TRAINING REQUIREMENTS FOR RESEARCH INVOLVING HUMAN SUBJECTS

Biomedical
REQUIREMENTS FOR PARTICIPATION IN HUMAN SUBJECT RESEARCH

1. Submit a current Financial Conflict of Interest Disclosure
   • [http://www.creighton.edu/researchservices/rco/coi/coidisclosure/](http://www.creighton.edu/researchservices/rco/coi/coidisclosure/)

2. Complete the three required online courses
   • CITI Group 1 – Biomedical Basic Course for the Protection of Human Subjects in Research Course
   • CITI Health Information Privacy and Security (HIPS) Course
   • CITI Biomedical Responsible Conduct of Research (RCR) Course
   • CITI Good Clinical Practice (GCP) course
FINANCIAL CONFLICT OF INTEREST DISCLOSURE

To access the Financial Conflict of Interest Disclosure go to:

http://www.creighton.edu/researchservices/rco/COI/coidisclosure/

For questions, call the Research Compliance Education Office at 402-280-2680 or researchcomped@creighton.edu
CREATING YOUR NEW CITI ACCOUNT

• Create a NEW account with CITI.

• Log onto the CITI website by going to www.citiprogram.org.

• Click “Register” to go to the registration page. Only create a new account if this is the first time you will ever complete CITI course(s).
Search for Creighton University to select your Organization Affiliation.

Continue to Step 2.
You will enter your name and your primary email address. Please use your personal email address in this field so you will have access to your CITI account if you

A secondary email address is a good idea, but not required.

Continue to Step 3.
You will create your CITI username on this page, password and security questions and answer.

Continue to Step 4.
CITI asks gender/ethnicity/race questions. If you would prefer not to answer, select “Prefer not to answer”.

Continue to Step 5
On this page CITI is asking for information about you. Please note that you are only required to complete the questions with the red (*) asterisk; the remaining are optional.

**For the institutional email address, please use your personal email assigned to you by Creighton University or your employer.**
TO SELECT THE CITI COURSES THAT YOU WILL NEED TO COMPLETE, PLEASE SELECT THE OPTIONS AS SHOWN BELOW

<table>
<thead>
<tr>
<th>Select Curriculum - Creighton University (311)</th>
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</thead>
<tbody>
<tr>
<td>* Indicates a required field.</td>
</tr>
</tbody>
</table>

* *PLEASE READ THE FOLLOWING QUESTIONS CAREFULLY AND SELECT THE APPROPRIATE ANSWER(S). THIS IS WILL ALLOW CITI TO ADD THE REQUIRED COURSES TO YOUR CITI ACCOUNT.*

Choose all that apply:

- [x] I will be involved in research with human subjects (IRB).
- [x] I am involved in clinical research and am listed on an FDA Form 1572, add the Good Clinical Practice (GCP) Course to my courses.
- [x] I will be involved in research or teaching activities that utilize live animal subjects (IACUC).
- [x] I am involved in research (including IRB, IACUC and/or IBC projects), I am required to complete RCR training as a class assignment and/or I am listed on a PHS funded project, I need to complete a course in the Responsible Conduct of Research (RCR).
- I am listed on an IBC project. I work with bio-hazardous materials, Bloodborne pathogens, select agents and/or involved with shipping of biological materials and/or dry ice. I must complete one or more Biosafety Courses.
- [ ] I am listed on a PHS funded project or I have disclosed a potential conflict of interest on my financial conflict of interest disclosure; I need to complete the Conflict of Interest Course (CDOI).
Select Curriculum - Creighton University

You will be provided a series of enrollment questions. Your responses will determine the curriculum for the courses you are going to take. Please read the questions carefully. Please read the responses carefully to make the best choice.

You will be participating

» Choose one answer

- I have never completed the Basic Course in the Protection of Human Subjects in Research through Creighton University's affiliation with the CITI Program. I need to complete the Basic Course.
- I have completed the CITI Basic Course through Creighton University within the last 3 years.
- Chart Review. I am only doing a retrospective chart review.

PLEASE NOTE: Before you choose the Refresher Course make sure this is the course that you are required to complete at this time. If you enroll in this course by mistake and complete the Refresher Course without previously completing the Basic Course you will be required to go back and complete the Basic Course. If you have any questions please contact the Creighton University Research Compliance Education Office. (402-280-2680).

Next »
Select Curriculum - Creighton University (311)

* indicates a required field.

If you will be involved with Human Subjects Research, what is your research focus?
Choose one answer

- I will be conducting Biomedical Research.
- I will be conducting Social/Behavioral Research.
- I will be conducting Social/Behavioral Research and I am required to have HIPAA training.
- My training needs to be RENEWED. I need to complete the Group 1 – Biomedical Refresher Course.
- My training needs to be RENEWED. I need to complete the Group 2 – Social/Behavioral Refresher Course.
Select Curriculum - Creighton University (311)

* indicates a required field.

You need to complete a Responsible Conduct of Research Course. Choose one answer:

- I am participating in biomedical research and need the **Biomedical Responsible Conduct of Research Course**.
- I am participating in social and behavioral research and need the **Social and Behavioral Responsible Conduct of Research Course**.
- I am participating in work and/or research in one of the physical sciences and need the **Physical Sciences Responsible Conduct of Research Course**.
- I am participating in research in one of the humanities and need the **Humanities Responsible Conduct of Research Course**.
- I completed a **Responsible Conduct of Research Basic** course within the last three years through Creighton University. I need to RENEW my training by completing the **Responsible Conduct of Research Refresh** course.
<table>
<thead>
<tr>
<th>Course</th>
<th>Status</th>
<th>Completion Report</th>
<th>Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical Responsible Conduct of Research Course</td>
<td>Not Started</td>
<td>Not Earned</td>
<td></td>
</tr>
<tr>
<td>CITI Health Information Privacy and Security (HIPS) for Clinical Investigators</td>
<td>Not Started</td>
<td>Not Earned</td>
<td></td>
</tr>
<tr>
<td>Good Clinical Practice and ICH (GCP)</td>
<td>Not Started</td>
<td>Not Earned</td>
<td></td>
</tr>
<tr>
<td>Group 1: Biomedical Research</td>
<td>Not Started</td>
<td>Not Earned</td>
<td></td>
</tr>
</tbody>
</table>

**My Learner Tools for Creighton University**
- Add a Course or Update Learner Groups
- View Previously Completed Coursework
- Update Institution Profile
- View Instructions page
- Remove Affiliation

**Click here to affiliate with another institution**

**Affiliate as an independent Learner**

THE COURSE NAME IS THE LINK TO THE COURSE.
TRAiNNING REQUIREMENTS
HAVE YOU COMPLETED ALL THREE REQUIREMENTS?

Do you have an email confirming your Financial Conflict of Interest Disclosure has been submitted?

Have you completed the four CITI BASIC courses and do you have copies of the three CITI completion reports for the three courses?

*IF YOU ARE MISSING ANYONE OF THESE, YOU ARE NOT FINISHED*
IF YOU HAVE ANY QUESTIONS REGARDING THE IRB TRAINING REQUIREMENTS PLEASE CONTACT

Research Compliance Education Coordinator
402-280-2680 (Office)
researchcomped@creighton.edu
IF YOU ARE GOING TO BE PARTICIPATING IN A HUMAN SUBJECTS RESEARCH PROJECT REQUIRING IRB REVIEW

• You must have an IRBNet User Profile. If you have never registered as a user with IRBNet, you must create your IRBNet User Profile.

• PLEASE DO NOT CREATE A NEW USER PROFILE IF YOU HAVE PREVIOUSLY CREATED ONE! If you are not sure whether or not you have an IRBNet account, please contact the IRB Office at 402-280-2126 or IRB@creighton.edu
To set up your USER PROFILE in IRBNet:

• Go to the instructions on the IRB website at: http://www.creighton.edu/researchservices/rcocommittees/irb/irbnet/

• Scroll down to the link titled “IRBNet Registration Instructions” and select.
CHECK LIST FOR IRBNET USER PROFILE
HAVE YOU COMPLETED THE FOLLOWING?

• Have you verified your IRBNet User Profile? *(This is done by clicking on the link in the email you received from IRBNet after registering.)*

• Have you linked your CITI training to your IRBNet User Profile by selecting “Add an External Account”. You will need your CITI member ID#?

• Have you verified that you want your CITI training linked to your IRBNet User Profile? *(This is done by clicking on the link in the email you received from IRBNet after entering your CITI Member ID#.)*

• You will not see your CITI training on your IRBNet profile until the following morning after you have verified the link.
CHECK LIST FOR IRBNET USER PROFILE
HAVE YOU COMPLETED THE FOLLOWING?

• DO NOT UPLOAD YOUR CITI COMPLETION REPORTS. Training must be loaded by CITI.

• YOU WILL NEED TO SUBMIT THE FOLLOWING TO THE IRB THROUGH YOUR IRBNET USER PROFILE:
  1. You should have received a confirmation email when you submitted your financial conflict of interest disclosure. You MUST upload the confirmation to your IRBNet User Profile and submit.
  2. If you have a CV and/or a Professional License, please upload to your user profile and submit.
IF YOU HAVE ANY QUESTIONS REGARDING IRBNET PLEASE CONTACT

IRB Office
402-280-2126 (Office)
irb@creighton.edu