



ABC's of Establishing an IRB

Medical Research Summit
Monday, March 19, 2001

Stephanie J. Taylor, CIP
864.455.8997
sttaylor@ghs.org



GREENVILLE HOSPITAL SYSTEM
Healthcare to a Higher Standard



Our System..Our Challenge

- ❖ Largest hospital system in state of South Carolina
- ❖ Nearly 6,000 employees
- ❖ Nearly 950 physicians
- ❖ 1081 beds, system-wide



Our Campuses

- ❖ Greenville Memorial Medical Campus
- ❖ Simpsonville Medical Campus
- ❖ Greer Medical Campus
- ❖ Travelers Rest Medical Campus
- ❖ Patewood Medical Campus



Highest Standard of Care

- ❖ Children's Hospital
- ❖ Heart Institute
- ❖ Women's Health Institute
- ❖ Cancer Center
- ❖ Roger C. Peace Rehabilitation Hospital



Partnerships for Education

- ❖ Medical University of South Carolina
- ❖ University of South Carolina School of Medicine
- ❖ Bob Jones University
- ❖ Greenville Technical College
- ❖ University of South Carolina - Spartanburg
- ❖ Lander University
- ❖ Tri-County Technical College
- ❖ Clemson University



A

Administrative Support

- . Report to highest entity in institution
- . Full backing and support of administration
- . IRB Administrator/Coordinator have full support of administration
 - * Interpersonal skills most important



B

Budget

- . Education
- . Membership Fees
- . Salaries
- . Cost of Holding
- . Supplies - Meetings
- . Space
- . Equipment



C

■ **Committee Members**

- Federal Regulations require a minimum of five members
- At least one member whose primary concerns are in scientific areas
- At least one non-scientific member
- At least one non-affiliated member



C

Committee Members

- . Community Member
 - Clergy
 - Former research participant
 - Retired school teacher
- . Chair/Vice-Chair



D

- **Documentation**

- Federal requirements listed in:
 - 45 CFR 46.115 - OHRP
 - 21 CFR 56.115 - FDA



D

Documentation

- . Document everything you do
 - telephone conversations
- . Policies & Procedures
 - be sure you can actually do what you say you will do



E

Education

- . Administrator/Coordinator/Chair visit similar IRB's
- . Attend Conferences – interaction with peers
- . Initial and continuing education of committee members



F

Forms

- . Full Board
 - Initial Review Application
 - Continuing Review
 - Revision/Amendment
 - Adverse Events
- . Expedited Review



F

Forms

- . Exempt
- . Sample Consent
- . Conflict of Interest – Committee members and investigators
- . Review forms for committee members



Additional Points

- Find a friend at FDA/OHRP
- Maintain audit-ready mind-set
- Get to know IRB Coordinators in your area
- Volunteer to serve on an IRB at a nearby institution



Additional Points

- Don't reinvent the wheel – get samples of forms, SOP, consents from other institutions
- Utilize McWIRB – www.mcwirb.org
- Prepare for investigator education
- Read, Read, Read
- Keep it simple