2008

Education of researchers

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Objectives

- General Overview of the Ethics of Research
- What do Researchers Need to Know
- How can researchers receive the appropriate information

Overview of Research Ethics

- Nuremberg Code
- Declaration of Helsinki
- Belmont Report
- International Council on Harmonization (ICH)
- Council for International Organizations of Medical Sciences (CIOMS) Guidelines

Nuremberg Code

- A document that states the basic requirements for conducting research that respects the fundamental rights of human subjects
  - See handout
- Standards from the Nuremberg Code have been incorporated in subsequent documents

Declaration of Helsinki

- Consists of the standards in the Nuremberg Code
- Makes two additional points
  - Interests of the subject should always be given higher priority than those of society
  - Every subject should get the best known clinical treatment

Belmont Report to the Code of Federal Regulations

- The Tuskegee Study
  - Ethical problems with research are identified.
- The Belmont Report
  - Fundamental principles for the ethical conduct of research
- The Code of Federal Regulations
  - Specific regulations adopted in 1974
  - IRBs formed

International Council on Harmonization (ICH)

Purpose was to harmonize:

- interpretation and application of technical guidelines and requirements for product registration

- to reduce or obviate duplicate testing during the research and development of new medicines.

Good Clinical Practices

- ICH Guidance
  - ICH E6 Good Clinical Practice: Consolidated Guidance

- An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

Good Clinical Practices

- Objective: to provide a unified standard for the European Union (EU), Japan, and the US to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

- Developed with consideration of current good clinical practices in EU, Japan, US, Australia, Canada, Nordic countries, and WHO
  - World Health Organization (WHO)

Council for International Organizations of Medical Sciences (CIOMS) Guidelines

- Developed in conjunction with the World Health Organization (WHO)

- Purpose:
  - "to prepare guidelines to indicate how the ethical principles that should guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be **effectively applied, particularly in developing countries**, given their socioeconomic circumstances, laws and regulations, and executive and administrative arrangements."

What Do Researchers Need to Know?

- Ethical codes
- Federal Regulations
- Federal agency guidelines
- State Statues
- Institutional guidelines
- Regional guidelines
- Local guidelines

Federal Agency Guidelines

- Relevant to their proposals and may consist of:
  - **Office of Human Research Protection (OHRP)**
  - **Department of Health and Human Services**
  - **Food and Drug Administration (FDA)**
  - **National Institutes of Health (NIH)**
  - **International Committee on Harmonization (ICH)**
  - **World Health Organization (WHO)**
  - **Office of Research Integrity (ORI)**
  - **Secretary's Advisory Committee on Human Research Protections (SACHRP)**
  - **Association for the Accreditation of Human Research Protection Programs (AAHRPP)**
  - **Joint Commission on Accreditation of Healthcare Organizations (JACHO)**

State Statues

- May include statues on:
  - Age of Majority
  - Consent
    - Minor spouse or parent may give consent, when.
    - Consent for Surgical or Medical Treatment
    - Experimental treatment, tests and drugs, consent to administer by third party
  - Confidentiality of reports and records, exceptions--violation, civil action for injunction, damages, costs and attorney fees--health care provider participating in judicial proceeding, immune from civil liability.
  - Death--Disposition of Dead Bodies

Institutional Guidelines

- These include:
  - Institutional guidelines
  - IRB Guidelines
  - Departmental Requirements

Institutional Guidelines - Examples

- Conflict of Interest
- Financial Management of Research Grants & Contracts
- Human Studies Education Policy
- Human Embryonic Stem Cell Research
- Intellectual Property & Technology Transfer
- Research Integrity

IRB Guidelines - Examples

- Consent
- Genetic
- Recruitment
- Risk and Data Monitoring
- Submission
- Tissue
- Vulnerable Populations

Departmental Guidelines - Examples

- Who may be listed as the PI
- Pre-IRB Scientific Review Process
- Who is the departmental signatory person
- Budgetary requirements/procedures

How can researchers receive the appropriate information?

- Tiered Approach
  - Educating the research staff
  - Educating the researchers themselves

Educating the Research Staff

- Voluntary courses
- University certificate and degree programs
- Involvement in educational steering committees
- CRA Forums
- One-on-one meetings

Voluntary courses

- Necessary Elements in the Fundamentals of Human Subjects Research
  - 3 day course
  - Covers:
    - **I. An Introduction to Human Subject Research**
      Objective: Explore the history of research ethics and emerging ethical considerations as new fields emerge. Learn what lead to the formation of current regulations governing human subject research, their implications, and how research is governed.
    - **II. Good Clinical Practice**
      Objective: Provide an overview of the research process from study origination through data collection and analysis.
    - **III. Institutional and Investigator Responsibilities**
      Objective: Explain responsibilities from study initiation through closure.

University certificate and Degree programs

- For clinical research coordinators
  - Certificate for those already with a degree or experience
  - Bachelor's for those that do not have a degree
  - Master's Degree for those with a bachelor's or already possessing another advanced degree

Sample Curriculum – Bachelor of Science Degree

- Required Core courses
  - 36 units, some to be applied to distribution requirements
    - Introduction to Anatomy and Physiology I & II
    - Principles of Biology I and II
    - Introduction to Chemistry
    - Introduction to Microbiology
    - Human Growth and Development
    - Biomedical Ethics
    - Psychology of Health
    - Leadership for Organizational Success

Sample Curriculum – Bachelor of Science Degree

- Required Career-Related Courses
  - 21 units, some to be applied to distribution requirements
    - Fundamentals of Clinical Research Management I and II
    - Pharmacology
    - Research Ethics and Regulatory Affairs
    - Business of Clinical Research
    - Introduction to Statistics for Health Sciences
    - Practicum/capstone

Sample Curriculum – Master's of Science

- Courses being discussed include:
  - Fundamentals of Site Management
  - Fundamentals of Clinical Monitoring
  - Drug Development Process
  - Medical Writing
  - Leadership
  - Trends in Health Policy
  - Advanced Statistics/Design
  - Epidemiology
  - Scientific Writing and Publishing
  - Organizational Management
  - Research Design
  - Electives

CRA Forums

- Brown Bag or lunch workshops
  - Discuss issues pertinent to research and the role of the study coordinator
  - Networking opportunity
- Q & A Forums

Educating Researchers

- One-on-one meetings
- Researchers as speakers
- Conferences
- Participation in IRB meetings
- Participation on Task Forces
- Education initiatives

One-on-one meetings

- Give personal attention and practical advise.
- Help the researcher apply the information to his/her particular study.
- Assist the researcher in working through the various ways that the ethical codes, regulations and guidelines can affect his/her research (i.e. assist with study design).

Researchers as Speakers

- In order to present material, you:
  - Have to know more than you are presenting.
  - Understand the material.
  - Be able to manipulate the information.
  - Be able to apply the information to new situations.
- No one knows the material better than someone who has “taught” the material.

Conferences

- Offer local conferences such as:
  - Town Hall meetings
  - Regional Conferences
  - Office of Research Integrity (ORI) conferences
  - Supporting IRB Offices (SIRBO) conference

Participation in IRB meetings

- New Member Orientation
- IRB member breakfasts and retreats
- Tip Sheets and short presentations at IRB meetings
- Reviewer's perspective

Participation on Task Forces

- Development of guidelines and policies
- Review of compliance issues
- Advisory committees

Education initiatives

- Research Fairs
- Collaborative IRB Training (CITI) program
- Faculty or departmental meetings
- Small group trainings

Education Initiatives

- Information posted on a website
- Compliance Newsletters
  - Where the PIs get CMEs or CEUs
- Ethics series
  - Gives credit for K Awardees
- Orientations
  - New Submitter's Orientation
  - New Member Orientation
  - Human Resources Orientation

References

- Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects
- Institutional Review Board Member Handbook, second edition, Robert Amdur and Elizabeth Bankert
- ICH Guidelines (Step 5, U.S.), Code of Federal Regulations
- Nuremberg Code
- Research Ethics Training Curriculum for Community Representatives, Family Health International