What CITI Training is required?

I need to renew my CITI training.

How to affiliate with UCD in CITI: step-by-step instructions for individuals who do NOT have a CITI account.

How to affiliate with UCD in CITI: step-by-step instructions for individuals who DO have a CITI account.

UCD + VA Affiliation: how to complete CITI training affiliations for the FIRST time.

UCD + VA Affiliation: Already affiliated with VA, completed the BASIC course, needs to add UCD affiliation.

UCD + VA Affiliation: Already affiliated with VA, completed the REFRESHER course, needs to add UCD affiliation.
What CITI training is required?

All individuals listed on a COMIRB submission must **add** one of the following groups of trainings:

1. **Group 1 Biomedical Investigators** ← this is the Human Subjects training requirement
2. **GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)** ← this is the GCP training requirement
3. **CITI Health Information Privacy and Security (HIPS) for...** ← this is the HIPAA requirement
   - a. Clinical Investigators OR
   - b. Students and Instructors

**OR**

1. **Group 2 Social and Behavioral Research** ← this is the Human Subjects training requirement
2. **CITI Health Information Privacy and Security (HIPS) for...** ← this is the HIPAA requirement
   - a. Clinical Investigators OR
   - b. Students and Instructors

**In order to add GCP to a CITI profile, Group 1 **MUST** be added to the individual’s CITI profile**

All study staff must be up-to-date on/complete their Human Subjects training (Group 1 or Group 2) as well as their HIPAA training (HIPS). Required training must be taken once every three years.

**If the study involves drugs or devices (attachment C and/or D is present on the Application for Protocol Review form) then the PI of the study must also complete GCP training.**

Notes:

1. In the past, COMIRB required the HIPAA course be completed only once. Now COMIRB requires the HIPAA course be retaken every three years with the Human Subjects refresher course. If the Human Subjects course was taken on or after May 1st, 2016, the HIPAA course must be current.
2. The HIPAA course does not need to be completed by investigators whose research takes place solely at the Downtown Denver Campus or the Colorado School of Public Health.
3. If a GCP course was taken by any study team member on or before August 31st, 2015, the GCP course will count as both the Human Subjects and GCP requirements until expiration.
4. If a GCP course was taken on or after September 1st, 2015, the Human Subjects course is required for all study members and the GCP is required for the PI if the application includes Attachments C and/or D.
I need to renew my CITI training.

1. If you have taken the CITI Courses before and are refreshing your education, log in to the CITI website at https://www.citiprogram.org/.

   Upon logging in, you should see a blue tab titled 'University of Colorado Denver Courses'.

   ![University of Colorado Denver Courses](https://www.citiprogram.org/)

   If you click on the tab, you should see the header 'Course' with a list of your courses and the status of the courses. If yours does not say 'University of Colorado Denver', please affiliate with UCD by following the steps here.

2. Under the 'Status' header for each course you need to complete should say either 'Not Yet Started' or 'Incomplete.' Complete the listed courses per COMIRB’s requirements here.

3. You may have selected additional courses, but COMIRB requires the following courses for all listed personnel (**these courses need to be completed every three years**):
   a. HS Course Requirement (pick one):
      i. Group 1 Biomedical Investigators, Basic Course
      ii. Group 2 Social and Behavioral Research
   b. HIPAA Course Requirement
      i. CITI Health Information Privacy and Security (HIPS)
         1. Make sure you selected either the course for “clinical investigators” or for “students and instructors.”
      ii. This required course is only available by clicking on Group 1 or Group 2 options.

         **Please note, in the past COMIRB required this course be completed only once. Now COMIRB will require that the HIPS course be retaken every three years with the HS refresher course.**

         If you have already taken the HIPS course, and it is expired, COMIRB requires that the HIPS course be retaken when your current HS course expires.

         ***This course does not need to be completed by investigators at the Downtown Denver Campus and investigators whose research is solely within the Colorado School of Public Health.***
   c. GCP Course Requirement – **PI’s only**
      i. This required course is only available by clicking on Group 1.
      ii. COMIRB gate-keeps GCP training only for Principal Investigators who have COMIRB applications with Attachment C and/or D.
      iii. Course name: GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus).
      iv. If a CITI GCP course was taken by any study team member on or before August 31st, 2015, the GCP course will count as both the HS and GCP requirements until expiration.
         1. Please note, when this course expires, you will be required to take both HS and GCP courses.
      v. If a GCP course was taken on or after September 1st, 2015, the HS group is required for all study members and GCP is required for the PI if the application includes Attachments C and/or D.
How to affiliate with UCD in CITI: step-by-step instructions for individuals who do NOT have a CITI account.

1. Go to the CITI Program website: [https://www.citiprogram.org/](https://www.citiprogram.org/)
2. Create an account
3. Affiliate with “University of Colorado Denver"
4. Complete steps 2-6 of the CITI learner registration.

Please note on step 6: Anything can be entered for the employee ID# or POI# initially. Once the POI# request has been processed, the investigator will receive their POI#, which should then be entered into their UCD CITI profile so InfoEd and CITI can link.
5. Step 7 is to add the appropriate trainings. COMIRB requires investigators take either Group 1: Biomedical Investigators or Group 2: Social and Behavioral Research.

* indicates a required field.

Choose one answer

- Group 1: Biomedical Investigators
- Group 2: Social and Behavioral Research
- Group 3: COMIRB Panel Members
- Group 4: Good Clinical Practice and ICH (GCP) for industry-sponsored studies only

Investigators should only pick Group 2 if they will solely be engaged in social/behavioral research.

**Group 1 required steps:** Select “Group 1” >> “GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)” >> “CITI Health Information Privacy and Security (HIPS) for Clinical Investigators” >> for the remaining pages investigators may click “No” or “Not at this time” at the bottom of each page.
6. Once registration is finalized, the investigator should immediately be brought to their UCD CITI Profile

7. If a PI has Attachments C or D in their Application, they are required to take the GCP course. COMIRB does not gate keep GCP courses for anyone other than PIs. This means COMIRB does not require co-investigators, PRAs, etc. to take the “GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)” course. **ALL individuals listed on a submission MUST complete the Group 1 and HIPS courses.** The status will indicate if a course is complete or not when it says “Passed xx/xx/xxx” in green lettering.

**EXAMPLE:**

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11/17/2014
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8. Once the POI# has been received, the individual **MUST** update their UCD CITI profile to reflect the appropriate POI# so the CITI courses can transfer to InfoEd.
How to affiliate with UCD in CITI: step-by-step instructions for individuals who DO have a CITI account.

1. Log into the CITI Program website: https://www.citiprogram.org/
2. Click “Main Menu” and then “Click here to affiliate with another institution.

3. Affiliate with “University of Colorado Denver
4. Complete the information requested by UCD. Please note: Anything can be entered for the employee ID# or POI# initially. Once the POI# request has been processed, the investigator will receive their POI#, which should then be entered into their UCD CITI profile so InfoEd and CITI can link.

5. Add the appropriate trainings. COMIRB requires investigators take either **Group 1: Biomedical Investigators or Group 2: Social and Behavioral Research**.

Investigators should only pick Group 2 if they will solely be engaged in social/behavioral research.

**Group 1 required steps:** Select “Group 1” >> “GCP for Clinical Trials with Investigational Drugs and Medical
6. Once registration is finalized, the investigator should immediately be brought to their UCD CITI Profile

7. If a PI has Attachments C or D in their Application, they are required to take the GCP course. COMIRB does not gate keep GCP courses for anyone other than PIs. This means COMIRB does not require co-investigators, PRAs, etc. to take the “GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)” course. ALL individuals listed on a submission MUST complete the Group 1 and HIPS courses. The status will indicate if a course is complete or not when it says “Passed xx/xx/xxx” in green lettering.

EXAMPLE:

8. Once the POI# has been received, the individual MUST update their UCD CITI profile to reflect the appropriate POI# so the CITI courses can transfer to InfoEd.
1. VA employees must request a POI# for access to InfoEd (eRA) here: http://www.ucdenver.edu/research/comirb/POInumber/Pages/POIform.aspx
   POI# is required for step 9 below.
   VA Affiliation takes place starting at step 10.

2. Go to the CITI Program website: https://www.citiprogram.org/

3. Create an account
4. Affiiliate with “University of Colorado Denver

5. Complete steps 2-6 of the CITI learner registration.

Please note on step 6: Anything can be entered for the employee ID# or POI# **initially**. Once the POI# request has been processed, the investigator will receive their POI#, which should then be entered into their UCD CITI profile so InfoEd and CITI can link.
6. Step 7 is to add the appropriate trainings. COMIRB requires investigators take either Group 1: Biomedical Investigators or Group 2: Social and Behavioral Research.

![CITI - Learner Registration](image)

* indicates a required field.

![Human Subjects](image)

Investigators should only pick Group 2 if they will solely be engaged in social/behavioral research.

**Group 1 required steps:** Select “Group 1” >> “GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)” >> “CITI Health Information Privacy and Security (HIPS) for Clinical Investigators” >> for the remaining pages investigators may click “No” or “Not at this time” at the bottom of each page.
7. Once registration is finalized, the investigator should immediately be brought to their UCD CITI Profile.

8. If a PI has Attachments C or D in their COMIRB Application, they are required to take the GCP course. COMIRB does not gate keep GCP courses for anyone other than PIs. This means COMIRB does not require co-investigators, PRAs, etc. to take the “GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)” course.

   **ALL individuals listed on a submission MUST complete the Group 1 (or Group 2) and HIPS courses.** The status will indicate if a course is complete or not when it says “Passed xx/xx/xxx” in green lettering.

   **EXAMPLE:**

   Passed
   11/17/2014

9. Once the POI# has been received, the individual **MUST** update their UCD CITI profile to reflect the appropriate POI# so the CITI courses can transfer to InfoEd.
10. Once all UCD CITI Training is complete, please add the Denver VA as an affiliate. Click on “Main Menu,” then, “Click here to affiliate with another institution”

11. Affiliate with “VA Denver, CO-554”
12. Complete the forms, and once you have filled in the required information, please select one of the following options:

**Question 1**

Click to indicate which situation best describes your status in VA human subjects web-based training:

- I am not involved in VA research with human subjects, so I am not required to take VA training in this area. (No VA human subjects protection coursework will be added to your curriculum.)
- I am (or expect to become) involved in research with human subjects at the VA, but have never completed training in human subjects protection that satisfies VA requirements, or have been told that I must take the Basic course. (You will be placed in the first stage of the VA human subjects protection curriculum.)
- I am (or expect to become) involved in research with human subjects at the VA, and have previously completed training in human subjects protection that satisfies VA requirements, or have been told that I qualify to take the Refresher course. (You will be placed in the refresher stage of the VA human subjects protection curriculum.)
- I am (or expect to become) involved in Biomedical research with human subjects at both the VA and the VA’s affiliate, but have never completed training in human subjects protection that satisfies VA requirements, or have been told that I must take the Basic course. (You will be placed in the first stage of the human subjects protection curriculum for Biomedical Investigators that satisfies the requirements of both VA and the VA’s affiliate.)
- I am (or expect to become) involved in Biomedical research with human subjects at both the VA and the VA’s affiliate, and have previously completed training in human subjects protection that satisfies VA requirements, or have been told that I qualify to take the Refresher course. (You will be placed in the refresher stage of the human subjects protection curriculum for Biomedical Investigators that satisfies the requirements of both VA and the VA’s affiliate.)
- I am (or expect to become) involved in Social and Behavioral research with human subjects at both the VA and the VA’s affiliate, but have never completed training in human subjects protection that satisfies VA requirements, or have been told that I must take the Basic course. (You will be placed in the first stage of the human subjects protection curriculum for Social and Behavioral research that satisfies the requirements of both VA and the VA’s affiliate.)
- I am (or expect to become) involved in Social and Behavioral research with human subjects at both the VA and the VA’s affiliate, and have previously completed training in human subjects protection that satisfies VA requirements, or have been told that I qualify to take the Refresher course. (You will be placed in the refresher stage of the human subjects protection curriculum for Social and Behavioral research that satisfies the requirements of both VA and the VA’s affiliate.)

**Option 1:** Pick this option if you selected “Group 1 Biomedical Investigators” when you affiliated with UCD.

**Option 2:** Pick this option if you selected “Group 2 Social Behavioral Research” when you affiliated with UCD.

Your course work should automatically complete with the VA Affiliation (this is an example if you completed Group 1):

![CITI Program](image-url)
UCD + VA Affiliation: Already affiliated with VA, completed the BASIC course, needs to add UCD affiliation

1. Retrieve POI#. If VA employee needs to request a POI#, do so here: http://www.ucdenver.edu/research/comirb/POInumber/Pages/POIform.aspx
   If a VA employee has access to InfoEd (eRA) and does not know their POI#, please call the COMIRB Help Desk (303-724-1055) and they can provide it to you.

2. Log into the CITI Program website: https://www.citiprogram.org/
3. Click “Main Menu” and then “Click here to affiliate with another institution.”

4. Affiliate with “University of Colorado Denver”
5. Complete the information requested by UCD. Please note: Anything can be entered for the employee ID# or POI# initially. Once the POI# request has been processed, the investigator will receive their POI#, which should then be entered into their UCD CITI profile so InfoEd and CITI can link.

6. Add the appropriate trainings. COMIRB requires investigators take either Group 1: Biomedical Investigators or Group 2: Social and Behavioral Research.
Investigators should only pick Group 2 if they will solely be engaged in social/behavioral research.

**Group 1 required steps:** Select “Group 1” >> “GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)” >> “CITI Health Information Privacy and Security (HIPS) for Clinical Investigators” >> for the remaining pages investigators may click “No” or “Not at this time” at the bottom of each page.

7. Once affiliation is finalized, the investigator should immediately be brought to their UCD CITI Profile.

**Please note, your Group 1 Biomedical Investigator Course or Group 2 Social and Behavioral course should automatically be completed if you are up-to-date on your VA CITI training. Please contact the COMIRB Help Desk (303-724-1055) if this is not the case.**

8. If a PI has Attachments C or D in their Application, they are required to take the GCP course. COMIRB does not gate keep GCP courses for anyone other than PIs. This means COMIRB does not require co-investigators, PRAs, etc. to take the “GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)” course.

**ALL individuals listed on a submission MUST complete the Group 1 and HIPS courses.** The status will indicate if a course is complete or not when it says “Passed xx/xx/xxx” in green lettering.

EXAMPLE:

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Passed  
11/17/2014
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9. Once the POI# has been received, the individual **MUST** update their UCD CITI profile to reflect the appropriate POI# so the CITI courses can transfer to InfoEd.
UCD + VA Affiliation: Already affiliated with VA, completed the REFRESHER course, needs to add UCD affiliation

1. Retrieve POI#. If VA employee needs to request a POI#, do so here: http://www.ucdenver.edu/research/comirb/POInumber/Pages/POIform.aspx  
   If a VA employee has access to InfoEd (eRA) and does not know their POI#, please call the COMIRB Help Desk (303-724-1055) and they can provide it to you.

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7. Once affiliation is finalized, the investigator should immediately be brought to their UCD CITI Profile

![CITI Registration Screenshot]

**Please note, your Group 1 Biomedical Investigator Course or Group 2 Social and Behavioral course WILL NOT automatically be completed as you are up-to-date on your VA REFRESHER training. Please email the COMIRB Help Desk (comirb@ucdenver.edu) and include your VA CITI completion report. COMIRB will contact CITI and request CITI manually add the refresher course to your UCD profile. Once CITI manually adds the refresher course, the VA course previously taken should automatically transfer over to the UCD affiliation.**

8. If a PI has Attachments C or D in their Application, they are required to take the GCP course. COMIRB does not gate keep GCP courses for anyone other than PIs. This means COMIRB does not require co-investigators, PRAs, etc. to take the “GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)” course. **ALL individuals listed on a submission MUST complete the Group 1 and HIPS courses.** The status will indicate if a course is complete or not when it says “Passed xx/xx/xxx” in green lettering.

**EXAMPLE:**

9. Once the POI# has been received, the individual **MUST** update their UCD CITI profile to reflect the appropriate POI# so the CITI courses can transfer to InfoEd.

![CITI Profile Screenshot]