OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Education
	SUBJECT	HHRI Clinical Researcher Initial and Continuing Training and Education
	SOP #	5.1
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	May 1, 2021

OBJECTIVE

Describe the training and education requirements for personnel involved in human research conducted under the auspices of Hennepin Healthcare System (HHS)/Hennepin Healthcare Research Institute (HHRI). These procedures apply to all human research under the jurisdiction of the Hennepin Healthcare IRB.

NOTE: The Hennepin Healthcare IRB may modify minimum training and education requirements when deemed appropriate for approval criteria. Training and education requirements to do NOT apply to IRB approval for Humanitarian Use Device (HUD) submissions.

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

CITI Online Training
Required Training by Research Role
Consent Competency Training
Phlebotomy Competency Training
HHS Employees and HIPAA Training
Clinical Research Coordinator Certification Reimbursement

1. **Principal Investigator responsibilities**
   a. The Principal Investigator must ensure that the research personnel have completed all institutional and site-specific required training.
   b. The Principal Investigator may delegate site/study-specific training to an experienced preceptor and the task of documenting all research personnel training

but retains primary responsibility for training and research personnel conduct of trial related duties. IMPORTANT: For IRB submissions in Cayuse Human Ethics (HE), the PI or designee is responsible for verifying that the CITI information for required modules can be viewed in the submission and hasn't expired for each individual listed.

c. 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.

   Please Note: In some cases, study personnel will be required by a sponsor to be listed on the Form FDA 1572 as a Sub-Investigator, despite being internally classified as non-Investigator personnel (e.g. Manager, Coordinator, RA, etc.) based on study role and qualifications. When this occurs, it's important to continue to refer to study personnel *internally* by their functional study role. In practical terms, this means noting them as such on the Delegation of Authority Log (DOA), Training Log, IRB submission and ongoing correspondence, etc. In a case like this, the only place study personnel would be listed as Sub-Investigator would be on the actual Form FDA 1572 document.

d. The Office for Education and Quality in Clinical Research (EQ) will consult with the Principal Investigator or designated study personnel on any questions concerning appropriate training assignments.

2. **Key personnel required training (e.g., Principal Investigators, Co-Principal Investigator, Co-Investigators/Sub-Investigators, other key collaborators)**
   See attachments "CITI Online Training", "Required Training by Research Role" for training requirements. Documentation of completed training is maintained by EQ.

3. **All other personnel required training (e.g., coordinators, assistants, NRCs)**
   See attachments "CITI Online Training", "Required Training by Research Role" for training requirements. Documentation of completed training is maintained by EQ.

4. **IRB member required training**
   See attachments "CITI Online Training", "Required Training by Research Role" for training requirements. Documentation of completed training is maintained by EQ.

5. **IRB Chair/Vice Chair required training**
   See attachments "CITI Online Training", "Required Training by Research Role" for training requirements. Documentation of completed training is maintained by EQ.

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 HHS/HHRI campus, but not completed at the AAHRPP accredited parent organization, the specified training will be required.
c. For training completed at a non-AAHRPP accredited organization, training will be evaluated based on HHRI requirements. If it does not meet current HHRI requirements, training completion will be required.
d. Completion records must be submitted to the EQ; alternatively, personnel may affiliate with the HHRI in CITI for record transfer.
e. The EQ Director will make the final determination whether training conducted outside of stated HHRI requirements is acceptable.
f. Determination of education due dates will be timed from the end date of training.
g. Documentation of completed training is maintained by EQ.

7. **Additional resources**
   a. All research personnel and other personnel will have full access to the HHRI website to access pertinent information and Standard Operating Procedures and/or may be provided with specific materials as necessary for research role. These may include:
      1. EQ clinical research training materials
      2. Clinical Research Standard Operating Procedures
      3. Human Research Protection Office (HRPO) website/webpage
      4. HHRI Sponsored Project Administration: Guidance and Procedures

8. **Continuing training and education requirements**

Research personnel listed with the IRB are required to maintain compliance with continuing requirements:

a. All CITI courses are due every three (3) years, except for HIPAA training -it is due annually.
b. The CITI Good Clinical Practice (GCP) training will be required every three years for all research personnel listed with the IRB on a clinical trial (all federal agency definitions apply).
c. HHRI Research Training (In-person) and Consent Competency are one-time training sessions conducted when research personnel are initially onboarded with HHRI. However, this training may be required again if EQ staff deem it necessary for review/re-training of study conduct requirements or the study personnel request refresher training.
d. Hazardous Materials Shipping training will be required every two years as applicable to researcher's assigned duties.
      1. It is the responsibility of the Principal Investigator, supervisor, or research personnel to notify EQ when duties change and such training becomes required.
e. Bloodborne Pathogens training will be required yearly as applicable to researcher's assigned duties.
      1. It is the responsibility of the Principal Investigator, supervisor, or research personnel to notify EQ when duties change and such training becomes required.

f. Documentation of completed training is maintained by EQ.
g. See attachments: CITI Online Training, Required Training by Research Role, Consent Competency Training, and HHRI Phlebotomy Competency Training requirements, and HHS Employees and HIPAA Training for further details.

9. **Research will not be approved or reapproved by the IRB until all identified personnel have completed the appropriate training.**

CITI Online Training

Learner Category	CITI Courses Required				
	Basic Category (every 3 years)	HIPAA (annually)	COI (every 3 years)	GCP (every 3 years)	IRB Chair/ Vice Chair
Biomedical Research	Biomedical Category	Yes	Yes	Yes	No
Social-Behavioral Research	Social-Behavioral Category	Yes	Yes	Yes	No
Secondary /Observational Research	Secondary/Observational Category	Yes	Yes	No	No
IRB Member	IRB Committee Member Category	Yes	Yes	Yes	No
IRB Chair/Vice Chair	IRB Chair/Vice Chair Category	Yes	Yes	Yes	Yes
Administrative Personnel	Administrative Category	Yes	Yes	No	No

CITI Training Classifications/Learner Categories

1. **Biomedical or Social-Behavioral Research Category:** The most commonly assigned classification for clinical trial researchers. The Biomedical track is most often for studies that involve an investigational drug or device and the Social-Behavioral track is most often for clinical trials that are other than biomedical. This category encompasses, but is not limited to:
   a. All investigators and non-investigator personnel directly involved with any aspect of a clinical research study that requires expedited or full review from the IRB 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 clinical 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.
   d. This category will apply to any researcher listed with the IRB as study personnel on a federally funded clinical trial.

2. **Secondary/Observational Research Category:** This category includes:
   a. Investigators and non-investigator research personnel involved in secondary data, retrospective, or observational research.
      1. This category is for researchers who are only involved in these types of studies.
      2. If a researcher changes from conducting secondary data, retrospective or observational research and moves up to higher risk research such as a clinical trial, additional training in that category will be required.

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.
   c. Individuals identified by supervisor as needing this specific training.

4. **IRB Member Category:** This category includes all members of the IRB/CRC.

5. **IRB Chair/Vice Chair Category:** This category includes the Chair/Vice Chair of the IRB.

Required Training by Research Role

Role	CITI Online Training	Investigator Clinical Trial Training	HHRI Research Training (In-Person)	Consent Competency	Bloodborne Pathogens	Hazardous Materials Shipping	Phlebotomy
Key personnel	R	R if research is non-exempt	N/A	N/A	N/A	N/A	N/A
Other personnel -	R	N/A	R if research is non-exempt	R if role involves consenting	R if role involves biospecimen handling	R if role involves biospecimen shipping	R if role involves phlebotomy
IRB Chair, Vice-Chair, and Members	R	R	N/A	N/A	N/A	N/A	N/A

R= Required; N/A = Not Applicable

Research Roles

Key personnel: Required to complete CITI online training and non-CITI clinical trial investigator training; non-CITI clinical trial investigator training is not required for *Exempt* research.

All personnel – Exempt category 4 ONLY research (data only): Required to complete CITI online training for secondary/observational research category. Please note: if researcher moves into conducting more than data only research, additional training will be required.

Other personnel:

Minimum requirements:

Required to complete CITI online training and HHRI Research Training (in-person)

Additional requirements:

- If research role involves consenting: **Consent Competency** training must be completed.
- If research role involves biospecimen handling**: Bloodborne Pathogens** training must be completed.
- If research role involves phlebotomy: **Phlebotomy Competency** training must be completed.
- If research role involves biospecimen shipping**: Hazardous Materials Shipping** training must be completed.

Please note: If a researcher's role changes, they and/or their supervisor are required to notify EQ and complete all additional required training for the updated role. Documentation of completed training based on the role in the study will be required for initial IRB approval and/or continued IRB re-approval.

Consent Competency Training

As of 5/1/2021, all new HHRI study personnel who have been delegated the task of obtaining informed consent as part of their study role, regardless of level of experience, must complete a one-time, interactive introduction to conducting the informed consent process.

For new study personnel as of 5/1/2021, this training must be completed before conducting informed consent activities.

The Consent Competency training involves the following:

1. Introduction to the informed consent process
2. Review of mock consent form and demonstration of starting and conducting the informed consent process
3. Small group practice with techniques and documentation of the informed consent process
4. EQ will notify the research personnel and supervisor with feedback of the assessment

Please Note: Shadowing and mentorship is important for new study personnel to be successful in building confidence in their approach and knowing that they are properly conducting informed consent.

EQ staff are always willing to set up additional opportunities for any/all study personnel to review requirements and practice the process.

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Phlebotomy Competency Training

All HHRI study personnel who have been delegated phlebotomy tasks as part of their study roles, regardless of level of experience, must pass a yearly Phlebotomy Safety and Competency Assessment through the EQ office.

If this competency assessment has not been passed or is past due, study personnel cannot perform study phlebotomy activities.

If a licensed medical professional who is an HHS employee performs phlebotomy as part of standard of care, and also performs phlebotomy for study purposes but executes no other study tasks, they will not need to be assessed by EQ to be allowed to perform phlebotomy for a study. If, however, they conduct any other study tasks, such as obtaining consent, study form completion, test article administration, etc., they will need to go through HHRI research training requirements and be added to the study via the IRB.

The Phlebotomy Safety and Competency Assessment involves the following:

1. Watching instructional videos
2. Technique instruction by an EQ staff member
3. Practice on an artificial arm until comfortable with technique
4. If needed:
    a. Further practice on artificial arm, with or without EQ staff offering guidance
    b. Supervised live venipuncture performance with other employee(s) who are up to date on the Phlebotomy Safety and Competency requirements
    c. Supervised live venipuncture performance with EQ staff, if available and willing
5. Competency assessment by EQ staff of venipuncture performance on live volunteer
6. Successful completion of written Phlebotomy Knowledge Check
7. EQ will notify supervisor of outcomes of the assessment, including whether addition training is needed/required. Once EQ staff have deemed the employee competent to perform phlebotomy on study participants, specific communication will be provided to the supervisor.

When new personnel will be asked to perform phlebotomy but have no experience or training, they will complete the following:

1. Introduction to Phlebotomy with EQ staff.
    a. Includes surface education on anatomy, technique, approved areas to draw, trouble-shooting, etc.
    b. EQ reserves the option to utilize other HHRI/HCMC education opportunities when available and appropriate.
2. Observation of phlebotomy by approved personnel
3. Practice on artificial arm
4. Watch instructional videos
5. Technique instruction by EQ staff
6. Practice on artificial arm until comfortable with technique
7. If needed:

a. Further practice on artificial arm, with or without EQ staff offering guidance
b. Supervised live venipuncture performance with other employee(s) who are up to date on the Phlebotomy Safety and Competency requirements
c. Supervised live venipuncture performance with EQ staff, if available and willing

8. Competency assessment by EQ staff of venipuncture performance on live volunteer
9. Successful completion of written Phlebotomy Knowledge Check
    a. Initial permission granted to begin performing phlebotomy only under supervision of approved experienced personnel
10. Once deemed competent by EQ staff to perform phlebotomy on study participants, supervisor will be notified.

Please Note: It is the policy of HHRI that blood draws for HHRI research can only be performed by venipuncture in the antecubital site. No blood may be drawn from any other sites, or any lines or ports. If a need arises to use this method, please connect with EQ and we will help researchers walk through how to connect with HHS medical personnel to provide this type of blood draw.

HHS Employees and HIPAA Training

HHS employees who have direct patient contact and/or access to Epic for their job and complete HHS Annual Required Training (ART) that includes HIPAA modules, 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. EQ will track this training through collaboration with HHS.

Clinical Research Coordinator Certification Reimbursement

The Office for Education and Quality in Clinical Research (EQ) 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 documentation that examination was completed and passed

Please Note:

1. Any active HHRI research employees may seek CRC certification reimbursement if they also meet the certifying institution's requirements to sit for the exam.
2. EQ 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 EQ for the CRC Certification Reimbursement form:

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