Does the IRB require training for investigators?

In order to ensure that human subjects are adequately protected from research risk, both the University of Chicago and certain funding agencies set requirements for the training of investigators and their research staff. This training generally involves education on some combination of aspects of federal regulations, ethical principles, and university-specific policies. Training is usually required for investigators both upon beginning work in research at this institution and on an ongoing basis as new guidance, regulations, and areas of concern in research emerge.

The BSD requires training for all researchers per policy "Faculty and Staff Training Requirements for the Conduct of Clinical Research." Training is required every 3 years.

The IRB suggests the CITI website (www.citiprogram.org) to complete this training requirement.

Note that human subject protection training is also mandatory for research staff on any NIH-funded project.

What is the BSD training policy?

In summer 2009, the Clinical Research Policy Board approved the Medical Center policy, "Faculty and Staff Training Requirements for the Conduct of Clinical Research." This policy applies to all faculty and staff involved in the conduct of clinical research. Faculty and staff will be expected to complete on-going training with acceptable documentation **every three years**.

The Research Training Program Options document provides the various options for completing the training requirement. The OCR encourages the use of the online CITI training program to complete this requirement. Collaborative Institutional Training Initiative (CITI) is a web-based training program. CITI is not only a national standard, but also allows the Office of Clinical Research to easily monitor compliance. CITI home page: www.citiprogram.org

Full IRB approval of any clinical research project is contingent on all investigators and staff involved in the research completing the training.

Training Policy *SEE APPENDIX A*
Research Training Program Options (initial training) *SEE APPENDIX B*
Refresher Training Options *SEE APPENDIX C*

How do I log in to CITI?

You will need to use your University CNet ID and password to log into CITI and affiliate with University of Chicago. If you do not have a CNet ID, a UCHAD ID and password may be used. If you are an incoming faculty member and do not yet have a CNet or UCHAD ID, please

contact University Research Administration for assistance in early access to University resources. If you are not affiliated with the University of Chicago as an employee or student, you will not be able to use the U of C access to CITI. In this case, other training can be obtained.

Select the University of Chicago as your "Participating Institution" and fill out all other necessary registry information. Once this is completed you will be required to complete 4 enrollment questions. This will determine the modules you will need to complete.

CITI training also offers modules on Good Clinical Practices (GCP). Researchers have the opportunity to complete these modules for sponsors who require that this training be completed.

If you previously completed CITI training at another institution, be sure to log back into CITI using your existing account and affiliate with The University of Chicago. You will receive credit for courses you have completed in the past if they are the same courses the U of C requires.

My research group would like to attend a training presentation on a specific topic. Whom should we contact?

Researchers seeking an introduction to IRB review in the BSD or who have specific training topics in mind may contact James Lynch, Associate Director of Education/Quality Assurance for Human Subjects in the Office of Clinical Research, to determine if applicable training might already be scheduled or planned or if such a session could be provided. He can be reached at 773-834-1613 or via email to jlynch@bsd.uchicago.edu.

The OCR hosts monthly workshops during the academic year on a variety of research topics. If you are interested in a topic that could be of value to the larger research community, suggestions for workshop sessions are welcomed. Please contact clinicresearch@bsd.uchicago.edu with suggestions for topics and/or presenters.

The IRB office strives to develop a stronger interactive relationship between the IRB staff and researchers. Research groups are encouraged to utilize Office Hours or contact the IRB administrator on call for guidance as submissions are being prepared. See our "Contact Us" page for more information.

How can I access HIPAA training?

If you are a non-BSD individual and need to complete HIPAA training, it can be accessed through the following link:

REDCap HIPAA training

APPENDIX A

Biological Sciences Division
Office of Clinical Research
Clinical Research Policy 110

Page 1 of 2
Effective Date:
Version #2.0:
Last Review: 5/8/20

Title: Faculty and Staff Training Requirements for the Conduct of Clinical Research

1.0 Purpose: To ensure that faculty and staff engaged in clinical research are appropriately trained in research conduct, ethics and protocol management with the goals of protecting human subjects, institutional compliance and applicable federal regulations.

2.0 Scope: This policy applies to all faculty and staff involved in the conduct of clinical research. No individual will be permitted to conduct research activities involving human subjects without meeting the Clinical Research Faculty Advisory Board's training requirements.

3.0 Responsibility:

3.1 Definitions:

3.1.1 Faculty – includes principal investigators, co-investigators, and other University of Chicago Faculty that are involved in the research process. This includes but is not limited to faculty listed on the grant or contract application; faculty listed on a FDA form 1572/Investigator Agreements; faculty who are named as contact persons in the informed consent documents or research recruitment materials; faculty who provide supervision of the persons who are obtaining informed consent to participate in research of faculty that provide any direct patient care to the subjects within the trial.

3.1.2 Research Staff – This includes all personnel who assist the Principal Investigator (PI) in the research process including but not limited to research coordinators, research nurses, data managers, regulatory managers, students, volunteers and all other non-faculty who are assigned research duties by the PI on the delegation of authority log and listed as personnel on the IRB protocol submission.

3.1.3 Initial Training Requirements – Describes minimum degree of prior training required by research staff before they will be permitted to participate in the conduct, review, or oversight of human subject research.

3.1.4 Continuing Training Maintenance – Describes the minimum amount of mandatory training that must be documented every three years to be permitted to continue to participate in the conduct, review, or oversight of human subject research.

3.2 Training Requirements:

3.2.1 Faculty and Research Staff – Initial Training Requirements – Prior to participation in any clinical research protocol within UChicago Medicine, faculty and staff will be required to complete the current training expectations as

determined by the Clinical Research Faculty Advisory Board and the Council of the BSD Institutional Review Board.

3.2.2 Continuing Training Maintenance Requirements (on-going Training) for all Faculty and Staff – Faculty and staff will be expected to complete on-going training with acceptable documentation every three years. What is deemed acceptable will be determined by Clinical Research Faculty Advisory Board and the Council of the BSD Institutional Review Board.

3.3 Monitoring of Compliance – Department administration will be responsible for ensuring compliance with this policy and keeping training documentation for all faculty and research staff. The Office of Clinical Research will verify training requirements are met when new protocols are submitted for institutional review and approval. Documentations of any training received through external sources must be provided.

3.4 Failure to Comply – **Failure to Comply** – Failure to Comply with this policy will be reported to Dean of Clinical Research, Chairman of the Institutional Review Board, Chief Compliance Officer, and the Chief Medical Officer for determination of corrective action.

4.0 Oversight Responsibility: This policy is managed by the Office of Clinical Research. Revisions to the policy will be made periodically by the Clinical Research Faculty Advisory Board and Dean of Clinical Research.

Document Control Change Summary

Version	Effective Date	Summary of Changes
1.0	6/12/2006	N/A
2.0	6/2/2020	Updated template, added reference, changed University of Chicago Hospitals to UChicago Medicine, Replaced Clinical Research Policy Board with Clinical Research Faculty Advisory Board;

APPENDIX B

Training Options

For Biomedical Faculty, Investigators, Research Staff or Administration

The *Faculty and Staff Training Requirements for the Conduct of Clinical Research Policy* that went into effect in 2009 requires all faculty and staff to complete INITIAL TRAINING and REFRESHER TRAINING every 3 years.

One of the following training programs for faculty and staff is required.

1. **CITI:** http://www.citiprogram.org

CITI Human Subjects Protection (9 modules- 8 required and 1 elective)
Title: **Biomedical Faculty/Investigators, Research Staff, or Administration Staff**

A. Biomedical 101
   1. Belmont Report and CITI Course Introduction.
   2. History and Ethics of Human Subjects Research
   3. Basic Institutional Review Board (IRB) Regulations & Review Process
   4. Informed Consent
   5. Populations in Research Requiring Additional Considerations and/or Protections
   6. Vulnerable Subjects: Research Involving Children
   7. Health Privacy Issues for Researcher
   8. University of Chicago
   9. 1 Required Elective Module

B. Good Clinical Practice – optional

Instructions for CITI: https://voices.uchicago.edu/ocr/human-subjects-protection-trainingciti/

2. **Graham School *Clinical Trials Management and Regulatory Compliance certificate* course ***

The University of Chicago Graham School offers a certificate program focusing on the design and management of human subject research. Completion of 2 certificate courses will fulfill the policy. Visit the website for additional information and to register:
https://grahamschool.uchicago.edu/php/clinicaltrialsmanagement/

*documentation of completion will be required

Other available training:

- **Fundamentals of Clinical Research offered by OCR**
  http://bsdocr.bsd.uchicago.edu/fac-staff/education/fundamentals.html

For more information or for help determining the acceptability of other training programs, please contact clinicresearch@bsd.uchicago.edu

APPENDIX C

Refresher Training Options

For Biomedical Faculty, Investigators, Research Staff or Administration

The *Faculty and Staff Training Requirements for the Conduct of Clinical Research Policy* that went into effect in 2009 requires all faculty and staff who have completed initial human subject protection training to complete refresher training every 3 years as part of the continuing training maintenance requirements.

ONLY *ONE* OF THE FOLLOWING TRAINING PROGRAMS IS REQUIRED:

1) CITI http://www.citiprogram.org
Instructions for Enrolling:

1. Individuals who have previously completed the Basic Course

The Refresher module will be automatically added to your Learner's Menu 180 days prior to your date of expiration. The Refresher Module only applies to individuals who fulfilled the original training requirement through CITI.

Refresher Module:

A. Biomedical 101 Refresher Course
   i. Belmont Report and CITI Course Introduction
   ii. History and Ethics of Human Subjects Research
   iii. Basic Institutional Review Board (IRB) Regulations & Review Process
   iv. Informed Consent
   v. Populations in Research Requiring Additional Considerations and/or Protections
   vi. Vulnerable Subjects: Research Involving Children
   vii. Health Privacy Issues for Researchers
   viii. University of Chicago
   ix. 1 Required Elective Module

B. Good Clinical Practice

2. Individuals who have not complete CITI training

Register to complete the Basic Course to fulfill the refresher requirement. Instructions for registering for the first time can be found in Attachment A.

2) Fundamentals of Clinical Research
Individuals who have never taken the Fundamentals of Clinical Research course are encouraged to participate in the training offered by OCR. The course is offered during the fall, winter and spring quarters.
The schedule of classes and online registration can be found at:
http://bsdocr.bsd.uchicago.edu/fac-staff/education/fundamentals.html

3) Graham School *Clinical Trials Management and Regulatory Compliance certificate* course
The University of Chicago Graham School offers a certificate program focusing on the design and management of human subject research. Completion of 2 certificate courses will fulfill the

policy. Visit the website for additional information and to register: https://grahamschool.uchicago.edu/php/clinicaltrialsmanagement/

4) Other training options

Individuals who have fulfilled an alternative human subjects training course can petition to have this training recognized as fulfilling the refresher requirement. Training must be completed prior to your original training expiration date and within the past year. Please email the OCR with documentation of your training. The OCR will determine appropriate training requirements on a case by case basis.

BSD/UCMC Programs

Other training programs offered through the BSD/UCMC may be accepted as refresher training. Some currently recognized programs include:

1. Clinical Research Training Program (CRTP)*
   - EPOR Track I
   - Track II
2. Human Subject Protection training program
3. Other*

*A certificate of training must be provided

External Programs

Submit certificate of completion to clinicresearch@bsd.uchicago.edu for OCR determination of compliance with policy.

For more information or for help determining the acceptability of other training programs, please contact clinicresearch@bsd.uchicago.edu