

IRB Compliance With Regulation

FERCAP International Conference

Dr. Brad Waite

Coordinator, International IRB Fellowship
Western Institutional Review Board (WIRB)

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WIRB

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 helps 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?

Questions/Comments

