Chapter 3: Experimental and Sampling Design, Ethics
Section 2.6: The Question of Causation

Learning goals for this chapter:

- Identify unit/subject, sample, population, treatment, factors and levels, and response variable from a story.
- Recognize whether a story is an experiment, observational study, or anecdotal evidence.
- Explain the difference between population and sample and between taking a census and sampling.
- Decide the correct type of sampling used in a story and explain the benefits/drawbacks of each: voluntary response, simple random sample (SRS), stratified random sample, multistage random sample, catch and release sample.
- Explain and identify sources of sampling bias: undercoverage, nonresponse, response bias.
- Discuss sampling variability and bias and how to reduce them.
- Understand the difference between a parameter and a statistic.
- Explain what a sampling distribution is.
- Know the 3 principles of experimental design: randomization, replication, and control group.
- Talk about lurking variables, placebos, control groups, the placebo effect, and double-blind experiments in context.
- Identify and outline the specific type of experimental design in a story: completely randomized, randomized block, matched pairs.
- Use SPSS for random selection (sampling) or assignment (experiment).
- Know the difference between causation, confounding, and common response when applied to a specific story.
- Explain the ethics of experimental design with humans (in context): review board, informed consent, individual data kept confidential.
- Explain the ethics of experimental design with animals (in context): replacement, reduction, refinement (3 Rs).
Overview of how to answer a research question:

1. Pick a specific question you want to answer.
2. Decide on your population.
3. Select a sample. The choices for this class are:
   - voluntary response (the only one not random, not the best)
   - simple random sample
   - stratified random sample
   - multistage sample
   - catch-and-release sample

4. Observational study or experiment?
   If observational study, just state the sampling design.
   If experiment, the choices for this class are:
   - completely randomized design
   - block design
   - matched pairs

5. Collect the data.
6. Analyze the data. Don’t forget to look at graphs first.
7. State your conclusions.

What can go wrong?
- sampling (bias, nonresponse, undercoverage, variability)
- experiment (not using a control, not randomizing, not replicating, lurking variables)
- survey (unclear or biased wording, sampling design, date)

Causation is not the same thing as association!
- Causation
- Confounding
- Common response

Principles of Ethical Experiments with humans
- Planned studies should be reviewed by a board to protect subjects from harm.
- All subjects must give their informed consent before data are collected.
- All individual data must be kept confidential. Only summaries can be made public. (Anonymity is not the same as confidentiality.)

Principles of Ethical Experiments with animals
- Replacement—use non-animal models or species lower on the phylogenetic scale.
- Reduction—reduce the number of animals by careful experimental design.
- Refinement—reduce unnecessary pain and distress.
• “Just Say No—To Bad Science” by Sharon Begley, Newsweek, 5/7/07
  http://www.msnbc.msn.com/id/18368217/site/newsweek/

  “A Big Dose of Skepticism” by Jerry Adler, Newsweek, 12/10/07
  http://www.newsweek.com/id/73283

“I will not report any amazing new treatments for anything, unless they were tested in
large, randomized, placebo-controlled, double-blind clinical trials published in high-
quality peer-reviewed medical journals.”  New Year’s resolution for Jerry Adler, health
columnist for Newsweek, 12/10/07.

“Just because someone with a Ph.D. or M.D. performs a clinical trial doesn’t mean that
[it] possesses any credibility whatsoever…The vast majority are worse than useless.”  R.
Barker Bausell, biostatistician at the University of Maryland and author of “Snake Oil
Science”

“Journalists needing to liven up those dull statistics are notorious suckers for anecdotes—
even a respected New York Times writer Bausell mentions who, apropos of a large study
that cast doubt on using glucosamine for arthritis, that she was sure it worked anyway,
because it helped her dog.”  Jerry Adler in Newsweek, 12/10/07

“[The real problem today] is that people don’t understand what is and isn’t science.”
Alan Leshner, CEO of the American Association for the Advancement of Science and
promoter of science literacy, quoted in Newsweek, July 2nd/9th, 2007.

“When Doug Kirby sat down recently to update his 2001 analysis of sex-education
programs, he had 11 studies that were scientifically sound, using rigorous methods to
evaluate whether a program met its goals of reducing teen pregnancy, cutting teens’ rates
of sexually transmitted diseases, and persuading them to practice abstinence (or, if they
didn’t, to use condoms).  He also had a pile of studies that were too poorly designed to
include.  It measured three feet high.”  Sharon Begley, Newsweek, 5/7/07.

“Claims for abstinence-only [sex education] also rest on measurements not of sexual
activity, but attitudes.  The Bush administration ditched the former in favor of assessing
whether, after an abstinence-only program, kids knew that abstinence can bring ‘social,
psychological, and health gains.’  If enough answered yes, the program was deemed
effective.  Anyone who is or was a teen can decide if knowing the right answer is the
same as saying no to sex…A study of another abstinence program found it did a
phenomenal job of getting girls to postpone their first sexual encounter.  One problem:  it
evaluated only girls who stayed in the program.  Girls who had sex were thrown
out…Some studies follow kids only for a few months…There is such a thing as good
science and less good science.”  Sharon Begley, Newsweek, 5/7/07.

“Statistical thinking will one day be as necessary for efficient citizenship as the ability to
read and write.”  H.G. Wells
**Population:** the entire group of individuals that we want information about

**Census:** attempt to get information from every member of the population (inventory, short version of the U.S. Census)

For the 2010 census, the Jeffersonville, IN center could hire as many as 2,400 people (starting in 2007) with an average hourly wage of $12.36. (J&C, 6/15/07) The Census Bureau performs at least one dress rehearsal 2 states in spring 2008 ahead of time to look for problems. Wireless handheld computers were going to be used in 2010 to collect data door-to-door from people who do not return the paper forms, but there devices are not working as planned. (J&C 4/25/08)

www.census.gov

The American Community Survey is conducted annually by the U.S. Census Bureau. It will replace the “long form” of the census that comes out every 10 years. Everybody will continue to receive the “short form” of the census every 10 years.

Taking a census would be expensive and time consuming, so we usually instead choose to take a sample.

**Sample:** a part of the population that we actually examine in order to gather information about the whole population

*Counting Es activity* (demonstrating census vs. sampling)

**Design of a sample:** the method used to choose the sample from the population

- **Voluntary Response Sample:** (NOT RANDOM, NOT THE BEST, sometimes the only ethical choice for experiments using people)
  - consists of people who choose themselves by responding to a general appeal.
  - biased because people with strong opinions (especially negative opinions) are most likely to respond.

- **Random Selection of a Sample:** (MUCH BETTER)
  - eliminates bias by allowing impersonal chance to do the choosing
  - gives all individuals an equal chance to be chosen
Types of Random Sampling (for this class):

- **Simple random sample of size n (SRS):** consists of n individuals from the population chosen in such a way that every set of n individuals has an equal chance to be the sample actually selected *(like pulling names out of a hat, but we will use SPSS to do this or the random number table, Table B, in the appendix)*

  We could randomly select 120 people from a master list of all students taking STAT 301 this semester.

- **Stratified random sample:** first divide the population into groups of similar individuals, called **strata**. Then choose a separate SRS in each stratum and combine these SRSs to form the full sample. *(like separating out people by their age: 30s, 40s, 50s, 60s, etc. and choosing a separate sample from each age group)*

  Similar to blocks in experiments. **We could sort the students by their lecture section and take a SRS of 10 students from each of the 12 sections of STAT 301 to get a total sample size of 120.**

- **Multistage sampling design:** used when you have a population that is so big that you cannot possibly write down the entire population so you sample in stages.

  For example, when you want information on all US residents, you could break down the population into their state or residence and then select a SRS of states. Then you could select a SRS of counties from the states that made it into your sample. Then you could use a SRS to select 10 individuals from each of the selected counties.

- **Capture-Recapture sampling design:** a type of repeated SRS sampling biologists use to estimate the size of animal populations and also by the government when estimating number of households in an area. Take a SRS from the population and label them somehow (for wildlife, tags are often used). Then later take a new SRS and find the % of this sample that were also in your original sample (have tags).

  \[
  \frac{\text{# tagged in original sample}}{\text{total # sampled originally}} = \frac{\text{# tagged in second sample}}{\text{population size}}
  \]
**How do you take a sample?** You can use SPSS or the random number table in the back of the book (Table B).

**Strategy:** Give all of our names numbers in order from 01 through 12. Then look at our randomized numbers from Table B. Draw a line under every 2 digits. The 4<sup>th</sup> unique (not repeated) 2-digit combinations which are between 01 and 12 are your sample.

**Example:** A club at Hogwarts needs to take a random sample of 4 members to be representatives at a Worldwide Wizarding Workshop. Each member should have an equal chance of being selected. Here are the 12 club members:

<table>
<thead>
<tr>
<th></th>
<th>Harry</th>
<th>Ron</th>
<th>Neville</th>
<th>George</th>
<th>Ginny</th>
<th>Dumbledore</th>
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<tbody>
<tr>
<td>01</td>
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<tr>
<td>02</td>
<td>Hermione</td>
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a) Use the random number table (Table B) starting at line 130 to take a SRS of 4 members.

69051 64817 87174 09517 84534 06489 87201 97245

05007 16632 81194 14873 04197 85576 45195 96565

68732 55259 84292 08796 43165 93739 31685 97150

45740 41807 65561 33302 07051 93623 18132 09547

b) Use SPSS to take a SRS of 4 members.

Enter all the names in one column. Click on the column and then click Data → Select Cases → Random sample of cases → Sample → Exactly 4 cases from the first 12 cases → Continue → OK. You will see a “1” by exactly 4 of the 12 names. These are the selected members for your sample. All the other 8 names will have a 0, meaning they are not selected for the trip. From the Data Editor page:

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<tr>
<td>Harry</td>
<td>1</td>
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<tr>
<td>Hermione</td>
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<tr>
<td>Ron</td>
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<td>Luna</td>
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<td>Neville</td>
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<tr>
<td>Sirius</td>
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<td>McGonigal</td>
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<td>Dumbledore</td>
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<td>Lupin</td>
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Grandma’s Veggies May Have Been More Nutritious (whole story is good, but focus on the story staring at 1:30 - 3:00 and 4:00 - 5:45 minutes in):

Problems with sampling:

- **Undercoverage**: occurs when some groups in the population are left out of the process of choosing the sample (*homeless people, immigrants, military people serving overseas, college students, cell phone users with no land lines*).

- **Nonresponse**: occurs when an individual chosen for the sample can’t be contacted or does not cooperate (*hanging up on a telemarketer*).

- **Response Bias**: occurs when the behavior of the respondent or interviewer changes the sample results *the respondent lying, the race or sex of the interviewer influencing the respondent, faulty memory of the respondent, poor interviewing technique, wording of questions—When human pollsters call potential voters, they can get a slightly more pro-Obama result than when a computer voice calls the same voters. This is why Obama often seems to lose a few points between the final polls and Election Day. Newsweek 5/5/08.)*

How you are going to get your information from your sample?

**Observational study**: observes individuals and measures variables of interest but does not attempt to influence the responses. *(Stand back and watch.)* A *survey* is one type of observational study.

**Experiment**: deliberately imposes some treatment on individuals in order to observe their responses. *(Make the individuals do something in particular.)*

**Anecdotal Evidence**: based on haphazardly selected individual cases, which often come to our attention because they are striking in some way. *(“News of the Weird” or a “Dateline” lead story) These cases need not be representative of any larger group of cases. Anecdotal evidence is NOT good science!*

A survey is a form of observational study.

**To see how good a survey actually is, you should look for:**

- Wording of exact question posed
- Sampling design
- Amount of non-response
- Date of the survey
Example: (Problem 3.55, p. 260) Comment on each of the following as a potential sample survey question. Is the question clear? Is it slanted toward a desired response?

a) “Some cell phone users have developed brain cancer: Should all cell phones come with a warning label explaining the danger of using cell phones?”

b) “Do you agree that a national system of health insurance should be favored because it would provide health insurance for everyone and reduce administrative costs?”

c) “In view of escalating environmental degradation and incipient resource depletion, would you favor economic incentives for recycling or resource-intensive consumer goods?”


Why are experiments better than observational studies?

- In principle, experiments can give good evidence for causation. Observational studies are not as good at this. (See the end of these notes for more information from Section 2.6)

- Experiments allow us to study the combined effects of several factors. (Interactions between factors can be very important.)

- Experiments allow us to study the specific factors we are interested in, while controlling the effects of lurking variables.

Other important terms:

**Experimental units:** the individuals on which the experiment is done

**Subjects:** human experimental units

**Treatment:** a specific experimental condition applied to the units

**Factors:** explanatory variables in an experiment

**Levels:** the specific values of the factors which will be used

**Response variable:** what is being measured on each unit/subject
Simplest designed experiment: apply a single treatment and observe the response.

- This is ok in very controlled situations, but you may miss **lurking variables**, especially if you are using living subjects

- May miss confounding with the **placebo effect**: a patient responds favorably to being treated, not to the treatment itself (your mind tricks you into getting better even though the medicine has no effect)

- **Bias**: the study systematically favors certain outcomes (if you have no control group, your study will be biased towards finding the new medicine effective)

- **Lack of realism**: if the subjects know they’re in an experiment, they might not behave naturally during the treatment

**How can we make an experiment objective and fair? (The 3 principles of experimental design.)**

- To help detect placebo effect, use a **control group**: group of patients who receives a sham treatment (sugar pills instead of the medicine). Double-blind is best because then neither the subject nor the experimenter knows whether they are in the treatment or control group until the experiment is completely finished. (This avoids unconscious bias by the experimenter.)

- **Randomization**: rely on chance to divide experimental units into groups that does not depend on any characteristic of the experimental units and that does not rely on the judgment of the experimenter in any way

- **Replication**: Use enough experimental units to reduce chance variation. (Use as many subjects as possible!)
“Does chronic lack of sleep affect weight gain?” (J&C 12/21/04)  State whether the situation is anecdotal evidence, an observational study, or an experiment (and why you chose that particular type). If it is an observational study or an experiment, identify the population, the sample, the unit/subject and the response variable(s). If it is an experiment, identify the treatment.

a)  “In the study conducted by Dr. Shahrad Taheri and colleagues at Stanford University and the University of Wisconsin-Madison, the scientists examined the data from 1,024 volunteers in a long-term sleep study conducted at the Wisconsin campus. They examined the sleep logs kept by the subjects as well as the duration of their sleep during nights spent at a sleep lab. Analyzing blood samples taken from the subjects, the researchers found a clear pattern. Those who slept the least had the most ghrelin (an appetite-suppressing hormone) and the least leptin (a “stop eating” hormone), and for those who slept the longest, vice versa. The scientists also found that the subjects with the least sleep had a larger body mass index.”

b) “In another study conducted at the University of Chicago, researchers artificially altered the sleep patterns of 12 healthy men. Each were given 2 days of restricted sleep (just 4 hours in bed) or extended sleep (10 hour in bed) on 2 occasions. All men consumed the same amount of calories during the sleep regimens and blood samples were regularly drawn. Again, the scientists found increases in ghrelin and decreases in leptin associated with sleep deprivation. They also found that the volunteers rated themselves as significantly hungrier—especially for high calorie foods—when they had been deprived of sleep.”

c)  “Dr. Taheri says he has firsthand knowledge of the hunger inducing powers of sleep deficits—the craving for salty, fatty food and the resulting extra heft that so many new doctors experience when going through their sleep-deprived medical residencies.”
What are our choices for type of experiment?

- **Completely randomized design**: all experimental units are allocated at random among all the treatments.

- **Randomized block design**: separating out groups of experimental units or subjects that are known before the experiment to be similar in some way that is expected to affect the response to treatments, another form of control. Random assignment of units to treatments is carried out separately within each block (blocks can be of any size).

- **Matched pairs design**: There are two different approaches. Both use just 2 treatments (note the word “pair”).

  Everybody gets both treatments, in random order.

  Or use identical twins.
Choose pairs of subjects that are closely matched. Within each pair, randomly assign who will receive which treatment. Identical twins are the most common example of this. One twin receives Treatment 1, the other twin receives Treatment 2.

All subjects receive both treatments in random order. Randomly divide all subjects into two groups. Group 1 receives Treatment 1 first and then Treatment 2. Group 2 receives Treatment 2 first and then Treatment 1. This allows you to measure whether the order the treatments are given matters. Left hand vs. right hand is a common use of this type of test.

**Flowers example:** Can flowers brighten up your mood? Dr. Jeannette Haviland-Jones of Rutgers University did a study over a three-day period using 140 to 150 female subjects from the ethnically diverse community of New Brunswick, N.J. They were divided into three age groups: 20-39, 40-59, and over 60. From a previous focus group, she learned that people consider fruit baskets and large decorative candles to be equivalent to bouquets of flowers when people need to give a gift. So fruit baskets and candles were used as the gifts for the control group. Research participants were told that they had joined a study on moods and would receive one gift during the study. Interviewers talked to each participant before and after the study to gauge mood levels. Then gifts were prepared for each participant. Vases of flowers, baskets of fruit, and large candles were hidden in “Rutgers” boxes. When the research assistants delivered the gifts, they were not allowed to look inside, only to show the study participants which gift they were receiving. The R.A.s recorded the participants’ spontaneous reactions (no smile, a social or polite smile involving only the mouth, or a “true smile” involving not just the mouth but the crinkling of the eyes). The results were clear, 100% of those receiving flowers reacted with a true smile. Only 90% of participants receiving fruit and 77% of participants receiving the candle responded with a “true smile.” Even after Dr. Haviland-Jones switched around R.A.s and interviewers halfway through the study, fearing some sort of bias, the results were the same. In addition, 11 of 40 flower recipients hugged the R.A. who delivered them, and about 10% invited the R.A. to return to their home at the end of the delivery day. No such results accompanied recipients of fruit or candles. *(J&C 11/8/05)*

a. Is this an observational study or an experiment? How do you know?

b. What type of design is this? Draw an outline.
c. Did Dr. Haviland-Jones use the 3 principles of experimental design? How?

*Example:* Our 12 club members need to learn a new computer program. Jim thinks playing classical music in the background helps people to retain information better. Pam believes drinking coffee while training helps. Their boss Michael decides to design an experiment to test out their theories. He will divide the club members into 4 groups and then give them a multiple choice test about the new computer program.

a) What are the factors and their levels?

b) What are the treatments?

c) What is the unit/subject?

d) What is the response variable?

e) Outline the design of the experiment. What type is it?
Statistical Inference: use a fact about a sample to estimate the truth about the whole population

Parameter:
- a number that describes the population
- a fixed number, but in practice we do not know its value

Statistic:
- a number that describes a sample, from the data we collect
- its value is known when we have taken a sample, but it can change from sample to sample (sampling variability)
- often used to estimate an unknown parameter

Example: (from 4th edition of M&M) Voter registration records show that 68% of all voters in Indianapolis are registered as Republicans. To test a random digit dialing device, you use the device to call 150 randomly chosen residential telephones in Indianapolis. Of the registered voters contacted, 73% are registered Republicans. Are the boldface numbers parameters or statistics?

Bias vs. variability

Bias concerns the center of the sampling distribution. Your results are biased if the statistic for your sampling distribution is shifted away from the population parameter. Choosing a random sample will reduce bias.

Variability describes how spread out the sampling distribution is for the statistic. This spread is determined by the sampling design and the sample size n. Larger samples have smaller variability—the population size is not important to variability.

We want both small bias and small variability!

***

The Question of Causation (Section 2.6 in IPS)

When we talked about observational studies vs. experiments, we said that an observational study can’t give good evidence towards causation. Well-designed experiments can help you show causation.

In experiments, you usually try to prove that the explanatory variable causes change in the response variable. You might have a strong association, but how do you prove causation?
**Causation:**
- x and y are associated
- x causes y to change

*Flowers example:* Giving someone flowers causes them to express a “true smile.”

**Common response:**
- x and y are associated
- z is really what causes changes in both x and y

*Sleep example:* The amount of daily exercise a person gets affects both sleep time and hormone levels.

**Confounding:**
- x is associated with y and z
- x is associated with z
- x and z both have effects on y
- it is impossible to separate which affects are from x alone or z alone
- x and z can be either explanatory or lurking variables

*Example:* The amount of daily exercise and the number of hours of sleep a person gets both affect hormone levels.

**Even a very strong association between 2 variables is not by itself good evidence that there is a cause-and-effect link between the variables.**

*Example:* Researchers have found that gray haired people die at a higher rate than people with other hair colors. Does this mean that the gray hair causes death?

**You need a carefully controlled experiment to be able to show causation.**

The *flowers example* was a carefully controlled experiment, so we have evidence that flowers do cause a person to express a “true smile.”

**Even when direct causation is present, it is rarely a complete explanation of an association between 2 variables.**

*Example:* Do you think sleep is the only thing that determines whether you have a higher body mass index?
Even well-established causal relations may not generalize to other settings.

Once you take your subjects/units out of the lab and back into the real world, the cause/effect relationship might not still work. Lurking variables could interfere with this relationship. Real life is messy!

*Example:* In a 2004 article in the Journal of American Medical Association, researchers found that women who took the most antibiotics (for at least 501 days of their adult lives) have double the risk of developing breast cancer compared to women who didn’t use the drugs. Does this mean that antibiotics use *causes* breast cancer? Explain what could be going on.

If it’s so hard to do, how can you show causation?

It appears that lung cancer is associated with smoking. How do we know that smoking causes lung cancer? What if there is a genetic predisposition that causes people both to get lung cancer AND to become addicted to smoking, but the smoking itself doesn’t CAUSE lung cancer?

We can evaluate the association using the following criteria:

- The association is strong.
- The association is consistent.
- Higher doses are associated with stronger responses.
- Alleged cause precedes the effect.
- The alleged cause is plausible.
DATA ETHICS (Section 3.4 in IPS)

Basic data ethics for experiments with humans:
- Planned studies should be **reviewed by a board** to protect the subjects from harm.
  - “The interests of the subject must always prevail over the interests of science and society.” 1964 Helsinki Declaration of the World Medical Association
- All subjects must give their **informed consent** before data are collected.
  - For behavioral studies do not require consent if the researcher is merely observing behavior in a public space, but the researcher cannot hide information that might influence the subject’s willingness to participate.
- All **individual data must be kept confidential**. Only summaries can be made public.
  - Anonymity means that subjects’ names are not known even to the director of the study. Follow-up or clarification is impossible with anonymity.
  - Anonymity is not required, just confidentiality.
  - Confidentiality means that the researchers are aware of the subjects’ identities, but they do not publish that information.

Discuss the following studies with regard to ethics:


In 1930, syphilis was common among black men in the rural South, a group that had almost no access to medical care. The Public Health Service Tuskegee study recruited 399 poor black share croppers with syphilis and 201 others without the disease in order to observe how syphilis progressed when no treatment was given. Beginning in 1943, penicillin became available to treat syphilis. The study subjects were not treated. In fact, the Public Health Service prevented any treatment until work leaked out and forced an end to the study in 1970s.

Lasting impact of Tuskegee Study: NPR, 10/2/06, “Female Hormone May Help Heal Brain Injuries”

Jonah Goldberg, National Review, “Tall tales surrounding the Tuskegee experiment”
http://article.nationalreview.com/?q=Njg4MzdkYTQ0YjZjYWUwOWQzOTg0OWVmYWVjMDY5ZTM=

“Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present”, Harriet Washington (2007), interviewed on NPR:

Psychologists observe that people have a “personal space” and get annoyed if others come too close to them. We don’t like strangers to sit at our table in a coffee shop if other tables are available, and we see people move apart in elevators if there is room to do so. Americans tend to require more personal space than people in most other cultures. Can violations of personal space have physical as well as emotional effects?

Investigators set up shop in a men’s public rest room. They block off urinals to force men walking in to use either a urinal next to an experimenter (treatment group) or a urinal separate from the experimenter (control group). Another experimenter, using a periscope from a toilet stall, measured how long the subject took to start urinating and how long he kept at it.

Domestic Violence

How should police respond to domestic violence calls? In the past, the usual practice was to remove the offender and order him to stay out of the household overnight. Police were reluctant to make arrests because the victims rarely pressed charges. Women’s groups argued that arresting offenders would help prevent future violence even if no charges were filed. Is there evidence that arrest will reduce future offenses? That’s a question that experiments have tried to answer.

A typical domestic violence experiment compares two treatments: arrest the suspect and hold him overnight, or warn the suspect and release him. When police officers reach the scene of a domestic violence call, they calm the participants and investigate. Weapons or death threats require an arrest. If the facts permit an arrest but do not require it, an officer radios headquarters for instructions. The person on duty opens the next envelope in a file prepared in advance by a statistician. The envelopes contain the treatment in random order. The police either arrest the suspect or warn and release him, depending on the contents of the envelope. The researcher then watch police records and visit the victim to see if the domestic violence reoccurs.

The first such experiment appeared to show that arresting domestic violence suspects does reduce their future violent behavior. As a result of the evidence, arrest has become the common police response to domestic violence.
The Environmental Protection Agency is set to release the first-ever federal standards governing use of data from tests that expose human subjects to toxic pesticides, but lawmakers and some medical experts said the rules fail to adequately protect children and pregnant women.

The proposal -- which was obtained yesterday from the advocacy group Public Employees for Environmental Responsibility and will become public within weeks -- would limit the instances in which pesticide manufacturers could expose children and pregnant women to toxic chemicals, and would establish an independent board to gauge whether such human experiments meet established ethical standards. But the new rules, which will be subject to public comment before taking effect in about six months, allow some tests on vulnerable subjects and do not apply to studies conducted before the guidelines become law.

Much of the controversy centers on whether it is acceptable to expose children and pregnant women to pesticides under any circumstances. One EPA official, who asked not to be identified because the agency has not published its proposal, said the EPA wanted to let manufacturers keep the option of testing on children such products as mosquito and tick repellents to ascertain their efficacy.

For years, federal officials allowed manufacturers to conduct human studies on the grounds that they provided a clearer picture of how pesticides could affect the environment and public health. President Bill Clinton imposed a moratorium in 1998 out of concern that such tests harmed volunteers; although President Bush initially backed the moratorium, his administration abandoned it in 2003 to satisfy a court ruling in favor of pesticide makers, which argued that the federal government had not engaged the public fully enough before banning the information. EPA officials now consider data from human experiments on a case-by-case basis when judging whether to approve pesticides.
Interview with Dr. Ezekial J. Emanuel, Department Head, Clinical Bioethics, National Institutes of Health Clinical Center (by Geoffrey Cowley, Newsweek, 7/06, p. 8)

For the third time in two months, the Journal of the American Medical Association’s editors learned belatedly that the authors of a published study had financial ties to companies with a stake in their findings.

In a recent analysis of psychiatric-drug studies, researchers found nearly 80% of those with corporate sponsors got positive results; only 48% did for independent trials. That doesn’t necessarily mean that the sponsored studies were biased. A drug company doesn’t fund a major clinical trial unless it strongly suspects the treatment is a good bet. If you were an industry exec and half your human trials failed, you’d be out of work in a hurry.

So what’s the real worry? Besides biased interpretation, I think it’s the issue of selective reporting. A company will often publish its best trial results two or three times in different forms, but data that would provide a more complete picture of the risks and benefits don’t make it into the journals. We need public registries for trial data, and participation should be mandatory.

More from this interview at: http://www.msnbc.msn.com/id/14091979/site/newsweek/


Recommended fiction book (Good plot and well-developed characters, very well written—shows you what life in a research lab is really like and the ethical problems that can occur. Trust me, it’s excellent and almost impossible to put down!)
What about animal research?

(https://ori.dhhs.gov/education/products/RCRintro/c04/5c4.html)

Public Health Service
US Government Principles for the Utilization and Care
of Vertebrate Animals Use in Testing, Research and Training

Researchers should:

1. Follow the rules and regulations for the transportation, care and use of animals.
2. Design and perform research with consideration of relevance to human or animal health, the advancement of knowledge, or the good of society.
3. Use appropriate species, quality, and the minimum number of animals to obtain valid results, and consider non-animal models.
4. Avoid or minimize pain, discomfort, and distress when consistent with sound scientific practices.
5. Use appropriate sedation, analgesia, or anesthesia.
6. Painlessly kill animals that will suffer severe or chronic pain or distress that cannot be relieved.
7. Feed and house animals appropriately and provide veterinary care as indicated.
8. Assure that everyone who is responsible for the care and treatment of animals during the research is appropriately qualified and trained.
9. Defer any exceptions to these principles to the appropriate IACUC. (Link)

Further practical advice on ways to assure appropriate respect for animals can be found in the “three Rs of alternatives” devised by Russell and Burch in 1959:

- **Replacement**—using non-animal models such as microorganisms or cell culture techniques, computer simulations, or species lower on the phylogenetic scale.
- **Reduction**—using methods aimed at reducing the numbers of animals such as minimization of variability, appropriate selection of animal model, minimization of animal loss, and careful experimental design.
- **Refinement**—the elimination or reduction of unnecessary pain and distress.

Some ethical concerns for animal research not easily answered:
- How much pain and suffering is acceptable?
- Do some species deserve more consideration than others?
- Which experiments are absolutely necessary?