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/Protocol
- Thesis Paper
- Patient Information & Consent Form
- HIPAA Authorization Form
- HIPAA De-Identified Certification Form
- Limited Data Set
- CUSHR IRB Application & Approval Letter/Notification
- Letters of Support
- Data Collection Instrument
- Demographic Sheet
- Survey/Questionnaire

Submission Requirements for Initial and/or 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:

- HIPAA Authorization Form
- Patient Information & Consent Form
- Model Consent Template
- Investigator's Brochure
- Package Insert
- Off-Site SAE Tracking 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