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, privacy, and welfare of research subjects in a consistent manner throughout the Decatur Memorial Hospital research community. Regular IRB members and the IRB Co-Chairs 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.

The IRB administrator and/or Director of Clinical Research will establish the educational and training requirements. IRB staff and members, along with members of the research community will receive initial and ongoing training regarding the responsible review and oversight of research, and all policies and accompanying procedures. Physician users are not members of the research community, but still require training in areas germane to the humanitarian use device and relevant policies.

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 research subjects 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).

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 research subjects 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).

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 training programs:

- CITI Program
- Association of Clinical Research Professionals (ACRP)

3.1.1 A certificate of completion must be provided to the IRB administrator prior to the initiation of any research activity.

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
- GCP training sponsored by large academic centers

3.2.1 A certificate of completion must be provided to the IRB administrator prior to the initiation of any research activity.

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. Nurse Anesthetist Student Training

4.1 These students must complete one of the following human subjects protection training programs:
- CITI Program
- Association of Clinical Research Professionals (ACRP)

4.1.1 A certificate of completion must be provided to the IRB administrator prior to the initiation of any research activity.

5. Protocol Specific Training

5.1 All research staff will 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 will complete a training program and/or receive proctored training as required by the device manufacturer.

SCOPE

This SOP applies to all IRB members, the IRB administrator, members of the research community, nurse anesthetist students, and physician users.