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

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 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

View Audit

Submitting User Information

Campbell, Brian
Email: bcampbell@emmes.com **Phone:**

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Name of Signatory Institution

Children's Oncology Group

General Information

Add Note

1. Enter Study ID Number.

(Required)

Add Note

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

Add Note

2. Enter Principal Investigator email address.

(Required)

Add Note

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.

(Required)

Add Note

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

Description of Incident, Experience, or Outcome

Add Note

1. Enter the date incident, experience, or outcome occurred.

(Required)

Add Note

2. Describe the incident, experience, or outcome and/or add an attachment.

(Required)

Add Note View Audit

Attachment:

Add Attachment

No Attachments added.

Add Note

3. Has the Cooperative Group/sponsor, the Study Chair, or a Federal agency been notified of this incident, experience, or outcome?

(Required)

- Yes
- No

Add Note

If Yes, identify those notified.

Add Note View Audit

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

Add Attachment

No Attachments added.

Add Note

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

(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

Add Note

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

Add Note View Audit

Attachment:

Add Attachment

No Attachments added.

Add Note

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

(Required)

- Yes
- No

Add Note

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 View Audit

Attachment:

Add Attachment

No Attachments added.

Add Note

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

(Required)

- Yes
- No

Add Note

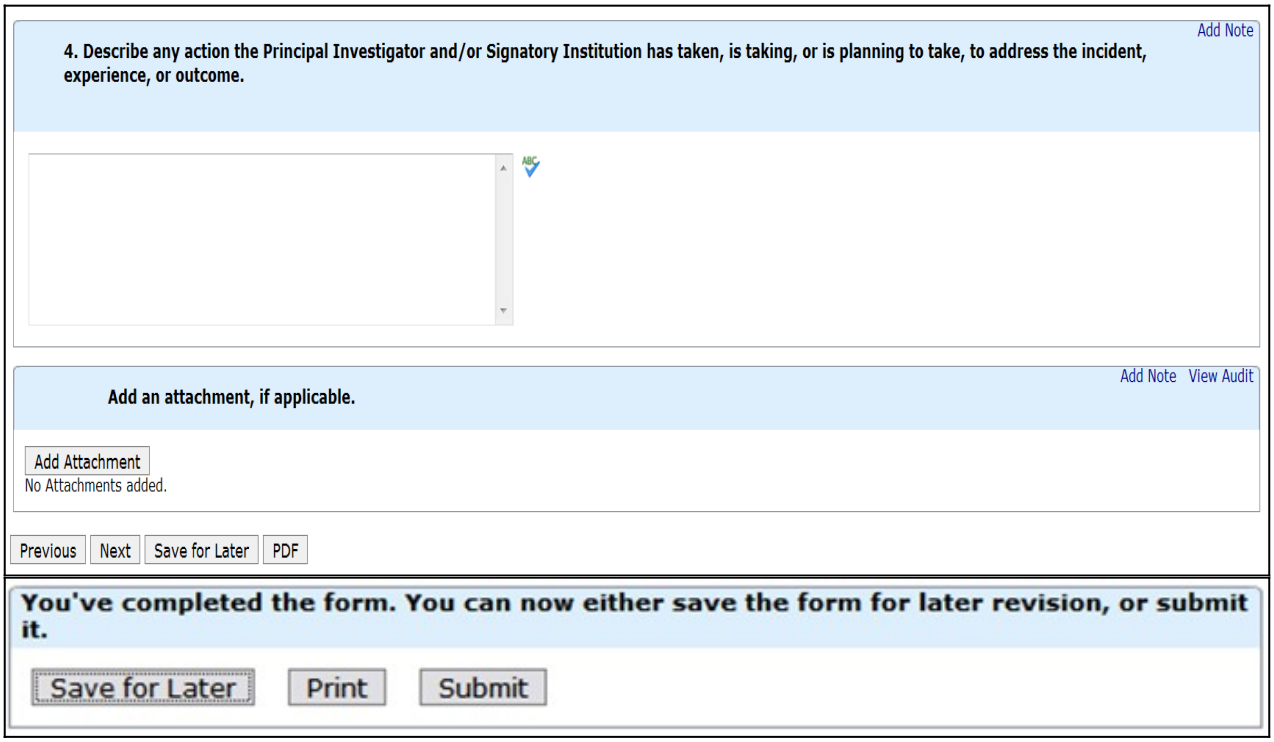
If Yes, describe how the incident, experience, or outcome placed the study participant or others at a greater risk of harm and/or add an attachment.

Add Note View Audit

Attachment:

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.
Add Attachment
No Attachments added.
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You've completed the form. You can now either save the form for later revision, or submit it.
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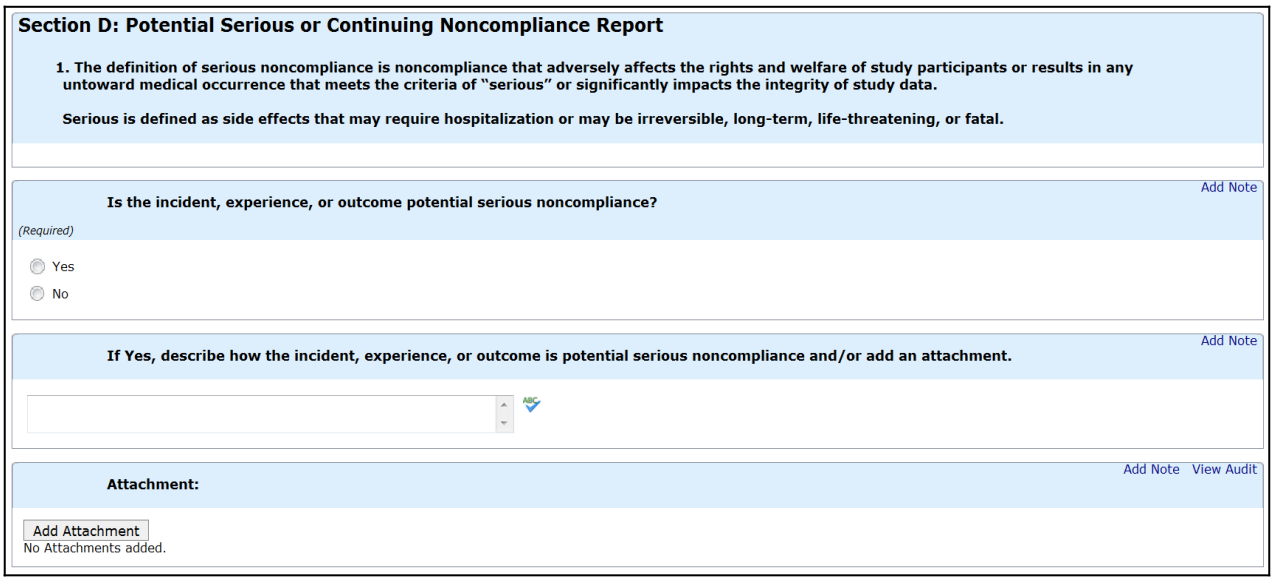
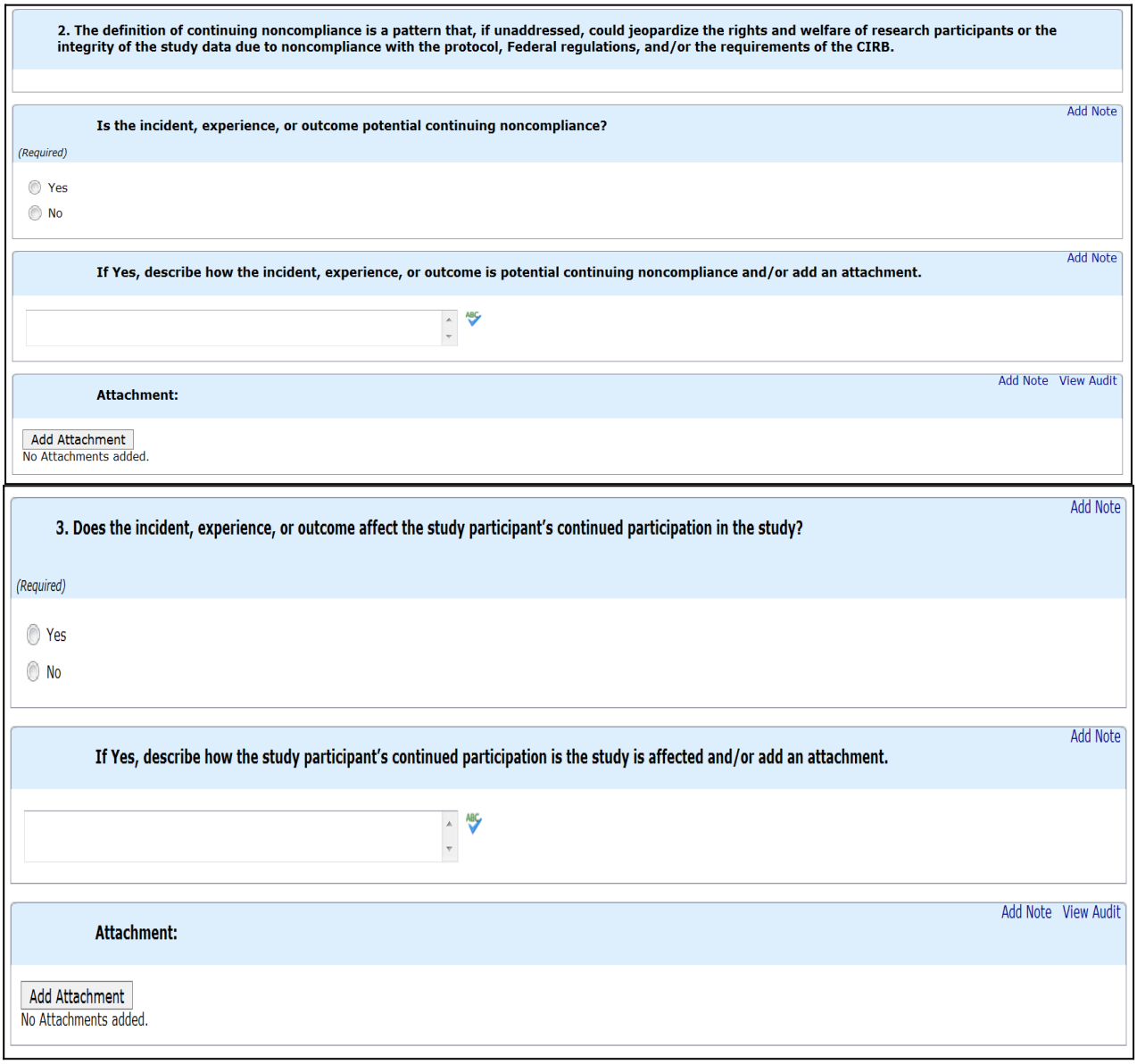
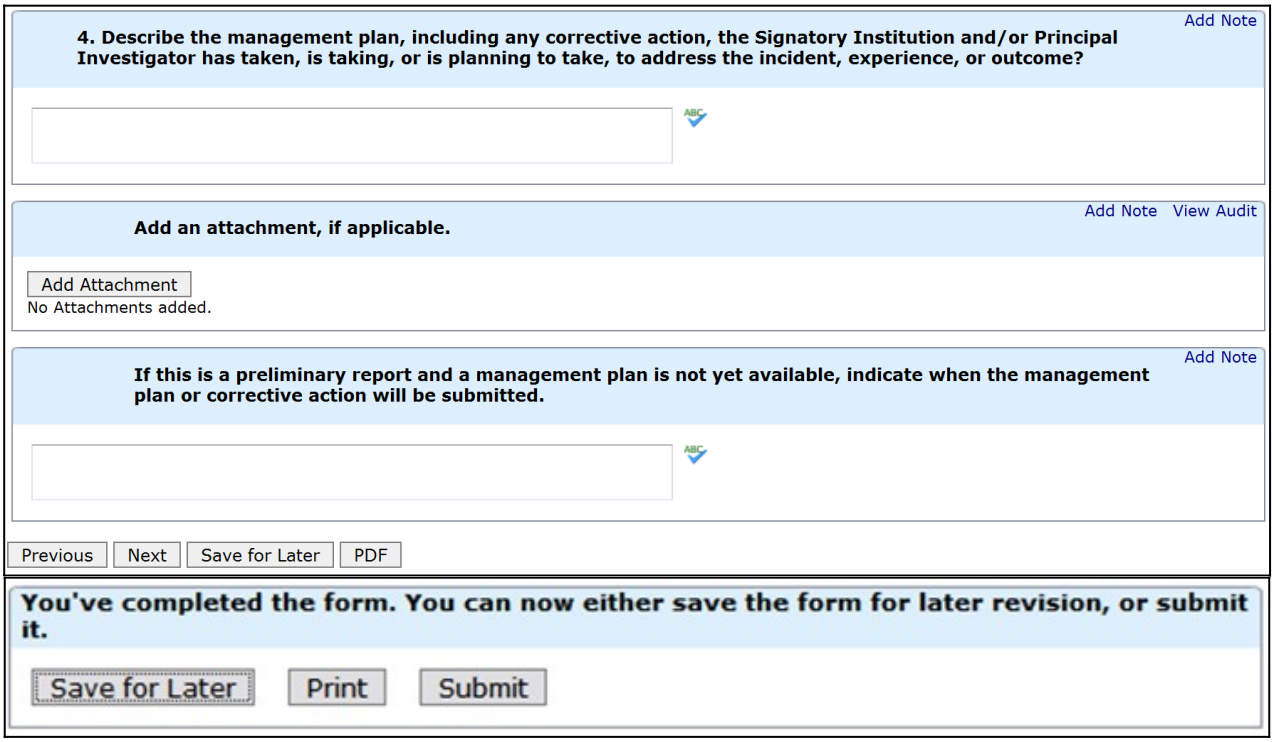
Print
Submit


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.
Add Note View Audit
Attachment:
Add 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.
Add Note
Is the incident, experience, or outcome potential continuing noncompliance?
(Required)
Yes
No
Add Note
If Yes, describe how the incident, experience, or outcome is potential continuing noncompliance and/or add an attachment.
Add Note View Audit
Attachment:
Add Attachment
No Attachments added.
Add Note
3. Does the incident, experience, or outcome affect the study participant's continued participation in the study?
(Required)
Yes
No
Add Note
If Yes, describe how the study participant's continued participation is the study is affected and/or add an attachment.
Add Note View Audit
Attachment:
Add Attachment
No Attachments added.


Add Note
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 View Audit
Add an attachment, if applicable.
Add Attachment
No Attachments added.
Add Note
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.
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You've completed the form. You can now either save the form for later revision, or submit it.
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