

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: TRAINING AND EDUCATION

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 10/00; 5/09

POLICY:

Training of the IRB Administrator and Members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner throughout the Decatur Memorial Hospital research community.

The IRB Members, staff and others charged with the responsibility for reviewing, approving, and overseeing human subject research should receive detailed training in the regulations, guidelines, ethics and policies applicable to human subjects research.

The IRB Administrator establishes the educational and training requirements. Initial and ongoing training is provided and documented in the IRB office. New or revised SOPs will be presented at conveyed meetings, and posted on the DMH IRB web site.

Specific Policies

IRB Administrator Training

The IRB Administrator will complete training in the protection of human research subjects through the University of Miami's Collaborative IRB Training Initiative (CITI) online training course so long as the Administrator is a Public Responsibility in Medicine and Research (PRIM&R) member. This training must be repeated every two years.

The IRB Administrator will complete training in the protection of human research subjects through the web-based training program offered by the NIH Office of Extramural Research. This training must be repeated every three years.

The IRB Administrator will receive initial and ongoing training in the areas germane to his or her responsibilities, including all SOPs.

The IRB Administrator will be encouraged to attend workshops, such as PRIM&R, and other educational opportunities focused on IRB functions and human subject research. Decatur Memorial Hospital will support such activities to the extent possible and as appropriate for the level of responsibility.

The IRB Administrator will be encouraged to maintain his or her expertise through IRB certification and other forms of credentialing.

IRB Member Training

IRB Members will complete training in the protection of human research subjects through the web-based training program offered by the NIH Office of Extramural Research. This training must be completed every three years.

IRB Members will participate in initial and continuing training in areas germane to their responsibilities, including all SOPs.

Principal Investigators and Key Study Personnel (KSP) Training

Decatur Memorial Hospital does not require their Investigators or KSP to complete training in the protection of human research subjects through the University of Miami's Collaborative IRB Training Initiative (CITI) online training course; however, if it is a training requirement through some other institution, the DMH IRB requires a copy of the completion certificate.

Principal Investigators and Key Study Personnel will complete training in the protection of human research subjects through the web-based training program offered by the NIH Office of Extramural Research. This training must be repeated every three years.

Principal Investigators and Key Study Personnel will receive initial and continuing training in the areas germane to their responsibilities, including all SOPs.

Key Study Personnel will be encouraged to maintain their research expertise through CCRP credentialing as provided by the Society of Clinical Research Associates (SoCRA).

DMH Nurse Anesthesia Students/Bradley University

These students must complete either the Collaborative IRB Training Initiative (CITI) online training course or the NIH web-based training program; not both. Certificates of completion are only valid for three years.

Millikin University Students

These students must complete training in the protection of human research subjects through the web-based training program offered by the NIH Office of Extramural Research

Documentation

Educational records and training certificates of completion shall be maintained in the IRB office.

APPLICABLE TO:

These policies and procedures apply to all IRB Members, the IRB Administrator, Principal Investigators, and Key Study Personnel at Decatur Memorial Hospital.

RESPONSIBILITY:

The IRB Administrator in conjunction with the Director of Clinical Research is responsible for establishing, conducting and/or supervising all relevant training programs.

APPROVED BY:

President and CEO