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

OMB Text

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the NCI CIRB is protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the NCI CIRB at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the NCI CIRB. Information provided will be combined for all participants and reported as summaries. You are being requested to complete this instrument so that we can conduct activities involved with the operations of NCI CIRB Initiative.

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.*

Add Note

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

Signatory Institution Information

View Audit

Submitting User Information

Campbell, Brian

Email:	bcampbell@emmes.com		
Contact Roles	Investigator, User		
Address:		**Phone:**	

View Audit

Name of Signatory Institution

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 before submitting.

1. List of Component Institutions

Component Institution #1
Component Institution #2

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.

2. List of Affiliate Institutions:

Affiliate Institution #1
Affiliate Institution #2

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

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>.

(Required)

- Yes
- No
- No Component or Affiliate Institutions

Add Note

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

(Required)

Add Note View Audit

If applicable, an attachment can be added here.

Add Attachment
No Attachments added.

Add Note

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

(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.

Add Note

Office Name

Add Note

Responsible Person

Add Note

Phone Number

Add Note

Email address

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.

Community Descriptors

Add Note

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

Add Note

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?

(Required)

- Yes
- No

Add Note

If Yes, please explain.

Add Note View Audit

If applicable, an attachment can be added here.

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

Add Note

If Yes, please explain.

Add Note View Audit

If applicable, an attachment can be added here.

Add Attachment
No Attachments added.

Previous Next Save for Later PDF

Previous Next Save for Later PDF

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

Save for Later Print Submit