

## 10. Foundations of Research

### Ethics in Research: a lesson from history.

In 1932 the US Public Health Service began a study of syphilis, using an initial group of 600 impoverished, African-American sharecroppers from Macon County, Alabama. At first, the men received free medical care, meals, and burial insurance. Of the original 600, 399 had previously contracted syphilis.

The participants were not told of their diagnosis. They were also not told when funding for medical treatment ran out, and were instead told they were being treated for "bad blood." Even after penicillin became

provides the foundation for the oversight and regulation of research involving human subjects. The report is available [online](#). Today, the Office of Human Research Protection (OHRP) in the Department of Health and Human Services promulgates regulations regarding federally funded research. Every US institution that receives federal funds and undertakes human subjects research must establish an [Institutional Review Board \(IRB\)](#). The IRB reviews all research involving human subjects for compliance with , and no research may be undertaken without Board approval.

There are a few exceptions, such as the kinds of research projects you will do in this class. They are exempt since they are not invasive, risks are minimal, and don't involve protected classes such as children or prisoners.

available as a successful therapy in the late 1940s, both treatment and information about the diagnosis were withheld from the subjects.

In 1974, a whistle blower revealed the severe ethical lapses of this study. Known today as the [Tuskegee Syphilis Study](#), it is the arguably the most egregious violation of ethics in the history of US biomedical research. Congress responded to the revelation of this study by passing the National Research Act. Among other things, this law established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The law mandated that the Commission determine the basic ethical principles that should underlie research in the behavioral and medical sciences. The Commission was further charged with establishing guidelines to assure that research is conducted in compliance with those principles.

The Commission first met in 1976 in the Belmont Conference Center of the Smithsonian Institution. Intensive meetings, discussions, and public hearings continued for three years, and in April of 1979 the Commission published what is now known as the Belmont Report. This report

### Belmont Report: Basic Ethical Principles

We quote directly the three basic ethical principles identified in the Belmont Report.

1. **Respect for Persons.** Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.
2. **Beneficence.** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.
3. **Justice.** Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally.

### Belmont Report: Ethical Principles applied to Research

1. **Informed Consent.** To quote the Belmont report, “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.”

This includes **information** on such things as the research procedure, the purposes of the research, anticipated risks and benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.

The researcher needs to be sure the subject **comprehends** the information given. It shouldn't be rushed, and it should be given in language

going.

3. **Selection of Subjects.** There should be fair procedures and outcomes with respect to the selection of subjects. For example, using only prisoners, or low-income persons in risky drug trials imposes higher risks on those populations and would be unfair and violate the principle of justice.

### Research Questions

The launching pad for research is to start with a general area of interest and start asking questions.

For example, you might have noticed you have one friend who is terrified of spiders, while another thinks spiders are cool. So, **fear of spiders** might be a general area of interest.

Thinking further, you might wonder why people have different reactions to spiders. This leads some possible questions.

1. Are there some **characteristics** that people who are fearful of spi-

the subject can understand.

The subject must be a volunteer, free from undue pressure or constraints. The researcher needs to pay special attention to persons with diminished mental capacity, minors, or those in prison. Anything that reduces the voluntary character of participation violates informed consent. **Coercion** happens when there is a direct threat of harm to the subject. **Undue influence** occurs if the inducements to participate are excessive or improper.

2. **Assessment of Risks and Benefits.** The onus here is first on the researcher to balance the benefits of the research against the risks to subjects. If risk of harm to subjects is excessive relative to the benefits, the research should not be undertaken. It's also the responsibility of the researcher to give the subjects realistic information about the likelihood and character of harm. Harm could include physical discomfort or pain, but could also include psychological, social, legal, or other harm. Similarly, benefits generally relate to public health or welfare, but are uncertain while the research is on-

ders share with each other but not with people who are not fearful of spiders:

- (a) maybe one gender is more likely to be fearful of spiders than the other;
- (b) maybe people who fear spiders are more prone to anxiety in general;
- (c) maybe there is a difference in **risk-taking** between people who are afraid of spiders and those who are not.

2. Are people who are afraid of spiders more likely to be afraid of other things:

- (a) maybe people who are afraid of spiders are more likely to be also be afraid of insects than people who are not afraid of spiders;
  - (b) maybe they are more likely to be afraid of other things, like high places, or loud noises, than people who do not fear spiders;
3. Is there a common kind of traumatic personal experience, such as a spider bite, that people who fear spiders are more likely to share

than those who do not fear spiders?

Each of these questions are more specific than the original general topic. The sub-questions are more specific yet. We are **refining** our research question.

In developing a research question regarding a treatment or therapy, PICOT provides a set of questions to help guide and structure the process.

P	Population	What population are you studying or what Problem are you trying to solve
I	Intervention	What intervention do you plan
C	Control	What is your control or what will you use to compare your intervention against
O	Outcome	How will you measure the outcome of your intervention
T	Time	How much time will this take?

To settle on a **research question**, we need to consider some specific features:

- our question should be **realistic**;
- our question should be **quantifiable**;
- our question should be **falsifiable**;

- it should be **feasible** to answer our question.

### Realistic Questions.

A **realistic** question builds on prior observations or theories. Realistic questions pose reasonable connections. It's not reasonable, for example, to suppose that shoe size would be connected with fear of spiders, although it's possible that are or education might.

### Quantifiable Questions

To be **quantifiable** means you should be able to gather quantitative evidence to answer the question. Each of the above three questions satisfy this requirement. Notice question two is a more specific form of question one in that it asks if people who are afraid of spiders have other specific fears.

Notice, too, that all of the questions involve **comparing** those who fear spiders with those who do not. Comparing two groups is a fundamental feature of most deductive research and one hallmark of quantifiable research questions. This leads to the concept of independent and dependent variables.

### Independent and Dependent Variables

We can imagine that we would gather several pieces of information on research subjects for the spider project:

- Does the subject fear spiders?
- What is the gender of the subject?
- Does the subject have other anxieties?
- How open is the subject to risk-taking?

Each of these pieces of information represent **variables** that we will need to measure. Typical, this measurement would involve designing a questionnaire to ask each subject. In some instances, such as gender, we can just ask the subject directly. In other cases, such as risk-taking or anxiety, we might use a **scale** or set of questions that measure the trait indirectly. We'll talk more about scales in a later lecture.

The point here, though, is that the context of our project imposes a fundamental difference on the above variables. Our basic question is "How are people who fear spiders different from those who do not?" Broadly speaking, we suspect that "fear of spiders" **depends** on these on these other factors. So, in this example,

“Fear of spiders” is a **dependent variable** and the other variables like gender, anxiety, and risk-taking are **independent variables**.

The distinction between dependent and independent variables is fundamental to empirical deductive research. We'll return to these concepts repeatedly in the rest of the course. In the context of research objectives, we are formulating questions that describe relationships between **independent variables** and **dependent variables**.

### Falsifiable Research Questions

On it's simplest level, a **falsifiable** question is one that can be **disproved**. For example, the following would not be a falsifiable research question.

Do people who are fearful of spiders share common characteristics?

If this were false, then people who are fearful of spiders would share **no** common characteristics, a patently absurd assertion. They would all have tongues, for example, or ears. For the same reason, this is not a **reasonable** question.

For research question one, we are instead asking if people who are fearful of spiders are more likely to share a set of traits—fearful of ants, for example—than people who are **not** afraid of spiders. In other words, we would be **comparing** those who are fearful of spiders with those who are not—see the PICOT structure above.

Our question implicitly asks if we can **make predictions** about who is likely to be fearful and who is not based on a set of traits. **Falsifiable** questions **imply conjectures or predictions** that we can tested by gathering evidence. The sub-questions for question one are more specific and are both quantifiable and falsifiable.

### Feasible Questions

Finally, it must be possible to actually gather evidence to answer the question. Question three, about similar traumatic life experiences, is probably too broad and general to meet this criterion. The **Raven Paradox** is an example of a research question that meets the above criteria but also exposes some paradoxes.

### Research Hypotheses

Formulating research hypotheses is the final foundational step in research. A well-posed research question is most often phrased as a **question**. For example, we might ask

Is there a difference in education between people who are fearful of spiders and those who are not?

Or possibly

Is there a difference in age between people who are fearful of spiders and those who are not?

A research hypothesis is a statement that speculates about the **relationship** between dependent and independent variables.

Thus, the hypotheses that correspond to the above question involve replaying **“is there”** with **“We hypothesize there is...”**

We hypothesize there is a difference in education between people who are fearful of spiders and those who are not.

We hypothesize there is a difference in age between people who are fearful of spiders and those who are not.

We could even be more specific about the relationship between the **dependent variable** fear of spiders and the **independent** variables, education and age.

We hypothesize that those with less education are more likely to be fearful of spiders.

We hypothesize that a younger people are more likely to be fearful of spiders.

To summarize this section, **ethical research projects** must include

- Informed consent of the subjects;
- An assessment of potential risks and benefits; and
- Fair procedures and outcomes with respect to the selection of subjects.

**Research objectives** involve formulating a set of questions regarding possible **relationships** between **dependent** and **independent** variables. Research objectives should be

- quantifiable;
- falsifiable; and
- feasible.

**Research hypotheses** formalize research objectives as affirmative specifications.