

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: RESEARCH SUBMISSION REQUIREMENTS

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 5/09

POLICY:

IRB Members often rely solely on the documentation submitted electronically by Investigators for initial and continuing review. Therefore, this material must provide IRB Members with enough information about a study to assess if it adequately meets the IRB's criteria for approval.

New submission will be scheduled for IRB review by the IRB Administrator. The maximum number of protocols to be reviewed is six (6) per meeting. An exception to this rule can be made if approved by the IRB Co-Chairperson.

Specific Policies

Submission Requirements for New Investigators

Upon receipt of the following documents in the IRB office, an IMEDRIS account can be created.

- Curriculum Vitae or Resume [signed & dated]
- Copy of Medical License or Nursing License
- The University of Miami's Collaborative IRB Training Initiative (CITI) Training Course Completion Certificate if required by another institution
- NIH Training Certificate
- Investigator's Assurance

Submission Requirements for Nursing Students

Nursing students can only gain access into IMEDRIS from the IRB office. An appointment will be necessary to complete the online submission.

Once in IMEDRIS, the system will prompt the user for the protocol and study documents, the consent documents, and/or the investigational product information. The appropriate documents will need to be submitted, as necessary. It is best if these documents are received in the IRB office prior to the appointment. These documents typically consist of the following:

- Abstract
- Data Collection Instrument
- Demographic Sheet
- HIPAA Authorization Form
- IRB Contingent Approval Letter [for DMH Nurse Anesthesia Students/Bradley University]
- Letters of Support
- Nursing Research Council Approval Letter [for Millikin students]
- Patient Information & Consent Form
- Survey/Questionnaire

Submission Requirements for Initial and Continuing Reviews

Again, IMEDRIS will prompt the user for the protocol and study documents, the consent documents, and/or the investigational product information. The appropriate documents will need to be submitted, as necessary. These documents are known as submission components and submission components for most researchers will consist of a variation of the following:

- Appendices
- Case Report Forms
- Frequently Asked Questions
- HIPAA Authorization Form
- Investigator's Brochure
- Model Consent Template

- Off-Site SAE Tracking Form
- Package Insert
- Patient Information & Consent Form
- Protocol
- Survey/Questionnaire

Submission Requirements for Humanitarian Use Devices

Humanitarian use devices are not considered research, but still fall under IRB jurisdiction per FDA. The IRB's responsibilities as provided under 21 CFR 56, include the following: (1) Approval before the HUD is administered; (2) Initial review at a convened meeting; (3) Continuing review, to also include the receipt of any medical device reporting forms; and (4) Withdrawal of approval for safety reasons or failure of the device user to follow FDA regulations or IRB procedure.

Again, IMEDRIS will prompt the user for the protocol and study documents, the consent documents, and/or the investigational product information. Physicians who wish to use a humanitarian use device at Decatur Memorial Hospital must submit the appropriate documents. Most often, these documents will consist of the following:

- FDA approval order [letter]
- Summary of Safety and Probable Benefits
- Professional Labeling [Instructions for Use]
- Patient Labeling [Patient Information Booklet]
- Patient Information & Consent Form
- Package Insert

Action Taken if Documentation is Not Adequate or Additional Information is Required

If the IRB or IRB Administrator determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. No incomplete submission will be reviewed by the IRB.

APPLICABLE TO:

These policies and procedures apply to all research submitted to the IRB.

RESPONSIBILITY:

The IRB Administrator is responsible for maintaining current research submission requirements for interested Investigators.

The IRB Administrator is responsible for reviewing consent forms prior to the IRB meeting, ensuring that all elements of informed consent are included in the Patient Information & Consent Form.

APPROVED BY:

President and CEO