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Present

IRBs IN THE COMMUNITY HOSPITAL SETTING

Second Annual Medical Research Summit

March 24-26, 2002

Grand Hyatt Hotel, Washington, D.C.

COMMON IRB ISSUES

- **Failure of IRB Leadership**
- **Failure to Conduct or Document Substantive or Meaningful Reviews**
- **Failure to Obtain Sufficient Information/Data regarding Risks to Subjects**
- **Inadequate or Inappropriate IRB Participation**
- **Inadequate Training - IRB, Staff and Researchers - Lack of Detailed Understanding of Regulations**
- **Failure to Monitor Continuing Reviews**
- **Inappropriate Use of Expedited Procedures**
- **Inadequate Quorum and Membership**
- **Absence of Community Members**
- **Inadequate Record Keeping - Lack of Minutes/Tracking**
- **Inadequate or Insufficient Resources/Support**

COMMON IRB ISSUES

- **Inadequate/Non-existent Consent Form Review, Procedures or Forms**
- **Inadequate Consideration - Additional Safeguards**
- **Inadequate Descriptions of Side Effects/Toxicity by Investigators**
- **Failure to Assure IND/IDE submissions**
- **Inadequate Adverse Event Reporting or System**
- **Inappropriate Implementation of Substantial Study Changes without IRB Approval**
- **Issuance of Approval Letters Prior to Receiving or Confirming Revisions**
- **Inadequate Consideration of Conflicts of Interest**
- **Failure to Assure Privacy & Confidentiality**

SITES AT WHICH DEFICIENCIES WERE FOUND

- **3/99: West LA VA Medical Center – OPRR suspends all research**
- **5/99: Duke University - OPRR shuts down enrollment**
- **8/99: University of Illinois - OPRR halts enrollment of all federally-funded research**
- **9/99: University of Colorado - Limited shut down by FDA & OPRR**
- **9/99: Institute for Human Gene Therapy, University of PA (IHGT) - All studies halted; researchers requested to check all records; FDA stops other Gene Therapy studies**
- **1/2000: Virginia Commonwealth University (VCU) - FDA & OPRR shut down enrollment**
- **1/2000: University of Alabama (UAB) - OPRR requires re-review of several projects**
- **6/2000: University of Oklahoma - OHRP suspends all clinical trials**
- **7/2001: Johns Hopkins University School of Medicine - OHRP suspends all federally supported research**

COMMUNITY HOSPITAL ISSUES

- Perceptions

- ☞ Should Be More Deferential to Researchers, Sponsors and IRBs at Large Institutions

- ☞ Lack of Responsiveness

- Site Issues

- ☞ IRB as Hospital Committee vs. Medical Staff Committee

- ☞ Facility Resources

- ❖ Facility Suitability/Equipment/Staffing

COMMUNITY HOSPITAL ISSUES

Site Issues Continued . . .

- ☞ Physician Competency/Privileges
- ☞ Hospital Administrative Involvement
 - ❖ Inconsistencies
 - ❖ Contractual Terms & Agreements
- ☞ Financial Arrangements and Accounting Practices
 - ❖ Independent Physicians
 - ❖ Hospital Accounting Staff
 - ❖ Tax Exempt Status Issues

COMMUNITY HOSPITAL ISSUES

- Compliance

- ☞ State & Federal Statutes, Regulations and Common Law

- ☞ Accreditation

- ❖ Budgetary Constraints (Cost & Additional Staff)
 - ❖ IRB Compliance Audits (Conducted by Hospital & IRB)
 - ❖ Investigator Compliance Audits (Conducted by Hospital & IRB)
 - ❖ Mandatory Educational & Training Requirements (IRB, Investigators & Staff)

COMMUNITY HOSPITAL ISSUES

Compliance Continued . . .

- Federalwide Assurance (FWA)
 - ❖ Mandatory Educational Requirements (IRB, Hospital and Staff)
 - ❖ Submission of Federal Documents

- HIPAA
 - ❖ Effective April 2003
 - ❖ Focus on Use of Identified or De-Identified Information in Research Involving or Not Involving Treatment
 - ❖ Traditional Confidentiality Standards and Practices May Not Suffice

COMMUNITY HOSPITAL ISSUES

- Cooperative and Delegated Review
 - ☞ Within a Hospital
 - ☞ With Unaffiliated Entities
 - ☞ Issues
 - ❖ Proximity of Institutions
 - ❖ Allocation of Responsibilities for Initial and Periodic Review; Compliance Monitoring
 - ❖ Local Facilities and Capabilities
 - ❖ Community Attitudes
 - ❖ Exchanges of Information
 - ❖ Institution-Specific Legal Issues
 - ❖ IRB Contact
 - ❖ Institutional Authorization and Oversight
 - ❖ Documentation of Arrangements

SOLUTIONS TO SOME COMMON IRB PROBLEMS

- IRB Review Fees

- ☞ Written Policy (Model Provided in Hand Outs)

- ☞ Issues

- ❖ Rationale
 - ❖ Amount
 - ❖ Applicability
 - ❖ Flexibility
 - ❖ Implementation

SOLUTIONS TO SOME COMMON IRB PROBLEMS

- Standardized Materials

- ☞ Investigator Packet

- ❖ IRB Initial Review Instructions and Procedures for Protocol Submission and Review

- ❖ Meeting Attendance; Copies; Deadlines

- ❖ Required Documents

- ❖ Protocol; Informed Consent; Investigator Brochure; Approval Request Form; Advertisements; Statement of Assurances

SOLUTIONS TO SOME COMMON IRB PROBLEMS

Standardized Materials Continued . . .

☞ IRB Forms

- ❖ Consent Form Guidance with Model Language
- ❖ Request for Approval
- ❖ Statement of Assurances
- ❖ Request for Continuation
- ❖ Adverse Event Report
- ❖ Notification of Change (Protocol/Consent Form)
- ❖ Final Report

SOLUTIONS TO SOME COMMON IRB PROBLEMS

- Cooperative and Delegated Review
 - ☞ Memorandum of Understanding (MOU) - (Model Provided in Hand Outs)
- Preliminary IRB Review
- Routine Distribution of Educational Materials

SOLUTIONS TO SOME COMMON IRB PROBLEMS

- Comprehensive IRB Procedural Manual
 - ☞ Nature of IRB (Hospital vs Medical Staff Committee)
 - ☞ IRB Jurisdiction
 - ❖ Define Nature & Scope of Research Eligible for Review
 - ❖ Define "Research"
 - ❖ Define "Human Subject"
 - ❖ Specify Exemptions from IRB Approval Requirements

SOLUTIONS TO SOME COMMON IRB PROBLEMS

IRB Procedural Manual Continued . . .

☞ IRB Procedures

- ❖ Submission of Proposed Study
- ❖ Material to be Submitted
- ❖ Medical Device Studies - Special Requirements
- ❖ Humanitarian Use Devices (HUDs)
- ❖ Discretion of IRB Chair to Require Preliminary Review by Other Committees or Institutional Officials

SOLUTIONS TO SOME COMMON IRB PROBLEMS

IRB Procedural Manual Continued . . .

☞ IRB Manner of Conducting Business

- ❖ Quorum
- ❖ Expedited Review
- ❖ Cooperative Review
- ❖ Communications with Researchers and Sponsors
- ❖ Reporting as specified in Regulations and Institutional Policy

SOLUTIONS TO SOME COMMON IRB PROBLEMS

IRB Procedural Manual Continued . . .

☞ IRB Records

- ❖ Types of Records
- ❖ Retention of Records
- ❖ Inspection of Records
- ❖ Confidentiality

☞ Criteria For Approval

- ❖ Basic Criteria
- ❖ Additional Safeguards for Vulnerable Subject Groups
- ❖ Grounds for Disapproval

SOLUTIONS TO SOME COMMON IRB PROBLEMS

IRB Procedural Manual Continued . . .

- ☞ Informed Consent Requirements
 - ❖ Procedures for Obtaining Informed Consent
 - ❖ Basic Elements (Federal and State Law)
 - ❖ Additional Elements

- ☞ Monitoring of Research
 - ❖ Unanticipated and Serious Adverse Events
 - ❖ Complaints

SOLUTIONS TO SOME COMMON IRB PROBLEMS

IRB Procedural Manual Continued . . .

- Routine Periodic Review and Re-Approval
- Investigation of Suspected Research Misconduct
- Suspension or Withdrawal of IRB Approval; Basic Fair Procedure