

Enhancing Clinical Investigation
by Improved Management

Monday June 23, 2008
10:00 – 10:15
“IRB Models Case Study”

Alternative IRB Processes:
University of Rochester Model



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TLAs – three letter acronyms

- AMC – Academic Medical Center
- CBPR – Community-Based Participatory Research
- FDA – Food and Drug Administration
- FWA – Federal-Wide Assurance
- HHS – Dept of Health and Human Services
- IRB – Institutional review board
- MOU – Memorandum of Understanding/Agreement
- OHRP – Office for Human Research Protection
- PBR – Practice-based Research (networks)
- PI – Principal investigator
- SOP – standard operating procedures

UR Internal Board Structure

- 3 biomedical, 1 behavioral/social science
- “traditional model” best for:
 - 1 PI, 1 site
 - 1 PI, many sites (affiliated)
 - many PIs, many sites (coordination center)
- different study types may benefit from different IRB “management” models

Cooperative / Collaborative Studies Between Universities / AMCs

- Idea sharing / development
 - specialization
 - people
 - equipment
- Resource sharing
- Continuation of Fellow / Resident / Mentor relationships

Intra-Institutional Agreements

- “traditional cooperative model”
 - both sites conduct IRB review, or
 - one site reviews, the other accepts
 - amend FWA for each study (or types)
 - MOA/MOU between organizations
- either model adds some “administrative burden” up front (-)

CBPR / PBR Networks

- Community involvement
 - addresses community “social” concerns (+)
- Practice-based studies
 - sponsored studies
 - community involvement (medical issues)(+)

Independent Investigator Agreements (IIA)

- traditional model “with a twist”
- FWA for each site (if federal \$)
 - AMC IRB reviews for sites as “IRB of record”
 - site accepts IRB determinations and oversight
 - MOA/MOU
 - (develop / use model form)

Industry-sponsored Clinical Trials

- “specialty” research area (FDA regulations - parts 312 and 812)
 - IND / IDE regulations
 - added reports (IND/IDE, AE, SAE)
- highly competitive - “need for speed”
 - same protocol used at multiple sites
 - one protocol review plus many site / PI reviews

External Board

- “out sourcing model”
 - add to FWA - “just another IRB”
 - MOA/MOU between organizations
 - shared policies (SOP)
 - handshaking / local knowledge
 - “two heads are better than one” (+)
 - pre-established sponsor relationships (+)
 - loss of income (-)
 - may need to increase institutional support for internal boards

City-wide / Regional Networks

- Cooperation v. Competition
- Recruitment / Increased patient access (+)
 - increased subject pool
 - shorter enrollment time
 - quicker completion
 - greater diversity

IRB “Federation” Model

- Each site / institution / IRB is independent
- Each site can be “lead” (PI-driven)
- Each can accept lead-IRB review - or not
- Needs a central locus for “administration”
 - web site for info sharing
 - meeting support (organizational, educational)
 - amend FWA for group studies (CTSA)
 - MOA/MOU between all organizations

New Collaborations Mean New Approaches

- Flexibility enables cooperation and efficiency
 - Regulations and guidance
 - Regulatory agencies
 - IRBs
 - Administration (e.g., legal) and institutional policy

Possible CTSA HRPP Model

- Institutional IRB
 - single site, single PI / team
- Cooperative Agreements
 - “one-off” collaborations (CTSA, CBPR, PBRN)
- Central IRB (independent or CTSA)
 - industry sponsored multi-site studies
- Federated IRB Agreements
 - CTSA / Regional / City -wide multi-site studies
