SI 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 40 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.

Add Note

Please refer to the Quickguide on Completing The Annual Signatory Institution Worksheet for further guidance.

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Reason for submission:

(Required)

- ○ First submission to the CIRB of an Annual Signatory Institution Worksheet About Local Context
- ○ Revised submission of the Annual Signatory Institution Worksheet About Local Context

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Signatory Institution Information

Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

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Name of Signatory Institution

CIRB Operations Office ▾

Site Reviewer Add Note View Audit

No answer provided.

Add Note

If there are any changes to the Submitting User Information, please update within the user's Identity and Access Management (IAM) account.

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1. What type of studies does this Signatory Institution intend to open with the CIRB?

(Required)

- ☐ Phase 2/3 and Large Phase 2 Adult Studies
- ☐ ETCTN and Group Phase 1 and 2 Adult Studies
- ☐ Cancer Prevention and Control Studies
- ☐ Pediatric Studies

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2. Verify the list of Component Institutions

- The EMMES Corporation

If there are any changes to the list of Component Institutions, update your roster in Roster Update Management System (RUMS).

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3. Verify the list of Affiliate Institutions

If there are any changes to the list of Affiliate Institutions, update your roster in the Roster Update Management System (RUMS).

State and Local Law

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4. What is your state law and corresponding institutional policy regarding legally authorized representatives?

(Required)

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If applicable, an attachment can be added here.

Add Attachment

Add Note View Audit

5. What are the other state or local laws that govern the conduct of research at your institution?

(Required)

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If applicable, an attachment can be added here.

Add Attachment

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6. What is the age of majority in your state?

(Required)

Research Oversight

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7. Do you have an IRB that operates at your Signatory Institution?

(Required)

- Yes
- No

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If Yes, identify the office, the person, and the person's title at your institution to whom the IRB reports.

Office Name

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Responsible Person

Add Note View Audit

Phone

Add Note View Audit

Email Address

8. **Identify the office, the person, and the person's title at your institution responsible for the oversight of the conduct of research for studies open under the CIRB. (This person cannot be a Principal Investigator who will open studies with the CIRB or someone who enrolls or interacts with study participants at study visits.)**

Please refer to the Oversight Q&A Quickguide for further guidance.

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Office Name

Add Note View Audit

Responsible Person

Add Note View Audit

Phone Number

Add Note View Audit

Email address

Add Note

Describe, in detail, how this person(s) ensures the safe and appropriate performance of the research at the Signatory Institution and at all Component and Affiliate Institutions, including:

NOTE: SOPs, organizational charts, and other documents to support the oversight structure should be attached after item 8(e).

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a) Ensuring the initial and ongoing qualifications of investigators and research staff.

(Required)

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b) Overseeing the conduct of the research, including how the person identified fulfills this responsibility.

(Required)

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c) Monitoring protocol compliance, including how the person identified fulfills this responsibility.

(Required)

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d) Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects.

(Required)

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e) Providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research.

(Required)

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If applicable, an attachment(s) can be added here for questions a through e.

Add Attachment

Add Note

9. Identify the office, the person, and the person's title at your institution responsible for identifying, managing, and reporting to the CIRB potential unanticipated problems and/or serious or continuing noncompliance

Add Note View Audit

Office Name

Add Note View Audit

Responsible Person

Add Note View Audit

Phone Number

Add Note View Audit

Email address

Add Note View Audit

Describe, in detail, how this person(s) identifies and manages and reports to the CIRB potential unanticipated problems and/or serious or continuing noncompliance.

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If applicable, an attachment can be added here.

Add Attachment

Financial Conflicts of Interest

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10. Describe how the Signatory Institution gathers and evaluates Principal Investigator and research staff financial conflicts of interest for studies on the CIRB menu. Any policies related to the management of conflict of interest should be attached.

(Required)

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If applicable, an attachment can be added here.

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Institutional Policies Pertaining to the Consent Form for CIRB-Approved Studies

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11. Describe your institutional policies and guidelines that govern the informed consent document.

(Required)

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If applicable, an attachment can be added here.

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12. Provide the boilerplate language that is added to the CIRB-approved consent form. This is standard language required by the institution that is inserted into the existing CIRB-approved consent form, such as, birth control language, coverage of research injury, required phone numbers for the study doctor, and a person unaffiliated with the study who can answer general clinical trial questions, etc.

Note: Boilerplate language cannot replace language in the CIRB-approved consent form without CIRB approval. Any language that will be replaced must be clearly identified in the submission. Required NCI Consent Form template language and the risks for agents cannot be changed.

Please refer to the Boilerplate Q & A Quickguide for further guidance.

(Required)

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If applicable, an attachment (in Word format) can be added here.

Note: If you are submitting an updated Worksheet and have revised boilerplate language, submit a "track changes" and a clean Word version of the boilerplate language to clearly indicate what has changed from the current CIRB-approved boilerplate language.

Add Attachment

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13. Provide the institutional letterhead used for the informed consent document, if applicable (attach a blank copy of letterhead to be used).

Add Attachment

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14. Provide any other institutional requirements for the informed consent documents or additional documents used in research at your institution.

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If applicable, an attachment (in Word Format) can be added here.

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15. Provide the institution's plan for implementation of changes to the boilerplate language, letterhead, or other institutional requirement identified in this submission for any study currently open with the CIRB. This language should be used for any initial study opening with the CIRB.

(Required)

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Community Descriptors

16. Does the community have a positive attitude toward the conduct of research?

(Required)

- ○ Yes
- ○ No

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If No, please explain.

Add Note View Audit

17. Is there anything else the CIRB should know about the anticipated study participant population at the Signatory Institution?

(Required)

- Yes
- No

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If Yes, please explain.

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If applicable, an attachment can be added here.

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Additional Information

18. Is there anything else the CIRB should know about the Signatory Institution's local context?

(Required)

- Yes
- No

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If Yes, please explain.

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If applicable, an attachment can be added here.

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Additional Materials for Review (If Applicable)

Complete this section if you have any of the following additional materials to be reviewed by the CIRB.

19. Translated documents. Translated documents include, the institution's boilerplate language, short forms, template assent form, or template document for consent at age of majority. If short forms are being submitted for review, attach your institutional policy for short form use.

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

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If applicable, an attachment can be added here.

Add Attachment

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20. Assent form or consent at the age of majority form documents used by the Signatory Institution.
(Required)

Enter "N/A" for adult studies or how assent is documented for Pediatric and age of majority.

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If applicable, an attachment can be added here

Add Attachment

Next Save for Later More

Form Completed

You've completed the form. You can now either save the form for later revision, or submit it.

Go Back Save for Later Print Submit