



OMB#: 0925 – 0625

Expiry Date: 01/31/2014

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the NCI CIRB is protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the NCI CIRB at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the NCI CIRB. Information provided will be combined for all participants and reported as summaries. You are being requested to complete this instrument so that we can conduct activities involved with the operations of NCI CIRB Initiative.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0625). Do not return the completed form to this address.

**Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution**

Authorization Agreement

A. Name of Organization Providing IRB Review: National Cancer Institute Central Institutional Review Board (CIRB)

NCI CIRB’s Organization Number: IORG0000460
Adult CIRB IRB Registration Number: IRB00000781
Pediatric CIRB IRB Registration Number: IRB00004296

B. Name of Signatory Institution Relying on the NCI CIRB: *Insert Institution Name*

Signatory Institution’s OHRP Federalwide Assurance (FWA) Number: *Insert FWA#*

- 1. A Signatory Institution’s “Component Institution” is defined by the NCI CIRB as meeting all of the following criteria:**
- a. the Component Institution operates under a different name than the Signatory Institution but the Signatory Institution has legal authority for the Component Institution;
 - b. the FWA number for the Component Institution is the same as the Signatory Institution;
 - c. the local context considerations of the Component Institution are the same as the Signatory Institution;
 - d. the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution; and
 - e. the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.

List the Signatory Institution’s Component Institution(s) by name:

1. *Insert Component Institution Name(s), or state none*

2. A Signatory Institution’s “Affiliate Institution” is defined by the CIRB as meeting all of the following criteria:

- a. the local context considerations of the Affiliate Institution are the same as the Signatory Institution;

**Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution**

- b. the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution; and
- c. the conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.

List the Signatory Institution's Affiliate Institution(s) by name:

1. *Insert Affiliate Institution Name(s) and FWA #, or state none*

C. Authorization

The review performed by the NCI CIRB will meet the human subject protection requirements of *Insert Signatory Institution Name* OHRP-approved FWA. The NCI CIRB will follow written procedures for reporting its findings and actions to appropriate officials at *Insert Signatory Institution Name*. Relevant minutes of CIRB meetings, and supporting documents, are available to the Signatory Institution via the NCI CIRB website at any time. *Insert Signatory Institution Name* remains responsible for ensuring compliance with the NCI CIRB's determinations and with the terms of the Signatory Institution's OHRP-approved FWA. This document should be kept on file at the Signatory Institution and at the CIRB Operations Office and must be provided to OHRP upon request.

The Officials signing below agree that the NCI CIRB provides IRB review as described in the "Division of Responsibilities between the NCI CIRB and the Signatory Institution" for *Insert Signatory Institution Name* and all Component and Affiliate Institutions.

This document will go into effect upon the signature of the Signatory Institution and the NCI.

Name and Title of Signatory Official for the Signatory Institution:

Name

Title

Signature

Date

Name and Title of Signatory Official for NCI:

Jeffrey S. Abrams, M.D.

Name

Acting Director for Clinical Research
Division of Cancer Treatment and Diagnosis
National Cancer Institute

Title

**Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution**

Signature

Date

Send 2 originals to the NCI CIRB Operation Office:

NCI CIRB Operations Office
c/o The EMMES Corporation
401 N. Washington Street, Suite 700
Rockville, MD 20850

**Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution**

Division of Responsibilities

The responsibilities of the NCI CIRB are to:

- 1) Maintain an NCI CIRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
 - a) Post the roster of NCI CIRB membership on the public side of the NCI CIRB website;
- 2) Conduct initial, amendment, and continuing review of studies as well as review of any other study-specific documents submitted by the Study Chair to the NCI CIRB;
- 3) Conduct review of local context considerations:
 - a) as outlined in the following Worksheets: the Annual Signatory Institution Worksheet About Local Context for NCI CIRB Review, the Annual Principal Investigator Worksheet About Local Context, and the Study-Specific Worksheet About Local Context;
- 4) Conduct review of potential unanticipated problems and/or serious or continuing noncompliance when the Signatory Institution or other entity reports an incident, experience, or outcome to the CIRB. This review includes the following step:
 - a) report any unanticipated problem and/or serious or continuing noncompliance determination to OHRP, the FDA, and the NCI Signatory Official;
- 5) Conduct review of individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB) or equivalent monitoring body;
- 6) Post all study-specific documents related to CIRB reviews to the restricted access side of the CIRB website;
 - a) Notify research staff and institutional designees of all CIRB actions, per written procedures, via institution-specific correspondence, broadcast emails, and access to the restricted area of the CIRB website;
- 7) Notify the Signatory Institution immediately if there is ever a suspension or restriction of the CIRB's authorization to review a study; and
- 8) Post the NCI CIRB Standard Operating Procedures on the public side of the CIRB website.

The responsibilities of the Signatory Institution are to:

- 1) Comply with the NCI CIRB's requirements and directives;
- 2) Report to the NCI CIRB the names of any Component or Affiliate Institutions that rely on the Signatory Institution's IRB.
 - a) Component Institutions are defined by the NCI CIRB as meeting all of the following criteria:
 - the Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the Component Institution;
 - the FWA number for the Component Institution is the same as the Signatory Institution;

**Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution**

- the local context considerations of the Component Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
 - the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
 - the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.
- b) Affiliate Institutions are defined by the NCI CIRB as meeting all of the following criteria:
- the local context considerations of the Affiliate Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
 - the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
 - the conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.
- 3) Ensure the safe and appropriate performance of the research at the Signatory Institution and at all Components and Affiliates. This includes, but is not limited to:
- a) ensuring the initial and ongoing qualifications of investigators and research staff;
 - b) overseeing the conduct of the research;
 - c) monitoring protocol compliance;
 - d) maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
 - e) providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
 - f) investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, the institution must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences;
- NOTE: As part of ensuring safe and appropriate performance of research the Signatory Institution has the authority to observe any aspect of the research process including observing the consent process. The CIRB retains the authority to direct this to be done when necessary.
- 4) Provide updates in a timely manner to the NCI CIRB whenever a Signatory Institution Principal Investigator is no longer the responsible party for a study under the purview of the NCI CIRB;
- 5) Notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review;
- 6) Complete and submit the Annual Institution Worksheet About Local Context, the Annual Investigator Worksheet About Local Context, and any other worksheets/forms required by the NCI CIRB for participation;

**Authorization Agreement/Division of Responsibilities
Between the NCI Central Institutional Review Board and the Signatory Institution**

- 7) Decide on a study-by-study basis whether to open the study through the NCI CIRB or to conduct its own local IRB full Board review. Indicate the decision to open a study through the NCI CIRB by submitting a Study-Specific Worksheet About Local Context;
- 8) In the local consent form:
 - a) incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form;

NOTE: Including HIPAA Authorization language as part of boilerplate language is permitted. The CIRB does not approve the HIPAA Authorization language as it does not function as a Privacy Board however the CIRB will accept HIPAA Authorization language when submitted as part of the boilerplate.
 - b) make no language changes to the consent form with the exception of NCI CIRB-approved boilerplate language;
 - c) obtain NCI CIRB approval of changes to the boilerplate language prior to implementation; and
 - d) obtain NCI CIRB approval of translations of the consent form prior to implementation;
- 9) Maintain a regulatory file for each study under NCI CIRB purview as per local institution and sponsor policy; and
- 10) Conduct full board review of any study enrolling prisoners, since the NCI CIRB is not constituted to review studies enrolling prisoners.