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## Revisit FDA & OHRP, ICH & GCP, International Research

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### **1. Revisit FDA & OHRP**

- a. Mission, History
- b. Reg #s
- c. FDA Regs, OHRP regs
- d. Waivers, Vulnerables
- e. Emergency use of a test article
- f. Audits & inspections
- g. SAE / UPX discuss in terms of FDA, PI, HHS, IRB, Sponsor (reporting responsibilities and definitions)
- h. FDA required IC to say FDA can inspect, but HHS is silent

### **2. ICH & GCP**

ICH = International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use

Pharmaceutical industry/regulatory agencies from US, Japan & EU

The guideline that primarily effects IRBs is E6, ICH harmonized tripartite guideline: Guideline for Good Clinical Practice. The E6 guideline has eight parts: 1. Glossary, 2. Principles, 3. IRBs, 4. Investigator, 5. Sponsor, 6. Protocol and amendments, 7. Investigator's brochure, 8. Essential documents.

In U.S, compliance with ICH E6 is voluntary, and is not a federal regulation. However, most pharmaceuticals require ICH requirements be met, while the institution defines applicability.

What is GCP, ICH?

History of ICH & GCP ?

Jurisdiction?

### **3. International Research**

IRB Considerations: language, culture, funding, infrastructure problem in poor countries

What are issues when US IRB is reviewing intl (no idea of local customs, etc.)

Money: IF HHS gives money for research –HHS wants an FWA, if a US partner they want dual reviews. If no IRB in the country, they want USA IRB + ????

FDA: jurisdiction when data from any study will be used to support application for drug/device/biological.

Short discussion of regulations FDA/HHS versus ethics of international research

- FWA
- Foreign FWA / equivalence

**Students:** There are lots of issues in performing, conducting and reviewing international research, so be clear on what is ethical and what is regulatory and whose perspective is being discussed...

Considerations related to locals, language, culture, funding, and infrastructure problems in poor countries.

International issues differ if you are a local, a researcher, an IRB from the USA, or a partner IRB.

Understand International Research from different perspectives/levels:

Foreign country ethics/regs must be 'equivalent' to Belmont and 45CFR46 (says OHRP)

### 1. USA IRBs

What do USA IRBs need to think about to protect local subjects?

Is there a need for a local IRB or ministry of health?

What does a USA PI have to do meet local requirements?

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What does a USA IRB have to do if one of their researchers is involved in international research?

### 2. Locals

What kind of IRB/Health Ministry/etc exists in the foreign country, if any?

Who can review the study to represent local subjects?

Need to ensure that local customs are respected

Informed Consent is the biggest issue, why?

### 3. US Sponsor/Federal Funding Agency

### 4. US/ FDA/ HHS/ other/ jurisdiction if funding or if oversight (they are different!)