Authorization Agreement Between the NCI Central Institutional Review Board (CIRB) and the Relying Signatory Institution

Name of Organization Providing CIRB Review: National Cancer Institute

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

Name of Signatory Institution Using the CIRB: Leland Stanford Junior University

Signatory Institution’s OHRP Federalwide Assurance (FWA) Number: FWA00000935

Registration Number(s) of IRB(s) at Signatory Institution:
IRB 1    IRB00000348
IRB 3    IRB00000350
IRB 4    IRB00000351
IRB 5    IRB000004593
IRB 6    IRB000004947
IRB 7    IRB000005136
IRB 8    IRB000006208

List Component Institutions that rely on the Signatory Institution’s IRB for studies approved by the CIRB. Component Institutions are defined by the 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. 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 and the Signatory Institution is monitored by the same office.

List Component Institution(s) by name: None

List Affiliate Institutions that rely on the Signatory Institution’s IRB for studies approved by the CIRB. Affiliate Institutions are defined by the 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 and the Signatory Institution is monitored by the same office.

List Affiliate Institution(s) by name and FWA number: Stanford Hospital and Clinics FWA00000934; Lucile Salter Packard Children’s Hospital at Stanford FWA00000933

NCI CIRB - Original  Version 02/17/12
The Officials signing below agree that **Leland Stanford Junior University** and all Component and Affiliate Institutions listed above may use the NCI CIRB(s) reviews, as described in the accompanying document, "**Division of Responsibilities between the NCI CIRB and the Signatory Institution.**"

**Check appropriate box (or boxes)**

The review performed by the NCI Adult ☒ Pediatric ☒ CIRB(s), in partnership with the **Leland Stanford Junior University**, will meet the human subject protection requirement of the relying Institution’s OHRP-approved FWA. The CIRB will follow written procedures for reporting its findings and actions to appropriate officials at the Signatory Institution. The Signatory Institution remains responsible for ensuring compliance with the 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.

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:** Ann M. Arvin, M.D., Vice Provost and Dean of Research

**Signature and Date:** 03/01/2012

**Name and Title of Institutional Official for NCI:**

Jeffrey S. Abrams, M.D.
Acting Director for Clinical Research
Division of Cancer Treatment and Diagnosis
National Cancer Institute

**Signature and Date:** Jeffrey S. Abrams 03/01/2012
Division of Responsibilities between the NCI CIRB and the Signatory Institution

The responsibilities of the CIRB are to:

1) Conduct initial, continuing, and amendment review of studies as well as review of any other study-specific documents submitted by the Study Chair to the CIRB;

2) Review local context considerations:
   a) as outlined in the following Worksheets: the Annual Institution Worksheet About Local Context for CIRB Review and the Annual Principal Investigator Worksheet About Local Context; and
   b) when submitted on a study-specific basis using the Study-Specific Worksheet About Local Context;

3) Conduct review of potential unanticipated problems and/or serious or continuing noncompliance when the Cooperative Group or local institution reports an incident, experience, or outcome to the CIRB. This review includes the following steps:
   a) determine whether the incident, experience, or outcome is an unanticipated problem and/or constitutes serious or continuing noncompliance;
   b) determine whether the local institutional management plan is adequate; and
   c) report any unanticipated problem and/or serious or continuing noncompliance to OHRP, the FDA, and the NCI Institutional Official;

4) Conduct review of individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB);

5) Maintain a 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;

6) Provide notification to research staff and institutional designees of all CIRB actions via institution-specific correspondence, broadcast emails, and access to the restricted area of the CIRB Website;

7) Post all study-specific documents related to CIRB reviews to the restricted access side of the CIRB website;

8) Post the roster of CIRB membership and the CIRB Standard Operating Procedures on the public side of the CIRB website; and

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

The responsibilities of the Signatory Institution are to:

1) Comply with the CIRB’s requirements and directives;

2) Report to the CIRB the names of any Component or Affiliate Institutions that rely on the Signatory Institution’s IRB.
   a) Component Institutions are defined by the 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. 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 and the Signatory Institution is monitored by the same office.

b) Affiliate Institutions are defined by the 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 and the Signatory Institution is monitored by the same office.

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 qualifications of research staff;
   b) monitoring protocol compliance;
   c) maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
   d) providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
   e) investigating, managing, and providing notification to the 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 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;

4) Provide updates to the CIRB whenever a principal investigator is no longer the responsible party for a study under the purview of the CIRB;

5) Notify the CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the 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 required by the CIRB for participation;

7) Decide on a study-by-study basis whether to open the study through the CIRB or to conduct its own local IRB full Board review. Indicate the decision to open a study through the CIRB by submitting a Study-Specific Worksheet About Local Context;

8) In the local informed consent document:
   a) use CIRB-approved boilerplate language;
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 informed consent document with the exception of CIRB-approved boilerplate language;

c) obtain CIRB approval of changes to the boilerplate language prior to implementation; and

d) obtain CIRB approval of translations of the informed consent document prior to implementation;

9) Maintain a regulatory file for each study under CIRB purview as per local institution and Cooperative Group policy; and

10) Conduct full board review of any study enrolling prisoners, since the CIRB is not constituted to review studies enrolling prisoners.