

3 - Study-Specific Worksheet About Local Context -- Type of Submission

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)

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.

Study-Specific Worksheet About Local Context -- Signatory Institution Information

Signatory Institution Information View Audit

Submitting User Information

Walter, Jay

Business Address: 12 My Court
Anyplace, CA 21701

Business Phone: (215)707-3390

Enter the Study ID Number. Add Note

(Required)

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Study-Specific Worksheet About Local Context -- Original PI

General Information Add Note

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

(Required)

Walter, Jay PhD

Email: **Business Phone:**

If the message "Contact not found." appears, it means that this PI cannot be found in the CIRB database. Email the Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to determine what action is required.

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General Information

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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.

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](#)

Vulnerable Populations (Question 29 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](#)

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

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

No Attachments added.

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 Cooperative 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 this study may not be opened at my institution and 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)*

To sign, enter password for JWalter001 as of 11/27/2012 After entering your password, click 'Next' below, and then 'Submit' on the final screen to submit this Worksheet for CIRB review.

PI Intent to Comply

The PI taking over the study will receive an email requesting confirmation of information included in this Worksheet and confirming the intent to comply with the Federal regulations pertaining to human research protections and Cooperative Group/sponsor directives pertaining to this study.

The responsibility of the conduct of this study will not be under this PI at your institution until the PI confirms "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".

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

3 - Study-Specific Worksheet About Local Context -- Type of Submission

OMB Text

OMB#: 0925 - 0625 Expiry Date: 1/31/2014
STATEMENT OF CONFIDENTIALITY
Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

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

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

(Required)

If the email address is listed as "Contact not found.", email the Helpdesk at nciirbcontact@emmes.com or call 1-888-657-3711 to determine what action is required to have the email validated in IRBManager.

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

(Required)

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

No *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.*

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(Required)

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(Required)

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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](#)

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No Attachments added.

Study-Specific Worksheet About Local Context -- PI Confirmation of Intent to Comply Revised Worksheet

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 Cooperative 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.

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Study-Specific Worksheet About Local Context -- PI Intent to Comply - Change of PI Revised Worksheet

PI Intent to Comply

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