

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Education
	SUBJECT	Non-Employee Initial and Continuing Training and Education
	SOP #	5.2
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	September 4, 2020

OBJECTIVE

Describe the training and education requirements for non-HHRI investigators, sub-investigators, and staff performing in a direct clinical research role as identified on the Human Subjects Research Committee Request for Review Submission. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research that is conducted within the Hennepin Healthcare System (HHS).

APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Protection of Human Subjects
21 CFR 50 Protection of Human Subjects
21 CFR 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions
FDA Compliance Program Guidance Manual 7348.811: Clinical Investigators
Hazardous Materials Safety: www.iata.org; www.icao.org; www.transportation.gov
Collaborative Institutional Training Initiative (CITI): <https://www.citiprogram.org>
[HHRI Policy VII:08 Non-Employee Utilization](#)

REFERENCES TO RELATED SOPs

All SOPs are applicable to this SOP

ATTACHMENTS

Training Classifications/Learner Categories

1) Principal Investigator

- a) The Principal Investigator must ensure that all research staff have completed institutional and site-specific required training.
- b) The Principal Investigator may delegate site-specific training to an experienced preceptor but retains primary responsibility for training and employee conduct of trial related duties.
- c) The Office for Education and Quality in Clinical Research (OEQCR) will consult with the Principal Investigator with any questions concerning appropriate training assignments.

2) All new non-investigator individuals

- a) Communicate with the OEQCR staff concerning required education if questions occur over the appropriate training requirements.
- b) New non-employee, non-investigators obtaining informed consent or interacting with protected health information (PHI) for research protocols must:
 - i) Attend the OEQCR in-person HHRI Research Training.

- ii) If a new non-employee has extensive clinical research experience OEQCR in-person training may be waived or abbreviated based on the decision of the OEQCR Director
- c) All clinical research staff will complete online courses through the Collaborative Institutional Training Initiative (CITI) program. Required courses are based on research role. See table below:

Learner Category	Courses Required				
	Basic Category (every 3 years)	HIPAA (annually)	COI (every 3 years)	GCP (every 3 years)	IRB Chair/ Vice Chair
Biomedical Researcher	Biomedical Category	Yes	Yes	Yes	No
Social-Behavioral Researcher	Social-Behavioral Category	Yes	Yes	Yes	No
Biomedical Researcher – Statistician*	Biomedical Category	Yes	Yes	No	No
Administrative Staff	Administrative Category	Yes	Yes	No	No
HSRC Member	HSRC Member Category	Yes	Yes	Yes	No
HSRC Chair/Vice Chair	HSRC Category	Yes	Yes	Yes	Yes

- d) The OEQCR will consult with the Principal Investigator and/or supervisor with any questions concerning appropriate training assignments.
- e) Bloodborne pathogen/hazardous materials training will be assigned as appropriate according to federal and state requirements, research role and HHRI Human Resources classification in HHRI Policy VII:08 Non-employee Utilization
- f) The OEQCR staff will provide materials as appropriate (or demonstrate materials that are on the HHRInstitute.org website). These may include but not be limited to:
 - i) OEQCR mandatory clinical research training materials
 - ii) Hennepin Healthcare Research Institute Sponsored Project Administration: Guidance and Procedures
 - iii) Clinical Research Standard Operating Procedures
- g) Documentation of completed OEQCR required training will be maintained in the OEQCR.
- h) Training records for all research personnel working on a specific study must be kept in the study’s regulatory binder or a note to file should be placed in the regulatory binder that identifies the training documentation location within the department.

3) Principal Investigators, Co-Investigators and Sub-investigators

- a) Principal Investigators, Co-Investigators and Sub-investigators will complete the CITI Biomedical and/or Social-Behavioral, Annual HIPAA and Safety Training for Researchers, Good Clinical Practice, and Conflict of Interest courses.
- b) Principal Investigators, Co-Investigators and Sub-Investigators will complete the one-time IRB course titled, “Hennepin Healthcare Mandated Human Subjects Protection Training”.
- c) Documentation of completed required training will be maintained in the OEQCR.

4) **Reciprocity**

- a) Whether CITI or other, training from an AAHRPP accredited organization will be accepted if it is current within the three-year time period.
- b) If specified training is mandatory for research performed on the HHS campus, but not completed at the AAHRPP accredited parent organization, the specified training will be required.
- c) For non-AAHRPP organization training, documentation of specific modules or in-house courses completed is required.
- d) Completion records must be submitted to the OEQCR; alternatively new personnel may affiliate with the HHRI for CITI record transfer.
- e) The OEQCR Director will make the final determination whether training is acceptable.
- f) Education will be timed from the end date of training.
- g) Documentation of completion of OEQCR required training will be maintained in the OEQCR.

5) The Human Subject Research Committee will not approve/reapprove any study where study staff, as identified by the HSRC or OEQCR, has not completed training.

6) Failure of a non-employee to maintain training requirements may result in the dissolution of the relationship with HHRI.

7) **Additional resources**

- a) All Investigators, Co-Investigators, Sub-Investigators and research personnel, will have full access to the HHRI website to access pertinent information and Standard Operating Procedures.

8) **Continuing training and education requirements**

- a) CITI Biomedical and/or Social-Behavioral categories will be required every three years.
- b) HIPAA training is required every year.
- c) Conflict of interest education will be required:
 - i) Initially and every three years
 - ii) When financial conflict of interest policies are revised in a manner that changes researcher requirements
 - iii) If a researcher is non-compliant with financial conflict of interest policies and procedures
- d) Good Clinical Practice training will be required every three years for all investigators and research personnel listed as study staff on a clinical trial (all federal agency definitions apply).
- e) Hazardous materials training will be required every two years as applicable to employee's assigned duties.
 - It is the responsibility of the Principal Investigator, supervisor, or study staff to notify the OEQCR when duties change and such training becomes required
- f) Bloodborne pathogen training will be required yearly as applicable to study staff's assigned duties.

- It is the responsibility of the Principal Investigator, supervisor, or study staff to notify the OEQCR when duties change and such training becomes required
- g) Documentation of completion of required training will be maintained in the OEQCR.
- 9) Research will not be approved or reapproved by the HSRC until all identified persons have completed the appropriate training.

Training Classifications/Learner Categories

- 1) **Biomedical or Social-Behavioral Researcher Category:** The most commonly assigned classification. This category encompasses, but is not limited to:
 - a) All investigators and non-investigative personnel directly involved with any aspect of clinical research study that requires Exempt, Expedited or Full Review from the Human Subjects Research Committee
 - b) Individuals having responsibilities that encompass the need to have increased knowledge of the clinical research process. Examples include individuals who supervise others, act as part of a multi-disciplinary research team, or are responsible for the education or preceptor duties of others in clinical research
 - c) Individuals identified by a supervisor as needing training included in the Biomedical or Social-Behavioral category
- 2) **Biomedical – Statistician Researcher Category:** This category includes statisticians who will:
 - a) All statistician investigators and non-investigative statistician personnel directly involved with any aspect of a clinical research study that requires an Expedited Review from the Human Subjects Research Committee
 - i) Statistician Researchers who are going through Full Committee review will be required to complete additional training. See section 5 above for details.
 - b) Statisticians having responsibilities that encompass the need to have knowledge of the clinical research process. Examples include statisticians who supervise others, act as part of a multi-disciplinary research team, or are responsible for the education or preceptor duties of others in clinical research
 - c) Although the Good Clinical Practice (GCP) course typically is not required for this category, if a statistician is listed as study personnel for a federally funded clinical trial, they will be required to complete the GCP course.
- 3) **Administrative Category:** This category encompasses, but is not limited to:
 - a) Individuals having peripheral responsibilities in relationship to the research process
 - b) Examples include individuals employed to manage overall administrative duties for a research group or study, but are not involved in research activities related to adhering to a specific IRB approved protocol.