



OMB Text	Add Note
<p>OMB#: 0925 - xxxx Expiry Date: xx/xx/xxxx</p> <p>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.</p> <p style="text-align: center;">NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN</p> <p>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.</p>	

Reason for submission:	Add Note
<p>(Required)</p> <p><input type="radio"/> Open New Study: This study is not opened at the Signatory Institution. This is the first submission to the CIRB of a Study-Specific Worksheet About Local Context for this study at this Signatory Institution.</p> <p><input type="radio"/> Change of PI: This study is currently open at the Signatory Institution with the CIRB. This Worksheet is being submitted due to a change in Principal Investigator for this study.</p> <p><input type="radio"/> Revision: This study is already opened at the Signatory Institution. This is a revision to the existing Study-Specific Worksheet About Local Context for this study at this Signatory Institution.</p>	

Signatory Institution Information	Add Note View Audit
Submitting User Information	
<p>Campbell, Brian Email: bcampbell@emmes.com</p>	

Enter the Study ID Number. (Click here if you would like to review a list of studies currently covered by NCI CIRB)	Add Note
<p>(Required)</p> <input type="text"/>	

Signatory Institution	Add Note
<p>(Required)</p> <p>Children's Oncology Group ▼</p>	

Calculated Field	Add Note View Audit
<p>No answer provided.No answer provided.</p>	

Site Reviewer	Add Note
<p>No answer provided.</p>	

General Information

[Add Note](#)

1. Enter the email address of the Principal Investigator who is requesting to open this study.

(Required)

If the PI's name does not appear above the email address field, this means there is no active account associated with this email address. Please confirm the email address is correct and that it is the email address associated with the PI in IAM.

If the email address is correct and the PI name still does not appear, you will need to complete a Signatory Personnel Form to add the PI to the CIRB roster and send it to your Signatory Institution Primary Contact Person for approval and submission to the NCI CIRB Helpdesk for inclusion onto to your institution's roster with NCI CIRB.

The topics listed below reflect those asked on the Annual Principal Investigator Worksheet About Local Context which has already been completed. Indicate for each topic whether or not there are any changes from the information previously provided. If there are changes, please describe. If any of the 'Changed' answers can be supported by an attachment, an attachment can be added in Question 33.

[Add Note](#)

General Information (Questions 1-2 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No Change
 Changed

If 'Changed', describe changes.

[Add Note](#)

Research Staff (Questions 3-5 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No Change
 Changed

If 'Changed', describe changes.

[Add Note](#)

Principal Investigator Resources (Questions 6-7 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No change
 Changed

If 'Changed', describe changes.

[Add Note](#)

Recruitment (Questions 8-9 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)

(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Compensation to Study Participants (Question 10 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)

(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Informed Consent Process (Questions 11-20 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)

(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Pharmacy Information (Questions 21-22 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)

(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Measures to Protect Confidentiality (Question 23 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No Change
- Changed

If 'Changed', describe changes.

[Add Note](#)

Measures to Protect Privacy (Question 24 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No Change
- Changed

If 'Changed', please describe.

[Add Note](#)

Emergency Resources (Question 25 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No Change
- Changed

If 'Changed', describe changes.

[Add Note](#)

Using a Legally Authorized Representative (LAR) (Questions 26-28 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No Change
- Changed

If 'Changed', describe changes.

[Add Note](#)

Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)] (Questions 30-32 on the Annual Principal Investigator Worksheet About Local Context)

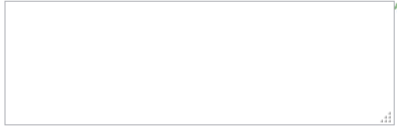
[Add Note](#)

(Required)

- No Change
 Changed

If 'Changed', describe changes.

[Add Note](#)



Additional Information (Question 33 on the Annual Principal Investigator Worksheet About Local Context)

[Add Note](#)

(Required)

- No Change
 Changed or New Information

If 'Changed or New Information', describe changes or new information.

[Add Note](#)



If any of the 'Changed' answers can be supported by an attachment, an attachment can be added here.

[Add Note](#)

PI Intent to Comply

[Add Note](#)

The PI opening the study will receive an email requesting confirmation of information included in this Worksheet. The PI will also be asked to confirm their intent to comply with the Federal regulations pertaining to human research protections and sponsor directives pertaining to this study.

This study will not be opened at your institution until the PI completes "Intent to Comply" and receives an approval letter from the CIRB.

Click 'Next' below, and then 'Submit' on the final screen to submit this Worksheet to the PI for his/her confirmation of "Intent to Comply".

PI Confirmation of Intent to Comply

[Add Note](#)

Confirmation of Intent to Comply:

I, as Principal Investigator, confirm I will comply with the Federal regulations pertaining to human research protections in addition to CIRB and Network Group/sponsor directives pertaining to this study. As Principal Investigator, I confirm that I oversee all sub-investigators and research staff assisting with this study and am responsible for their compliance with the same.

I realize that no study-related activities may begin until I receive an approval letter from the CIRB.

By entering my password below I declare my confirmation to comply.

(Required)

After entering your password, click 'Next' below, and then 'Submit' on the final screen to submit this Worksheet for CIRB review.