Institutional Review Board Policy Manual

INITIAL REVIEW/APPROVAL

PURPOSE: To describe criteria for IRB initial review and approval of research protocols.

POLICY: This policy states the minimal requirements that all research proposals involving human subject participation must meet in order to be approved for conduct at McLeod Health.

PROCEDURE

Criteria for IRB Approval of Research

The IRB will review protocols for investigational drugs and devices as requested by the Principal Investigator. All research proposals that intend to enroll human subjects must meet certain criteria before study-related procedures can be initiated. The criteria are based on the principles of justice, beneficence and respect as discussed in the Belmont Report. In addition, the protocols are subject to the criteria of the DHHS and the FDA. Certain other criteria that are unique to the McLeod Health system may apply and must be met as well. The PI must have adequate staff and resources available to comply with federal regulations and IRB policies and procedures.

Investigators new to the McLeod Health organization seeking to continue research from another location, please note: ALL studies must be approved by the convened McLeod Health IRB before being conducted at any McLeod Health location. This rule applies even if your study was previously approved by a different IRB.

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research.
Submission of Documentation:

All documentation for initial approval must be submitted as follows:

1. A “New Protocol Application” form must be completed and submitted electronically. Please note the study must be reviewed administratively. The signature of the Administrator or Vice President must be obtained before submitting to the IRB.

2. The following documentation should be attached and submitted electronically:
   a. The current protocol version for the study.
   b. The current consent form with HIPAA documentation included.
   c. A copy of the contractual agreement from the study sponsor.
   d. A Physician/Presenter Financial Disclosure form.
   e. A copy of the principal investigator(s) CV.

New Principal Investigators

The NIH “Protecting Human Research Participants” education needs to be completed before submitting your first protocol to the IRB. The “Individual Investigator Agreement” must be reviewed and signed by the PI as well.

Forms and all documentation are to be typed and submitted electronically to the IRB Coordinator. An annual calendar is provided to all Principal Investigators listing the deadline submission dates.

Full Board Review

All research involving human subjects must be reviewed and approved by the Full Board at a convened meeting. All Full Board applications are placed on the agenda at a convened meeting where appropriate discussion and voting for approval, modification, or disapproval take place. The Principal Investigator, Co-Investigator, or his/her designee, must attend the IRB meeting where the protocol has been placed on the agenda and must present the proposed protocol for review to the IRB. All studies involving FDA regulated products will be reviewed and approved under FDA regulations.

The IRB will have authority to review and approve, disapprove or modify all research activities involving investigational drugs or devices. The IRB will have the authority to place any restrictions on a protocol in order to protect the subject’s rights and welfare and to comply with FDA and DHHS regulations.

The IRB will review and attempt to determine the potential hazards, legal rights, and potential benefits to the human subjects involved in the research.
The IRB has the authority to request additional information from the Principal Investigator as needed for the review of the protocol.

- The IRB may require verification of information submitted by the Principal Investigator. The need to verify any information will be determined by the IRB. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

- The IRB conducts the scientific evaluation to determine that the use of human subjects is relevant and appropriate to answer the questions being asked and to ensure the soundness of the research design.

**Notification**

The IRB will provide the Principal Investigator with the format for submitting protocol status reports. The content of these reports enables the IRB to determine if the research shall continue in original form, be amended, suspended or terminated. The IRB will inform the Principal Investigator in writing of all decisions made concerning the protocol.

The IRB shall notify investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

An Investigator may appeal the decision of the IRB by addressing – in writing, within ten (10) days of an initial adverse IRB decision – the issues raised during the committee’s review. The appeal will then go before the IRB for review. The resulting decision of the IRB will be final and is not subject to appeal. The investigator will be informed in writing of the final status of the appeal.

**Changes to Approved Research**

If, after initial review and approval, a study needs to be altered in any way (e.g. protocol changes, ICF updates, new PI/RN, or changes to the drug/device label), it must go through additional review and be approved by the IRB before changes can be initiated. This does not apply if the change must be made in order to eliminate apparent immediate hazards to human subjects. In such a case, the PI must notify the IRB soon afterward regarding the change that was made and the circumstances warranting it.

**Applicable Regulations and Guidelines**

- The Belmont Report
- New Protocol Application
Criteria for IRB Approval of Research: 45 CFR 46.111 and 21 CFR 56.111

Approved: 9/09  
Revised: 7/15, 5/16  
18319.IRB.I-05

This Policy has been reviewed and approved for:

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