Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 301: IRB SUBMISSION REQUIREMENTS

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 submissions will be scheduled for IRB review by the IRB administrator. The maximum number of protocols to be reviewed is six (6) per meeting, unless otherwise approved by the IRB Co-Chair.

IMEDRIS access will be granted upon receipt of the required documentation. Nursing students will need to schedule an appointment with the IRB administrator to complete their submissions.

Humanitarian use devices are not considered research, but still fall under IRB jurisdiction per FDA.

PROCEDURES

1. Required Documentation

1.1 New Investigators

1.1.1 Curriculum Vitae/Resume [signed and dated]

1.1.2 Copy of Medical License

1.1.3 Human Subjects Protection Training Certificate

1.1.4 Good Clinical Practice Training Certificate

1.1.5 Investigator's Assurance

1.1.6 Financial Disclosure Form

1.2 Research Staff

1.2.1 Human Subjects Protection Training Certificate

1.2.2 Good Clinical Practice Training Certificate

1.3 Nursing Students

1.3.1 Human Subjects Protection Training Certificate

1.3.2 Investigator's Assurance

1.4 Physician Users of Humanitarian Use Devices

1.4.1 Copy of Medical License

1.4.2 Signed Statement of Responsibilities

1.4.3 Training record as specified by local mandate or device manufacturer

2. Essential Study Documents for IMEDRIS

2.1 Patient Information & Consent Form

2.2 HIPAA Authorization [or Data Use Agreement]

2.3 Protocol

2.4 Investigator's Brochure, Prescribing Information, or Package Insert

2.5 Surveys/Questionnaires

2.6 Data Collection Tool

2.7 Patient Materials

3. Potential Documents for Physician Users of Humanitarian Use Devices

3.1 FDA Approval Order [Letter]

3.2 Summary of Safety and Probable Benefits

3.3 Professional Labeling [Instructions for Use]

3.4 Patient Labeling [Patient Information Booklet]

3.5 Device Brochure [Package Insert]

3.6 Patient Information & Consent Form [if used off-label]

4. IRB Considerations

4.1 Research

4.1.1 Investigators may be required to submit additional information

4.1.2 Incomplete submissions may be rejected and not placed on the IRB agenda

4.2 Humanitarian Use Devices

The IRB's responsibilities, as provided under 21 CFR 56, include the following:

4.2.1 Approval before the HUD is administered

4.2.2 Initial review at a convened meeting

4.2.3 Continuing review must also include any medical device reporting forms, if applicable

4.2.4 Withdrawal of approval for safety reasons or failure of the physician user to follow FDA regulations or IRB procedure

SCOPE

This SOP applies to the IRB Co-Chair, IRB administrator, Investigators, research staff, nursing students, and physician user of HUDs.