Data Ethics

- ***Example 1:*** **A new surgical method is proposed to benefit Parkinson's patients.**
- **To accurately test the effectiveness of the surgery, we should use a *placebo-controlled* randomized clinical trial.**
- **Placebo in this case? A "fake" surgery.**
- **Some of the patients with Parkinson's disease will be cut into without anything being done to them.**
- **Is it ethical to put these patients through this?**

Data Ethics (Continued)

- ***Example 2:*** **Study to determine how much alcohol it takes to raise BAC past the legal limit.**
- **Participants (college students) randomly assigned to drink a certain number of beers (between 1 and 9).**
- ***Response*****: Blood alcohol content measured 1/2 hour after the final beer.**
- ***Explanatory variables*****: Amount of beer, age, gender.**
- **Drinking a significant amount of beer could be risky.**
- **Is this study ethical?**

- **Sometimes it's obvious when researchers are being unethical.**
- **With statistical studies, there are often gray areas.**
- **These are most worrying when the study uses human subjects.**
- **Certain clinical trials could put subjects' health at risk.**
- **Laws are in place to protect subjects in federally funded experiments.**

Institutional Review Board

- **Most universities, medical research centers, etc. have these.**
- **They review any proposed study that involves human subjects.**
- **Can request changes if study is too risky for subjects, or if subjects not adequately informed of risks.**
- **Often these review boards are overloaded with work.**
- **1999: At Duke Medical Center, 2000 studies involving human subjects were ongoing.**
- **Government had to halt research involving human subjects there to ensure better review and protection.**

Informed Consent

- **Human subjects in an experiment must be informed about nature of a study and any possible risks.**
- **Subjects must consent *in writing* to participate.**
- **In a sample survey, participants should be told what types of questions will be asked and how much time it will take.**
- **Who can consent for prisoners? For very ill patients? For schoolchildren?**

Informed Consent (Continued)

- ***Example 1*: If a patient is suffering from dementia, can he give informed consent to be in a clinical trial?**
- ***Example 2*: If a child forgets to bring a signed consent form from her parents, can she participate in a study at school?**
- **Unethical researchers may not mention all risks, or alternative studies/treatments.**
- **Sometimes consent forms can be many pages of fine print to cover all the risks – scares off participants?**

Confidentiality

- ***Confidentiality:*** **When the researcher cannot identify or report the responses of any individuals.**
- **Generally, good studies will only report statistics that *summarize* the data.**
- **However, databases will still contain identifying information for individual responses.**
- **Who will have access to these databases after the study is over?**
- ***Anonymity*: When the researcher doesn't know the identity of each respondent.**
- **This is somewhat rare, because follow-up studies or investigation cannot be done.**

Clicker Quiz 1

Which is NOT a possible ethical dilemma faced by an Institutional Review Board?

A. Studies may be quickly approved to reduce the workload on the board.

B. Proposed studies may involve colleagues of the board members.

C. Studies may include members of the board as participants.

Ethical Issues in Clinical Trials

- **Clinical trials are of great benefit: they show which approaches truly work and which are no better than placebos.**
- **But most of the benefits will go to future patients, not to the patients in the trial.**
- **However, the patients in the trial have to accept any risk from the treatment – is this fair?**
- **Which is more important, the interests of the subjects in the trial, or the interests of the scientific community as a whole?**

Ethical Issues in Clinical Trials (Continued)

- **Which is more important, the interests of the subjects in the trial, or the interests of the scientific community as a whole?**
- **World Medical Association (1964) said that interests of the *subjects* must come first.**
- **Putting overall interests of medicine first can lead to some extreme examples of unethical behavior.**

Tuskegee Syphilis Study

- **In 1930s, Public Health Service recruited 399 poor black sharecroppers with syphilis and 201 without it.**
- **Goal of study was to investigate the progression of syphilis when it was left untreated.**
- **In 1940s, penicillin became a standard treatment for syphilis, but subjects were not given any treatment.**
- **Public Health Service tried to prevent subjects from receiving treatment.**
- **Eventually this came to light in 1972 and study was ended.**
- **Embarrassing example of scientific investigators putting their interests ahead of the patients'.**

Clicker Quiz 2

Which of the following is NOT an ethical concern about placebo-controlled randomized clinical trials?

A. The treatment of interest may not work and may have unknown side effects.

B. The treatment of interest may work well and half the patients are instead given the placebo.

C. The placebo may not work and may have unknown side effects.

D. Some of the patients most in need of the treatment may be assigned to the placebo group.

More Ethical Concerns about Placebos

- **If a current treatment exists, should a placebo be used as a control instead of that existing treatment?**
- **One side: The placebo forms a true baseline measure for determining whether the new drug "works."**
- **Another side: If the existing drug works better than a placebo, it's unethical to give sick patients NO treatment whatsoever.**
- **Recall the fake surgery example: Is that ethical?**
- **What if the patients agree to the consent form? Is there a risk of injury from the fake surgery?**

Clicker Quiz 3

Which is an ethical distinction between the "placebo pill" example and the "placebo surgery" example?

A. The placebo surgery is more expensive and diverts valuable resources from other aspects of the study.

B. The placebo surgery carries risk of side effects, while the placebo pill does not.

C. Both of the above.

D. Neither of the above.

Behavioral and Psychological Studies

- **Should psychologists be allowed to observe people's behavior in public without their knowledge/consent?**
- **What if the behavior is in a "private place" (like a restroom)?**
- **Does it matter if there is no potential harm to the subjects? Would knowing about the study cause emotional harm?**
- **Many behavioral studies rely on the subjects having no knowledge (or limited knowledge) about the purpose of the study.**
- **Another example of a questionable randomized trial: the domestic violence experiment (arrest or warn?)**

Clicker Quiz 4

Ethical studies generally pose little risk to the participants. Which is an example of minimal risk to a subject in a study?

A. A finger prick to draw a drop of blood.

B. Drawing blood from the arm for a set of blood tests.

C. Inserting a tube in the arm to draw blood regularly.

D. Amputation of the arm.