Add Note

OMB #: 0925-0753 **Expiration Date: 05/31/2024**

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.

Reason for submission: Add Note View Audit

(Required)

- 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

Add Note View Audit

Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

1. Enter Principal Investigator email address. Add Note

(Required)

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 complete a Signatory Personnel Form to add the PI to the CIRB roster and send it to your Signatory Institution Primary Contact Person for approval and submission to the NCI CIRB Helpdesk for inclusion onto to your institution's roster with NCI CIRB.

2. Name of Signatory Institution Add Note

Children's Oncology Group

Calculated Field Add Note View Audit

*No answer provided.*Campbell, Anne M M.D. *FIRST SUBMISSION

Research Staff

Add Note

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

(Required)

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

(Required)

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? Add Note

(Required)

- Yes
- No

If Yes, attach the institutionally-approved management plan. Add Note

Add Attachment

NOTE: Principal Investigator Education, Training, and Experience Add Note

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

Principal Investigator Resources

Add Note

6. How many actively accruing research studies, for which you are the PI, do you have open, including CIRB-approved and those not reviewed by the CIRB?

(Required)

a. List CIRB-approved studies by Study ID Number. Add Note

7. How many study participants are currently receiving study intervention for studies for which you are the PI? Add Note

(Required)

Recruitment

Add Note

8. Describe how potential study participants are identified and recruited to CIRB-approved studies.

(Required)

If applicable, an attachment can be added here. Add Note

Add Attachment

9. Identify recruitment materials usually used: Add Note

(Required)

- [ ] Network Group/sponsor-supplied handouts
- [ ] Locally-developed educational materials (Reminder: Study-specific material requires CIRB approval)
- [ ] Other

Please describe. Add Note

Compensation to Study Participants

Add Note

10. The CIRB is aware that there is typically no compensation provided for CIRB-approved studies to study participants. Describe any compensation/incentives provided by the SignatoryInstitution or others to study participants enrolled in CIRB-approved studies, for example: parking validation, cafeteria voucher, other.

(Required)

Informed Consent Process

Add Note

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? Add Note

(Required)

12. Who is authorized to obtain consent? Add Note

(Required)

13. How long does the potential study participant have to review the consent document before a response is required, including time to take the consent document home? Add Note

(Required)

14. Who is available to answer questions? Add Note

(Required)

15. How is the potential study participant's understanding of consent assessed? Add Note

(Required)

16. How is the informed consent process conducted with non-English speaking potential study participants? Add Note

(Required)

17. Who provides consent? Add Note

(Required)

- [ ] Potential study participant
- [ ] Parent for potential pediatric study participant
- [ ] Legally Authorized Representative
- [ ] Other

Check all that apply.

Please explain. Add Note

18. For what languages are translations routinely provided? Add Note

(Required)

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

If applicable, an attachment can be added here. Add Note

Add Attachment

Reminder: Translations must be CIRB-approved prior to presenting to a potential study participant.

19. Describe your institution's policy regarding assent by children or impaired adults. Add Note

(Required)

If applicable, an attachment can be added here. Add Note

Add Attachment

20. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research. Add Note

(Required)

Pharmacy Information

Add Note

21. Will the drugs/agents used in the study be managed by a pharmacist?

(Required)

- Yes
- No

If a pharmacist will be managing the drugs/agents used in the study, provide the name and title of the pharmacist at each practice location where research will be conducted. Add Note

If the drugs/agents will not be managed by a pharmacist, provide the name and title of the responsible person for the drugs/agents at each practice/location where research will be conducted. Add Note

22. How is the pharmacist/responsible person provided with a copy of the protocol at each practice location? Add Note

(Required)

Measures to Protect Confidentiality

Add Note

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).

23. Check all measures that will be used to maintain the confidentiality of identifiable information. Add Note

(Required)

- ☐ 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. Add Note

Measures to Protect Privacy

Add Note

Privacy is defined as the study's 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.

24. Check all measures that will be used to maintain the study participant's privacy. Add Note

(Required)

- ☐ 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. Add Note

Emergency Resources

Add Note

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

(Required)

- ☐ ACLS trained personnel and crash cart
- ☐ BCLS 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. Add Note

Using a Legally Authorized Representative (LAR)

Add Note

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

(Required)

- Yes
- No

27. At your institution, describe who may serve as an LAR. Add Note

If applicable, an attachment can be added here. Add Note

Add Attachment

28. Provide a description of how you assess a potential study participant's ability to provide consent. Add Note

If applicable, an attachment can be added here. Add Note

Add Attachment

Site Reviewer Add Note

No answer provided.

Vulnerable Populations

Add Note

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.

29. Check all vulnerable populations from which you intend to enroll. Add Note

(Required)

- [ ] Children
- [ ] Pregnant women
- [ ] Economically disadvantaged
- [ ] Educationally disabled
- [ ] Physically disabled
- [ ] None
- [ ] Other

Please describe. Add Note

For each vulnerable population checked, indicate safeguards. Add Note

Safeguards for Children

Add Note

Check all safeguards you use for children.
(Required)

- [ ] Youth Information Sheets
- [ ] Assent
- [ ] Extra Monitoring
- [ ] Researchers credentialed in pediatrics
- [ ] Other health professionals with pediatrics experience
- [ ] Other

Please describe.

Add Note

Safeguards for Pregnant Women

Add Note

Check all safeguards you use for pregnant women.
(Required)

- [ ] Inclusion is scientifically appropriate based on preclinical studies
- [ ] Information is provided pertaining to how study intervention could impact the woman and the fetus
- [ ] Other

Please describe.

Add Note

Safeguards for Economically Disadvantaged

Add Note

Check all safeguards you use for the economically disadvantaged.
(Required)

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

Please describe.

Add Note

Safeguards for Educationally Disabled

Add Note

Check all safeguards you use for the educationally disabled.

(Required)

- [ ] 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.

Add Note

Safeguards for Physically Disabled

Add Note

Check all safeguards you use for the physically disabled.

(Required)

- [ ] Treatment facility is accessible
- [ ] Assistance is available, as needed
- [ ] Witness to consent is available, as needed
- [ ] Other

Please describe.

Add Note

Other Vulnerable Populations

Add Note

Describe all safeguards you use for 'Other' vulnerable populations.

(Required)

Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)]

Add Note

Confirm the following statements by choosing 'Yes'.

30. No inducements will be offered to terminate a pregnancy. Add Note

(Required)

- Yes
- No

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

(Required)

- Yes
- No

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

(Required)

- Yes
- No

33. Is there anything else the CIRB should know about local context considerations? Add Note

(Required)

- Yes
- No

If Yes, please explain. Add Note

If applicable, an attachment can be added here. Add Note

Add Attachment