

# Creighton University – InfoEd

## Responding to an IRB Modification Required Request

Last update: August 2022

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If you need help accessing InfoEd or need a profile created contact the Research Compliance Office at:

Phone: 402-280-3074

Email: [researchcomped@creighton.edu](mailto:researchcomped@creighton.edu).

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### Login to InfoEd

**Step 1:** Go to <https://creighton.infoedglobal.com>

**Step 2:** Use the Creighton University single-sign-on (SSO) by selecting **Click Here**.

or

Non-SSO users, using the login boxes enter in your assigned username and password.

Select the Sign in button.

Additional login and setup information is found in the InfoEd User Access Guide.

Your submission has been reviewed and is in a status of Modification Required. The IRB Administrator reviewing your application is requesting revisions. Please follow these instructions to update your application.

Per IRB policy your revisions should be completed and returned to the IRB within 60 days.

### 1. Logging into InfoEd and reviewing Assignment History comments.

To complete the requested revisions and see the comments from the IRB Administrator, click 'Log in' from the email link or access InfoEd at <https://creighton.infoedglobal.com>.

Submissions with the status of Modification Required are found in the Assignments tab. If using the Assignment tab, select the record number to open the Assignment page.

#### Assignments Tab:

The screenshot shows the 'Assignments' tab in the InfoEd system. The navigation bar includes Home, My Profile, Locate My Records, Locate Records, Calendar, Messages, Assignments, and a Quick Find search box. On the left, there is a sidebar with links for Sponsored Projects, Financial Tracking, Human Protocol, Env Health and Safety, Conflict of Interest, and SPIN. The main content area displays a table of assignments with the following columns: Module, Record Number, Record Owner / PI, Object, Record Status, Subject, and Assigned. A record with Record Number 2003339 is selected, and a pop-up window shows details for 'Modification Required'.

Module	Record Number	Record Owner / PI	Object	Record Status	Subject	Assigned
Human Subjects	2003339	Test, Password	Initial Application	Modifications Required	Modifications Required	27-Jul-2022 1:28:34 PM

Record Title: Modification Required  
Research Type: Biomedical  
Review Type: Not Human Subject Research  
Determination Date To:  
Risk Level:  
Administrator Name:

Assignment window:

**Assignment** I am done Close

Drag a column header and drop it here to group by that column

Module	Record Number	Record Owne...	Object	Record Status	Subject	Assigned
Human Subjects	2003339	Test, Password	Initial Application	Modifications Required	Modifications Required	27-Jul-2022 3:25:34 PM

Record Title	Modification Required
Research Type	Biomedical
Review Type	Not Human Subject Research
Determination Date To	
Risk Level	
Administrator Name	

Your submission has been reviewed. The administrator reviewing your file has questions or concerns that need to be addressed. Please follow these instructions to update your application:

- To see the comments left by the reviewer click 'Log In' in this email.
- When the page opens click on the eform listed on the top of the page.
- Open the form and uncheck the completed box on the top right-hand side of the form.
- See the notes made by the administrator by looking for the yellow triangle symbol with the exclamation mark in it.
- Make any changes required.
- When you are finished, recheck the completed box in the upper right-hand corner of the form.
- When the application closes click 'I am done' on the top right-hand side of the initial screen. Your changes will be sent back to the administrator for review.

Document/Form	Type	Status	Show Current Route	(Route History)
Creighton University HS eForm	Application	Completed	PDF	(Mandatory Form)
Test.docx	Attachment	Completed		(Mandatory Form)

Review the Assignment History for comments from the IRB Administrator.

**Finalize Assignment**

**Supporting Attachments (Optional)** [Add](#)

No Attached Documents

Comments:

Next Step/Decision: Return to Office

Assign to: Seiffert, Rosa - Research Comj

Assigned Date	Assigned To	Duration	Instructions	Completed Date	Completed By
17-Aug-2022 8:32:22 AM	Rosa Seiffert	0 days	Returned to Office - Initial	17-Aug-2022 8:51:54 AM	Rosa Seiffert

Comments	This is a status history comment, also comments within the application eforms.
Attachments	No documents have been attached.

## 2. Review comments within the application.

Open eforms by selecting the application listed under the Document/Form section.  
Example: Select the Creighton University HS eform.

**Assignment** I am done Clos

Drag a column header and drop it here to group by that column

<input checked="" type="checkbox"/>	Module	Record Number	Record Owner / PI	Object	Record Status	Subject	Assigned
<input checked="" type="checkbox"/>	Human Subjects	2003339	Test, Password	Initial Application	Modifications Required	Modifications Required	27-Jul-2022 1:28:34 PM

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Document/Form	Add	Type	Status		Show Current Route	(Route History)
Creighton University HS eForm		Application	Completed	PDF		(Mandatory Form)
Test.docx		Attachment	Completed			(Mandatory Form)

## 3. Unlocking the submission application.

The Complete box is found on the top right-hand side of all eforms.  
Uncheck the blue checkbox within the Complete box to unlock the form.

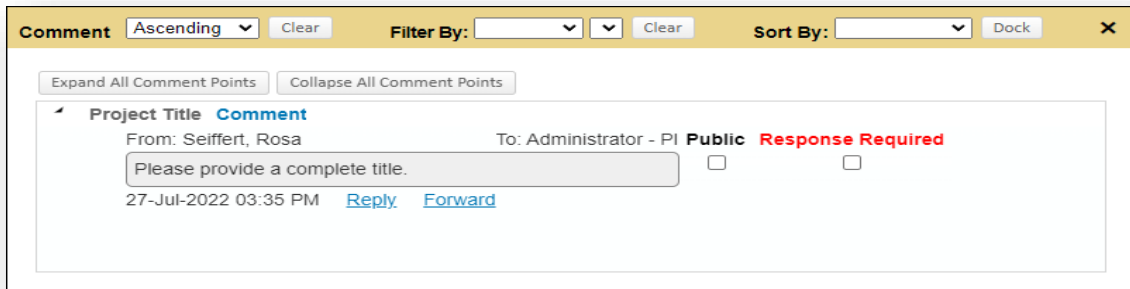
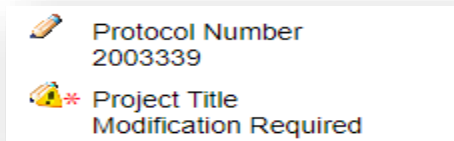
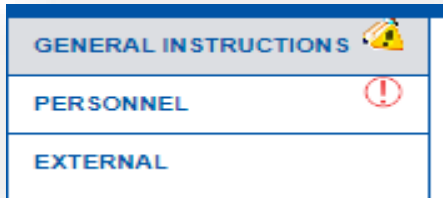
Close
Print
Form History
Save
Comments Panel
Complete

Updated By: Password Test @ 27-Jul-2022 01:19:01 PM

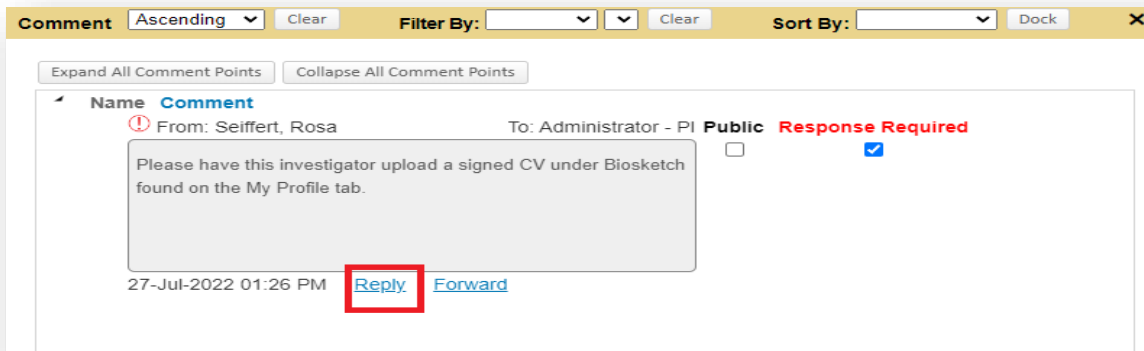
<p>GENERAL INSTRUCTIONS</p> <p>PERSONNEL <span style="color: red;">⚠</span></p> <p>EXTERNAL</p> <p>INVESTIGATORS/PERSONNEL</p> <p>PROJECT SITES</p> <p>FUNDING</p>	<p><b>GENERAL INSTRUCTIONS</b></p> <hr/> <p>Completion of this form is the first step in seeking human subject research approval at Creighton University. This form is to be completed by the Principal Investigator or his/her designee. All research personnel must complete required training, acknowledgements and financial disclosure per Creighton University <a href="#">policy</a>.</p>
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#### 4. Reviewing and responding to comments.

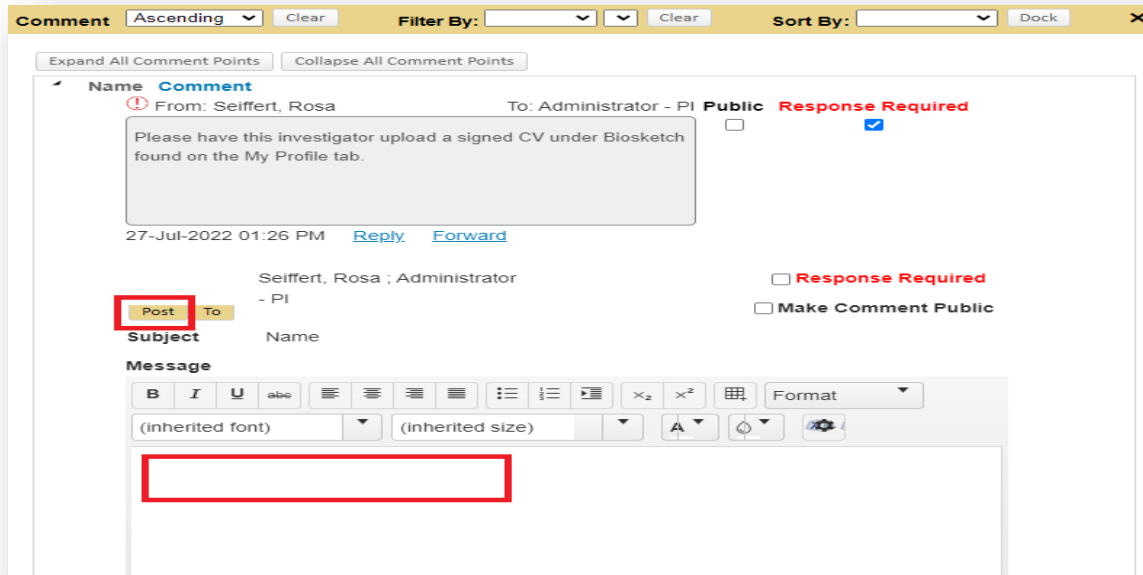
Review comments made by the IRB Administrator by selecting the yellow triangle and red exclamation marks. The red exclamation marks require a response from you. All comments can be seen within the left menu bar. To open and view comments, select the exclamation marks from within the application.



Select the reply link when required to add a comment.



Within the Message window add your comment and select the Post button. Please do not use the Response Required or Make Comment Public.

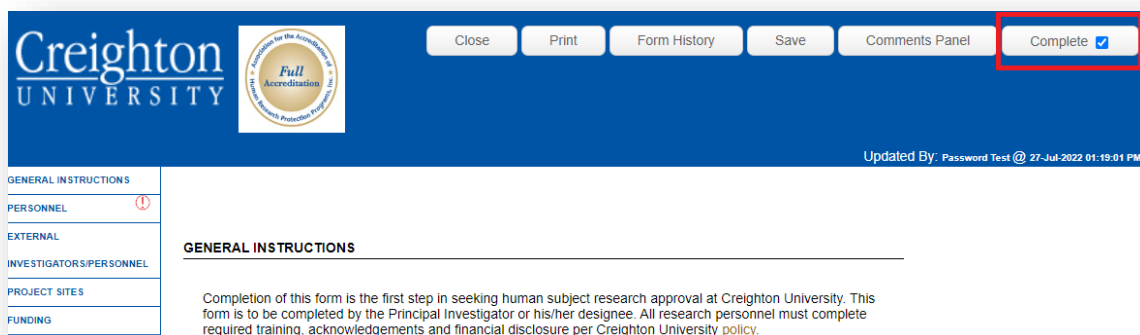


5. **Make requested revisions to the application.**

Make revisions as requested to the application.

6. **Completing and locking the application.**

When all revisions and comments have been made, check the Complete box.



## 7. Returning the application to the IRB Office.

After closing the eform application, select the “I am Done” button on the right top of the assignment window. Only after the I am Done button is selected will the application be returned to the IRB Office.

After returning the application to the IRB Office verify the following:

1. Your Assignments tab is empty and your submission status is Returned to Office.

