C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

**OMB#:0925-0753** **Expiration Date: 05/31/2024**

**STATEMENT OF CONFIDENTIALITY**

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

**NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN**

Public reporting burden for this collection of information is estimated to average 15 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

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

## Authorization Agreement Section

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

**NCI CIRB's Organization Number:** IORG0000460
**Adult CIRB – Late Phase Emphasis IRB Registration Number:** IRB00000781
**Adult CIRB – Early Phase Emphasis IRB Registration Number:** IRB00009430
**Pediatric CIRB IRB Registration Number:** IRB00004296
**Cancer Prevention and Control CIRB IRB Registration Number:** IRB00010018

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

**Signatory Institution's OHRP Federalwide Assurance (FWA) Number**:

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.

   **An updated roster of your Component Institution(s) must be maintained in the Roster Update Management System (RUMS).**

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;
   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.

**An updated roster of your Affiliate Institution(s) must be maintained in the Roster Update Management System (RUMS).**

## C. Authorization

The review performed by the NCI CIRB will meet the human subject protection requirements of the Signatory Institution's OHRP-approved FWA. The NCI CIRB will follow written procedures for reporting its findings and actions to appropriate officials at the Signatory Institution. Relevant minutes of CIRB meetings and supporting documents are available to the Signatory Institution. The Signatory Institution 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 Section of this document for the Signatory Institution and all Component and Affiliate Institutions identified.

This document will go into effect upon the signatures of the Signatory Official for the Signatory Institution and the Signatory Official for the NCI.

**Name and Title of Signatory Official for the Signatory Institution:**

_____
Name

_____
Title

_____
Signature

_____
Date

**Name and Title of Signatory Official for the NCI:**

Margaret Mooney, M.D., M.B.A.
_____
Name

Acting Cancer Therapy Evaluation Program Associate Director
Division of Cancer Treatment and Diagnosis
National Cancer Institute
_____
Title

_____
Signature

_____
Date

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

**Division of Responsibilities Section**

**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 as outlined in the following Worksheets:
   a) Annual Signatory Institution Worksheet;
   b) Annual Principal Investigator Worksheet; and,
   c) Study-Specific Worksheet;

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;
   a) This review includes reporting any unanticipated problem and/or serious or continuing noncompliance determination to OHRP, the FDA, and the Signatory Official for the NCI;

5) Report any suspension or termination of CIRB approval to OHRP, FDA, and the Signatory Official for the NCI;

6) Conduct review of individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB) or equivalent monitoring body;

7) Post study-wide documents related to CIRB reviews to a secure website and notify research staff and institutional designees of the postings;

8) Provide institution-specific documents related to CIRB reviews via email to research staff and institutional designees;

9) Notify the Signatory Institution immediately if there is ever a suspension or restriction of the CIRB's authorization to review a study;

10) Post the NCI CIRB Standard Operating Procedures on the public side of the CIRB website; and

11) Review investigator requests for enrolled participants to continue on a CIRB-approved study while incarcerated. Conduct a convened review for enrolled participants on a study to fulfill the regulatory requirements of subpart C.

**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 meet the following definitions:
   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;
      - The local context considerations of the Component Institution are the same as the Signatory Institution;

- The boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution; 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;
- The boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution; 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 Component and Affiliate Institutions. 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 replaced. The CIRB requires submission and approval of the Annual Principal Investigator Worksheet prior to finalizing the replacement Principal Investigator;

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 Signatory Institution Worksheet, the Annual Investigator Worksheet, and any other worksheets/forms required by the NCI CIRB for participation;

7) Have CIRB-approved Principal Investigator complete and submit the Study-Specific Worksheet to open a study;

8) Incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form to create the consent form to use for a specific study:
   a) Make no language changes to the consent form with the exception of NCI CIRB-approved boilerplate language;
   b) Obtain NCI CIRB approval of changes to the boilerplate language prior to implementation; and
   c) 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) Notify the CIRB if a study participant becomes incarcerated while enrolled in a study under the CIRB's purview. If the investigator deems it in the best interest of the study participant to remain on the study while incarcerated provide justification to the CIRB.