**OMB #0925- 0753 Expiration Date: 03/31/2026**

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? Provide the section and pages numbers that pertain to the relevant information if documents for these policies have been attached.

If applicable, an attachment can be added here. (Add attachments)

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

[ ]  Yes

[ ]  No

 If yes, list applicable state or local laws. Provide the section and page numbers that pertain to the relevant information if documents for these laws have been attached.

If applicable, an attachment can be added here. (Add attachments)

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. Provide details of the research oversight structure at your institution:

 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

 Attach an organizational chart showing the reporting lines between the responsible person and the other key individuals. (Add attachments)

8a) Describe the process for ensuring the initial and ongoing qualifications of the investigators and research staff. Items that address this question include standard operating procedures that detail the process, forms that are required within the institution to document qualifications, or the name of a system at the institution where this information is maintained. Specify what actions the responsible person or designee takes to ensure these processes are followed.

8b) Describe the processes and/or procedures used for oversight of the conduct of research at your institution (include your Component and/or Affiliate institutions as applicable). Specify what actions the responsible person or designee takes to ensure these processes are followed.

Note: The processes and/or procedures would include:

* + what studies are open;
	+ how many study participants are enrolled at the institution;
	+ knowing when an investigator is being audited and the outcome of the external audit; and
	+ determining when the study is completed.

 This is generally achieved through different communication pathways, including regular meetings, ad hoc meetings, and reports provided to the responsible person or designee.

8c) Describe the processes and/or procedures used to monitor protocol compliance. Specify what actions the responsible person or designee takes to ensure these processes are followed.

 The monitoring process usually includes, but is not limited to:

* + ensuring the correct consent forms are used,
	+ enrolled study participants meet the eligibility criteria,
	+ study procedures are conducted per protocol, and
	+ study agent is administered per protocol.

 It should also address the frequency of internal audits which should occur at least annually.

 8d) Describe the methods used to identify any changes to state, local, or institutional requirements and/or regulations related to the protection of human subjects. Identify how changes are communicated to the investigators and research staff.

 Note: This response should focus on institutional policy and not study protocols.

 8e) Describe the mechanism to receive and address concerns from local study participants and others about the conduct of the research. Specify what actions the responsible person or designee takes to ensure these concerns are addressed.

Attach any supporting documents for questions a through e. (Add attachments)

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

Office Name

Responsible Person

Person’s Title

Phone Number

Email address

 Describe how this person receives notification of potential unanticipated problems and/or serious or continuing noncompliance.

Describe how this person or designee investigates potential unanticipated problems and/or serious or continuing noncompliance.

Describe who reports potential unanticipated problems and/or serious or continuing noncompliance to the CIRB.

If applicable, attachments supporting the answers above can be added here. (Add attachments)

**Financial Conflicts of Interest**

10. Institutions must have a comprehensive policy the covers how financial conflicts of interest are handled for all research staff for studies on the CIRB menu. Describe how the Signatory Institution gathers and evaluates 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 here. (Add attachments)

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

11. Describe your institutional policies and guidelines that govern the informed consent document as it pertains to CIRB-approved studies or provide pages numbers and sections that cover these if your institutional policies and guidelines are attached.

If applicable, an attachment can be added here. (Add attachments)

11a. Do local policies allow for remote consent?

[ ]  Yes

[ ]  No

  If so, attach policies (Add attachments)

12. Provide the boilerplate language that is ***added*** to the CIRB-approved consent form.

Please refer to the following links for more information:

[**Boilerplate Q & A**](https://ncicirb.org/institutions/institution-quickguides/managing-site/boilerplate-language-q)

[**Guidelines For Permitted Boilerplate Language Additions**](https://ncicirb.org/institutions/institution-quickguides/managing-site/guidelines-permitted-boilerplate-language-additions)

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.

Attach a copy of your institution’s boilerplate language in Word format. If there are changes, a track changes version and a clean version in Word format should be attached. (Add attachments)

12a. Translated boilerplate language.

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. (Add attachments)

13. Provide the information to be included in the header and footer of the CIRB-approved institutional documents, if applicable attach a blank copy of document to be used or an institutional logo. Note: The study ID, Protocol Version Date, and page numbers must be included in the consent form.

14. For Pediatric studies, summarize your policy on obtaining and documenting assent. If attaching a policy, provide a brief summary of the policy and indicate what sections address how assent is obtained and documented.

If applicable, attach a policy or an assent form. (Add attachment)

14a. For Pediatric studies, summarize your policy on obtaining and documenting consent until age of majority. If attaching a policy, provide a brief summary of the policy and indicate what sections address how consent is obtained at the age of majority.

If applicable, attach a policy or an age of majority form. (Add attachment)

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

 NOTE: Do not include HIPAA documents. These are institutional requirements and not reviewed by the CIRB.

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

15a. Translated documents include the 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. (Add attachments)

16. Once CIRB approval is received, approved boilerplate language must be updated in the consent document within 30 days of the next CIRB amendment for all studies open to enrollment. If the requirements for your site are more stringent than 30 days after the next CIRB amendment is activated, describe the plan and process for implementing any changes to the boilerplate language, letterhead, or any other institutional document or requirement identified in this submission and state the timeline for completing the actions.

[ ]  Comply with CIRB requirements stated above

[ ]  Following more stringent institutional requirements

Please describe:

**Community Descriptors**

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

[ ]  Yes

[ ]  No

 If No, please explain

18. 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. (Add attachments)

**Additional Information**

19. 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. (Add attachments)