Study Specific Worksheet

Add Note

OMB #: 0925-0753 **Expiration Date: 07/31/2021**

STATEMENT OF CONFIDENTIALITY

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

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 (0925-0753). Do not return the completed form to this address.

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Please refer to the Quickguide on Completing the Study Specific Worksheet for further guidance.

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Reason for submission:

(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.
○ 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.

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Signatory Institution Information

Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

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

(Required)

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Signatory Institution

(Required)

CIRB Operations Office ▾

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No answer provided.No answer provided.

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General Information

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 contact your Signatory Institution's RUMS Update Person and request that this PI be added to the CIRB Roster in RUMS.

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No answer provided.

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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.

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

(Required)

- No Change
- Changed

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

(Required)

- No Change
- Changed

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

(Required)

- No change
- Changed

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5. Recruitment (Questions 8-9 on the Annual Principal Investigator Worksheet About Local Context)

(Required)

- No Change
- Changed

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6. Compensation to Study Participants (Question 10 on the Annual Principal Investigator Worksheet About Local Context)

(Required)

- No Change
- Changed

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7. Informed Consent Process (Questions 11-20 on the Annual Principal Investigator Worksheet About Local Context)

(Required)

- No Change
- Changed

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8. Pharmacy Information (Questions 21-22 on the Annual Principal Investigator Worksheet About Local Context)

(Required)

- No Change
- Changed

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

(Required)

- ○ No Change
- ○ Changed

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

(Required)

- ○ No Change
- ○ Changed

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

(Required)

- ○ No Change
- ○ Changed

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

(Required)

- ○ No Change
- ○ Changed

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13. Vulnerable Populations (Question 29 on the Annual Principal Investigator Worksheet About Local Context)

(Required)

- ○ No Change
- ○ Changed

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14. 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)

(Required)

- ○ No Change
- ○ Changed

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

NOTE: If there are any changes to the documents approved by the CIRB, use track changes to clearly identify the requested changes. Only track additional changes and not changes that are already part of your institution's approved boilerplate language.

(Required)

- ○ No Change
- ○ Changed or New Information

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

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

Add Attachment

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Additional Study-Specific Materials for Review (If Applicable)

Complete this section if you have any of the following study-specific materials to be reviewed by the CIRB.

16. Recruitment material(s).

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17. Assent form or consent at the age of majority form.

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If applicable, an attachment can be added here.

Add Attachment

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18. Translated documents for this study. Translated documents include, the institution's boilerplate language, short forms, template assent form, or template document for consent at age of majority.

Note: The following documents are required when submitting translated material:
1. **CIRB-approved English language document(s) corresponding to the translated document with a version or version date**
2. **Translated version(s) of the CIRB-approved English language document with a version or version date that matches the English version**
3. **Translator's Certificate(s) of Accuracy or equivalent document(s) with reference to the version or version date**

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If applicable, an attachment can be added here.

Add Attachment

Study ID Number for the Transfer of Review Responsibilities from the CIRB to the new IRB for Study #2 Add Note View Audit

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Form Completed

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

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