Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 102: TRAINING AND EDUCATION

POLICY

Training of the IRB administrator and members of the IRB is critical if the IRB is to fulfill its mandate to protect the rights, welfare, and safety of research subjects in a consistent manner throughout the Decatur Memorial Hospital research community. IRB members are expected to complete human subjects protection training and good clinical practice training. When appropriate, education pertaining to existing or new IRB policies and procedures, as well as the regulations, will be presented at a convened meeting.

All members of the research community are required to complete human subjects protection training, in addition to initial and ongoing training in good clinical practice. IMEDRIS training will be provided to members of the research community who require access to this software. All IRB policies will be made available online at https://memorial.health/medical-services/research/.

Student researchers consist of nursing students, nurse anesthesia students, and pharmacy residents – any of whom may also be seeking their doctorate. Training for these individuals may vary from human subjects to good clinical practice to doctoral student researcher, or any combination thereof.

Physician users are not members of the research community, but still require training in areas germane to the use of humanitarian use devices and relevant policies.

The IRB administrator and/or Manager of Clinical Research will establish the educational and training requirements. Evidence of all training shall be maintained by the IRB administrator.

PROCEDURE

1. IRB Administrator Training

1.1 The IRB administrator will complete training in the protection of human subjects research and good clinical practice. The IRB administrator may complete any of the training options offered to the research community (see Members of the Research Community below). Good clinical practice training is required to be taken every 3 years with a 60-day grace period to be in compliance.

1.2 The IRB administrator will be encouraged to attend workshops and conferences hosted by PRIM&R, and other educational opportunities focused on IRB function. Decatur Memorial Hospital will support such activities to the extent possible.

1.3 The IRB Administrator will be encouraged to maintain his or her expertise through IRB certification and other relevant certifications.

2. IRB Member Training

2.1 IRB members will complete training in the protection of human subjects research and good clinical practice. IRB members may complete any of the training options offered to the research community (see Members of the Research Community below). Good clinical practice training should be taken every 3 years, but IRB members are afforded more flexibility since they do not have to complete NCI's Registration and Credential Repository.

2.2 IRB members may be offered individual opportunities to attend workshops hosted by PRIM&R and other organizations to the extent that Decatur Memorial Hospital is able to support such activities.

2.3 IRB members will have access to educational books and relevant reading material.

3. Members of the Research Community Training

3.1 Investigators and members of his or her research staff must complete one of the following human subjects protection (HSP) training programs:

- CITI Program
- Association of Clinical Research Professionals (ACRP)
- National Institutes of Health (NIH)

3.1.1 While the HSP training is no longer offered by the NIH, it is training that if previously completed does fulfill this requirement.

3.2 Investigator and members of his or her research staff must also complete one of the following good clinical practice training programs:

- National Drug Abuse Treatment, Clinical Trials Network (NIDA)
- CITI Program
- NCI-sponsored training
- In-house programs

3.2.1 Good clinical practice training is required to be taken every 3 years with a 60-day grace period to be in compliance.

3.3 Investigators and members of his or her research staff may receive additional training in areas germane to their responsibilities through various workshops and/or conferences.

3.4 Research staff will be encouraged to maintain their expertise through CCRP certification as provided by the Society of Clinical Research Associates (SoCRA).

3.5 Research staff will have access to educational books and relevant reading material.

4. Student Researchers

4.1 Students must complete training in either human subjects research/HSP, good clinical practice, or doctoral student researcher from one of the following programs:

- National Drug Abuse Treatment, Clinical Trials Network (NIDA)
- CITI Program
- Association of Clinical Research Professionals (ACRP)

5. Protocol Specific Training

5.1 Research staff are required to follow the training requirements as outlined in the protocol and/or as specified by the research base and/or sponsor.

6. Proctored Training

6.1 Physician users of a humanitarian use device (HUD) may need to complete a training program and/or receive proctored training as required by the device manufacturer.

7. Documentation

7.1 Evidence of training in human subjects research, human subjects protection, good clinical practice, and/or doctoral student researcher shall be maintained by the IRB administrator.

7.2 Protocol specific training shall be documented as required. Evidence of protocol specific training is not required by the IRB Office.

7.3 Completion of a training program or proctored training for a humanitarian use device shall be documented by the proctor and evidence of the HUD training shall be maintained by the IRB administrator.

SCOPE

This SOP applies to all IRB members, the IRB administrator, members of the research community, student researchers, and physician users.