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National Cancer Institute

Central Institutional Review Board

Instruction Manual for Worksheet
Completion in IRBManager

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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.

The screenshot shows the login interface for IRBManager. At the top left is the CIRB logo (National Cancer Institute Central IRB Initiative). Below it is a 'Login' heading. A red-bordered box contains the login form with the following elements: 'User Name' (empty text box), 'Password' (empty text box), 'Client' (text box containing 'nci'), a checked checkbox for 'Remember Client', a 'Login' button, and a 'Forgot Password?' link. At the bottom of the page, there is a footer with the text: 'Copyright ©2000-2012 BEC All Rights Reserved. Privacy & Security Statement | Terms of Use'.

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 every 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.

Home Find Help Joan's Settings Sign off

My IRBManager

Studies (0 Active)
 There are **0 active** and **19 total** studies at Test University.

xForms (0 Active)
 You have **0 unsubmitted** xForms.
 You have **0 xForms** being processed by the CIRB.
 Research staff at Test University have **21 unsubmitted** and **43 total** xForms.

Events (7 Open)
 Only show events where I am:
 You have **1 Rollover** events.
 You have **2 Study Closure or Transfer of Review Respon** events.
 You have **3 Study Specific** events.
 You have **1 Study Specific Amendment** events.
 You have **7 Total Open** events.

My Studies (11 Active)

Study	Site	PI	Description	Status
ACOSOG-Z4032-Test University	Test University	Malley, Haley MD, PhD	A Randomized Phase III Study of Sublobar Resection versus Sublobar Resection Plus Brachytherapy in High Risk Patients with Non-Small Cell Lung Cancer (NSCLC), 3 cm or Smaller	Independent Model - Active
ACOSOG-Z6051-LifeBridge Health, Inc.	LifeBridge Health, Inc.	Malley, Haley MD, PhD	A Phase III Prospective Randomized Trial Comparing Laparoscopic-Assisted Resection Versus Open Resection for Rectal Cancer	Independent Model - Active

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)

The screenshot displays the IRBManager web application. On the left, a navigation menu includes sections for 'Actions', 'Recent Items', 'Messages', and 'My Documents & Forms'. The 'Actions' section contains a red arrow pointing to the 'Start xForm' button. The main content area is titled 'My IRBManager' and includes a search bar and navigation links like 'Help', 'Joan's Settings', and 'Sign off'. Below this, there are several summary sections: 'Studies (0 Active)', 'xForms (0 Active)', 'Events (7 Open)', and 'My Studies (11 Active)'. The 'Events' section features a pie chart and a list of event types. The 'My Studies' section contains a table with columns for Study, Site, PI, Description, and Status.

Study	Site	PI	Description	Status
ACOSOG-Z4032-Test University	Test University	Malley, Haley MD, PhD	A Randomized Phase III Study of Sublobar Resection versus Sublobar Resection Plus Brachytherapy in High Risk Patients with Non-Small Cell Lung Cancer (NSCLC), 3 cm or Smaller	Independent Model - Active
ACOSOG-Z6051-LifeBridge Health, Inc.	LifeBridge Health, Inc.	Malley, Haley MD, PhD	A Phase III Prospective Randomized Trial Comparing Laparoscopic-Assisted Resection Versus Open Resection for Rectal Cancer	Independent Model - Active

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.

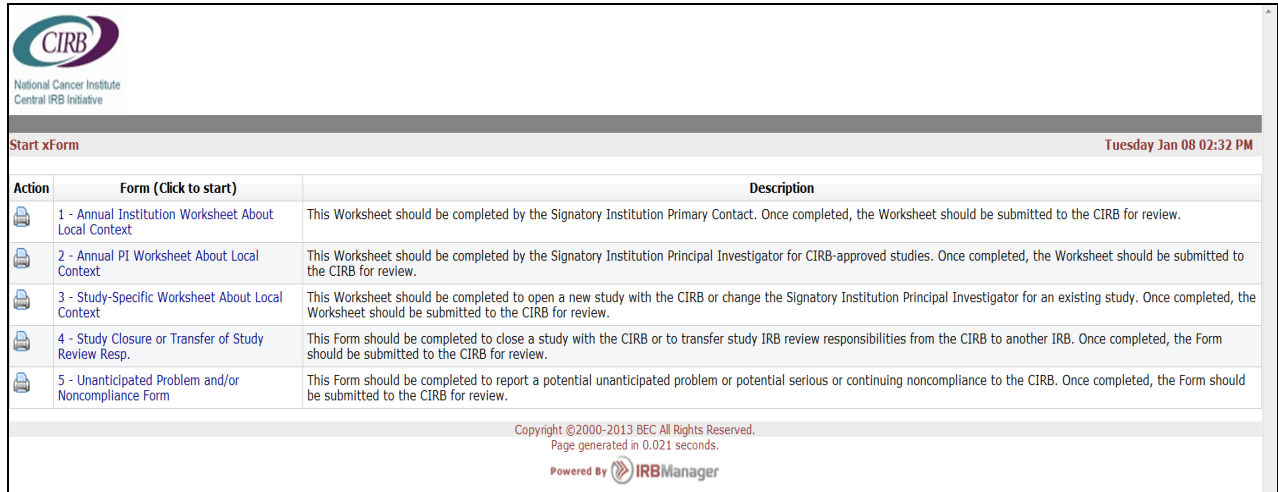


Figure 4

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).

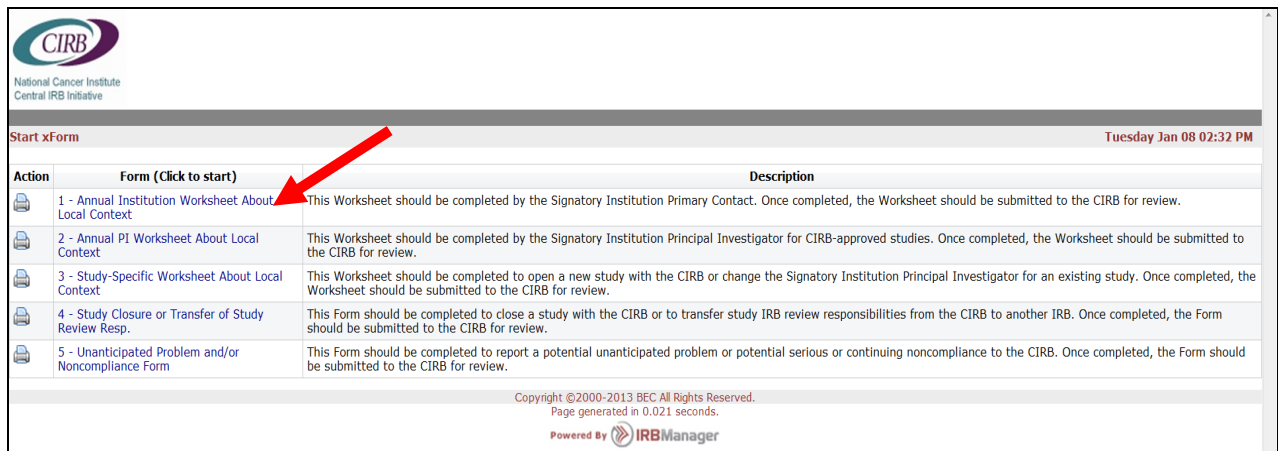


Figure 5

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.

Annual Institution Worksheet About Local Context -- Institution Information

OMB Text

OMB#: 0925 - 0046-16 Expiry Date: 2/28/2013
 STATEMENT OF CONFIDENTIALITY
 Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN
 Public reporting burden for this collection of information is estimated to average 30 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 (0925-0046-16). Do not return the completed form to this address.

Reason for submission: Add Note

(Required)

- First submission to the CIRB of an Annual Signatory Institution Worksheet About Local Context
- Revised submission of the Annual Signatory Institution Worksheet About Local Context

Figure 6

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.

Signatory Institution Information View Audit	
Submitting User Information	
Campbell, Brian Email: <input type="text" value="bcampbell@emmes.com"/> <input type="text" value=""/> Contact Roles: Investigator, User Address: <input type="text" value=""/> Phone: <input type="text" value=""/>	
Name of Signatory Institution View Audit	
Children's Oncology Group	
If there are any changes to the Submitting User Information or Name of Signatory Institution, contact the Helpdesk at ncicirbcontact@emmes.com before submitting.	
1. List of Component Institutions	
Component Institution #1 Component Institution #2	
If there are any changes to the list of Component Institutions, enter the name of the Component Institution below and complete the Add or Remove Component Institution Form . Add Note	
<input type="text" value=""/>	
2. List of Affiliate Institutions:	
Affiliate Institution #1 Affiliate Institution #2	
If there are any changes to the list of Affiliate Institutions, enter the name of the Affiliate Institution below and complete the Add or Remove Affiliate Institution Form . Add Note	
<input type="text" value=""/>	
3. The Signatory Institution confirms that all Component and Affiliate Institutions listed conform to the CIRB's definition. The CIRB definitions can be found at <link>. Add Note	
(Required)	
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> No Component or Affiliate Institutions	

Figure 7

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.

State and Local Law		Add Note
4. What is your state law and corresponding institutional policy regarding legally authorized representatives?		
<i>(Required)</i>		
<input type="text"/>		
If applicable, an attachment can be added here. Add Note View Audit		
<input type="button" value="Add Attachment"/> No Attachments added.		
5. What is the age of majority in your state?		Add Note
<i>(Required)</i>		
<input type="text"/>		
6. What are the other state or local laws that govern the conduct of research at your institution?		
<i>(Required)</i>		
<input type="text"/>		
If applicable, an attachment can be added here. Add Note View Audit		
<input type="button" value="Add Attachment"/> No Attachments added.		
7. Provide an explanation how your institution ensures compliance for each state or local law.		Add Note
<i>(Required)</i>		
<input type="text"/>		

Figure 8

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.

Research Oversight	
8. Identify the office and person at your institution responsible for the oversight of the conduct of research.	
Office Name	<input type="text"/>
Responsible Person	<input type="text"/>
Phone Number	<input type="text"/>
Email address	<input type="text"/>
9. Identify the office and person at your institution responsible for identifying, managing, and reporting to the CIRB potential unanticipated problems and/or serious or continuing noncompliance.	
Office Name	<input type="text"/>
Responsible Person	<input type="text"/>
Phone Number	<input type="text"/>
Email address	<input type="text"/>

Figure 9

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

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.

<p>Institutional Policies Pertaining to the Informed Consent Document for CIRB-Approved Studies Add Note</p>	
<p>11. Describe your institutional policies and guidelines that govern the informed consent document.</p> <p>(Required)</p> <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>	
<p style="text-align: center;">If applicable, an attachment can be added here. Add Note View Audit</p> <p>Add Attachment No Attachments added.</p>	
<p>12. Provide the boilerplate language that is added to the CIRB-approved informed consent document. This is standard language required by the institution that is inserted into the existing CIRB-approved informed consent document, such as, birth control language, coverage of research injury, required phone numbers for the study doctor, and a person unaffiliated with the study who can answer general clinical trial questions, etc.</p> <p>(Required)</p> <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>	
<p style="text-align: center;">If applicable, an attachment (in Word format) can be added here. Add Note View Audit</p> <p>Add Attachment No Attachments added.</p> <p style="text-align: center;"><i>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 what has changed from the current CIRB-approved boilerplate language.</i></p>	
<p>13. Provide the institutional letterhead used for the informed consent document, if applicable (attach a blank copy of letterhead to be used). Add Note View Audit</p> <p>Add Attachment No Attachments added.</p>	
<p>14. Provide any other institutional requirements for informed consent documents, if applicable. Add Note</p> <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>	
<p style="text-align: center;">If applicable, an attachment (in Word Format) can be added here. Add Note View Audit</p> <p>Add Attachment No Attachments added.</p>	

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.

Community Descriptors Add Note	
<p>15. List the counties that comprise your institution's local catchment area. The CIRB Operations Office will obtain demographic data from the US census track using the counties for CIRB review.</p> <p><i>(Required)</i></p> <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>	
<p>16. Does the community have a positive attitude toward the conduct of research? Add Note</p> <p><i>(Required)</i></p> <p> <input type="radio"/> Yes <input type="radio"/> No </p>	
<p>If No, please explain. Add Note</p> <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>	
<p>17. Is there anything else the CIRB should know about the anticipated study participant population at the Signatory Institution? Add Note</p> <p><i>(Required)</i></p> <p> <input type="radio"/> Yes <input type="radio"/> No </p>	
<p>If Yes, please explain. Add Note</p> <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>	
<p>If applicable, an attachment can be added here. Add Note View Audit</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p><input type="button" value="Add Attachment"/> No Attachments added.</p> </div>	

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.

Additional Information Add Note

18. Is there anything else the CIRB should know about the Signatory Institution's local context?

(Required)

Yes

No

If Yes, please explain. Add Note

If applicable, an attachment can be added here. Add Note View Audit

No Attachments added.

Figure 13

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.

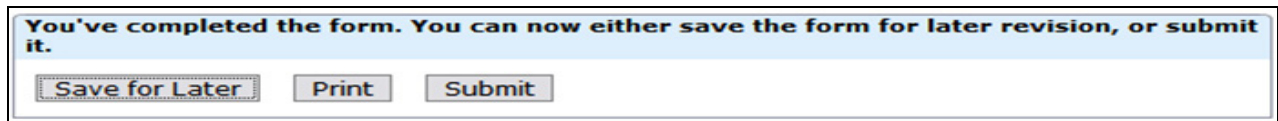


Figure 14

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)

Action	Form (Click to start)	Description
	1 - Annual Institution Worksheet About Local Context	This Worksheet should be completed by the Signatory Institution Primary Contact. Once completed, the Worksheet should be submitted to the CIRB for review.
	2 - Annual PI Worksheet About Local Context	This Worksheet should be completed by the Signatory Institution Principal Investigator for CIRB-approved studies. Once completed, the Worksheet should be submitted to the CIRB for review.
	3 - Study-Specific Worksheet About Local Context	This Worksheet should be completed to open a new study with the CIRB or change the Signatory Institution Principal Investigator for an existing study. Once completed, the Worksheet should be submitted to the CIRB for review.
	4 - Study Closure or Transfer of Study Review Resp.	This Form should be completed to close a study with the CIRB or to transfer study IRB review responsibilities from the CIRB to another IRB. Once completed, the Form should be submitted to the CIRB for review.
	5 - Unanticipated Problem and/or Noncompliance Form	This Form should be completed to report a potential unanticipated problem or potential serious or continuing noncompliance to the CIRB. Once completed, the Form should be submitted to the CIRB for review.

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Page generated in 0.021 seconds.
Powered By IRBManager

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.

Annual PI Worksheet About Local Context -- PI Information

OMB Text

OMB#: 0925 - 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 60 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 (0925-0046-16). Do not return the completed form to this address.

Reason for submission: Add Note

(Required)

First Submission of the Annual Principal Investigator Worksheet About Local Context

Revised Submission of the Annual Principal Investigator Worksheet About Local Context

Figure 16

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.

Figure 17

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.

Figure 18

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.

Annual PI Worksheet About Local Context -- Information

2. Name of Signatory Institution View Audit

Test University
12 Street
Ste. 304
Anyplace, CA, 21701

Figure 19

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.

Research Staff		Add Note
3. How many sub-investigators do you have supporting you in conducting CIRB-approved research?		
<i>(Required)</i>		
<input type="text"/>		
4. How many research nurses/CRAs do you have supporting you in conducting CIRB-approved research?		Add Note
<i>(Required)</i>		
<input type="text"/>		
5. Have you or any of your research staff reported a financial conflict of interest related to any studies on the CIRB menu that resulted in a management plan?		Add Note
<i>(Required)</i>		
<input type="radio"/> Yes <input type="radio"/> No		

Figure 20

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.

NOTE: Principal Investigator Education, Training, and Experience
<i>No additional information is required. Information pertaining to investigator education, training, and experience is captured annually through the NCI Investigator Registration.</i>

Figure 21

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.

Principal Investigator Resources		Add Note
6. How many actively accruing research studies, for which you are the PI, do you have open, including CIRB-approved and those not reviewed by the CIRB?		
<i>(Required)</i>		
<input type="text"/>		
a. List CIRB-approved studies by Study ID Number.		Add Note
<input type="text"/>		
7. How many study participants are currently receiving study intervention for studies for which you are the PI?		Add Note
<i>(Required)</i>		
<input type="text"/>		

Figure 22

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.

Recruitment Add Note

8. Describe how potential study participants are identified and recruited to CIRB-approved studies.
(Required)

If applicable, an attachment can be added here. Add Note View Audit

Add Attachment
No Attachments added.

9. Identify recruitment materials usually used: Add Note
(Required)

Cooperative Group/sponsor-supplied handouts
 Locally-developed educational materials (Reminder: Study-specific material requires CIRB approval)
 Other

Please describe. Add Note

Figure 23

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.

Compensation to Study Participants Add Note

10. 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.
(Required)

Figure 24

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.

Informed Consent Process	
Answer the following questions regarding the process used to introduce a trial to a potential study participant and obtain their informed consent.	
11. Where does the consent discussion take place?	Add Note
(Required)	
<input type="text"/>	
12. Who is authorized to obtain consent?	Add Note
(Required)	
<input type="text"/>	

<p>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? Add Note</p> <p>(Required)</p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<p>14. Who is available to answer questions? Add Note</p> <p>(Required)</p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<p>15. How is the potential study participant's understanding of consent assessed? Add Note</p> <p>(Required)</p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<p>16. How is the informed consent process conducted with non-English speaking potential study participants? Add Note</p> <p>(Required)</p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<p>17. Who provides consent? Add Note</p> <p>(Required)</p> <p><input type="checkbox"/> Potential study participant <i>Check all that apply.</i></p> <p><input type="checkbox"/> Parent for potential pediatric study participant</p> <p><input type="checkbox"/> Legally Authorized Representative</p> <p><input type="checkbox"/> Other</p>
<p>Please explain. Add Note</p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>

<p>18. For what languages are translations routinely provided? Add Note</p> <p><i>(Required)</i></p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<p>If translations are routinely provided, what process is currently used to translate the informed consent document? Add Note</p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<p>If applicable, an attachment can be added here. Add Note View Audit</p> <div style="border: 1px solid gray; padding: 5px;"><p><input type="button" value="Add Attachment"/> No Attachments added. <i>Reminder: Translations must be CIRB-approved prior to presenting to a potential study participant.</i></p></div>
<p>19. Describe your institution's policy regarding assent by children or impaired adults. Add Note</p> <p><i>(Required)</i></p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<p>If applicable, an attachment can be added here. Add Note View Audit</p> <div style="border: 1px solid gray; padding: 5px;"><p><input type="button" value="Add Attachment"/> No Attachments added.</p></div>
<p>20. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research. Add Note</p> <p><i>(Required)</i></p> <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>

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 Add Note	
21. Will the drugs/agents used in the study be managed by a pharmacist? (Required)	
<input type="radio"/> Yes <input type="radio"/> No	
If a pharmacist will be managing the drugs/agents used in the study, provide the name and title of the pharmacist at each practice location where research will be conducted. Add Note	
<div style="border: 1px solid gray; height: 60px; width: 100%;"></div>	
If the drugs/agents will not be managed by a pharmacist, provide the name and title of the responsible person for the drugs/agents at each practice/location where research will be conducted. Add Note	
<div style="border: 1px solid gray; height: 60px; width: 100%;"></div>	
22. How is the pharmacist/responsible person provided with a copy of the protocol at each practice location? Add Note	
(Required)	
<div style="border: 1px solid gray; height: 60px; width: 100%;"></div>	

Figure 26

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

Confidentiality is defined as the study participant’s understanding of, and agreement to, the ways identifiable information pertaining to them will be stored and shared. Identifiable information can be printed, electronic, or visual (such as photographs).

23. Check all measures that will be used to maintain the confidentiality of identifiable information. [Add Note](#)

(Required)

- Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
- Computer-based files will be available to study personnel through the use of access privileges and passwords.
- Prior to obtaining access to identifiable information, study personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
- Whenever feasible, identifiers will be removed from study-related information.
- Other

Please describe. [Add Note](#)

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.

Measures to Protect Privacy

Privacy is defined as the study's participant's ability to control how other people see, touch, or obtain information about them. Violations of privacy can involve circumstances such as being seen without clothing or partially clothed, being photographed without consent, being asked personal questions in a public setting, etc.

24. Check all measures that will be used to maintain the study participant's privacy. Add Note

(Required)

- Use of drapes or other barriers to vision for subjects who are required to disrobe.
- Consent is obtained prior to collecting photographs involving study participants.
- Sensitive information is collected and used with respect to maintaining privacy.
- Individuals are not identified publicly without their consent.
- Other

Please describe. Add Note

Figure 28

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.

Emergency Resources Add Note

25. Check all resources available at the site to treat emergencies resulting from study-related procedures.

(Required)

- ACLS trained personnel and crash cart
- BCLS trained personnel
- Emergency response team within facility
- Emergency drugs and supplies to stabilize study participant until emergency personnel arrive
- Staff available to call 911
- Other

Please describe. Add Note

Figure 29

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.

Using a Legally Authorized Representative (LAR) [Add Note](#)

26. Do you plan on enrolling study participants through an LAR?
(Required)

Yes
 No

27. At your institution, describe who may serve as an LAR. [Add Note](#)

ABC

If applicable, an attachment can be added here. [Add Note](#) [View Audit](#)

No Attachments added.

28. Provide a description of how you assess a potential study participant's ability to provide consent. [Add Note](#)

ABC

If applicable, an attachment can be added here. [Add Note](#) [View Audit](#)

No Attachments added.

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”.

Vulnerable Populations

Note about prisoners: The CIRB is not constituted to review research involving prisoners. If an investigator wishes to enroll prisoners in a study, IRB review must be conducted by the local IRB.

29. Check all vulnerable populations from which you intend to enroll. [Add Note](#)

Children
 Pregnant women
 Economically disadvantaged
 Educationally disabled
 Physically disabled
 Other

Please describe. [Add Note](#)

For each vulnerable population checked, indicate safeguards.

[Previous](#) [Next](#) [Save for Later](#) [PDF](#)

Figure 31

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.

Safeguards for Children Add Note

Check all safeguards you use for children. (Required)

Youth Information Sheets
 Assent
 Extra Monitoring
 Researchers credentialed in pediatrics
 Other health professionals with pediatrics experience
 Other

Please describe. Add Note

Previous
Next
Save for Later
PDF

Figure 32

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.

Safeguards for Pregnant Women Add Note

Check all safeguards you use for pregnant women. (Required)

Inclusion is scientifically appropriate based on preclinical studies
 Information is provided pertaining to how study intervention could impact the woman and the fetus
 Other

Please describe. Add Note

Previous
Next
Save for Later
PDF

Figure 33

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.

Safeguards for Economically Disadvantaged [Add Note](#)

Check all safeguards you use for the economically disadvantaged. (Required)

- Cost burden is fully explained
- No financial incentives are provided
- Social services are available to assist study participant
- Other

Please describe. [Add Note](#)

Previous Next Save for Later PDF

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.

Safeguards for Educationally Disabled [Add Note](#)

Check all safeguards you use for the educationally disabled. (Required)

- Verbal explanation of the research is provided in lay language
- Extra time is available to answer questions
- At the potential study participant's request, family members/significant others can participate in informed consent process
- Caregiver to assist with medications and identifying adverse events
- Translations are available, if needed
- Other

Please describe. [Add Note](#)

Previous Next Save for Later PDF

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.

Safeguards for Physically Disabled [Add Note](#)

Check all safeguards you use for the physically disabled. (Required)

Treatment facility is accessible

Assistance is available, as needed

Witness to consent is available, as needed

Other

Please describe. [Add Note](#)

Previous Next Save for Later PDF

Figure 36

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

Other Vulnerable Populations [Add Note](#)

Describe all safeguards you use for 'Other' vulnerable populations. (Required)

Previous Next Save for Later PDF

Figure 37

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 [45 CFR 46.204 (h), (i), (j)]

Confirm the following statements by choosing 'Yes'.

[Add Note](#)

30. No inducements will be offered to terminate a pregnancy.

(Required)

Yes

No

[Add Note](#)

31. Research team will have no part in decisions related to the timing, method, or procedures used to terminate the pregnancy.

(Required)

Yes

No

[Add Note](#)

32. Research team will have no part in determining the viability of a neonate.

(Required)

Yes

No

Figure 38

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.

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.

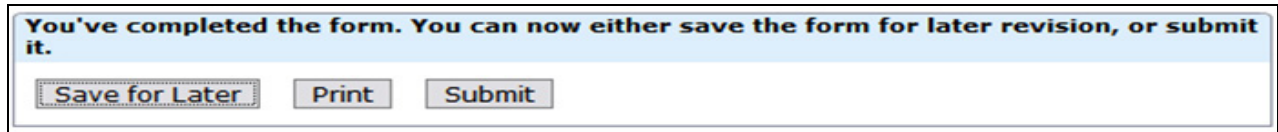


Figure 39

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”.

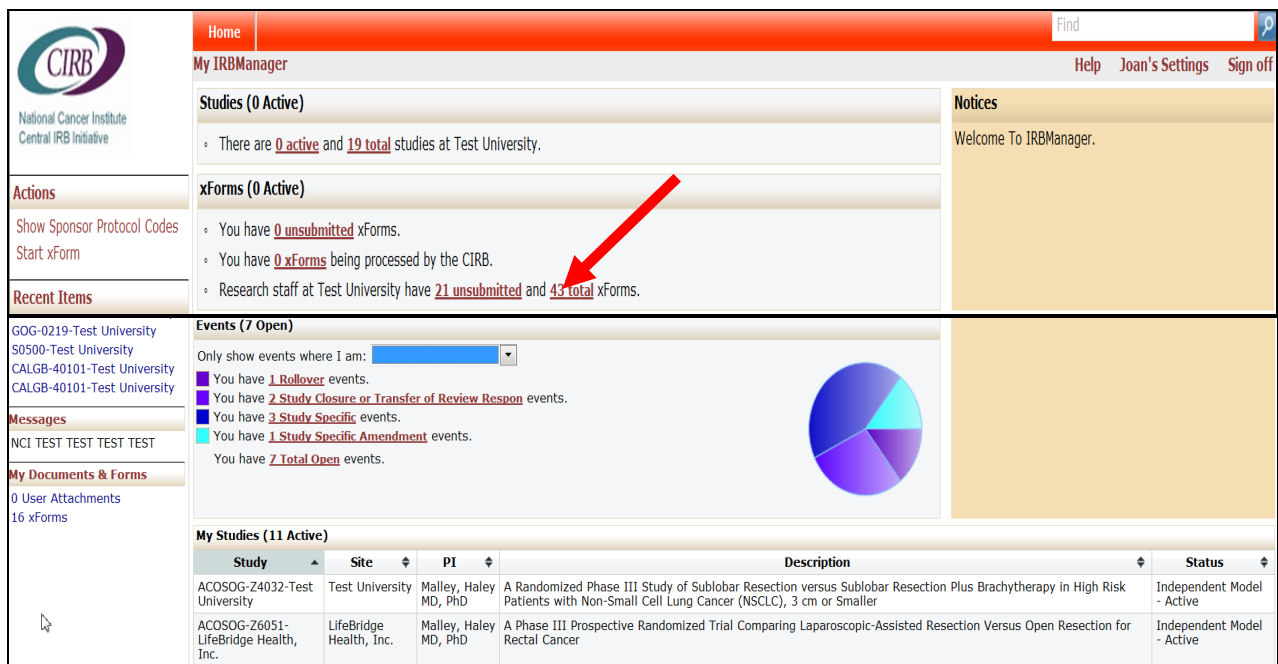


Figure 40

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)

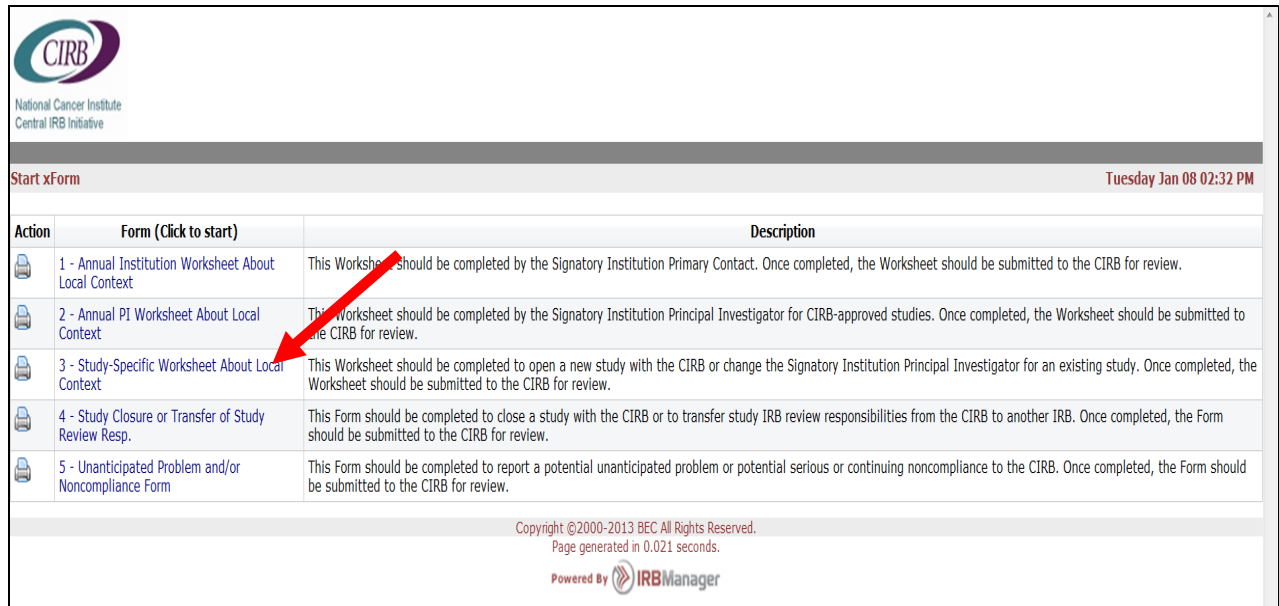


Figure 41

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.

Study-Specific Worksheet About Local Context -- Type of Submission

OMB Text

OMB#: 0925 - 0046-16 Expiry Date: 2/28/2013
 STATEMENT OF CONFIDENTIALITY
 Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN
 Public reporting burden for this collection of information is estimated to average 30 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 (0925-0046-16). Do not return the completed form to this address.

Reason for submission: Add Note

(Required)

Open New Study: This study is not opened at the Signatory Institution. This is the first submission to the CIRB of a Study-Specific Worksheet About Local Context for this study at this Signatory Institution.

Change of PI: This study is currently open at the Signatory Institution with the CIRB. This Worksheet is being submitted due to a change in Principal Investigator for this study.

Previous Next Save for Later PDF

Figure 42

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.

Figure 43

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.

Figure 44

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.

Study-Specific Worksheet About Local Context -- Original PI

General Information Add Note

1. Enter the email address of the Principal Investigator who is requesting to open this study.

(Required)

If the message "Contact not found." appears, it means that this PI cannot be found in the CIRB database. Email the Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to determine what action is required.

Previous Next Save for Later PDF

Figure 45

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 33.

General Information (Questions 1-2 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)
(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Research Staff (Questions 3-5 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)
(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Principal Investigator Resources (Questions 6-7 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)
(Required)

No change
 Changed

If 'Changed', describe changes. [Add Note](#)

Recruitment (Questions 8-9 on the Annual Principal Investigator Worksheet About Local Context) [Add Note](#)
(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Compensation to Study Participants (Question 10 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required)
<input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Informed Consent Process (Questions 11-20 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required)
<input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Pharmacy Information (Questions 21-22 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required)
<input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Measures to Protect Confidentiality (Question 23 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required)
<input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Measures to Protect Privacy (Question 24 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required)
<input type="radio"/> No Change <input type="radio"/> Changed

If 'Changed', please describe.	Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>	
Emergency Resources (Question 25 on the Annual Principal Investigator Worksheet About Local Context)	Add Note
<i>(Required)</i>	
<input type="radio"/> No Change <input type="radio"/> Changed	
If 'Changed', describe changes.	Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>	
Using a Legally Authorized Representative (LAR) (Questions 26-28 on the Annual Principal Investigator Worksheet About Local Context)	Add Note
<i>(Required)</i>	
<input type="radio"/> No Change <input type="radio"/> Changed	
If 'Changed', describe changes.	Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>	
Vulnerable Populations (Question 29 on the Annual Principal Investigator Worksheet About Local Context)	Add Note
<i>(Required)</i>	
<input type="radio"/> No Change <input type="radio"/> Changed	
If 'Changed', describe changes.	Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>	

Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)] (Questions 30-32 on the Annual Principal Investigator Worksheet About Local Context) Add Note

(Required)

No Change
 Changed

If 'Changed', describe changes. Add Note

33. If any of the 'Changed' answers can be supported by an attachment, an attachment can be added here. Add Note View Audit

Add Attachment
No Attachments added.

Figure 46

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).

Study-Specific Worksheet About Local Context -- PI Confirmation of Intent to Comply First Submission

PI Confirmation of Intent to Comply Add Note

Confirmation of Intent to Comply:

I, as Principal Investigator, confirm I will comply with the Federal regulations pertaining to human research protections in addition to CIRB and Cooperative Group/sponsor directives pertaining to this study. As Principal Investigator, I confirm that I oversee all sub-investigators and research staff assisting with this study and am responsible for their compliance with the same.

I realize that this study may not be opened at my institution and no study-related activities may begin until I receive an approval letter from the CIRB.

By entering my password below I declare my confirmation to comply. *(Required)*

To sign, enter password for JWalter001 as of 11/27/2012 After entering your password, click 'Next' below, and then 'Submit' on the final screen to submit this Worksheet for CIRB review.

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.

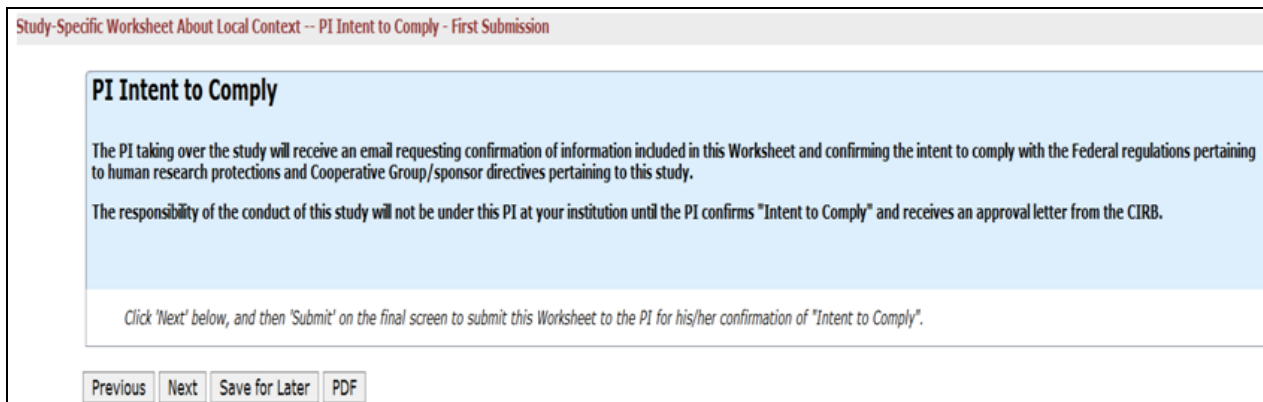


Figure 48

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.

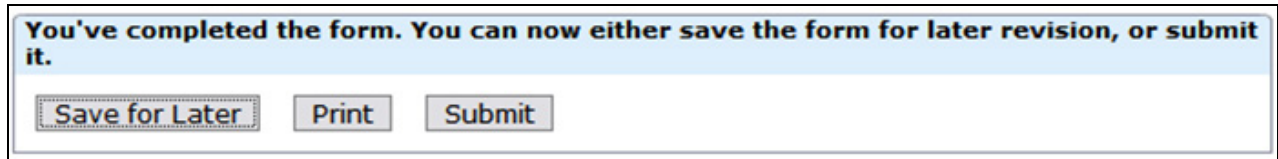


Figure 49

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).

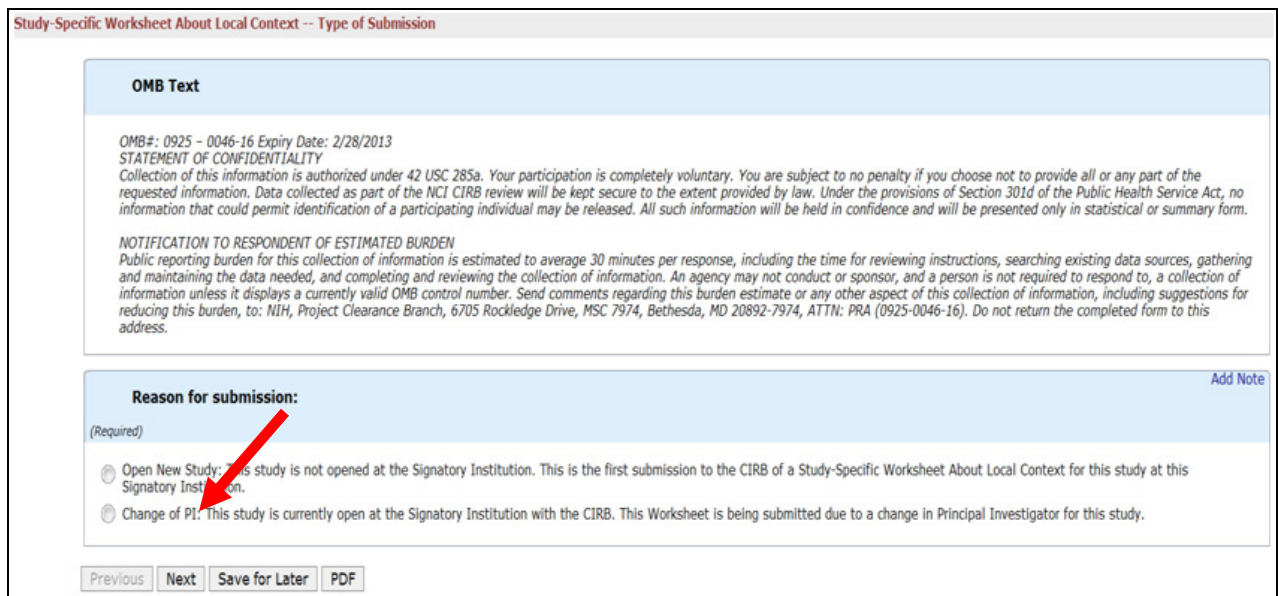


Figure 50

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

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.

Study-Specific Worksheet About Local Context -- Change of PI

Enter the email address of the Signatory Institution Principal Investigator who will be taking over this study. Add Note

(Required)

If the email address is listed as "Contact not found.", email the Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711 to determine what action is required to have the email validated in IRBManager.

Has the replacement Principal Investigator submitted an Annual Principal Investigator Worksheet About Local Context? Add Note

(Required)

Yes *If Yes, complete the remainder of this Worksheet based on the replacement Annual Principal Investigator Worksheet About Local Context.*

No *If No, submit the Annual Principal Investigator Worksheet About Local Context before submission of the Study-Specific Worksheet About Local Context via the "Start XForms" screen.*

Previous Next Save for Later PDF

Figure 52

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](#)

(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

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

(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

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

(Required)

No change
 Changed

If 'Changed', describe changes. [Add Note](#)

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

(Required)

No Change
 Changed

If 'Changed', describe changes. [Add Note](#)

Compensation to Study Participants (Question 10 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required) <input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Informed Consent Process (Questions 11-20 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required) <input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Pharmacy Information (Questions 21-22 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required) <input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Measures to Protect Confidentiality (Question 23 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required) <input type="radio"/> No Change <input type="radio"/> Changed
If 'Changed', describe changes. Add Note
<div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
Measures to Protect Privacy (Question 24 on the Annual Principal Investigator Worksheet About Local Context) Add Note
(Required) <input type="radio"/> No Change <input type="radio"/> Changed

If 'Changed', please describe.	Add Note
<input type="text"/>	
Emergency Resources (Question 25 on the Annual Principal Investigator Worksheet About Local Context)	Add Note
(Required)	
<input type="radio"/> No Change <input type="radio"/> Changed	
If 'Changed', describe changes.	Add Note
<input type="text"/>	
Using a Legally Authorized Representative (LAR) (Questions 26-28 on the Annual Principal Investigator Worksheet About Local Context)	Add Note
(Required)	
<input type="radio"/> No Change <input type="radio"/> Changed	
If 'Changed', describe changes.	Add Note
<input type="text"/>	
Vulnerable Populations (Question 29 on the Annual Principal Investigator Worksheet About Local Context)	Add Note
(Required)	
<input type="radio"/> No Change <input type="radio"/> Changed	
If 'Changed', describe changes.	Add Note
<input type="text"/>	

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.

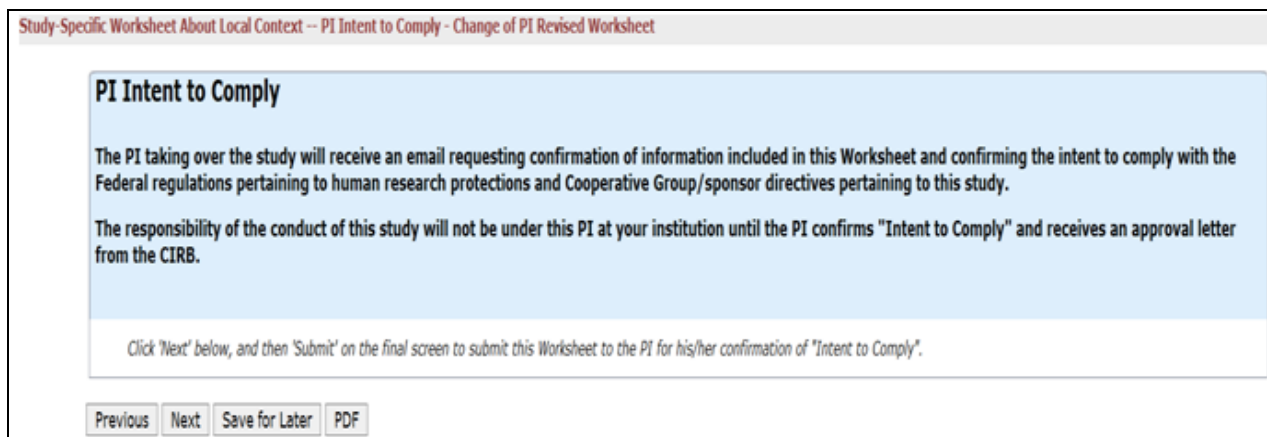


Figure 55

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.

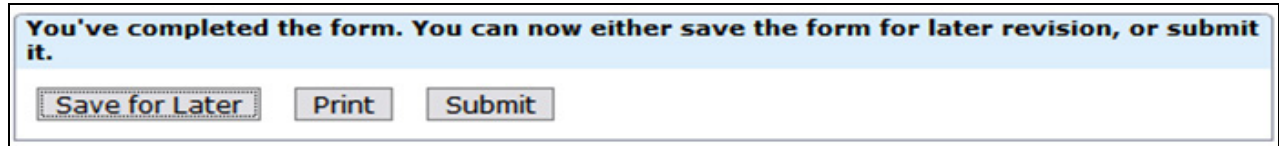


Figure 56

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.

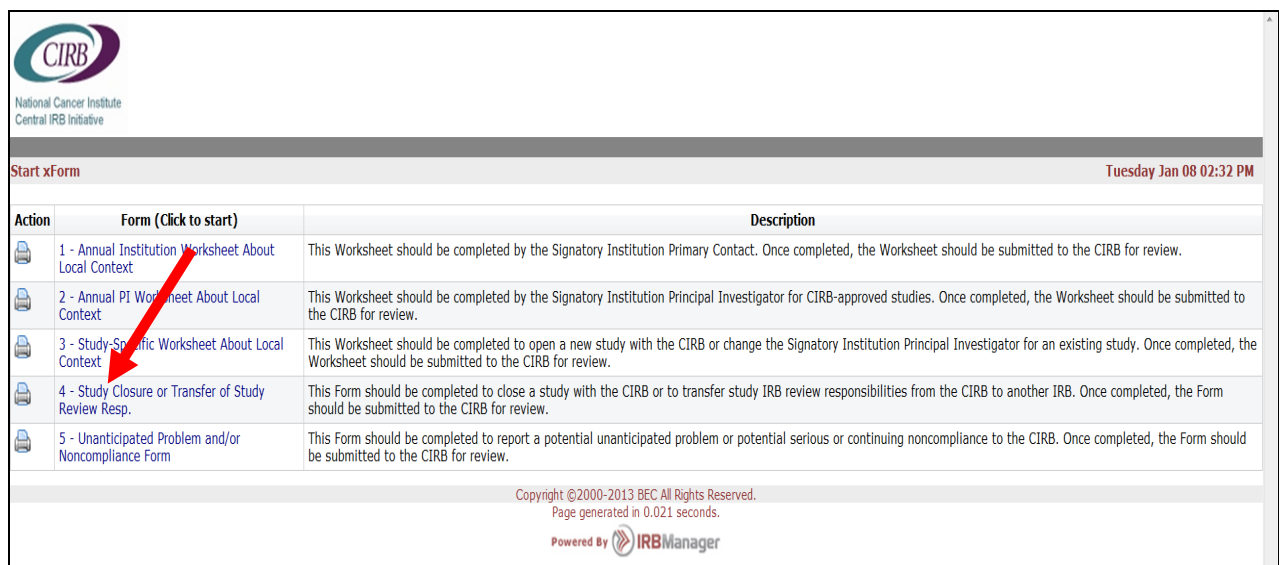


Figure 57

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.

The screenshot shows a web-based form for the NCI CIRB. At the top left is the NCI CIRB logo. A 'Next' button is in the top right. The main heading is '4 - Study Closure or Transfer of Study Review Resp. -- General Information'. Below this is a section titled 'OMB Text' which contains the following text:

OMB#: 0925 - 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 60 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 (0925-0046-16). Do not return the completed form to this address.

Below the OMB text is a section titled 'Signatory Institution Information' with a 'View Audit' link. It is divided into two sub-sections:

Submitting User Information

Walter, Jay PhD
 Email: Business Phone:

Name of Signatory Institution

Test University
 12 Street
 Ste. 304
 Anyplace, CA, 21701

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.

The screenshot shows a web form with three main sections. The first section, 'Study-Specific Information', has a header with 'Add Note' and a sub-header 'Enter the Study ID Number.' followed by a text input field. The second section, also with 'Add Note', has a sub-header 'Enter current Principal Investigator email address.' and a '(Required)' label above a text input field. The third section, 'Study Closure or Transfer of Study IRB Review Responsibility', has a header with 'Add Note' and a sub-header 'Which action are you requesting for this study?' with a '(Required)' label. Below this are two radio button options: 'Study Closure' and 'Transfer of Study IRB Review Responsibility from the CIRB to another IRB'. A red arrow points to the 'Study Closure' radio button. At the bottom of the form are four buttons: 'Previous' (disabled), 'Next', 'Save for Later', and 'PDF'.

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 intervention(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)

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.

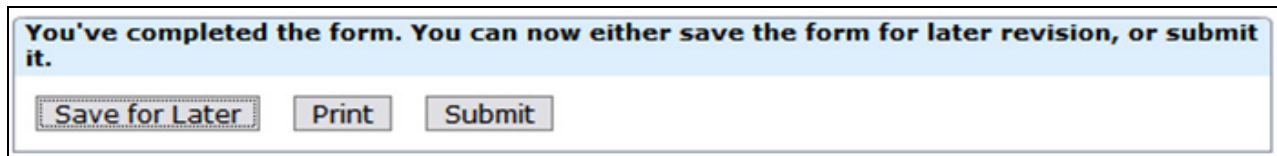



Figure 61

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.


Next

National Cancer Institute
Central IRB Initiative

4 - Study Closure or Transfer of Study Review Resp. -- General Information

OMB Text

OMB#: 0925 - 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 60 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 (0925-0046-16). Do not return the completed form to this address.

Signatory Institution Information View Audit

Submitting User Information

Walter, Jay PhD

Email: **Business Phone:**

Name of Signatory Institution View Audit

Test University
12 Street
Ste. 304
Anyplace, CA, 21701

Figure 62

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

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

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)

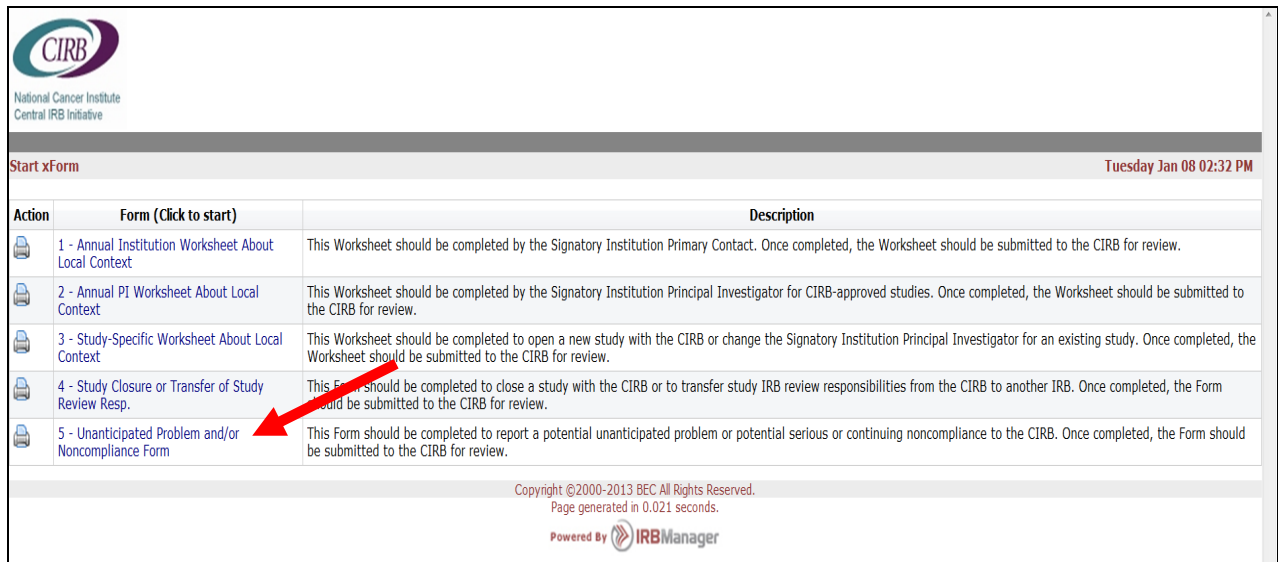


Figure 66

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.

Unanticipated Problem and/or Noncompliance Form -- CIRB Form

OMB Text

OMB#: 0925 - 0046-16 Expiry Date: 2/28/2013

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review will be kept secure to the extent provided by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be held in confidence and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 60 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 (0925-0046-16). Do not return the completed form to this address.

Signatory Institution Information View Audit

Submitting User Information

Walter, Jay

Email: Business Phone:

Name of Signatory Institution View Audit

Test University
12 Street
Ste. 304
Anyplace, CA, 21701

Figure 67

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.

General Information Add Note	
1. Enter Study ID Number.	
<i>(Required)</i>	
<input type="text"/>	
If more than one study is affected, enter the additional study ID numbers below. Add Note	
<input type="text"/>	
2. Enter Principal Investigator email address. Add Note	
<i>(Required)</i>	
<input type="text"/>	
If more than one Principal Investigator is affected, enter the additional names below. Add Note	
<input type="text"/>	
3. Enter each study's Protocol Version Date associated with the incident, experience, or outcome. Add Note	
<i>(Required)</i>	
<input type="text"/>	
4. Enter the Study Participant(s) Registration Number(s), if the incident, experience, or outcome involved a study participant(s). Add Note	
<input type="text"/>	

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.

Description of Incident, Experience, or Outcome		Add Note
1. Enter the date incident, experience, or outcome occurred.		
<i>(Required)</i>		
<input type="text"/>		
2. Describe the incident, experience, or outcome and/or add an attachment.		Add Note
<i>(Required)</i>		
<input type="text"/>		
Attachment:		Add Note View Audit
<input type="button" value="Add Attachment"/>		
No Attachments added.		


<p>3. Has the Cooperative Group/sponsor, the Study Chair, or a Federal agency been notified of this incident, experience, or outcome? Add Note</p> <p><i>(Required)</i></p> <p> <input type="radio"/> Yes <input type="radio"/> No </p>			
<p>If Yes, identify those notified. Add Note</p> <p> <input type="text"/>  </p>			
<p>Attach a copy of the notification and any response(s) received from those notified. Include the AdEERS report, if applicable. Add Note View Audit</p> <p> <input type="button" value="Add Attachment"/> No Attachments added. </p>			
<p>4. Did the incident, experience, or outcome occur while the CIRB-approved protocol was followed as writtten? Add Note</p> <p><i>(Required)</i></p> <p> <input type="radio"/> Yes <i>If Yes, complete Section C Unanticipated Problem.</i> <input type="radio"/> No <i>If No, complete Section D Serious or Continuing Noncompliance.</i> </p>			
<input type="button" value="Previous"/>	<input type="button" value="Next"/>	<input type="button" value="Save for Later"/>	<input type="button" value="PDF"/>

Figure 69

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		Add Note
1. Is this incident, experience, or outcome unexpected?		
<i>(Required)</i>		
<input type="radio"/> Yes <input type="radio"/> No		
If Yes, describe how the incident, experience, or outcome is unexpected and/or add an attachment.		Add Note
<div style="border: 1px solid gray; height: 20px; width: 100%;"></div> <div style="text-align: right; font-size: small; color: blue;">ABC </div>		
Attachment:		Add Note View Audit
<div style="border: 1px solid gray; padding: 2px; display: inline-block; margin-bottom: 5px;">Add Attachment</div> No Attachments added.		

<p style="text-align: right;">Add Note</p> <p>2. Is this incident, experience, or outcome related or possibly related to participation in the research?</p> <p><i>(Required)</i></p> <p> <input type="radio"/> Yes <input type="radio"/> No </p>
<p style="text-align: right;">Add Note</p> <p>If Yes, describe how the incident, experience, or outcome is related or possibly related to participation in the research and/or add an attachment.</p> <div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
<p style="text-align: right;">Add Note View Audit</p> <p>Attachment:</p> <div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">Add Attachment</div> No Attachments added.
<p style="text-align: right;">Add Note</p> <p>3. Did the incident, experience, or outcome place the study participant(s) or others at a greater risk of harm?</p> <p><i>(Required)</i></p> <p> <input type="radio"/> Yes <input type="radio"/> No </p>
<p style="text-align: right;">Add Note</p> <p>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.</p> <div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
<p style="text-align: right;">Add Note View Audit</p> <p>Attachment:</p> <div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">Add Attachment</div> No Attachments added.
<p style="text-align: right;">Add Note</p> <p>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.</p> <div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div>
<p style="text-align: right;">Add Note View Audit</p> <p>Add an attachment, if applicable.</p> <div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">Add Attachment</div> No Attachments added.
<p> <input type="button" value="Previous"/> <input type="button" value="Next"/> <input type="button" value="Save for Later"/> <input type="button" value="PDF"/> </p>

Figure 70

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.

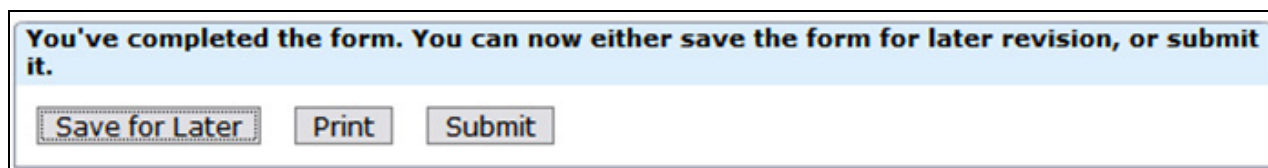


Figure 71

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.

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:

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.	
<hr/>	
Is the incident, experience, or outcome potential continuing noncompliance? Add Note	
<i>(Required)</i>	
<input type="radio"/> Yes <input type="radio"/> No	
If Yes, describe how the incident, experience, or outcome is potential continuing noncompliance and/or add an attachment. Add Note	
<input type="text"/> 	
Attachment: Add Note View Audit	
<input type="button" value="Add Attachment"/> No Attachments added.	

3. Does the incident, experience, or outcome affect the study participant's continued participation in the study? Add Note	
<i>(Required)</i>	
<input type="radio"/> Yes <input type="radio"/> No	
If Yes, describe how the study participant's continued participation in the study is affected and/or add an attachment. Add Note	
<input type="text"/> 	
Attachment: Add Note View Audit	
<input type="button" value="Add Attachment"/> No Attachments added.	

The screenshot shows a web form with a light blue header for question 4: "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?". To the right of the question is a link "Add Note". Below the question is a large text input field with a small "ABC" icon and a dropdown arrow on the right. Below this is another light blue header: "Add an attachment, if applicable." with links "Add Note" and "View Audit" to the right. Underneath is a button "Add Attachment" and the text "No Attachments added.". Below that is a third light blue header: "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." with a link "Add Note" to the right. This is followed by another large text input field with the "ABC" icon and dropdown arrow. At the bottom of the form are four buttons: "Previous", "Next", "Save for Later", and "PDF".

Figure 72

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.

The screenshot shows a summary screen with a light blue header containing the text: "You've completed the form. You can now either save the form for later revision, or submit it." Below the header are three buttons: "Save for Later", "Print", and "Submit".

Figure 73