National Cancer Institute Central IRB Initiative

3 - Study-Specific Worksheet About Local Context -- Change of PI

OMB Text Add Note

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

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Reason for submission: Add Note

(Required)

- ○ 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.
- ○ 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.
- ○ 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.

Signatory Institution Information Add Note View Audit

Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

Enter the Study ID Number. (Click here if you would like to review a list of studies currently covered by NCI CIRB) Add Note

(Required)

Signatory Institution Add Note

(Required)

Children's Oncology Group

Calculated Field Add Note View Audit

No answer provided.No answer provided.

Site Reviewer Add Note

No answer provided.

Enter the email address of the Signatory Institution Principal Investigator who will be taking over this study. Add Note

(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.

Has the replacement Principal Investigator submitted an Annual Principal Investigator Worksheet About Local Context? Add Note

(Required)

- Yes
- No

If Yes, complete the remainder of this Worksheet based on the replacement Annual Principal Investigator Worksheet About Local Context.

If No, submit the Annual Principal Investigator Worksheet About Local Context before submission of the Study-Specific Worksheet About Local Context via the "Start XForms" screen.

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

Add Attachment

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)

Sign...

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