Certified IRB Professional (CIP) Exam
How to Prepare

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Background

- Bachelors of Science Degree
- 6 Years IRB Experience
  - IRB Analyst
  - IRB Manager
  - IRB Assistant Director
- Took the CIP Exam March 2005

Background Cont.

- Training:
  - CITI
  - Human Subjects Lecture (Speaker)
  - Regional & National Conferences
  - Local Ethics Classes
  - IRB Meetings

Eligibility

- Bachelor's Degree + 2 years IRB experience within the past seven years, or
- No Bachelor's Degree but 4 years IRB experience within the past ten years

CIP Code of Ethics

- Professional conduct (Honesty, integrity)
- Prime consideration to human subjects
- Apply Belmont Principles
- Adhere to laws/regulations
- Respect rights and dignity of all (Cultural sensitivity)

CIP Code of Ethics Cont.

- Disclose COI
- No insider trading
- Confidentiality and privacy
- Continuing education
- Facilitate communication (Shared responsibility)

Certified IRB Professional (CIP) Exam
How to Prepare

- Register
- Study
- Sleep
- Sacrifice
- Share
- Team-up

Learning Style

- Four General Styles:
  - Visual – Written Format
    - Note taking
  - Nonverbal – Picture or Design Format
  - Kinesthetic – Hands on Activity
    - Two or more years experience critical
  - Verbal
    - Tape record notes
- Identify your style:
  - http://www.ldpride.net/learning_style.html
  - http://www.engr.ncsu.edu/learningstyles/ilsweb.html
  - http://www.chaminade.org/inspire/learnstl.htm

Study Tools

- Start a study notebook right away - Outline
- Make copies of critical information so you do not have to search for it every time you study
- Organize by study focus groups
  1. Foundations and Concepts of IRB Practice (25%)
  2. Organizational and Personnel Knowledge (15%)
  3. IRB Functions and Operations (45%)
  4. Records and Reports (15%)
- Include notes per topic
- Study groups

Identify Your Resources

- Ask Management if there are study resources
  - Independent IRB offices
  - Research Centers & Academic Institutions
- Who has taken the test?
  - Pointers on what they studied and what they would do differently
  - Can they mentor you – discuss questions & ask you questions
  - Study Groups

Identify Your Resources Cont.

- Take any possible pre-tests to identify areas to work on:
  - IRB Management Function – Exam
  - Collaborative IRB Training Initiative (CITI) exam or CD Rom exam

Example Questions

- Take 30 minutes and answer the questions
- Check your answers – How did you do?

Foundation & Concepts

- History
- Research Ethics (Belmont, Professional codes, COI, Research Design Issues)
- Regulatory Applications and Audits, HIPAA
- Regulatory Definitions

Organizational & Personnel Knowledge

- IRB Committee Organization
- Institutional Considerations
- IRB Office Organization
- Educational Programs

IRB Functions & Operations

- IRB Review Requirements
- IRB Staff Review

Records & Reports

- Rosters
- Audit/Monitoring
- Policies & Procedures
- Assurances
- Documentation – File Maintenance
- Regulatory Reports
- Training Records

What are areas to work on?

- Children
- Prisoners
- HIPAA
- FDA/non-FDA
- Equipoise
- Emergency Treatment
- Behavioral vs. Clinical
- Certification of Confidentiality

Study Focus

- Current Practice
  - Review your policies and procedures
- Regulatory
  - Review and know the regulations
    - 45 CFR 46; 21CFR 11, 50, 54, and 56
    - Review the “Frequently Asked Questions”
- Guidance
  - OHRP Guidance: http://www.hhs.gov/ohrp/policy/index.html#topics
  - FDA Information Sheets: http://www.fda.gov/oc/ohrt/irbs/

Study Focus Cont.

- Current Practice should comply with Regulations and Guidance
  - Do not assume that current practice is always correct
  - Test is regulation driven not institution practice driven
- Ethical Principles (Read and re-read)
  - Belmont Report
  - Declaration of Helsinki
  - Nuremberg Code

Study Focus Cont.

- Know how to APPLY the ethical principles and regulations to specific situations
- Understand the IRB meeting process (ATTEND the meetings)
- Understand training requirements of Investigators, Members, and Staff
- Know when Policies and Procedures are required to perform the IRB functions

Set Timelines – 3 Months

- Pre – testing
- Studying
- Testing after study
- Prepare for the day of the test

The Exam

- Get plenty of rest the night before
- Eat a good breakfast
- Arrive early
- Make SURE to answer ALL of the questions
  - What is your style of taking a test?

After the Exam

- Second guess every answer – NOT
- Have an adult beverage
- Await the results – two to four weeks
- Scream and shout when you get the results that you passed
- Or , set a time to take the test a second time as soon as you can and focus your study on the areas where your score was the lowest – No limit to how many times the test can be taken

Valid CIP Certification

- Valid for 3 years
- Re-certification
  - Re-examination – every six years
  - Continuing Education – 30 hours CE every three years or retake test

A Few Resources

- Institutional Review Board – Management and Function
- IRB – Management and Function Study Guide
- Protecting Study Volunteers in Research: A Manual for Investigative Sites
- CIP Handbook for Candidates
  - http://www.ptcny.com/PDF/CCIP2006.pdf
- Belmont Report, Declaration of Helsinki, and Nuremberg Code
- Regulations/Guidance/Interpretations

A Few Resources Cont.

- FDA Information Sheets: http://www.fda.gov/oc/ohrt/irbs/
- OHRP Guidance: http://www.hhs.gov/ohrp/policy/index.html#topics

Questions ?