

Attachments for 0925-0046-19

#19A Potential Unanticipated Problems and/or Serious or Continuing
Noncompliance Reporting Form

#19B Locally-Developed Material Submission Form

Attachment 19A: Potential Unanticipated Problems and/or Serious or Continuing Noncompliance Reporting Form

OMB#: 0925-0046-19 Expiry Date: 2/28/2013

PRIVACY ACT NOTIFICATION STATEMENT

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 private under the Privacy Act. 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 presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 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 (0925-0046-19). Do not return the completed form to this address.

Potential Unanticipated Problems and/or Serious or Continuing Noncompliance Reporting Form

**(Submit this form with your supporting documentation to the CIRB via email at
localcontextcirb.emmes.com.)**

Federal Regulation 21 CFR 56.108(b)(1) and 45 CFR 46.103(b)(5) require the IRB to “follow written procedures for ensuring prompt reporting to the IRB...any unanticipated problems involving risks to human subjects or others...”.

Per the CIRB SOPs, an unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied;

- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Per the CIRB SOPs, serious noncompliance is defined as noncompliance that adversely affects the rights and welfare of study participants. Continuing noncompliance is defined as a systematic and habitual disregard of the requirements of Federal regulations pertaining to human subjects protection and/or of the requirements or decisions of the CIRB.

Reports of unanticipated problems and/or serious or continuing noncompliance submitted to the CIRB must include: 1) a detailed description of the incident, experience, or outcome, and 2) a comprehensive management plan, if applicable, detailing corrective and preventative measures put in place to address the incident, experience, or outcome. The management plan may be captured on this form or provided as a separate document.

Report serious adverse events that meet the criteria for an unanticipated problem within 7 days from when the PI becomes aware. Report other unanticipated problems or serious or continuing noncompliance within 14 days from when the PI or others become aware.

If a management plan is not yet complete, please indicate so in the relevant section and indicate when the management plan will be submitted.

Section A: General Information

1. Date of Report Completion: _____
2. Principal Investigator Name: _____
3. Name of Person Completing the Report if other than the PI: _____
 - a. Email Address: _____
 - b. Phone Number: _____

Section B: Description of Incident, Experience, or Outcome

1. The incident, experience, or outcome is being reported as a(n):
 - Unanticipated Problem (complete Section C)
 - Serious or Continuing Noncompliance (complete Section D)
 - Unanticipated Problem and Serious or Continuing Noncompliance (complete Sections C and D)

2. Date incident, experience, or outcome occurred. _____

3. Provide a description of the incident, experience, or outcome. _____

4. Have other Federal agencies, Cooperative Groups, or DSMB been notified of this incident, experience, or outcome? Yes No

If Yes, identify those notified. _____

5. Study Number Associated with Event: _____
 - a. Study Title: _____

 - b. Protocol Version Date: _____

Section C: Potential Unanticipated Problem Report

1. Describe how the incident, experience, or outcome is **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied. _____

2. Describe how the incident, experience, or outcome is **related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research). _____

3. Describe how the incident, experience, or outcome suggests that the research places participants or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized. _____

4. Describe the effect of the incident, experience, or outcome on participants' continued participation in the study. _____

5. Describe the effect of the incident, experience, or outcome on this research at your institution. _____

a. In your judgment, should this research continue as planned?

Yes No

If No, indicate the changes that should occur. _____

6. Detail your management plan by describing the specific action(s) the institution is taking or plans to take to address the problem and to prevent a recurrence of the incident, experience, or outcome. _____
- a. If this is a preliminary report and a management plan is not yet available, indicate when the management plan will be submitted. _____

NOTE: A management plan may also be submitted as an attachment to this form.

Section D: Serious or Continuing Noncompliance Report

1. Describe, if applicable, how the incident, experience, or outcome is indicative of serious noncompliance. _____

2. Describe, if applicable, how this incident, experience, or outcome is indicative of continuing noncompliance. _____

3. Describe the effect of the incident, experience, or outcome on participants' continued participation in the study. _____

4. Describe the effect of the incident, experience, or outcome on this research at your institution. _____
 - a. In your judgment, should this research continue as planned?
 Yes No

If No, indicate the changes that should occur. _____

5. Detail your management plan by describing the specific action(s) the institution is taking or plans to take to address the serious or continuing noncompliance and to prevent a recurrence of the incident, experience, or outcome. _____
 - a. If this is a preliminary report and a management plan is not yet available, indicate when the management plan will be submitted. _____

NOTE: A management plan may also be submitted as an attachment to this form.

Attachment 19B: Principal Investigator Worksheet for CIRB Pilot

OMB#: 0925-0046-19 Expiry Date: 2/28/2013

PRIVACY ACT NOTIFICATION STATEMENT

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 private under the Privacy Act. 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 presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 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 (0925-0046-19). Do not return the completed form to this address.

Locally-Developed Material Submission Form

(Submit this form with the participant-directed materials to the CIRB via email at localcontextcirb.emmes.com. One study per form.)

Section A: General Information

1. Date of Report Completion: _____
2. Principal Investigator Name: _____
3. Name of Person Completing the Report if other than the PI: _____
 - a. Email Address: _____
 - b. Phone Number: _____
4. Study Number Associated with Materials: _____
 - a. Study Title: _____
 - b. Protocol Version Date: _____

5. The materials being submitted are:

- Recruitment and/or Educational Materials (complete Section B)
- Translated Materials (complete Section C)
- Both (complete Sections B and C)

Section B: Locally-Developed Participant-Directed Materials

NOTE: PIs are encouraged to submit drafts for CIRB review to avoid incurring expenses related to the production of materials that might be revised by the CIRB.

1. Identify the recruitment and/or educational materials that are being submitted at this time:

- | | | |
|---------------------------------------|---|---|
| <input type="checkbox"/> Newspaper Ad | <input type="checkbox"/> Recruitment Letter | <input type="checkbox"/> Informational Article |
| <input type="checkbox"/> Poster/Flyer | <input type="checkbox"/> Website/Internet Posting | <input type="checkbox"/> Phone Screening Script |
| <input type="checkbox"/> Brochure | <input type="checkbox"/> Radio/Media Script | <input type="checkbox"/> Other: _____ |

2. Please choose one option:

- This material is new and has not yet been IRB-approved.
- This IRB-approved material is being submitted to the CIRB with modifications as outlined below:

NOTE: A track changes version and a clean version of the material must be included with the submission.

Section C: Translated Materials

In order for the CIRB to review and approve translated documents, the English language version of the document must already have CIRB approval.

1. CIRB review and approval of the following translated study-specific documents is requested.

Check all that apply:

- Informed Consent Document (ICD). If the study has multiple ICDs, list ICD titles below:

1. _____

2. _____

3. _____

4. _____

- Other documents (list below):

1. _____

2. _____

3. _____

4. _____

2. The following documents are required (Check off below when document is attached):

- CIRB-approved English language document(s) corresponding to the translated document

- Translated version(s) of the CIRB-approved English language document

- Translator's Certificate(s) of Accuracy or equivalent document(s)

If you have any questions regarding the completion of this request, please contact the CIRB Helpdesk at 888-657-3711 or ncicirbcontact@emmes.com.