**Annual Principal Investigator Worksheet**

**OMB #: 0925-0753                                                                                                             Expiration Date: 3/31/2026**

 **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 20 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 (0925-0753). Do not return the completed form to this address.**

|  |
| --- |
| **Please refer to the Quickguide on** [**Completing the Annual Principal Investigator Worksheet**](https://ncicirb.org/institutions/institution-quickguides/managing-site/completing-the-annual-principal-investigator-worksheet) **for further guidance.** |

Reason for submission:

[ ]  First Submission of the Annual Principal Investigator Worksheet About Local Context

[ ]  Revised Submission of the Annual Principal Investigator Worksheet About Local Context

**Signatory Institution Information**

Submitting User Information (auto-populated)

1. Enter Principal Investigator email address.

*If the PI's name does not appear above the email address field, this means there is no active account associated with this email address.  Please confirm the email address is correct and that it is the email address associated with the PI in IAM.*

*If the email address is correct and the PI name still does not appear, you will need to contact your Signatory Institution’s RUMS Update Person and request that this PI be added to the CIRB Roster in RUMS.*

2. Name of Signatory Institution (select from auto-populated)

*If the name of your Signatory Institution does not populate in this field, you must add the PI to your institution roster in RUMS. For more information on updating the roster, go to Updating Your CIRB Institution Roster.*

**Research Staff**

3. How many sub-investigators do you have supporting you in conducting CIRB-approved research?

 [ ]  0

 [ ]  1-2

[ ]  3-5

[ ]  6-7

[ ]  8-10

[ ]  11-15

[ ]  16-35

[ ]  36-50

[ ]  51+

4. How many research nurses/CRAs do you have supporting you in conducting CIRB-approved research?

 [ ]  0

[ ]  1-3

[ ]  4-5

[ ]  6-7

[ ]  8-10

[ ]  11-22

[ ]  23-29

[ ]  30+

5. Have you or any of your research staff reported a financial conflict of interest related to any studies on the CIRB menu that resulted in a management plan?

[ ]  Yes

[ ]  No

 If Yes, attach the institutionally-approved management plan.

**NOTE: Principal Investigator Education, Training, and Experience**

No additional information is required. Information pertaining to investigator education, training, and experience is captured annually through the NCI Investigator Registration.

**Principal Investigator Resources**

6. CIRB-approved studies by Study ID Number for this PI. (auto-populated)



7. How many study participants are currently receiving study intervention for CIRB studies for which you are the PI? \*This number should **not** include study participants who are in long-term follow-up or receiving labs and scans only.

 [ ]  0-5

[ ]  6-10

[ ]  11-20

[ ]  21-40

[ ]  41+

**Recruitment**

8. Identify recruitment methods usually used:

**NOTE:  Network-supplied recruitment materials are approved by the CIRB and posted to the CTSU website. Only if there are content changes made to these materials do the sites need to submit via a Study-Specific Worksheet. The addition of contact information is permitted.**

NOTE: Locally developed recruitment materials require CIRB approval and should be submitted using the Annual Signatory Institution Worksheet or Study-Specific Worksheet.

[ ]  Network Group/sponsor-supplied materials

[ ]  Locally developed recruitment materials

[ ]  None

Please describe.

9. Indicate how potential study participants are identified for CIRB-approved studies.

[ ]  Using recruitment materials as indicated in question 8.

[ ]  Through usual clinical practice.

[ ]  Referrals from other providers.

[ ]  Using a separate IRB-approved screening protocol (reviewed and approved by another IRB)

**Compensation to Study Participants**

10. Does your institution provide any compensation/incentives to study participants enrolled in CIRB-approved studies that is NOT otherwise being offered to non-study participants?

 □ No compensation or reimbursement is offered to patients on studies unless specifically stated in a protocol or provided to all patients receiving treatment.

 □ Yes, study participants receive additional compensation/incentives.

 If yes, please describe.

**Informed Consent Process**

Answer the following questions regarding the process used to introduce a trial to a potential study participant and obtain their informed consent.

11. Where does the consent discussion take place? Check all that apply.

[ ]  In the physician’s office.

[ ]  In a private clinic area or inpatient hospital room.

[ ]  Other. Please describe.

12. Who is authorized to obtain consent? Check all that apply.

[ ]  Principal Investigator

[ ]  Sub-investigators

[ ]  Research Coordinator

[ ]  Research Nurses

[ ]  Other – Please explain

13. Who is available to answer questions? Check all that apply.

[ ]  Principal Investigator

[ ]  Sub-investigators

[ ]  Research Coordinator

[ ]  Research Nurses

[ ]  Other – please explain

14. Does the PI confirm that each potential study participant has as much time as needed to review the consent document before a response is required, including time to take the consent document home to review and discuss with others?

[ ]  Yes

[ ]  No

15a. How is the potential study participant’s understanding of the consent document and the study assessed? Check all that apply.

[ ]  Teach-back technique

[ ]  Question-and-answer dialogue

[ ]  Open-ended discussion

[ ]  Other – please explain

15b. Describe how you assess a potential study participant’s capacity to make a fully informed decision (i.e. assess for alertness, memory, language, and visual-spatial skills, whether the potential patient can distinguish between past and present, etc.).

If applicable, an attachment can be added here.

16. How is the informed consent process conducted with non-English speaking potential study participants? Check all that apply

[ ]  Only English-speaking participants are enrolled by this PI.

[ ]  Non-English-speaking participants are consented using a fully translated, CIRB-approved consent form in their native language.

[ ]  Non-English-speaking participants are consented using a translator and short form consents.

[ ]  Translators or translation services are available for use during the consent process and throughout the study (explain below how this would be documented).

[ ]  Other – please explain.

Select the short forms that may be used at your Institution. Check all that apply.

□ Institutional short forms may be used (CIRB approved).

□ CIRB short forms may be used.

□ No short forms will be used by this PI at this institution.

If short form consent is conducted at your institution, attach a copy of your institution’s policy for short form use.

17. Who provides consent? Check all that apply.

[ ]  Potential study participant

[ ]  Parent for potential pediatric study participant

[ ]  Legally Authorized Representative

18. For what languages are fully translated consent forms routinely provided?

 [ ]  Arabic

 [ ]  Chinese

 [ ]  Farsi

 [ ]  French

 [ ]  Greek

 [ ]  Italian

 [ ]  Korean

 [ ]  Polish

 [ ]  Russian

 [ ]  Spanish

 [ ]  Vietnamese

 [ ]  Other

 [ ]  None

 If translations are routinely provided, what process is currently used to translate the informed consent document?

 [ ]  CIRB-approved translated Spanish informed consent documents posted on the CTSU website are used.

 [ ]  A translation service is used to translate the informed consent document.

 If applicable, an attachment can be added here.

19. Describe or attach your institution’s policy regarding assent by children or impaired adults for this Principal Investigator. (select all that apply)

 [ ]  This Principal Investigator enrolls impaired adult study participants. Please provide or attach your institution’s policy on obtaining assent by impaired adults.

 [ ]  This Principal Investigator enrolls pediatric study participants. Please provide or attach your institution’s policy on obtaining assent by children.

 [ ]  No children or impaired adults will be enrolled by this Principal Investigator.

 NOTE: The CIRB makes a determination regarding the requirement for assent and the age determination. Institutions enrolling children must obtain assent from any child in the age range determined by the CIRB. The documentation of the assent is per local policy and should be described here. If a child in the age range determined by the CIRB cannot provide assent, an assent waiver must be requested from the CIRB and obtained prior to enrollment of the child. Consult the Completing the Assent Waiver Worksheet for further instructions

20. Describe your institution’s process to receive and address concerns from study participants and others about the conduct of the research by answering each question below.

a) How do participants know the process for raising a concern?

b) How would participants make a complaint or raise a concern about a study?

 c) When a complaint or concern is received, who receives the complaint and who is responsible for ensuring that the complaint or concern is resolved?

 Note: Also, include to whom complaints or concerns would be sent and resolved if these issues involve the PI or study/research team.

Add Attachment (if applicable)

**Measures to Protect Confidentiality**

Confidentiality is defined as the study participant’s understanding of, and agreement to, the ways identifiable information pertaining to them will be stored and shared. Identifiable information can be printed, electronic, or visual (such as photographs).

21. Check all measures that will be used to maintain the confidentiality of identifiable information.

[ ]  Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.

[ ]  Computer-based files will be available to study personnel through the use of access privileges and passwords.

[ ]  Prior to obtaining access to identifiable information, study personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

[ ]  Whenever feasible, identifiers will be removed from study-related information.

[ ]  Other Please describe.

**Measures to Protect Privacy**

Privacy is defined as the study participant’s ability to control how other people see, touch, or obtain information about them. Violations of privacy can involve circumstances such as being seen without clothing or partially clothed, being photographed without consent, being asked personal questions in a public setting, etc.

22. Check all measures that will be used to maintain the study participant’s privacy.

[ ]  Use of drapes or other barriers to vision for subjects who are required to disrobe.

[ ]  Consent is obtained prior to collecting photographs involving study participants.

[ ]  Sensitive information is collected and used with respect to maintaining privacy.

[ ]  Individuals are not identified publicly without their consent.

[ ]  Other Please describe.

**Emergency Resources**

23. Check all resources available at the site to treat emergencies resulting from study-related procedures.

 [ ]  ACLS (Advanced Cardiovascular Life Support) trained personnel and crash cart

 [ ]  BCLS (Basic Life Support) trained personnel

 [ ]  PALS (Pediatric Advanced Life Support) trained personnel

 [ ]  Emergency response team within facility

[ ]  Emergency drugs and supplies to stabilize study participant until emergency personnel arrive

 [ ]  Staff available to call 911

 [ ]  Other Please describe.

**Using a Legally Authorized Representative (LAR)**

24. Do you plan on enrolling study participants through an LAR?

[ ]  Yes

 [ ]  No

25. At your institution, describe who may serve as an LAR. Check all that may apply.

 Even if you responded ‘No’ to question 24, please answer this question if there is a possibility that study participants may be enrolled through a LAR or confirm ‘No LAR will be used.’

[ ] Parents

[ ] Legal Guardian

[ ] Family member

[ ] Individual authorized to make surrogate health care decisions

[ ] Spouse/Domestic Partner

[ ] Family member/ Adult Child

 [ ] Other (please describe)

 [ ] No LAR will be used

If applicable, an attachment can be added here.

**Vulnerable Populations**

26. For each vulnerable population, indicate safeguards or select "Not Enrolled."

Note about prisoners: The CIRB is not constituted to review research involving prisoners. If an investigator wishes to enroll prisoners in a study, IRB review must be conducted by the local IRB.

.

[ ]  Safeguards for Children

Check all safeguards you use for children.

* + - * Youth Information Sheets
			* Assent
			* Extra monitoring
			* Researchers credentialed in pediatrics
			* Other health professionals with pediatrics experience
			* Children not enrolled
			* Other

Please describe.

[ ]  Safeguards for Pregnant Women

 Check all safeguards you use for pregnant women.

* + - * Inclusion is scientifically appropriate based on preclinical studies
			* Information is provided pertaining to how study intervention could impact the woman and the fetus
			* Pregnant women not enrolled
			* Other

Please describe.

[ ]  Safeguards for Economically disadvantaged

 Check all safeguards you use for Economically disadvantaged.

* + - * Cost burden is fully explained
			* No financial incentives are provided
			* Social services are available to assist study participant
			* Other

Please describe.

[ ]  Safeguards for Educationally disadvantaged

 Check all safeguards you use for Educationally disadvantaged.

* + - * Verbal explanation of the research is provided in lay language
			* Extra time is available to answer questions
			* At the potential study participant’s request, family members/significant others can participate in informed consent process
			* Caregiver to assist with medications and identifying adverse events
			* Translations are available, if needed
			* Other

Please describe.

[ ]  Safeguards for Physically disadvantaged

 Check all safeguards you use for Physically disadvantaged.

* + - * Treatment facility is accessible
			* Assistance is available, as needed
			* Witness to consent is available, as needed
			* Other

Please describe.

[ ]  Safeguards for Employees

Check all safeguards you use for Employees.

* + - * Records are confidential
			* Participation is private
			* Supervisor does not request participation and is not informed of those who do participate.
			* Employees not enrolled
			* Other

Please describe.

[ ]  Other Vulnerable Populations

Describe all safeguards you use for ‘Other’ vulnerable populations.

**Additional Confirmations When Investigators Enroll Pregnant Women or Women Who May Become Pregnant On Study [45 CFR 46.204 (h), (i), (j)]**

27. The PI confirms the following statements are true by choosing ‘Yes’.

 No inducements will be offered to terminate a pregnancy.

[ ]  Yes

 Research team will have no part in decisions related to the timing, method, or procedures used to terminate the pregnancy.

[ ]  Yes

 Research team will have no part in determining the viability of a neonate.

[ ]  Yes