Standards for Research with Human Participants

OBJECTIVES

1) NIH, OHRP and the Common Rule

Overall Objectives

Upon completion of each unit (or any subset or all of the units), attendees should be better able to:

1. List relevant standards for research with human participants on the covered topic areas
2. Perform the application for relevant standards for research with human participants on the covered topic areas

2) IRBs

Objectives:

Upon completion of this activity, attendees should be better able to apply these concepts for research on human volunteers (Numbers refer to sections of Code of Federal Regulations [CFR]):

1. IRB Functions and Operations 46.108, 109
2. Reviews and Expedited Reviews 46.110
3. Concept of Minimal and Greater than Minimal Risk
4. Criteria for IRB Approval 46.111
5. Multicenter (Cooperative Studies) 46.114
6. Suspending or Terminating Research 46.113, 46.123 (Data Safety Monitoring is addressed in Session IX)

This course will not cover:

1. University of Minnesota IRB’s process for submission which may be found at http://www.research.umn.edu/irb/sitemap.html
2. Rules for research on pregnant women, fetuses, prisoners or children or neonates
3) Data Integrity/Confidentiality

Objectives

Upon completion of this activity, attendees should be better able to recognize how to use confidentiality with regard to:

1. IRB Concerns
2. NIH Certificates of Confidentiality
3. DSM Reviews
4. Journal Standards

4) Informed Consent

Objectives

Upon completion of this activity attendees should be better able to apply these ideas to Informed Consent for research on human volunteers:

1. Differences between informed consent to treatment and to research
2. Informed consent regulations and waivers
3. Pitfalls in Communication
   a) Therapeutic Misconception
   b) Equipoise
   c) Illiteracy/Innumeracy
   d) Withdrawal of Consent
5) Impaired Capacity to Consent

Objectives

Upon completion of this activity attendees should be better able to apply these standards to research:

1. Definition of Impaired Consent Capacity
   a. Assessing Impaired Consent Capacity for research

2. Managing Impaired Consent Capacity
   a. Legally Authorized Representatives
   b. Persons who are Incompetent or Under Holds
   c. Consent Monitors
   d. Fluctuating Capacity to Consent

3. Using Assent

6) Vulnerable Persons

Objectives

Upon completion of this activity attendees should be better able to apply these concepts to research on human volunteers:

1. Definition of vulnerability

2. Differences between vulnerability and impaired decision making capacity

3. Typical situations where vulnerability is an issue in research with human participants

4. Ways to manage vulnerability

7) Conflicts of Interest

Objectives

Upon completion of this activity attendees should be better able to apply conflict of interest as a cross cutting concern for:

1. IRB operations

2. Data Safety Monitoring Boards

3. FDA Panels

4. Publication / Peer Review

5. NIH Grant Review/submission
**8) Scientific Publication**

*Objectives*

Upon completion of this activity attendees should be better able to apply these concepts to scientific publication:

1. Misconduct: Plagiarism, Conflicts of Interest, Duplicate Publication, Open Access Journals
2. Guidelines: ICJME, COPE CONSORT, STROBE, PRISMA, STARD, etc.
3. Standards for Peer Review

**9) Data Safety Monitoring**

*Objectives*

Upon completion of this activity attendees should be better able to:

1. List the purpose of DSM and the fact of variances in DSM policies
2. Identify when a DSM might be required
3. Identify structures for DSM
4. Identify the outcomes of DSM assessments

**10) International Research**

*Objectives*

Upon completion of this activity attendees should be better able to apply these concepts to scientific publication:

1. Regulatory Standards for End Product Approval (Guidance for Good Clinical Practice)
2. Ethics Standards: WMA, CIOMS, Nuffield Council, WHO, UNAIDS
3. University IRB standards
4. The requirement for local benefit
5. The problem of ‘comparator’ arms in low resource countries
11) Research Misconduct

Objectives

Upon completion of this activity attendees should be better able to apply these items for research on human volunteers:

1. Definitions of research misconduct
2. How to report misconduct
3. Misconduct Investigations and Penalties
4. Whistleblower Protections
5. Appeals

12) Clinical Trial Registries

Objectives

Upon completion of this activity attendees should be better able to apply these issues to their work with Clinical Trials Registries:

1. Aims of Certified Trial Registries
2. FDA/NIH Regulations
3. Journal policies regarding trial registration