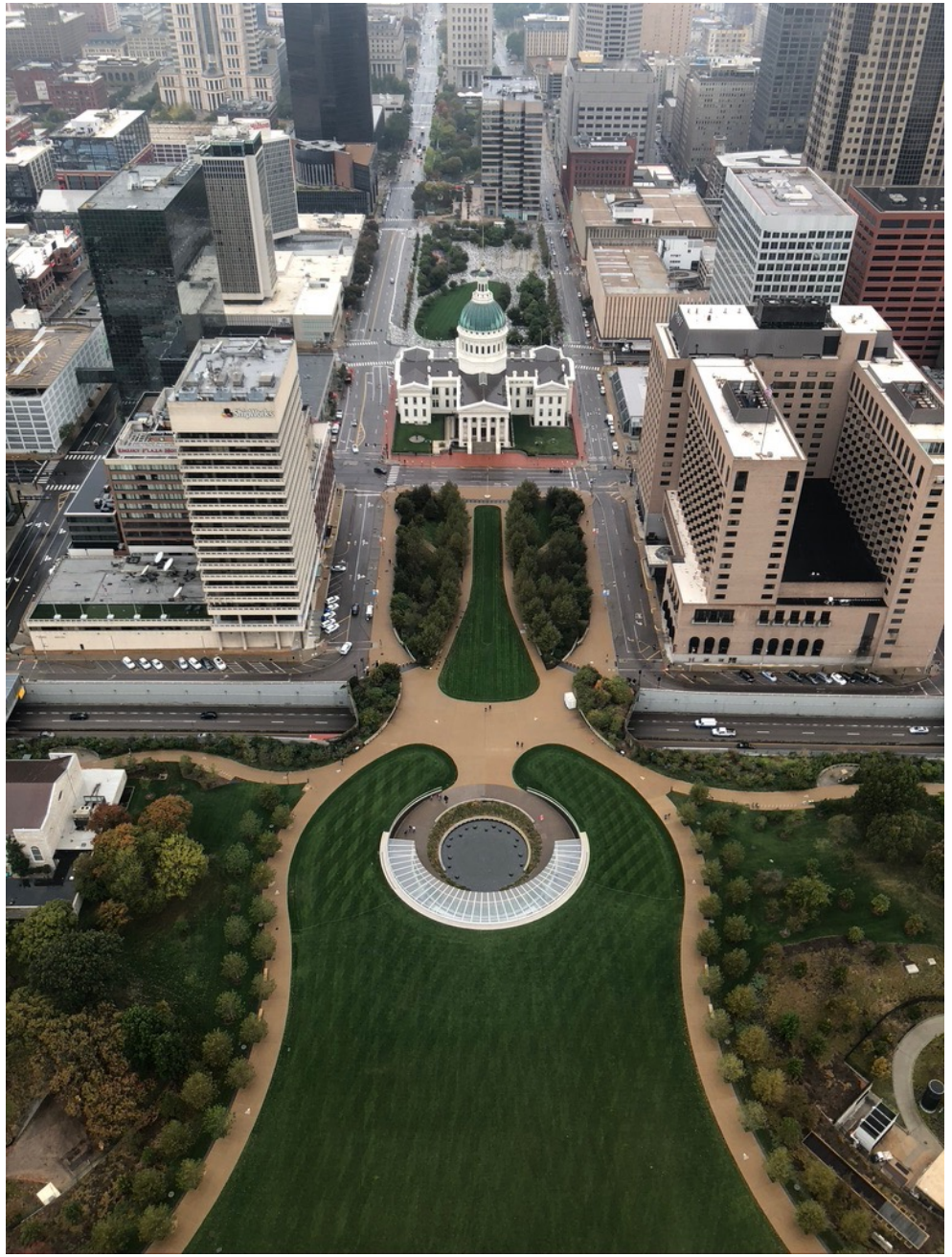
More talking…

Unit 3 – Data Ethics and Measurement

Your Silly Professor Colton



Unit 3 - Outline

Unit 3 – Data Ethics

- Example
- Data Ethics Principles
    - Honesty
    - IRB
    - Informed Consent
    - Confidentiality
- Clinical Trials

Review: Logic of Experimental Design

- **Randomization** produces groups of subjects that should be similar, on average, in all respects before the treatment is applied.
- **Comparative design** exposes all groups to similar conditions, other than the treatments they receive.

Different Groups in an Experiment

- **Treatment Groups**
  - The group the receives the treatment.
- **Control Group**
  - The group that does not receive the treatment.
  - We have a control group to compare our treatment groups to.
  - We have to know what the “base” level of our response is.

Ethics in Action

Setup

- Jim, an operations manager for a local office of a full-service brokerage firm, wishes to emphasize the excellent advisory services provided by its brokers.
- In a previous survey of clients regarding the advice received from brokers:
  - 20% rated it *poor*
  - 5% rated it *below average*
  - 15% rated it *average*,
  - 10% rated it *above average*
  - 50% rated it *outstanding*.
- After instituting several changes, another client survey was conducted which showed the following results:
  - 5% *poor*, 5% *below average*, 20% *average*, 40% *above average*, and 30% *outstanding*.
- In discussing these results, the management team expressed concern that the percentage of clients who considered their advisory services *outstanding* fell from 50% to 30%.
- One member of the team suggested an alternative way of summarizing the data.
  - By coding the categories on a scale from 1 = poor to 5 = outstanding and computing the average, they found that the average rating increased from 3.65 to 3.85 as a result of the changes implemented.
  - Jim only included the average ratings for the client surveys in his report to the corporate office

Questions

- Identify the ethical dilemma in this scenario.
- What are the undesirable consequences?
- Propose an ethical solution that considers the welfare of all stakeholders.

Data Ethics: Principles

- The production and use of data, like all human endeavors, raise ethical questions.

Honesty

- There are procedures and guidelines to ensure HONEST reporting of data and results.
- Using deception or publishing fake data is clearly unethical.
- Other situations are not so clear.
- How honest must researchers be about real data?

Example: Missing details

- Research and experiments are LONG processes, publications can't say everything…
- What if subjects were chosen in a biased way?
- Was data only reported on SOME subjects?
- Did they try several analyses and only report the ones that supported their goal?

Example: Missing details 2

The statistician John Bailar screened more than 4000 medical papers in more than a decade as consultant to the New England Journal of Medicine.

He says, “When it came to the statistical review, it was often clear that critical information was lacking, and the gaps nearly always had the practical effect of making the authors’ conclusions look stronger than they should have.”

The situation is no doubt worse in fields that screen published work less carefully.

Data Ethics: Principles

Most complex issues of data ethics

- Collecting data from people!
- Ethical issues are more severe for experiments that impose some treatment on people than for sample surveys that simply gather information.

Necessary Basic Standards

- There are some **basic standards of data ethics** that must be obeyed by any study that gathers data from human subjects, whether sample survey or experiment.
- 3 BIG ONES
  - Institutional Review Board
  - Informed Consent
  - Confidentiality
- These are in place to PROTECT subjects.

Data Ethics: Principles

Institutional Review Board

- The purpose of an **institutional review board** (often abbreviated IRB) is to protect the rights and welfare of human subjects.
    - For every study involving human subjects, whoever sponsors the research sets up an IRB.
- What does the IRB do??
    - The IRB does NOT decide whether a study will produce valuable information or is statistically sound.
    - The board reviews the plan of the study and can require changes.
    - It reviews the consent form to ensure that subjects are **informed** about the nature of the study and about any potential risks.
    - It then monitors progress at least once a year.
- Even projects that pose minimal or no risk to subjects must have an IRB.

Data Ethics: Informed consent

Informed Consent

- Both words in the phrase “informed consent” are important, and both can be controversial.
  - Children?
  - Unable to give consent? E.g. unconscious patients
  - Not getting a NO, does this mean YES?

- What is in an informed consent??
  - Subjects must be informed *in advance* (before collecting any data) about the nature of a study and any risk of harm it may bring.
  - In the case of a sample survey, physical harm is not possible.
    - The subjects should be told what kinds of questions the survey will ask and about how much of their time it will take.

- Subjects must consent, usually in writing.

Data Ethics: Confidentiality

Prior principles were both BEFORE any data is collected.

- IRB looks at the plan.
- Informed consents gets the subjects.
- Ethical problems do NOT disappear once these are achieved.

Confidentiality

- It is important to protect the subjects' privacy by keeping *all data* about individuals **confidential**.
  - Researchers know the respondent (subject), but their data is kept **secret**.
- Only summary statistics about grouped data can be reported, NOT individual records.

Anonymity

- NOT the same as confidentiality.
- With this, the respondent is NOT known or can NOT be linked with information.
- This is rare, and has a big disadvantage:
  - Prevents follow-up!

Data Ethics: Clinical Trials

Clinical Trials

- Clinical trials are experiments that study the effectiveness of medical treatments on actual patients.
- Randomized comparative experiments are the ONLY way to see the **true effects** of new treatments.

Considerations

- Both medical ethics and international human rights standards say that "the interests of the subject must always prevail over the interests of science and society."

Data Ethics: Clinical Trials

Considerations

Medical treatments can harm as well as heal.

- Clinical trials produce great benefits, but most of these benefits go to future patients.
- We must **balance** future benefits against present risks to the people in the trial.
- Interests of the subjects must prevail.

Are placebo controls ethical?

- You are testing a new drug.
- Is it **ethical** to give a placebo to a control group if an effective drug already exists?
- Maybe yes (true baseline), maybe no (inferior treatment)….

When to stop a study?

- **When** is it okay to conclude the new treatment is effective enough to STOP the experiment and give it to the control group?
- **When** are the negative effects bad enough to STOP a study before we maybe see the potential benefits?