



Clinical Research Support Center

OFFICE OF REGULATORY COMPLIANCE

UNIVERSITY OF COLORADO

DENVER | ANSCHUTZ MEDICAL CAMPUS

Job Aid: Human Subjects Research Startup: Basic Steps

Accessing InfoEd, Submitting to the Human Subjects Research Portal, and Submitting to COMIRB

Author: Erin McDonagh, Regulatory Facilitator | Version 4.0, 27 Jan 2022

Helpful links

COMIRB – Initial Submissions: <https://research.cuanschutz.edu/comirb/home/submission-guides/initial-submission>

HSR portal: <https://research.cuanschutz.edu/crs/clinical-research-support/clinical-research-administration/human-subject-research-portals>

COMIRB forms and templates (including protocol templates):
<https://research.cuanschutz.edu/comirb/home/forms/comirb-forms>

Clinical Research Support Researcher Toolkit (templates for regulatory binders, SOPs and more):
<https://research.cuanschutz.edu/crs/clinical-research-support/our-services/clinical-trial-toolkit>

Support:

For help with general research and start-up related questions:

- Contact the CRS help desk: clinicalresearchsupportcenter@ucdenver.edu

For help with COMIRB & InfoEd:

- Go to [COMIRB's office hours](#) (no appointment necessary)
- Contact [COMIRB's help desk](#).
- Attend a hands-on InfoEd basics session, free to CU and affiliate students and staff. Upcoming sessions are listed as **CTSA33 - COMIRB Beginner's Guide to eRA (InfoEd) Basic Navigation and Processes**, on the [Research Events Calendar](#). CU learners can register in Skillssoft.

Research Startup Steps (If you've been involved with research before, you may be able to skip a couple of these):

1. **Gain access to InfoEd** ([more information](#))

InfoEd/eRA is the online database used to submit your study to COMIRB for IRB review or create a record in order to have your study's status tracked when using an external IRB. Access to InfoEd is automatic for most faculty and staff, but students and other researchers from our affiliates may need to take additional steps to gain access.

For faculty and students, log into InfoEd at <https://era.cu.edu>. Choose "Denver" or "Anschutz", your choice, and your login will be your CU credentials.

If you do not have InfoEd access, complete and submit the Person of Interest (POI) Form by clicking [here](#).

- Once your request is processed (usually about 2 days), your personal profile will be granted access.
- You'll receive an email that your POI number has been linked to your CU login. Wait one day for it to become active, then you should be able to log into InfoEd.

2. **Do your CITI training** – make sure to use your employee ID number or POI number to ensure it syncs with InfoEd.

- Complete online education courses through the [Collaborative Institutional Training Initiative \(CITI\) website](#).
- Instructions for registering for an account and completing your courses are available [here](#). Refer to the FAQ on this page for instructions.
- Refresh this education every 3 years.
 - The system does not send reminders; therefore, it is your responsibility to make sure you keep your CITI training up to date.

3. Upload a **current CV** to InfoEd (This is a requirement for individuals who will be listed as Investigators).

- Click "My profile" → "Biosketch" → "Add" → enter a name for your resume in the pop-up, and click "Choose File" → browse for your current CV → click "Upload" → The pop-up window will close, then click "Save" in the top right corner of the window.

4. Begin assembling and filling out the required documents for your COMIRB submission

- Review COMIRB's [list of documents required for IRB review](#) to get a sense of what forms/documents you'll need to submit. **The protocol is a good starting point.**
- Go to COMIRB's ["Forms" web page](#) to access the various forms and templates and begin filling them out.

- If you have questions or concerns about which documents you'll need or how to fill them out, contact COMIRB at COMIRB@ucdenver.edu, or come to [COMIRB Office Hours](#)

5. Create your submission in InfoEd

Creating your submission in InfoEd will generate a protocol number for your study. You'll need this number to submit to the Human Subjects Research (HSR) portal (step 6) for review, then you'll need the "clearance letter" obtained via the HSR portal to finish your submission to COMIRB in InfoEd (step 7), so there's a little back and forth from here on out – You'll create a submission in InfoEd, then you'll submit to the HSR portal, THEN you'll finish submitting your study to COMIRB in InfoEd.

- In InfoEd, go to "Human Protocol".
- Select "Create New Human Protocol".
- Click "Continue".
- Enter the protocol title – NOTE: You can't go back and change that title once you leave this screen. If you need to change your protocol title, contact COMIRB.
- Select the P.I. – This DEFAULTS to the person creating it, but you can just type in the PI's [last name], [first name] to look them up. If you need to change the PI later, you will need to contact COMIRB.

Once you hit "Continue", this will take you to initial application screen, which contains a list of mandatory documents that will eventually need to be submitted to COMIRB. For now, just worry about the Personnel Form.

You MUST add yourself onto the personnel form before closing out, otherwise you will not be able to access the study!

- To add someone, open the personnel form and click the little yellow plus sign lower on the left-hand side, then look them up by clicking on the letter of their last name, then search by typing [last name], [first name]. Pick a role for each person you're adding.
- Add any key personnel that will need access to the study in InfoEd or will be primary contacts for COMIRB. Other research staff and PRAs don't need to be added.
- Faculty advisors/mentors are considered full investigators and need to have everything (CV, COI) that a P.I. would have.
- Sometimes someone is a primary investigator and primary contact – In that case, add them twice.
- When done, click the "Complete" checkbox and then "Save".
 - To remove people, just uncheck "Complete" on the personnel form in top corner; then you can re-edit.

6. **Submit to the Human Subjects Research (HSR) Portal** (requires protocol number, personnel form, and protocol)

- Access the HSR Portal [here](#). Complete the questions, provide your COMIRB protocol number, and upload your protocol to the portal. Additional documentation may be required, based on the specifics of your protocol (e.g., Draft CTA, Investigational Brochure, etc.).
- After you submit, the portal administrator will triage review of your protocol to the appropriate departments.
- You will either get an automatic HSR Portal clearance email

OR

- You will receive notice that further review (i.e., PRMS/SARC) is required. Once that review is complete, the portal team will send you an HSR Portal clearance email.

Once you receive the HSR Portal clearance email from the portal team, you will need to upload it into InfoEd to finalize your submission to COMIRB.

Do you need OnCore training?

- Submitting your study to the HSR Portal will determine whether your study will require a build in OnCore.
- You or other study team members may need to access OnCore to manage protocol details and complete signoffs in the system. System signoffs must be completed to open your protocol to accrual.
 - If you're not sure who on your team needs OnCore access, contact oncoresupport@ucdenver.edu after you receive your HSR Portal clearance email.
 - Visit the [OnCore Access and Training webpage](#) for more information.
- Anyone on your team who needs access to OnCore and doesn't already have it should then:
 - Fill out the [OnCore Access Request Form](#)
 - Based on the information you provide on the form, you will be instructed as to which trainings you need to attend. **Be sure to note this information before you submit the form.**
 - Then, register for training in Skillsoft. You can search for the different OnCore courses by entering "OnCore" in the "Search Content" field.
 - Once you complete your training, you'll be equipped with the knowledge you need to manage your protocol in OnCore. Access to OnCore will be granted after you complete your training and certification exercises. Contact oncoresupport@ucdenver.edu if you have any questions.

7. **Submit your study to COMIRB for review**

For help, go to [COMIRB's office hours](#) (no appointment necessary), contact [COMIRB's help desk](#), or attend a hands-on InfoEd basics session (CTSA33 on the [Research Events Calendar](#)).

- Besides the Protocol and Application, [other documents may be required for COMIRB review](#). Other required documents include (but are not limited to):
 - **Consent Form**
 - **Advertising/recruitment materials** (if applicable)
 - **Institutional approval letter** (that email from the HSR portal)
 - **PI Attestation form** (located on the COMIRB [Forms page](#))
 - The PI can fill this out and electronically sign, or wet-ink sign/scan/ for upload to InfoEd OR
 - A coordinator can email the form to the PI and the PI can confirm their agreement to follow the rules in a reply email. The email should be uploaded to InfoEd with the form.

- Make sure to include version numbers and dates when uploading your documents, especially protocols and applications.

To upload documents to InfoEd

- Log into InfoEd and go to the “Initial Application” for your study.
- Click the link to upload each listed document in the Initial Application.
- For documents that aren’t listed:
 - Click the blue word “Add” directly next to/right of the header “Document/Form” (toward the left side of the page).

Initial Application		Created on: 18-Jul-2019	Status: In Development	
Document/Form	Add	Type	Status	Submit
Application Form		Application/Protocol Summary	Incomplete	Upload (Mandatory Form)
Personnel eForm 1-3-15		Personnel Form	Incomplete	Upload (Mandatory Form)
PI Attestation		[COMIRB Use Only]	Incomplete	Upload (Mandatory Form)
Routing - Initial 5-27-19		[COMIRB Use Only]	Incomplete	Upload (Mandatory Form)

- In the “Upload” pop-up:
 - Click “Browse”, locate the document, then click “Open” in the bottom right, then “Add” in the top right corner.
 - Pick a category from the dropdown under the “Browse” button.
 - Edit the name of the document to include a version date (e.g., “Protocol v 01.01.2019”).
 - Click upload in the top right.
- You can upload the next document immediately.
- Click the close button to complete upload of your documents – **don’t just “X” out!**

- When you are ready to send everything to COMIRB for review, click “Submit” on the top right-hand side.
8. The submission will then be routed to appropriate COMIRB panel for **IRB review**. COMIRB will make their determination and notify you.
9. **Register your study on ClinicalTrials.gov** (if applicable)
- You must register your **human subjects research** on [ClinicalTrials.gov](https://clinicaltrials.gov) before enrolling your first participant if:
 - the study is an Investigator-Initiated Trial (IIT) with a CU faculty member as its Principal Investigator,
 - AND**
 - your study is an Applicable Clinical Trial (ACT) – here is a [checklist](#) to help make that determination, **OR**
 - your study is a clinical trial (including behavioral & phase 1 trials) which is wholly or partially funded by NIH or another government agency, **OR**
 - you plan to publish research from your clinical trial in an ICMJE-affiliated journal, **OR**
 - you are otherwise required to register by the funder (e.g., Bill & Melinda Gates Foundation; PCORI-funded studies, including observational studies).
 - If you are not sure whether you need to register, if you need help registering your study, or to request a ClinicalTrials.gov account:
 - Email Clinical Research Support at clinicalresearchsupportcenter@ucdenver.edu
 - Visit [our ClinicalTrials.gov webpage](#).
 - Note: Please do not contact ClinicalTrials.gov directly for access or with questions. Contact clinicalresearchsupportcenter@ucdenver.edu.

If you need help assembling your study regulatory binders, SOPs, or subject binders, refer to the templates in our [Researcher Toolkit](#).

Please email us at clinicalresearchsupportcenter@ucdenver.edu if you have any questions!