IRB Compliance With Regulation

FERCAP International Conference

Dr. Brad Waite
Coordinator, International IRB Fellowship
Western Institutional Review Board (WIRB)

November 23, 2008
Bangkok, Thailand
What Is Important?

1) Protect the rights, welfare and safety of research subjects
Why Regulations?

- Regulations help to ensure that processes are in place to provide that protection.
- Regulations help maintain consistency and standardization in those processes.
- Regulations provide a means of enforcing compliance to those processes.
What If There Are No Regulations?

Guidelines provide a similar framework to help ensure consistency and standardization.

- WHO - Operational Guidelines for Ethics Committees That Review Biomedical Research
- CIOMS Guidelines
- ICH - GCP
Where To Start?

Determine the applicable standard:

e.g.,

- FDA Regulations
- International Guidelines
- Institution-Specific Requirements
- SIDCER Recognition Programme Standards
- AAHRPP Accreditation Standards
What Is Next?

Develop written procedures to address the requirement of the standard

Written SOPs should address:
- Purpose of the Board;
- Authority of the Board;
- Board Relationships;
- Organization and Membership;
- Management of the Board;
- Functions of the Board;
Example

See WIRB SOP Index Handout
What Is Next?

- Use evaluation instruments and checklists as a guide for the procedures to address: e.g.
  
  ✓ FDA Self Evaluation Checklist
  http://www.fda.gov/oc/ohrt/irbs/irbchecklist.html

  ✓ AAHRP Self Evaluation Standards
  http://www.aahrpp.org/Documents/D000108.PDF
What Is Next?

• Use evaluation instruments and checklists as a guide for the procedures to address: e.g.

  ✓ SIDCER Self-Evaluation Tool
  http://www.fercap-sidcer.org/home.asp

  ✓ WHO - Operational Guidelines for Ethics Committees That Review Biomedical Research
  http://www.who.int/sidcer/publications/en/
Now What?

Training on the SOPs
Parties to include in training:
- Chairmen
- Administrator
- Members
  - Staff
- ?Investigators?
Now What?

Training on the SOPs

DOCUMENT TRAINING
Now What?

Review on a regular basis
Finally

Audit:

- May be internal or external
- Identifies weaknesses/deficiencies
- Reveals training opportunities
- Prepares for recognition/certification inspections
Remember!

Our primary goal is?