National Cancer Institute Central IRB Initiative

1 - Annual Institution Worksheet About Local Context -- Institution Information

OMB Text

Add Note

OMB#: 0925 – xxxx *Expiry Date: xx/xx/xxxx*

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Reason for submission:

Add Note

(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

Signatory Institution Information

Add Note View Audit

Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

Name of Signatory Institution

Add Note

Children's Oncology Group

Site Reviewer

Add Note

No answer provided.

If there are any changes to the Submitting User Information or Name of Signatory Institution, contact the Helpdesk at ncicirbcontact@emmes.com before submitting.

Add Note

1. Check all applicable Network Group memberships for the Signatory Institution. Add Note

(Required)

- [ ] Alliance Main Member
- [ ] Alliance Affiliate Member
- [ ] COG Main Member
- [ ] COG Affiliate Member
- [ ] ECOG-ACRIN Main Member
- [ ] ECOG-ACRIN Affiliate Member
- [ ] NCIC CTG Main Member
- [ ] NCIC CTG Affiliate Member
- [ ] NRG Main Member
- [ ] NRG Affiliate Member
- [ ] SWOG Main Member
- [ ] SWOG Affiliate Member
- [ ] ETCTN Member

Indicate Main Member Institutions for each Network Group with Affiliate memberships: Add Note

2. List of Component Institutions Add Note

If there are any changes to the list of Component Institutions, enter the name of the Component Institution below and complete the Add or Remove Component Institution Form. Add Note

3. List of Affiliate Institutions: Add Note

If there are any changes to the list of Affiliate Institutions, enter the name of the Affiliate Institution below and complete the Add or Remove Affiliate Institution Form. Add Note

4. The Signatory Institution confirms that all Component and Affiliate Institutions listed conform to the CIRB's definition. The CIRB definitions can be found at on the CIRB website. Add Note

(Required)

- ( ) Yes
- ( ) No
- ( ) No Component or Affiliate Institutions

State and Local Law

Add Note

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

(Required)

If applicable, an attachment can be added here.

Add Note

Add Attachment

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

Add Note

(Required)

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

Add Note

(Required)

If applicable, an attachment can be added here.

Add Note

Add Attachment

Research Oversight

Add Note

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

(Required)

- Yes
- No

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

Add Note

Office Name

Responsible Person

Add Note

Phone Add Note

Email Address Add Note

9. Identify the office and person at your institution responsible for the oversight of the conduct of research. (This person cannot be a Principal Investigator who will open studies with the CIRB.) Add Note

Office Name Add Note

Responsible Person Add Note

Phone Number Add Note

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: Add Note

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

(Required)

b) Overseeing the conduct of the research. Add Note

(Required)

c) Monitoring protocol compliance. Add Note

(Required)

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

(Required)

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

(Required)

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

Add Attachment

10. Identify the office and person at your institution responsible for identifying, managing, and reporting to the CIRB potential unanticipated problems and/or serious or continuing noncompliance. Add Note

Office Name Add Note

Responsible Person Add Note

Phone Number Add Note

Email address Add Note

Describe, in detail, how this person(s) identifies and manages potential unanticipated problems and/or serious or continuing noncompliance. Add Note

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

Add Attachment

Financial Conflicts of Interest

Add Note

11. Describe how the Signatory Institution gathers and evaluates Principal Investigator and research staff financial conflicts of interest for studies on the CIRB menu.

(Required)

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

Add Attachment

Institutional Policies Pertaining to the Informed Consent Document for CIRB-Approved Studies

Add Note

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

(Required)

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

Add Attachment

13. Provide the boilerplate language that is added to the CIRB-approved informed consent document. This is standard language required by the institution that is inserted into the existing CIRB-approved informed consent document, 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. Add Note

(Required)

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

Add Attachment

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.

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

Add Attachment

15. Provide any other institutional requirements for informed consent documents, if applicable. Add Note

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

Add Attachment

Note: The boilerplate language and any other institutional requirements provided in questions 14, 15, and 16 will be reviewed and approved by the CIRB. Changes to the boilerplate language or other institutional requirements require CIRB review and approval before implementation. Add Note

Community Descriptors

Add Note

16. List the counties that comprise your institution's local catchment area. The CIRB Operations Office will obtain demographic data from the US census track using the counties for CIRB review.

(Required)

17. Does the community have a positive attitude toward the conduct of research? Add Note

(Required)

- Yes
- No

If No, please explain. Add Note

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

(Required)

- Yes
- No

If Yes, please explain. Add Note

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

Add Attachment

Additional Information

Add Note

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

(Required)

- Yes
- No

If Yes, please explain. Add Note

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

Add Attachment