IRBManager

INSTRUCTION MANUAL

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1.0   IRBManager

1.1   What Is IRBManager?

IRBManager is an electronic research portal that serves as the "front door" for the submission, tracking, and retention of research protocols and research compliance documents. This includes Human Subjects Review Council (HSRC) application forms. Users can fill out and submit forms directly in IRBManager, and all forms, attachments, and documents submitted with a participating study will be accessible via IRBManager. IRBManager is a fully web-based system that is accessible both on- and off-campus.

1.2   How Do I Access IRBManager?

IRBManager can be accessed here: https://cwu.my.irbmanager.com. The following login page will appear:

1.2.1   CWU-Affiliated Users

Click the "To login using your CWU username and password click here" link (or simply click the large CWU logo in the middle of the page).

You will then be prompted to enter your CWU email and network password in a separate pop-up window.

Upon entering your credentials, you will automatically be redirected to the IRBManager Dashboard screen (homepage).

1.2.2   Externally Affiliated Users

Non-CWU users (i.e., project co-investigators at another institution, etc.) must be issued an IRBManager username and password to access the system. This is done manually by the HSRC administrator. Contact the administrator via email at hsrc@cwu.edu. Include in the subject line "IRBManager Access for Non-CWU User." Provide an email address for the non-affiliated user.

Upon being added to the system, the new user will receive an email with their username and temporary password. Once non-CWU users receive their initial IRBManager credentials, they can login at the same login page using the "Non-CWU affiliated users, click here to login" link.

If you have forgotten your password, please click the "Forgot Password?" link.

2.0   Passwords

2.1   CWU-Affiliated Users

CWU users are prompted for their username and current network password upon login to IRBManager. (If your CWU network password has recently changed, you will need to enter your new network password the next time you login into IRBManager.) You will never need to change your password in IRBManager.

2.2   Externally Affiliated Users

For those unaffiliated with CWU, on your first log-in, you will be prompted to change your password.

Your new password must be at least 6 characters long and contain characters, from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (e.g. !, @, #, ~).

To change your password and proceed:

1. Enter current password.
2. Enter new password (see requirements above) and then enter new password again to confirm 3. Click "Update"

If on any future logins you enter the wrong username/password three times, IRBManager locks your account as a security precaution. If that happens, you can click the "Forgot Password" link from the login screen. After filling in the information requested, a new password will be emailed to you and your account will be unlocked.

Once you log in with your username and password, you will be able to provide an electronic signature on any xForm by entering your password.

3.0   Navigating the Home Page – Dashboard

On the left side of the page, there are several headers:

1. Actions
2. Recent Items
3. Messages (note: will not appear if there aren't any messages posted)
4. Useful Links (note: will not appear if there are no links posted)
5. My Documents and Forms

3.1   Actions

Access forms by clicking "Start xForm" to see a full list and description of available forms. Please note that certain forms (e.g., Modification, Continuing Review) can only be completed for a protocol active in IRBManager. These forms are not available from the Dashboard.

3.2   Recent Items

The hyperlinks under this heading will show the most recent items you have viewed in IRBManager. You can click on any link under "Recent Items" to go directly to that item.

3.3   My Documents and Forms

This heading shows how many attachments and "xForms" you have submitted.

Note: If you click the "xForms" link, it will take you to a separate page showing your forms. On this page, under the "Actions" menu on the left side of the screen, there is a toggle button to "Show Complete/Hide Complete" forms. If you do not see previously completed forms on this screen, it likely means you need to press the "Show Complete" button.

3.4   Studies

This shows the studies you are associated with (as principal investigator, coinvestigator, research assistant, or faculty advisor) and shows studies you are the Principal Investigator on.

Note: By clicking on the underlined link, you will be taken to a separate screen showing the studies with which you are associated.

3.5   xForms

The xForms tab shows the forms currently active at this time for the user. An xForm is also referred to as a submission.
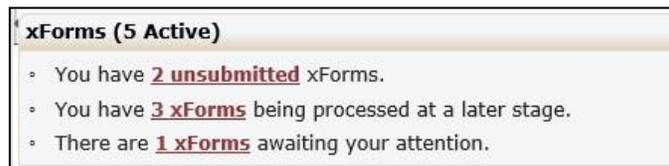
In this view of the Dashboard:
- "You have 2 unsubmitted xForms" = the user has 2 xForms (submissions) started but has not yet submitted them for further processing. (The user may have clicked "Save for Later" or just closed a form before pressing the "Submit" button at the end of the form.)

  Note: By clicking the underlined link, "2 unsubmitted," the user can go straight to the unsubmitted xForms.

- "You have 3 xForms being processed at a later stage" = the user currently has 3 forms being processed. In this case, the user has successfully submitted the forms, and forms are currently under review at a later stage in the processing cycle (e.g., faculty advisor review, department chair signature or processing by HSRC administrator).

- "You have _ xForms in error" = the user has a form that has a back-end error. This is a software issue that the HSRC administrator will be made aware of and will resolve.

- "There are 1 xForms awaiting your attention" = the user has 1 form that requires their attention and will not be processed to the next stage until the user addresses and submits the form. This will appear if someone else sends a form to the user. (For example, a faculty advisor will see this when a PI sends a form to them for review and approval. A PI would see this if the HSRC administrator returned a form for clarifications, etc.).

Note: By clicking the underlined link, "1 xForms," the user can go straight to the xForm that needs attention.

3.6   Events

The events section of the Dashboard shows the submissions open by submission type.

This section shows all open events and the submission name, such as continuing review, initial submission, and modifications.

Note: An event stays open until the board is notified of the approval. It is possible for the xForm to be complete and approved, but the event is still open until a board meeting occurs.

3.7   My Studies

Study	Site	PI	Title	Expires	Status
2017-001-ONL	Online data collection	TEST, Researcher	Testing the New Electronic Submission System	10/09/2018	Open
2017-003-ONC	On campus	TEST, Researcher	Test Test Test - Ignore Please	01/02/2019	Open
2017-004-ONL	Online data collection	TEST, Researcher	To Test Expedited Approval with Conditions - Testing New System	10/23/2018	Open

This is a list of all the studies the user is associated with active studies.

Note: By clicking on the blue link under "Study" the user can go straight to the study. Information in each column can be sorted by clicking the arrow in the column heading:
- Studies can be sorted by protocol number.
- Site can be sorted alphabetically.
- PI is sorted alphabetically.
- Study Title can be sorted alphabetically.
- Expiration dates are sorted by numerical date.
- Status is grouped and sorted alphabetically.

3.8   Top Headings
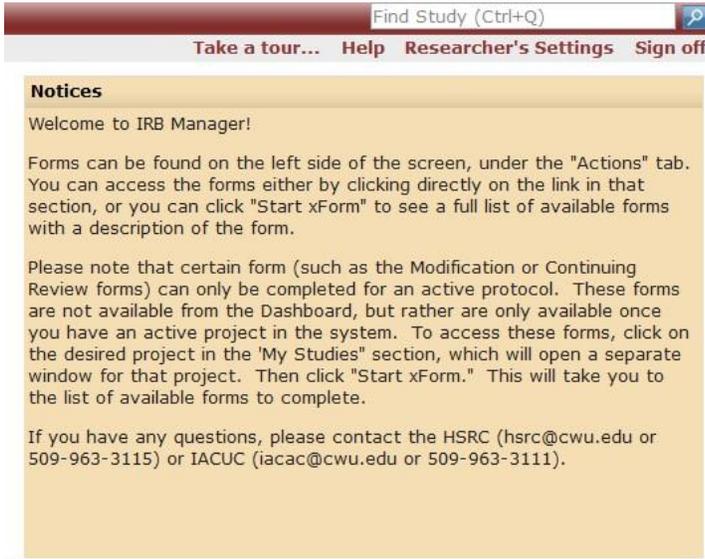
Find Study search bar – Search to find existing studies. Studies can be searched by protocol number, site, PI name, title, expiration date, or status.

Take a tour… - Provides an overview of the sections on the Dashboard.

Help – Hovering over the "Help" button brings up several options, including "Contact Administrator." Clicking on "Contact Administrator" allows you to send an email directly to HSRC via the system.

(Note: If you click on "Help," rather than hovering over "Help", you will get a message saying there is no help available for this page.)

Researcher's Settings – allows the user to edit their profile settings. "Researcher" will be replaced with your first name.

Under Researcher's Settings you can:
1. Change your password (applicable for non-CWU users only)
2. Change your profile.
3. Change your phone number.
4. Change your address.
5. View your CITI training expiration(s)
6. View last 25 logins.
7. Create an email signature.
8. Linked Clients - (not applicable)

Sign off – Click to log off IRBManager.

3.8.1 Change My Password

This is applicable only for users **without** a CWU email. Click on "change password" link. You will then see this view:

1. Enter old password.
2. Enter new password. Your new password must be at least 6 characters long and contain characters, from at least 3 of these groups: uppercase letters, lowercase letters, numbers, and special characters (e.g. !, @, #, ~).
3. Click "Update."

3.8.2 Change Your Profile

1. Click on "Change My Profile" link. You will then see this view:

2. Update your name.
3. Click "Update."

3.8.3 My Phone Numbers

1. Click on "My Phone Number" link.
2. Under "Actions", click "Add Phone" link. You will then see this view:

3. To update your phone number, you will see this view:

Phone Book (1)				
Action	Primary	Type	▼	Number	⬍
📝❌	✓	Home		123-456-7890

4. Click the "hand holding a piece of paper" icon and then "Update Phone."

3.8.4 My Address

1. Click on "My Address(es)" link.
2. Under "Actions", click "Add Address" link. You will then see this view:

Address Book Add - TEST, Researcher (cwu.researcher@gmail.com)	Help Researcher's Settings Sign off
Contact Name	
Full Name: TEST, Researcher	Email: cwu.researcher@gmail.com
Address Book	
Address Type: [⌄]	Country: United States [⌄]
Street: [ ]	
Line 2: [ ]	
Line 3: [ ]	
City: [ ]	
State/Province: [⌄]	Zip/Postal Code: [ ]
Primary Address: ☑	
[Add Address] [Reset] [Cancel]	

3. To update your address, you will see this view:

Address Book (1)										
Action	Primary	Type	▼	Street	⬍	City	⬍	State	⬍	Zip	⬍	Country	⬍
📝❌	✓	Home		123 Main Street		Ellensburg		Washington		98926		United States

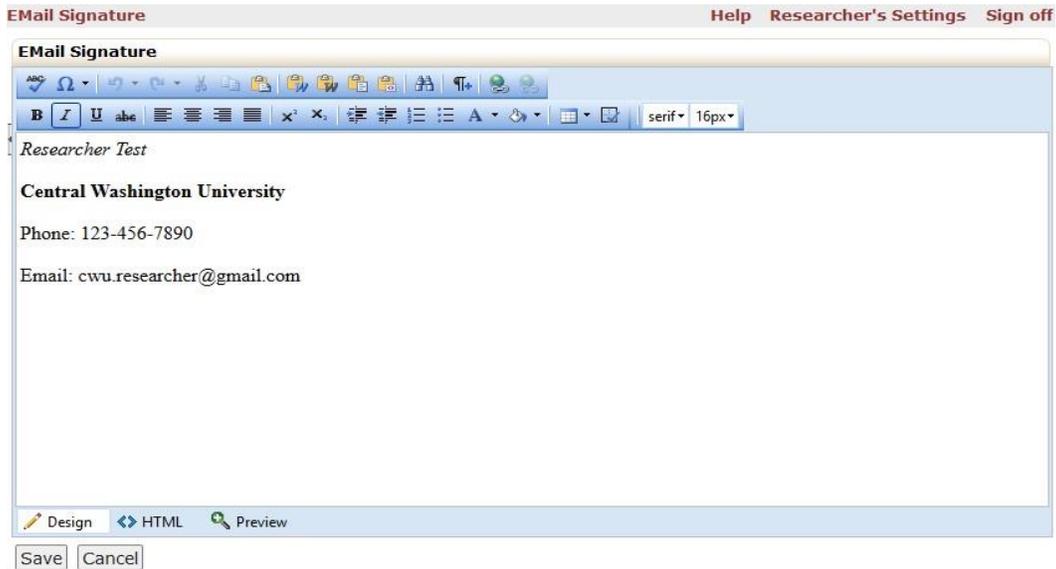4. Click the "hand holding a piece of paper" icon and then "Update Address".

3.8.5 Log-In Information

Lists the time and date of the last 25 times the user logged into IRBManager.

3.8.6 Email Signatures

Allows you to enter an email signature when sending email(s) through IRBManager.

1. Click on "Email Signature" link.
2. Enter your signature.
3. Click "Save."

EMail Signature

Researcher Test

Central Washington University

Phone: 123-456-7890

Email: cwu.researcher@gmail.com

Design   HTML   Preview

Save Cancel

Note: You may copy/paste a signature (with an image) from another platform into IRBManager. If entering information directly, use 'shift+enter' to eliminate double spaces between line text.

3.9   User Attachments

This function allows the user to attach documents (certificates, forms, etc.) to their IRBManager account. These documents will be available on any "Add Attachment" question asked on an "xForm". They can be accessed by clicking on the "My Profile" tab in the pop-up window that appears when clicking "Add Attachment."

Add Attachment

Add Attachment

Name:

(leave blank to use name of uploaded file)

Type: Training/Certification ▼

File(s):
(Limit: 50)   My computer   Dropbox   box   My Profile

	Name	Type
☐	Conflict of Interest Form_Test_08.25.2017	Conflict of Interest Disclosure Form

Attach   Cancel
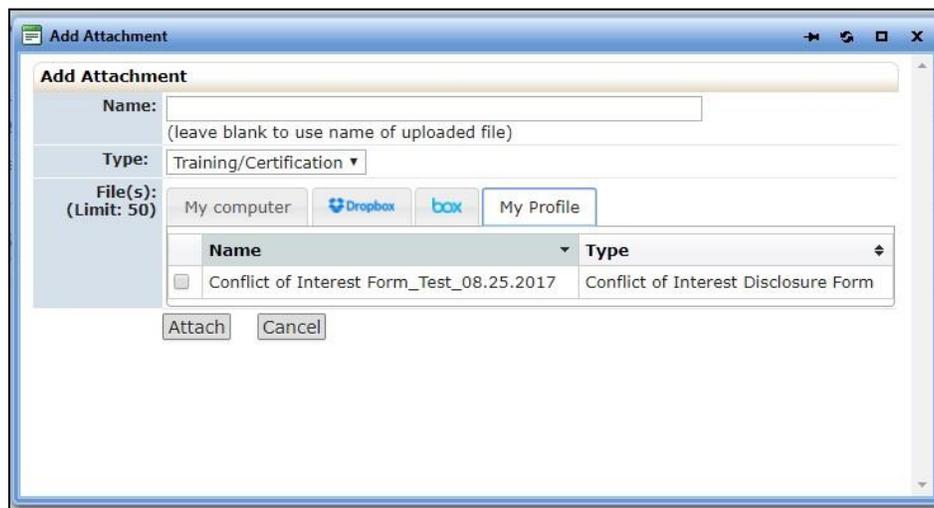
4.0   Navigating the Study Protocol Page

From the home page, you can access the study details for each of your studies. Click on the blue Study Code (Protocol Number) link under "My Studies" at the bottom of the home page to access the specific study. You can click on any blue link in this section to view more information.

4.1   Study

This section notes all of the basic information about the individual protocol:

- Study - Protocol number.
- Sponsor – HSRC (type of funding source, if any)
- Committee - HSRC
- Category – college or parent department
- Grants (if applicable) – how different than sponsor?
- Agent Type - methodologies used in the study.
- CRO (clinical research organization) - not applicable
- Study Title
- Year - of initial review
- Expedited Category – HSRC only (approved expedite category 1-9)
- Level of Review – HSRC only (NHSR, Exempt, Expedited, Full Board, Deferred to IRB of record)
- Comments

4.2   Study-Site

This section notes information about the study and the study site, such as:

Study-Site			
Site(s): ONL - Online data collection		**PI:** TEST, Researcher	
Status: Open		**Additional:** N	
Approval: October 10, 2017 for 12 months		**Expiration:** October 9, 2018	
Initial Approval: August 31, 2017		**Other Expirations:**	
Comments:			

- Site(s) (primary location of study)
- Status (open, pending, withdrawn, closed, etc.)
- Approval date (recent/current approval of continuing/annual renewal)
- Initial approval date
- PI – Principal Investigator
- Additional (not applicable)
- Expiration date (CITI certification)
- Other Expirations (if more than one expiration type)
- Comments (not currently being used)

4.3 Contacts

This section lists the contact(s) and role(s), if any, associated with the study.

▼Contacts (1)		
Action	**Name** ▼	**Role** ⇕
📝 ✖	Researcher, Test Ph.D.	Co-Investigator, Faculty/Staff

4.4 Events

This section lists all the IRB "events" or submissions that have been or are being conducted for this protocol. The event line contains the following sections:

- Event - type of event (Initial Submission, Modification, Continuing Review, Closure, etc.)
- Att – number of attachments associated with that event.
- FE – follow up event (currently not a field being used).
- Instance/UDF – information about an event; may be blank depending on responses in xForm.
- Start – the date the event was started or loaded into IRBManager.
- Complete – the date the event was completed and reported to the board.
- Last Mtg – shows the last meeting this event or review was submitted to. Even if a submission is expedited, it will show up in the meeting minutes for that month.

You can click on the blue event link in this section to view information specific to the event. After clicking on the blue link, it will take you to the event details (See section 5.0 Event Details).

5.0   Event Details

Event Details are specific to the event or submission for a study.

5.1   Study Site

The Study Site section shows basic study information, including protocol number, title, name of principal investigator, etc.

5.2   Event

The Event section shows specific details about the submission you are viewing.

These include:
- Type (Initial Submission, Continuing Review, Modification Request, etc.)
- Started
- Instance (for HSRC, documents or information modification event)
- Completed
- Committee (HSRC)
- Review Type (level of review for the event)
- Acknowledge/Approval/Determination Date - the date the event was completed.

5.3   Notes

Lists the summary of communication on the study, including any notes from HSRC to the research team and emails between HSRC and the research team that were sent within the IRBManager system. This section may be empty for many studies, and therefore not displayed.

Notes (1)			
Note	**Entered** ▲	**By** ♦	**Type** ♦
This study qualifies for waiver of signed, documentation consent.	10/24/2017	Sandra.Martinez@cwu.edu[deleted]	Reviewer

5.4   Steps

This shows the steps of the submission with the dates. Each event will have the steps listed with a planned date, actual date and when (if applicable) it will go to the full board for either review.

Steps (9)					☑ Hide Skipped
Step	**Planned**	**Actual**	**Complete**	**Minutes**	**Micro Note**
Receive Submission	10/24/2017	10/24/2017	Yes		
Internal Review		10/24/2017	Yes		
Send for Expedited Review		10/24/2017	Yes		
Notify Full Board of Expedited Approval	10/24/2017	04/18/2018	Yes	01/12/2018	
Notify PI of Review Decision		10/24/2017	Yes		
Approval Obtained		10/24/2017	Yes		

5.5   Actions in the Event Details

In the event details screen, Actions available are as follows:

- Attachments – shows the attachments related to the event.
- Send Email – Allows user to email HSRC administrator directly from IRBManage.r
- X-Forms – shows the form used to submit the event.

5.5.1 Attachments
"Attachments" Button: These are the attachments uploaded by the PI. This may also include consent forms, survey instruments and all other documents provided for this submission.

"Generated Docs" Button: These are the documents that have been generated by HSRC for this study.

5.5.2 xForms
Shows the application associated with the event. This is the application completed by the researcher.

6.0   xForms (Application Forms)

6.1   How to Open an xForm

6.1.1 Opening a New xForm for a New Study
On the left side of the screen, click "Start xForm" under the Actions menu.

This will open a new screen with a list of all of the application forms available and a description of each form. Click on the name of the form you wish to complete.

Note: Only certain forms are available from the Dashboard (i.e. new HSRC application forms). Forms that can be completed only after a study is approved (such as a Modification Request or Continuing Review form) are not available from the Dashboard; these must be opened from within a study (Section 6.2 below).
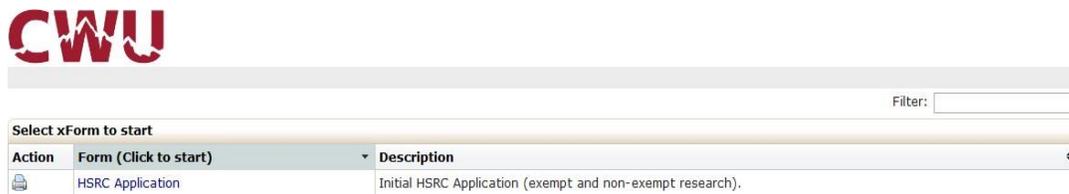
As described in more detail in Section 6.4 below, these forms use smart logic to guide the user through a series of questions. Depending upon the responses provided, additional questions may or may not appear. If you wish to see the entire form (i.e., all questions, regardless of the user's responses), this can be done by clicking the Print icon to the left of the form name.

6.1.2   Opening a New xForm for an Existing Study (Modification Request, Continuing Review, etc.)

In order to complete an event (submission) for an active study, such as a Continuing Review, Modification Request or Termination/Closure Report, you must first go to the study. Active studies can be found in the "My Studies" section on the bottom of the Dashboard (see Section 3.7 above).

Study-Site
Update
Add Attachment
Add Contact
Add Event
Add Note
Expirations
Generate Doc
Send EMail
Start xForm
xForms (1)

Once you are in the study, you click the Start xForm button under the "Study-Site" menu on the left. This will open a new screen with a list of all of the application forms available and a description of each form. Click on the name of the form you wish to complete.

6.1.3   Opening an Existing Unsubmitted Form

To return to a form you previously began, but did not yet submit, you can access the form via one of two methods:

- The "xForms" link under the "My Documents and Forms" menu on the left side of the Dashboard (see Section 3.3)
- The "You have _ unsubmitted xForms" link from the "xForms" section in the middle of the Dashboard (see Section 3.5)

Click on the form name to open the form and continue work on it.

6.2   Completing an xForm

6.2.1 General Instructions

xForms use smart logic to guide the user through a series of questions. Depending upon the responses provided, additional questions may appear. For example, if you answer that your study is funded, subsequent questions will prompt you to describe the funding source. If you indicate that you do not have funding related to the study, those subsequent questions asking about funding details will be hidden.

The majority of questions in the xForms require a response; however, some may be optional. IRBManager will not allow the user to submit the form until all required responses have been completed.

Note that some information in the form may be automatically generated. For example, when completing a Continuing Review form, the system will automatically populate the study details (such as project title, name of PI, etc.) on the top of the form.

Please carefully read all instructions provided on the form and answer all required questions.

6.2.2 Navigation Buttons at the Top of Each Page

The top of each xForm page will contain a header that looks as follows:
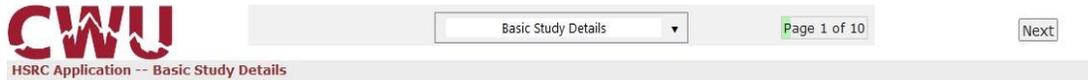
6.2.2.1 Page Titles Drop-down Menu

Allows you to "jump" between pages of a form before completing all required questions on a page. Note that depending on the responses to the questions in a form, entire pages of questions may not be required. Therefore, there may be some pages that are not listed in the drop-down menu.

6.2.2.2 Page Numbers

Shows "Page x of y" on each page of the form. Allows you to "jump" between pages of a form before completing all required questions on a page.

6.2.2.3 Next Button

Saves your progress on the current page and takes you to the next page in the form.

6.2.3 Navigation Buttons at the Bottom of Each Page

The bottom of each xForm page will contain a footer that looks as follows:
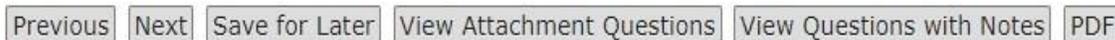
- Previous – Saves your progress on the current page and takes you to the previous page in the form.
- Next – Saves your progress on the current page and takes you to the next page in the form.
- Save for Later – Saves your current progress.
- View Attachment Questions – Shows only the questions in the form that have "Add Attachment" buttons.
- View Questions with Notes – Shows only those questions where a note has been added via the "Add Note" feature in the xForm (Section 6.2.4 Below) [Not available to HSRC investigators]
- PDF – Allows you to print/make/save the form as a PDF file. Note: Clicking "PDF" does not save the changes that you make to the form. To save changes to the form, you must click "Save for Later" before signing out of IRBManager.

6.2.4 Attaching Documents

Attachments can be added to xForms wherever an "Add Attachment" button is found.
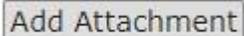
Add Attachment

Documents to be attached will depend on the xForm being submitted. For example, these may include consent forms, recruitment materials, letters of cooperation, etc.

To attach a document:
1. Click "Add Attachment".
2. Enter the name for your attachment. (Optional. If left blank, the system will use the filename.)
3. Select the type of attachment in the drop-down list. (On some questions only a certain type of document is intended to be attached, and the type is pre-set.)
4. Click the "Browse" button to locate the file on your computer or drag-and-drop file(s) into the box.
5. Click "Attach" to finish the process.
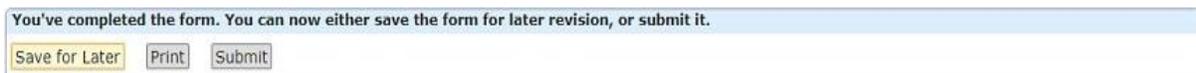
6.2.5 Signatures

Most xForms require the submitter to electronically sign the form and attest to the accuracy of the information provided within the form, as well as other compliance stipulations. This electronic signature is equivalent to a paper signature.

CWU-affiliated users: Click the "Sign" box. This will bring up a pop-up window for you to enter your CWU email and network password.

Externally affiliated users: Enter your IRBManager password in the signature box.

6.3   Submitting an xForm

Once all of the required questions have been answered and the form has been signed, IRBManager will allow you to advance to the submission screen.

You've completed the form. You can now either save the form for later revision, or submit it.
Save for Later   Print   Submit

You may either save the form for later, print the form, submit the form, or press the browser's back button to return to the previous page in the form.

You must click the "Submit" button to advance the form to the next person/office in the review process. The form will automatically route to the next person who is required to review and sign the form—you do not need to specifically add anyone to the form. If you choose any other action than "Submit," the form will remain in your list of unsubmitted xForms and will not reach HSRC.

Note: *Clicking "Submit" is equivalent to routing the paper version of the form for signatures. Once "Submit" is pressed, you will <u>not</u> have the opportunity to make any changes to the form unless it gets returned to you by someone who has reviewed it (e.g., faculty advisor, HSRC administrator, etc.).*

If an application form is submitted by someone other than the PI, the form will be routed to the PI. Only the PI can submit the form and forward to the next person in the review process.

Once the form has been submitted to HSRC (after PI submission and authorizing officials' approval), IRBManager will automatically assign a study event on the protocol page (see Section 4.0). You can then click on the event name (blue link) to track the event progress.

7.0 Authorizing Official Review

Authorizing Officials include faculty sponsors and department chairs. The following forms require Authorizing Official (AO) signature before being routed to the HSRC:
- Initial HSRC Application (New Protocol Submission Form)
- HSRC Modification Form (if PI is student)
- HSRC Continuing Review Form (if PI is student)

Certain departments may have additional review requirements for other forms. If these exist, they are automatically built into IRBManager and do not require additional action by the PI. All routing to AOs occurs automatically in IRBManager when the PI clicks "Submit."

AOs are automatically notified by the system via email when a PI has submitted a protocol for approval.

7.1 AO Viewing of Protocol

AOs can access the protocol via one of two methods.

7.1.1 Via Email
The AO will receive an email similar to the one below:

Hello "$$FacultySponsor$$",

Please review the HSRC application submitted by "$$ResearcherName$$" for the study, "$$StudyTitle$$". To sign and submit the application to the HSRC, please review the 'Investigator's Responsibilities and Assurances" page in the application. As faculty sponsor you agree to oversee the research and abide by the same assurances. If changes need to made to application, you may return the form to the student investigator and inform them of the revisions needed.

Click here to access the application directly: $$Form$$.

Let me know if you have any question.
Regards,
Sandy Martinez
Human Protections Administrator

The link in the email will take the AO directly to the form. (The AO will be prompted for their CWU email address and network password upon clicking the link.)

7.1.2   Via Dashboard

Alternatively, the AO can access the protocol from the xForms section in the middle of their Dashboard, under the "There are _ xForms awaiting your attention."

Clicking on the underlined link will open a screen with all xForms awaiting attention by the AO.

To open the form, click on the form name in blue.

Note: If the AO has xForms awaiting their attention for other reasons (such as from their role as a PI or committee member), the forms needing approval can be filtered by clicking the "Show forms requiring approvals ONLY" checkbox in the upper right of the screen.

7.2   Protocol Review

7.2.1   Reading the PI's protocol

Upon clicking open the form, the AO will see the entire application form as submitted by the PI. To review the protocol, simply scroll through the page. Additional features to aid in the review process:
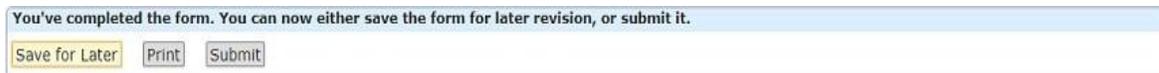
- "Hide Help Text" – this hides the form instructions the PI viewed when filling out the form. When this is checked, all responses from the PI will still be visible.
- Page Name Drop-Down menu at top of page – Use this to jump to a particular section of the form.
- Textbox – At the end of the application, you will be asked whether this application has been evaluated and determined to be complete and ready for submission to the HSRC. If the answer is 'No', you will be prompted to detail the changes that need to be made to the application in the textbox provided.

7.2.2 Completing the AO Review

Once you have finished reading the protocol, click "Next" either at the top of the page or at the very bottom of the page. This will take you to the AO review page.

If you approve the protocol:
1. Answer "Yes" to the question asking if the protocol is ready for submission to HSRC.
2. Read the AO attestation and electronically sign the form by clicking the "Sign" box and entering your CWU email address and network password.
3. Click "Next" to take you to the submission page.
4. Click "Submit."

You've completed the form. You can now either save the form for later revision, or submit it.
Save for Later   Print   Submit

Note: You must click "Submit" for the form to be routed to HSRC for processing.

If you require changes to the protocol:
1. Answer "No" to the question asking if the protocol is ready for submission to HSRC.
2. Enter the changes you want the PI to make in the text box. All text entered in this text box will be sent to the PI via email.
3. Click "Next" to take you to the submission page.
4. Click "Submit" to route the form back to the PI.
5. The PI will receive an email indicating you require changes. Once the PI has made the changes, the form will be routed back to the AO again for approval.

7.3   Post-AO Approval

For all forms requiring AO approval, the AO will be copied on all emails from HSRC to the PI, including final decision notifications.

Note: If HSRC needs to return the form to the PI for any reason, the AO approval process will need to be repeated upon re-submission of the form by the PI.

8.0   Help and Support

If you have any questions or problems using IRBManager, please contact the HSRC administrator at (509) 963-3115 or hsrc@cwu.edu.