**OMB #0925- 0753 Expiration  Date: 06/30/2020**

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 40 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.

 **Annual Signatory Institution Worksheet**

Reason for submission:

[ ]  First submission to the CIRB of an Annual Signatory Institution Worksheet

[ ]  Revised submission of the Annual Signatory Institution Worksheet

**Signatory Institution Information**

Submitting User Information (auto-populated)

Name of Signatory Institution (auto-populated)

If there are any changes to the Submitting User Information please update within user’s Identity and Access Management (IAM) account.

1. What type of studies does this Signatory Institution intend to open with the

CIRB?

[ ]  Phase 2/3 and Large Phase 2 Adult Studies

[ ]  ETCTN and Group Phase 1 and 2 Adult Studies

[ ]  Cancer Prevention and Control Studies

[ ]  Pediatric Studies

2. Verify the list of Component Institutions (auto-populate)

If there are any changes to the list of Component Institutions, update your roster in Roster Update Management System (RUMS).

3. Verify the list of Affiliate Institutions (auto-populate)

If there are any changes to the list of Affiliate Institutions, update your roster in the Roster Update Management System (RUMS).

**State and Local Law**

4. What is your state law and corresponding institutional policy regarding legally authorized representatives?

If applicable, an attachment can be added here

5. What are the other state or local laws that govern the conduct of research at your institution?

If applicable, an attachment can be added here.

6. What is the age of majority in your state?

**Research Oversight**

 7. Do you have an IRB that operates at your Signatory Institution?

[ ]  Yes

[ ]  No

 If Yes, identify the office, the person, and the person’s title at your institution to whom the IRB reports.

 Office Name

 Responsible Person

 Person’s Title

 Phone Number

 Email address

 8. Identify the office, the person, and the person’s title at your institution responsible for the oversight of the conduct of research for studies open under the CIRB. (This person cannot be a Principal Investigator who will open studies with the CIRB or someone who enrolls or interacts with study participants at study visits.)

 Office Name

 Responsible Person

 Person’s Title

 Phone Number

 Email address

 Describe, in detail, how this person(s) ensures the safe and appropriate performance of the research at the Signatory Institution and at all Component and Affiliate Institutions, including:

 NOTE: SOPs, organizational charts, and other documents to support the oversight structure should be attached after item 9(e).

1. Ensuring the initial and ongoing qualifications of investigators and research staff;
2. Overseeing the conduct of the research, including how the person identified fulfills this responsibility;
3. Monitoring protocol compliance, including how the person identified fulfills this responsibility;
4. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects; and
5. Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research.

9. Identify the office, the person, and the person’s title at your institution responsible for identifying, managing, and reporting to the CIRB potential unanticipated problems and/or serious or continuing noncompliance.

Office Name

Responsible Person

Person’s Title

Phone Number

Email address

 Describe, in detail, how this person(s) identifies and manages and reports to the CIRB potential unanticipated problems and/or serious or continuing noncompliance.

**Financial Conflicts of Interest**

10. Describe how the Signatory Institution gathers and evaluates Principal Investigator and research staff financial conflicts of interest for studies on the CIRB menu. Any policies related to the management of conflict of interest should be attached.

 If applicable, an attachment can be added here.

**Institutional Policies pertaining to the Consent Form for CIRB-Approved Studies**

11. Describe your institutional policies and guidelines that govern the informed consent document.

If applicable, an attachment can be added here.

12. Provide the boilerplate language that is ***added*** to the CIRB-approved consent form. This is standard language required by the institution that is inserted into the existing CIRB-approved consent form, such as, birth control language, coverage of research injury, required phone numbers for the study doctor, and a person unaffiliated with the study who can answer general clinical trial questions, etc.

Note: Boilerplate language cannot replace language in the CIRB-approved consent form without CIRB approval. Any language that will be replaced must be clearly identified in the submission. Required NCI Consent Form template language and the risks for agents cannot be changed.

Note: Revisions to previously approved boilerplate language should be highlighted in the Word document using track changes.

If applicable, an attachment (in Word format) can be added here.

13. Provide the institutional letterhead used for the consent form, if applicable (attach a blank copy of letterhead to be used).

14. Provide any other institutional requirements for informed consent documents, if applicable.

If applicable, an attachment (in Word Format) can be added here.

15. Provide the institution’s plan for implementation of changes to the boilerplate language, letterhead, or other institutional requirement identified in this submission for any study currently open with the CIRB. This language should be used for any initial study opening with the CIRB.

**Community Descriptors**

16. Does the community have a positive attitude toward the conduct of research?

[ ]  Yes

[ ]  No

 If No, please explain

17. Is there anything else the CIRB should know about the anticipated study participant population at the Signatory Institution?

[ ]  Yes

[ ]  No

If Yes, please explain.

If applicable, an attachment can be added here.

**Additional Information**

18. Is there anything else the CIRB should know about the Signatory Institution’s local context?

[ ]  Yes

[ ]  No

If Yes, please explain.

If applicable, an attachment can be added here.

**Additional Materials for Review (If Applicable)**

*Complete this section if you have any of the following additional materials to be reviewed by the CIRB.*

19. Translated documents. Translated documents include, the institution’s boilerplate language, short forms, template assent form, or template document for consent at age of majority.

Note: The following documents are required when submitting translated material:

1. CIRB-approved English language document(s) corresponding to the translated document with a version or version date
2. Translated version(s) of the CIRB-approved English language document with a version or version date that matches the English version
3. Translator’s Certificate(s) of Accuracy or equivalent document(s) with reference to the version or version date

If applicable, an attachment can be added here. *(Allow for unlimited attachments)*

20. Assent form or consent at the age of majority form documents used by the Signatory Institution.

If applicable, an attachment can be added here. *(Allow for unlimited attachments)*