

# IRBManager

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USER GUIDE FOR RESEARCHERS

Institutional Review Board (IRB)  
IOWA STATE UNIVERSITY | OFFICE OF RESEARCH ETHICS

# Researcher's Guide to IRBManager

This guide includes information about IRBManager, the web-based system for IRB application submission, IRB review, and study management. Use IRBManager to submit an xForm (IRB application) for both new studies and those requiring subsequent review (modification, continuing review). Learn how the xForm (IRB application) moves from submission through the IRB review process, and how to access approved protocols and corresponding materials.

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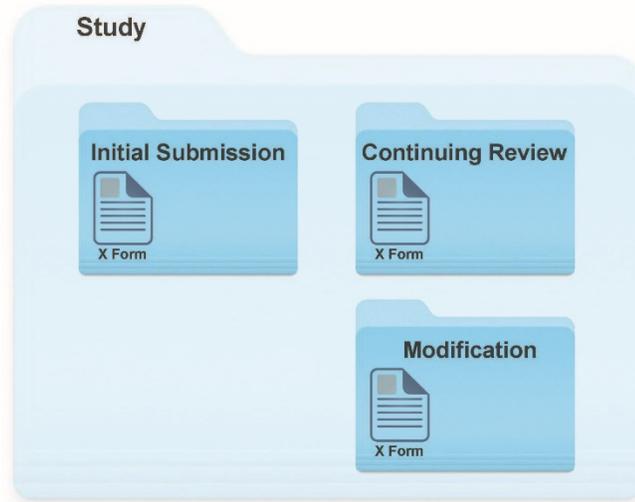
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## COMPONENTS OF A STUDY

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The IRBManager system acts as a filing system containing study information, xForms (IRB applications), communication documents, study status information, etc.



### Study, Study Site & Events

These are the components that make up an entire project within IRBManager.

<b>xForm</b>	IRB Forms (e.g., IRB Application, IRB Study Status Check-In, etc.)
<b>Pages</b>	Sections within the xForm (application)
<b>Event</b>	Type of Submission (e.g., Conversion – historical paper-based event information, Initial Submission, Modification, Continuing Review, Adverse Event, IRB Authorization/Reliance Agreement, etc.)
<b>Study Site</b>	Detailed Study Information (e.g., approval dates, expirations, enrollment status, etc.)
<b>Study</b>	General Study Information (e.g., title, IRB ID, exempt or expedited determination, sponsors, etc.) – Acts as a folder that contains all information about the project. <i>Note: Clicking on the IRB ID number opens the Study.</i>

## IRB APPLICATION TYPES AND ROLES

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### xForm Types

#### **IRB Application**

- A new study requiring IRB review may be submitted by completing the [IRB Application](#) xForm. This form may be started by locating the “Submit an IRB Application for a NEW Study” link or the “Submit a New Study” button on the dashboard.
- The **IRB Application** xForm is used for Initial Submission as well as any [Amendments](#) for Continuing Review or Modifications to the Study.

*Note: Once an IRB Application xForm is approved/completed, a copy of that xForm will be automatically published to the Study Information page. This “[Reference xForm](#)” links to the approved/completed IRB Application xForm from the most recent event for your study. The Reference xForm may be used to view the most recent complete protocol for your study and when copying for Amendment.*

#### **Does My Study Require IRB Oversight**

- If a researcher is unsure if IRB oversight is required, they may complete this form for guidance. If IRB oversight is not required, a notification will be sent to the PI by the system with confirmation. This form may be started by locating the “Does My Study Require IRB Oversight” link on the dashboard.

#### **IRB Study Status Check-In**

- The IRB requests an update every three years for studies that do not require continuing review. This xForm includes a short list of questions that provide the IRB information on the study’s status. This form may be started by locating the Study. Under the “Actions” menu on the left side of the screen, select “Start xForm” and choose “IRB Study Status Check-In”.

#### **Adverse Events/Unanticipated Problems**

- Investigators must promptly report any serious adverse events or unanticipated problems related to the research to the IRB. This form may be started by locating the Study. Under the “Actions” menu on the left side of the screen, select “Start xForm” and choose “Adverse Events/Unanticipated Problems”.

Other types of xForms are in development (e.g., Preliminary Determination, etc.) and will be available in the near future.

## Roles in IRBManager

- **Submitting User** - individual who initiates the form. It may or may not be the PI on the project.
- **Collaborator** - individuals with access to the stage that the form is in - they can be added using the [collaborator link](#) and provided with options for access (edit, manage, submit, etc.) and an email will automatically be sent to them informing them that they have access to the xForm.  
*Note: Adding collaborator(s) allows multiple persons to work on an IRB application.*
- **PI** - Principal Investigator
- **Supervising Investigator** - individual who is supervising the project for student projects, or who will be the Co-investigator for individuals not eligible to serve as PI alone (per ISU's [PI Eligibility Guidelines](#))
- **Co-Investigators** - **ISU Faculty or P&S Staff** investigators who may be also be responsible for the study, or other ISU P&S Staff or Faculty working on the study.
- **Research Staff** - individuals working on the study, but are not ISU P&S Staff or Faculty. This includes
  - Research assistants, student personnel, hourly staff, transcribers, coders, etc.; and
  - **Non-ISU/Unaffiliated Investigators/Researchers** - individuals who are not affiliated with ISU who are working on the study, or who may be responsible for study procedures at their own institution.

## ACCESSING IRBMANAGER

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Before study personnel can be added to IRB applications, individuals need to complete two steps:

1. Log into IRBManager one time using their ISU NetID and password, to establish themselves as a contact in the system. Individuals will be automatically established as a contact after logging into the system once—there are no additional forms to complete for ISU-affiliated persons.
2. Complete Human Subjects Training through CITI.

When both of these steps have been completed, IRB Manager will sync with CITI, verifying training. CITI and IRB Manager sync overnight, so personnel can be added to studies as early as the day after both steps have been completed.

### Log In to IRBManager

<https://iastate.my.irbmanager.com/>

Username: ISU netID

Password: ISU password



### Human Subjects Protection Training

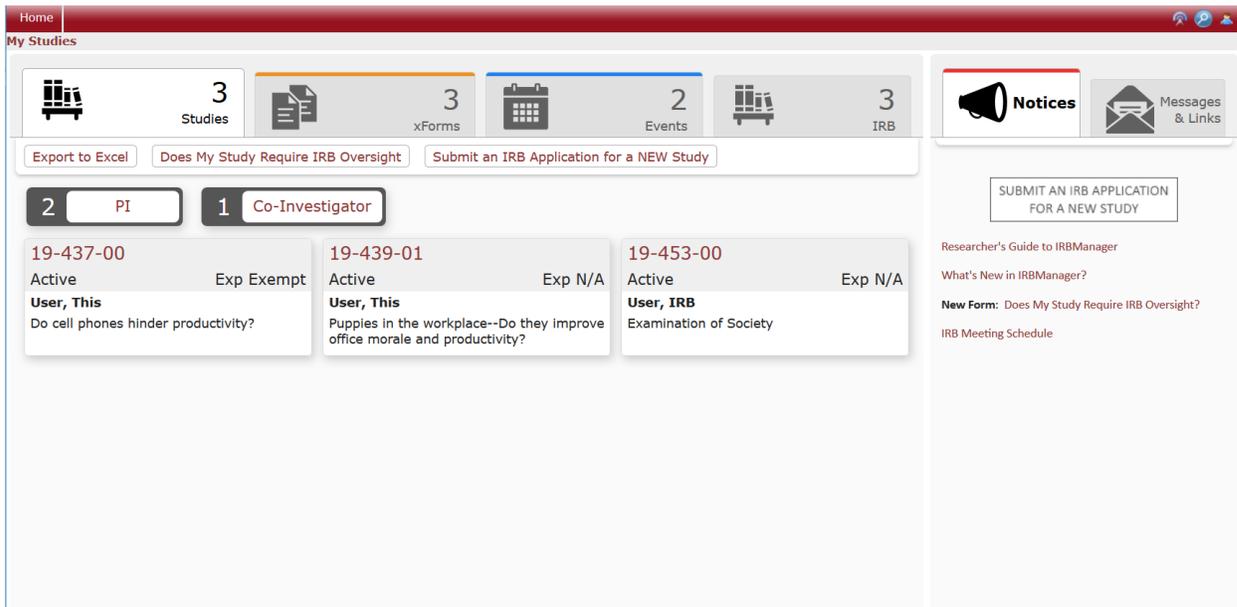
Human Subjects Protection Training through [CITI](#) must be complete for all personnel in order to submit the IRB Application. CITI training records are updated in IRBManager once per day in the morning. If the CITI training shows as “Missing” within the application, there are a few reasons this may occur.

- The individual has not completed required modules for the Social/Behavioral Research Course or Biomedical Research Course to meet the human subjects training requirement in CITI.
- The individual did not document their affiliation with ISU **and** use their ISU email as their primary email to set up their CITI account.
- The individual signed in to IRBManager for the first time the day of application completion.

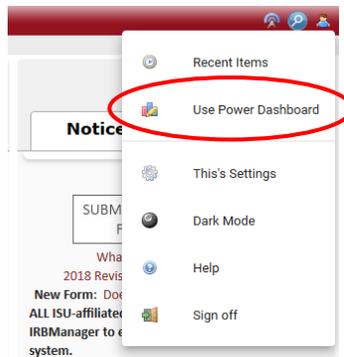
*Note: CITI training records are updated in IRBManager once every 24 hours, usually overnight. If an individual's training is listed as "Missing" in the IRB application, please wait until IRBManager is updated the next day before submitting your application. If after the update the training still shows as "Missing", please contact the IRB office.*

## IRBMANAGER DASHBOARD

The dashboard is the hub of the xForms (applications) and the landing page when logging in to IRBManager. Studies and Events that individuals are associated with can be located here. The dashboard shows a variety of tabs with the flexibility to move the tabs around for a customized view. Clicking on the buttons under each tab allows you to view and sort the studies, events, or xForms.



Some users may prefer the Power Dashboard, which contains the same Studies, Events, and xForms, but with a classic view. From the Bubble Dashboard, you can switch to the Power Dashboard using the Settings Menu. Locate the person icon to access the Settings Menu on the upper right side of the screen and select "Use Power Dashboard".



To revert back to the Bubble Dashboard, when in the Power Dashboard, click on "Settings" in the upper right side of the screen and select "Switch Dashboard".



## Areas of the Dashboard



(upper right)



### Go to Switchboard (Dashboard)

- This returns the user to the dashboard from another screen.
- Alternatively, the **Home** button (upper left) will do the same.



### Study Search

- This shows a “Find Study” field to locate your specific studies – the main folder holding all applications (xForms). The Study shows information about the overall project including the Events (e.g., modification, continuing review, etc.).
- This field does not locate individual [xForms](#) (applications).



### Menu

- The settings within this link include “Recent Items”, “My Settings” – to locate “My Expirations”, among other personal details for your IRBManager account.



### Notices

- Used by the IRB to relay frequently requested information or special notifications.
  - Full Committee meeting schedule
  - Submit a New Study button
  - New information



### Messages & Links

- Used by IRB to relay general information.
- “How To” guidance, information and/or tutorials



2

Studies

**Studies (Active Studies)**

- The [studies](#) you are associated with (i.e., PI, Supervising Investigator, Co-I, or Research Staff

2 PI

1 Co-Investigator

- Studies expiring soon



4

xForms

**xForms (Active xForms)**

- The number of unsubmitted [xForms](#) – the IRB applications that you have initiated (as the submitter)
- The number being processed at a later stage (after application data entry)
- xForms awaiting your attention (e.g., review and sign, etc.)
- *Note: Clicking the buttons in this section shows the xforms (IRB applications) that meet the criteria selected.*

1 Awaiting Your Attention

1 Unsubmitted

2 Being Processed At A Later Stage



2

Events

**Events (Open Events)**

- The number of [events](#) you have open (i.e., that have not been approved or otherwise finalized)
- *Note: Clicking on the buttons allows you to sort the events by role or event type.*

2 PI

1 Initial Submission

1 IRB Authorization/Reliance Agreement

Does My Study Require IRB Oversight

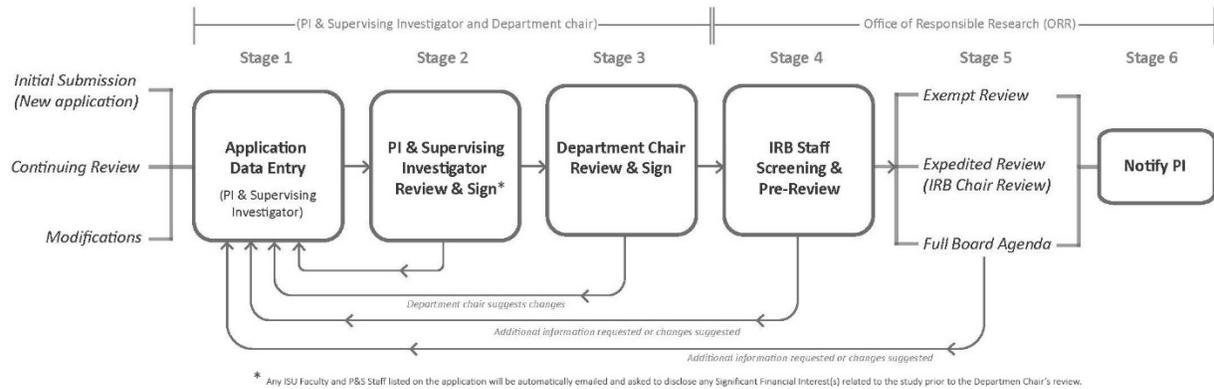
Submit an IRB Application for a NEW Study

**Actions**

- The main actions that will occur in IRBManager will be listed here.
  - Submit an IRB Application for a New Study
  - Does My Study Require IRB Oversight

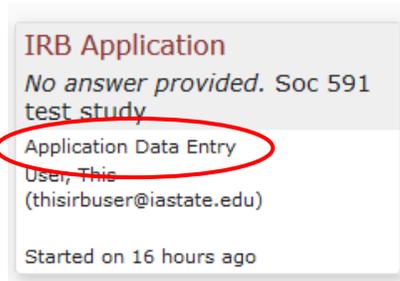
## IRB APPLICATION REVIEW PROCESS OVERVIEW

An IRB Application xForm is entered by the researchers in IRBManager. The submission process involves the xForm moving through stages of data entry and PI, Supervising Investigator, Conflict of Interest (COI) Check, and Department Chair reviews where the involved parties agree to the assurances and sign off on the xForm. Following agreement, the xForm is routed to the IRB office where IRB staff screen the application to determine the level of review and conduct IRB staff pre-review, followed by formal IRB review. Lastly, the PI (and Supervising Investigator) is notified of the final outcome.



### Description of IRB Application xForm Stages

IRB Application xForms move through various stages during the submission and review processes. Researchers can view the stage of their applications on the Dashboard by clicking the xForms button.



*Note:* In IRBManager, the following xForm stages indicate that the **application is not in the hands of the IRB office**: Application Data Entry, PI Review and Signature, Supervising Investigator Review and Signature, COI Check, and Department Chair Review and Signature.

The following xForm stages indicate the **application is in the hands of the IRB office**: IRB Staff Screening, IRB Staff Pre-Review, Exempt Review, Expedited Review, Full Committee Pre-Review, Full Committee Review – Primary Review, Full Committee Post-Meeting Actions, and Final Event Processing.

- 1. Application Data Entry**
  - Information about the study is entered into the IRB Application xForm. Questions in the xForm are conditioned such that only relevant questions will be visible and required for submission. In this stage, researchers working on the study together may collaborate on xForm completion.
  
- 2. PI Signature, Supervising Investigator Signature, and Department Chair Signature**
  - The xForm will be routed through the signature stages electronically. An email will be sent to notify the appropriate individual(s) of any action that should be taken on the form. The PI, then Supervising Investigator (when necessary), and Department Chair must review assurances and electronically sign in agreement.
  - A **COI Check** occurs before the xForm is routed for Department Chair signature. This intermediary stage requires verification of any Significant Financial Interest related to the research. The PI and any ISU faculty or P&S staff listed as personnel in the application in Table 1 will receive an email with instructions on completing this step.
  
- 3. IRB Staff Screening (Receive Submission)**
  - IRB application is screened by IRB staff to determine if it contains the necessary information for review and whether it is eligible for Exemption, Expedited, or Full Committee review.
  - Once IRB staff make this determination, an IRB ID is assigned by the system and the xForm and all materials are “loaded” and recognized by the system as a Study. Concurrently, an Event (Initial Submission, Modification, Continuing Review) will be established for the xForm (application). This process is similar to the IRB receiving a paper application, assigning it an IRB ID, and placing it into a file.
  
- 4. IRB Staff Pre-Review or Full Committee Pre-Review**
  - IRB staff conduct a preliminary review of the IRB Application xForm to ensure it is complete and ready for the final reviewer or the Full Committee to conduct the formal review.
  
- 5. Exempt Review or Expedited Review**
  - The IRB Application xForm is directed to an assigned reviewer and undergoes formal Exempt or Expedited review.
  
- 6. Full Committee Review – Primary Review or Full Committee Post Meeting Actions**
  - The IRB Application xForm is assigned to a Full Committee agenda. It is also assigned to a primary reviewer who conducts an in-depth review in preparation for final review by the convened IRB.
  - After the convened meeting, Post-Meeting Actions will occur in order to document the committee’s findings.
  
- 7. Final Event Processing (Notify PI of Final Outcome)**
  - During the Final Event Processing Stage, the PI will be notified of the final determination for their study once the review is complete. An email notification will be sent automatically from IRBManager informing the PI and Supervising Investigator that the determination letter and any

approved and stamped materials are available for viewing and retrieval from within IRBManager.

*Note: The review process is fluid and an IRB Application xForm may be returned to the PI at any stage for revisions or more information. When this occurs, an email is sent to the Submitter, PI, Supervising Investigator, and/or Department Chair to notify them of any action they need to take on an IRB application.*

## STUDY STATUS & EVENT STEPS

These are some of the indicators showing an xForm's location in the review process, and if the study may commence or continue (i.e., whether IRB approval is active, etc.).

### Study Status

The status of the IRB's determination for the study (details located under the Study Site)

Study 19-250-00 (IRB)				Help IRB's Settings Sign off			
<b>▼ Study</b>							
<b>Study:</b>	19-250			<b>Sponsor(s):</b>			
<b>Committee:</b>	IRB #1			<b>Sponsor Id:</b>			
<b>Category:</b>				<b>Grants:</b>			
<b>Department:</b>	Office for Responsible Research			<b>CRO:</b>			
<b>Agent Types:</b>	SBER			<b>Year:</b>	2019		
<b>Title:</b>	Effectiveness of Outdoor Activities on Wellbeing			<b>HIPAA:</b>	No		
<b>2018 Common Rule Date:</b>	4/01/2019			<b>FDA Study:</b>	No		
<b>Expedited Categories:</b>	7 - Individual or group characteristics or behavior; surveys, interviews, etc.			<b>Comments:</b>			
<b>Study-Site</b>							
<b>Site(s):</b>	00 - Unspecified			<b>PI:</b>	User, IRB		
<b>Status:</b>	Active			<b>Additional:</b>	N		
<b>Approval:</b>	May 23, 2019			<b>Expiration:</b>	N/A		
<b>Initial Approval:</b>	April 1, 2019			<b>Other Expirations:</b>	Non-Exempt Approval Expiration - 05/22/2020		
<b>Comments:</b>							
<b>▼ Events (2)</b>							
Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg	
Modification	4			05/23/2019	05/23/2019		
Initial Submission	4			04/01/2019	05/23/2019		

IRBManager Study Status Categories	
Under IRB Oversight	Not Under IRB Oversight
<p><b>Conversion</b> – Indicates the study was imported into IRBManager.</p> <p><b>New from PI (under IRB review)</b> – Study is undergoing the review process and a determination has NOT yet been made.</p> <p><b>Active</b> - Approval/Determination is granted. Human subjects research procedures including recruitment, data collection, etc. may commence.</p> <p><b>Data Analysis Only</b> – The remaining human subjects research procedures only involve analysis of private and identifiable data.</p> <p><b>Enrollment Closed – Clinical Data Follow-up</b> – Enrollment is complete and the remaining research procedures involve clinical data follow-up (uncommon).</p> <p><b>Enrollment Closed – Data Collection Continues</b> – Enrollment is complete, but data collection continues from enrolled participants.</p> <p><b>IAA – Deferred to External IRB</b> – An IRB at a collaborating institution agreed to oversee the research procedures for the study; and ISU’s IRB agreed to defer IRB oversight to that institution.</p>	<p><b>IAA – Not Established</b> – IRB determined that a reliance agreement for IRB oversight with a collaborating institution is not established.</p> <p><b>IRB Approval Not Required</b> – Study does not require IRB oversight, often due to the study not meeting the definition(s) of research and/or human subjects.</p> <p><b>Withdrawn - PI Directed</b> – Study is Not Approved as the PI requested to withdraw the IRB application.</p> <p><b>Withdrawn - PI Non-Response</b> – IRB returned the application to Application Data Entry for more information and PI did not respond to the request in the requested timeframe.</p> <p><b>Closed - Approval Lapsed</b> – An IRB application was not submitted and reviewed prior to the continuing review date. The Study is considered Administratively Closed until approval is reinstated.</p> <p><b>Closed - PI Directed</b> – The PI requests the Study to be closed.</p> <p><b>Closed – Administratively Closed</b> – IRB determined that the study is closed to IRB oversight for reasons other than a lapse in approval. The Study is considered Administratively Closed until approval is reinstated</p> <p><b>Approval Suspended</b> – IRB suspended approval of the research (uncommon).</p> <p><b>Approval Terminated</b> – IRB terminated approval of the research (uncommon).</p> <p><b>Disapproved by IRB Committee</b> – IRB disapproved the research (uncommon).</p>

## Event Steps

On the Event page in IRBManager, you can view the processing steps associated with a specific IRB Application xForm.

Steps (6) <input checked="" type="checkbox"/> Hide Skipped					
Step	Planned	Actual	Complete	Minutes	Micro Note
Receive Modification	05/23/2019	05/23/2019	Yes		
IRB Staff Screening & Pre-Review		05/23/2019	Yes		
Expedited/IRB Chair Review		05/23/2019	Yes		
Notify PI of Final Outcome		05/23/2019	Yes		

*Note: Not all steps will be visible and those that appear will be based on the review of the particular application.*

- **Receive Submission** – The IRB application is in the hands of the IRB and considered received.
- **IRB Staff Screening & Pre-Review** – The IRB application is sent to the IRB staff to ensure application is ready for final review.
- **Exempt Review** – The IRB application is sent to an Exempt reviewer for review.
- **Expedited/IRB Chair Review** – The IRB application is sent to the IRB Chair for expedited review. This step/stage refers to the determination category, not speed.
- **Assign to Full Board Agenda for Review** – The IRB application is added to a Full Board agenda for the Full Committee review at an upcoming committee meeting.
- **Notify PI of Final Outcome** – This is the step/stage that the PI will be notified of the IRB determination.
- **Notify Full Board of Approval/Committee Determination** – This step/stage is an informational notice to the IRB Full Committee only to notify the members of the final determination of the Study.

## SUBMITTING AN APPLICATION FOR A NEW STUDY

From the Dashboard click on **Submit an IRB Application for a New Study**.

A blank IRB Application xForm will be available for completion. Both exempt and non-exempt research is submitted through the same application. The xForm is conditioned to show and hide questions based on information entered.

A drop-down menu at the top of the xForm allows users to quickly move between sections. However, we recommend completing the form in order as additional questions appear throughout the xForm based on responses to questions on prior pages.

The screenshot shows the top navigation bar of the IRB application. On the left is the Iowa State University logo. In the center, there is a 'Collaborators' link with a person icon, which is circled in red. To its right is a dropdown menu currently set to 'Basic Study and PI Information'. Further right is a 'Page 1 of 14' indicator and a 'Next' button. Below the navigation bar, the main content area is titled 'IRB Application -- Basic Study and PI Information'. The form itself has a header 'Basic Study Information' with 'Add Note' and 'View Audit' links. The 'Submitter' section shows 'Bappe, Roxanne' with an email field containing 'rbappe@iastate.edu' and a 'Phone:' label. Below this is a 'Title of Project' text area. At the bottom of the form, there is a prompt: 'Please enter the email address of the principal investigator. If you are the principal investigator, please enter your own email address.' with an empty input field.

### Adding Collaborators

The individual who starts an xForm (submitting user) is the only person who will have access to that form in Application Data Entry unless others are added as collaborators. The IRB Office recommends manually adding the PI and Supervising Investigator as collaborators on the study with edit, manage, submit access at the beginning of the Application Data Entry stage to allow them to contribute to the application's completion.

1. Click on the "Collaborators" link at the top of an application to add individuals as collaborators on the xForm.

This screenshot is identical to the one above, showing the top navigation bar and the 'Basic Study Information' section of the IRB application form. The 'Collaborators' link is circled in red.

2. Enter the email address of the individual to be added as a collaborator.

Action	Collaborator	Permission
	Agnitsch, Kerry	Edit, manage, and submit

3. Select the collaborator access:
  - Edit – allows the individual to make changes to the form.
  - Edit & Manage – allows the individual to make changes to the form and add other collaborators.
  - Edit, Manage & Submit – allows the individual to make changes to the form, add collaborators, and submit the form in that stage.
4. Type in the “Note for Collaborator” field the text that you would like included in the automated email notification that will be sent to the collaborator.
5. Once added, the collaborator should see the xForm on their dashboard under “xForms awaiting your attention”.

*Note: Collaborators that are added at any stage are not retained once out of that stage. However, when an xForm is returned to the submitter from a later stage - such as when the IRB office returns the form for more information – the system is set up to include the PI and Supervising Investigator as collaborators automatically. If you wish for the collaborators to have continued access, you will need to re-add them when the form is returned to you.*

## Entering Study Personnel

Study personnel are listed by entering their ISU email address into relevant fields in the form. The Key Personnel section includes prompts for information about each individual’s role in the study. Click “Add” at the end of the row to save each entry.

Please enter email address for key personnel.*	CITI HSR Trng Exp*	Collecting Data from Participants	Involved in Recruitment or Obtaining Consent	Access to Identifiable Research Data	Qualifications*	Roles in the Research*	Action
<input type="text"/>		<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="text"/>	<input type="text"/>	<b>Add</b>

**IMPORTANT:** If an ISU affiliated individual is not recognized when their email address is entered, they must [log in to IRBManager](#) using their ISU credentials one time. Logging in to IRBManager one time establishes individuals as an ISU contact in the system and allows them to be included as study personnel.

For persons who do not have an ISU email address, the form includes the option to “Add New Non-ISU Contact” in the Key Personnel section.

IRBManager automatically verifies human subjects protection training for all study personnel. Training through the CITI modules must be complete for all study personnel before the xForm may be submitted.

**IMPORTANT:** If CITI training is “Missing”, please see the guidance on [CITI Training Updates](#).

**Denying Access to IRB Application and Materials:** By default, final copies of IRB Applications and related materials are visible to all study personnel. This includes the ability for study personnel to view xForms and initiate a Copy for Amendment. If personnel should not have access to the applications and related materials, be sure to select “Deny access to the IRB Application for all persons in this table.” under the respective table in the IRB Application. Those listed in the table for whom access is denied will not be able to view the applications and materials and “(no access)” will be listed behind their role on the Study.

**Table 1 - ISU Faculty and P&S Staff ONLY:**

*(Required)*

Please enter the name of the ISU Faculty and P&S Staff.*	CITI HSR Trng Exp*	Collecting Data from Participants	Involved in Recruitment or Obtaining Consent	A I R
<input type="text"/>		<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	<input type="checkbox"/>
<input type="checkbox"/> Deny access to the IRB Application for all persons in this table.				

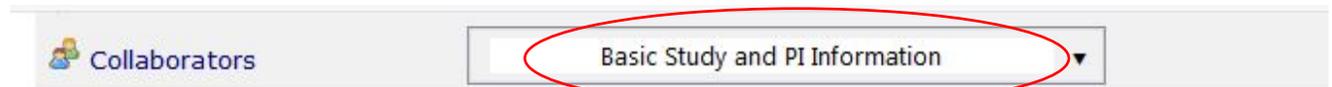
## Uploading Documents

Documents, such as informed consent documents, data collection materials, recruitment materials, grant proposals, etc., are uploaded as attachments in relevant sections of the xForm. Informed consent forms and recruitment materials **must be a Word document or PDF**.

See the Submission Tips at the end of this guide for important information regarding Uploading Documents as Attachments.

## Form Navigation and Saving

At the top of the page is a drop-down menu that allows users to quickly move between sections of the xForm. The system auto-saves content before moving to another section when this drop down menu is used.



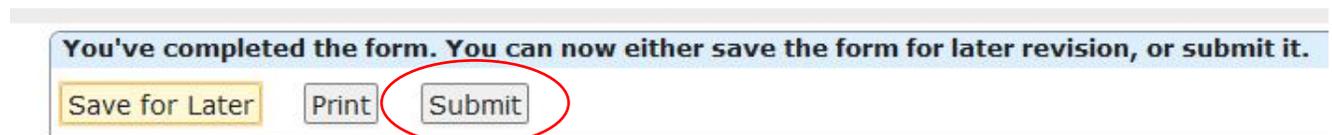
At the bottom of the page, several options are available. Clicking “Next” saves content, ensures all required fields are answered, and navigates to the next page in the xForm. Users may also “Save for Later”—clicking this will save content and close the xForm.



*Note: If more than one person is simultaneously answering a question in the IRB Application xForm, responses can be accidentally overwritten. Be sure your plans for completing the application are communicated with collaborators to ensure the information you intend to include is retained. We recommend that only one person answer questions in the application at a time. Others can contribute by using the “Add Note” feature on each question to leave instruction for the editor to incorporate into the application.*

## Submitting the xForm

When the form is complete, be sure to click Submit. If you close the browser or save without submitting, the form will not route to the next stage.



## AMENDMENTS – CONTINUING REVIEW, MODIFICATION, OR CLOSURE

IRBManager allows researchers easy access to current and complete study information. The most recent IRB Application xForm) provides a clear picture of complete approved protocol at any given time. Additionally, having a fully complete xForm will make processing subsequent amendments simpler. Amendments to a Study include: continuing review, continuing review with modification, modification, or closure.

The first IRB Application xForm submitted for the study is called the Initial Submission. To seek approval of modifications or submit a request for continuing review or closure, the most recent approved IRB Application xForm must be *copied for amendment* and changes made within that copied form.

The copied form is a complete copy of the previously approved IRB Application xForm; thus, researchers will not need to enter study information into the xForm again. However, responses should be updated as necessary so the application reflects the research procedures going forward, and some new questions may appear depending on the type of amendment (continuing review, modification, closure), or if changes are made to answers within the form. The questions in the xForm are programmed to skip unnecessary questions, yet show new questions when needed.

This section of the guide provides instructions for the Amendment process.

**Tip:** If you have recently submitted an application (a new Initial Submission or Amendment for Modification or Continuing Review), you must wait until review of that submission is complete before submitting another application. To request changes before the review is complete, please contact the IRB office to have the xForm returned to you. A study with an application still under review cannot be amended.

## AMENDMENTS FOR A STUDY PREVIOUSLY REVIEWED IN IRBMANAGER

Step 1: **Locate the Study** to be closed, modified or submitted for a continuing review.

Study ID	Status	Expiration	Study Title
19-437-00	Active	Exp Exempt	Do cell phones hinder productivity?
19-439-01	Active	Exp N/A	Puppies in the workplace--Do they improve office morale and productivity?
19-453-00	Active	Exp N/A	Examination of Society

Step 2: Click on the IRB ID to open the Study details.

Step 3: Locate the most recent reviewed Event for the Study that is an Initial Submission, Modification, Continuing Review, or Continuing Review with Modification. Other events, such as a Status Check, Adverse Event, etc. do not contain the study protocol and may NOT be copied for amendment.

▼ Events (2)						
Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
Modification	4			05/23/2019	05/23/2019	
Initial Submission	4			04/01/2019	05/23/2019	

Step 4: Click on the Event to open the Event details.

Step 5: Click on the xForms on the left menu (within the Event details screen). The screen should show the xForm that was reviewed with the Stage/Status marked as complete.

Step 6: In order to have an updated protocol that includes all research plans at any point in time, modifications and continuing review xForms will be processed using a "Copy for Amendment" function in the system. This allows a copy of the previously approved xForm to be revised and include all current research procedures. Click on the folder icon to the left of the xForm name. This will create a "Copy for Amendment" that can be edited.

Action	Form	Identifier	Stage/Status
	IRB Application	No answer provided. Testing Research that does not involve human subjects	Complete

*Note: The copied xForm (not complete and without the folder icon next to it) will now be listed under the Study, not the event. It will remain under the Study until it is sent to the IRB for review and determined that it is ready for review as a new event (Continuing Review, Continuing Review with Modification, Modification, or Closure). It may more easily be located under the xForms link under My Documents & Forms, or within the "unsubmitted xForms" total under My Studies – xForms on the dashboard.*

Step 7: Within the xForm, select the type of application. The first page of the xForm will indicate it is a non-initial submission and the application type should be selected (continuing review, modification, closure – both continuing review and modification may be selected when modifying a study in conjunction with renewing approval).

Add Note View Audit

Please select below to indicate the type of application you are submitting.

- To renew approval, select continuing review.
- For changes to your study, please select modification.
- You may select both options if you wish to modify your study in conjunction with renewing approval.
- If your project no longer requires IRB oversight, please select project closure.

(Required)

Continuing Review

Modification

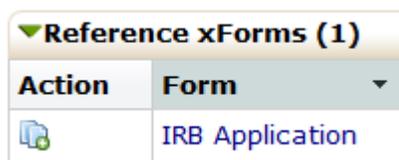
Project Closure

Step 8: As with an Initial Submission, **add collaborators** (PI, Supervising Investigator) to the xForm so that the appropriate individuals have access to the form in this stage.

Step 9: **Finish completing the form and submit.**

### Using Reference xForms to Copy for Amendment

Once an IRB Application xForm is approved/completed, a copy of that xForm will be published to the Study Information page (mid-way down). This “**Reference xForm**” links to the most recent approved/completed IRB Application xForm (from the most recent event) for your study. When available and as an alternative to moving through the steps above to Copy for Amendment, you may simply **click on the papers icon** next to the Reference xForm in order to **Copy for Amendment**.



▼ Reference xForms (1)	
Action	Form
	IRB Application

Depending on the type of the most recent submission, the full-study protocol may be hidden in the Reference xForm (e.g., the last Amendment for Modification changed personnel only). Regardless of its visible content, the Reference xForm should be used to Copy for Amendment. Selecting Modification or Continuing Review options early in the copied form will make visible the hidden fields so you may update it accordingly.

Refer to [Steps 7 – 9](#) above to complete the Amendment process.

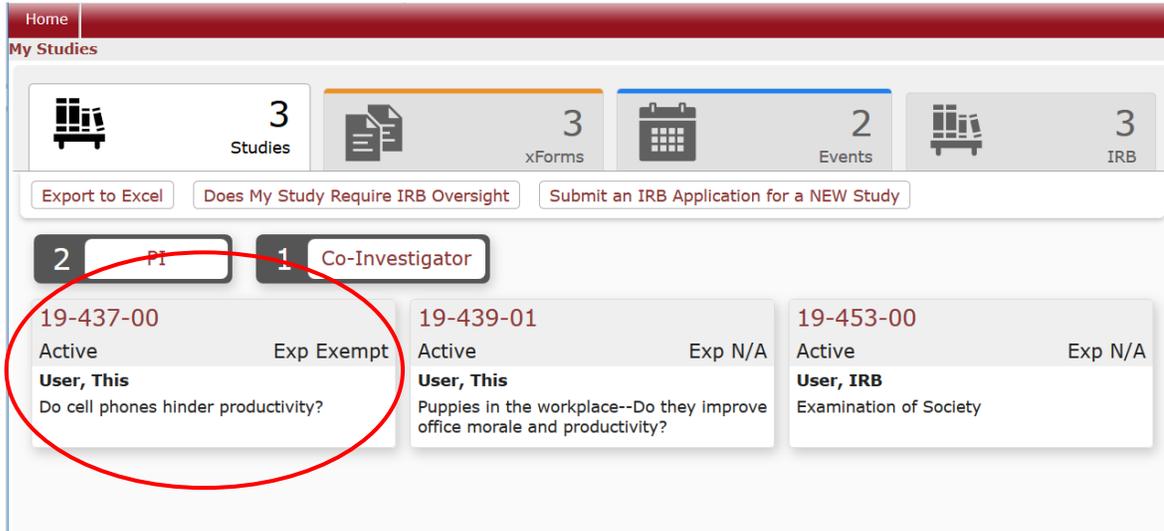
### AMENDMENTS FOR A STUDY SUBMITTED FOR REVIEW PRIOR TO IRBMANAGER LAUNCH

**Tip:** This process should be used ONLY ONCE for any study submitted on paper for review prior to IRBManager launch. If you have already used this process for the study you need to amend, please refer to these [instructions](#) to proceed.

Basic protocol information about studies submitted prior to IRBManager is available in IRBManager. Studies can be located by searching using the IRB ID number assigned to it at the time of review. These studies will have a study status of “**Conversion**” indicating that basic protocol information was imported.

*Note:* Copies of previously approved paper applications may be located under the [Historical Attachments](#) Event within the Study.

Step 1: **Locate the Study** to be closed, modified or submitted for a continuing review.



Step 2: **Click on the IRB ID** to open the Study details.

Step 3: In the Actions menu on the left, **click on Start xForms** to access the Pre-IRBManager Amendment Form.



Step 4: The Pre-IRBManager Amendment form includes basic study information and a link to a **blank IRB Application** you will need to complete.



Step 5: Within the xForm, **select the type of application**. The first page of the xForm will indicate it is a non-initial submission and the application type should be selected (continuing review, modification, closure – both continuing review and modification may be selected when modifying a study in conjunction with renewing approval).

Add Note View Audit

Please select below to indicate the type of application you are submitting.

- To renew approval, select continuing review.
- For changes to your study, please select modification.
- You may select both options if you wish to modify your study in conjunction with renewing approval.
- If your project no longer requires IRB oversight, please select project closure.

(Required)

Continuing Review

Modification

Project Closure

*Note: The first time an amendment for a study reviewed prior to IRBManager launch is submitted in IRBManager, a modification to add all study personnel must be included.*

Step 6: As with an Initial Submission, **add collaborators** (PI, Supervising Investigator) to the xForm so that the appropriate individuals have access to the form in this stage.

Step 7: **Finish completing the form and submit.**

## SUBMITTING OTHER STUDY-SPECIFIC FORMS – STUDY STATUS CHECK-IN OR REPORTABLE EVENT

**Tip:** Forms used to report information about a study (i.e., Study Status Check-In, Adverse Events/Unanticipated Problems) to the IRB should be started from the Study Information page for the specific Study.

Step 1: **Locate the Study** for the xForm you wish to submit.

Step 2: **Click on the IRB ID** to open the Study details.

Step 3: In the Actions menu on the left, **click on Start xForms** to access study-specific xForms.

Select xForm to start	
Action	Form (Click to start)
	Adverse Events/Unanticipated Problems
	IRB Study Status Check-In
	Pre-IRBManager Amendment Form

Step 4: Basic study information will be visible in the form to ensure you are completing the xForm for the correct study.

Step 5: As with all xForms, **add collaborators** (PI, Supervising Investigator) to the xForm so that the appropriate individuals have access to the form in this stage.

Step 6: **Finish completing the form and submit.**

## LOCATING APPROVED INFORMATION & MATERIALS

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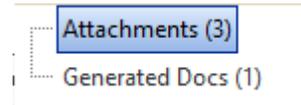
IRBManager stores all study information and materials. Basic study information is visible when selecting the study to view. Uploaded materials, final approved materials, determination letters, etc. are stored under the “Actions” menu within each event (i.e., Initial Submission, Continuing Review, Historical Attachments, etc.) for the study.

### Locating Approved Information & Materials for Studies Approved in IRBManager

Approved materials are located **within each Event** under the “Actions” menu.



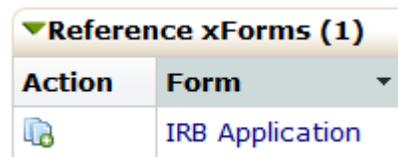
- Approved Documents are located under “Attachments” and Approval/Determination Letters are located under “Generated Docs”.



- Approved IRB Applications are located under “xForms”
- Clean copies of materials are located as links within the approved “xForm”

### Using Reference xForms to View the Approved Protocol

An alternate way to view the most recent approved/completed IRB Application is to locate the [Reference xForm](#) on the Study Information page. Clicking on the IRB Application link under Reference xForms allows you to view the most recently approved IRB application xForm.



Action	Form
	IRB Application

*Note: If the most recently approved IRB Application only contained personnel changes, protocol fields unrelated to personnel changes will be hidden within the Reference xForm. Please refer to the IRB Application xForm included in the most recent Event for which the complete protocol was approved (e.g., a previously approved Initial Submission, Modification, or Continuing Review event).*

## Historical Study Records – Locating Information & Materials for Studies Approved Prior to IRBManager Launch

An event called “Historical Attachments” is available in the list of events under the Study. Copies of paper-based IRB approved protocols, determination letters, or related documents for these studies are located under “Attachments”. If access to the previously-approved paper applications is needed, contact the IRB Office to request that those attachments be made visible.



## SUBMISSION AND USE TIPS

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### General Tips

- If copying text from another source to paste into your IRB Application, use your browser’s “paste as plain text” feature. Background code from the original text source can cause glitches in IRBManager.
- There are links throughout the IRB Application to relevant guidance, templates, etc. Click on this symbol where located in the xForm to access the guidance.



### Personnel Table Tips

- Complete the Personnel Tables appropriately, adding \*only\* ISU faculty and P&S staff members in Table 1, and all other members of the research team in Table 2, and use the Add Contact form for non-ISU personnel when necessary.
- When adding a non-ISU contact, a confirmation email will be sent to the submitter. Once the email is received, the contact may be added to the form.
- Human Subjects Protection Training must be complete before the application may be submitted.

### Document Naming Conventions

- Be intentional with document naming
  - Use consistent naming conventions for documents.

- Use *descriptive* file names (e.g., Group\_1\_Informed\_Consent). Descriptive file names are VERY helpful for reviewers.
- Use *distinctive* file names (e.g., Control Consent, Condition 1 Consent, Condition 2 Consent, instead of three items all named “Consent”). Unique names allow researchers to quickly find the right item when updating materials, and enable IRB reviewers to easily communicate about specific documents. Uploading items one at a time will automatically capture the document’s distinctive file name.
- Using the same filename for a document when replacing the previous version is helpful to the reviewer so that it is clear what was replaced. The document name may include version number or dates, but maintaining the descriptive part of the name (e.g., child\_assent\_letter.doc, parental\_consent\_letter.doc, etc.) is requested.

### Uploading Documents as Attachments

- Each attachment should only contain one document type (e.g., recruitment letter, informed consent document, survey questions, etc.) and should only contain what is requested in the particular question of the application. For instance, when uploading data collection materials, do not include or attach consent or recruitment documents.
- If more than one type of data collection materials will be used (e.g., survey questions, interview questions, etc.), upload them separately.
- Approval stamps are applied to materials based on the file type (i.e., recruitment materials, informed consent documents). The IRB expects that stamped versions of the documents will be used in the recruitment and consent process. Recruitment and consent materials should not be included within data collection materials files as they will not be stamped.
- *Note: Informed consent documents and recruitment materials are not normally required for initial review of exempt research.*

### Replacing Attached Documents

- When an attachment has been revised, replace the document in the application using the green “replace” icon next to the document name.



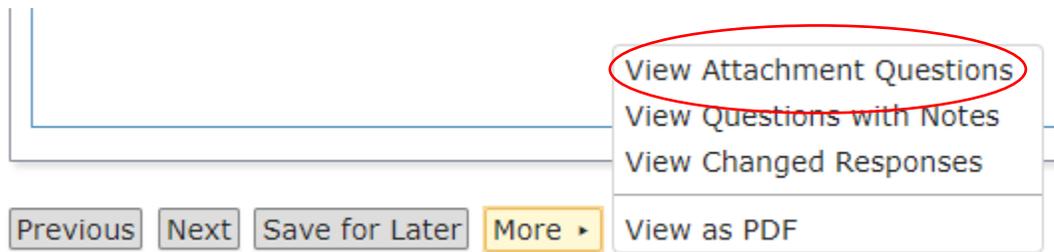
- When an attachment should be permanently removed, use the red “x” icon to delete it.



### Locate Attachments in the IRB Application

- Before submitting an application, be sure to ensure all materials related to the study have been attached. Click on the “View Attachment Questions” button at the bottom of the application to reveal a new window that will show only the questions that involve attachments.

- After IRB review, clean copies (without approval stamps) of attachments will remain in the IRB Application and may be accessed using “the “View Attachment Questions” button.



## Notifications

IRBManager sends automated email notifications to those that should take the next action on an IRB application. A link to the IRB application is provided within the email for ease of accessing the form. Some examples include:

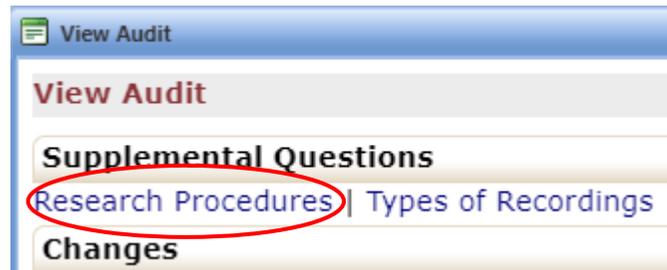
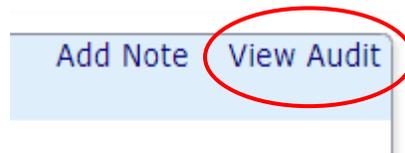
- Notifying the Supervising Investigator to review an application for which the PI is not eligible to serve as PI alone.
- Notifying personnel to confirm any Significant Financial Interests related to the research (i.e., COI Check).
- Notifying Department Chairs when an application is ready for departmental review.
- Notifying investigators when the IRB is requesting additional information or action on their IRB application. The email will be sent to the Submitter, PI, and Supervising Investigator.
- Notifying investigators of upcoming Study expirations that require continuing review. The email will be sent to the Submitter, PI, Supervising Investigator, and Co-Investigators.
- Notifying investigators when approval has lapsed and the study is closed. The email will be sent to the Submitter, PI, Supervising Investigator, and Co-Investigators.

## Information Requested by the IRB Office

- The xForm may be returned to the Application Data Entry stage during the review process for additional information requested by the IRB office
- An email will be sent to the submitter, PI, and Supervising Investigator informing them that the IRB requests more information.
- Notes will be provided within the xForm alongside the question(s) they pertain to with detailed information about the requests.
- In addition to updating the questions as necessary, notes may be added by the submitter, PI, or Supervising Investigator for clarification in response to the IRB’s requests.

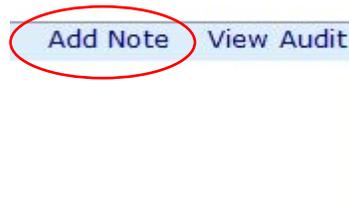
## View Audit Feature

Each section in any xForm has an audit trail feature, tracking changes to text fields and attachments throughout the life of the form. To see exactly what has changed in any given section of an xForm, simply select View Audit, and if relevant, the appropriate sub-option.

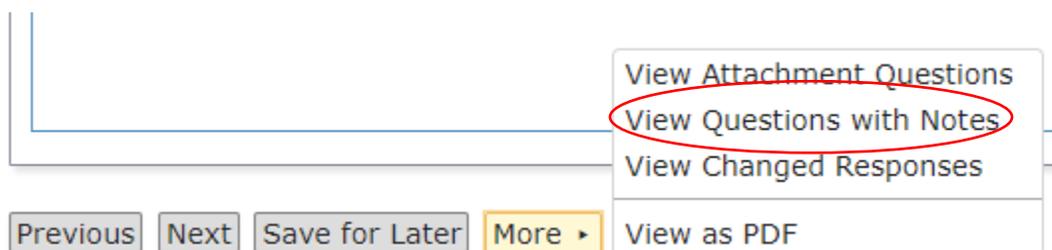


## Notes Feature

- Notes may be added in the xForm. Notes are essentially electronic sticky-notes; using this feature allows easy communication between researchers and IRB Staff (or any others working on the xForm). Notes can be added and removed as needed; notes removed by the research team prior to submission will not be available to IRB Staff.



- Notes are not retained when an IRB Application xForm is copied for amendment. Therefore, notes do not replace complete responses to questions or within application fields. Any information pertinent to the IRB Application must be incorporated into relevant application fields.
- An option to view a summary of the notes on the form is available, which is helpful when collaborating on the Application Data Entry stage of the form, or when the IRB returns the xForm to the submitter for additional information.



## PDF of IRB Application

- A PDF of any xForm is available for download at the bottom of the opened xForm.
- The completed xForm may be saved as a PDF for ease of collaboration and record-keeping.

