OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Education
	SUBJECT	HHRI Employee Initial and Continuing Training and Education
	SOP #	5.1
	EFFECTIVE DATE	August 6. 2008
	REVISION DATE	September 4, 2020

OBJECTIVE

Describe the training and education requirements for Hennepin Healthcare Research Institute (HHRI) or Hennepin Healthcare System (HHS) investigators, sub-investigators, and staff (0.1 FTE or higher) performing in a direct clinical research role or employed by HHRI/HHS in an ancillary role. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research that is conducted within 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

REFERENCES TO RELATED SOPs

All SOPs are applicable to this SOP

ATTACHMENTS

HHS Employees and HIPAA Training
Training Classifications/Learner Categories
Clinical Research Coordinator Certification Reimbursement

1) **Principal Investigator**
   a) The Principal Investigator must ensure that the research staff/new employee has completed all 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 clinical research employees**
   a) Attend HHRI centralized orientation.
   b) Communicate with the Office for Education and Quality in Clinical Research (OEQCR) staff concerning required education if questions occur over the appropriate training requirements.

c) New non-investigator HHRI employees 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 employee has extensive clinical research experience OEQCR in-person training may be waived or abbreviated based on the decision of the OEQCR Director
d) 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:

	CITI Courses Required				
Learner Category	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

e) The OEQCR will consult with the Principal Investigator and/or supervisor with any questions concerning appropriate training assignments.
f) Bloodborne pathogen/hazardous materials training will be assigned as appropriate according to federal and state requirements.
g) The OEQCR staff will provide the new employee with orientation 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
h) Documentation of completed OEQCR required training will be maintained in the OEQCR.
i) 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) **HSRC members**
   a) All members must complete the CITI Human Subjects Research Committee (HSRC) Member, Annual HIPAA and Safety Training for Researchers, Good Clinical Practice, and Conflict of Interest courses.
   b) All members must complete a one-time IRB course titled, "Hennepin Healthcare Mandated Human Subjects Protection Training".

c) Documentation of completed OEQCR required training will be maintained in the OEQCR.

4) **HSRC Chair/Vice Chair**
   a) The HSRC Chair and Vice Chair must complete the CITI HSRC Member, Annual HIPAA and Safety Training for Researchers, Good Clinical Practice, IRB Chairs and Vice-Chairs, and Conflict of Interest courses.
   b) HSRC Chair and Vice Chair must complete a one-time IRB course titled, "Hennepin Healthcare Mandated Human Subjects Protection Training".
   c) Documentation of completed OEQCR required training will be maintained in the OEQCR.

5) **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 OEQCR required training will be maintained in the OEQCR.

6) **Reciprocity**
   a) Whether CITI or other, training from an organization accredited by The Association for the Accreditation of Human Research Protection Programs (AAHRPP) will be accepted if it is current within the three-year time period.
   b) If specified training is mandatory for research performed on the HCMC campus, but not completed at the AAHRPP accredited parent organization, the specified training will be required.
   c) For non-AAHRPP accredited organizations, 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 in CITI for record transfer.
   e) The OEQCR Director will make the final determination whether training conducted outside of stated HHRI requirements is acceptable.
   f) Education will be timed from the end date of training.
   g) Documentation of completion of required training will be maintained in the OEQCR.

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

8) **Additional resources**
   a) All Principal Investigators, Co-Investigators, Sub-Investigators, research personnel, and general staff will have full access to the HHRI website to access pertinent information and Standard Operating Procedures.

9) **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. See ADDITIONAL GUIDANCE "HHS/HCMC Employees and HIPAA Training."
   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.
      i) It is the responsibility of the Principal Investigator, supervisor, or employee to notify the OEQCR when duties change and such training becomes required
   f) Bloodborne pathogen training will be required yearly as applicable to employee's assigned duties.
      i) It is the responsibility of the Principal Investigator, supervisor, or employee 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.

10) Research will not be approved or reapproved by the HSRC until all identified persons have completed the appropriate training

HHS Employees and HIPAA Training

HHS employees, who have direct patient contact and/or access to Epic for their job, are exempted from the requirement to complete the CITI Annual HIPAA and Safety Training for Researcher course. Per HHS Policy #027740, Protected Health Information (PHI), as a condition of employment with HHS, employees who have direct patient contact and/or access to Epic are required to complete HIPAA training annually. OEQCR will track this training through collaboration with HHS.

CITI 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 a 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.

4) **Human Subjects Research Committee Member Category:** This category encompasses all members of the Human Subjects Research Committee

5) **Human Subjects Research Committee Chair/Vice Chair Category:** This category encompasses the Chair/Vice Chair of the Human Subjects Research Committee

Clinical Research Coordinator Certification Reimbursement

The Office for Education and Quality in Clinical Research (OEQCR) will provide reimbursement for Clinical Research Coordinator (CRC) certification when the following qualifications have been met:

- CRC certification has been completed by a nationally recognized organization such as SoCRA or ACRP
- CRC must be employed with HHS/HHRI at the time the exam was passed
- CRC must provide proof that examination was completed and passed

Please Note:

1. Any active research staff qualify to seek CRC certification reimbursement if they also meet the certifying institution's requirements to sit for the exam.
2. OEQCR will also reimburse for re-certification costs.
3. At this time, reimbursement is limited to the CRC certification exam and re-certification only.

To request reimbursement, please contact the OEQCR for the CRC Certification Reimbursement form:

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