

OHRP Activities in Building International Ethical Review Capacity

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Objectives

- OHRP international activities
- Institutional review board registration
- Federalwide assurances
- Issues/concerns

OHRP International Activities

- Had international scope for years
- Formalized in 2002
- Three staff members
- Sponsor workshops
- Speak at conferences
- HSRS International Working Group
- International compilation

Consultations / Capacity Building

- Presentations – US and internationally
- Host international delegations and fellows
- Telephone consultations
- Track trends and key developments in international human subjects research

- Support three international workshops/year:
Cameroon, Ethiopia, Nigeria and South Africa
- One week course on ethical conduct of clinical research:
 - Vienna School of Clinical Research
 - Participants from African nations

HSRS International Working Group

- 18 federal departments and agencies that sponsor human research internationally
- Monthly meetings – topics for 2008
 - Convention of Oviedo
 - International social-behavioral research
 - Multi-site IRB review
 - ICH-GCP
 - Australia
 - Human biological materials
 - Confidentiality
 - Research in extremely low-resource countries

International Compilation of Human Subject Protections

- List laws, regulations, and guidelines for human subjects research in 92 countries
- Categories
 - General
 - Drugs
 - Privacy/data collection
 - Human biological materials
 - Genetic research
 - Embryos, stem cells, cloning

IRB Registration

- Regulations Require IRB Review
- Registration Allows Verification
- Location, Leadership, Contact, Members
- Register Electronically
<http://ohrp.cit.nih.gov/efile/>
- 6216 Total
180 In Africa

Federalwide Assurance (FWA)

- Regulations Require Assurance of Compliance with Regulatory Provisions
- Must have review by a registered IRB
- FWA Is the Only Current Assurance
- Can Establish Electronically
<http://ohrp.cit.nih.gov/efile/>
- 10,526 Total FWAs
381 in Africa

Issues / Concerns

- Low resource environments
 - Physical and human infrastructure
 - To support research
 - To sustain impact
 - Helicopter research
 - What benefit to subjects, community
 - Desperation driving enrollment
 - Ethical imperialism
 - Imposing US values, or allowing double standard?

Questions?