PI Worksheet

Add Note

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

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.

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Please refer to the Quickguide on Completing the Annual Principal Investigator Worksheet for further guidance.

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Reason for submission:

(Required)

- First Submission of the Annual Principal Investigator Worksheet About Local Context
- Revised Submission of the Annual Principal Investigator Worksheet About Local Context

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Signatory Institution Information

Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

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1. Enter Principal Investigator email address.

(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 contact your Signatory Institution's RUMS Update Person and request that this PI be added to the CIRB Roster in RUMS.

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2. Name of Signatory Institution

(Required)

Calculated Field Add Note View Audit

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

Research Staff

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

(Required)

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

(Required)

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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?

(Required)

- ○ Yes
- ○ No

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If Yes, attach the institutionally-approved management plan.

Add Attachment

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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

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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)

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a. CIRB-approved studies by Study ID Number for this PI

Study-Site	Role	Title	Sponsor
test_Peds-Abington Memorial Hospital-Asplundh Cancer Pavilio	Investigator	testing	
TEST-Abington Memorial Hospital-Asplundh Cancer Pavilio	Investigator	Test	

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

(Required)

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Recruitment

8. Identify recruitment methods usually used:

NOTE: When a protocol includes study-specific recruitment activities, these activities are approved as part of the CIRB's approval of the study and need not be recorded on this worksheet.

(Required)

- ☐ Network Group/sponsor-supplied handouts
- ☐ Locally developed recruitment materials
- ☐ Other (social media, websites, etc.)
- ☐ None

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Please describe.

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

(Required)

- ☐ 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)

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Compensation to Study Participants

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

(Required)

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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.

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11. Where does the consent discussion take place?

(Required)

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12. Who is authorized to obtain consent?

(Required)

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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?

(Required)

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14. Who is available to answer questions?

(Required)

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

(Required)

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

(Required)

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

Add Attachment

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17. Who provides consent?

(Required)

Check all that apply.

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

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Please explain.

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18. For what languages are translations routinely provided?

(Required)

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

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If applicable, an attachment can be added here.

Add Attachment

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

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19. Describe your institution's policy regarding assent by children and/or impaired adults as applicable.

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

(Required)

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If applicable, an attachment can be added here.

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

(Required)

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Pharmacy Information

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

(Required)

- Yes
- No

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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.

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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.

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

(Required)

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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).

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

(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

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Please describe.

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Measures to Protect Privacy

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.

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

(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

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Please describe.

Emergency Resources

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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

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Please describe.

Using a Legally Authorized Representative (LAR)

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

- ( ) Yes
- ( ) No

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

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If applicable, an attachment can be added here.

Add Attachment

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

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If applicable, an attachment can be added here.

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Site Reviewer

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No answer provided.

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