

**OMB Text**

OMB#: 0925 - 0625

Expiry Date: 01/31/2014

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 15 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

Phone:

**Name of Signatory Institution**

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Children's Oncology Group

**General Information**

[Add Note](#)

**1. Enter Study ID Number.**

(Required)

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

[Add Note](#)

**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)



**Attachment:**

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

[Add Attachment](#)

No Attachments added.

**3. Has the Cooperative 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](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

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

[Add Note](#)

(Required)

- Yes *If Yes, complete Section C Unanticipated Problem.*
- No *If No, complete Section D Serious or Continuing Noncompliance.*

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## 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](#) [View Audit](#)

Add Attachment

No Attachments added.

### 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](#) [View Audit](#)

Add Attachment

No Attachments added.

### 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](#) [View Audit](#)

Add Attachment

No Attachments added.

[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](#) [View Audit](#)

**Add an attachment, if applicable.**

No Attachments added.

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

**Section D: Potential Serious or Continuing Noncompliance Report**

**1. The definition of serious noncompliance is noncompliance that adversely affects the rights and welfare of study participants or results in any untoward medical occurrence that meets the criteria of "serious" or significantly impacts the integrity of study data.**

Serious is defined as side effects that may require hospitalization or may be irreversible, long-term, life-threatening, or fatal.

[Add Note](#)

**Is the incident, experience, or outcome potential serious noncompliance?**

(Required)

Yes

No

[Add Note](#)

**If Yes, describe how the incident, experience, or outcome is potential serious noncompliance and/or add an attachment.**

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**Attachment:**

No Attachments added.

2. The definition of continuing noncompliance is a pattern that, if unaddressed, could jeopardize the rights and welfare of research participants or the integrity of the study data due to noncompliance with the protocol, Federal regulations, and/or the requirements of the CIRB.

Is the incident, experience, or outcome potential continuing noncompliance?

[Add Note](#)

(Required)

- Yes  
 No

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

[Add Note](#)

Attachment:

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[Add Attachment](#)  
No Attachments added.

3. Does the incident, experience, or outcome affect the study participant's continued participation in the study?

[Add Note](#)

(Required)

- Yes  
 No

If Yes, describe how the study participant's continued participation in the study is affected and/or add an attachment.

[Add Note](#)

Attachment:

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

[Add Attachment](#)  
No Attachments added.

**4. Describe the management plan, including any corrective action, the Signatory Institution and/or Principal Investigator 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](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

**If this is a preliminary report and a management plan is not yet available, indicate when the management plan or corrective action will be submitted.**

[Add Note](#)



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