

TITLE NUMBER EFFECTIVE REVIEWED	Review for Studies Approved by the Independent Model National Cancer Institute (NCI) Pediatric Central Institutional Review Board (PedCIRB) (Formerly entitled Facilitated IRB Review for Studies Approved by the National Cancer Institute (NCI) Pediatric Central Institutional Review Board (PedCIRB))	<input checked="" type="checkbox"/> FINAL
	IRB-28	<input type="checkbox"/> DRAFT
	May 8, 2006	<input type="checkbox"/> RESCINDED
	June 3, 2014	

POLICY

In accordance with the Seattle Children's OHRP approved FWA and the Authorization Agreement/Division of Responsibilities Between the NCI Central Institutional Review Board (CIRB) and Seattle Children's; Seattle Children's will rely on the NCI Central Institutional Review Board for human subjects protections requirements for Children's Oncology Group clinical trials that are opened via the Central Institutional Review Board independent model.

PROCEDURE:

Seattle Children's IRB (IRB) and Institutional Responsibilities

1. Seattle Children's will comply with NCI CIRB's requirements and directives.
2. At least annually, Seattle Children's will review the local context considerations, including boilerplate language, institutional requirements, and affiliate and component institution information.
 - a. Any updates that are required before the annual submission of the Annual Institution Worksheet About Local Context will be submitted to the NCI CIRB in a timely manner.
 - b. The Annual Institution Worksheet About Local Context and any other worksheets/forms required by the NCI CIRB for participation will be submitted annually.
3. Seattle Children's will continue to ensure the safe and appropriate performance of the research as described within the Authorization Agreement/Division of Responsibilities Between the NCI Central Institutional Review Board (CIRB) and Seattle Children's according to local policy.
 - a. The Seattle Children's IRB policy entitled Reporting Incidents (IRB-30) does not apply to studies under the NCI CIRB Independent Model. Reporting Incidents for NCI CIRB Independent Model studies is described herein.
 - b. The Seattle Children's IRB policy Adverse Event Reporting (IRB-26) does not apply to studies under the NCI CIRB Independent Model. Reporting Incidents for NCI CIRB Independent Model studies is described herein.

New Clinical Trials

1. The IRB will review all notifications of intent to open new Children's Oncology Group clinical trials by Investigators in order to make study-by-study determinations about whether it is appropriate to open any given study through the NCI CIRB Independent Model.
2. The IRB will notify the investigator in the event that the Seattle Children's IRB determines that the specific study may not be opened via the NCI CIRB Independent Model.
 - a. Studies involving prisoners cannot be opened via the NCI CIRB Independent Model.
3. The IRB will assign a local IRB number for each study that is opened according to the NCI CIRB Independent Model.
4. The IRB will review and may grant HIPAA waiver requests if appropriate.

Modifications to Approved NCI CIRB Clinical Trials

1. The IRB does not require any notification or review of any NCI CIRB approved modifications made to a NCI CIRB Independent Model approved clinical trial that has been opened locally.

Safety Reports, Action Letters, Protocol Enrollment Closures, IND Safety Reports, and Patient/Parent Letters

1. The IRB does not require any notification or review of any NCI CIRB reviewed safety reports, action letters, protocol enrollment closures, IND safety reports, and patient / parent letters.

Annual Status Reports

1. The IRB does not require submission of any annual status reports for studies that are opened and approved under the NCI CIRB Independent Model.

Adverse Event Reporting

1. Only adverse events that meet the definition of an unanticipated problem or serious/ continuing noncompliance according to this policy will be reviewed by the IRB.
2. The IRB will make its determination about whether the reported adverse event meets the required definition, and if so, will then complete and submit the NCI CIRB form "Potential Unanticipated Problem or Serious or Continuing Noncompliance Form" to NCI CIRB.

Reporting Incidents

1. Only Incidents that meet the definition of an unanticipated problem or serious/ continuing noncompliance according to this policy will be reviewed by the IRB.
2. The IRB will make its determination about whether the reported Incident meets the required definition, and if so, will then complete and submit the NCI CIRB form "Potential

Unanticipated Problem or Serious or Continuing Noncompliance Form” to NCI CIRB.

Study Closure

1. The IRB will acknowledge by noting the closure of clinical trials previously opened according to the NCI CIRB Independent Model.

Investigator Responsibilities

General Responsibilities

1. The investigator is responsible for ensuring compliance with all local policies, laws, federal regulations, CIRB policies and CIRB approved clinical trial materials.
2. At least annually the Investigator will review, complete, and submit the “Annual Investigator Worksheet About Local Context.”
3. The Principal Investigator will immediately notify the IRB in the event that he or she is no longer the responsible party for a study under the purview of the NCI CIRB.
4. The Investigator is responsible for maintaining and having available a regulatory file for each study opened according to the NCI CIRB Independent Model, including but not limited to documentation of study personnel Human Subjects Protections training, initial study approval, amendments, required Incident and safety reports, consent forms, assent forms as applicable, and HIPAA Authorization forms.
5. The Investigator is responsible for maintaining and having available research charts for each subject enrolled on an NCI CIRB Independent Model approved clinical trial, including but not limited to documentation of informed consent, assent as applicable, HIPAA authorization, Incident reports and adverse event reports as applicable.
6. The investigator is responsible for notifying the IRB immediately in the event that a subject’s status changes such that they meet the regulatory definition of a prisoner while participating in a clinical trial approved under the NCI CIRB Independent Model.

New Clinical Trials

1. The investigator is responsible for notifying the IRB of intent to open an NCI CIRB Independent Model approved study.
2. The investigator will incorporate local context boilerplate language that has been NCI CIRB-approved into the NCI CIRB-approved model consent form.
3. The investigator will maintain a regulatory file for each study under NCI CIRB purview that will be available for local IRB review upon request.

Modifications to Approved NCI CIRB Clinical Trials

1. The investigator will incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form.
2. The investigator will maintain a regulatory file for each study under NCI CIRB purview that will be available for local IRB review upon request.

- The investigator will retain a “tracked changes” version of the changed informed consent document within the regulatory file to show that the appropriate NCI CIRB-approved boilerplate language was incorporated into the NCI CIRB-approved model consent form.

Annual Status Reports

1. The investigator will retain all NCI CIRB annual continuing review materials within their locally maintained regulatory file.

Adverse Event Reporting

1. The investigator will report adverse events as defined within this policy in a timely manner.
2. The investigator must ensure all adverse events are documented within the research chart according to the NCI CIRB Independent Model approved clinical trial.

Reporting Incidents

1. The investigator will report Incidents meeting the definition of an unanticipated problem or potential serious or continuing noncompliance according to this policy in a timely manner.
2. The investigator will retain documentation of all Incidents occurring on a study within the research chart.

Study Closure

1. The investigator will notify the IRB of the intent to close a clinical trial previously opened according to the NCI CIRB Independent Model.

Definitions

PCIRB – NCI Pediatric Central Institutional Review Board.

Unanticipated Problem¹ – 1) Incident, experience, or outcome is unexpected; 2) incident, experience, or outcome is related or possibly related to participation in the research; 3) incident,

experience, or outcome placed the study participant(s) or others at a greater risk of harm.

Serious noncompliance¹ - Noncompliance that adversely affects the rights and welfare of study participants or results in any untoward medical occurrence that meets the criteria of “serious” or significantly impacts the integrity of study data. Serious is defined as side effects that may require hospitalization or may be irreversible, long-term, life-threatening, or fatal.

Continuing noncompliance¹ - A pattern that, if unaddressed, could jeopardize the rights and welfare of research participants or the integrity of the study data due to noncompliance with the protocol, Federal regulations, and/or the requirements of the CIRB. **Resources**

NCI CIRB - Annual Institution Worksheet About Local Context

NCI CIRB - Annual Investigator Worksheet About Local Context

¹NCI CIRB - Potential Unanticipated Problem or Serious or Continuing Noncompliance Form.

APPROVED BY

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