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IMPLEMENTATION**

**OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS**

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**SOP Title: TRAINING REQUIREMENTS FOR THE NIH HUMAN RESEARCH  
PROTECTION PROGRAM (HRPP)**

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Chairs, IRB Administrators, Protocol Navigators**

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## SOP 25: TRAINING REQUIREMENTS FOR THE NIH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

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## **SOP 25: TRAINING REQUIREMENTS FOR THE NIH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)**

### **25.1 PURPOSE**

This SOP describes training requirements for researchers in the NIH Human Research Protection Program (HRPP).

### **25.2 POLICY**

All **incoming** Intramural Research Program (IRP) scientists are required to complete training to assure that they understand when research activities involve human subjects research and what is required when they conduct this type of research.

Clinical investigators **who are engaged in human subjects research (HSR)** are required to have **human subjects protections training and, as applicable,** additional training commensurate with their roles and responsibilities. Good Clinical Practice (GCP) training **also is required** when research is regulated by the Food and Drug Administration (FDA). **For more information about FDA-regulated research,** see SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications **and References** below.

IRBs may require additional training for investigators who do not demonstrate understanding of specific areas or when investigators undertake a new type of research (for example, research with prisoners).

### **25.3 DEFINITIONS**

- A. **Behavioral Research:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or survey, interview, oral history or focus group research, program evaluation, human factors evaluation, or quality assurance methodologies (see **25.5.2** below).

- B. Biomedical Research:** Basic, clinical, and translational medical research conducted to investigate the causes, treatments, and cures for both common and rare diseases.
- C. Clinical Research:** Research that includes interactions with humans; including studies of mechanisms of disease; therapies or interventions for disease; clinical trials; or studies to develop new technologies related to disease.
- D. Collaborative Institutional Training Initiative (CITI):** CITI is a subscription service that provides research ethics education to the members of the research community. For more information about features of the CITI, courses see **Appendix 1**.
- E. (The) Ethical and Regulatory Aspects of Clinical Research:** This seven (7) week course is offered by the Clinical Center (CC) Bioethics Department each fall and provides a comprehensive overview of the ethical issues in human subjects research in the United States. For more information, see **Appendix 2**.
- F. Epidemiological Research:** is the study of the patterns, causes, and effects of health and disease conditions in defined populations.
- G. FDA-regulated Research:** Includes all clinical investigations regulated by the FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic (FD and C) Act, as well as clinical investigations that involve test articles subject to regulation under the FD and C Act or under sections 351 or 354-360F of the Public Health Service Act, 21 CFR 56.102 (j), including any drug for human use, biological product for human use, medical device for human use, human food additive, color additive or electronic product. FDA regulated research does not include research that has been determined to be exempt from FDA regulation. (For more information, see SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications). NIH Investigators who conduct FDA-regulated research at sites in the United States must follow FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (referred to as GCP for the purposes of this SOP) (see **References** below).

**H. Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

**I. Investigator:** An “investigator” is any individual who is involved in conducting HSR studies. Such involvement includes:

1. Obtaining information about living individuals by intervening or interacting with them for research purposes;
2. Obtaining identifiable private information about living individuals for research purposes;
3. Obtaining the voluntary informed consent of individuals to be subjects in research; or
4. Studying, interpreting, or analyzing identifiable private information or data for research purposes

The PI also has the discretion to appoint as AIs, for the IRB’s approval, including those who are not engaged in HSR (see SOP 19 - Investigator Responsibilities). Within the Intramural Research Program (IRP), one investigator is designated the Principal Investigator (PI) with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects. (For more information see **References** for the link to the OHRP FAQ, “Who are “investigators”? (*sic*)).

The PI may designate some investigators as a sub-type of investigator on the protocol, e.g., “Associate Investigators” (AIs).

**J. NIH Intramural Clinical Protocol Application:** A completed Application submitted to an NIH IRB via the designated IRB system (iRIS™ or PTMS), at the time of initial (IR) or continuing review (CR), amendment or study closure. It includes a certification by the PI of training completed by investigators and other study staff/personnel listed on the Application.

**K. Non-NIH Investigator:** includes individuals who are Adjunct Principal Investigators, Guest Researchers, Special Volunteers, contractors, Intramural Research and Cancer Research Training Awardees and collaborators from academia and industry (see SOP 20 - NIH HRPP Requirements for Collaborative Research).

**L. Social Behavioral Research:** Research involving the study of the interactions of biological factors with behavioral or social variables and how they affect each other. This includes but is not limited to, individual or group characteristics or behavior (e.g., research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior). Methodologies may include basic and applied research; research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

## 25.4 TRAINING RESOURCES

Training curricula are specified on the OHSRP website (see below) for each type of research conducted or reviewed. Categories include: Clinical Research, Epidemiological and Social Behavioral Research, or HRPP staff (IRB Chairs, Members and staff, and OHSRP professional staff).

Courses are accessed via the OHSRP website under the “Required HRPP Training” link (see **Appendix 2**). Each user should select the link below the appropriate research category to gain access to the correct curriculum.

IRB member training is provided under the “HRPP Staff: Chairs, Members and Staff of the NIH IRBs and OHSRP professional staff” link on the OHSRP website (see **References** below).

On-line training courses include those offered by CITI (See **Appendix 1**) and the NIH Clinical Research Training (CRT, see **Appendix 2**).

**Successful completion of** “The Ethical and Regulatory Aspects of Clinical Research,” a course offered annually by the CC Bioethics Department, may be applied towards clinical research/biomedical training or used as a refresher course for the clinical research or biomedical training. **To** receive credit for this course the student must attend at least 6 of 7 classes and pass the exam with a

score of at least 80 percent. For more information, contact the Department of Bioethics, (see **Appendix 2** below).

## **25.5 TRAINING REQUIREMENTS FOR THE NIH HRPP COMMUNITY**

The NIH HRPP community includes NIH IRP investigators, NIH IRB members and staff, OHSRP professional staff **and the Institutional Official (IO)**.

For an overview of training requirements **for NIH staff** by role and type of research conducted, (see **Appendix 3**).

### **25.5.1 ALL INTRAMURAL RESEARCH PROGRAM (IRP) INVESTIGATORS**

**All incoming IRP investigators are required to take the “Responsible Conduct of Research” course including the specific module, “What is Human Subjects Research?” training. This module assists investigators to understand when they are engaged in human subjects research, and when review by an IRB or a determination by OHSRP (regarding the need for IRB review) is required before research may commence.**

### **25.5.2 IRP INVESTIGATORS CONDUCTING CLINICAL RESEARCH**

Courses are accessed via the HRPP Training page for “Clinical Research” (see **Appendix 2**). Additional courses may be required by the PI or IRB according to the type of research to be conducted, (see **25.5.5** below).

A. Investigators **conducting** non-FDA regulated Research:

1. Required training:

- a. NIH Clinical Research Training (CRT); or
- b. CITI Biomedical course; or
- c. The Ethical and Regulatory Aspects of Clinical Research offered by CC Bioethics

2. Optional or Just-in-time Training: includes additional courses listed on the OHSRP training website pages or any of the just-in-time CITI Courses in **25.5.5** below. NIH IRBs or Institutes/Centers (ICs) may also require that investigators conducting non-FDA-regulated research take GCP training.

B. Investigators **conducting** FDA-regulated Research:

The training below is required for investigators conducting FDA-regulated research **(including research involving INDs/IDEs, Non-significant risk (NSR) devices, off-label use of approved drugs and Investigational new Drug (IND) exemptions)**. For more information, see SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications.

**FDA regulated research conducted at sites in the United States will be consistent with FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (referred to as GCP for the purposes of this SOP) (see **References** below).**

NIH IRBs or ICs may also require that investigators conducting non-FDA-regulated research take GCP training.

1. Required training:
  - a. Either the NIH Clinical Research Training (CRT); or
  - b. CITI Biomedical course; or
  - c. The Ethical and Regulatory Aspects of Clinical Research offered by CC Bioethics.
2. The NIAID GCP course or one of the CITI GCP courses based on the role of the investigator on the study.
3. Optional or Just-in-time Training: includes additional courses listed on the OHSRP training website pages or any of the just-in-time CITI courses in **25.5.5** below.

### **25.5.3 IRP INVESTIGATORS CONDUCTING EPIDEMIOLOGICAL OR SOCIAL BEHAVIORAL RESEARCH**

Courses are accessed via the HRPP Training page for “Epidemiological and Behavioral Research” (see **Appendix 2**).

A. Investigators and **conducting** epidemiological or social behavioral research

1. Required training:

a. NIH Clinical Research Training (CRT); and

b. CITI Social and Behavioral course

2. Optional or Just-in-time Training: includes additional courses listed on the OHSRP training website pages or any of the just-in-time CITI courses in **25.5.6** below

### **25.5.4 HRPP STAFF: CHAIRS, MEMBERS AND STAFF OF THE NIH IRBS AND OHSRP PROFESSIONAL STAFF**

Courses are accessed via the HRPP Training page (see **Appendix 2**). Non-NIH IRB members should contact OHSRP to gain access to the required training resources.

A. All HRPP Staff including IRB Chairs and Members, IRB Administrative Staff, and OHSRP professional staff:

1. Required training:

a. NIH Clinical Research Training (CRT); or

b. CITI Biomedical course or CITI Social and Behavioral course; or

c. The Ethical and Regulatory Aspects of Clinical Research offered by CC Bioethics.

2. Either the NIAID GCP course or the CITI GCP for PI's course

3. Optional or Just-in-time Training: The IRB Chair may determine that the additional CITI modules will be required according to the type of research reviewed by the IRB, but are otherwise optional, see **25.5.5** below.

#### B. Incoming IRB Members:

In addition to the requirements listed above, incoming IRB members must also complete the following requirements prior to becoming an active member:

##### 1. Required training:

- a. NIH IRB Member Training, (see **Appendix 2**)
- b. Attend the OHSRP IRB member in-person orientation; and
- c. Attend and observe one IRB meeting in-person

### **25.5.5 OPTIONAL OR JUST-IN-TIME TRAINING**

In general, the just-in-time CITI courses listed below are optional (e.g., GCP courses are optional, for investigators who do not conduct FDA-regulated research.) However, IRBs or PIs may require investigators to complete these courses and IRB Chairs may require IRB members or staff to take these courses based on the type of research reviewed by the IRB. If protocol-specific training is required by the IRB, the IRB should document the specific requirement. A stipulation is one mechanism to document a protocol-specific requirement; for more information about verifying compliance see **25.7** and **25.9** below.

- A. Biomedical- Vulnerable Subjects - Research with Children
- B. Biomedical- Vulnerable Subjects- Research with Pregnant Women, Human Fetuses or Neonates
- C. Biomedical- Vulnerable Subjects- Research with Prisoners
- D. Biomedical- Vulnerable Subjects- Workers/Employees

- E. Genetic Research in Human Populations
- F. Stem Cell Research Oversight
- G. NIAID GCP course
- H. CITI GCP modules
- I. International Studies- ICH Overview and ICH- Comparison Between ICH GCP E6 and US FDA Regulations, available to those staff who complete the CITI GCP course
- J. Unanticipated Problems and Reporting Requirements in Biomedical Research
- K. Unanticipated Problems and Reporting Requirements in Social and Behavioral Research

## **25.6 REFRESHER TRAINING FOR THE NIH HRPP COMMUNITY**

Courses are accessed via the HRPP Training page on the OHSRP website, (see **Appendix 2**). Refresher courses are specified for each type of research conducted: Clinical Research, Epidemiological and Social Behavioral Research.

- A. Refresher Cycle: Refresher courses must be completed on a three (3) year cycle. The Director OHSRP, advised by the HRPP Education Committee, will specify the refresher course or options for each refresher cycle. All refreshers must be completed by December 31<sup>st</sup> in the year of expiration. All applicable NIH staff must complete the specified refresher course(s) by this deadline.
- B. The IRB, Clinical Director or PI may stipulate the type of refresher training to be taken, or may require training sooner than three-year intervals. In the absence of a prescribed refresher course, investigators may choose to take other modules relevant to the type of research conducted (see **25.6.D** below).

- C. OHSRP may require additional courses when new policies or regulations go into effect. OHSRP will designate whether such courses may be considered to meet the requirement for refresher training.
- D. Other refresher courses may be chosen according to the type of research conducted:
  - 1. The following courses may be refreshed using CITI; the refresher courses will appear in CITI after the expiration date of the previous course in the series (e.g. 3 years after the user completed the basic CITI course):
    - a. Clinical Research: CITI Biomedical refresher modules
    - b. Epidemiological and Social Behavioral: CITI Social and Behavioral refresher modules
  - 2. Other CITI modules, or The “Ethical and Regulatory Aspects of Clinical Research” offered by CC Bioethics may be taken as refresher courses.

## 25.7 DOCUMENTATION OF NIH HRPP-REQUIRED TRAINING, REFRESHER TRAINING AND OPTIONAL TRAINING FOR NIH STAFF

- A. NIH staff are responsible for downloading the Certificate of Completion for each completed course to provide proof of training. NIH staff must maintain proof of training in their research records and/or regulatory binders **and provide records upon request.**
- B. OHSRP will maintain a read-only database for the verification of **completion records for** required HRPP training courses, refresher courses, and optional training courses. IRB staff must check this database to verify that training is completed. **Note that training vendors, per specified agreements, will provide completion records. Learners are responsible for maintaining complete training records per item A above.**
- C. Transfer of proof of training:
  - 1. Newly employed NIH staff coming to the NIH can transfer CITI training courses completed in the last 12 months, through CITI to the NIH CITI

account. However, the user must establish an NIH CITI account before contacting the CITI helpdesk. For assistance transferring credits, contact the CITI helpdesk at 305-243-7970. Courses completed within 12 months of transfer will provide credit towards initial training.

2. Newly employed NIH staff coming to the NIH can transfer their NIAID GCP training completed at a non-NIH institution in the last 12 months, by providing the proof of training to OHSRP for inclusion in the HRPP training database.
- D. OHSRP will maintain the training records of IRB Chairs, Vice Chairs, Members, IRB administrative staff and OHSRP professional staff.
- E. IRB Administrative Staff Training Records will be maintained in the IRB Office.

## **25.8 REQUIRED TRAINING FOR NON-NIH INVESTIGATORS**

This applies to non-NIH Investigators working on NIH intramural protocols (including those performing multisite research at non-NIH locations who are relying on an NIH IRB). The NIH HRPP does not provide training for these investigators.

- A. Non-NIH investigators working on NIH intramural protocols that are reviewed by a NIH IRB must comply with training as required by their home institution. Non-NIH investigators must provide to the NIH PI proof that they have fulfilled the training requirements of their home institution. Unless otherwise specified in an agreement, such as a reliance agreement, the NIH PI will certify to the NIH IRB that non-NIH investigators have completed HSR and GCP, as applicable, training required by their home institution. See **item B** for institutions that do not have required HSR training.
- B. If the home institution of a non-NIH Investigator (e.g. such as a physician in private practice), does not require human subjects protections or GCP training (as applicable) the investigator must take and provide evidence of training to the NIH PI. Unless otherwise specified in an agreement, such as a reliance agreement, the NIH PI will certify to the NIH IRB that non-NIH investigators have completed HSR and GCP, as applicable. Possible

training sources include free, open-access courses such as “Protecting Human Research Participants” offered by the NIH Office of Extramural Research or NIAID GCP offered to non-NIH users (see Appendix 2 “Training Resources” items M and E). Alternatively, investigators could use other publically available sources for a fee (e.g. Collaborative Institutional Training Initiative (CITI) see **Appendix 2**).

## **25.9 ACTIVITIES THAT MAY NOT COMMENCE UNTIL TRAINING REQUIREMENTS ARE MET**

- A. NIH investigators may not serve on an IRB-approved study unless they have satisfied the applicable NIH HRPP training requirements. IRBs are responsible for confirming that investigators have satisfied the NIH HRPP training requirements as a condition of approval including protocol-specific training as required by the IRB. The PI will certify to the IRB that training required by the PI of NIH investigators, and non-NIH investigators has been completed prior to their participation on the study. For more information, see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRB). Training records for NIH investigators should be verified by PIs and IRB staff by confirming the completion record in the OHSRP training database or if not contained in the database, by providing a copy of a valid completion certificate to the PI and the IRB.
  
- B. IRB Chairs, Vice Chairs or members or staff may not serve or continue to serve on an NIH IRB unless they have satisfied the NIH HRPP training requirements.

## **REFERENCES**

- A. OHRP FAQ, “Who are “investigators”?” (*sic*):  
<http://answers.hhs.gov/ohrp/questions/7214>
  
- B. FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>

C. OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php>

## **LIST OF APPENDICES**

Appendix 1- CITI Training Information

Appendix 2- Training Resources

Appendix 3- NIH IRP HRPP Training Requirements

## APPENDIX 1- CITI TRAINING INFORMATION

- A. The following CITI modules offer test-out:
  - 1. CITI Good Clinical Practice both PI and non-PI
  - 2. Biomedical Modules
  - 3. Social and Behavioral Modules
- B. Test-out is not offered for just-in-time, optional or refresher courses.
- C. To test-out of a required course, the user must score 80% in the required content area.
- D. Each module takes 20-30 minutes to complete.
- E. If the user cannot complete the entire training, the user should complete the current module and return to the course later.
- F. The user must achieve a score of 80% for each module quiz in order to receive a Certificate of Completion for each module.
- G. If you have completed CITI courses at another institution in the last 12 months and would like credit for those courses, contact the CITI helpdesk at 305-243-7970 and request that your records be merged with your NIH account. However, you must first establish an NIH account prior to contacting CITI and provide an NIH CITI Member ID in order for the transfer to be completed.
- H. CITI training is transferrable to other non-NIH institutions when you leave the NIH or as may be required by other collaborating institutions, contact the CITI helpdesk at 305-243-7970 for assistance.
- I. CITI offers Continuing Medical Education credits for a fee, for more information select "CE Credits Status" on the CITI landing page.

## APPENDIX 2- TRAINING RESOURCES

- A. Behavioral Research (Taken from 45 CFR 46.110(a) List of Categories item #7): <http://www.hhs.gov/ohrp/policy/expedited98.html>
- B. Clinical Research Training page:  
<https://federation.nih.gov/ohsr/nih/biomed.php>
- C. Collaborative Institutional Training Initiative (CITI): [www.citiprogram.org](http://www.citiprogram.org)
- D. NIAID GCP Learning Center:  
<https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx>
- E. NIH Clinical Research Training (CRT) Course:  
<http://crt.nihtraining.com/login.php>
- F. NIH IRB Member Training: <https://federation.nih.gov/ohsr/nih/irbmenu.php>
- G. Required HRPP Training: <https://federation.nih.gov/ohsr/nih/investigator-training.php>
- H. The Ethical and Regulatory Aspects of Clinical Research:  
<http://www.bioethics.nih.gov/hsrc/>
- I. “Protecting Human Research Participants” offered by the NIH Office of Extramural Research: <http://phrp.nihtraining.com/users/login.php>
- J. Module on What is Human Subjects Research?:  
<https://researchethics.od.nih.gov/>

**APPENDIX 3- NIH IRP HRPP TRAINING REQUIREMENTS TABLE**

Table 1- The table below describes the NIH Intramural Research Program (IRP) Human Research Protection Program (HRPP) Training Requirements for Clinical, Epidemiological and Social Behavioral Investigators HRPP Staff including IRB Chairs, Members, Staff and OHSRP Professional Staff

<b>ROLES:</b>	<b>Clinical Principal Investigators (PIs) and Associate Investigators (AIs) for non-FDA regulated Studies</b>	<b>Clinical PIs and AIs conducting FDA-regulated Research</b>	<b>Epidemiological/ Behavioral/ Social Science/ Health Outcomes and Health Services Investigators</b>	<b>HRPP Staff (including IRB Members, Staff and OHSRP Professional Staff)</b>
<b>COURSES</b>				
"Responsible Conduct of Research" is required for all incoming investigators	X	X	X	X
Clinical Center On-line Clinical Research Training (CRT)	X		X	X
CRT w/out Regulatory Module		X		
	<b>OR</b>	<b>OR</b>		<b>OR</b>

CITI Bio-Medical Modules	X	X		X*
	OR	OR		OR
Ethical and Regulatory Aspects of Clinical Research	X	X		X
CITI Behavioral Research Training Modules			X	X*
<b>KEY</b>	<p>X = Required</p> <p>*HRPP staff should check w/their Chairs to determine if they should complete the CITI Biomedical or CITI Social Behavioral modules.</p>			
<b>ROLES:</b>	<b>Clinical Principal Investigators (PIs) and Associate Investigators (AIs) for non-FDA regulated Studies</b>	<b>Clinical PIs and AIs conducting FDA-regulated Research</b>	<b>Epidemiological/ Behavioral/ Social Science/ Health Outcomes and Health Services Investigators</b>	<b>HRPP Staff</b>
NIAID GCP Modules 2-4		X		X

		OR		OR
CITI GCP Training and as applicable below*		X		X
New Member: OHSRP On-Line IRB Member Training				X
New Member: Attend the OHSRP IRB member in-person training				X
New member: Attend an IRB meeting				X
<b>Additional Courses</b>	Any course above or additional CITI courses may be required by the Institute/Center, Clinical Director or IRB, depending on the investigator role and research subjects. They are otherwise optional unless indicated under the roles above.			
<b>KEY</b>	X = Required			

<b>CITI GCP Modules</b>	
GCP Introduction	<b>X</b>
Overview of New Drug Development	<b>X</b>
ICH Overview	If International
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	If International
Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices	<b>X</b>
Investigator Obligations in FDA-Regulated Clinical Research	<b>X</b>
Managing Investigational Agents According	<b>X</b>

<b>CITI Just-in-Time Training</b>
Vulnerable Subjects - Research w/Children
Vulnerable Subjects - Pregnant Women, Human Fetuses, and Neonates
Vulnerable Subjects - Research Involving Prisoners
Vulnerable Subjects - Workers/Employees
Genetic Research in Human Populations
Stem Cell Research Oversight (Part I)
Stem Cell Research Oversight (Part II)

to GCP Requirements	
Conducting Clinical Trials of Medical Devices	ONLY if IDE
<b>CITI GCP Modules</b>	
Informed Consent-An Ongoing Process	<b>X</b>
Detection and Evaluation of Adverse Events	<b>X</b>
Reporting Serious Adverse Events	<b>X</b>
Audits and Inspections in Clinical Trials	Per role
Monitoring of Clinical Trials by Industry Sponsors	Per protocol

International Studies (see CITI GCP for optional modules regarding ICH in an international setting)
<b>CITI Just-in-Time Training</b>
Unanticipated Problems and Reporting Requirements in Biomedical Research
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research