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

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**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 (0925-0625\*). 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.

[ ]  Change of PI: This study is currently open at the Signatory Institution with the CIRB. This Worksheet is being submitted due to a change in Principal Investigator for this study.

[ ]  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.

**General Information**

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

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 33.

2. General Information (Questions 1-2 on the Annual Principal Investigator Worksheet)

 [ ]  No change

 [ ]  Changed

 If ‘Changed’, describe changes

3. Research Staff (Questions 3-5 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

4. Principal Investigator Resources (Questions 6-7 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

5. Recruitment (Questions 8-9 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

6. Compensation to Study Participants (Question 10 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

7. Informed Consent Process (Questions 11-20 on the Annual Principal Investigatorb Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

8. Pharmacy Information (Questions 21-22 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

9. Measures to Protect Confidentiality (Question 23 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

10. Measures to Protect Privacy (Question 24 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

11. Emergency Resources (Question 25 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

12. Using a Legally Authorized Representative (LAR) (Questions 26-28 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

13. Vulnerable Populations (Question 29 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

14. Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)] (Questions 30-32 on the Annual Principal Investigator Worksheet)

[ ]  No change

[ ]  Changed

 If ‘Changed’, describe changes

15. Additional Information (Question 33 on the Annual Principal Investigator Worksheet)

NOTE: If there are any changes to the documents approved by the CIRB, 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.*

1. Recruitment material(s).

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

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

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

1. Translated documents for this study.

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

* CIRB-approved English language document(s) corresponding to the translated document
* Translated version(s) of the CIRB-approved English language document
* Translator’s Certificate(s) of Accuracy or equivalent document(s)

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.