J-PAL
ABDUL LATIF JAMEEL POVERTY ACTION LAB

Ethical Considerations for Randomized Evaluations

Course Overview

1. Why Evaluate
2. Theory of Change & Measurement
3. Why & When to Randomize
4. How to Randomize
5. Sample Size & Power
6. Ethical Considerations for Randomized Evaluations
7. Threats & Analysis
8. Randomized Evaluation from Start to Finish
9. Applying & Using Evidence
10. The Generalizability Framework

Learning Objectives

1. Gain a deeper understanding of ethical principles in research and how they came to be
2. Understand the ethical principles which guide all research and what these translate to in practice when conducting randomized evaluations
3. Understand the role of Institutional Review Boards in randomized evaluations

I. **Ethics Principles**

II. Ethical considerations with RCTs

III. Institutional Review Boards

Origins of Today's Ethical Standards

1. **Nazi experimentation**

   → Nuremberg Trials (1945-46)

   → Nuremberg Code (1947)

   → Declaration of Helsinki (1964)

2. **Public Health Service's Tuskegee Syphilis Study (1932-72)**

   → National Research Act

   → The Belmont Report (1978)

AP Images

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AP Images

Belmont principles

Respect for Persons

Beneficence

Justice

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978. *The Belmont Report*

Case Study

Building social cohesion between Christians and Muslims through soccer in post-ISIS Iraq

Salma Mousa

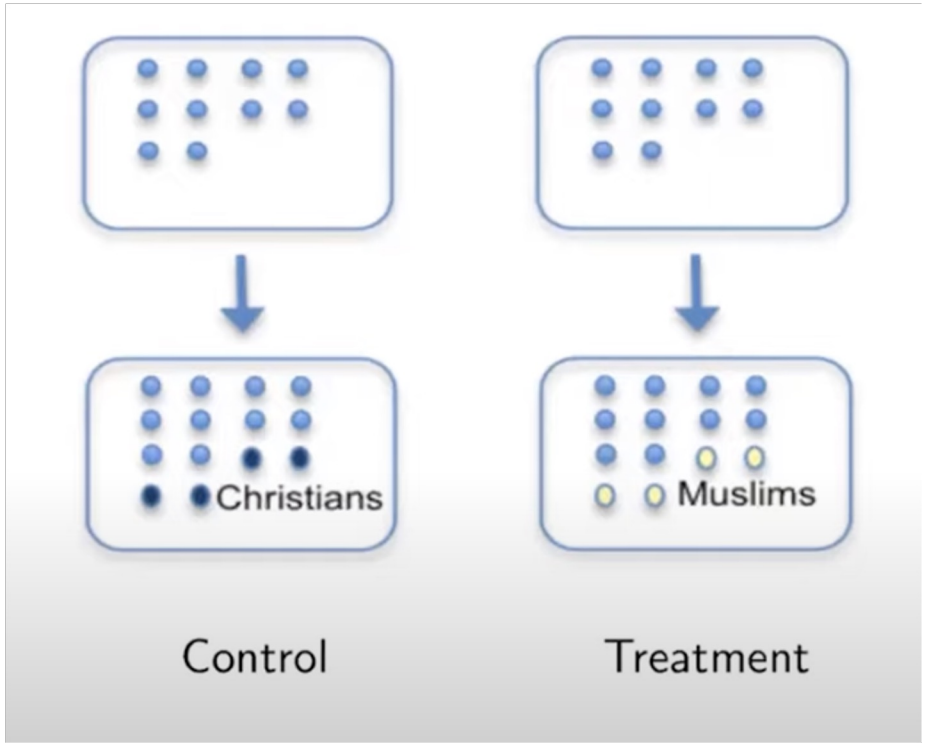
The Intervention: Inter-Religious Soccer Leagues on Social Cohesion

- The intervention was implemented in Iraq right after ISIS lost control of regions in Iraq and Syria (i.e., post-ISIS)
  - A ten-week soccer league consisting of 51 Christian soccer teams in Erbil and Qaraqosh
  - Two conditions for participating:
    - All players had to agree to complete a brief survey on their displacement experience and their views on Iraqi society before and after the league;
    - All players had to agree to being allocated three additional players on their 9-person roster

J-PAL Evaluation Summary: https://www.povertyactionlab.org/evaluation/overcoming-trust-deficit

Salma Mousa's Study: Inter-Religious Soccer Leagues on Social Cohesion in Post-ISIS Iraq

- Team were randomly assigned to treatment or control
  - Teams in the treated group received three additional Muslim players
  - Those in the control group received three additional Christian players.
- Findings were mixed



Any Questions?

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Belmont principles

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Ethical principles for human subjects research

Respect for persons

- Individuals should be treated as autonomous agents
  - Capable of making their own decisions

Respect for persons requires that we seek *informed consent* for their participation in research

Respect for persons in human subjects research

Elements of informed consent:

- Information: research purpose, procedures, risks & benefits
  - Do not lie or deceive
- Comprehension: information delivered to facilitate understanding
- Subjects must voluntarily decide to participate in the study
  - No coercion (threats)
  - No undue influence

Respect for persons in human subjects research

- Persons with diminished autonomy are entitled to additional protection
  - Children, individuals with cognitive impairment, or individuals who are very ill may not be capable of deliberation or self-determination
  - Incarcerated individuals, or individuals vulnerable to manipulation or subject to the authority of research representatives, may not be able to make a truly voluntary decision

Challenges of informed consent

Research is never independent of the social context and history of a given setting

- Potential subjects may be overly optimistic about participation yielding benefits or feel that they must comply
- Recognize power dynamics between study team and target population
- Try to understand expectations of potential subjects

Logistics of documenting consent

- Default is written documentation of informed consent—i.e., a signature or fingerprint
- Figure out the right person to obtain consent from

Salma Mousa's Approach to Respect

Study team shared details of the study to prospective participants by paying special attention to the aspects of participant experience that may be most controversial.

- Study participants were told that a major aim of the soccer league was community building among Christians and Muslims
- Team captains were informed that they were receiving three additional players (who may be Muslim)

Because participants were aware of all aspects of the soccer league and their experiences as players in the league, they could make an **informed decision** on whether to participate

Feedback & Discussion: Q&A

1. When and how might written documentation of informed consent present a challenge?
2. Under what conditions might we find that seeking informed consent is not necessary?
3. Under what conditions would seeking informed consent present an ethical challenge itself?

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Ethical principles for human subjects research

Beneficence: Do no harm

- Do not administer a treatment that is known to be harmful
- Do not withhold a benefit that would otherwise be available
- Rule becomes difficult to apply when there is 'genuine uncertainty' about an intervention's effectiveness

Beneficence in human subjects research

Minimize Risks. These may include…

- Adverse effects of the intervention
- Psychological or emotional burden of responding to sensitive survey questions
- Breach of confidentiality
- Breach of privacy

Beneficence and risk: Privacy

- What might you infer about an individual who stepped into or out of this van?
- What risk of harm is associated?

Mobile Medical Unit from the Daybreak LifeCare Center in Columbia, SC

Beneficence in human subjects research

Maximize Benefits.

- Typically, the "anticipated benefit to society in the form of **knowledge to be gained** from the research" rather than compensation for study participation
- Learn what works and scale up or down as appropriate; influence funding or policy decisions

Salma Mousa's Approach to Beneficence

Concerns about harm to participants:

- After the fighting stopped, Muslim people from surrounding areas started migrating into predominantly Christian neighborhoods.
- When the study was conducted, Christian-Muslim relations in the areas were "marked by mutual distrust and de facto segregation."
- There was a risk that mixing hostile groups in a post-conflict setting could lead to more violence.
- Mousa measured harms through collecting data about red cards and other examples of violence on the field.

Salma Mousa's Approach to Beneficence

Mousa took the following steps to reduce the risk of harm:

- Worked to mitigate power differentials among everyone involved in the study, including participants and researcher staff
- Ensured local preference drives the intervention
- Used local community input to inform details of the intervention

Beyond participants of research: Risks to program and research staff

Research can impose physical risks on staff

- Heightened exposure to everyday risks
- Safety and physical risks of violence

Research can impose emotional or psychological burdens on staff

- Assigning individuals to a control group
- Interviewing subjects about sensitive topics
- Witnessing extreme vulnerability or distress

Ensuring the safety and protection of research staff

- Enforce and emphasize the importance of field team safety and security protocols
- Ensure staff are prepared for worst case scenarios and have access to support
- Provide additional training and support for staff as appropriate

Lead Researcher's Ethical Obligations to Staff

- Ensure the safety of data collectors doing field research.
  - Danger in transportation
  - Violence

- Example: US Census
  - over 700 assaults on interviewers in 2010
  - In 2020, concern over risk and adequacy of precautions for COVID-19
  - Trained in safety, protocols to call 911, etc.

If you see practices that make you uncomfortable, speak up!

https://www.census.gov/newsroom/blogs/director/2011/06/senseless-assaults-on-decent-public-servants.html
https://www.timesonline.com/story/news/2020/09/27/u-s-census-workers-met-anger-distrust/3547138001/

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Justice in human subjects research

"Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. **Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society**. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, **unjust social patterns may nevertheless appear** in the overall distribution of the burdens and benefits of research. **Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects**."

- The Belmont Report

WHAT RELATED ISSUES MIGHT COME UP IN A STUDY YOU ARE INVOLVED WITH?

Ethical principles for human subjects research

Justice

- Fairness in the allocation of risks and benefits
- No one group should bear all the risk while another reaps all the benefits

Will the target population included in the study benefit from subsequent applications of the research?

Justice and allocation of resources

If resources are scarce and in high demand, randomization may be a fair way to allocate resources, even in the absence of a study.

- "First-come, first-serve" may not ensure that those who are most in need would have access

Justice and representativeness

Study population should represent the **population experiencing the problem**, and the **population that stands to benefit**

- Convenient, manipulable: not a valid justification for sample selection

- Sub-populations or those who are difficult to reach:
  - Don't exclude unless they do not stand to benefit from the research
  - Important to examine heterogeneous effects

It may be more costly to do this!

Justice and representativeness

Pregnant Women Get Conflicting Advice on Covid-19 Vaccines

The W.H.O. and the C.D.C. provide differing views, and experts partly blame a lack of data because expectant mothers have been excluded from clinical trials.

A pregnant woman being vaccinated in Tel Aviv. The C.D.C. and the W.H.O. differ in their guidance for expectant mothers. Jack Guez/Agence France-Presse — Getty Images

Published Jan. 28, 2021 Updated Feb. 2, 2021

"The difference of opinion between the C.D.C. and the W.H.O. is not rooted in scientific evidence, but the lack of it: Pregnant women have been barred from participating in clinical trials of the vaccines, a decision in line with a long tradition of excluding pregnant women from biomedical research, but one that is now being challenged.

While the rationale is ostensibly to protect women and their unborn children, barring pregnant women from studies pushes the risk out of the carefully controlled environment of a clinical trial and into the real world. The practice has forced patients and providers to weigh sensitive, worrisome issues with little hard data about safety or effectiveness.

...

The uncertainty isn't limited to Covid vaccines: Many if not most medications, including widely used drugs, have never been tested in pregnant women. It can take years or decades for adverse side effects to come to light in the absence of a study with a control group for comparison."

NYT News article

Mousa Approach to Justice

- The study population was selected in part because Mousa was familiar with the area and had existing contacts there (i.e., a convenience sample) and that it enabled her to carry out the study design (e.g., mixed Christian/Muslim team membership)
- Safeguards and other study design decisions ensured that no one group (Christians or Muslims) beared the risks
- The larger population beyond town residents, including both Muslims and Christians, stood to benefit from the study

Questions about the Belmont principles?

Respect for Persons

Beneficence

Justice

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Feedback & Discussion:

What do we owe to the control or comparison group?

Can we justify having a comparison group that does not receive any form of the program? Under which circumstances?

Beneficence and the comparison group

In a randomized evaluation, the Control or Comparison group is not offered the intervention offered to the Treatment group. That doesn't mean they are denied services otherwise due.

Standard of care: Comparison group receives the status quo; is not denied access to care to which they are entitled

Beneficence and evaluation design

Randomized evaluations can be designed such that we are not withholding treatments that are already available, and can be designed to ensure those most in need always receive the treatment.

- Encouragement design
- Expand eligibility

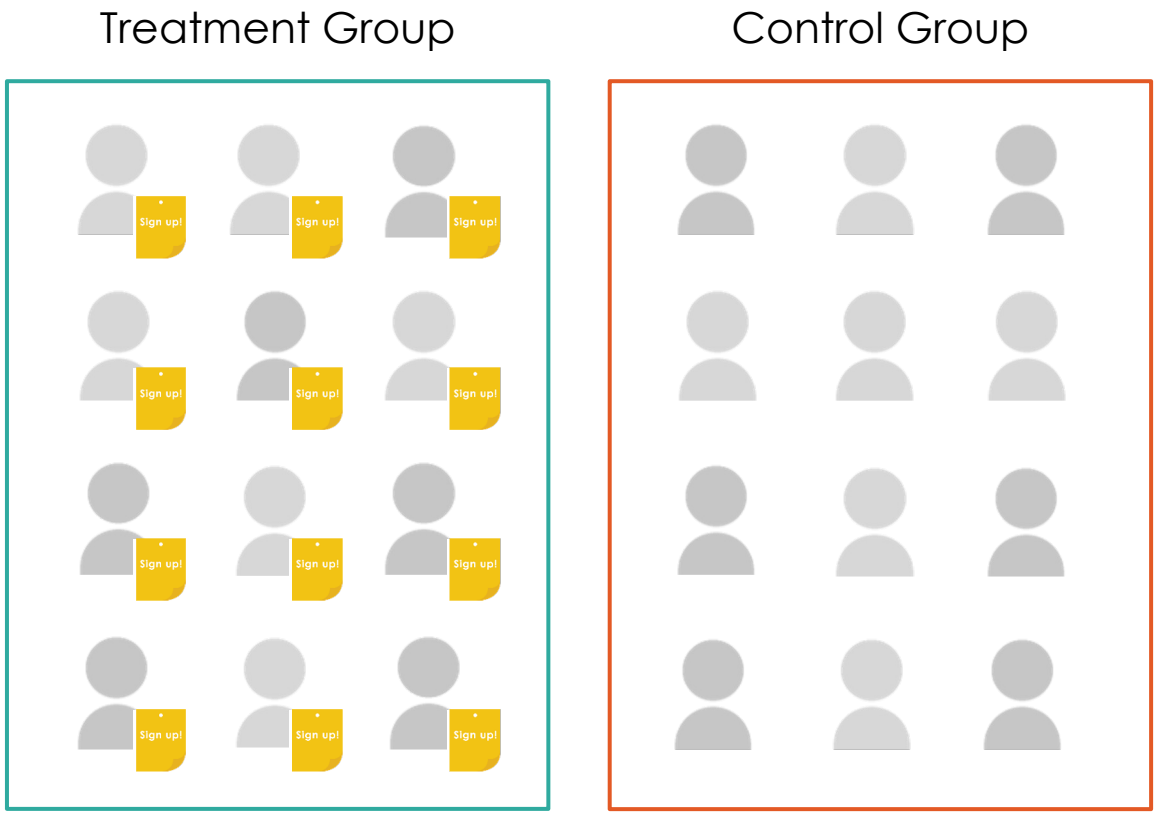
How we could use a randomized evaluation to evaluate an entitlement program like SNAP?

Supplemental
Nutrition
Assistance
Program

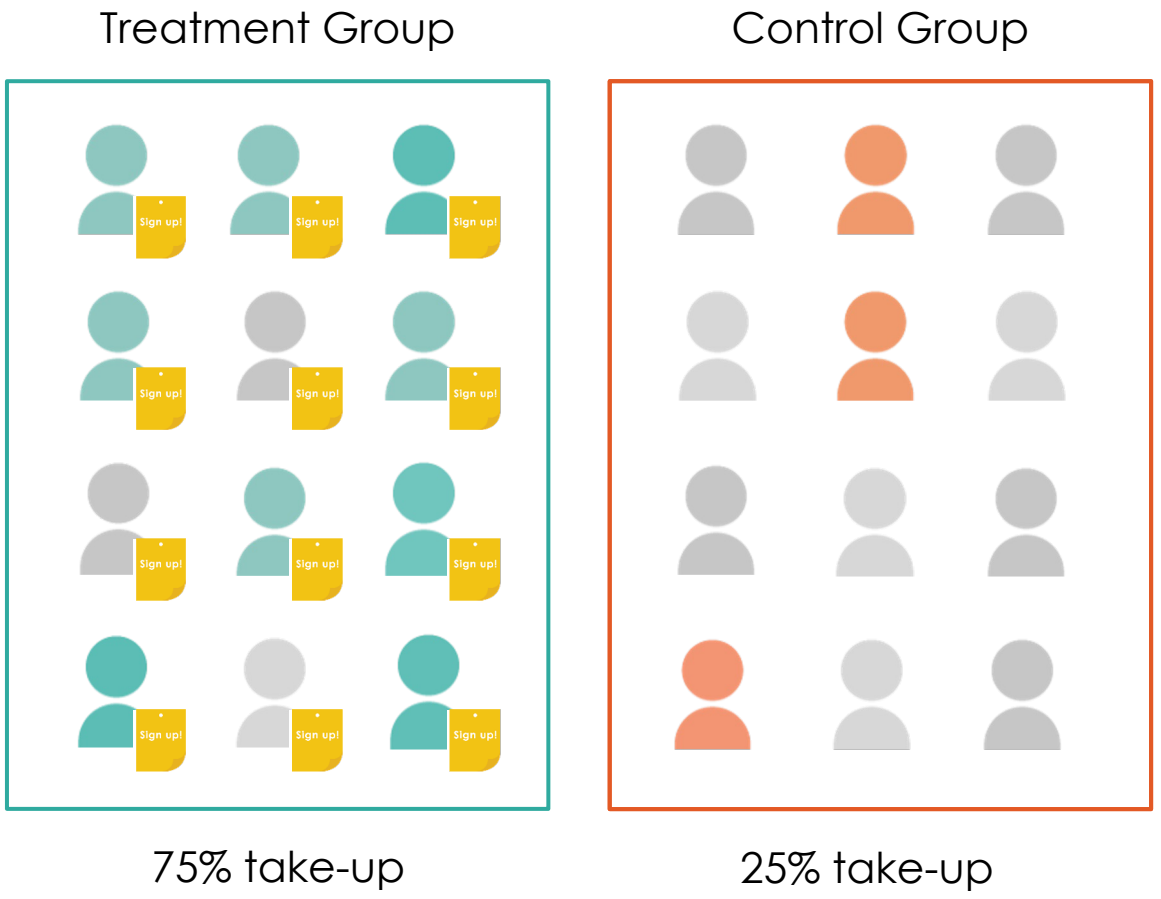
We talked about this yesterday during the How to Randomize lecture?

J-PAL Evaluation Summary: https://www.povertyactionlab.org/evaluation/snap-take-evaluation

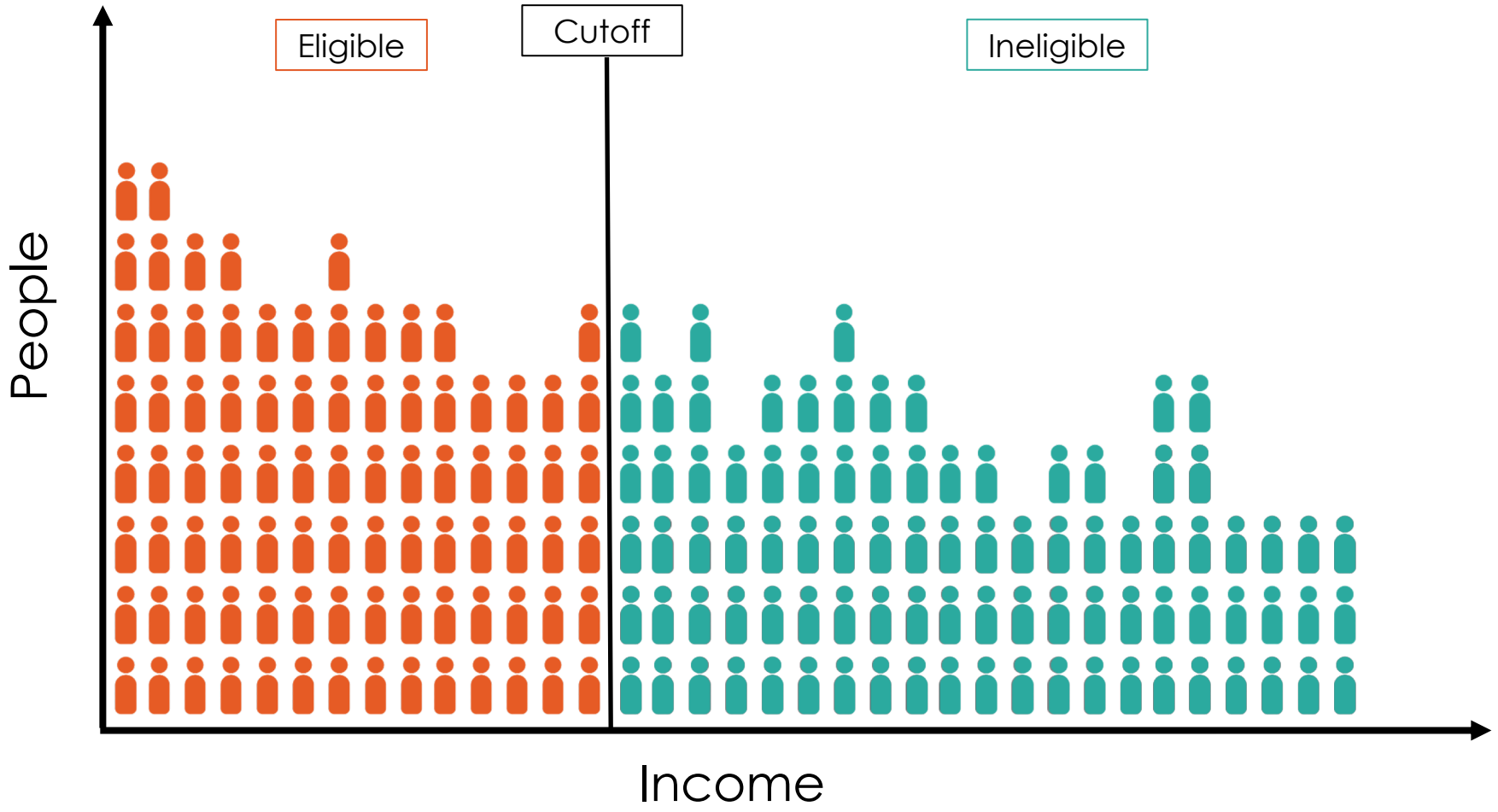
Encouragement design



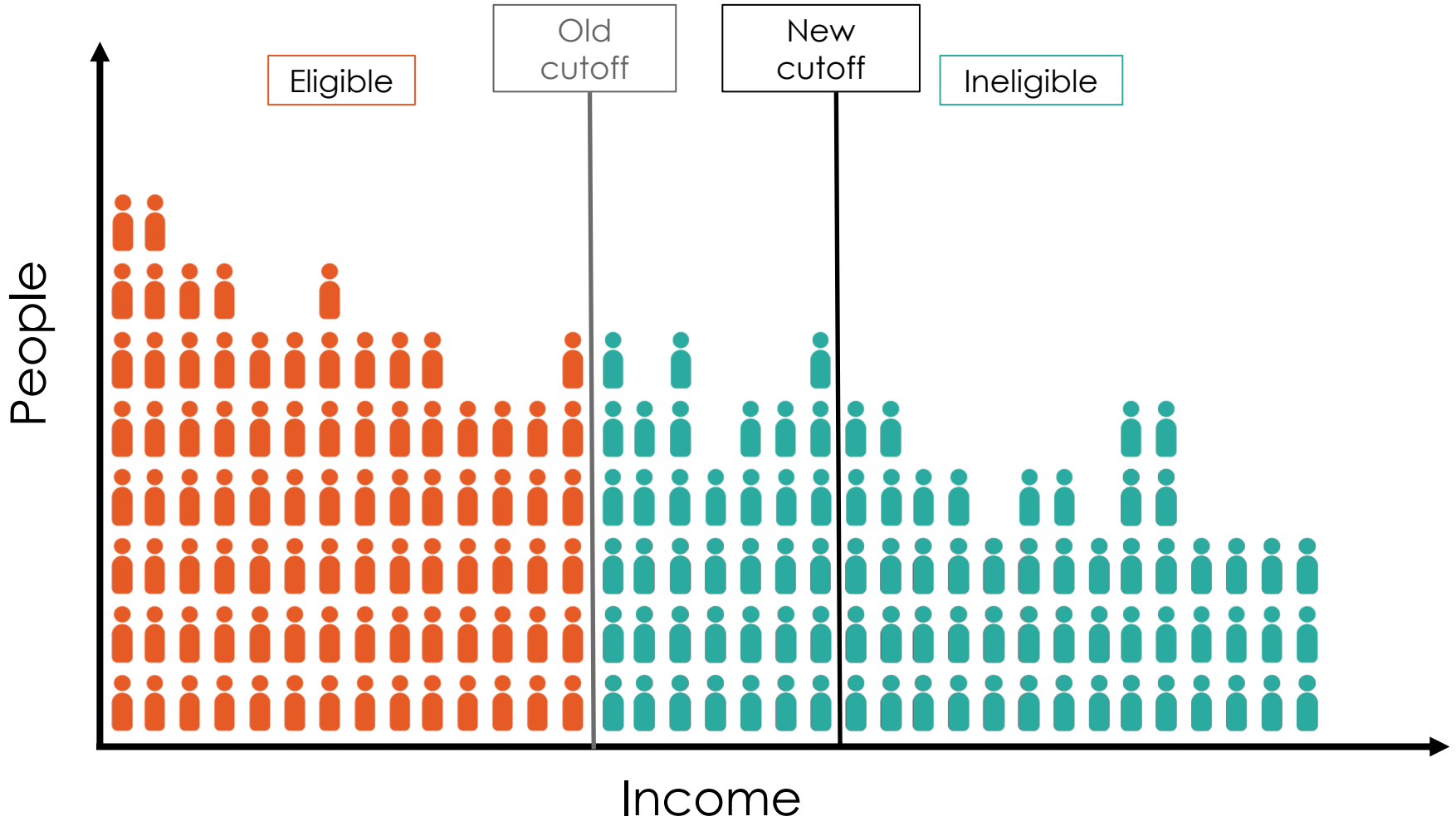
Encouragement design



Eligibility cutoff or targeting criteria



Expand eligibility and randomize among the newly eligible



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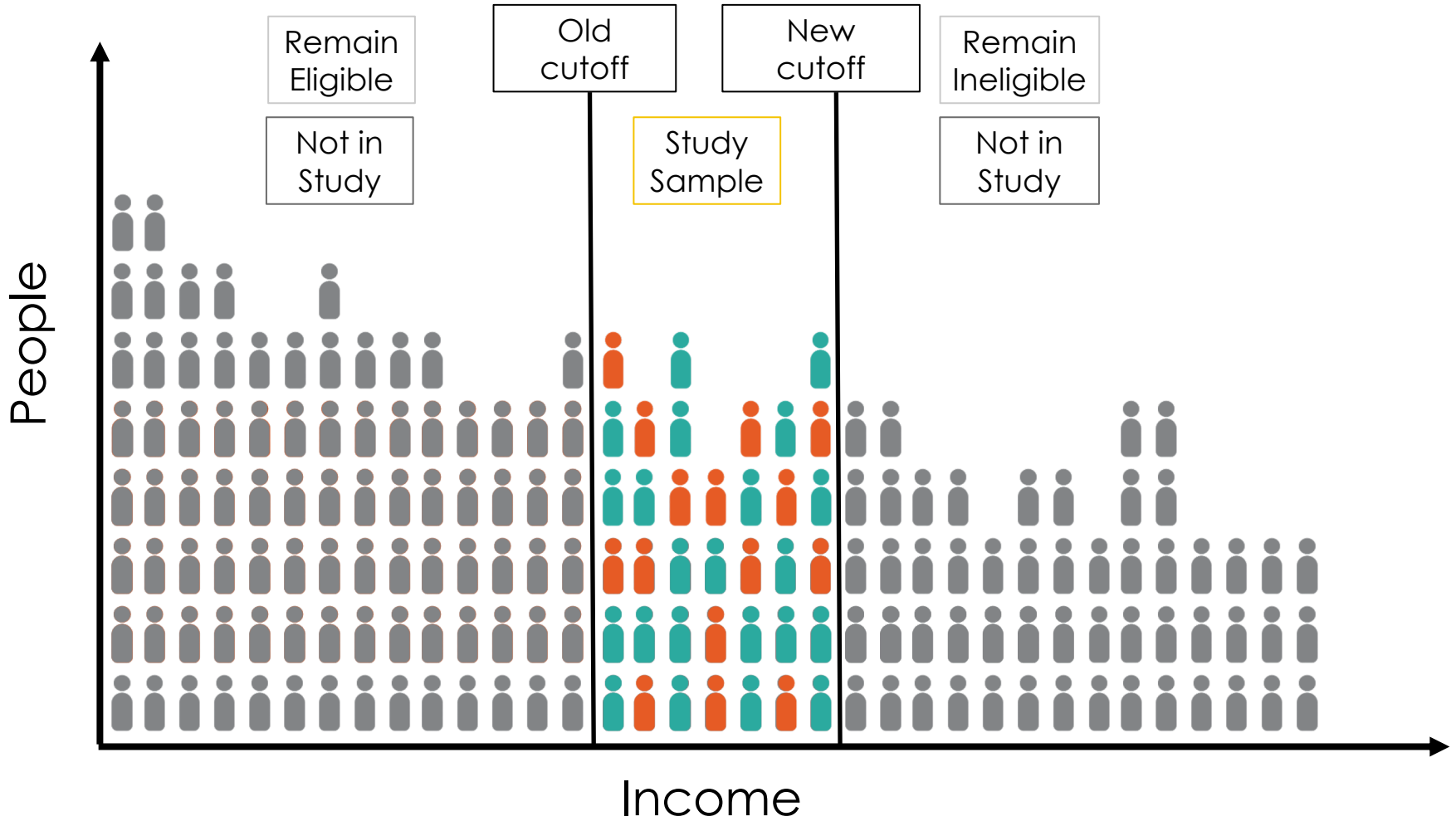

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Ethics review

- Researchers have primary responsibility for ensuring an ethical study
- Many countries, institutions, and funders also require that research involving human subjects be overseen by an independent body that protects the rights and welfare of those subjects.

Ethics review

- Institutional Review Board (IRB), Research Ethics Committees (RECs), etc
- Some operate at the institutional level
  - universities, hospitals, research orgs
- Others at the regional or national levels
- If you are doing research in another country, need approval by review boards in home institution and in study region

Limitations of IRBs

- Can only review based on the information you provided
- Are composed of regular, fallible, opinionated individuals
- Do not have scope to review "practice" in the absence of research
- Do not have scope to review the full societal context
- IRB approval does not protect you from all controversy

→ don't outsource your ethics ←

TO THINK ABOUT….

- What do you think is YOUR ROLE in ensuring ethical practices of a randomized evaluation?

Credits

- Created by Anja Sautmann, based partly on slides by Lindsey Shaughnessy, Marc Shotland, Rohit Naimpally, and others. The original presentation benefited from conversations with Laura Costica, Laura Feeney, and Nilmini Herath. Laura Costica shared her IRB talk and inspired several slides.
- Updated by Cat Darrow, Laina Sonterblum

To reference this lecture, please cite as:

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Related research resources include…

- Ethical conduct of randomized evaluations: https://www.povertyactionlab.org/resource/ethical-conduct-randomized-evaluations
- Institutional Review Board (IRB) proposals: https://www.povertyactionlab.org/resource/institutional-review-board-irb-proposals
- Designing an intake and informed consent process: https://toolkit.povertyactionlab.org/resource/define-intake-and-consent-process
- Data Security: toolkit.povertyactionlab.org/resource/data-security-procedures-researchers

References on ethics and principles

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- The Markkula Center for Applied Ethics, Santa Clara University, specifically: https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/
- The Stanford Encyclopedia of Philosophy, specifically: https://plato.stanford.edu/entries/capability-approach/
- Lay description of research ethics: How to make field experiments more ethical, Washington Post, https://www.washingtonpost.com/news/monkey-cage/wp/2014/11/02/how-to-make-field-experiments-more-ethical/?noredirect=on&utm_term=.21c1d339fd4f
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