Policy and Procedure

INTEGRIS	**ENTITY/HOSPITAL** **INTEGRIS Health**	**NUMBER** **SYS-IRB-101**
	MANUAL **System Policies**	**EFFECTIVE DATE** **2014/11**
	SUBJECT **NATIONAL CANCER INSTITUTE CENTRAL IRB**	**REVISED**

1.0 PURPOSE

The purpose of this policy is to provide guidelines for employees and medical staff members of INTEGRIS Health (INTEGRIS) relating to clinical trials sponsored by the National Cancer Institute (NCI) and collaborations with the NCI Central Institutional Review Board (CIRB).

2.0 POLICY

It shall be the policy of the INTEGRIS Institutional Review Board (IH IRB) to participate in the NCI CIRB Initiative and to facilitate review of certain NCI-approved protocols as described herein. The CIRB Initiative is sponsored by the NCI in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

3.0 PROCEDURE

The following procedures are established to assist the IH IRB and investigators ensure compliance with applicable guidelines relating to Facilitated Review (as defined below) of NCI-approved protocols.

3.1 Submission Requirements to the IH IRB. Investigators applying for initial approval of a NCI-approved protocol must submit the following to the IH IRB:

- 3.1.1 CIRB-approved protocol documents.
- 3.1.2 CIRB-approved informed consent documents.
- 3.1.3 CIRB approval letter (when it becomes available).
- 3.1.4 Any other IH IRB-required documents, such as the IRB application form.

3.2 Pre-IRB Committee. The IH Pre-IRB Committee is a sub-committee of the IRB that is comprised of the IRB Chair and a minimum of two additional IRB members. The Pre-IRB Committee meets a minimum of once per month. The Pre-IRB Committee is the body designated by IH to conduct Facilitated Reviews.

3.3 Facilitated Review. The Pre-IRB Committee will conduct a Facilitated Review of CIRB-approved studies for consideration of local context issues. IRB staff will obtain CIRB minutes, scientific and non-scientific review materials from the CIRB for review.

3.4 Review and Determinations. The Pre-IRB Committee will review submissions to determine on a case-by-case basis whether (1) to accept the CIRB review as the review of record and perform a Facilitated Review or (2) to conduct a full review of the protocol. The Pre-IRB Committee shall make one of the following determinations as a result of its review of CIRB-approved protocols submitted for review:

- 3.4.1 Accept the CIRB submission without changes.
- 3.4.2 Accept the CIRB submission with *de minimus* modifications.
- 3.4.3 Not accept the CIRB review and require that the investigator submit the protocol for review by the convened IH IRB.

The IH IRB will notify the CIRB each time it completes a Facilitated Review indicating acceptance or rejection of the CIRB review of a protocol.

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4.0 RESPONSIBILITY

Where an IH facility is being considered as a site for an NCI-approved protocol/study, the following outlines the responsibilities of the IH IRB and the CIRB with respect to such study:

4.1 Responsibilities of the CIRB:
- 4.1.1 Initial review of the study
- 4.1.2 Continuing review of the study
- 4.1.3 Review of amendments related to the study
- 4.1.4 Review of adverse events

4.2 Responsibilities of the IH IRB:
- 4.2.1 Initial acceptance or rejection of CIRB review of the study
- 4.2.2 If CIRB review is accepted, to perform a Facilitated Review for such study
- 4.2.3 Provide oversight of local conduct of the study
- 4.2.4 Review locally occurring adverse events

5.0 SCOPE

5.1 These policies and procedures apply to investigators submitting CIRB-approved protocols for Facilitated Review, to IRB staff, and to IRB members of the Pre-IRB Committee.