National Cancer Institute
Central IRB Initiative

5 - Unanticipated Problem and/or Noncompliance Form -- CIRB Form

OMB Text

Add Note

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

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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.*

Signatory Institution Information

Add Note View Audit

Submitting User Information

Campbell, Brian

Email: bcampbell@emmes.com

Name of Signatory Institution Add Note

(Required)

General Information Add Note

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

Add Attachment

4. Did the incident, experience, or outcome occur while the CIRB-approved protocol was followed as writtten? 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

Add Attachment

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

Add Attachment

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

Add Attachment

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

Add Attachment