NIH HRPP SOP 25 v.1

HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL & IMPLEMENTATION

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 25

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

Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB Chairs, IRB Administrators, Protocol Navigators

Approval: [Signature]

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DHHS/NIH/OD/OIR/OHSRP
# 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), including key research personnel as defined below in Section 25.3.

25.2 POLICY

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

Clinical researchers and clinical research support staff are required to have additional training commensurate with their roles and responsibilities. This includes Good Clinical Practice (GCP) training when research is regulated by the Food and Drug Administration (FDA) (see SOP 15 “Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications”). 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 25.5.3, 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 3 “CITI Training Information”.

E. **(The) Ethical and Regulatory Aspects of Clinical Research**: This seven (7) week course is offered by the Clinical Center 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 1 “Training Resources” below.

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 GCP guidance (See GCP below).

H. **Guideline for 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:** For the purposes of the HHS regulations, the Office for Human Research Protections (OHRP) interprets an “investigator” to be any individual who is involved in conducting human subjects research studies. Such involvement may include:

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; and

4. Studying, interpreting, or analyzing identifiable private information or data for research purposes

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually 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 Appendix 1 for the link to the OHRP FAQ, “Who are “investigators”)

J. **Key Research Personnel (KRP):** Key research personnel are those individuals who: 1) obtain consent from human subjects; 2) recruit human subjects; 3) evaluate the response of human subjects, including adverse or unanticipated events and 4) analyze or interpret identifiable study data. For more information see SOP 21 “Conflicts of Interest Requirements for Researchers and Research Staff” and SOP 19 “Investigator Responsibilities”

K. **NIH Intramural Clinical Protocol Application:** A completed Application submitted to an NIH IRB at the time of initial or continuing review, study
closure or amendment. It includes a statement of training completed by investigators and other study staff/personnel listed on the Application.

L. **Research Staff:** Include tenure-track investigators, senior investigators, staff scientists/staff clinicians, research fellows/clinical fellows, post-doctoral fellows, senior scientists/clinicians; regardless of whether the research conducted has a clinical focus (see Appendix 1 for a link to the “Research Ethics Case Discussions”).

M. **Research Staff who Obtain Informed Consent:** These research staff are not recognized on the protocol roster as investigators on the study but work with the IRB-approved protocol and have been deemed by the Principal Investigator as qualified to administer informed consent.

N. **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, Basic Science Research or HRPP staff (IRB Chairs, Members and Staff, and OHSRP Staff).

Courses are accessed via the OHSRP website under the “Required HRPP Training” link (see Appendix 1) 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 “NIH IRB Member Training” link on the OHSRP website (see Appendix 1).

The Ethical and Regulatory Aspects of Clinical Research course is an in-person course offered annually by the CC Bioethics Department. Credit for successful
completion of this course may be applied towards clinical research/biomedical training or used as a refresher course for the clinical research or biomedical training. In order 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 or see Appendix 1 for the link.

25.5 TRAINING REQUIREMENTS

For an overview of training requirements for IRP investigators and research staff by role and type of research conducted, see Appendix 2 “NIH IRP HRPP Training Requirements”.

25.5.1 NIH RESEARCH STAFF

Newly employed IRP research staff must complete required initial training before commencing research activities.

Courses are accessed via the HRPP Training page for “Basic Science Researchers”, (see Appendix 1).

A. **Required training:** All newly employed IRP scientists regardless of whether they conduct research involving human subjects or not, are required to complete:

1. The computer-based “NIH Research Ethics” course; and

2. The Office of Intramural Research (OIR) Ethics Case Studies which are required annually

B. **Optional training:** includes additional courses listed on the OHSRP training website pages or any of the just-in-time CITI courses in Section 25.5.5 below. For the current list of available courses and additional guidance, see the OHSRP training website:

1. OHRP Training Video: Research Use of Human Biological Specimens and Other Private Information
2. OHRP Guidance: Guidance on Research Involving Coded Private Information or Biological Specimens (October 16, 2008)

3. OHRP Guidance: Issues to Consider in the Research Use of Stored Data or Tissues (November 7, 1997)


5. Basic Science Research Training

25.5.2 NIH INVESTIGATORS ENGAGED IN CLINICAL RESEARCH

Courses are accessed via the HRPP Training page for “Clinical Research” see Appendix 1 for the link. Additional courses may be required by the PI or IRB according to the type of research to be conducted, (see Section 25.5.5 below for more information.)

A. Principal Investigators and Key Research Personnel engaged in 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.

B. Principal Investigators and Key Research Personnel engaged in FDA-regulated Research

The training below is required for investigators and KRP conducting FDA-regulated research, for more information, see SOP 15 “Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications”. However, 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), CITI Biomedical course or the Ethical and Regulatory Aspects of Clinical Research offered by CC Bioethics.
   b. The NIAID Good Clinical Practice (GCP) course or the CITI Good Clinical Practice for Non PI's 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 Section 25.5.5 below.

C. Research staff who obtain informed consent

1. Required training: NIH Clinical Research Training (CRT)

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 Section 25.5.5 below.

25.5.3 NIH INVESTIGATORS ENGAGED IN EPIDEMIOLOGICAL OR SOCIAL BEHAVIORAL RESEARCH

Courses are accessed via the HRPP Training page for “Epidemiological and Behavioral Research” (see Appendix 1 for the link).

A. Clinical Principal Investigators and Key Research Personnel engaged in epidemiological or social behavioral research

1. Required training:
   a. NIH Clinical Research Training (CRT); and
b. CITI Social and Behavioral Educational Modules

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 Section 25.5.5 below.

B. Research Staff who Obtain Informed Consent

1. Required training: NIH Clinical Research Training (CRT)

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 Section 25.5.5 below.

25.5.4 HRPP STAFF

Courses are accessed via the HRPP Training page for “Epidemiological and Behavioral Research”, (see Appendix 1 for the link).

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

1. Required training:

   a. NIH Clinical Research Training (CRT)

   b. CITI Social and Behavioral Educational Modules;

   and

   c. Either the NIAID Good Clinical Practice (GCP) course, the CITI Good Clinical Practice for PI’s course or The Ethical and Regulatory Aspects of Clinical Research offered by CC Bioethics.

2. 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 Section 25.5.5 below.

B. IRB Members
In addition to the requirement listed in 25.5.4.A.1 above, IRB members must also complete:

1. Required training:
   a. NIH IRB Member Training, (see Appendix 1 for the link)
   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

Just-in-Time CITI courses will be required if conducting research involving these subject areas, but are otherwise optional (e.g. GCP courses are optional, for research staff who do not conduct FDA-regulated research.) IRBs or PIs may also require investigators or research staff to complete these courses.

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

J. Unanticipated Problems and Reporting Requirements in Biomedical Research

K. Unanticipated Problems and Reporting Requirements in Social and Behavioral Research

25.6 REFRESHER TRAINING

Courses are accessed via the HRPP Training page on the OHSRP website, (see Appendix 1 for the link). Refresher types are specified for each type of research conducted: Clinical Research, Epidemiological and Social Behavioral Research, Basic Science Research or HRPP staff. Each user should select the link below the appropriate category to gain access to the correct curriculum.

A. Refresher Cycle: Refresher courses must be completed on a three (3) year cycle based on the anniversary of the completion of initial training requirements.

B. Required Courses: All refresher courses are according to the type of research conducted.

   1. The following courses must be refreshed using CITI:
      a. Clinical Research: CITI Biomedical refresher modules
      b. Epidemiological and Social Behavioral: Social and Behavioral refresher modules
      c. FDA-regulated research: CITI GCP modules

   2. Note that the Ethical and Regulatory Aspects of Clinical Research offered by CC Bioethics may be taken as a refresher for the CITI Biomedical course.
3. Research staff is also required to take the annual Research Ethics Case Discussions offered by the Office of Intramural Research, regardless of the type of research conducted.

4. OHSRP may require additional courses when new policies or regulations go into effect.

25.7 DOCUMENTATION OF NIH HRPP REQUIRED TRAINING, REFRESHER TRAINING AND OPTIONAL TRAINING

A. Investigators and study personnel are responsible for downloading a Certificate of Completion for each completed course to provide proof of training and must maintain proof of training in the research records and/or regulatory binders.

B. OHSRP will maintain a read-only database for the verification of required training courses, refresher courses, and optional training courses by completion date.

C. Transfer of proof of training:

1. Newly employed investigators and research staff coming to the NIH can transfer CITI training course(s) completed in the last 12 months, through CITI to the NIH CITI account. 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 investigators and research staff coming to the NIH can transfer their NIAID GCP training completed 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, and OHSRP Staff.

E. IRB Administrative Staff Training Records will be maintained in the IRB Office.
APPENDICES

Appendix 1- Training Resources

Appendix 2- NIH IRP HRPP Training Requirements

Appendix 3- CITI Training Information

APPENDIX 1- TRAINING RESOURCES

A. Basic Science Research Training:

B. Behavioral Research (Taken from 45 CFR 46.110(a) List of Categories item #7): http://www.hhs.gov/ohrp/policy/expedited98.html

C. Clinical Research Training:

D. Collaborative Institutional Training Initiative (CITI):
   www.citiprogram.org

E. FDA Good Clinical Practice (GCP): Guidance for Industry E6 Good Clinical Practice Consolidated Guidance:


G. NIAID GCP Learning Center:
   https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx

H. NIH Clinical Research Training (CRT) Course:
   http://crt.nihtraining.com/login.php
I. NIH IRB Member Training:  

J. NIH Research Ethics: http://researchethics.od.nih.gov/

K. OHRP FAQ, Who are "investigators:  
http://answers.hhs.gov/ohrp/questions/7214

L. OHRP Guidance: Guidance on Research Involving Coded Private Information or Biological Specimens (October 16, 2008):  
http://www.hhs.gov/ohrp/policy/cdebiol.html

http://www.hhs.gov/ohrp/policy/gina.html

N. OHRP Guidance: Issues to Consider in the Research Use of Stored Data or Tissues (November 7, 1997):  
http://www.hhs.gov/ohrp/policy/reposit.html

O. OHRP Training Video: Research Use of Human Biological Specimens and Other Private Information:  
http://www.youtube.com/watch?v=yp5GzAmXIPM


Q. Required HRPP Training:  

R. Research Ethics Case Discussions:  

S. Research Conduct and Ethics Case Studies:  
http://sourcebook.od.nih.gov/ResEthicsCases/cases-toc.htm

T. The Ethical and Regulatory Aspects of Clinical Research:  
http://www.bioethics.nih.gov/hsrc/
APPENDIX 2- 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; Basic Science Researchers; Research and HRPP Staff including IRB Members and Coordinators

<table>
<thead>
<tr>
<th>ROLES: Cls/Principal Investigators (PIs) and Key Research Personnel (KRP) for non-FDA regulated Studies</th>
<th>Cls/Pls and KRP conducting FDA-regulated Research</th>
<th>Research Staff who obtain consent</th>
<th>Epidemiologic/Behavioral/Social Science/Health Outcomes and Health Services Pls and KRP</th>
<th>NIH Scientists Not Engaged in HSR</th>
<th>HRPP Staff</th>
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<tbody>
<tr>
<td>COURSES</td>
<td>BASIC- Introductory</td>
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<tr>
<td>Clinical Center On-line PI Clinical Research Training (CRT)</td>
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<td>CRT w/out Regulatory Module</td>
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<tr>
<td>CITI Bio-Medical-Module</td>
<td>X</td>
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<tr>
<td>Ethical and Regulatory Aspects of Clinical Research</td>
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<tr>
<td>CITI Behavioral Research Training Module</td>
<td>Clinical Principal Investigators (PIs) and Key Research Personnel (KRP) for non-FDA regulated Studies</td>
<td>Clinical PIs and KRP conducting FDA-regulated Research</td>
<td>Research Staff who obtain consent</td>
<td>Epidemiological / Behavioral/ Social Science/ Health Outcomes and Health Services PIs and KRP</td>
<td>NIH Scientists Not Engaged in HSR</td>
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<td><strong>ROLES:</strong></td>
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<td>Clinical PIs and KRP conducting FDA-regulated Research</td>
<td>Research Staff who obtain consent</td>
<td>Epidemiological / Behavioral/ Social Science/ Health Outcomes and Health Services PIs and KRP</td>
<td>NIH Scientists Not Engaged in HSR</td>
<td>HRPP Staff</td>
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<td><strong>Advanced- FDA/GCP</strong></td>
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<td>NIAID GCP Modules 2-4</td>
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<td>OR</td>
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<tr>
<td>CITI GCP Training and as applicable below*</td>
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<td><strong>Research Ethics</strong></td>
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<tr>
<td>&quot;OIR Introduction to Responsible Conduct of Research &quot; aka &quot;NIH Research Ethics Course&quot;</td>
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<td><strong>IRB Training</strong></td>
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<td>OHSRP On-Line Training for IRB Members</td>
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<tr>
<td>Attend the OHSRP IRB member in-person training</td>
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<td>Attend an IRB meeting</td>
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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.

**KEY**
- √ = Required
- X = May be used for credit for previously completed course work but not preferred for new training.

### CITI GCP Modules

| Module                                                                 | Required
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<tr>
<td>GCP Introduction</td>
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<tr>
<td>Overview of New Drug Development</td>
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<tr>
<td>ICH Overview</td>
<td>If International</td>
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<tr>
<td>ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations</td>
<td>If International</td>
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<tr>
<td>Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices</td>
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### CITI Just-in-Time Training

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<th>Module</th>
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<tr>
<td>Vulnerable Subjects - Research w/Children</td>
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<td>Vulnerable Subjects - Pregnant Women, Human Fetuses, and Neonates</td>
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<td>Vulnerable Subjects - Research Involving Prisoners</td>
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<td>Vulnerable Subjects - Workers/Employees</td>
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<tr>
<td>Genetic Research in Human Populations</td>
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<tr>
<td>CITI GCP Modules</td>
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<td>---------------------------------------------------------------------------------</td>
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<tr>
<td>Investigator Obligations in FDA-Regulated Clinical Research</td>
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<tr>
<td>Managing Investigational Agents According to GCP Requirements</td>
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<tr>
<td>Conducting Clinical Trials of Medical Devices</td>
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<tr>
<td>Only if IDE</td>
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<tr>
<td>Informed Consent-An Ongoing Process</td>
</tr>
<tr>
<td>Detection and Evaluation of Adverse Events</td>
</tr>
<tr>
<td>Reporting Serious Adverse Events</td>
</tr>
<tr>
<td>Audits and Inspections in Clinical Trials</td>
</tr>
<tr>
<td>Monitoring of Clinical Trials by Industry Sponsors</td>
</tr>
</tbody>
</table>
APPENDIX 3- 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 at a later time.

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.

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 "CME/CEU Credits" by your completed course work on the CITI landing page.