Add Note

OMB #: 0925-0753 Expiration Date: 07/31/2021

STATEMENT OF CONFIDENTIALITY

The purpose of the information collection 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.

Signatory Institution Information

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1. Submitting User Information

Name

Email: Business Phone:

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2. Enter the Study ID Number. (Click here if you would like to review a list of studies currently covered by NCI CIRB)

(Required)

3. Enter the email address of the Investigator providing this notification

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(Required)

4. Signatory Institution

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(Required)

CIRB Operations Office

5. Enter the Study Participant Registration Number or another unique anonymous identifier for participant.

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There should be a separated worksheet for each participant and study impacted.

(Required)

6. Date study participant enrolled and what study arm (if any). Add Note View Audit

(Required)

7. Date study participant incarcerated. Add Note View Audit

(Required)

8. How and when the PI was notified of the participant's incarceration. Add Note View Audit

(Required)

9. Anticipated length of incarceration Add Note View Audit

(Required)

10. Type of incarceration Add Note View Audit

(Required)

- ○ Full incarceration
- ○ Home confinement
- ○ Intermittent sentence (jail on the weekends or intermittent blocks of time)
- ○ Other

11. Is remaining in the study while incarcerated in the participant's best interest? Add Note View Audit

(Required)

- ○ Yes
- ○ No (the subject will be removed from the study)

Describe justification: Add Note View Audit

(Required)

12. Does the participant's status as a prisoner affect the risks or potential benefits of participation in the study? Add Note View Audit

(Required)

- ○ Yes
- ○ No

13. Are there risks to the participant if treatment is discontinued because of the participant's incarceration? Add Note View Audit

(Required)

- Yes
- No

14. Will study visits and/or treatment be potentially missed while incarcerated? Add Note View Audit

(Required)

- Yes
- No

15. How will study visits and/or treatment be handled/ distributed while the participant is incarcerated? Add Note View Audit

(Required)

16. Is there a need for follow-up examination or care of the participant after study participation has ended? Add Note View Audit

(Required)

- Yes
- No

17. Attach any additional documentation Add Note View Audit

Add Attachment

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