



OMB Text

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OMB#: 0925 - xxxx

Expiry Date: xx/xx/xxxx

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.

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.

Signatory Institution Information

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Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

Name of Signatory Institution

[Add Note](#)

(Required)

General Information

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

(Required)

If more than one study is affected, enter the additional study ID numbers below.

[Add Note](#)

Site Reviewer

[Add Note](#)

No answer provided.

2. Enter Principal Investigator email address. Add Note
(Required)

If more than one Principal Investigator is affected, enter the additional names below. Add Note

3. Enter each study's Protocol Version Date associated with the incident, experience, or outcome. Add Note
(Required)

4. Enter the Study Participant(s) Registration Number(s), if the incident, experience, or outcome involved a study participant(s). Add Note

Description of Incident, Experience, or Outcome Add Note
1. Enter the date incident, experience, or outcome occurred.
(Required)

2. Describe the incident, experience, or outcome and/or add an attachment. Add Note
(Required)

3. Has the Network Group/sponsor, the Study Chair, or a Federal agency been notified of this incident, experience, or outcome? Add Note
(Required)
 Yes
 No

If Yes, identify those notified. Add Note

Attach a copy of the notification and any response(s) received from those notified. Include the AdEERS report, if applicable. Add Note

4. Did the incident, experience, or outcome occur while the CIRB-approved protocol was followed as written? Add Note
(Required)
 Yes
 No
*If Yes, complete Section C Unanticipated Problem.
If No, complete Section D Serious or Continuing Noncompliance.*

Section C: Potential Unanticipated Problem

[Add Note](#)

1. Is this incident, experience, or outcome unexpected?

(Required)

- Yes
- No

If Yes, describe how the incident, experience, or outcome is unexpected and/or add an attachment.

[Add Note](#)

Attachment:

[Add Note](#)

2. Is this incident, experience, or outcome related or possibly related to participation in the research?

[Add Note](#)

(Required)

- Yes
- No

If Yes, describe how the incident, experience, or outcome is related or possibly related to participation in the research and/or add an attachment.

[Add Note](#)

Attachment:

[Add Note](#)

3. Did the incident, experience, or outcome place the study participant(s) or others at a greater risk of harm?

[Add Note](#)

(Required)

- Yes
- No

If Yes, describe how the incident, experience, or outcome placed the study participant or others at a greater risk of harm and/or add an attachment.

[Add Note](#)

Attachment:

[Add Note](#)

4. Describe any action the Principal Investigator and/or Signatory Institution has taken, is taking, or is planning to take, to address the incident, experience, or outcome.

[Add Note](#)

Add an attachment, if applicable.

[Add Note](#)