Ethical Considerations for Research with Human Participants

Outline

- Belmont Report
  - Research vs practice
  - Respect for persons
  - Beneficence
  - Justice
  - Applications
- APA Ethical Code
  - Benefit vs risk
  - Informed consent
  - Inducements and deception
  - Debriefing
  - 45 CFR 46
  - Examples

The Belmont Report

- The Belmont report is the basis of our thinking about research ethics
Research vs. Practice

What is the difference between research and practice with regards to ethics?

Basic Ethical Principles

Respect for persons
- Individuals should be treated as autonomous agents
- Persons with diminished autonomy are entitled to protection
  - Minors
  - Prisoners
  - Mental disability
- Enter into research voluntarily and with adequate information

Beneficence
- Do not harm
- Maximize possible benefits and minimize possible harm
- Individual vs. society at large
Basic Ethical Principles

✧ Justice
   ✧ Who should receive the benefits of research and bear its burdens?

Applications

✧ Informed consent / Respect for Persons
   ✧ Contents
   ✧ "Reasonable volunteer"
   ✧ Incomplete disclosure
   ✧ Only if necessary to accomplish goals and
   ✧ No undisclosed risks above minimal risks and
   ✧ Debriefing
   ✧ Comprehension
   ✧ Voluntariness

Applications

✧ Assessment of risks and benefits / Beneficence
   ✧ Chance and severity
   ✧ Risks to participant must be outweighed by benefits to participant plus benefits to society at large
   ✧ Brutal or inhumane treatment is never justified
   ✧ Minimize risks necessary to achieve research goals
Applications

- Selection of participants / Justice
  - Fair procedures and outcomes in the selection of research participants

The Definitive Sources

- All research involving human participants and/or their records within the Psychology Department at UD or conducted by members of the APA
- 45 CFR 46
  - All research involving human participants and/or their records at UD or which have federal funding

Benefit vs Risk

- Benefit must outweigh risk
  - Benefit to individual and society
  - Risk – magnitude and likelihood
  - Risk must be minimized
    - "Minimal risk"
APA Standard 8.02: Informed Consent

✧ Get informed consent which consists of:
  ✧ Purpose
  ✧ Procedure
  ✧ Duration
  ✧ Factors that might influence willingness to participate
  ✧ Benefits of research
  ✧ Incentives for participation
  ✧ Confidentiality and limits of confidentiality
  ✧ Right to decline participation or withdraw
  ✧ Contact information

APA Standard 8.05: Dispensing with Informed Consent

✧ Formal consent need not occur if:
  ✧ The research does not create harm or distress and involves:
    ✧ Normal educational practices, or
    ✧ Anonymous questionnaires, or
    ✧ Naturalistic observation, or
    ✧ Archival research
  ✧ And, disclosure of responses would not place participants at risk of criminal or civil liability or damage financial standing or employability or reputation

APA Standards 8.06 & 8.07: Inducements and Deception

✧ Inducements for participating should not be excessive
✧ Deception in research is used only if:
  ✧ no alternative method exists and
  ✧ the potential gain in knowledge is significant and
  ✧ the research does not involve physical pain or severe emotional distress
✧ Debriefing must explain why deception was used
✧ Participants must be permitted to withdraw their data
APA Standard 8.08: Debriefing

- Purpose of study and expected results should be given as soon as possible
- Remove any misconceptions that participant had
- Deception should be removed

45 CFR 46

- 45 CFR 46 establishes the IRB – institutional review board
- IRB decides what type of review is needed:
  - exempt
  - expedited
  - full
- Must have IRB approval before study can begin

Is It Ethical?

- To study whether bystanders will help an ill person, a psychologist fakes a heart attack on a subway in New York. Another psychologist inconspicuously records the number of people who help the "ill" person.
Is It Ethical?

Wonder Drug M has been shown to drastically increase the ability to memorize words in adults with no side effects. To determine if Wonder Drug M also increases high school students' ability to memorize words, 50 high school students were recruited. The procedure was thoroughly explained to all students, and all of their questions were answered. Each student then agreed to participate in the experiment and signed an informed consent form. After participating, each student was debriefed.

Is It Ethical?

A researcher studying demand characteristics has participants perform billions upon billions of addition problems while listening to Carl Sagan chant ancient Egyptian love songs. The researcher is primarily interested in how long each participant will continue to add. If the participant knew the true purpose of the experiment the results would be tainted, so the researcher created a cover story that he was investigating the effects of different types of music on performance. The participants (all of legal age) participated voluntarily, and gave informed consent, and were debriefed afterwards.

Is It Ethical?

An auditory perception experiment was performed. All participants were of legal age, participated voluntarily, gave informed consent, and were debriefed. One of the participants, Craig Johnson, performed poorly on the test because of a profound hearing loss in both ears. Knowing that Craig was taking intro psych, the researcher informed Craig's professor of the hearing loss, hoping that that professor would get Craig to sit near the front of the class so that Craig would be more likely to hear.
IACUC

♦ Institutional Animal Care and Use Committee
♦ "IRB" for studies involving animals
♦ Established by the USDA Animal Welfare Act and the NIH Public Health Service Policy on the Humane Care and Use of Animals

IACUC

♦ Protocol review
  ♦ Minimize discomfort, distress, pain
  ♦ Procedures than cause more than momentary or slight pain or distress are performed with sedation, analgesia or anesthesia
  ♦ Animals that would experience severe or chronic pain that cannot be relieved will be humanely euthanized
  ♦ Appropriate living conditions
  ♦ Medical care available
  ♦ Personnel will be appropriately qualified and trained

IACUC

♦ Inspections of facilities every six months
♦ Review concerns or complaints involving animal care and use
Is It Ethical?

- A researcher wants to know if grooming in mice is a learned behavior or is innate. To test this, the researcher proposes to conduct an experiment on 10 new born mice. As soon as the animals are born, they will be anesthetized and their front limbs will be amputated under anesthesia. This procedure will ensure that they will not be reinforced for making random grooming movements that remove debris from their bodies. The mice will then be returned to their mothers. The animals will be observed on a regular schedule using standard observation techniques. Limb movements will be recorded and analyzed. If grooming is learned then the mice should not make grooming movements with their stumps as the movements will not remove dirt. If, however, grooming movements are innate, then the animals should eventually show grooming-like movements with the stumps.

Herzog (1988) – Good Mouse vs. Bad Mouse

- Good mouse
- Bad mouse
- Feeder mice
- Ethics are arbitrary
  - Change across time
  - Change across cultures