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1.0  Accessing IRBManager for Worksheets and Forms

The following individuals may request access to IRBManager:
1. Signatory Institution Primary Contacts
2. Signatory Institution Principal Investigators
3. Research staff supporting Signatory Institution Principal Investigators

Access to IRBManager is necessary to complete and submit the following Worksheets/Forms:
1. Annual Signatory Institution Worksheet About Local Context
2. Annual Principal Investigator Worksheet About Local Context
3. Study-Specific Worksheet About Local Context
4. Potential Unanticipated Problem and/or Serious or Continuing Noncompliance Reporting Form
5. Transfer of Study IRB Review Responsibility or Study Closure Form

Login information (User Name and Password) sent via email from the CIRB Operations Office is the same for the CIRB Website and IRBManager. When you are identified as an individual at your institution requiring access to IRBManager, you will receive an email from the CIRB Operations Office notifying you that you have been granted access and reminding you to use the same User Name and Password you have already been provided.

The User Name identifies who is working in the system and provides a record of who is responsible for adding, modifying or deleting information. For this reason, it is very important that you do not share your User Name and Password.

1.1  Accessing IRBManager

To access IRBManager, go to https://irbmanager.becirb.com/. (Figure 1)

- Enter your “User Name” and “Password” in the fields provided.
- Enter “NCI” as the “Client” (not case sensitive).
- Clicking the checkbox in front of “Remember Client” is optional.
- Click the “Login” button.

![Figure 1]
You will be taken to the IRBManager “Home” screen. Within IRBManager, all Worksheets and Forms are stored as xForms. On the “Home” Screen, there is information about Studies, xForms, and Events. (Figure 2)

The “Studies” section lists the following:
- How many studies are active: This is the number of the active studies for a Signatory Institution Principal Investigator if the Signatory Institution Principal Investigator logs in, or the number of active studies for a Signatory Institution if the Signatory Institution Primary Contact or research staff log in.
- How many studies have ever been submitted to the CIRB: This is the number of all studies ever submitted to the CIRB for a Signatory Institution Principal Investigator if the Signatory Institution Principal Investigator logs in, or the number of all studies ever submitted to the CIRB for a Signatory Institution if the Signatory Institution Primary Contact or research staff log in.

By clicking the hyperlinks, you go to a listing of those studies.

The “xForms” section lists the following:
- The number of unsubmitted xForms.
- The number of xForms currently being process by the CIRB.
- The number of xForms for each Signatory Institution Principal Investigator by name.
- The number of xForms submitted for the Signatory Institution.

By clicking on the hyperlinks, you go to the specific listing of xForms.

The “Events” section lists the cumulative total of Worksheets or Forms directly related to studies, such as the Study-Specific Worksheet About Local Context, Study Closure or Transfer of Study IRB Review Responsibility Form, Potential Unanticipated Problem or Serious or Continuing Noncompliance Form, and One-Time Roll-Over Worksheet for studies that were rolled over from the facilitated review model to the independent model.
Figure 2
1.2 Starting a New Worksheet/Form

To begin working on a new Worksheet or Form click the “Start xForm” button located under the “Actions” section. (Figure 3)
A new window will open showing the list of the three Worksheets and two Forms available (Figure 4). Click on the Worksheet or Form you would like to start completing.

2.0 Completing the “Annual Signatory Institution Worksheet About Local Context”

This Worksheet should be completed by the Signatory Institution Primary Contact. All responses should take into consideration the local context of the Signatory Institution.

**NOTE: Summary of How to Access Worksheet/Form**

From your “Home” screen click the “Start xForm” button, which can be found under the “Actions” section, then click on the Worksheet you would like to complete (Figure 5). The first screen of the Worksheet will appear. Each screen is detailed below.

Click on the “Annual Signatory Institution Worksheet About Local Context” (Figure 5).
2.1 OMB Text and Reason for Submission

The required Office of Management and Budget (OMB) Statement of Confidentiality and additional required language is at the top of the Worksheet (Figure 6).

Below the OMB Text are two options for the “Reason for submission” of the Worksheet. Select the appropriate reason by clicking the radio button next to the description.

Select “First submission to the CIRB of an Annual Signatory Institution Worksheet About Local Context” for the initial submission of the Worksheet.

Select “Revised submission of the Annual Signatory Institution Worksheet About Local Context” for any subsequent revisions to an existing Worksheet, including the annual confirmation.

![Figure 6](image.png)

2.2 Signatory Institution Information (Figure 7)

The Submitting User Information, Name of Signatory Institution, Question 1, and Question 2 are auto-populated from information provided by your institution during enrollment for the person logged in to IRBManager. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

If there are any changes to the list of Component and/or Affiliate Institutions that are auto-populated, list the change in the text box provided in Questions 1 and 2, and complete the Add or Remove Component Institution Form or Add or Remove Affiliate Institution Form. Both are located at the following URL: https://www.ncicirb.org/CIRB_Update_Person_Inst_Info.asp and submit to the CIRB via email at ncicirbcontact@emmes.com.
For Question 3, confirm if the Component and/or Affiliate Institutions listed are correct by selecting the appropriate radio button.
2.3 State and Local Law (Figure 8)

Answer Questions 4 through 7 in the text boxes. Each text box allows for up to 4000 characters. Use the “Add Attachment” button to attach additional information as needed. Attachments may include local policies and procedures, etc.

For Question 4, describe your state law and corresponding institutional policy regarding legally authorized representatives. If you would rather attach your policy, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the policy.

For Question 5, enter a number to indicate the age of majority in your state.

For Question 6, describe other state or local laws that govern the conduct of research at your institution. If you would rather attach a description of the laws, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 7, describe how your institution ensures compliance for each state or local law. If you would rather attach a description, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.
2.4 Research Oversight (Figure 9)

For Question 8, provide the information requested for the office and person at your Signatory Institution responsible for the oversight of the conduct of the research.

For Question 9, provide the information requested for the office and person at your Signatory Institution responsible for identifying, managing, and reporting potential unanticipated problems and/or serious or continuing noncompliance to the CIRB.

**NOTE:** If the person in Question 8 is the same individual identified in Question 9, you may enter “same as above” for the Question 9 responses.

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2.5 Financial Conflicts of Interest (Figure 10)

For Question 10, describe how the Signatory Institution gathers and evaluates Signatory Institution Principal Investigator and research staff financial conflicts of interest for studies on the CIRB menu. If you would rather attach a description of the procedures, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

![Figure 10](image)

2.6 Institutional Policies Pertaining to the Informed Consent Document for CIRB-Approved Studies (Figure 11)

For Question 11, describe your institutional policies and guidelines that govern the informed consent process for CIRB-approved Studies. If you would rather attach policies and guidelines, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 12, provide all boilerplate language required by your Signatory Institution. Remember this language will be CIRB-approved and any changes must be approved before implementation. If you would rather attach the boilerplate language, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document. Only boilerplate language pertaining to studies reviewed by the CIRB is required to be provided for review and approval.

**NOTE:** If you are submitting an updated Worksheet and have revised boilerplate language, submit a “track changes” and a clean Word version of the boilerplate language to clearly indicate to the CIRB what has changed from the current CIRB-approved boilerplate language.

For Question 13, if your Signatory Institution requires the use of letterhead, click the “Add Attachment” button to attach a blank copy of the letterhead. It is acceptable to mark the letterhead “VOID”, if required by the institution.
For Question 14, provide any other institutional requirements for the informed consent document. Remember these institutional requirements will be CIRB-approved and any changes must also be approved before implementation. If you would rather attach a document with the requirements, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

**Figure 11**
2.7 Community Descriptors (Figure 12)

Answer Question 15 using the text box provided. “Catchment area” is defined as the specific geographic region from which potential study participants are recruited.

Answer Yes or No for Question 16. If your community does not have a positive attitude toward the conduct of research, describe any events and/or situations of which you are aware that have adversely affected the community’s attitude toward research using the text box provided.

For Question 17, describe any other information about the anticipated study participant population at your Signatory Institution. If you would rather attach a document describing the anticipated study population, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

Figure 12
2.8 Additional Information (Figure 13)

Answer Yes or No for Question 18. If there is anything else the CIRB should know about the local context of the Signatory Institution, provide an explanation of the additional local context using the text box provided. If you would rather attach a document describing the additional local context information, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

NOTE ABOUT NAVIGATION BUTTONS: The “Previous” navigation button option is not available when it appears as “half-bright”, or gray, as shown above. When the button is active, and the font is black, clicking it will take you to the previous screen without saving the data entered on the current screen.

The “Next” navigation button saves the data entered on the current screen and takes you to the next screen. If required fields are not completed, red text will appear at the top of the screen indicating which fields need to be completed.

The “Save for Later” navigation button saves all data entered up to that point in the Worksheet. The Worksheet will be exited after clicking this option. When you are ready to resume working on the saved Worksheet you can find it in the “My Documents & Forms” section of the IRBManager “Home” screen.
The “PDF” option automatically converts all data entered up to that point in the Worksheet to a PDF which can be saved locally on your computer for reference.

Click “Next” when complete to move to the next screen.

2.9 Worksheet Submission to the CIRB (Figure 14)

When all information is complete on the Worksheet, the Worksheet is ready for submission to the CIRB. Click “Submit” to save the information and submit to the CIRB for review.

If the information is not complete on the Worksheet, click “Save for Later” to save your progress and exit the system.

If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document per printing procedures on your computer, you will be returned to this screen.

You must click “Submit” for the Worksheet to be provided to the CIRB for review.

![Image](image.png)

**Figure 14**

3.0 Completing the “Annual Principal Investigator Worksheet About Local Context”

To be completed by each Signatory Institution Principal Investigator opening a CIRB-approved Study.

**NOTE: Summary of How to Access Worksheet/Form**

*From your “Home” screen click the “Start xForm” button which can be found under the “Actions” section and click on the Worksheet you would like to complete (Figure 15). The first screen of the Worksheet will appear. Each screen is detailed below.*

Click on the “Annual PI Worksheet About Local Context”. (Figure 15)
3.1 OMB Text and Selecting Reason for Submission (Figure 16)

The required Office of Management and Budget (OMB) Statement of Confidentiality and additional required language is at the top of the Worksheet.

Below the OMB Text are two options for the “Reason for submission” of the Worksheet. Select the appropriate reason by clicking the radio button next to each description.

Select “First Submission of the Annual Principal Investigator Worksheet About Local Context” for the initial submission of the Worksheet.

Select “Revised Submission of the Annual Principal Investigator Worksheet About Local Context” for any subsequent revisions to an existing Worksheet, including the annual confirmation.
3.2 Signatory Institution Information (Figures 17-18)

The Submitting User Information is auto-populated from information provided by your institution during enrollment and is based on your login. (Figure 17) If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

For Question 1, enter the email address of the Signatory Institution Principal Investigator (PI).

Once the email address of the Signatory Institution Principal Investigator has been entered in the text box provided and the keys named “Enter” or “Return” or “Tab” on your keyboard have been clicked, the Signatory Institution Principal Investigator information will auto-populate. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

If “Contact not found.” appears (Figure 18), email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to determine next steps to add the investigator to the database.
NOTE ABOUT NAVIGATION BUTTONS: The “Previous” navigation button option is not available when it appears as “half-bright”, or gray, as shown above. When the button is active, and the font is black, clicking it will take you to the previous screen without saving the data entered on the current screen.

The “Next” navigation button saves the data entered on the current screen and takes you to the next screen. If required fields are not completed, red text will appear at the top of the screen indicating which fields need to be completed.

The “Save for Later” navigation button saves all data entered up to that point in the Worksheet. The Worksheet will be exited after clicking this option. When you are ready to resume working on the saved Worksheet you can find it in the “My Documents & Forms” section of the IRBManager “Home” screen.

The “PDF” option automatically converts all data entered up to that point in the Worksheet to a PDF which can be saved locally on your computer for reference.

Click “Next” when complete to move to the next screen.

3.3 Name of Signatory Institution (Figure 19)

For Question 2, information about the Signatory Institution will auto-populate for the Principal Investigator. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

![Figure 19](image)

3.4 Research Staff (Figure 20)

For Question 3, enter the number of sub-investigators under your supervision for all CIRB-approved trials that are actively accruing study participants.

For Question 4, enter the number of research nurses/CRAs under your supervision for all CIRB-approved trials that are actively accruing study participants.

For Question 5 describe if you or any research staff at your Signatory Institution have reported a financial conflict of interest. If you would rather attach a document describing the reported financial conflict of interest, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.
3.5 Signatory Institution Principal Investigator Education, Training and Experience (Figure 21)

There is no information to complete for this section since investigator qualifications to conduct the study have been previously captured in an NCI database.

3.6 Signatory Institution Principal Investigator Resources (Figure 22)

For Question 6, enter the number of actively accruing research studies, including CIRB-approved studies and studies not reviewed by the CIRB. In the text box provided, list the CIRB-approved studies by Study ID Number. This is a text box and can be populated with data separated by commas or as a vertical list.

For Question 7, enter the number of study participants receiving study intervention for all studies for which you are the Signatory Institution Principal Investigator. This includes CIRB-approved studies and those not reviewed by the CIRB.
3.7 Recruitment (Figure 23)

For Question 8 describe the process of recruiting study participants for CIRB-approved studies. Use the “Add Attachment” button to attach additional information as needed.

For Question 9, click the box next to the appropriate selection. Use the text box provided to describe additional information as needed.

![Figure 23](image)

3.8 Compensation to Study Participants (Figure 24)

The CIRB is aware that there is typically no compensation provided for CIRB-approved studies to study participants. Describe any compensation/incentives provided by the Signatory Institution or others to study participants enrolled in CIRB-approved studies, for example: parking validation, cafeteria voucher, other.

If none, indicate “N/A” in the text box.

![Figure 24](image)
3.9 Informed Consent Process (Figure 25)

For Questions 11-17, describe the process used to introduce a trial to a potential study participant and obtain their consent to participate. Questions 11 through 16 are open text boxes to allow for a description. Question 17 requires checking the appropriate box.

For Question 18, provide the languages for which translations are routinely provided or enter “N/A” if your Signatory Institution does not routinely translate the consent document. If you would rather attach your Signatory Institution’s policy, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 19, describe your Signatory Institution’s policy regarding assent by children or impaired adults. If you would rather attach your Signatory Institution’s policy, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 20, describe your Signatory Institution’s process to receive and address concerns from study participants and others about the conduct of the research.
13. How long does the potential study participant have to review the consent document before a response is required, including time to take the consent document home?

14. Who is available to answer questions?

15. How is the potential study participant’s understanding of consent assessed?

16. How is the informed consent process conducted with non-English speaking potential study participants?

17. Who provides consent?

- Potential study participant
- Parent for potential pediatric study participant
- Legally Authorized Representative
- Other

Please explain.
18. For what languages are translations routinely provided?

(Required)

If translations are routinely provided, what process is currently used to translate the informed consent document?

If applicable, an attachment can be added here.

Reminder: Translations must be CIRB-approved prior to presenting to a potential study participant.

19. Describe your institution’s policy regarding assent by children or impaired adults.

(Required)

If applicable, an attachment can be added here.

20. Describe your institution’s process to receive and address concerns from study participants and others about the conduct of the research.

(Required)

Figure 25
3.10 Pharmacy Information (Figure 26)

Question 21 asks if a pharmacist is responsible for the management of the study drug and/or agents provided by the study. Provide the name and title of the pharmacist or responsible person at each practice/location.

For Question 22, describe how the pharmacist or responsible person is provided with a copy of the protocol at each practice location.

![Pharmacy Information](image-url)
3.11 Measures to Protect Confidentiality (Figure 27)

Review the definition of Confidentiality at the top of the screen before responding to this question.

For Question 23, select all the measures that will be used to maintain the confidentiality of identifiable information by checking the appropriate boxes. Select “Other” as necessary and provide a description in the text box provided.

![Measures to Protect Confidentiality](image)

Figure 27

3.12 Measures to Protect Privacy (Figure 28)

Review the definition of Privacy at the top of the screen before responding to this question.

For Question 24, select all the measures that will be used to maintain the study participant’s privacy by checking the appropriate boxes. Select “Other” as necessary and provide a description in the text box provided.
3.13 Emergency Resources (Figure 29)

For Question 25, select all the resources available at the site to treat emergencies from study-related procedures by checking the appropriate boxes. Select “Other” as necessary and provide a description in the text box provided.
3.14 Using a Legally Authorized Representative (LAR) (Figure 30)

For Question 26, select “Yes” or “No” if you plan on enrolling study participants using an LAR.

For Question 27, describe who may serve as an LAR at your institution. If you would rather attach your institution’s policy, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 28, describe how you assess a potential study participant’s ability to provide consent. If you would rather attach your institution’s policy, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

Figure 30

Click “Next” when complete to move to the next screen.
3.15 Vulnerable Populations (Figure 31)

Question 29 requires identification of the vulnerable populations that could be enrolled in a CIRB-approved study at your Signatory Institution.

For each vulnerable population you select, a new screen will appear with safeguards that correspond with each selection. A text box is provided if you select “Other”.

![Figure 31](image)

Click “Next” when complete to move to the next screen.

3.16 Safeguards for Vulnerable Populations (Figures 32-37)

Figures 32 thru 37 illustrate the different safeguards that appear when a vulnerable population has been checked.

If you select “Children” as the vulnerable population, the safeguards for that category will appear in a new window (Figure 32). Select the appropriate safeguards for that population.
If you select “Pregnant Women” as the vulnerable population, the safeguards for that category will appear in a new window (Figure 33). Select the appropriate safeguards for that population.
If you select “Economically Disadvantaged” as the vulnerable population, the safeguards for that category will appear in a new window (Figure 34). Select the appropriate safeguards for that population.

Figure 34

If you select “Educationally Disabled” as the vulnerable population, the safeguards for that category will appear in a new window (Figure 35). Select the appropriate safeguards for that population.

Figure 35
If you select “Physically Disabled” as the vulnerable population, the safeguards for that category will appear in a new window (Figure 36). Select the appropriate safeguards for that population.

![Figure 36](image)

If you select “Other” as the vulnerable population, describe the vulnerable population and the safeguards in the text box (Figure 37).

![Figure 37](image)
3.17 Additional Confirmations When Investigator Intends to Enroll Pregnant Woman [45 CFR 46.204 (h), (i), (j)] (Figure 38)

Enter a response for each question by clicking on the appropriate radio button for Parts A, B, and C.

![Additional Confirmations When Investigator Intends to Enroll Pregnant Women][1]

Click “Next” when complete to move to the submission screen.

3.18 Worksheet Submission to the CIRB (Figure 39)

When all information is complete on the Worksheet, the Worksheet is ready for submission to the CIRB. Click “Submit” to save the information and submit to the CIRB for review.

If the information is not complete on the Worksheet, click “Save for Later” to save your progress and exit the system.

---

[1]: Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)]
If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document, you will be returned to this screen.

You must click “Submit” to submit to the CIRB for review.

Figure 39

4.0 Completing the “Study-Specific Worksheet About Local Context”

This Worksheet must be submitted by the Signatory Institution Principal Investigator to open a study.

The Study-Specific Worksheet confirms information or captures changes in information provided on the “Annual Principal Investigator Worksheet About Local Context” that are necessary for the conduct of this specific study.

You might find it helpful to have a copy of the Annual Principal Investigator Worksheet available for reference. To access a copy of the “Annual Principal Investigator Worksheet About Local Context”, go to the “Home” screen and click on the “xForm” hyperlink in the “xForms” section. (Figure 40) Click on your Annual Principal Investigator Worksheet and it will open in a new window for your viewing. You can refer to this Worksheet while completing the “Study-Specific Worksheet About Local Context”.

Figure 40
NOTE: Summary of How to Access Worksheet/Form

From your “Home” screen click the “Start xForm” button which can be found under the “Actions” section and click on the Worksheet you would like to complete (Figure 41). The first screen of the Worksheet will appear. Each screen is detailed below.

Click on the “Study-Specific Worksheet About Local Context”. (Figure 41)

![Figure 41]

4.1 OMB Text and Reason for Submission (Figure 42)

The required Office of Management and Budget (OMB) Statement of Confidentiality and additional required language is at the top of the Worksheet.

Below the OMB Text are two options for the “Reason for submission” of the Worksheet. Select the appropriate reason by clicking the radio button next to each description.

The following instructions pertain to Option 1 – Open a New Study. Select this option when the study is not opened with the CIRB at the Signatory Institution. Clicking this option will be this is the first submission to the CIRB of a Study-Specific Worksheet About Local Context for this study at the Signatory Institution.
NOTE ABOUT NAVIGATION BUTTONS: The “Previous” navigation button option is not available when it appears as “half-bright”, or gray, as shown above. When the button is active, and the font is black, clicking it will take you to the previous screen without saving the data entered on the current screen.

The “Next” navigation button saves the data entered on the current screen and takes you to the next screen. If required fields are not completed, red text will appear at the top of the screen indicating which fields need to be completed.

The “Save for Later” navigation button saves all data entered up to that point in the Worksheet. The Worksheet will be exited after clicking this option. When you are ready to resume working on the saved Worksheet you can find it in the “My Documents & Forms” section of the IRBManager “Home” screen.

The “PDF” option automatically converts all data entered up to that point in the Worksheet to a PDF which can be saved locally on your computer for reference.

Click “Next” when complete to move to the submission screen.

NOTE: For “Change of PI” instructions (Option 2) please go to section 4.7.

4.2 Signatory Institution Information (Figure 43)

The Submitting User Information is auto-populated from information provided by your Signatory Institution during enrollment by the Signatory Institution. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

Enter the Study ID Number in the field provided.

If you are not sure of the Study ID Number, you can click the hyperlink above to search the CIRB Website or search for a study within IRBManager using the percentage sign.
“%” followed by whatever consecutive numbers of the Study ID Number that you know and ending with another percentage sign “%”.

For example, use %1305% to look for E1305 or use %240% to look for GOG-0240.

Click "Next" when complete to move to the next screen.

4.3 General Information (Figure 44)

For Question 1, enter the email address of the Signatory Institution Principal Investigator for this study. Once the email has been entered, click “Enter” or “Return” or “Tab” on your keyboard and the Signatory Institution Principal Investigator information will auto-populate.
If “Contact not found.” appears (Figure 45), email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to determine next steps to add this person to the database.

![Figure 45](image.png)

Click “Next” when complete to move to the next screen.

4.4 Study-Specific Changes to Annual Principal Investigator Worksheet (Figure 46)

The topics listed below reflect those asked on the Annual Principal Investigator Worksheet About Local Context which has already been completed. Indicate for each topic whether or not there are any changes from the information previously provided. If there are changes, please describe. If any of the “Changed” answers can be supported by an attachment, an attachment can be added in Question 33.
The topics listed below reflect those asked on the Annual Principal Investigator Worksheet About Local Context which has already been completed. Indicate for each topic whether or not there are any changes from the information previously provided. If there are changes, please describe. If any of the 'Changed' answers can be supported by an attachment, an attachment can be added in Question 3.

### General Information (Questions 1-2 on the Annual Principal Investigator Worksheet About Local Context)

**Required**
- [ ] No Change
- [ ] Changed

**If Changed**, describe changes.

### Research Staff (Questions 3-5 on the Annual Principal Investigator Worksheet About Local Context)

**Required**
- [ ] No Change
- [ ] Changed

**If Changed**, describe changes.

### Principal Investigator Resources (Questions 6-7 on the Annual Principal Investigator Worksheet About Local Context)

**Required**
- [ ] No Change
- [ ] Changed

**If Changed**, describe changes.

### Recruitment (Questions 8-9 on the Annual Principal Investigator Worksheet About Local Context)

**Required**
- [ ] No Change
- [ ] Changed

**If Changed**, describe changes.
Compensation to Study Participants (Question 10 on the Annual Principal Investigator Worksheet About Local Context)

- No Change
- Changed

If 'Changed', describe changes.

Informed Consent Process (Questions 11-20 on the Annual Principal Investigator Worksheet About Local Context)

- No Change
- Changed

If 'Changed', describe changes.

Pharmacy Information (Questions 21-22 on the Annual Principal Investigator Worksheet About Local Context)

- No Change
- Changed

If 'Changed', describe changes.

Measures to Protect Confidentiality (Question 23 on the Annual Principal Investigator Worksheet About Local Context)

- No Change
- Changed

If 'Changed', describe changes.

Measures to Protect Privacy (Question 24 on the Annual Principal Investigator Worksheet About Local Context)

- No Change
- Changed

Add Note
<table>
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<tr>
<th><strong>If 'Changed', please describe.</strong></th>
<th>Add Note</th>
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<td>- Changed</td>
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<th><strong>If 'Changed', describe changes.</strong></th>
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<tr>
<th><strong>Using a Legally Authorized Representative (LAR) (Questions 26-28 on the Annual Principal Investigator Worksheet About Local Context)</strong></th>
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<tr>
<td>- No Change</td>
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<td>- Changed</td>
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<tr>
<th><strong>Vulnerable Populations (Question 29 on the Annual Principal Investigator Worksheet About Local Context)</strong></th>
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<tr>
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<td>- Changed</td>
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<th><strong>If 'Changed', describe changes.</strong></th>
<th>Add Note</th>
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Click “Next” when complete to move to the next screen.

4.5 Principal Investigator Confirmation of Intent to Comply (Figures 47-48)

If the Signatory Institution Principal Investigator is completing the Worksheet, read the statement and enter your password as declaration of your intent to comply as Signatory Institution Principal Investigator of this study (Figure 47).

If the user completing the Worksheet is not the Signatory Institution Principal Investigator, click “Next” and then “Submit” on the final screen to send an email automatically to the Signatory Institution Principal Investigator to notify him/her to log in to IRBManager to review the Worksheet (Figure 48). The Worksheet cannot be
submitted to the CIRB for review until the Signatory Institution Principal Investigator completes the intent to comply and submits the Worksheet.

![Study Specific Worksheet About Local Context – PI Intent to Comply - First Submission](image)

**Figure 48**

Click “Next” when complete to move to the next screen.

**NOTE:** It is necessary that the Signatory Institution Principal Investigator logs into IRBManager to confirm the intent to comply and to submit the Worksheet to the CIRB for review. Refer to the NOTE at the beginning of Section 12.0 for brief instructions on how to access this Worksheet.

The Signatory Institution Principal Investigator reviews the Worksheet and clicks “Next” at the bottom of the screen to progress through the Worksheet. On the Confirmation of Intent to Comply screen at the end of the Worksheet, the Signatory Institution Principal Investigator should enter their password to confirm intent to comply.

If the Signatory Institution Principal Investigator has any comments on the answers provided by the original user who created the Worksheet, the Signatory Institution Principal Investigator can use the “Note” feature to make a comment. When the Worksheet is submitted to the CIRB, the CIRB will respond to the user who created the Worksheet so the appropriate edits can be made.

### 4.6 Worksheet Submission to the CIRB (Figure 49)

The Signatory Institution Principal Investigator is the only person who can submit the Worksheet to the CIRB.

If all information is complete on the Worksheet and the Signatory Institution Principal Investigator has entered his/her password, the Worksheet is ready for submission to the CIRB. Click "Submit" to save the information and submit to the CIRB for review.

If the information is not complete on the Worksheet, click “Save for Later” to save your progress and exit the system.
If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document, you will be returned to this screen.

You must click “Submit” to submit to the CIRB for review.

4.7 Change of Principal Investigator (Figure 50)

The following instructions pertain to Option 2— “Change of PI”. Select this option when the study is currently open at the Signatory Institution with the CIRB. This is a Study-Specific Worksheet About Local Context due to a change in Signatory Institution Principal Investigator for this study at the Signatory Institution (Figure 50).

Click “Next” when complete to move to the next screen.

4.8 Signatory Institution Information (Figure 51)

The Submitting User Information is auto-populated from information provided by your signatory institution during enrollment. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.
Enter the Study ID Number in the field provided and click “Enter” or “Return” or “Tab” on your keyboard and the Study Title information will auto-populate.

The Study ID Number should match the Study ID Number provided on the CIRB Website https://www.ncicirb.org/CIRB_Protocols.asp.

If you are not sure of the Study ID Number, you can click the hyperlink above to search the CIRB Website or search for a study within IRBManager using the percentage sign “%” followed by whatever consecutive numbers of the Study ID Number that you know and ending with another percentage sign “%”.

For example, use %1305% to look for E1305 or use %240% to look for GOG-0240.

![Figure 51](image)

Click “Next” when complete to move to the next screen.

4.9 Signatory Institution Principal Investigator Information (Figure 52)

On the next screen, enter the email address of the Signatory Institution Principal Investigator who will be taking over this study and click “Enter” or “Return” or “Tab” on your keyboard and the Signatory Institution Principal Investigator information will auto-populate. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

If “Contact not found.” appears, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to determine the next steps to add the investigator to the database.

Confirm using the radio button on the next section if an Annual Principal Investigator Worksheet About Local Context has been submitted to the CIRB for review and approval.
NOTE: If an Annual Principal Investigator Worksheet About Local Context has not yet been submitted to the CIRB, click “Save for Later” and follow the instructions beginning at section 3.0.

Click “Next” when complete to move to the next screen.

![Figure 52](image_url)

4.10 Study-Specific Changes to Annual Principal Investigator Worksheet (Figure 53)

The topics listed below reflect those asked on the Annual Principal Investigator Worksheet About Local Context which has already been completed by the replacement Principal Investigator. Indicate for each topic whether or not there are any changes from that information. If there are changes, please describe. If any of the “Changed” answers can be supported by an attachment, an attachment can be added in Question 33.
The topics listed below reflect those asked on the Annual Principal Investigator Worksheet About Local Context which has already been completed. Indicate for each topic whether or not there are any changes from the information previously provided. If there are changes, please describe. If any of the 'Changed' answers can be supported by an attachment, an attachment can be added in Question 33.

General Information (Questions 1-2 on the Annual Principal Investigator Worksheet About Local Context)

- Add Note
- No Change
- Changed

If 'Changed', describe changes.

Research Staff (Questions 3-5 on the Annual Principal Investigator Worksheet About Local Context)

- Add Note
- No Change
- Changed

If 'Changed', describe changes.

Principal Investigator Resources (Questions 6-7 on the Annual Principal Investigator Worksheet About Local Context)

- Add Note
- No change
- Changed

If 'Changed', describe changes.

Recruitment (Questions 8-9 on the Annual Principal Investigator Worksheet About Local Context)

- Add Note
- No Change
- Changed

If 'Changed', describe changes.
<table>
<thead>
<tr>
<th>If 'Changed', please describe.</th>
<th>Add Note</th>
</tr>
</thead>
</table>

**Emergency Resources (Question 25 on the Annual Principal Investigator Worksheet About Local Context)**

(Required)
- No Change
- Changed

<table>
<thead>
<tr>
<th>If 'Changed', describe changes.</th>
<th>Add Note</th>
</tr>
</thead>
</table>

**Using a Legally Authorized Representative (LAR) (Questions 26-28 on the Annual Principal Investigator Worksheet About Local Context)**

(Required)
- No Change
- Changed

<table>
<thead>
<tr>
<th>If 'Changed', describe changes.</th>
<th>Add Note</th>
</tr>
</thead>
</table>

**Vulnerable Populations (Question 29 on the Annual Principal Investigator Worksheet About Local Context)**

(Required)
- No Change
- Changed

<table>
<thead>
<tr>
<th>If 'Changed', describe changes.</th>
<th>Add Note</th>
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</table>
Figure 53

Click “Next” when complete to move to the next screen.

4.11 Principal Investigator Confirmation of Intent to Comply (Figures 54-55)

If the Signatory Institution Principal Investigator is completing the Worksheet, read the statement and enter your password as declaration of your intent to comply as Signatory Institution Principal Investigator of this study (Figure 54).

Figure 54

If the user completing the Worksheet is not the Signatory Institution Principal Investigator, click “Next” and then “Submit” on the final screen to send an email automatically to the Signatory Institution Principal Investigator to notify him/her to log in to IRBManager to review the Worksheet (Figure 55). The Worksheet cannot be
submitted to the CIRB for review until the Signatory Institution Principal Investigator completes the intent to comply and submits the Worksheet.

![Worksheet Image](image.png)

**Figure 55**

Click “Next” when complete to move to the next screen.

**NOTE:** It is necessary that the Signatory Institution Principal Investigator logs into IRBManager to confirm the intent to comply and to submit the Worksheet to the CIRB for review. Refer to the NOTE at the beginning of Section 4.0 for brief instructions on how to access this Worksheet.

The Signatory Institution Principal Investigator reviews the Worksheet and clicks “Next” at the bottom of the screen to progress through the Worksheet. On the Confirmation of Intent to Comply screen at the end of the Worksheet, the Signatory Institution Principal Investigator should enter their password to confirm intent to comply.

The Signatory Institution Principal Investigator can use the “Note” feature to make a comment for the question(s) with the error, submit the Worksheet to the CIRB, and the CIRB will respond to the user who created the Worksheet so the appropriate edits can be made.

The Signatory Institution Principal Investigator is the only person who can submit the Worksheet to the CIRB.

4.12 Worksheet Submission to the CIRB (Figure 56)

If all information is complete on the Worksheet, the Worksheet is ready for submission to the CIRB. Click “Submit” to save the information and submit to the CIRB for review.

If the information is not complete on the Worksheet, click “Save for Later” to save your progress and exit the system.
If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document, you will be returned to this screen.

You must click “Submit” to submit to the CIRB for review.

Figure 56

5.0 Completing the “Study Closure or Transfer of Study IRB Review Responsibility Form”

This Form should be completed by the Signatory Institution Principal Investigator to close a study or transfer study IRB review responsibility from the CIRB to another IRB.

NOTE: Summary of How to Access Worksheet/Form
From your “Home” screen click the “Start xForm” button which can be found under the “Actions” section and click on the Worksheet you would like to complete (Figure 57). The first screen of the Worksheet will appear. Each screen is detailed below.

Click on “Study Closure or Transfer of Study Review Resp.”. (Figure 57)

If you plan to use this Form to close a study, refer to Section 5.1 for instructions.

If you plan to use this Form to transfer study IRB review responsibilities from the CIRB to another IRB, refer to Section 5.2 for instructions.

Figure 57
5.1 Study Closure

5.1.1 OMB Text and Signatory Institution Information (Figure 58)

The required Office of Management and Budget (OMB) Statement of Confidentiality and additional required language is at the top of the Worksheet.

The Signatory Institution Information is auto-populated from information provided by your institution during enrollment. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

![OMB Text and Signatory Institution Information](image)

**Figure 58**

5.1.2 Study ID Number and Requested Action (Figure 59)

Enter the Study ID Number in the field provided. (Figure 59)

The Study ID Number should match the Study ID Number provided on the CIRB Website (https://www.ncicirb.org/CIRB_Protocols.asp).

If you are not sure of the Study ID Number, you can click the hyperlink above to search the CIRB Website or search for a study within IRBManager using the...
percentage sign “%” followed by whatever consecutive numbers of the Study ID Number that you know and ending with another percentage sign “%”.

For example, use %1305% to look for E1305 or use %240% to look for GOG-0240.

Enter the email address of the current Signatory Institution Principal Investigator in the text box provided and click “Enter” or “Return” on your keyboard. Information about the Signatory Institution Principal Investigator will auto-populate. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

Select the radio button next to “Study Closure” to request this action for the study you entered.

**Figure 59**

**NOTE ABOUT NAVIGATION BUTTONS:** The “Previous” navigation button option is not available when it appears as “half-bright”, or gray, as shown above. When the button is active, and the font is black, clicking it will take you to the previous screen without saving the data entered on the current screen.

The “Next” navigation button saves the data entered on the current screen and takes you to the next screen. If required fields are not completed, red text will appear at the top of the screen indicating which fields need to be completed.

The “Save for Later” navigation button saves all data entered up to that point in the Worksheet. The Worksheet will be exited after clicking this option. When
you are ready to resume working on the saved Worksheet you can find it in the “My Documents & Forms” section of the IRBManager “Home” screen.

The “PDF” option automatically converts all data entered up to that point in the Worksheet to a PDF which can be saved locally on your computer for reference.

Click “Next” when complete to move to the next screen.

5.1.3 Confirmation of Conditions Met for Study Closure (Figure 60)

To close a study with the CIRB, three conditions must be met: the study must be closed to accrual at the Signatory Institution and all Component and/or Affiliate Institutions relying on the Signatory Institutions for this study; all study participants on this study must have completed study invention(s) and follow-up activities OR no study participants were enrolled; and there will be no further research activities for this study.

As a reminder, if this study is open at the Component and/or Affiliate Institutions, submission of this Study Closure Form closes the study at all institutions.

Click the following three conditions to indicate that each of these criteria have been met. (Figure 60)

Click “Next” when complete to move to the next screen.
5.1.4 Submission to the CIRB (Figure 61)

If all information is complete on the Form, the Form is ready for submission to the CIRB. Click “Submit” to save the information and submit to the CIRB for review.

If the information is not complete on the Form, click “Save for Later” to save your progress and exit the system.

If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document, you will be returned to this screen.

You must click “Submit” to submit to the CIRB for review.

![Figure 61](image)

5.2 Transfer of Study IRB Review Responsibility from the CIRB to Another IRB

5.2.1 OMB Text and Signatory Institution Information (Figure 62)

The required Office of Management and Budget (OMB) Statement of Confidentiality and additional required language is at the top of the Worksheet.

The Signatory Institution Information is auto-populated from information provided by your institution during enrollment. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.
5.2.2 Study ID Number and Requested Action (Figure 63)

Enter the Study ID Number in the field provided.

The Study ID Number should match the Study ID Number provided on the CIRB Website (https://www.ncicirb.org/CIRB_Protocols.asp).

If you are not sure of the Study ID Number, you can click the hyperlink above to search the CIRB Website or search for a study within IRBManager using the percentage sign “%” followed by whatever consecutive numbers of the Study ID Number that you know and ending with another percentage sign “%”.

For example, use %1305% to look for E1305 or use %240% to look for GOG-0240.

Enter the email address of the current Signatory Institution Principal Investigator in the text box provided and click “Enter” or “Return” on your keyboard. Information about the Signatory Institution Principal Investigator will auto-populate. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.
Select the radio button next to “Transfer of Study IRB Review Responsibility from the CIRB to another IRB” to request this action for the study you entered.

**Figure 63**

**NOTE ABOUT NAVIGATION BUTTONS:** The “Previous” navigation button option is not available when it appears as “half-bright”, or gray, as shown above. When the button is active, and the font is black, clicking it will take you to the previous screen without saving the data entered on the current screen.

The “Next” navigation button saves the data entered on the current screen and takes you to the next screen. If required fields are not completed, red text will appear at the top of the screen indicating which fields need to be completed.

The “Save for Later” navigation button saves all data entered up to that point in the Worksheet. The Worksheet will be exited after clicking this option. When you are ready to resume working on the saved Worksheet you can find it in the “My Documents & Forms” section of the IRBManager “Home” screen.

The “PDF” option automatically converts all data entered up to that point in the Worksheet to a PDF which can be saved locally on your computer for reference.

Click “Next” when complete to move to the next screen.

5.2.3 Attach IRB Approval Letter (Figure 64)

To transfer IRB review responsibility from the CIRB to another IRB, a copy of the full board IRB approval letter for this study from the IRB that is accepting responsibility must be attached. The IRB that is accepting responsibility must
have approved the study before the transfer so there is no lapse in IRB oversight of the study.

Click on the “Add Attachment” button and attach the approval letter (Figure 64).

![Figure 64](image)

Click “Next” when complete to move to the next screen.

5.2.4 Form Submission to the CIRB (Figure 65)

If all information is complete on the Form, the Form is ready for submission to the CIRB. Click “Submit” to save the information and submit to the CIRB for review.

If the information is not complete on the Form, click “Save for Later” to save your progress and exit the system.

If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document, you will be returned to this screen.

You must click “Submit” to submit to the CIRB for review.

![Figure 65](image)

6.0 Completing the “Potential Unanticipated Problem or Serious or Continuing Noncompliance Form”

To be completed by the Signatory Institution Principal Investigator to report potential unanticipated problems or serious or continuing noncompliance to the CIRB.
NOTE: Summary of How to Access Worksheet/Form

From your “Home” screen click the “Start xForm” button which can be found under the “Actions” section and click on the Worksheet you would like to complete. The first screen of the Worksheet will appear. Each screen is detailed below.

Click on “Potential Unanticipated Problem or Serious or Continuing Noncompliance Form”. (Figure 66)

6.1 OMB Text and Signatory Institution Information (Figure 67)

The required Office of Management and Budget (OMB) Statement of Confidentiality and additional required language is at the top of the Form.

The Signatory Institution Information is auto-populated from information provided by your institution during enrollment. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.
6.2 General Information (Figure 68)

For Question 1, enter the Study ID Number in the field provided.

The Study ID Number should match the Study ID Number provided on the CIRB Website (https://www.ncicirb.org/CIRB_Protocols.asp).

If you are not sure of the Study ID Number, you can click the hyperlink above to search the CIRB Website or search for a study within IRBManager using the percentage sign “%” followed by whatever consecutive numbers of the Study ID Number that you know and ending with another percentage sign “%”.

For example, use %1305% to look for E1305 or use %240% to look for GOG-0240.

NOTE: If more than one study is affected by the potential unanticipated problem or serious or continuing noncompliance, enter the additional study numbers in the text box provided.

For Question 2, enter the email address of the current Signatory Institution Principal Investigator in the text box provided and click “Enter” or “Return” or “Tab” on your keyboard. Information about the Signatory Institution Principal Investigator will auto-populate. If the auto-populated information is not accurate, email the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to correct.

NOTE: If more than one Signatory Institution Principal Investigator has a study that is affected by the potential unanticipated problem or serious or continuing noncompliance,
enter the name(s) of the additional Signatory Institution Principal Investigator(s) in the text box provided.

For Question 3, enter the Study’s Protocol Version Date associated with the incident, experience, or outcome.

For Question 4, enter the Study Participant Registration Number (if applicable). More than one Study Participant Registration Number can be added to the text box.

**Figure 68**

6.3 **Description of Incident, Experience, or Outcome (Figure 69)**

For Question 1, enter the date the incident, experience, or outcome occurred.

For Question 2, provide a description of the incident, experience, or outcome in the text box provided. If you would rather attach a document describing the incident, experience, or outcome, enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.
For Question 3, indicate if the Cooperative Group/sponsor, Study Chair, or Federal agency has been notified of this incident, experience, or outcome by selecting “Yes” or “No”. If “Yes”, identify those notified of the incident, experience, or outcome in the text box below and attach a copy of the notification. A written response from those notified, if available, should be attached. Click the “Add Attachment” button to attach each document.

For Question 4, indicate if the incident, experience, or outcome occurred while the CIRB-approved protocol was followed as written by selecting “Yes” or “No”. Depending on whether the incident, experience, or outcome occurred while the CIRB-approved protocol was followed as written, the submission will qualify as either a potential unanticipated problem report or serious or continuing noncompliance. If “Yes”, complete “Section C”. If “No”, complete “Section D”.

NOTE: Instructions for completing “Section C” are provided in Sections 6.4-6.5. Instructions for completing “Section D” are provided in Sections 6.6-6.7.
NOTE ABOUT NAVIGATION BUTTONS: The “Previous” navigation button option is not available when it appears as “half-bright”, or gray, as shown above. When the button is active, and the font is black, clicking it will take you to the previous screen without saving the data entered on the current screen.

The “Next” navigation button saves the data entered on the current screen and takes you to the next screen. If required fields are not completed, red text will appear at the top of the screen indicating which fields need to be completed.

The “Save for Later” navigation button saves all data entered up to that point in the Worksheet. The Worksheet will be exited after clicking this option. When you are ready to resume working on the saved Worksheet you can find it in the “My Documents & Forms” section of the IRBManager “Home” screen.

The “PDF” option automatically converts all data entered up to that point in the Worksheet to a PDF which can be saved locally on your computer for reference.

Click “Next” when complete to move to the next screen.
6.4 Section C – Potential Unanticipated Problem (Figure 70)

For Question 1, indicate if this incident, experience, or outcome is unexpected by selecting “Yes” or “No”. If “Yes”, describe how the incident, experience, or outcome is unexpected. If you would rather attach a description, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 2, indicate if the incident, experience, or outcome is related or possibly related to participation in research by selecting “Yes” or “No”. If “Yes”, describe how the incident, experience, or outcome was related or possibly related to participation in research. If you would rather attach a description, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 3, indicate if the incident, experience, or outcome placed the study participant(s) or others at a greater risk of harm by selecting “Yes” or “No”. If “Yes”, describe how the incident, experience, or outcome placed the study participant(s) or others at a greater risk of harm. If you would rather attach a description, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 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. If you would rather attach a description, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

**Section C: Potential Unanticipated Problem**

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.

   Attachment:

   Add Attachment
   No Attachments added.
### 2. Is this incident, experience, or outcome related or possibly related to participation in the research?

(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.

Attachment:

No Attachments added.

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

(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.

Attachment:

No Attachments added.

### 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 an attachment, if applicable.

No Attachments added.
6.5 Submission to the CIRB (Figure 71)

If all information is complete on the Form, the Form is ready for submission to the CIRB. Click “Submit” to save the information and submit to the CIRB for review.

If the information is not complete on the Form, click “Save for Later” to save your progress and exit the system.

If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document, you will be returned to this screen.

You must click “Submit” to submit to the CIRB for review.

![You've completed the form. You can now either save the form for later revision, or submit it.](image)

Figure 71

6.6 Section D – Potential Serious or Continuing Noncompliance Report (Figure 72)

The definition of **serious** noncompliance is noncompliance with the protocol, Federal regulations, and/or the requirements of the CIRB 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.

For Question 1, indicate if the incident, experience, or outcome could be serious noncompliance by selecting “Yes” or “No”. If “Yes”, describe how the incident, experience, or outcome is potentially serious noncompliance. If you would rather attach a description, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

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

For Question 2, indicate if the incident, experience, or outcome could be continuing noncompliance by selecting “Yes” or “No”. If “Yes”, describe how the incident, experience, or outcome is potentially continuing noncompliance. If you would rather attach a description, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.
For Question 3, indicate if the incident, experience, or outcome affected the study participant’s continued participation in the study by selecting “Yes” or “No”. If “Yes”, describe how the incident, experience, or outcome affected the study participant’s continued participation in the study. If you would rather attach a description, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

For Question 4, describe any action the Signatory Institution and/or Principal Investigator has taken, is taking, or is planning to take, to address the incident, experience, or outcome. If you would rather attach the management plan, you may enter a note about the attachment in the text box and click the “Add Attachment” button to attach the document.

**NOTE:** If this is a preliminary report and a management plan is not yet available, indicate when the management plan will be submitted in the text box provided.
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.

<table>
<thead>
<tr>
<th>Is the incident, experience, or outcome potential continuing noncompliance?</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Required)</td>
</tr>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>

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

Attachment:

Add Attachment
No Attachments added.

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

<table>
<thead>
<tr>
<th>(Required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>

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

Attachment:

Add Attachment
No Attachments added.
6.7 Submission to the CIRB (Figure 73)

If all information is complete on the Form, the Form is ready for submission to the CIRB. Click “Submit” to save the information and submit to the CIRB for review.

If the information is not complete on the Form, click “Save for Later” to save your progress and exit the system.

If you would like to preview the information you have provided, generate a hard copy for your records, or save as a PDF, select “Print”. Once you have printed the document, you will be returned to this screen.

You must click “Submit” to submit to the CIRB for review.