M6728

Ethics in Research
Informed Consent/IRBs
Reporting Research Results

Goals
- Understand the history of ethics in research
- Describe ethical issues related to the conduct of research
- Assess the components and quality of informed consent forms
- Understand the need for ethics in research in the future
- Assess the ethics of research protocols

The Nuremberg Code
- Prototype, 1947
- Voluntary consent
- Should contribute to good of society, unprocurable in other ways
- Avoid all unnecessary harm/suffering
- Benefit exceeds risk
Other Formalized Codes (>30)

- Declaration of Helsinki, 1961
  - When research is conducted in context of care
  - Differentiates between therapeutic and non-therapeutic research
- Professional codes of ethics

Treatment
- Patient needs help
- Offers direct benefit
- Patient initiates contact
- Patient has chosen to seek treatment before reviewing form

Research
- Researcher needs help
- Often no direct benefit to patient
- Researcher initiates contact
- Patient unaware of research before reviewing form

The Belmont Report, 1979

Ethical Principles and Guidelines for the Protection of Human Subjects of Research
NIH, PHS, HHS
Do we need ethical codes in research?

The Tuskegee Experiment
But even today?

Concepts

- Volunteers - Human Subjects
- Permission - Informed Consent
- Oversight - Institutional Review Boards
- Documentation - Assurance and Records
- Self-Interest - What’s it to you?

Respect for Persons

Acknowledgement of autonomy
Protection of those with diminished autonomy
Beneficence

Do no harm.
Maximize benefits, minimize risks

Justice

Fairness in distribution of risks and benefits

Principle 1

Respect participants’ capacity to consent and determine degree and duration of participation
Principle 2

Prevent harm, promote good for participants

Principle 3

Respect participants, their families and significant others, valuing their diversity

Principle 4

Ensure that benefits and burdens of research are equitably distributed in selecting participants
Principle 5

Protect privacy of participation

Principle 6

Use appropriate checks and balances throughout the study to ensure ethical integrity

Principle 7

Report suspected or known incidents of misconduct
Principle 8

Maintain competency in subject matter, methods, and relevant professional and societal issues

Principle 9

Maximize benefits with least possible harm or suffering

Conflicts for the Researcher

- Social: Rights of individual vs. common good for public
- Personal: Needs of patient vs. need to expand knowledge
### Involvement in Research

- 60.1% would consider, even without personal benefit
- 26% would join only for personal benefit
- 13.8% would not join
- Men and those with higher education were more likely to join to help others (p<0.01)

### What Do Pts. Want to Know?

- Purpose of study: 86.2%
- What they will have to do: 85.1%
- Risks and benefits: 84.4%
- Who investigator is: 81.5%
- Why they are asked to join: 80.4%
- How information will be used: 79.6%
- Time commitment: 79.2%

### Perceptions of Involvement

- Received adequate information: 64.1%
- Received written explanation: 68.2%
- Read information provided: 77.6%
- Sure of study purpose: 69.4%
- Discussed study before joining:
  - with family or friend: 44.3%
  - with health professional: 28.7%
More Perceptions

• Had unanswered questions 30.0%
• Felt pressured to join 10.2%
• Were glad they joined 83.3%
• Would join again 79.6%

What Patients Don’t Know

• 40.8% didn’t know there was a committee to protect their rights
• 39.9% thought only physicians did research
• 54.5% did not know that nurses did research

Implications

• Consent process should be enhanced to improve comprehension and/or perceptions of involvement
• Education and gender deserve consideration in patient education plans
• Informational materials may be helpful
What is scientific misconduct?

- Plagiarism
- Fabrication, falsification, forging
- Manipulation of design or methods
- Selective retaining/reporting of data
- Irresponsible collaboration
- Inadequate supervision
- Misuse of privileged information

For Informed Consent, Subjects Must Be

- Competent
- Able to comprehend
- Informed
- Willing

Informed Consent Indicated:

- Proposed activity goes beyond accepted or standard practice
- Proposed activity is not specifically directed toward treating the patient
Factors Influencing Pt. Response

- Position of person approaching the patient
- Method of approach
- Verbal communication given to patient

What Promotes Comprehension?

- Direct, brief presentation
- Information presented by nurse or health care team member
- Obtaining immediate recall of information

What Hinders Comprehension?

- Presentation of complex or threatening information
- Information presented by physician alone
- No effect of age or occupation
Anonymous or Confidential?

• Anonymous: Neither researcher nor subject can identify responses
• Confidential: Investigator knows subject identity, but assures privacy

Future Ethical Debates

Cloning
Genetics

Disparities in health
Resource use

Research Integrity Policies

Http://cpmcnet.columbia.edu/research/faculty.htm