Research Ethics

PSY 395 - Oswald

Human Research Abuses

- Nazi War Crimes
  - Desired to find a secret way of sterilizing large populations (ended at the end of the way – 1945)
  1. Dried plant juice was put into flour that was fed to the general population – supposed to sterilize women
  2. Intrauterine injections of a silver nitrate solution were given to women, without their consent during routine physical examinations.
  3. Men stood at a counter to complete forms while being exposed without their knowledge to sterilizing doses of X-ray radiation
  - During the trial at Nuremberg, fundamental ethical principles for the conduct of research involving humans were codified into the Nuremberg Code

Nuremberg Code

1. Voluntary consent of the human subject is absolutely essential
2. The experiment should yield fruitful results for the good of society, unprocurable by other methods or means of study
3. The experiment should be designed based on the results of animal experimentation and a knowledge of the natural history of the problem so that the anticipated results will justify the performance of the experiment
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
5. No experiment should be conducted where there is reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects
Nuremberg Code

6. The degree of risk to be taken should never exceed the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. Experiments should only be conducted by scientifically qualified persons.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end.
10. During the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if there is cause to believe that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Human Research Abuses

Tuskegee Study of Untreated Syphilis in the Male Negro
- 1932 to 1972
- 600 enrolled in an observational research study, without knowledge or consent. In exchange for participation (including an autopsy at death), they received free medical exams (to provide data for the study), transportation, and hot meals on the exam days, and $50 for burial expenses.
- Told they were being treated for “Bad Blood.”
- Learned in 1943 that Penicillin cures Syphilis.
- The longest non-therapeutic experiment on human beings in medical history.
- Symbolizes racism in medicine, ethical misconduct in human research, and government abuse of vulnerable people.
- In May of 1997, President Clinton issued a formal apology to the last eight survivors of the study.

Radiation Tests on Mentally Impaired Boys
- From 1946 to 1965, 19 boys who thought they were participating in a science club were fed radioactive milk by researchers who wanted to learn about the digestive system.
- The experiments were performed at the Fernald State School in Massachusetts.
- Researchers from Harvard and the MIT fed a radioactive form of iron and calcium to the boys, sometimes in their breakfast milk, to study the body’s ability to digest minerals.
Human Research Abuses

- The Jewish Chronic Disease Hospital Study
  - In 1963, studies at New York City’s Jewish Chronic Disease Hospital to develop information on the human transplant rejection process.
  - Involved the injection of live cancer cells into patients who were hospitalized with various chronic debilitating diseases.
  - Researchers said that consent had been given orally, but was not documented. Felt that documentation was unnecessary since it was customary to undertake much more dangerous medical procedures without the use of consent forms.
  - Patients were not told that they would receive cancer cells because, in the view of the investigators, this would frighten the patients unnecessarily. Investigators defended this view on the basis that they had good cause to predict that the cancer cells were going to be rejected.

Human Research Abuses

- The Willowbrook Study
  - 1963 to 1966, studies were carried out at the Willowbrook State School for “mentally defective persons.”
  - To gain an understanding of the natural history of infectious hepatitis.
  - The children were deliberately infected with hepatitis virus; early subjects were fed extracts of stools from infected individuals and later subjects received injections of more purified virus injections.
  - Investigators defended the deliberate injection of these children by pointing out that the vast majority of them acquired the infection anyway while at Willowbrook.
  - Parents found that they were unable to admit their child to Willowbrook unless they agreed to his or her participation in the studies.

Human Research Abuses

- What does the “37” stand for in Peter Gabriel’s song, “We do what we’re told—Milgram’s 37”?
  - Milgram Study (1963)
    - The number of fully obedient participants (out of 40) who fully conformed and continued to the highest level of obedience in shock studies.
    - Milgram found that 65% of his subjects, ordinary residents of New Haven, were willing to give apparently harmful electric shocks up to 450 volts to a pitifully protesting victim, simply because a scientific authority commanded them to, and in spite of the fact that the victim did not do anything to deserve such punishment.
    - Victim was, in reality, a good actor who did not actually receive shocks, and this fact was revealed to the subjects at the end of the experiment.
Millgram Studies
Main Study
- Advertised in the paper (Participants volunteered for a small money reward).
- Paid as soon as they arrived and it was made clear at the beginning of the experiment that they could leave whenever they wanted.
- Subject was told that this was an experiment of the effects of punishment on learning.
- Subject shown the shock generator, intervals of 15 volts from 15 to 450 volts.
- Ss introduced to the learner (described as a “mild inoffensive man”) and witnessed him being bound in the chair and electrode plate being placed on the wrist and the electrodes attached.
- Ss offered a sample shock of 45 volts (know what it is like, fair jolt even though current low).
- Instructions. Teacher reads a list of paired words. (Famous paradigm called paired associate learning). Learner has to learn these. Tested by being given one of the words and having to report the paired word.

If learner gets word wrong is given a shock 15 volts higher than preceding shock. Voltage is not decreased for correct answers.
- Only a matter of time under this design until maximum of 450 volts reached!
- Victim (confederate) asked to perform at chance level. Victim indicated answer by pressing one of four levers within reach of his bound hand.
- The victim gave responses to each question until the 300 volt point was reached. At this point all the teacher heard was a pounding on the wall and no response to the question from the victim.
- Experimenter instructs the teacher to treat the absence of a response as an incorrect response!
- Again at 315 volts now, the only response is a pounding on the wall to the next question.

At the higher voltages the victim gives absolutely no responses, giving the impression that he is at least unconscious if not dead.
- Subjects turned to the experimenter after no responses were given after 300 volts.
- The experimenter gave one of four scripted prods:
  - Please continue.
  - The experiment requires that you continue.
  - It is absolutely essential that you continue.
  - You have no other choice; you must go on.
- The experimenter would initially use prod one, but if the subjects refused to continue, would try prod 2, then 3 and finally 4, breaking off as soon as the subject continued.
- If asked about the danger to the learners health, the experimenter would give the following scripted prod:
  - “Although the shocks may be painful, there is no permanent tissue damage, so please go on”.
- The experiment would end with either the 450 volt shock being administered, or when the subject walked out!
National Guidelines for the Ethical Conduct of Human Research

- 1979 - The Belmont Report – Ethical Guidelines for the Protection of Human Subjects
  - Respect for Persons
    - acknowledges the dignity and freedom of every person and requires obtaining informed consent
  - Beneficence
    - researchers maximize benefits and minimize harm associated with research
  - Justice
    - equitable selection and recruitment, and fair treatment of research subjects
- Revised in 1991 and 2001
- APA Guidelines (1992)

Key Issues in the Conduct of Human Research

- Every research institution has an “Internal Review Board” (IRB) for the ethical review of proposed research
  - Self policing?
  - Some variance across boards but there are key themes consistent with National Guidelines and the APA (for Psychological Research)

6 Key Themes in Ethical Research

1. Informed Consent
2. Freedom from Coercion
3. Protection from Physical and Psychological Harm
4. Protection of Privacy, Confidentiality, or Anonymity
5. The Risk-Benefit Rule
6. Debriefing
Recent Examples

- Kansas Wesleyan University (A Methodist University)
  - A faculty member and graduate student decided to perform a survey of middle school aged children.
  - Part of the survey involved questions about specific sexual practices, preferences, and attitudes of the children surveyed. Several parents of children surveyed took exception to the survey that their children were asked to fill out at school.
  - Parents complained to the Governor’s Office.
  - The administration discovered that the graduate student had not submitted his project for IRB approval, and the University was acutely embarrassed.
  - This serious problem, caused by a simple project, could have been prevented if the student and faculty had reviewed, understood and complied with the IRB policies for conducting research involving human subjects.

More Recent Examples

- Middlemist et al (1976)
- Greenberg (1980) – Employee Theft

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Sample Materials

- Human Research Regulations
  - http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm
- MSU UCRHIS
  - http://humanresearch.msu.edu

Other Ethical Issues

- Ethics of Animal Research
- Ethics of Genetic research (e.g., cloning, Gene therapy, and Stem Cell Research)
- Right to Privacy Issues