



Expedited Applications: COMIRB Submission

Step 1: Obtain A COMIRB Protocol Number

1. Go to the [COMIRB website](#)
2. Log in using your e-mail and password
3. Click “Register” to obtain a login if you don’t have one
4. Select the “Protocol Manager” menu item on the left
5. From Protocol Manager select “Request New Number”
6. Choose your role on the protocol (PI or Study Coordinator) hit “Next”
7. Complete the rest of the request form and hit “Submit”
8. You will receive and E-Mail notification of your protocol number which you use on protocol application and related forms..

Step 2: Complete Human Subjects Training

1. Go to the website: www.citiprogram.org
2. Click on ‘Register for this Course’ located ABOVE the User Name and Password entry.
3. Select University of Colorado at Denver and Health Sciences Center - COMIRB as your institution in the “All Others” Participating Institutions.
4. Create your UserID and Password.
5. Enter Personal Contact Information.
6. Select “I have not previously completed an approved Basic Course.”
7. When you get to the table of contents page, click on the “Grade Book” link.
8. Complete all required CITI Modules.
9. Your CITI Completion will be automatically e-mailed to the COMIRB Office in step #3 was completed correctly.

Step 3: Complete HIPAA Research Training

1. Go to the website: <http://blackboard.cuonline.edu>.
If you are an employee of the Health Sciences Center – enter your 6 digit employee ID number as your username and again as your password. If you are a UCHSC student, use your student ID number as both username and password.
2. All UCDHSC affiliates, who are not UCDHSC employees (i.e. DH, VA, TCH), will need to be set up in PeopleSoft as what are called Persons of Interest (POIs). The POI number will then be used to login to Blackboard to take the appropriate training.
You will need to contact the Department Administrator of the individual listed on your specific Protocol that is associated with the UCDHSC (i.e.: the Principal Investigator, or Co-PI). Their department administrator will be able



to assign POI's, or direct you to someone within their department that has PeopleSoft access and will be able to assist you.

For more specific information on the process for assigning a POI number in PeopleSoft HRMS please see the PBS Step-By-Step Guide called "Add a Person (POI Types including Pre-Employment) – Workforce Administration Module. All PeopleSoft Step-By-Step guides are available at: <https://www.cu.edu/pbs/hrms/resources/sbs.html>

3. To enroll in the HIPAA Research Course-COMIRB Health Sciences Center, click on the UCDHSC Training tab.
Select the HIPAA Research Course-COMIRB Health Sciences Center and click the enroll button on the right of the course.
To take the test after the course, click HIPAA Research Review, (in green, second option.)
Once you have successfully completed the HIPAA Research Course-COMIRB Health Sciences Center with 80% or better, please print your certificate (located on the right upper corner of the screen under "Your Certificates") and fax, e-mail, or mail it to COMIRB.

Step 4: Complete The COMIRB Application

Complete the COMIRB Application for Protocol Review and include Attachment F: Researcher Requesting Expedited Review. Include all other relevant attachments. The application must have the Principal Investigator's (PI) signature and, if the researcher is a student, a faculty advisor signature.

The principal investigator must also submit a protocol outlining the science for review.

E-mail an electronic copy of the consent form to comirb@uchsc.edu.

Step 5: Submit The Application Packet

Submit one copy of the following documents to COMIRB:

1. Cover Letter
2. COMIRB *Application for Protocol Review* and *Attachments*
3. Protocol
4. HIPAA authorization form(s)
5. Consent Form (if applicable)
6. Grant (if federally funded)
7. COI disclosure form (and management plan if applicable)
8. Affiliate or other committee approvals (if applicable)



9. Non-Affiliated site approvals (if applicable)
10. Any supporting documents such as diaries, surveys, advertisements, etc.

Submit to the COMIRB administrative office:

**COMIRB/UCHSC, MS F490
13001 E. 17th Place, Room N3124
P.O. Box 6508**

All documents must be submitted with COMIRB protocol number, revision date, PI name, and page numbers in the header or footer.

Step 6: Review Determination

Expedited applications are reviewed by COMIRB Chair or designee. Review determinations usually take between 4-5 weeks. The investigator will be notified in writing of the review findings.