OBJECTIVE
Describe the training and education requirements for non-HHRI investigators, sub-investigators, and staff (0.1 FTE or higher) performing in a direct clinical research role as identified on the Human Subject 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 County Medical Center campus.

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
http://www.iata.org
CITI https://www.citiprogram.org

REFERENCES TO RELATED SOPs
All SOPs are applicable to this SOP

ATTACHMENTS
Training Classifications

1) Principal Investigator
   a) The Principal Investigator must ensure that all research staff has completed institutional and site specific required training.
   b) The Principal Investigator or employee supervisor 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) Meet with the OEQCR Director concerning required education if questions occur over the appropriate training requirements.
   b) Complete the CITI Primary, Secondary, Administrative modules as appropriate, Good Clinical Practices, and Conflict of Interest.
   c) 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) Minneapolis Medical Research Foundation Sponsored Project Administration: Guidance and Procedures
ii) Clinical Research Standard Operating Procedures
d) Documentation of required training will be maintained in the OEQCR.

3) It is the obligation of the non-employee to ensure that bloodborne pathogen training and hazardous materials training is maintained as appropriate (excluding visiting students/volunteers – see section 6 for more information).
a) Bloodborne pathogen/hazardous materials training will be available upon request of a non-employee.
b) Hazardous materials training will be available upon request of a non-employee.

4) Principal Investigators and Sub-investigators
   a) Must complete the CITI Primary Basic Course, Good Clinical Practices, and Conflict of Interest modules.
b) Documentation of required training will be maintained in the OEQCR.

5) Visiting Students/Volunteers
   a) Must complete the CITI Primary Basic Course, Good Clinical Practices, and Conflict of Interest modules.
b) Training will not be provided for the following prohibited activities:
   i) Operating heavy equipment including vehicles
   ii) Working with infectious or potentially infectious agents, including human blood, bodily fluid or performing phlebotomy
   iii) Obtaining informed consent
   iv) Handling, packing or transporting of biohazardous materials
   v) Access to EPIC if the individual is a Minor (under the age of 18)

6) Reciprocity
   a) Whether CITI or other, training from an AAHRPP accredited organization will be accepted if it is current within the 3 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 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 OEQCR required training will be maintained in the OEQCR.

7) 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.

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

9) Additional resources
   a) All Principal Investigators and Sub-Investigators will be added to the research personnel ListServ.
b) Non-HHRI clinical research personnel (except for causal appointments) will also be added to the ListServ.

c) The ListServ will be maintained by the OEQCR.
   i) Placement on the ListServ will be mandatory.
   ii) The OEQCR will monitor the ListServ to assure that no individual opts out while in an active research role.
   iii) The ListServ will be used to disseminate information including, but not limited to, policy changes, educational opportunities, meetings, news worthy items.
   iv) The OEQCR will further monitor the ListServ to assure that messages are delivered to respondents.

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

10) Continuing training and education requirements
   a) Human subject research training will be required every three years.
   b) Conflict of interest education will be required:
      i) As appropriate
      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
   c) Documentation of OEQCR required training will be maintained in the OEQCR.

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

1) **Primary 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 studies that require a Full/Expedited Review from the Human Subjects Research Committee
   
   b) Individuals having responsibilities that encompass the need to have increased knowledge of the clinical research process beyond that offered in the Secondary category. Examples include individuals that 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 Primary category

2) **Secondary Category:** This category encompasses, but is not limited to:
   a) Investigators performing only studies requiring an Exempt Review from the Human Subjects Research Committee
   
   b) Individuals having responsibilities that encompass a need to have basic knowledge of the clinical research process. Examples include individuals acting in data collection and statistics, medical residents performing retrospective studies, or HHRI support staff

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 involved in accounting or development departments

4) **Human Subject Research Committee Member Category:** This category encompasses:
   a) All members and support staff of the Human Subject Research Committee