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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***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 (0925-0625). Do not return the completed form to this address.*

## 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