This guide includes information about how to use IRBManager to submit an xForm (IRB application) for both new studies and those requiring subsequent review (modification, continuing review). It also describes 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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IRB REVIEW PROCESS OVERVIEW

The review process hasn’t changed, it is just handled electronically.

An xForm (IRB application) is entered by the researchers in IRBManager. The submission process involves the xForm moving through stages of data entry and PI, Supervising Investigator, 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 Stages

1. Application Data Entry
   - Information about the study is entered into the xForm (IRB application). 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 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 and the xForm and all materials are 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 xForm (application) 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 xForm (application) is directed to an assigned reviewer and undergoes formal Exempt or Expedited review.

6. **Assign to Full Board Agenda for Review**  
   - The xForm (application) 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.

7. **Notify PI of Final Outcome**  
   - 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 xForm (application) 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.*
ACCESSING IRBMANAGER

All personnel must log into IRBManager using their ISU NetID and password one time to establish themselves as a contact in the system before they can be added to IRB applications. 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.

We strongly advise having all study personnel log into IRBManager once, if they have not done so already, before you complete an IRB application.

**Log In to IRBManager**

https://iastate.my.irbmanager.com/
Username: ISU netID
Password: ISU password

**CITI Training Updates**

Human Subjects Training through CITI must be complete for all personnel in order to submit the IRB Application. If the CITI training shows as “Missing” within the application, there are a couple of reasons this may occur.

- The individual has not completed all modules for the Social/Behavioral Research Course or Biomedical Research Course to meet the human subjects training requirement in CITI.
- The individual signed in for the first time the day of application completion. CITI training records are updated in IRBManager overnight. IRBManager recognizes training in CITI that is taken by individuals who documented their affiliation with ISU and used their ISU email to set up their CITI account. If the individual’s contact is created after the CITI update for the day, training is complete, and their training is listed as “Missing” in the IRB application, please wait until IRBManager is updated overnight before submitting your application. If after the overnight 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.

Areas of the Dashboard

- **Find Study**
  - This field is used to locate specific studies – the main folder holding all applications.
    - Studies are considered the overall project and contain Events (e.g., modification, continuing review, etc.) and xForms (applications).
    - This field does not locate individual xForms (applications)

- **My Settings**
  - The settings within this link include “Change My Password”, “My Expirations”, among other personal details for your IRBManager account.

- **Actions**
  - The main actions that will occur in IRBManager will be listed here.
    - Submit an IRB Application for a New Study
    - Show Sponsor’s Study ID (rarely will this be used as the majority of studies the IRB reviews are not funded).

- **Recent Items**
  - This area lists the items that have been accessed most recently.
- **Messages**
  - Used by IRB to relay key information.

- **Useful Links**
  - "How To" guidance, information and/or tutorials

- **My Documents & Forms**
  - User Attachments – documents may be uploaded here so they are easy to find.
    - Examples may include:
      - Copy of a grant that covers multiple studies
      - Document templates that may be used on multiple studies
  - xForms – the IRB applications that you have initiated (as the submitter).

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

- **My Studies**
  - Studies (Active Studies)
    - The studies you are associated with
    - The studies you are listed as PI, Co-I, Supervising Investigator, or Investigative Staff
    - Studies expiring in the next 90 days
    - The next study that will expire
  - xForms (Active xForms)
    - The number of unsubmitted xForms
    - The number being processed at a later stage (after data entry)
    - xForms awaiting your attention
  - Events (Open Events)
    - The number of events you have open and the types – Initial Submission, etc.
    - Note: Pie Chart shows the types of Events that are open
COMPONENTS OF A STUDY

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.

<table>
<thead>
<tr>
<th>xForm</th>
<th>IRB Application Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pages</td>
<td>Sections within the xForm (application)</td>
</tr>
<tr>
<td>Event</td>
<td>Type of Submission (e.g., Conversion – historical event information, Initial Submission, Modification, Continuing Review, Adverse Event, etc.)</td>
</tr>
<tr>
<td>Study Site</td>
<td>Detailed Study Information (e.g., approval dates, expirations, enrollment status, etc.)</td>
</tr>
<tr>
<td>Study</td>
<td>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.</td>
</tr>
</tbody>
</table>
IRB APPLICATION PROCESS

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 Continuing Review or Modifications to the Study.

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

Roles, Permissions, Requirements & Expectations

○ 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.

○ 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 the VPR PI Eligibility guidelines)

○ ISU Faculty or P&S Staff Investigators – individuals including ISU Faculty or P&S Staff who may be Co-Investigators responsible for the study, or other personnel that are considered ISU P&S Staff or Faculty working on the study.

○ Other Individuals - 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.
  ○ 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.
Adding Collaborators

The submitter of an xForm will need to add the PI and Supervising Investigator as collaborators on the study with edit, manage, submit capabilities at the beginning of the data entry stage to allow them to access the xForm and contribute to the application’s completion.

○ Collaborator permission is not automatically given to others besides the submitter during data entry. Since they are also responsible for the Study, they should have this access. You will need to grant them this access manually. The collaborators that are added at any stage are not retained once out of that stage – in this instance, the data entry stage.

Note: When a form 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. As a reminder, this does not happen before the form is submitted to the IRB the first time, so the submitter will need to add those people and any additional collaborators they wish to include.
SUBMITTING AN APPLICATION FOR A NEW STUDY

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

A blank xForm will be available for completion. The form is conditioned to show and hide questions based on information entered. A drop-down menu at the top of the form allows users to quickly move between sections. However, we recommend completing the form in order as additional questions appear throughout the form based on responses to questions on prior pages.

**Entering Study Personnel**

Study personnel (including the PI and Supervising Investigator) 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” (on the right side of the table) to save each entry.

![Key Personnel Table]

**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.

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

IRBManager automatically verifies human subjects 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](#).

**Uploading Documents**

Documents, such as informed consent documents, data collection materials, recruitment materials, grant proposals, etc., are uploaded 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.
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 form. 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 and navigates to the next page in the xForm. Users may also “Save for Later”—clicking this will save content and close the xForm.

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.
STUDY STATUS & EVENT STEPS/STAGES

These are some of the indicators showing an xForm’s location in the review process, and if the procedures of a Study may commence.

○ **Study Status** – The status of the IRB’s determination (details located under the study site)
  
  ▪ **Conversion** – Indicates the study was imported into IRBManager.
  
  ▪ **New from PI (under IRB review)** – Study is undergoing the review process and a determination has NOT yet been made.
  
  ▪ **Open to Enrollment** - Approval/Determination is granted and human subjects research procedures including recruitment, data collection, etc. may commence.
  
  ▪ **Data Analysis Only** – The remaining human subjects research procedures only involve analysis of private and identifiable data.
  
  ▪ **Withdrawn - PI Directed** – Study is Not Approved as the PI requested to withdraw the IRB application.
  
  ▪ **Withdrawn - PI Non-Response** – IRB returned the application to Application Data Entry for more information and PI did not respond to the request in the requested timeframe.
  
  ▪ **Closed - Approval Lapsed** – An IRB application was not submitted and reviewed prior to the continuing review date. The Study is considered Administratively Closed until approval is reinstated.
  
  ▪ **Closed - PI Directed** – The PI requests the Study to be closed.
  
  ▪ **Approval Suspended** (rarely used)
  
  ▪ **Approval Terminated** (rarely used)
  
  ▪ **Disapproved by IRB Committee** (rarely used)

○ **Event Steps/Stages** – Where the xForm is in the review process (details located under the event)
  
  ▪ **Receive Submission** – The IRB application is in the hands of the IRB and considered received.
  
  ▪ **Staff 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.

- **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.
AMENDMENTS – CONTINUING REVIEW, MODIFICATION, OR CLOSURE

IRBManager allows researchers easy access to current and complete study information. The most recent xForm (IRB application) 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 xForm “IRB Application” 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 xForm (IRB Application) must be copied for amendment and changes made within that copied form.

The copied form is a complete copy of the previously approved xForm; thus, the entire xForm does not need to be completed again. However, 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.

AMENDMENTS FOR A STUDY PREVIOUSLY REVIEWED IN IRBMANAGER

Tip: Check the Study Status before considering an amendment. A study status of “Open to Enrollment” indicates that an Approval/Determination is granted and human subjects research procedures including recruitment, data collection, etc. may commence. Any changes must be submitted to the IRB for review and an approval/determination granted prior to implementation.

A study status of “New from PI (under IRB review)” indicates the study is undergoing the review process and a determination has NOT yet been made. To request changes before the review is complete, please contact the IRB office to have the xForm returned to you. A study still under IRB review cannot be amended.

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: Locate the most recent reviewed Event for the Study (Initial Submission, Modification, Continuing Review, or Continuing Review with Modification).

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 forms will be processed using a "Copy for Amendment" function in the system. This
allows a copy of the previously approved form 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.

Note: Two xForms will now be listed under the event. The copied xForm (not complete and without the folder icon next to it) is the one to work with. It will remain under that Event 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).

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.**
AMENDMENTS FOR A STUDY SUBMITTED FOR REVIEW PRIOR TO IRBMANAGER LAUNCH

Tip: Basic protocol information about studies submitted outside of IRBManager will be 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.

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 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).

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.
LOCATING APPROVED INFORMATION & MATERIALS

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

Locating Previously Approved Information & Materials for Studies Approved Prior to IRBManager Launch

An event called “Historical Attachments” will be available under the Study. At the time of continuing review or modification, if access to the previously approved materials is needed, contact the IRB Office.

- IRB approved protocols, determination letters, or related documents for these studies are located under “Attachments”.

SUBMISSION AND USE TIPS

Personnel Table Tips
- Complete the Personnel Tables appropriately 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 Training must be complete before the application may be submitted.

Document Naming Conventions
- Use consistent naming conventions for documents.
- 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.

Files for Upload
- Files for upload should only contain one document type. The file that will be uploaded should only contain what is requested in the particular question. For instance, when uploading data collection materials, do not include or attach consent or recruitment documents within the file.
- 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. If consent materials are included within data collection materials files, they will not be stamped. The IRB expects that stamped versions of the documents will be used in the recruitment and consent process.
- Informed consent documents and recruitment materials are not normally required for initial review of exempt research.

PDF of IRB Application
- PDF of the 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.
Notifications
IRBManager sends automated 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.
- 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.

Summary of Notes
- 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.
- 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.

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.