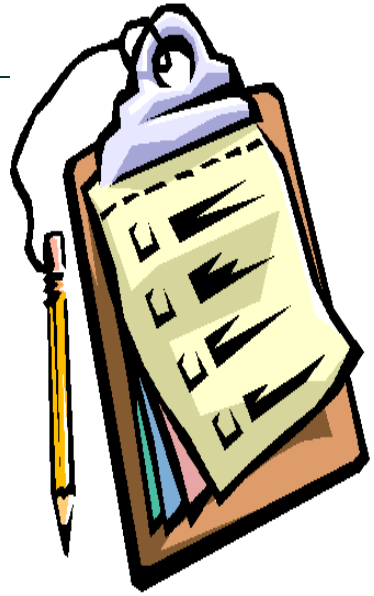
IRB7 Library and Policies: What You Need to Know

Amanda Coltes-Rojas, MPH, CIP, CHRC
Director, Regulatory Affairs & Educational Initiatives
Human Subject Research Office

Objectives:



- Describe how prior policies were incorporated into the IRB7 Toolkit
- List the types of documents in the IRB7 Toolkit and how they are used
- Identify where to find information and who to contact with questions
- Navigate HSRO website
- Describe the importance of AAHRPP Accreditation

Toolkit Components – incorporates regulatory requirements, guidance on regulations, State statutes, institutional policies, or best practices

- General documents (100s)
- SOPs (0-100)
- Worksheets (300s)
- Checklists (400s)
- Templates (500s)

General Documents

- Human Research Protection Program (HRPP) Plan (HRP-101) - general outline of rules and responsibilities
- Flowchart (HRP-102)
- Investigator Manual (HRP-103) – Investigator/study team responsibilities
- Brochure (HRP-104)

Standard Operating Procedures (SOPs)

Work instructions for how IRB/HSRO functions

- Provides all the information you need to know in regards to IRB operations and workflow
- They are identified as HRP (and a number)
- HRP stands for Human Research Protection

For example:
HRP-090 - SOP - Informed Consent Process
HRP-055 – SOP – Financial COI

Worksheets

- Regulatory considerations for IRB review and approval of Human Research - what the IRB is looking for in a study when conducting its review
  - Federal regulations
  - State laws/statutes
  - Institutional policies

Example:

- HRP-306 - Drugs
- HRP-307 - Devices
- HRP-314 - Criteria for Approval and Additional Considerations

Checklists

- Determinations to be made by the IRB as per federal regulations - what you need to know after the IRB review of a study

Example:

- HRP-402 - Non-Committee Review (designated/expedited review)
- HRP-410 - Waiver or Alteration of Consent Process
- HRP-416 - Research Involving Children

Templates

- Protocol (regular and minimal risk)
- Consent form (long and short)
- IRB determination letters

Research Policies (Vice Provost for Research)

- Research Policy/Guidelines Handbook
- New PI Training (HSR-P-001)
- External Audits For Research ((HSR-P-002)
- Clinical Research Trial Monitoring (HSR-P-003)
- Clinical Research Participant Enrollment and Tracking Policy (Velos)
- Clinical Trial Disclosure: Protocol Registration (HSR-P-101)
- Electronic Data Quality Policy for Clinical Research (POL-UMIT-EDQ-001-01)
- Conflict of Interest
- Export Compliance Policy (EXPORT-P-002)

HSRO Website (hsro.miami.edu)

- Information for researchers, sponsors, research participants
- Template ICFs, HIPAA forms
- IRB roster information and meeting deadlines
- Guidance documents
- HSRO eNews archive
- Educational activities archive
- Links to other websites (CITI, etc.)
- Contact information for HSRO staff

HSRO Contacts

- HSRO Leadership – Dr. Dushyantha Jayaweera
- Regulatory Issues
  - IRB specialists or analysts
  - Regulatory leadership (Amanda Coltes-Rojas, Evelyne Bital)
- Education – Joey Casanova
- General questions – Mireya Diaz DeArce, Kenia Viamonte
- Finance – Jeanette Mestepey

What you must do…

Familiarize yourself with the Toolkit documents, regulations, UM policies, etc.

Toolkit and Accreditation

Why seek accreditation?

- As an Institution, we are committed to continuous improvement and best practices
- Public trust and confidence
- Pharmaceutical companies and already accredited IRBs will only rely on accredited IRBs

What is accreditation?

- Visible indicator that our Human Research Protection Program (HRPP) follows rigorous standards for ethics, quality and protections for human subjects
- The accreditation process is designed to help organizations consistently meet ethical principles and standards for protecting research participants.
- UM must comply with AAHRPP accreditation standards

What is AAHRPP?

- Association for the Accreditation of Human Research Protection Programs (AAHRPP)
- An independent, non-profit accrediting body
- Voluntary, peer-driven, educational model
- Although not the sole accrediting body, AAHRPP is the largest and is recognized as such nationally and internationally

AAHRPP Accreditation Standards

- Domain I: The Organization
- Domain II: Institutional Review Board or Ethics Committee
- Domain III: Researcher and Research Staff

http://www.aahrpp.org/apply/process-overview/standards

Accreditation Process

- Conduct self-assessment (where we are vs. where we need to be prior to submittal)- COMPLETED 4th Quarter 2013
- Step 1 Application (Application and supporting materials)- SUBMITTED 1st Quarter 2014
- Feedback from AAHRPP on items requiring further development/ Gap analysis- RECEIVED June 20, 2014
- Response/Revisions- SUBMITTED August 4, 2014
- Step 2 Application (active study list, additional materials) NEED TO SUBMIT TWO WEEKS POST STEP 1 APPROVAL
- On-site evaluation of HRPP's performance (EXPECTED MARCH 2015)
- Site report provided for HRPP response
- Response to site report submittal
- Council review (EXPECTED JUNE 2015)
- Notification of accreditation status

Keep up-to-date!

In addition to the quarterly editions of ***HSRO eNews***, keep informed via the HSRO website (https://hsro.med.miami.edu)

This page offers recent news, regulatory tips, updates, and serves as the archive for the newsletter and listserv announcements.

Questions regarding the
IRB7 Toolkit

Human Subject Research Office
305-243-3195