INTEGRIS	ENTITY/HOSPITAL INTEGRIS Health	NUMBER SYS-IRB-102	
	MANUAL System Policy and Procedure	EFFECTIVE DATE 2/18/2015	
	SUBJECT CENTRAL IRB	Reviewed	Revised

1.0 PURPOSE

The purpose of this policy is to outline guidelines for the limited circumstances in which an external third party institutional review board or central institutional review board (collectively referred to as a CIRB) may be used for review and approval of INTEGRIS Health research activities while still providing an acceptable level of ethical oversight and human subject protections.

2.0 POLICY

The INTEGRIS Health IRB (IH IRB) will consider requests from Principal Investigators (PIs) to utilize a CIRB for certain studies conducted at INTEGRIS Health (INTEGRIS Studies, as more specifically described in Section 5.1 below) if (i) the CIRB is accredited by The Association for the Accreditation of Human Research Protections Programs (AAHRPP); (ii) the CIRB has been approved by the IH IRB and is included on the list of approved CIRBs maintained in the IH IRB office; and (iii) the study meets the criteria for use of a CIRB.

3.0 PROCEDURES

3.1 List of Approved CIRBs. The IH IRB will maintain a list of approved CIRBs, which will be available in the IH IRB Office and on the IH IRB SharePoint site.

3.1.1 Approval of CIRB by IH IRB. If the PI wishes to use a CIRB that is not included on the list of approved CIRBs, the following procedure must be followed in order to have the CIRB added to the list of approved CIRBs.

3.1.2 Form of Request. A CIRB Approval Form must be submitted to the IH IRB. Such form, which must be substantially the same as the example form attached to this policy, will include the name and phone number of the CIRB, the name(s) of sponsor(s) using the CIRB, and a contact person at the CIRB, if available. The CIRB Approval Form must be submitted no later than five (5) business days before the IH IRB meeting at which it will be reviewed.

3.1.3 Review and Approval. The full IH IRB will review the application at the next IRB meeting following the submission of the CIRB Approval Form. In determining whether to approve the CIRB, the IH IRB will consider the following factors:

3.1.3.1 Whether the CIRB has received Office of Human Research Protection (OHRP) determination letters or Food and Drug Administration (FDA) warning letters in the last year;

3.1.3.2 Whether any issues or concerns have arisen from previous experiences with the CIRB under consideration;

3.1.3.3 The reputation of the CIRB among its constituency; and

3.1.3.4 The willingness of the CIRB to permit IH IRB oversight of local issues that occur within the study.

3.1.4 List of Approved CIRBs. Once a CIRB has been approved by the IH IRB, it will be added to a list of approved CIRBs, which will be maintained in the IH IRB Office and on the IH IRB SharePoint site. Thereafter, the IH IRB will conduct an annual review of each CIRB on the approved list following the same procedures

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as above to determine whether to leave the CIRB on the approved list for another year.

3.1.5 IRB Authorization Agreement. A written Authorization Agreement must be in place between the IH IRB and each approved CIRB that, at a minimum, includes:

3.1.5.1 A statement regarding the extent to which the IH IRB agrees to rely on the CIRB for review and oversight of INTEGRIS Studies; and

3.1.5.2 A description of the regulatory requirements for which each party will assume responsibility.

3.2 Approval to use an IH IRB-approved CIRB for specific INTEGRIS Studies.

3.2.1 Form of Request. The PI or designee must submit the following information to the IH IRB Office **every time they wish to submit an INTEGRIS Study to an IH IRB approved CIRB:**

3.2.1.1 The name, brief description and sponsor of the study; and

3.2.1.2 The reason for requesting the use of an IH IRB-approved CIRB for the particular study.

3.2.2 Review and Approval. The IH IRB Office will convey the request to the IH IRB Chair. The IH IRB Chair will consider the following information in determining whether to approve the use of an IH IRB-approved CIRB for a particular INTEGRIS Study:

3.2.2.1 Whether "time is of the essence" for approval of the study;

3.2.2.2 Whether a conflict of interest exists that creates a need for external review;

3.2.2.3 Whether the sponsor requires the use of the CIRB for the study under consideration;

3.2.2.4 The existence of local, social, economic, political or cultural concerns that may be relevant to the study;

3.2.2.5 Whether the study involves a vulnerable population;

3.2.2.6 Whether the sponsor holds all Investigational New Drugs (INDs) and/or Investigational Device Exemptions (IDEs) for the protocol, as applicable;

3.2.2.7 Whether the protocol meets the NIH definition of a clinical trial (refer to appendix A for full NIH definition); and

3.2.2.8 Whether the study is otherwise suitable for CIRB review.

3.2.3 Letter to PI. If the IH IRB Chair approves the use of a CIRB for a particular INTEGRIS Study, the IH IRB Chair will send a letter notifying the PI of such approval and indicating that use of the CIRB is subject to the requirements of this policy.

3.2.4 Effect of CIRB Approval of an INTEGRIS Study. If an approved-CIRB is utilized for a particular INTEGRIS Study as permitted by this Section, the PI must:

3.2.4.1 Follow the procedures in Section 3.3 of this policy regarding IH IRB review and ratification of such study; and

3.2.4.2 **Refrain from enrolling patients until the CIRB approval is ratified pursuant to Section 3.3 of this policy**.

3.3 IH IRB Review Process for CIRB-Approved Studies.

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3.3.1 Submission of documents to the IH IRB. When a CIRB has approved a particular INTEGRIS Study, the PI or designee will submit to the IH IRB the following information, as applicable:

3.3.1.1 Initial Review. Within five (5) business days of receiving CIRB approval of an INTEGRIS Study, the PI or designee must submit a Short-Form New Study Application via IRB+.

3.3.1.2 Annual Continuing Review. Within five (5) business days of receiving a CIRB Continuing Review approval letter, the PI or designee must submit a Short-Form Continuing Review Application via IRB+.

3.3.1.3 UPIRSOs. Within five (5) business days of becoming aware of any Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) occurring locally as part of CIRB-approved INTEGRIS Studies, the PI or designee must submit an Unanticipated Problems Application via IRB+.

3.3.1.4 Closure of Study. PI or designee must submit a study closure report via IRB+ before an INTEGRIS Study approved by a CIRB pursuant to this policy may be officially closed.

3.3.2 Fees. Applicable IH IRB fees will be assessed for initial and continuing reviews of CIRB-approved INTEGRIS Studies.

3.3.3 Review and Ratification by IH IRB. The IH Pre-IRB Committee will take one of the following actions after reviewing the documents submitted pursuant to this Section:

3.3.3.1 Ratify the study; or

3.3.3.2 Reject the study, which will essentially "veto" the approval by the CIRB.

3.3.4 Letter to PI. Once the IH Pre-IRB Committee ratifies or vetoes a CIRB-approved study, the IH IRB Chair will send a letter notifying the PI of such action. If the study is ratified, the PI may begin enrolling patients. If the study is vetoed, the PI may not enroll patients and will notify the CIRB immediately that the study was vetoed by the IH IRB.

3.3.5 Notification of IH IRB. Once the IH Pre-IRB Committee ratifies or vetoes a CIRB-approved study, the IH IRB Chair will ensure that the IH IRB is notified in writing of the decision in the same manner as expedited reviews.

3.3.6 Patient Billing. Once a CIRB-approved study has been ratified by the IH IRB, the study coordinator must log study subjects to the INTEGRIS Investigational Device Committee (IDC) database for billing and identification purposes.

3.4 Exclusions. The following protocols are ***not*** eligible for review by a CIRB:

3.4.1 Investigator-initiated clinical trials, regardless of funding.

3.4.2 Protocols receiving funds from a federal or other not-for-profit funding agency, excluding NCI-sponsored trials.

3.4.3 Protocols requiring emergency use/review.

3.4.4 Research requesting waivers of informed consent.

3.4.5 Phase I/II research involving children.

4.0 SCOPE

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This policy applies to all organizations and personnel within INTEGRIS Health, Inc. that conduct clinical research.

5.0 TERMINOLOGY

5.1 INTEGRIS Study: A study is deemed to be an INTEGRIS Study if it meets any one of the following:

5.1.1 The research is sponsored by an IH or INTEGRIS-Affiliated Facility or program.

5.1.2 The research is conducted by or under the direction of any IH employee or an employee of an INTEGRIS-affiliated facility or program.

5.1.3 The research involves IH patients as subjects, IH property, or an IH or INTEGRIS-affiliated facility, institution or program.

5.1.4 The research involves the use of IH non-public information to identify or contact human research subjects or prospective subjects.

5.2 All terms used in this policy that are not otherwise defined will have the same definition as given in applicable statutes and regulations for research involving human subjects or in applicable IH IRB policies.