McLeod Health
The Choice for Medical Excellence.

Institutional Review Board Policy Manual

MEMBER TRAINING AND CONTINUING EDUCATION REQUIREMENTS

PURPOSE: This policy describes the training and education requirements for McLeod Health IRB members **and research staff. The McLeod Health IRB recognizes the importance of having a strong, comprehensive educational program that ensures that any individual understands the ethical principles and regulatory requirements related to the protection of human subjects.**

POLICY: Training of IRB members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of research subjects in a consistent manner throughout the McLeod Health research community. IRB members and others **responsible** for reviewing, approving, and overseeing human subject research shall receive detailed training in the regulations, guidelines, ethics, and policies applicable to **such** research.

PROCEDURE:

In order to fulfill their duties, IRB members **and IRB staff** are expected to be versed in regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of **the** McLeod Health Institutional Review Board germane to human subject protection. The IRB must be perceived to be fair and impartial, and immune from pressure by the investigators whose protocols are brought before to the Board.

Required Training

IRB members who are overseeing research on human subjects, as defined in 45 CFR 46.102-(f) and/or 21 CFR 56.102(e), that is managed, funded, or taking place in an entity under the jurisdiction of McLeod Health**,** will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and procedures.

Before acceptance to the IRB**,** potential members are invited to observe a board meeting. Each member is presented **with** an "IRB Member's Handbook/Orientation" for review upon acceptance to the Board by the IRB coordinator (includes reference materials). If new appointees to the board do not complete their orientation, they will not be assigned clinical studies to review.

All IRB members **must** have an orientation. They are required to successfully complete the orientation in human subject research established by McLeod Health and the **National Institutes of Health (NIH) "Protecting Human Research Participants"**

(required training). All certificates of completion must be submitted to the IRB coordinator. Acknowledgement forms for all reviewed documentation are to be returned to the IRB coordinator. Some of the required reading contained in the orientation consists of the following:

- The Belmont Report
- Declaration of Helsinki
- The Code of Federal Regulations (partial list)
  - 45 CFR 46 (DHHS)
  - 21 CFR 50 and 56 (FDA)
- Overview of Research Trials
- Primary Review (requirements and form)
- McLeod Health IRB Policies & Procedures (partial list)
  - Composition of the Board
  - Continuing Review
  - Federal-Wide Assurance
  - Initial Review/Approval
  - Minutes
  - Principal Investigator Responsibilities
- McLeod Health Administrative Policies & Procedures
  - Investigational Policy
  - Ethics - Conflict of Interest
- Confidentiality and Security Agreement
- ICH – Guideline for Good Clinical Practice
- Acknowledgement forms of review (All required reading documentation)

These are a few of the core documents for required reading. Over time, new documentation will be added and/or revised. Each IRB member is responsible for maintaining their handbooks when new and/or revised information is distributed.

IRB Chairs, IRB members, **and** IRB staff involved in the review of human subject research applications are required to successfully complete training prior to reviewing applications. Additional training includes familiarizing IRB members with regulations and McLeod Health procedures through orientation. **Continuing** education is presented at least quarterly at the IRB meetings. The IRB Chair, Vice-Chair, and IRB Coordinator will attend at least one national human subject research meeting.

Documentation

Training and continuing education will be documented in the minutes of the meeting in which training is presented. In addition, documentation will be added to the board member files.

The IRB coordinator periodically provides IRB members copies of articles **(considered education)** related to issues relevant to human research from various sources. **This is a part of ongoing education for the Board. A portion of a meeting may be dedicated to**

the discussion of new and relevant training information. Copies of these articles are maintained in the IRB Research office files.

For additional education several resource books which include Robert Amdur and Elizabeth A. Bankert "Institutional Review Board Member Handbook" are located in the IRB office.

Approved: 7/12
Revised: 7/15, 5/16
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This Policy has been reviewed and approved for:

McLeod Health Sites	Without Exceptions	Exceptions	N/A
McLeod Regional Medical Center of the Pee Dee, Inc.	X		
McLeod Medical Center Dillon	X		
McLeod Medical Center Darlington	X		
McLeod Physician Associates	X		
McLeod Regional Medical Center of the Pee Dee, Inc. d/b/a McLeod Home Health	X		
McLeod Regional Medical Center of the Pee Dee, Inc. d/b/a Hospice of the Pee Dee	X		
McLeod Loris Seacoast Hospital McLeod Seacoast (practice location)	X		
McLeod Loris Seacoast Hospital McLeod Loris (practice location)	X		
McLeod Regional Medical Center of the Pee Dee Inc., d/b/a McLeod Ambulatory Surgery Center	X		
McLeod Family Medicine Center	X		
McLeod Cheraw	X		