8/11/08

Review of CIP Course & Q&A

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Format will be brief, verbal review of topics below. NO POWER POINTS, JUST DISCUSSION. Last 30 minutes will be questions from Darcy and Susan to students. Any student who has taken CIP exam can help by addressing test strategies. PLEASE BRING YOUR TERMINOLOGY LIST and the CITI QUESTIONS, CIP examples below*. For Spring CIP exam, a 2 hour refresher may be offered.

1. Revisit FDA & OHRP

a. FDA Regs, OHRP regs
b. Vulnerable Populations (Subparts B, C, D)
c. Emergency use of a test article
d. Reportables: SAE / UPX - discuss in terms of FDA, PI, HHS, IRB, Sponsor (reporting responsibilities and definitions)

2. ICH & GCP (This topic never fully covered as K. Hurtado was absent)

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

CONSIDERATIONS: 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?
What does a USA PI have to do to meet USA requirements?
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!)

4. HIPAA?

SAMPLE EXAMINATION QUESTIONS:

In the following questions, choose the one best answer.

1. According to the Belmont Report, respect for persons typically demands that subjects
    1. share in the benefits of the research.
    2. gain maximum benefit from research.
    3. waive any rights or benefits from research.
    4. enter into research voluntarily with adequate information.

2. Which of the following is used to avoid bias in assigning subjects to experimental groups?
    1. Double blind
    2. Placebo control
    3. Clinical equipoise
    4. Paying subjects to participate

3. In most research, which of the following best assures confidentiality?
    1. Obtaining releases of information
    2. Storing research records in a locked cabinet for at least three years
    3. Following acceptable practices for coding and storing data
    4. Removing identifiers after the research ends

4. When reviewing research, the IRB should ensure that the consent process
    1. includes a consent monitor.
    2. is conducted by a third party.
    3. is the same for all populations.
    4. provides the subject sufficient opportunity to consider whether or not to participate.