OBJECTIVE
Describe the training and education requirements for newly hired HHRI investigators, sub-investigators, and staff (0.1 FTE or higher) performing in a direct clinical research role or employed by the HHRI in an ancillary role.

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 or HHRI employee Supervisor
   a) The Principal Investigator or employee supervisor must ensure that the research staff/new employee has completed all 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.

2) All new non-investigator employees
   a) Attend HHRI centralized orientation.
   b) Meet with the Office for Education and Quality in Clinical Research (OEQCR) Director concerning required education if questions occur over the appropriate training requirements.
   c) New non-investigator HHRI employees obtaining informed consent for research protocols:
      i) Attend the OEQCR Good Clinical Practice/Human Subject Protection didactic modules.
      ii) If a new employee has extensive clinical research experience OEQCR didactic clinical research training materials may be waived based on the decision of the OEQCR Director
      iii) Volunteers associated with the HHRI are not considered employees and therefore are not eligible to obtain informed consent or handling of infectious substances.
   d) Other new employees/research staff will complete the CITI Human Subject Research Committee Member, Primary, Secondary, or Administrative modules as appropriate, Good Clinical Practices, and Conflict of Interest.
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) Administrative and Clinical Research Safety Manual
   ii) OEQCR mandatory clinical research training materials
   iii) Hennepin Healthcare Research Institute Sponsored Project Administration: Guidance and Procedures
   iv) Clinical Research Standard Operating Procedures

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

3) HSRC members
   a) All members must complete the CITI Human Subjects Research Committee Member, Good Clinical Practices, and Conflict of Interest modules.
   b) Documentation of OEQCR required training will be maintained in the OEQCR.

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

5) 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) For non-AAHRPP accredited organizations, training, documentation of specific modules or in-house courses completed is required.
   c) Completion records must be submitted to the OEQCR, alternatively new personnel may affiliate with the HHRI for record transfer.
   d) The OEQCR Director will make the final determination whether training is acceptable.
   e) Education will be timed from the end date of training.
   f) Documentation of required training will be maintained in the OEQCR.

6) 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.

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

8) Additional resources
   a) All Principal Investigators and Sub-Investigators will be added to the research personnel ListServ.
   b) HHRI clinical research personnel (01. FTE or higher) will be added to the ListServ. This includes all individuals with the title of Research Nurse, Research Coordinator, Research Assistant, Project Coordinator, Research Manager, and Research Supervisor.
   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, 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) Human subject research training will be required every three years.
   b) 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 when duties change and such training becomes required
   c) 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 when duties change and such training becomes required
   d) 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
   e) Good Clinical Practice training will be required every three years.
   f) Documentation of required training will be maintained in the OEQCR.
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 employed in accounting

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