After you make a submission for COMIRB review, you will most likely receive one of several response letters from COMIRB through your assigned UC Denver.edu email. Make sure to check your CU Denver email frequently at https://webmail.ucdenver.edu, if you have forgotten your password visit https://passport.ucdenver.edu. If you are not CU Denver faculty or staff, you were assigned an email account when you applied for a POI Number. Please contact COMIRB@ucdenver.edu with questions.

These COMIRB responses may include:

1. **Certificate of Approval/Amendment Approval**: This letter indicates that your submission has been approved, and includes relevant dates of approval, as well as the documents approved for use with your study. Click here for instructions on how to retrieve your approved documents from the eRA(InfoEd) system. Watch for a notation at the beginning of the letter that indicates there have been changes requested by your next continuing review. Those requested changes will appear in the body of the letter.

2. **Minor Modifications Required**: This letter indicates that your submission will be eligible for approval after you make some minor changes to the documents that are stipulated by the reviewer(s). The stipulated changes will be listed in the body of the letter.

3. **Incomplete Submission/Return to PI**: This letter indicates that your submission was incomplete (i.e. it was missing essential documents). The requirements listed in the letter must be met before your submission can be considered for review.

4. **Referred/Deferred to Full Board or Deferred/Deferral**: These letters indicates that your submission includes issues that cannot be addressed by a single reviewer in an Expedited review, but instead must be reviewed by a Full Board of reviewers. You will receive a separate response letter for each submission reviewed. The response letter from COMIRB may or may not request that you make changes to that submission:
   a. If no changes are requested in a letter, you do not need to press the “Respond” button available next to the status, and your submission will be reviewed by a Full Board panel without any further actions necessary from you at that time.
   b. If changes are requested in a letter, this means that there are issues outlined in the letter you received that need to be addressed before your submission can be reviewed by a Full Board panel. Please take the steps outlined in these instructions to address the reviewer's comments.
If you receive a letter of **Minor Modifications, Deferral, Return to PI, or Referred to Full Board** please take the steps outlined in this document.

### STEP 1: LOGIN INTO ERA(InfoEd)

A. Navigate to [https://era.cu.edu](https://era.cu.edu) in your preferred Internet browser.

B. Enter your POI or CU Denver username and password. Select **DENVER** as the Campus.

C. Click the **SIGN IN** button.

### STEP 2: LOCATE AN EXISTING PROTOCOL

A. Select the **My Human Subjects Tab** from the menu located on the left-hand side of your browser window.

B. Click the **Search For** and enter the protocol number in the top field labeled **Protocol Number**.

C. Press Enter/Return. The results will appear at the bottom of the window. Select the ![icon](image) icon to open the study in a new window.
STEP 3: CREATE A RESPONSE

A. Review the SUBMISSIONS TAB once the study has opened. Here, previous eRA(InfoEd) submissions can be viewed. As indicated in the screenshot below, the current STATUS of your submission that requires a response could be: INCOMPLETE SUBMISSION, DEFERRED, or MINOR MODIFICATIONS.

![Submissions Table](image)

B. Click the blue **Respond** button to create a new submission that will allow you to respond to the issues outlined in the letter you received from COMIRB. Important Note: There may be multiple submissions that require a response from you. This means that you will need to click the **Respond** button for each submission, and need to go through the response process outlined in the steps below for each submission.

C. After you click the **Respond** link, you will then be asked to select what STATUS you are responding to. Select the appropriate response from the drop-down menu. Then click the Save button.

![Select Submission](image)

D. This will create a new RESPONSE TO submission and bring you to a new RESPONSE TO MINOR MODS/DEFERRAL/INCOMPLETE SUBMISSION (depending on which response you selected) screen. Please notice that everything you included in your original submission is now included in this submission with a status of completed, along with a new component titled COVER LETTER FOR RESPONSE TO REVIEW with a status of INCOMPLETE (outlined in green in the screenshot below).
**STEP 4: MAKE REQUESTED CHANGES**

A. Included in the letter you received from COMIRB requesting changes will be a description of what exactly the reviewer(s) would like the investigator to address within the documents that were submitted for review. Please **only** make changes to the documents requested by the committee. If you would like to make **additional changes** to the documents beyond the scope of what has been requested by the reviewer(s), please contact COMIRB at 303-724-1055.

B. Once you have made the necessary revisions to the documents, you will need to remove the old versions of those documents currently listed in the submission. To do this, click the **Remove** link next to the appropriate document.

C. To upload the revised version of that document, click the **Add** link. Which will open the upload window.

D. **NAME** the supporting document to be uploaded in the provided field. *Please name the document according to our [naming convention](#). Please remember to update the version date of documents when you revise the document. Please only update the version date of the documents you are revising.

E. Click on the button next to the subheading labeled **LOCATION**, and navigate to the folder, or location where you have saved the supporting document, and select it. **Please do not submit** Microsoft Office Documents in ‘read-only’ format.

F. Choose the appropriate **CATEGORY** that
most appropriately coincides with the supporting document. Please ignore the other sections marked out with red x’s in the screenshot to the right.

G. Click the **UPLOAD** button to add the document to the submission. Once the browser window has refreshed, click the **CLOSE** button to complete the document upload.

**Important Note:** Please pay particular attention to the instructions at the end of the letter you received from COMIRB. Please remember to upload a clean copy of each revised document, along with a copy of each revised document with the revised sections of text highlighted (meaning you will be separately uploading two copies of the revised document: one highlighted and one un-highlighted.) For Microsoft Word documents, COMIRB prefers that you use Word’s tracked change function to highlight documents. If you are submitting a completely new document, only a clean copy needs to be uploaded.

Also, you cannot electronically highlight the “Smart PDF” version of the Application for Protocol Review form, so you would only need to upload an un-highlighted copy of the revised document. **However,** if you are using the Microsoft Word version of the Application for Protocol Review form, please upload a highlighted and an un-highlighted copy because it is possible to use Word to highlight the revised sections.

**STEP 5: COMPLETE THE RESPONSE TO MINOR MOD/DEFERRAL/INCOMPLETE FORM**

A. To complete the **COVER LETTER FOR RESPONSE TO REVIEW** requirement, click the **Upload** link. This will allow you to upload a response cover letter.

Please include a point-by-point response to the requests from the Committee/Reviewer provided in the feedback letter you received requesting changes to your project. Your cover letter should also list the documents being included in your submission, along with version dates, to ensure the Reviewer(s) are clear on what documents are being submitted with this response.

**Step 6: Submit and Confirm COMIRB Has Received the Submission**

When the **NECESSARY** documents have been uploaded into the submission, you can **SUBMIT** to COMIRB

A. Click the **Submit** button located in upper right corner of the **RESPONSE** screen. If no button is present, please call COMIRB at 303-724-1055.

B. Select **ACCEPTED** on the **CERTIFICATION** window that appears. Click the **CONTINUE** button once you have finished.
C. Be aware that the next screen you see—ROUTE PATH SCREEN—only shows you the route your protocol is going to take. Your protocol has not yet been submitted until you click ‘submit’. Please do not click the link ‘Add New Person to Review Path’ marked out with a red X below. **If the submit it greyed out, please contact COMIRB at 303-724-1055:**

![ROUTE PATH SCREEN](image)

D. To confirm that COMIRB has received your submission. Check the STATUS in the top right-hand corner of the screen. If the status says IN DEVELOPMENT then the submission was not completed and you should click the submit button again or contact COMIRB at 303-724-1055. The PI should receive a submission confirmation e-mail, regardless of who submits.

E. When you have completed your submission, make sure to click the **Done** button in the top left hand corner of the screen to close the submission, otherwise, no one else will be able to edit the study later.

Mostly, COMIRB correspondence will be made through your UCDenver.edu email account at [https://webmail.ucdenver.edu](https://webmail.ucdenver.edu). If you have forgotten your password, please visit [https://passport.ucdenver.edu](https://passport.ucdenver.edu). If you are not CU Denver faculty or staff, you were assigned an email account when you applied for a POI Number.