

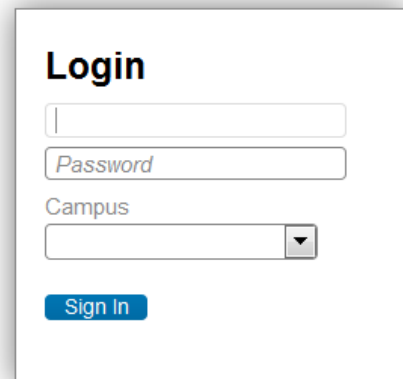
## eRA(InfoEd) Electronic Submission Instructions and Tips: Initial Application

This instructional document introduces users to submitting **NEW** research protocols electronically through the eRA(InfoEd) system. Make sure you know whether your project requires **EXEMPT**, **EXPEDITED**, or **FULL BOARD REVIEW**. Visit our [step-by-step guide](#) for more information. Before you can submit documents electronically, you should first review the following required elements to gain eRA(InfoEd) access. The [eRA\(InfoEd\) website](#) is where the COMIRB database and electronic submission website is housed. If you are an Employee of the University of Colorado Denver, you have the ability to log into this website 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) website requires Person of Interest (POI) Number. 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 On Study Access:** Access to studies on eRA(InfoEd) that are 'in development' is limited to the individuals listed on the study until its approval. This means only study personnel listed on the **PERSONNEL FORM (EFORM)** can edit or access the study prior to its submission to COMIRB. **If you are a coordinator working on a submission on behalf of your PI, make sure to complete the Personnel Form (Step 3.E. below) before exiting the submission to ensure that everyone has the necessary access.**

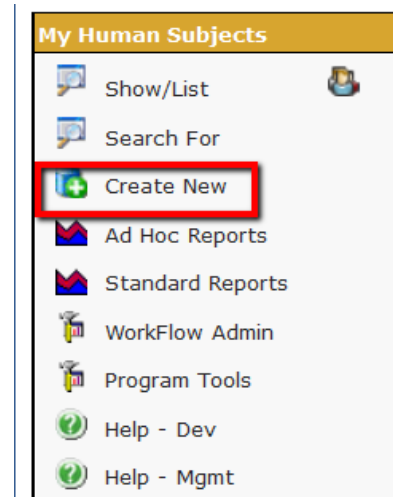
### STEP 1: LOGIN INTO ERA(INFOED)

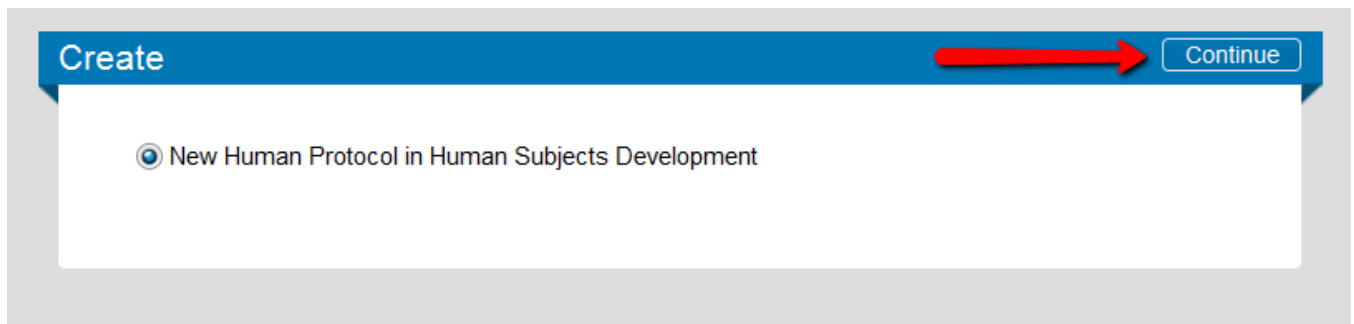
- Navigate to <https://era.cu.edu> in your preferred Internet browser.
- Enter your POI or CU Denver username and password. Select **DENVER** as the Campus.
- Click the **SIGN IN** button.



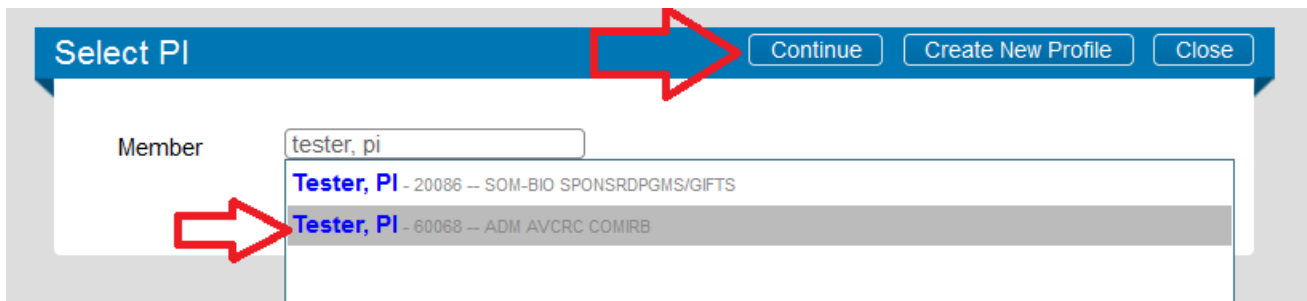
### STEP 2: Create A NEW PROTOCOL

- Select **MY HUMAN SUBJECTS TAB** from the menu located on the left-hand side of your browser window.
- Click the **CREATE NEW** and a **NEW** window will open.
- Click the **CONTINUE BUTTON**.

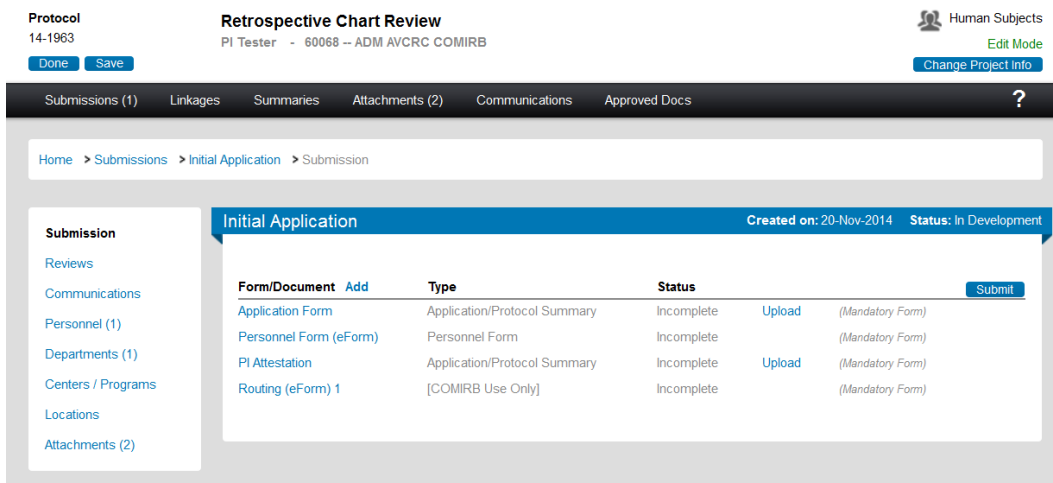




- D. Enter the protocol title and click the **CONTINUE BUTTON**.
- E. Select a **PRINCIPAL INVESTIGATOR**. Your name should appear in the field. To select someone else as the PI, delete your name from the field, then begin typing their name in the field in the format Last Name, First Name (e.g. Smith, John). There may be multiple listings for the same person. Please select the one with the relevant department after the name for the research being conducted.



- F. Click the **CONTINUE BUTTON**, refreshing the window to the **INITIAL APPLICATION** screen. Please note: once this screen refreshes, eRA(InfoEd) assigns your protocol number automatically. The number can be viewed in the upper left-hand corner of the screen. This is what the **INITIAL APPLICATION** screen looks like:






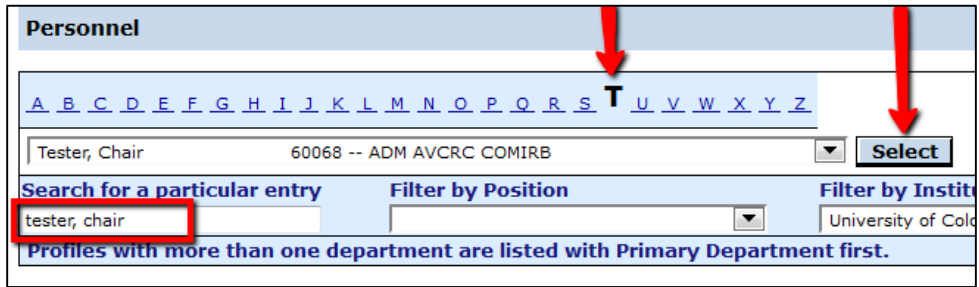
### STEP 3: COMPLETE PERSONNEL FORM (EFORM)

All individuals involved with the study should be included on the **PERSONNEL FORM (EFORM)**. It is the investigator's responsibility to ensure that the list of individuals included on the **PERSONNEL FORM (EFORM)** is accurate. Our new PDF Smart Application Form only includes room to list 3 individuals. These 3 individuals, along with everyone else involved in the study, should be listed on the **PERSONNEL FORM (EFORM)**.

- i. Click the linked document name to edit the **PERSONNEL FORM (EFORM)**.



- ii. Click the  button to add all of the personnel involved with your study, and click the  button to remove personnel. When you click the  button, the listed individuals are organized alphabetically according to **LAST NAME**. To select someone to add to the study, first select the first letter of the individual's last name from the list of letters, and then begin typing their last name into the "Search for a particular entry" field. The individual's name should then appear in the dropdown menu. Be careful when selecting a name; there may be more than one person with same name in the system. You may have to click on **DROP-DOWN MENU** to view other names. There may be multiple listings for the same person. Please select the one with the relevant department after the name for the research being conducted.



- iii. If an investigator has never been a part of a COMIRB study click [here](#) for information on obtaining access to the eRA(InfoEd) system and completing new investigator tasks.
- iv. Select an appropriate **ROLE** from the dropdown menu for each individual. Then, please make sure that the individuals you add have current Certifications that they completed the two required (starred) instructional courses: the **COMIRB HS (Human Subjects Protection)** course and **HIPAA Course**. The **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.

Primary Investigator  ~~Start Date~~ ~~End Date~~ \*Role

Certifications

Certification	Begin	End
CITI: Human Subj - Biomed Investig. Basic	07-Sep-2012	07-Sep-2015
HIPAA Research:CITI - HIPS-Clini Invest Basic	07-Sep-2012	
Human Subjects Protection (M)	07-Sep-2012	07-Sep-2015
*COMIRB HS Requirement	07-Sep-2012	07-Sep-2015
*COMIRB HIPAA Requirement	07-Sep-2012	
HIPAA Research (M)	07-Sep-2012	

- v. Please click [here](#) for information on how to update or complete Certifications for the courses, if necessary. **Also, Conflict of Interest Disclosures** need to be completed once per academic year. The system is reset each year September 1<sup>st</sup> at which time a new disclosure needs to be made. Instructions on how to refresh CITI Courses and submit a Conflict of Interest Disclosure can be found by clicking [here](#).
- vi. Please ignore the **START DATE** and **END DATE** marked out with red X's above.
- vii. If you find that you are unable to edit 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.



- v. Click the  button after everyone has been added, and then check  **COMPLETE** box located in the upper right corner of the browser window. The **PERSONNEL FORM (EFORM)** will close and return to the **COMPONENTS FOR INITIAL APPLICATION** screen.

**STEP 4: YOU ARE DONE!**

Once you have added all study personnel to the **PERSONNEL FORM (EFORM)**, you may exit the protocol by clicking the **DONE** button in the upper left-hand corner of the screen.

**NOTE:**

Once all initial application documents are complete and ready for submission through the eRA(InfoEd) Portal, refer to the **Initial Submission** instructions at the following link to complete the submission process: [How to complete Electronic Submissions using the eRA\(InfoEd\) system](#).