

**OMB Text**

OMB#: 0925 - 0625

Expiry Date: 01/31/2014

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**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 (0925-0625). 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**

[View Audit](#)

**Submitting User Information**

Campbell, Brian

**Email:** bcampbell@emmes.com

**Contact Roles:** Investigator, User

**Address:**

**Phone:**

**Name of Signatory Institution**

[View Audit](#)

Children's Oncology Group

**If there are any changes to the Submitting User Information or Name of Signatory Institution, contact the Helpdesk at [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) before submitting.**

**1. List of Component Institutions**

Component Institution #1  
Component Institution #2

**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](#)

**2. List of Affiliate Institutions:**

Affiliate Institution #1  
Affiliate Institution #2

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](#)

3. The Signatory Institution confirms that all Component and Affiliate Institutions listed conform to the CIRB's definition. The CIRB definitions can be found at [<link>](#).

[Add Note](#)

(Required)

- Yes  
 No  
 No Component or Affiliate Institutions

6. 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](#) [View Audit](#)

[Add Attachment](#)  
No Attachments added.

7. Provide an explanation how your institution ensures compliance for each state or local law.

[Add Note](#)

(Required)

9. 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.

Office Name

[Add Note](#)

Responsible Person

[Add Note](#)

Phone Number

[Add Note](#)

Email address

[Add Note](#)

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

[Add Note](#)

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

(Required)

[Add Note](#) [View Audit](#)

**If applicable, an attachment can be added here.**

[Add Attachment](#)  
No Attachments added.

[Add Note](#)

**12. 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.**

(Required)

[Add Note](#) [View Audit](#)

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

[Add Attachment](#)  
No Attachments added.

*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 Note](#) [View Audit](#)

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

[Add Attachment](#)  
No Attachments added.

[Add Note](#)

**14. Provide any other institutional requirements for informed consent documents, if applicable.**

[Add Note](#) [View Audit](#)

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

[Add Attachment](#)  
No Attachments added.

[Add Note](#)

**Community Descriptors**

**15. 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)

[Add Note](#)

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

(Required)

Yes

No

**If No, please explain.** [Add Note](#)

**17. 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](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

**Additional Information** [Add Note](#)

**18. 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](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

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

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