IRB MEMBER ORIENTATION

UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

Welcome and Introductions

Rhonda Oilepo, MS, CIP

Director, Human Research Protection Program

Belmont Report and Regulatory Criteria for Approval

Jane Wigginton, MD

Associate Professor – Emergency Medicine

Vice-Chair, IRB3

IRB Authority

- Approve
- Require modification to secure approval
- Disapprove
- Suspend
- Terminate

Ethical Principles Governing Human Research

- Respect for persons
- Beneficence
- Justice

Ethical Decision Making

- The rules that derive from the Belmont Principles are the regulatory criteria for approval.
- The regulatory criteria for approval contain all rules necessary to protect human subjects.

Principles
↓
Regulatory Criteria
↓
Ethical Decisions

Ethics versus Regulations

IRB Reviews to ensure…

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is obtained or appropriately waived from all prospective subjects and documented
- The research protocol includes a plan for data and safety monitoring
- Subjects' privacy and confidentiality are protected
- Appropriate additional safeguards are incorporated for any vulnerable subjects

What is the role of the IRB when approving research?

Wrong

- Improve the quality of the Science
- Decide which science should get limited resources

Right

- Determine whether the research meets the regulatory criteria for approval

IRB Meetings: Expectations and Responsibilities

Ahamed Idris, MD

Professor – Emergency Medicine

Chair, IRB4

IRB Member Responsibilities

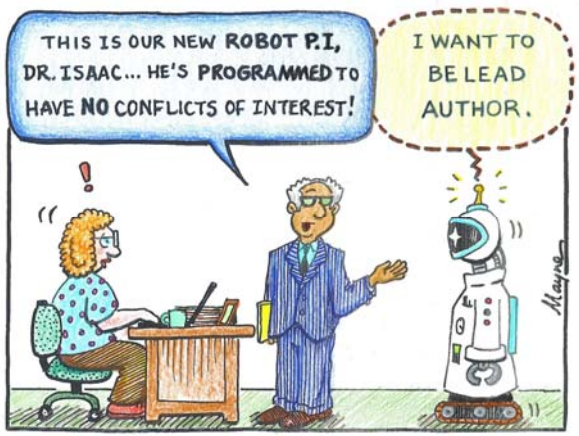
- Review protocols after agenda has been sent as soon as possible
- Attend scheduled meetings
- Ready to present your protocols
- Participate in the discussion of other protocols

Confidentiality

- Maintain confidentiality
  - –All study information, documents, and other knowledge gained by IRB membership
  - –IRB discussions, deliberations, and results

Conflicts of Interest

- Recuse yourself for any real or perceived conflicts of interest
- This includes financial or professional conflicts of interest
- IRB Agendas will identify conflicts based upon disclosures from the COI office and involvement in research protocols



Maintaining Quorum

- For the IRB to review proposed research at convened meetings, a majority of members (i.e., > 50%) must be present.
  - –E.g., IRB1 has 19 members; quorum requires at least 10 members to be present
- A **non-scientific member** is required for a quorum
- A licensed physician is required when reviewing FDA-regulated research

Meeting Flow

- **IRB agenda:**
  - –reportable events
  - –old business
  - –new studies
  - –continuing reviews
  - –modifications

Meeting Flow

- **Primary reviewer** will present a study
  - –Secondary reviewer presents any additional materials
- Chair will ask for a motion and a second and then open the study up to discussion
- Studies must be approved by a majority of members in the meeting room

IRB Member Housekeeping

Joshua Fedewa, MS, CIP

Associate Director, Human Research Protection Program

Membership Terms

- IRB Members are appointed for a 3 year term
- Each member will receive an appointment letter each September 1st
- Terms are renewable
- IRB Members are evaluated on an annual basis by Chair, Vice-Chair, and Director, HRPP

Meeting Attendance

- IRB meetings occur twice per month (1st, 2nd, 3rd, and 4th Mondays and Wednesdays)
- Finding an alternate: you are responsible for contacting a member with similar expertise if you cannot attend
- Contact the Chair, meeting manager, and the IRB Team Program Manager if you are unable to make it due to unforeseen circumstances

Pre-Review Process

- New studies scheduled for a meeting ~30 days from date of receipt
- HRPP conducts comprehensive pre-review in coordination with study team
  - –Checks for complete submissions
  - –Ensures regulatory criteria are met
  - –Confirms consistency between eIRB and study documents
- Studies not meeting the above criteria will not be assigned to an agenda

Primary/Secondary Reviewer System

- Primary reviewer summarizes the:
  - –New study: reason for the study
  - –Modification: major changes requested
  - –Continuing review: status of the study in the past year
- Primary reviewer will then discuss issues remaining to be resolved
- Secondary reviewer supplements the primary reviewer's findings

Agenda Assignments

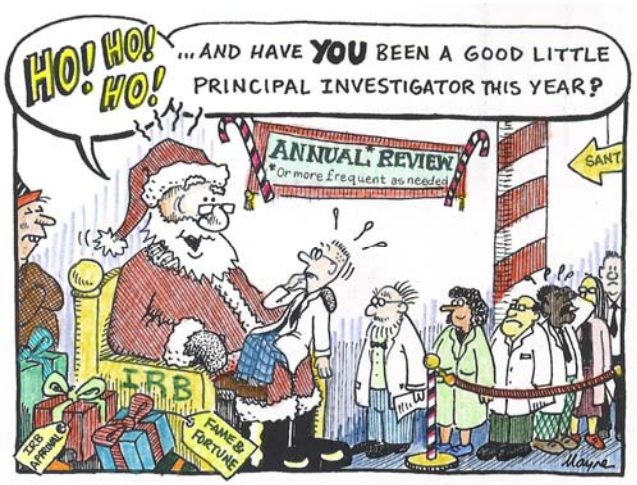
- Meeting agendas are finalized 6 days prior to the IRB meeting
- The Program Manager assigns all studies based upon expertise, experience, and equitability
- Meeting manager will send out the agenda and assign studies within eIRB

Preparing for IRB Meetings

- Review all studies on the agenda
  - –IRB members are responsible for reviewing each study in sufficient detail to make an informed decision
- Confirm any conflicts you may have
- Inform Chair, Meeting Manager, and Program Manager of any issues that would require a deferral
- Prepare presentation materials (based upon checklists and tools to come!)

Motions and Voting

- Generally, primary reviewer will be asked to make a motion
  - –Approved; Approved with stipulations; Deferred; Disapproved; Suspend; Terminate
- Each member will be asked to vote
  - –Yes, No, Abstain



Introduction of HRPP Staff

Rhonda Oilepo, MS, CIP

HRPP Leadership

- David Russell, PhD
  - – Vice Provost and Dean of Research (Institutional Official)
- Rhonda Oilepo, MS, CIP
  - – Director Human Research Protections Program (HRPP)
- Joshua Fedewa, MS, CIP
  - – Associate Director, HRPP; Investigator Relations Team
- Erik Soliz, CIP
  - – HRPP Program Manager, IRB Team
- Charles Akers
  - – HRPP Program Manager, Analysts Team
- Kellye Benton
  - – HRPP Program Manager, Quality Assurance and Monitoring
- Rania AlShahrouri
  - – HRPP Program Manager, Reliance (External IRB)

HRPP Analysts Team

- Charles Akers, Program Manager
- Erica Howard, Team Lead
- Deborah Cobb
- Allison Griffin, MS
- Reema Patel, MPH
- Rasija Nambiar, MSc, PGDPM
- Noelle Vinson, JD, MS.Ed
- Kelechi Echendu, MS
- Fallon Constantine

HRPP IRB Team

- Erik Soliz, CIP, Program Manager
- Kela Lewis, MBA
- Yvette King, CIM
- Kimberly Hawkins, CIP
- Weldon George, MPH

HRPP Investigator Relations Team

- Joshua Fedewa, MS, CIP, Associate Director
- Jeffrey Wilson, Team Lead
- Jahdai Dawes

HRPP Reliance Team

- Rania AlShahrouri, Program Manager
- Bonita Sawyer

HRPP Quality Assurance & Monitoring Team

- Kellye Benton, MS, Program Manager
- Scot St. Martin, CIA, CGAP, CRMA
- Kimberly Mapes
- Amber Hicks, MS

Charge of the IRB

David Russell, PhD

Vice Provost and Dean of Research

Institutional Official

Charge of the IRB

- To ensure that the rights and welfare of research subjects are adequately protected and all activities involving human subjects are in compliance with UT Southwestern Medical Center policies and federal and state regulations

- Protections of human subjects are provided by initial and continuing review and approval of the scientific and ethical issues related to research under the UT Southwestern Medical Center Human Research Protection Program

- See UT Southwestern Policy RES-151: Human Research Protection Program, which further specifies the authority of the IRB