eRA(InfoEd) Electronic Submission Instructions and Tips: Continuing Review

This instructional document introduces users to submitting Continuing Reviews of ongoing research protocols electronically through the eRA(InfoEd) system. Continuing review submissions must be submitted 45 days prior to their deadline. Submissions made after 45 days are not guaranteed to be reviewed before the protocol expires.

Electronic submissions to COMIRB are made through the eRA(InfoEd) system. If you are an employee of the University of Colorado Denver, you have the ability to log into this portal using your CU Denver employee login information. If, however, you are a researcher or staff member at a CU Denver Affiliate Site, user access to the eRA(InfoEd) system requires Person of Interest (POI) Number. If necessary, follow the instructions for obtaining access to the COMIRB eRA(InfoEd) data system and completing other tasks necessary to start or join a COMIRB study.

Important Note – Submitting An Amendment With A Continuing Review: If you would like to make any changes to your protocol, this must be submitted separately from your Continuing Review (meaning the investigator will have to go through the submission process twice to submit both an Amendment and a Continuing Review). The Continuing Review should only include documents that have been previously approved for use by COMIRB. Please submit the Amendment within 1 day of submitting the Continuing Review to ensure that they are reviewed concurrently. Click here for information on how to submit an Amendment.

**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 field labeled **PROTOCOL NUMBER**.
C. Press Enter/Return. The results will appear at the bottom of the window. Select the icon to open the study in a new window.

STEP 3: CHECK PERSONNEL CITI EDUCATION AND CONFLICT OF INTEREST DISCLOSURE

A. Once your study opens, the first step of the Continuing Review submission process is to ensure that all investigators and coordinators on your study have completed a recent Conflict of Interest Disclosure along with the necessary CITI Educational Courses. To do this, click the SUMMARIES tab, then click the PERSONNEL link.
B. The Research Personnel page will show you all of the research personnel currently active on your study. On this page, you can tell whether or not the research personnel have completed a recent Conflict of Interest Disclosure along with the necessary CITI Educational Courses. **Note:** individuals with the role of Administrator do not to complete the CITI Courses or a COI Disclosure.

To tell if everyone has completed a recent Conflict of Interest Disclosure, look in the column titled “COI” as indicated in the screen shot below. If the individual has an 🚹 image next to their name, that means they **have not** completed a recent COI disclosure, and need to do so prior to completing the Continuing Review submission. The other symbols, 🆘 or ✅, mean that they **have** completed a disclosure. Conflict of Interest Disclosures need to be completed once per academic year. The system is reset each year September 1st at which time a new disclosure needs to be made.

To tell if everyone has completed the necessary CITI Educational Courses, look below each person’s name. The two starred courses are the two required CITI courses: the COMIRB HS (Human Subjects Protection) Course and COMIRB HIPAA Course. The COMIRB HIPAA Course needs to be completed only once, so as long as it is listed, it is valid; however, the COMIRB HS Course needs to be updated every 3 years, so it is important to pay attention to the end date for this Certification.
C. If anyone needs to complete a COI Disclosure or refresh one of the required CITI courses. Click [here](#) for information on how to complete those tasks prior to submitting your continuing review to COMIRB.

D. After you have confirmed that all of the investigators and research coordinators have completed the required tasks, you are ready to navigate back to the **Submissions** TAB to start the continuing review submission. To do this, click on the **Submissions** tab in the navigation bar.

E. Review the **Submissions Screen**. Here, previous eRA(InfoEd) submissions can be viewed along with their corresponding submission statuses. Click the linked name of each submission to view and edit current and past submissions.
F. Select **CONTINUING REVIEW** from the drop-down menu located on the upper right-hand side of your browser window. Click the **ADD BUTTON** refreshing the window to the **AMENDMENT** screen.

The **CONTINUING REVIEW** screen looks like this:

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**Step 4: Complete the Continuing Review Application Submission**

The **COMPONENTS FOR CONTINUING REVIEW** screen serves as the workspace for uploading not only the required elements that must be completed with each study submission, but also all relevant supporting documentation. Below are links to the 5 steps required to submit a study for COMIRB review, you will find the links included again after each step in the process:

A. Download, edit, and upload the [Continuing Review Form](#)

B. Determine which [supporting documents](#) are needed for the review submission

C. Complete the [Personnel Form](#)

D. [PI Attestation Form](#)

E. [Submit to COMIRB](#)
A. **THE CONTINUING REVIEW FORM**

Download, edit, and upload the Continuing Review Form.

i. Download **CONTINUING REVIEW FORM** by clicking [here](#). Save the **CONTINUING REVIEW FORM** to your computer, then complete the form.

*To save the Continuing Review Form, or if it says Please Wait…, press the download icon in your internet browser to download the form to your desktop, then open the document from there using Adobe Reader (Always use an Adobe product to edit Continuing Review Form).

Download Icons - Firefox: 
![icon in the top right-hand corner](#); Chrome: ![icon in the bottom right-hand corner](#); Internet Explorer: ![icon in the top-left hand corner](#).

ii. On the **CONTINUING REVIEW** screen, click the **UPLOAD link**.

![Upload](#)

iii. Click on the button next to the subheading labeled **LOCATION**, navigate to the folder or location where you have saved the completed CRV form, and select it. (At this point you should be prepared to upload your completed form to the eRA(InfoEd) Portal.) **Please ignore the other fields on the upload page besides Location.**

![Upload](#)

iv. Once the document has been uploaded, click the linked document name **CR FORM** to view the uploaded form. Click the **REPLACE** link if you find that you need to replace the document you uploaded.
Step 4: Complete the Continuing Review Application Submission

   A. Download, edit, and upload the Continuing Review Form
   B. Determine which supporting documents are needed for the review submission
   C. Complete the Personnel Form
   D. PI Attestation Form
   E. Submit to COMIRB
B. Supporting Documents for Continuing Review

i. Click the hyperlink ADD link located on the CONTINUING REVIEW SCREEN.

![Continuing Review Screen](image)

<table>
<thead>
<tr>
<th>Form/Document</th>
<th>Type</th>
<th>Status</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR Form</td>
<td>CRV Form/Misc CRV Docs</td>
<td>Completed</td>
<td>Replace</td>
</tr>
<tr>
<td>Personnel Form (eForm) - CR</td>
<td>Personnel Form</td>
<td>Incomplete</td>
<td>(Mandatory Form)</td>
</tr>
<tr>
<td>PI Attestation</td>
<td>Internal Document</td>
<td>Incomplete</td>
<td>Upload</td>
</tr>
</tbody>
</table>

ii. *If your study uses the electronic version of the Application Form generated by the eRA(InfoEd) system please click here for instructions on how to add this Application Form to your submission. If not, move on to the next step.

iii. Name the supporting document to be uploaded in the provided field. *Please name the document according to our naming convention. Click here for a list of documents to be included for continuing review. Please do not update the version date of documents. The version date in the document name should reflect the version date on the document not the submission date.

iv. 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 the file.

*Please submit supporting documents as separate computer files and do not combine them as a single file; however, if you are using a version of the Application for Protocol Review form for which the Application and Attachments (A-T) are separate Microsoft Word files, please combine the Application and Attachments together as one PDF file, if possible. To do this, you will need the program Adobe Acrobat Pro.

v. Choose the CATEGORY that most appropriately coincides with the supporting document. Please ignore the other sections marked out with red x’s in the screenshot above.
vi. Click the **UPLOAD** button to add the document to the **CONTINUING REVIEW SCREEN**. Once the browser window has refreshed, click the **CLOSE** button to complete the upload. Select the linked name of each document to confirm that the supporting documents can be opened and are readable. Click the **REMOVE** link if you find that you need to completely remove the document.

![Image of Protocol v 11.24.14](image)

vii. Please always upload a **COVER LETTER** that generally outlines your request for review, includes any information you feel is important for the reviewer to be aware of, and includes an itemized list of all the documents included in the submission.

**Step 4: Complete the Continuing Review Application Submission**

A. Download, edit, and upload the [Continuing Review Form](#)

B. Determine which **supporting documents** are needed for the review submission

C. Complete the [Personnel Form](#)

D. [PI Attestation Form](#)

E. [Submit to COMIRB](#)
C. Personnel Form (eForm)

All individuals involved with the study should be included on the new interactive Personnel Form (eForm) available through the eRA(InfoEd) system. It is the investigator’s responsibility to ensure that the list of individuals included on the Personnel Form (eForm) is accurate. The Personnel Form should be identical to the individuals listed in the Application Form. If you are using the Smart PDF Application Form that only has space for 3 people to be listed, all additional Personnel, including the 3 people listed on the Application Form, should be listed on the Personnel Form.

Please follow these instructions to ensure that the personnel listed in the eRA(InfoEd) system are accurate.

If you wish to make changes to the personnel involved with your study, you must submit an Amendment requesting a change of personnel. If you only change those people listed in the Personnel Form and do not submit an Amendment, these personnel changes cannot be processed. Click here for information on how to submit an Amendment.

i. Click the linked document name to edit the Personnel Form (eForm).

ii. After you have confirmed that the personnel listed are correct, click the Save button, and then check the COMPLETE box located in the upper right corner of the browser window. The Personnel Form window will close and return to the COMPONENTS FOR CONTINUING REVIEW screen.

iii. If you find that you are unable to check COMPLETE box on the Personnel Form, click the CHECK OUT button in the top left hand corner of the form and ensure the form is “checked out” to you.
Step 4: Complete the Continuing Review Application Submission

A. Download, edit, and upload the Continuing Review Form

B. Determine which supporting documents are needed for the review submission

C. Complete the Personnel Form

D. PI Attestation Form

E. Submit to COMIRB
D. PI ATTESTATION FORM

The PI Attestation Form gives the ability for the Principal Investigator to have another individual listed on the study submit on behalf of the PI.

i. This requirement can be fulfilled in several different ways depending on whether or not the PI plans to submit themselves or plans to have another member of the study team submit on behalf of the PI. Click the linked name of the PI ATTESTATION form for instructions on the different options to meet this requirement.

ii. Once you have decided which option is appropriate for the PI, click the UPLOAD link to upload the appropriate document. Select the file location then click the upload button.

Step 4: Complete the Continuing Review Application Submission

A. Download, edit, and upload the Continuing Review Form

B. Determine which supporting documents are needed for the review submission

C. Complete the Personnel Form

D. PI Attestation Form

E. Submit to COMIRB

*Your submission should look approximately like this before you Submit to COMIRB (depending on the supporting documents you upload); the STATUS for all Forms should be COMPLETED:
<table>
<thead>
<tr>
<th>Form/Document</th>
<th>Add</th>
<th>Type</th>
<th>Status</th>
<th>Replace</th>
</tr>
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<tr>
<td>CR Form</td>
<td></td>
<td>CRV Form/Misc CRV Docs</td>
<td>Completed</td>
<td>Replace</td>
</tr>
<tr>
<td>Application Form v 11.24.14</td>
<td></td>
<td>Application/Protocol Summary</td>
<td>Completed</td>
<td>Replace</td>
</tr>
<tr>
<td>Consent Form v 11.24.14</td>
<td></td>
<td>Consent/Assent/Information Sheet</td>
<td>Completed</td>
<td>Replace</td>
</tr>
<tr>
<td>Cover Letter v 11.24.14</td>
<td></td>
<td>Emails/Letters</td>
<td>Completed</td>
<td>Replace</td>
</tr>
<tr>
<td>Personnel Form (eForm) - CR</td>
<td></td>
<td>Personnel Form</td>
<td>Completed</td>
<td>PDF (Mandatory Form)</td>
</tr>
<tr>
<td>PI Attestation</td>
<td></td>
<td>Internal Document</td>
<td>Completed</td>
<td>Replace</td>
</tr>
<tr>
<td>Protocol v 11.24.14</td>
<td></td>
<td>Protocol</td>
<td>Completed</td>
<td>Replace</td>
</tr>
</tbody>
</table>

Show Existing Protocol Attachments
**E. Submit and Confirm COMIRB Has Received the Submission**

When the **NECESSARY** documents have been uploaded into the submission, you can **SUBMIT** to COMIRB. Please note that this can only be done by the Principal Investigator for the study unless the appropriate form has been completed and uploaded for the PI Attestation Form.

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

ii. Select **ACCEPTED** on the **CERTIFICATION** window that appears. Click the **CONTINUE** button once you have finished.

iii. 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:**
iv. 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.

v. 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.**

vi. 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.