PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

CIP Body of Knowledge/Content Outline

I. Foundations and Concepts of IRB Practice 25%

A. Historical Background
B. Research Ethics
    1. Belmont Report
        a. Respect for Persons
        b. Beneficence
        c. Justice
    2. International Codes/Standards
        a. Nuremberg Code
        b. Declaration of Helsinki
        c. Council for International Organizations of Medical Sciences
        d. International Conference on Harmonisation
    3. Professional Codes
        a. CIP Code of Ethics
        b. Professional Association Codes
    4. Conflict of Interest
        a. IRB Members and Staff
        b. Investigators and Key Personnel
        c. Institutional
C. Research Design Issues
    1. Types of Study Designs
    2. Minimizing Risks
    3. Study Monitoring (DMC, Plans, etc.)
    4. Sample Size/Statistics
    5. Privacy, Confidentiality, and Data Security
    6. Deception
D. Regulatory Application
    1. HHS Regulations
        a. Applicability
        b. Exemptions
    2. Common Rule
        a. Applicability
        b. Agency Differences (e.g., DOD, DoEd, DOJ)
        c. Exemptions
    3. FDA Regulations (Human Subjects)
        a. Applicability
        b. Exemptions
    4. FDA Regulations (Drugs/Biologics/Devices)
        a. Applicability

        b. Exemptions
    5. State/Local Regulation
    6. Regulatory Audits
        a. FDA Bioresearch Monitoring Program
        b. OHRP Monitoring and Site Visits
        c. Sponsor/Cooperative Group Monitoring
    7. Health Insurance Portability and Accountability Act (HIPAA)
E. Definitions
    1. Research
    2. Human Subjects
    3. Minimal Risk
    4. Vulnerable Populations
    5. Engaged in Research

II. Organizational and Personnel Knowledge **12%**

A. IRB Committee Organization
    1. Authority
        a. Approve/Disapprove/Modify
        b. Suspend/Terminate
    2. Membership Requirements
    3. Quorum Requirements
    4. Reporting Lines
    5. Leadership Issues
B. IRB Office Organization
    1. Staff Responsibilities and Authorities
    2. Reporting Lines
    3. Management (Personnel and Resources)
C. Institutional Considerations
    1. Scientific Review
    2. Grants and Contracts Review
    3. Other Committee Review (RDRC, Biosafety)
    4. Institutional Review
    5. Institutional Responsibilities
    6. Research Misconduct
    7. Reliance Agreements and Central Review
D. Educational Program Design/Implementation
    1. Education Programs for IRB Staff
    2. Education Programs for IRB Members
    3. Education Programs for Investigators/Research Sites
    4. Education Programs for Institutional Officials

III. IRB Functions and Operations **45%**

A. IRB Review
    1. Levels of Review
        a. Exempt Procedures

    b. Expedited Review
    c. Convened Meeting Review
2. Types of Review
    a. Initial Review
    b. Continuing Review
    c. Amendment Review
    d. Adverse Event/Unanticipated Problems Review
    e. Final Reports/Study Closure
3. Criteria for Approval of Research
    a. Risk Determination and Minimization of Risks
        1. Minimal/Minor Increase/Greater than Minimal
        2. Significant/Non-Significant Risk Devices
        3. Procedure Review
    b. Risk-Benefit Analysis
    c. Equitable Subject Selection
        1. Inclusion/Exclusion of Children, Minorities, and Women
        2. Inclusion/Exclusion of Other Vulnerable Populations
    d. Informed Consent
        1. General Conditions
        2. Elements
        3. Waiver of Consent
        4. Documentation
        5. Waiver of Documentation
        6. HIPAA
    e. Monitoring Plans
    f. Protection of Privacy and Maintenance of Confidentiality
        1. Common Rule
        2. HIPAA
        3. Certificates of Confidentiality
        4. FERPA
        5. GINA/GWAS
    g. Additional Safeguards for Vulnerable Subjects
    h. Investigator and Site Qualifications
4. Emergency Uses
5. Treatment Uses
6. Subject Recruitment
    a. Advertisements
    b. Inclusion/Exclusion Criteria
    c. Incentives
7. Special Regulatory Requirements
    a. Fetuses, Pregnant Women, IVF
    b. Prisoners
    c. Children

d. Emergency-Setting Research
e. School Research (PPRA)

8. Human Subject Private Information
    a. Databases
    b. Document Repositories/Archives
    c. Record Repositories/Collections
    d. Specimen/Tissue Banks
    e. Data Security
9. International Research

B. IRB Staff Review
1. Staff Pre-Screening
2. Post-Meeting Communications/Review
3. Auditing
    a. IRB Office
    b. Investigators/Research Sites
    c. Program Assessment

C. Post-Approval Monitoring
1. Consent Process
2. Research
3. Protocol Deviations

IV. Records and Reports 18%

A. Policies, Procedures, and Membership
1. IRB Membership Records
2. IRB Policies
3. IRB Procedures and Forms

B. Assurances and Registration
1. Federalwide Assurance of Protection for Human Subjects (FWA)
2. IRB Registration

C. Regulatory Reports (Internal/External)
1. Noncompliance
2. Terminations/Suspensions
3. Subjects' Rights and Welfare (Injury, Adverse Events, and Unanticipated Problems)

D. Audit Reports, Monitoring, and Other Communications
1. Internal Procedure Audits
2. Study Monitoring Reports
3. External Audits (OHRP, FDA)
4. Accreditation
5. Clinical Trial Registries

E. Meeting Minutes
1. Attendance, Quorum, Voting
2. Discussion and Findings
3. Reports to the IRB

F. Document and File Maintenance

1. Study Files
2. IRB Management Files
3. Regulatory Documents

G. Archiving Requirements
    1. IRB Records
    2. Investigator Records
    3. HIPAA Records

H. IRB Information Management
    1. File Tracking
    2. Data Collection

I. Training Documentation
    1. IRB Members and Staff
    2. Investigators and Other Key Personnel
    3. Institutional Officials