Hartford HealthCare

Collaborative Institutional Training Initiative (CITI) Module Requirements for: Human Subject Protection (HSP), Responsible Conduct of Research (RCR), Good Clinical Practice (GCP) and Conflict of Interest (COI)

Purpose:

To describe the research ethics education requirements for all Hartford HealthCare (HHC) research personnel who interact with study participants or who have access to study participant information.

Scope:

The following entities are covered by this policy:

1. Charlotte Hungerford Hospital
2. Hartford Hospital
3. Institute of Living
4. The Hospital of Center Connecticut
5. MidState Medical Center
6. St. Vincent's Medical Center
7. Windham Hospital
8. William H. Backus Hospital
9. All Investigators/researchers without HHC affiliation who are participants in HHC studies

Policy:

As part of our institutional goal of maintaining training within the research community and promoting an organizational culture that encourages integrity and compliance at HHC, the Human Research Protections Program (HRPP) has adopted the web-based modules within the Collaborative Institutional Training Initiative (CITI) for certification in Human Subject Protection (HSP) and Animal Laboratory Welfare Training. These web-based modules are available at www.citiprogram.org. The HHC HRPP will be responsible for hosting and tracking module completion according to the requirements outlined below.

All personnel (employees, medical staff, students, and volunteers) involved with the conduct, administration, or review of human subjects' research must complete at least one training course in the basic group in **Human Subjects Protection** (Groups 1-6) and the course **Conflict of Interest – Stage 1**.

Investigators and research staff conducting federally-funded research (i.e. NIH supported), are required to take the **Responsible Conduct in Research (RCR) Course**.

The **Good Clinical Practice (GCP) Course** is required in the following two circumstances:

1. All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials (as defined by NIH) should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).
2. As requested by study sponsors for investigators and staff conducting industry-sponsored clinical trials.

The GCP course consists of 12 modules focused on Good Clinical Practice and ICH guidelines for investigators conducting FDA-regulated clinical drug/device trials. The CITI basic course should be completed before attempting this more advanced course.

All personnel performing research that involves the use of animals are required to complete the applicable CITI training modules in **Laboratory Animal Welfare**.

All Hartford HealthCare clinical research personnel who interact with study participants or who have access to study participant information shall initially complete the "Basic Course". Individuals will enroll in a Learner Group appropriate to their specific role in Human Subjects/Laboratory Animal Research. ***The "Basic Course" for each Learner Group consists of the Modules that have been pre-defined for that Group by the HRPP.***

There are 4 Learner Groups that can be used for researchers:

Group 1: Biomedical Research Investigators and Study Personnel

Group 2: Social & Behavioral Research Investigators and Study Personnel

Group 3: Students conducting no more than minimal risk research

Group 6: Research with Data or Laboratory Specimens ONLY (no direct contact with human subjects)

- Investigators and research staff conducting **both** biomedical **and** social/behavioral research (i.e., research that has its foundation in the Social/Behavioral Sciences, but involves FDA-regulated clinical drug trials)**,** should complete the requirements for **Learner Group 1** (Biomedical) only.

There are 2 Learner Groups that are used for IRB members and staff ONLY:

Group 4: IRB members

Group 5: Human Research Protections Program Staff

- IRB members that are **also** investigators should complete the required modules defined for **Learner Group 4 only**.

The minimum passing *aggregate* score for the quizzes is 80%. The Hartford HealthCare HRPP CITI institutional administrator receives automatic electronic mail notifications containing completion reports for each user.

Refresher Training using CITI modules will be required every 3 years; **the COI course after 4 years.** The modules completed previously may be repeated for recertification, unless the scope of one's research has changed within that time. All modules for recertification will be eligible for renewal every 3 (or 4) years on the anniversary date of the most recent CITI module completed. The CITI Program will e-mail users an alert 90 days prior to the expiration date.

The HRPP will accept documentation of CITI training from other institutions. The preferred method of providing this documentation is by setting up an affiliation with "Hartford Hospital" through one's existing CITI account. This allows the Hartford HealthCare HRPP staff to access your course completion history electronically and track your progress in our database. Please see the procedures described below.

The Principal Investigator (PI), co-investigators, and key personnel listed on IRB submissions must satisfactorily complete all required modules ***before the IRB can approve initial review or continuing review of a study.***

Satisfactory completion of all required modules is prerequisite as part of the "Just-In-Time" (JIT) information required for federal grants.

IMPORTANT IMPACT ON IRB APPROVAL

New research (exempt AND non-exempt) involving human subjects will not be approved by the IRB until all of the study personnel listed on the protocol have completed the human subject protection education requirements (the CITI program).

The addition of new study staff will not be approved by the IRB unless the individual(s) being added via the "Request for Change in Study Personnel" Form has completed these human subject protection education requirements.

At initial submission or continuing review, the research will not be (re-)approved by the IRB unless all of the study personnel listed on the protocol have completed these human subject protection education requirements.

The PI may elect to remove individuals from the study staff who have not completed the education requirements so that the study may be re-approved; however these individuals *may not continue to function as part of the study staff* unless and until they have completed the education requirements and an amendment to add them to the study staff has been submitted and approved by the IRB.

PIs are responsible for ensuring that the study staff listed on their protocols complete their continuing education requirements at the appropriate intervals. Completion of the CITI education requirements can be verified by accessing the study record in iRIS. Failure on the part of the study staff to comply with the human subject protection continuing education requirements will be considered non-compliance with IRB policies and procedures.

In addition to the mandatory education and training, investigators and study staff are strongly encouraged to take advantage of the many education and training opportunities offered through the HHC HRPP.

Procedure (NEW USERS):

1. Go to the Collaborative Institutional Training Initiative (CITI) website at http://www.citiprogram.org.

2. Beside New Users, click on "Register Here" link. (Note: If you already have a CITI username and password and have completed modules while at another institution follow the instructions below.)

3. From the "Participating Institutions" drop-down list, select "Hartford Hospital" (regardless of HHC institution that you are affiliated with).

4. Scroll down and complete the rest of the page with your personal information and click on Submit.

   ** ***Please be advised that HRPP staff has access to this information and your username shows up on printed versions of your completion reports/certificates. Choose a business-appropriate username that you would not be embarrassed to have your colleagues see on an official document.***

5. Complete the next page with your personal "Member Information" and click on Submit. Items with an asterisk (*) are required fields.

6. At the "Select Curriculum" screen, choose one answer that will determine the type of training you need (Human Subjects Course Only, Laboratory Animal Welfare Course

Only, or Human Subjects AND Lab Animal Welfare Courses). After making your selection, click on "Next Question".

7. At the next screen, choose the appropriate answer that describes whether you need the Basic Course for initial training or the Refresher Course. After making your selection, click on "Next Question".

8. At the next screen you will need to choose a Learner Group (1-6) appropriate for your role in Research. After making your selection, click on "Next Question".

9. The next screen will present the user with 2 additional Courses. Depending on your research activities, determine if you are required to complete them.

   The "Responsible Conduct of Research" is required if you are working on a study that is federally-funded (i.e. it has a grant from the NIH, NHLB, NIMH, NIAA, etc.).

   The "Good Clinical Practice (GCP) Course" is optional for everyone.

   If you do not meet any of these criteria, choose "N/A". After making your selection, click on "Next Question".

10. On the next page, click "No" to continue, unless you plan to affiliate with another institution at this time.

11. Click on the Main Menu link to begin the courses.

12. The "My Courses" column lists the courses that you have enrolled in. Click on the "Enter – Re-enter" link beneath "Status" (to the right of course name).

13. Complete "The Integrity Assurance Statement" and click on Submit.

14. Click on Belmont Report and CITI Course Introduction. Review the module and click on Take the quiz for Belmont Report and CITI Course Introduction in order to complete the module.

15. Complete the 3-question quiz and click on Submit.

16. Once you have successfully completed the Belmont Report quiz (under "Required Modules", there should be a completion date and a score), you can continue to complete other required modules/courses or come back and finish them at a later date.

17. The required conflict of interest module is in the Optional Modules on the Main Menu. This course is required for all researchers and staff. Once you have completed this module, the Optional Modules lists additional courses you can take. Click on the course name you would like to complete to launch the course.

18. Once you complete all required modules and courses, an email will automatically be generated and sent to the Hartford Hospital HRPP administrator.

Procedure (USERS THAT HAVE COMPLETED CITI AT ANOTHER INSTITUTION):

1. Go to the Collaborative Institutional Training Initiative (CITI) website at http://www.citiprogram.org.

2. Enter your username and password at the login and registration page. If you do not remember this information, choose the "Forgot login information" link. You will need to provide the e-mail address that is associated with your CITI user account. You will receive an e-mail from the CITI program with your information.

3. Once logged in, from your Main Menu select the "Affiliate with another institution" link.

4. Select Hartford Hospital at the "Participating Institutions" drop down menu and click submit.

5. Update any of your "Member Information." Items with an asterisk (*) are required fields.

6. Choose the type of research you will be conducting ("Human Subjects Course Only"). After making your selection, click on "Next Question".

7. Select "YES, I have completed the CITI Basic Course at ANOTHER INSTITUTION that uses CITI for training in the Protection of Human Research Subjects (UConn Health Center, Saint Francis Hospital, The Hospital of Central Connecticut, etc.)"

8. Choose a Learner Group for the Basic Course. After making your selection, click on "Next Question".

9. At the next screen choose Responsible Conduct in Research and/or Good Clinical Practice (only if these apply). After making your selection, click on "Next Question".

10. You will only need to complete the modules that are not common to the two institutions (These will show up in your Main Menu).

11. The "My Courses" column on the Main Menu lists the courses that you have enrolled in. Click on the "Incomplete – Re-enter" link beneath "Status" (to the right of course name) to complete any outstanding modules.

12. Complete "The Integrity Assurance Statement" and click on Submit.

13. The required **Conflict of Interest – Stage 1** is in the Optional Modules on the Main Menu. This course is required for all researchers and staff. Once you have completed this module, the Optional Modules lists additional courses you can take. Click on the course name you would like to complete to launch the course.

14. Once you complete all required modules and courses, an email will automatically be generated and sent to the Hartford Hospital HRPP administrator.

Printing documentation of completion of CITI Modules

If you wish to print documentation of completed modules for your records:

1. From the Main Menu, scroll down and click on Previous Coursework Completed.
2. Print this page.

To Remove Affiliation from an Institution

If you have selected the wrong institution and have not completed any modules, you can immediately remove that affiliation from your Main Menu. Click on “Remove my Affiliation” and click on “Submit”.

To Add/Change Affiliation with An Institution:

If you have mistakenly chosen the wrong institution, click on “Affiliate with another institution” on the Main Menu. Follow the prompts and answer all questions with an asterisk.

REFERENCES:

ICH-GCP E6(R2): Investigator Qualifications and Agreements

NOT-OD-00-039: Required Education in the Protection of Human Research Participants. Release Date: June 5, 2000 (Revised August 25, 2000) National Institutes of Health (NIH)

NOT-OD-10-019: Update on the Requirement for Instruction in the Responsible Conduct of Research Release Date: November 24, 2009. National Institutes of Health (NIH)

NOT-OD-16-148: Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials. Release Date: September 16, 2016. National Institutes of Health (NIH)

FDA Guidance: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009

Issued	06/01/2009
Proponent	Director, HRPP
Replaces	New Policy
Approved By	Institutional Review Board
Review Date	09/30/2010
Revised Date	09/16/2009, 7/1/2011, 7/1/2015, 3/15/2020

Element I.1.E.

Comprehensive List of Available CITI Modules for the "Basic Course" in Human Subjects Protection:	Group 1: Biomedical	Group 2: Social & Behavioual	Group 6: Data or Specimens Only Research	Group 4: IRB Members	Group 3: Students conducting no more than minimal risk research	Group 5: HRPP Staff
	Hartford Hosptial Learner Group Requirements					
Social & Behavioral Modules						
The Belmont Report (ID: 1127)		X				X
Students in Research - SBR (ID: 1321)						X
History and Ethical Principles - SBR (ID: 490)		X			X	X
Defining Research with Human Subjects - SBR (ID: 491)		X		X	X	X
The Regulations and The Social and Behavioral Sciences - SBR (ID: 502)		X		X		X
Assessing Risk in Social and Behavioral Sciences - SBR (ID: 503)		X		X		X
Informed Consent - SBR (ID: 504)		X				X
Privacy and Confidentiality - SBR (ID: 505)		X		X	X	X
Research with Prisoners - SBR (ID: 506)						X
Research with Children - SBR (ID: 507)				X		X
Research in Public Elementary and Secondary Schools - SBR (ID: 508)					X	X
International Research - SBR (ID: 509)					X	X
Internet Research - SBR (ID: 510)		X		X		X
Biomedical Modules						
Intro to the Belmont Report (ID: 1127)	X		X	X	X	X
History and Ethical Principles (ID: 498)			X	X		X
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	X		X	X	X	X
Informed Consent (ID: 3)	X			X	X	X
Social and Behavioral Research for Biomedical Researchers (ID: 4)				X		X
Records-Based Research (ID: 5)	X		X	X	X	X
Genetic Research in Human Populations (ID: 6)	X	X	X	X		X
Research With Protected Populations - Vulnerable Subjects: An Overview (ID: 7)			X	X		X
Vulnerable Subjects- Research With Prisoners (ID: 8)						X
Vulnerable Subjects- Research Involving Minors (ID: 9)				X		X
Vulnerable Subjects- Research Involving Pregnant Women and Fetuses in Utero (ID: 10)				X		X
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 11)				X		X
FDA-Regulated Research. (ID: 12)	X			X		X
Other Modules of Interest						
International Research (ID: 971)						X
Human Subjects Research at the VA (ID: 13)						X
HIPAA and Human Subjects Research (ID: 14)	X	X	X	X	X	X
Workers as Research Subjects-A Vulnerable Population (ID: 483)				X		X
Hot Topics (ID: 487)				X		X
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	X	X	X	X		X
The IRB Member Module - "What Every New IRB Member Needs to Know" (ID: 816)				X		X