submission to IRAC is not necessary for the first two recommendations above (a and b) prior to IRB review. Comments from the IRAC review will be communicated to the appropriate Chair or panel assigned to conduct IRB review according to the best practice.

3.3.7.2 The international study must be re-submitted to IRAC for the last recommendation above (c) prior to IRB review. Comments from the IRAC review will be communicated to the investigator according to the best practice.

3.3.8 After obtaining approval from COMIRB (and the local IRB/EC if applicable), investigators are responsible for submitting continuing reviews, unanticipated problems reports, and amendments until closure of the international studies, unless they are exempt international studies. Investigators of exempt international studies are responsible for submitting unanticipated problems reports and amendments that may change the exempt status, over the course of international studies.

4. RESPONSIBILITY

It is the responsibility of the Director, Assistant Director, designated Senior IRB administrator(s), IRAC coordinators, and IRAC members to implement this SOP. It is the responsibility of the COMIRB Director and Assistant Director to implement and monitor this SOP.

5. APPLICABLE REGULATIONS AND GUIDELINES: None.

6. **ATTACHMENTS:** None.

7. **PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

Who	Task
Director	Provide oversight to ensure this SOP is implemented.
Assistant Director	Provide oversight to ensure this SOP is implemented.
Senior IRB administrator	Designated Senior IRB administrator will chair IRAC meetings and provide oversight to ensure this SOP is implemented.
IRAC coordinators	Process international studies, coordinate IRAC meetings, facilitate communication between IRAC and IRB reviews.
IRAC members	Review international studies.