Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 301: IRB ACCESS & SUBMISSION REQUIREMENTS

POLICY

Access to the software system is provided to members of the research community upon need and fulfillment of the established training requirements. Once the need is over, access is removed by the deactivation of individual accounts.

Student researchers will generally have access to IMEDRIS for about a year. Student researchers are commonly pharmacy residents, nursing students, and nurse anesthesia students. Most often, these individuals are conducting quality improvement projects which can be reviewed by an IRB Co-Chair.

Humanitarian use devices are not considered research, but still fall under IRB jurisdiction per FDA. Access to IMEDRIS shall remain while IRB oversight is provided. Any initial HUD application and its annual review shall be reviewed by the convened IRB.

Clinical trials are research studies that must be reviewed by the IRB. IRB members rely on the documentation submitted electronically by Investigators. Therefore, the materials provided must contain sufficient information about the study for the convened IRB or the IRB Co-Chair to determine if it 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 an IRB Co-Chair.

PROCEDURES

1. New Users to IMEDRIS

1.1 The IRB Administrator will create new user accounts upon receipt of training documents.

1.2 The IRB Administrator will provide an overview of IMEDRIS and system training.

2. New Investigators - NCORP

2.1 Curriculum vitae, preferably signed and dated

2.2 Training documents

2.3 Investigators are required to complete the NCI's Registration and Credential Repository where the following documents are housed, but remain available at any given time:

2.3.1 Form FDA 1572

2.3.2 Biosketch

2.3.3 Medical license number and expiration date

2.3.4 GCP training certificate

2.3.5 Curriculum vitae, preferably signed and dated

2.3.6 Financial Disclosure Form

2.4 Investigators must also have documented Human Subjects Protection training on file with the IRB.

3. New Research Staff

3.1 With the exception of pharma regulatory, all new research staff are required to complete the NCI's Registration and Credential Repository where the following documents are housed, but remain available at any given time:

3.1.1 Biosketch

3.1.2 Medical license number and expiration date, if applicable

3.1.3 GCP training certificate

3.1.4 Financial Disclosure Form

3.2 Research staff must also have documented Human Subjects Protection training on file with the IRB.

4. Pharma Regulatory

4.1 Regulatory staff responsible for industry trials must have documented Human Subjects Protection training and Good Clinical Practice training on file with the IRB.

5. Student Researchers

5.1 The IRB administrator will provide student researchers with an Assurance Form to be signed by the student and their project director/advisor. The project director/advisor must be an employee of Decatur Memorial Hospital.

5.2 Student researchers who are conducting chart reviews will need to collaborate with the Legal Department at Memorial Health for the acquisition of a Data Use Agreement.

5.3 Documents required for IRB submission, if applicable:

5.3.1 IRB application

5.3.2 Letter of Invitation

5.3.3 Pre-/Post-Tests

5.3.4 PowerPoint Presentation/Training Module

5.3.5 Data Use Agreement

6. Physician Users of a Humanitarian Use Device

6.1 The IRB administrator will provide the new physician user with a copy of the IRB policy for Humanitarian Use Devices.

6.2 The IRB administrator will provide the new physician user with the Statement of Responsibilities for signature.

6.3 Documents required for IRB submission, if available:

6.3.1 FDA Approval Order [Letter]

6.3.2 Summary of Safety & Probable Benefits

6.3.3 Professional Labeling [Instructions for Use]

6.3.4 Patient Labeling [Patient Information Brochure/Booklet]

6.3.5 Device Brochure [Package Insert]

6.3.6 Informed Consent Document [supplied by device manufacturer]

7. Documents Required at Initial Review, at Continuing Review, or as Amendment

7.1 Patient Information & Consent Form

7.2 Model Consent Form

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

7.4 Protocol

7.5 Questionnaires

7.6 Patient Materials

7.7 Data Collection Tool

7.8 HIPAA Authorization

8. IRB Considerations

8.1 Research

8.1.1 Investigators may be required to submit additional information.

8.2 Humanitarian Use Devices

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

8.2.1 Approval before the HUD is administered

8.2.2 Initial review at a convened meeting

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

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

SCOPE

This SOP applies to all IRB members, all investigators, and all other members of the research community, physician users of HUDs notwithstanding.