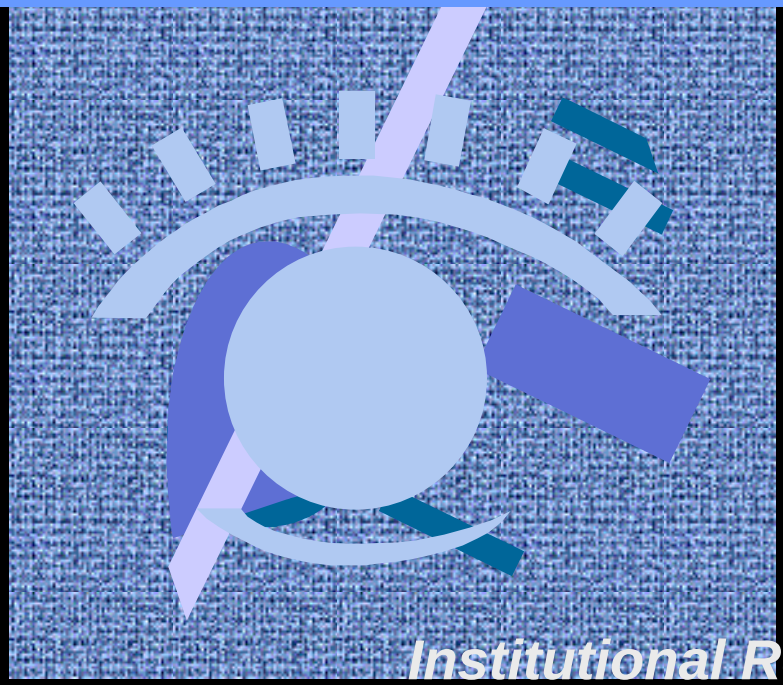
Health Care Compliance Association Medical Research Summit



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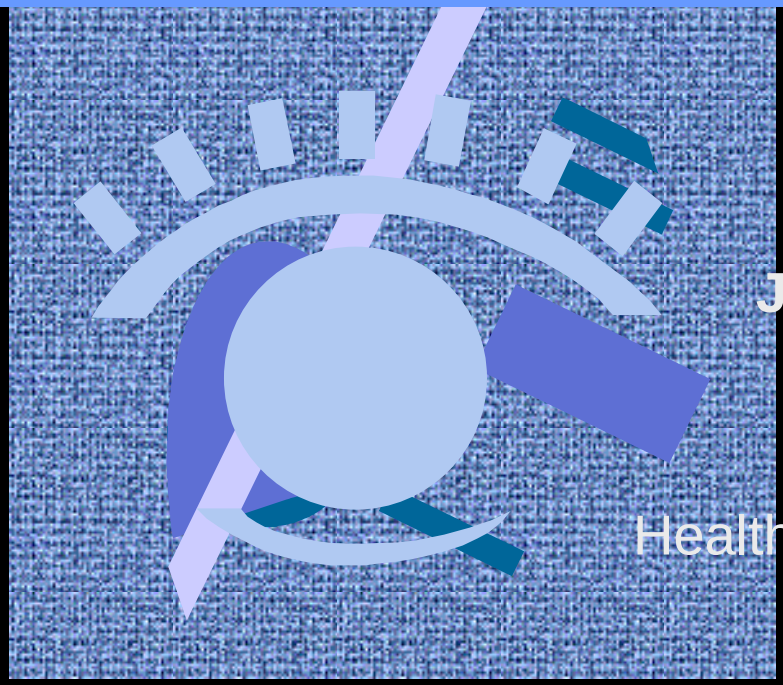
Washington, D.C.

Institutional Review Board (IRB) Operations: Using Central and Commercial IRBs

Presented by:



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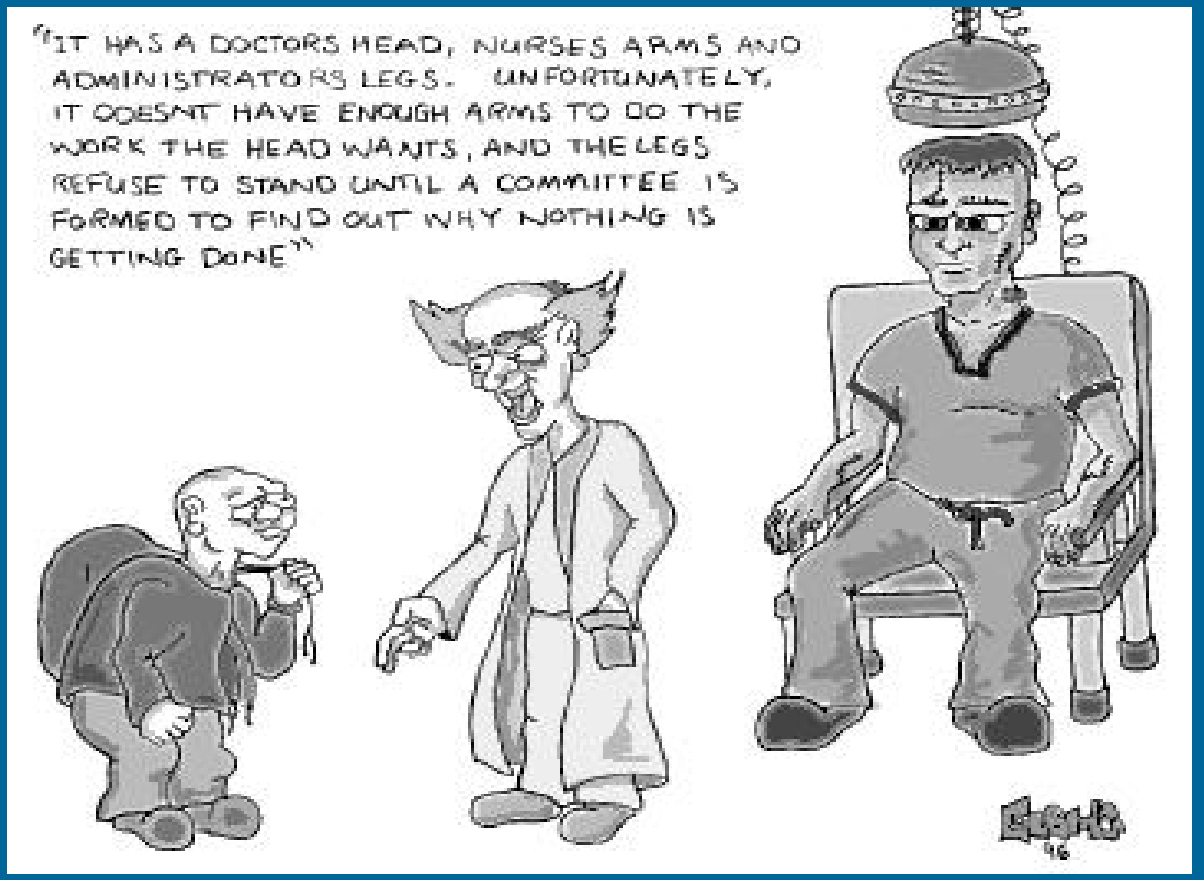
IRB Operations: Is Perception Reality?

IRB Operations: Clinical Research can be Complicated



IRB Operations: Evolution of IRBs

- 1974 passage of the National Research Act
  - established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- The Belmont Report
  - Respect, Beneficence, and Justice
- Key Regulations
  - 45 C.F.R. 46 (DEPARTMENT OF HEALTH AND HUMAN SERVICES)
  - 21 C.F.R. 56 (FOOD AND DRUG ADMINISTRATION)
- The Common Rule

IRB Operations: Emerging Legislation and Government Actions

Human Research Subject Protection Act - 06/13/2000

•Required Education in the Protection of Human Subjects: NIH Office of Extramural Affairs - 06/05/2000

•Recent Reports From the Office of the Department of Health and Human Services (HHS) Inspector General on Recruiting Human Subjects and Institutional Review Boards (IRBs) - 04/2000, 06/2000

•Food & Drug Administration (FDA) Initiatives to Protect Participates in Gene Therapy Trails - 05/07/2000

IRB Operations: Critical Functions

- Protection of Human Subjects
- Assurance of unbiased and well done clinical research

IRB Operations: Special Considerations for Centralized and Commercial IRBs

Overview

- Centralized IRBs have special attributes and challenges
- Commercial IRBs have special attributes and challenges that similar but also different
- Linked Centralized IRBs and Commercial IRBs have unique special attributes and challenges
- Key to Successful Management of linked IRBs is the Comprehensive Commitment to unified “Best Practices” in all Aspects of Each Site AND in the Coordination and Integration of all research sites
- The “Extra Dimension” of linked Centralized IRBs and Commercial IRBs Requires Special Attention (e.g., problems from each)

IRB Operations: Special Considerations for Centralized and Commercial IRBs

Key Success Factors:

-- Treat the process for managing individual research sites and the interactions among them as a distinct scientific protocol design element

-- As part of a sound scientific multi-site protocol, examine possible confounding factors and establish processes to control for them

-- Incorporate a sound scientific regimen oriented to best practices into the original study design and protocol and execute the protocol as designed

-- Pay special attention to human factors in study design and execution (e.g., “Quality, quality, quality, of course, we want quality. .. but please, do it quickly!”)

IRB Operations: Special Considerations for Centralized and Commercial IRBs

1. Human subjects protection (45 C.F.R. Part 46; 21 C.F.R. Parts 50 and 56) (continued)
   - the Institutional Review Board may fail to properly review a research proposal, may be keeping inadequate records of its review, or holding meetings without proper attendance and/or preparation
   - researchers are not reporting adverse affects of investigational drugs used on clinical trials to FDA or failing to obtain permission from the FDA to commercialize a product

Centralized IRBs

Attributes

- Faster Review
- Unified Review
- Cheaper

Challenges

- Who is really in charge?
- Difficulties in monitoring multiple sites with individualized cultures and existing IRB infrastructures

Commercialized IRBs

Attributes

- Cheaper than Academic IRB
- Attentive

Challenges

- Conflicts of Interest
- Commercial Pressures
- IRB Potentially Intertwined with Study Design

Combined Central/Commercial IRBs

Do the weaknesses of each compound exponentially when combined?