**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.**

**Study-Specific Worksheet**

Reason for submission:

[ ]  Open New Study: This study is not opened at the Signatory Institution. This is the first submission to the CIRB of a Study-Specific Worksheet for this study at this Signatory Institution.

[ ]  Revision: This study is already opened at the Signatory Institution. This is a revision to the existing Study-Specific Worksheet for this study at this Signatory Institution.

**Signatory Institution Information**

Submitting User Information (auto-populated)

Enter the Study ID Number.

Signatory Institution (selected from drop down options)

**General Information**

1. Enter the email address of the Principal Investigator who is requesting to open this study.

*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.*

The topics listed below reflect those asked on the Annual Principal Investigator Worksheet which has already been completed. Indicate for each topic whether or not there are any changes from the information previously provided. If there are changes, please describe. If any of the ‘Changed’ answers can be supported by an attachment, an attachment can be added in Question 12.

2. Research Staff/Principal Investigator Resources Sections

[ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

3. Recruitment Section of the Annual Principal Investigator Worksheet

[ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

4. Compensation to Study Participants Section of the Annual Principal Investigator Worksheet

[ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

5. Informed Consent Process Section of the Annual Principal Investigator Worksheet

[ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

6. Measures to Protect Confidentiality Section of the Annual Principal Investigator Worksheet

[ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

7. Measures to Protect Privacy Section of the Annual Principal Investigator Worksheet

[ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

8. Emergency Resources Section of the Annual Principal Investigator Worksheet

 [ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

9. Using a Legally Authorized Representative (LAR) Section of the Annual Principal Investigator Worksheet

 [ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

10. Vulnerable Populations Section of the Annual Principal Investigator Worksheet

 [ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

11. Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)] Section of the Annual Principal Investigator Worksheet

[ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

12. Additional Information

NOTE: If there are any changes to the documents approved by the CIRB in support of the questions on the Annual Principal Investigator Worksheet or any changes to the documents approved by the CIRB in support of this study, use track changes to clearly identify the requested changes. Only track additional changes and not changes that are already part of your institution’s approved boilerplate language.

[ ]  No change

 [ ]  Changed

 If ‘Changed or New Information', describe changes or new information.

If any of the ‘Changed’ answers can be supported by an attachment, an attachment can be added here.

**Additional Study-Specific Materials for Review (If Applicable)**

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

13. Recruitment material(s).

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

14. Assent form or consent at the age of majority form.

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

15. Translated documents for this study.

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)*

**Confirmation of Intent to Comply:**

I, as Principal Investigator, confirm I will comply with the Federal regulations pertaining to human research protections in addition to CIRB and Network Group/sponsor directives pertaining to this study. As Principal Investigator, I confirm that I oversee all sub-investigators and research staff assisting with this study and am responsible for their compliance with the same.

I realize that no study-related activities may begin until I receive an approval letter from the CIRB.

By entering my password below I declare my confirmation to comply.