



IRB Training Requirements

Emory IRB Webinar

March 10, 2016

Objectives

- Identify various training requirements for personnel conducting human subjects research
- Provide a brief description of the required courses
- Identify training(s) required for your specific role

The Belmont Report

All employees, faculty, staff, students and/or agents of Emory University engaged in the conduct of human subject research must have reviewed and be familiar with the principles of “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research”

- Basic Ethical Principles:
 - Respects for persons (voluntary consent; protection of vulnerable populations)
 - Beneficence (risk/benefit ratio)
 - Justice (selection of subjects; fairness)

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

Training Courses

- Collaborative Institutional Training Initiative (CITI)
- Health Insurance Portability and Accountability Act (HIPAA)
- Introduction to Clinical Research at Emory (CRC)
- Key Concepts in Clinical Research for Investigators

Collaborative Institutional Training Initiative (CITI)

- Required by IRB for all human subjects research
- CITI covers the historical development of human subject protections, as well as current information on regulatory and ethical issues. It consists of modules from two basic tracks:
 - Biomedical (Biomed) and
 - Social-Behavioral-Educational (SBE)

You must take either the biomedical or social-behavioral training course, whichever is the most appropriate for your type of research.

- Renewal: Every 3 years

How to create a CITI account?

The screenshot displays the CITI Program website interface. At the top, there is a navigation bar with a language selector (USA - English), a text size selector (A A), and links for Log In, Register, and Help. Below this is a blue header with the CITI PROGRAM logo and the text "Collaborative Institutional Training Initiative at the University of Miami". A search bar for the Knowledge Base is also present. A main navigation menu includes Home, About Us, Subscribing, Online Courses, CMEs/CEUs, Publications, News, and Contact Us. The central content area features a large banner for "21ST CENTURY RESEARCH" with details about a workshop and forum in April 2016. Below the banner are logos for OHRP, CITI PROGRAM, UNIVERSITY OF MIAMI, Research Institute, USF, and NSU. A statistic states "Over 8.7 million CITI Program courses have been completed since 2000". On the right side, there is a login section with fields for Username and Password, a Log In button, and a link for "Forgot Username or Password?". Below the login section are options for "Log in through my institution" and "Log in via SSO". At the bottom of the right section, there is a "Create an account" section with a Register button and a note: "Access requires registration as an affiliate of a subscribing CITI institution or as an unaffiliated learner."

Step-by-Step Guidance for Selecting Required Courses and Obtaining a CITI Account (with Emory affiliation)

<http://www.irb.emory.edu/documents/CITIregistration.pdf>

Frequently Asked Questions (FAQ's)

- If I have completed CITI training at another institution can I can transfer my completed modules from another institution?
 - Answer: Yes. You would need to affiliate with Emory in your CITI account
- Who has to take CITI?
 - Answer: Anyone conducting human subjects research activities at Emory, which includes working directly with human subjects or with identifiable data or biological specimens for research purposes. (i.e. Investigators, research nurses, coordinators, students, technicians working with identifiable data, and faculty advisors would all need to obtain CITI certification).
- Is Good Clinical Practice (GCP) training required?
 - Answer: No. GCP is not an IRB training requirement; however, other offices may require it.
- What if my expiration date is incorrect in CITI?
 - Answer: Don't worry, just let us know. CITI will not change the expirations dates.
- Will Biomedical Responsible Conduct of Research (RCR) course count towards my training requirement?
 - Answer: No. RCR is not required by the Emory IRB and will not count towards your training requirement.
- Do I have to upload my CITI certification in eIRB?
 - Answer: No. IRB staff can check training completion status online.

Key Concepts in Clinical Research for Investigators (KC)

- This is a **mandatory** training for Investigators conducting clinical trials at Emory. The course aims to move beyond the IRB required CITI modules and provide investigators with Emory-specific content such as disclosure of COIs or reporting adverse events and unanticipated problems.
 - Course is completed on-line in ELMS.
 - Renewal: Every 3 years.

Introduction to Clinical Research (CRC) at Emory

- This is a **mandatory** training for new and existing clinical research coordinators, research nurses, fellows, and residents working on clinical trials. The course is designed to provide a basic framework of the roles and responsibilities to equip coordinators with the tools to be successful in their job roles at Emory.
- The course can be completed in the 2-day classroom or on-line in ELMS (depending on years of experience as a study coordinator).

❖ Renewal: Every 3 years

The difference between KC and CRC courses

Key Concepts:

- Investigator responsibilities
 - FDA 1572
- Adverse Events reporting requirements
- Audits and Inspections
- Research Misconduct
- Conflict of Interest

CRC

- Overview of ORA functions and services
- Role of clinical research team
- Informed Consent process/subject recruitment tools
- Enrollment and research billing
- Study and Data Maintenance
- Study Close Out

HIPAA Courses

- Required by IRB for those who work with identifiable health information
- HIPAA and Research
 - This course covers regulations that govern who can access PHI for research. Provides an overview IRB waivers, authorizations and de-identification of health information.
- HIPAA in a Hurry
 - This course will summarize key elements of the Privacy Rule including who is covered, what information is protected, and how protected health information (PHI) can be used and disclosed.
 - You can access both courses through ELMS

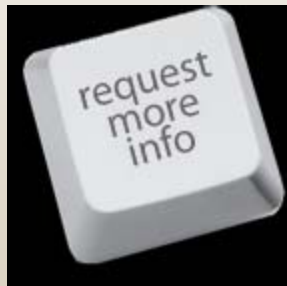
❖ *Renewal: Not required*

Individuals Not Affiliated With Emory But Working On An Emory Study

- If the Emory IRB is overseeing their participation:
 - Should complete all the required training (including intro or key concepts).
- If their participation is overseen by their home IRB:
 - Normally in this case, the person does not need to be listed on Emory IRB application, so Emory IRB would not look at their training
 - If for some reason we required them to be listed, they will just need to comply with their home IRB's requirements. If home IRB does not require training (e.g. international IRB), consult with IRB for options

For More Information:

- For additional information about courses, contact the Emory's OCR at OCR@Emory.edu or 404-778-4960.
- For course details and registration, please review the [Key Concepts User Guide](#) or the [Introduction to Clinical Research User Guide](#) to navigate ELMS and print certificate of completion.



IRB training requirements for your specific role?





Investigators

(PI, Co-I, or Resident/Fellow Acting as Co-I)

- Collaborative Institutional Training Initiative (CITI)
 - Biomedical or Socio-Behavioral
- Key Concepts in Clinical Research for Investigators
 - **If conducting a clinical trial*
- HIPAA course
 - *Those who work with identifiable health information within a covered entity*

Research Nurses, Research Coordinators

- Collaborative Institutional Training Initiative (CITI)
 - Biomedical or Socio-behavioral focus
- Introduction to Clinical Research at Emory
 - **If working on a clinical trial*
- HIPAA courses
 - *Those who work with identifiable health information within a covered entity*

Residents, Fellows, Others Acting As Coordinators on Clinical Trials

- In addition to CITI and HIPAA, must take ***Introduction to Clinical Research at Emory*** if:
 - There is no other coordinator on the study and you are fulfilling duties such as consenting and protocol management

Other Supporting Roles

- Other staff members who may not directly engaged with research participants but may have access to identifiable private information (i.e. data coordinator, regulatory specialist, research interviewer, office assistants, etc.)
 - Collaborative Institutional Training Initiative (CITI)
 - Biomedical or Socio-Behavioral focus
 - HIPAA
 - *Those who work with identifiable health information within a covered entity*

Adding or Changing a staff member
of your team?



Staff Add/Change Tool

HOME ABOUT POLICIES FORMS & GUIDANCE EDUCATION eIRB MEMBERS PARTICIPANTS

eIRB Training
Study Staff Change
eIRB FAQ
How To's
eIRB Additional Role Request

Enter eIRB
ENTER eIRB ▶

Home > eIRB Training > Study Staff Change

Study Staff Change

As of 4/11/2014, some changes to personnel on IRB studies may be done via this web form rather than a full amendment. Please review the following guidelines to know if this tool may be used for your request.

Please note, full board and expedited studies should notify the IRB of all staff changes; however, exempt studies do not need to provide such notice.

Who on the study may request staff changes?

- Investigators (Co- and Principal)
- Coordinators

What changes may be requested?

- Adding/Removing coordinators and "other study staff" (per eIRB)
- Adding Co-Investigators
- Removing Co-Investigators on minimal risk studies

What changes still require amendments?

- Changes to VA studies
- Any change of Principal Investigator
- Removal of a Co-Investigator on more than minimal risk studies
- Adding any study personnel with a financial conflict of interest

Requirements to be added to a study:

- Emory staff must have an eIRB account ([text/video instructions](#))
- [Current CITI certification](#)

Additional requirements for Emory (and certain CHOA) personnel being added to clinical trials:

- Completion of [Key Concepts training](#) (investigators, residents and fellows acting as investigators) - User Guide can be found [here](#)
- Completion of the [Introduction to Clinical Research Course](#) (research nurses, and clinical research coordinators) - User Guide can be found [here](#)

If your request meets these criteria, please click the button below:

Study Staff Change Request

Staff Add/Change Tool

<p>New Role: or current role if removing</p>	<p><input type="radio"/> Co-Investigator <i>Includes research fellows acting as investigators</i></p> <p><input type="radio"/> Coordinator* <i>Includes study nurses and research fellows acting as coordinators on clinical trials)</i></p> <p><input type="radio"/> Study Nurse not acting as coordinator*</p> <p><input type="radio"/> Research Fellow not acting as investigator or coordinator on clinical trial*</p> <p><input type="radio"/> Data analysis only</p> <p><input type="radio"/> Other Emory Personnel (please describe the role below)</p> <input type="text"/>	
<p>Is this a clinical trial*? *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.</p>	<p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>	
<p>Responsibilities: If adding</p>	<p><input type="radio"/> Consenting</p> <p><input type="radio"/> Interacting with Subjects</p> <p><input type="radio"/> Both</p> <p><input type="radio"/> None</p>	
<p>Completed Training click training titles for more information</p>	<p><i>Adding personnel who do not have the required training may represent Serious Noncompliance.</i></p> <p>Current CITI Certification from Emory or CHOA: <input type="radio"/> Yes <input type="radio"/> Removing (n/a) Required for <u>all</u> study personnel.</p> <p>Key Concepts: <input type="radio"/> Yes <input type="radio"/> n/a Required for PIs and Co-Is involved in clinical trials; includes research fellows acting as investigators.</p> <p>Intro to Clinical Research: <input type="radio"/> Yes <input type="radio"/> n/a Required for personnel who function in the role of a clinical research coordinator (e.g. recruiting, consenting, protocol management, data management, regulatory submissions, etc). Thus, it may apply to personnel who are not technically listed as coordinators, such as residents and fellows.</p>	

Friendly reminder



- Please refer to Office for Clinical Research (OCR) website for additional training requirements for clinical research staff.

<http://ocr.emory.edu/training/index.html>

Questions?



Thank You for
Listening

