J-PAL
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Ethics of Randomized Evaluations

Laura Feeney, J-PAL North America

Evaluating Social Programs Webinar Series, June 2020

Ethics of randomized evaluations

"Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials"

British Medical Journal (2003)

Case study: Nurse home visits for mothers

- **Partner and intervention**: The Nurse-Family Partnership (NFP) provides low-income, first-time mothers intensive support through regular home visits from early pregnancy through a child's 2nd birthday.

- **Sample and strategy**: Randomized at the individual level; almost 6,000 mothers in South Carolina, USA

"Charting the Course: Reflections on the South Carolina Nurse-Family Partnership Pay for Success Pilot"

Case study: Improving learning and education

- **Partner and intervention:** Pratham helps students build foundational skills in reading and math. Students are grouped by learning level rather than age or grade.
  - Several studies with variations in exact intervention or context/location

- **Sample and strategy:** Randomized at the school or village level, in schools and villages in India. Process monitoring and scale-up in many African countries, including Nigeria and Zambia.

TaRL activities taking place in a classroom in Gujarat, India. Photo: Luke Strathmann | J-PAL

Case study: Support for health care super-utilizers

- **Partner and intervention**: The Camden Coalition of Healthcare Providers provides an intensive care transition program to patients with 2+ hospital admissions in 6 months and multiple health or socio-economic challenges.

- **Sample and strategy:** Randomized at the individual level. 800 individuals in Camden, New Jersey, USA

Care management service providers conduct a home visit in Camden, New Jersey
Lynsey Addario

I. Ethics in Research with Human Subjects
II. Respect for Persons
III. Beneficence
IV. Justice
V. Institutional Review Boards
VI. Case study

Ethics in research with human subjects

- "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research", 1978
- Prompted by the Tuskegee Syphilis Experiment, conducted from 1932-1972
  - Enrolled 600 African-American sharecroppers, some of whom had syphilis
  - Researchers promised free medical treatment; delivered only placebos and diagnostics.
  - Did not reveal diagnosis, and actively blocked participants from effective treatment
- Had all the hallmarks of what would now be considered unethical research
  - Deception
  - Absence of informed consent
  - Dubious benefit to society as a whole, much less the study population

Belmont principles

Respect for Persons

Beneficence

Justice

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

International origins

- International codes and standards related to ethics of research with humans developed after WWII, including:
  - Declaration of Helsinki
  - Nuremberg Code
- These frameworks were also sources for many other countries' ethics frameworks

Belmont Report itself is a US creation, but the principles are broadly applicable and built off of these prior codes

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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*

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

Elements of informed consent:

- 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
  - Prisoners, or individuals vulnerable to manipulation or subject to the authority of research representatives, may not be able to make a truly voluntary decision

Challenges to 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

How to document consent: written vs oral consent

- Default is written documentation of informed consent—i.e., a signature or fingerprint
- When might a different process be more protective or respectful?

Send feedback via the Q&A

Include the # of the question you are responding to. Panelists will read out some responses. If comfortable, add your first name and where you're joining us from.

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, or would itself present an ethical challenge?

Case study: Support for super-utilizers

Background:

- Intake, consent, and random assignment conducted at bedside in the hospital.

Considerations:

- Ensuring comprehension and voluntariness

Cooper University Hospital in Camden, N.J. NYTimes: "These Patients are Hart to Treat" Mel Evans/Associated Press

Case study: Education interventions

Background:

- Random assignment is at the community or school level.

Considerations:

- Who should provide consent?
- Who is impacted?
- Which activities require consent?

J-PAL blog: "Zambia to scale Teaching at the Right Level program to 1,800 schools"

Questions & Comments

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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

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
- Risks to study personnel

Case study: Beneficence for research staff

Research can impose risks to research staff including enumerator and those conducting random assignment.

- Secondary traumatization, compassion fatigue, or burnout
- Dangerous work environment
  - Transportation
  - Violence

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
- Risks to study personnel

Plan in advance to minimize and mitigate risks **before** bad things happen.

Beneficence in human subjects research

Maximize Benefits.

- Typically, the "anticipated benefit to society in the form of **knowledge to be gained** from the research."

- Learn what works and scale up or down as appropriate
  - Funding
  - Disseminating results

Case study: Improving education. Pratham's "teaching at the right level" approach has been scaled up to improve learning opportunities for over 60 million students in India and Africa.

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

- **Support for super-utilizers**: Comparison group eligible for standard care from hospital (discharge plan)
- **Home visits for mothers**: Comparison group received a list of relevant resources and services (also received by treatment group)

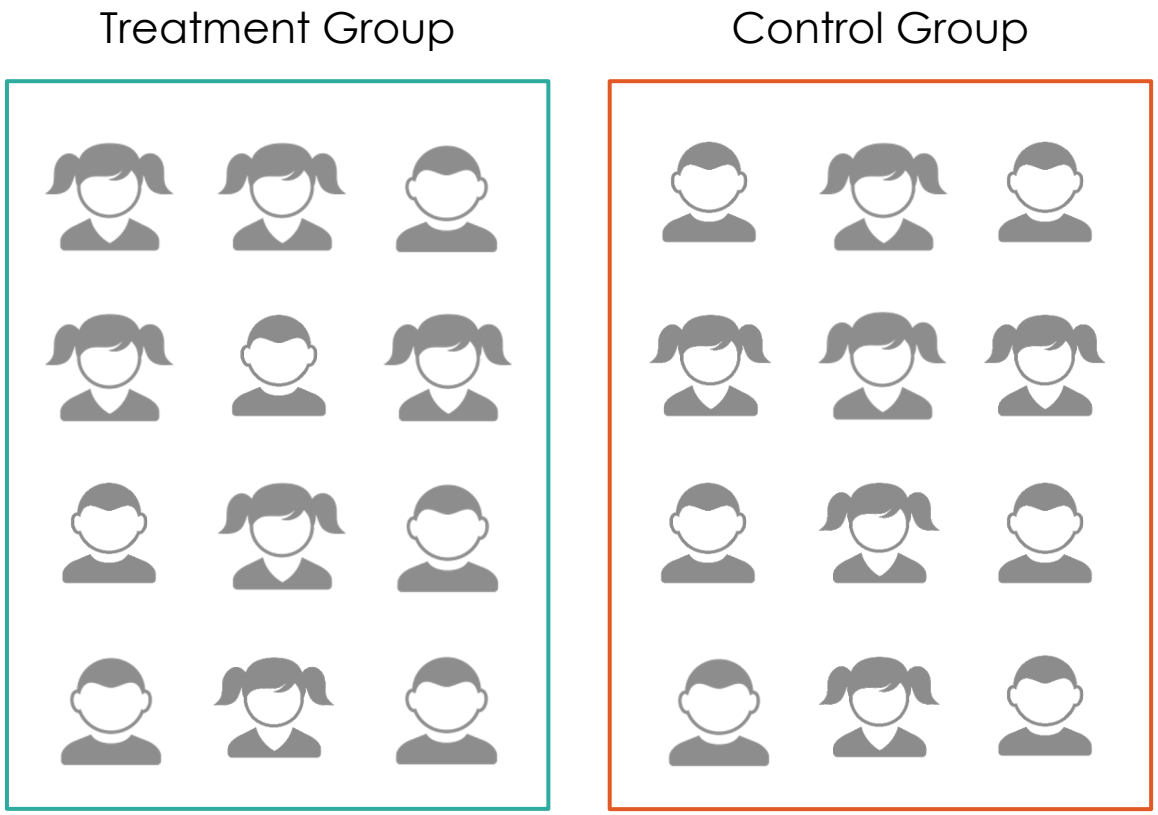
Beneficence and evaluation design

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

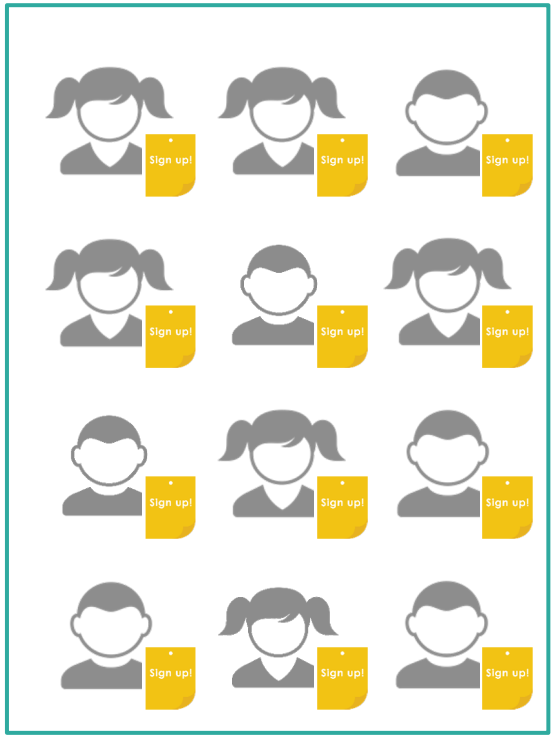
Case study: Increasing SNAP take-up

Case study: Increasing SNAP take-up



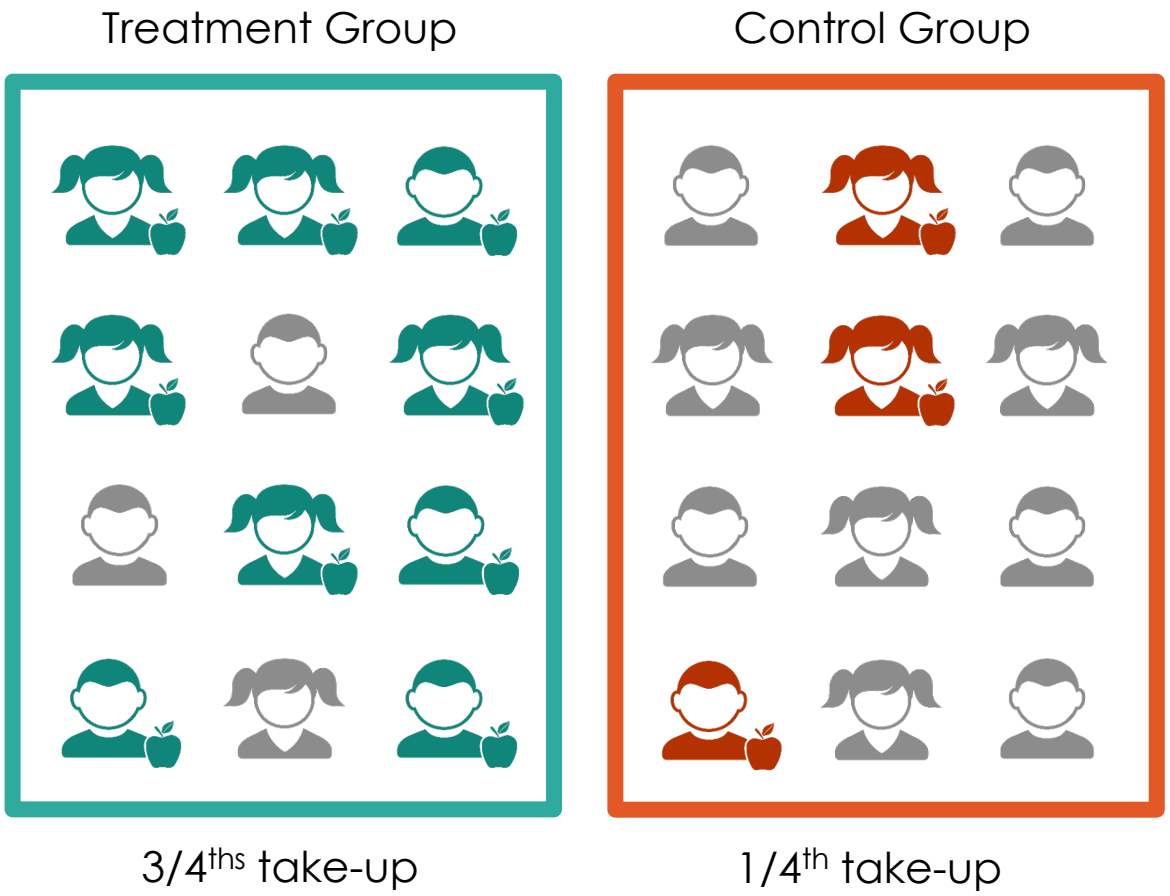
Encouragement design

Treatment Group



Control Group

Encouragement design



Eligibility cut-off or targeting criteria

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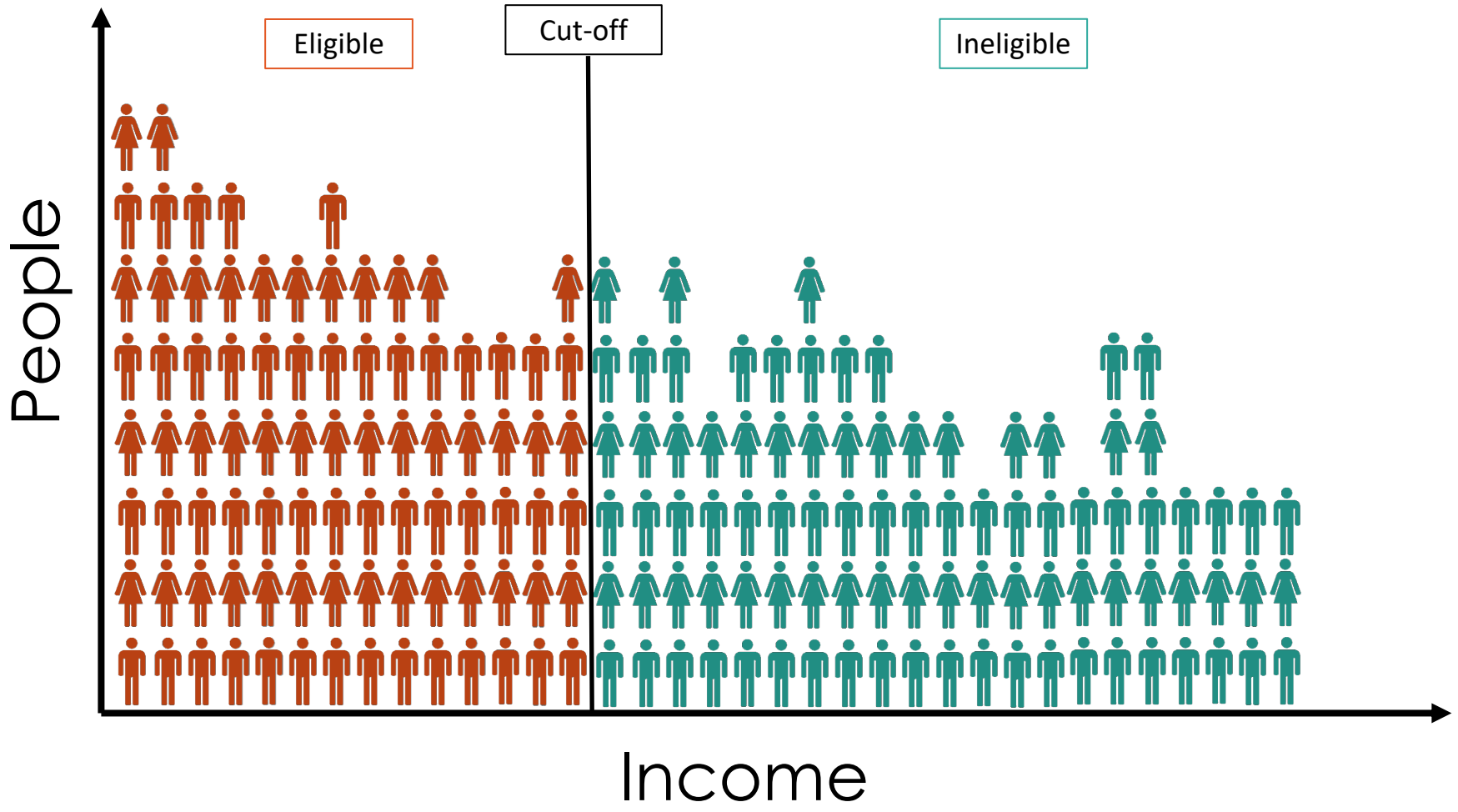
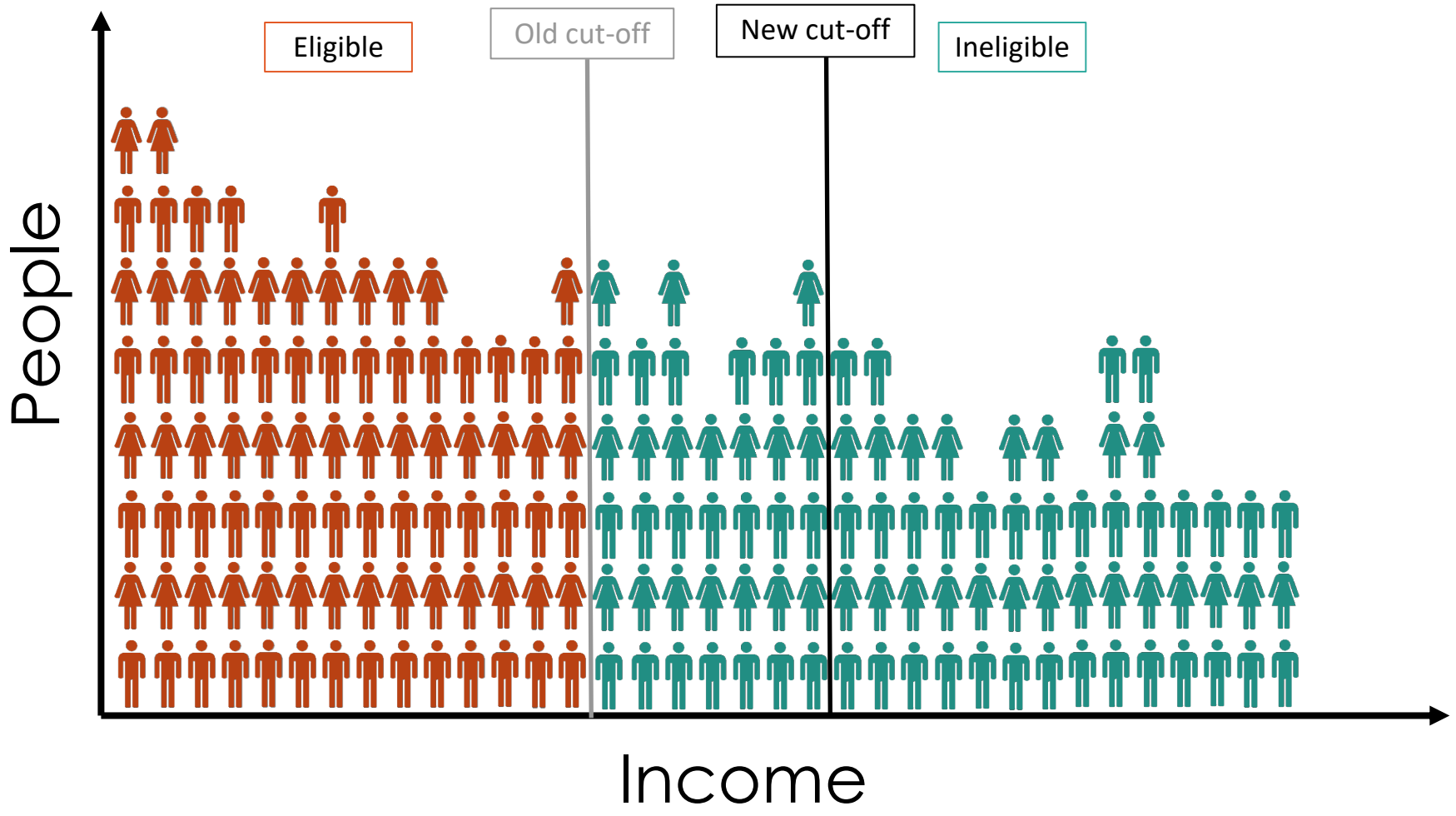


Expand eligibility and randomize among the newly eligible



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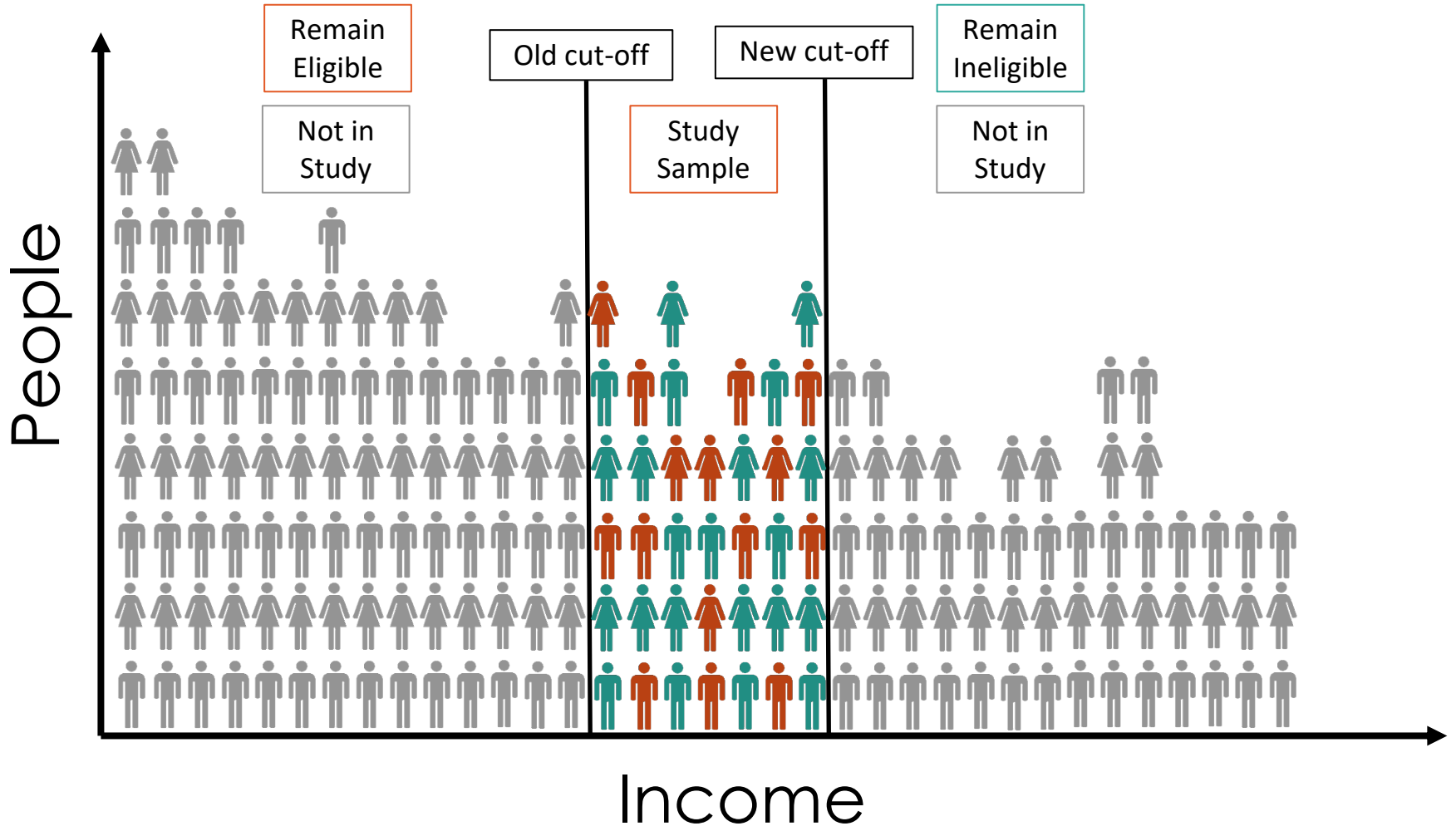

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Ethical principles for human subjects research

Justice

- Who benefits from research? Who bears its burdens?
- Fairness in the allocation of risks and benefits
- No one group should bear all the risk while another reaps all the benefits

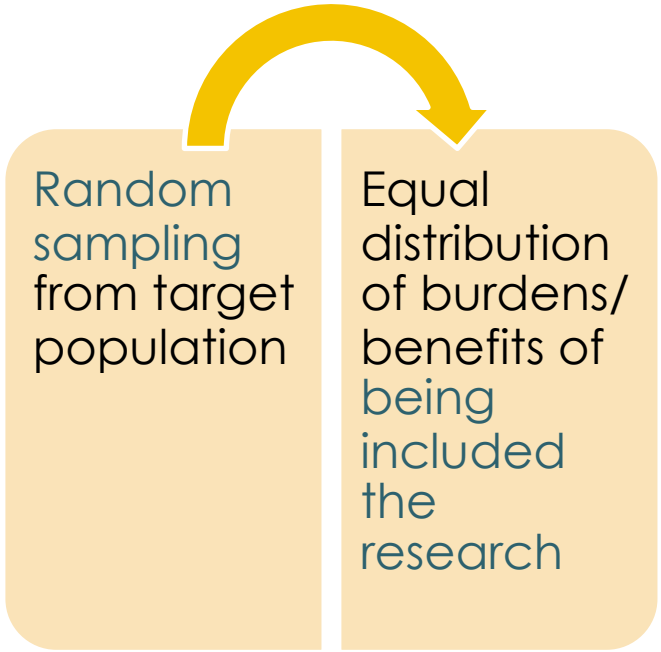
→ Will the target population benefit from subsequent applications of the research?

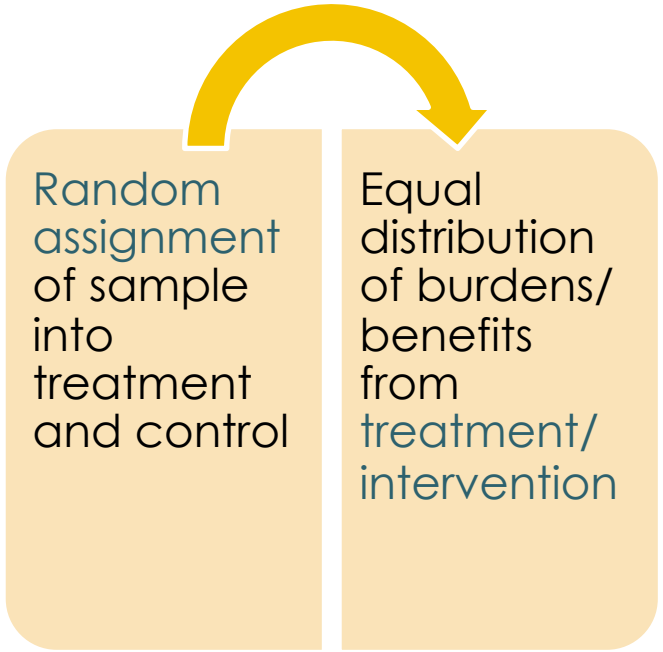
Justice in human subjects research

"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**."

Justice and randomized evaluations

Selection of the sample, subjects, and treatment recipients





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.

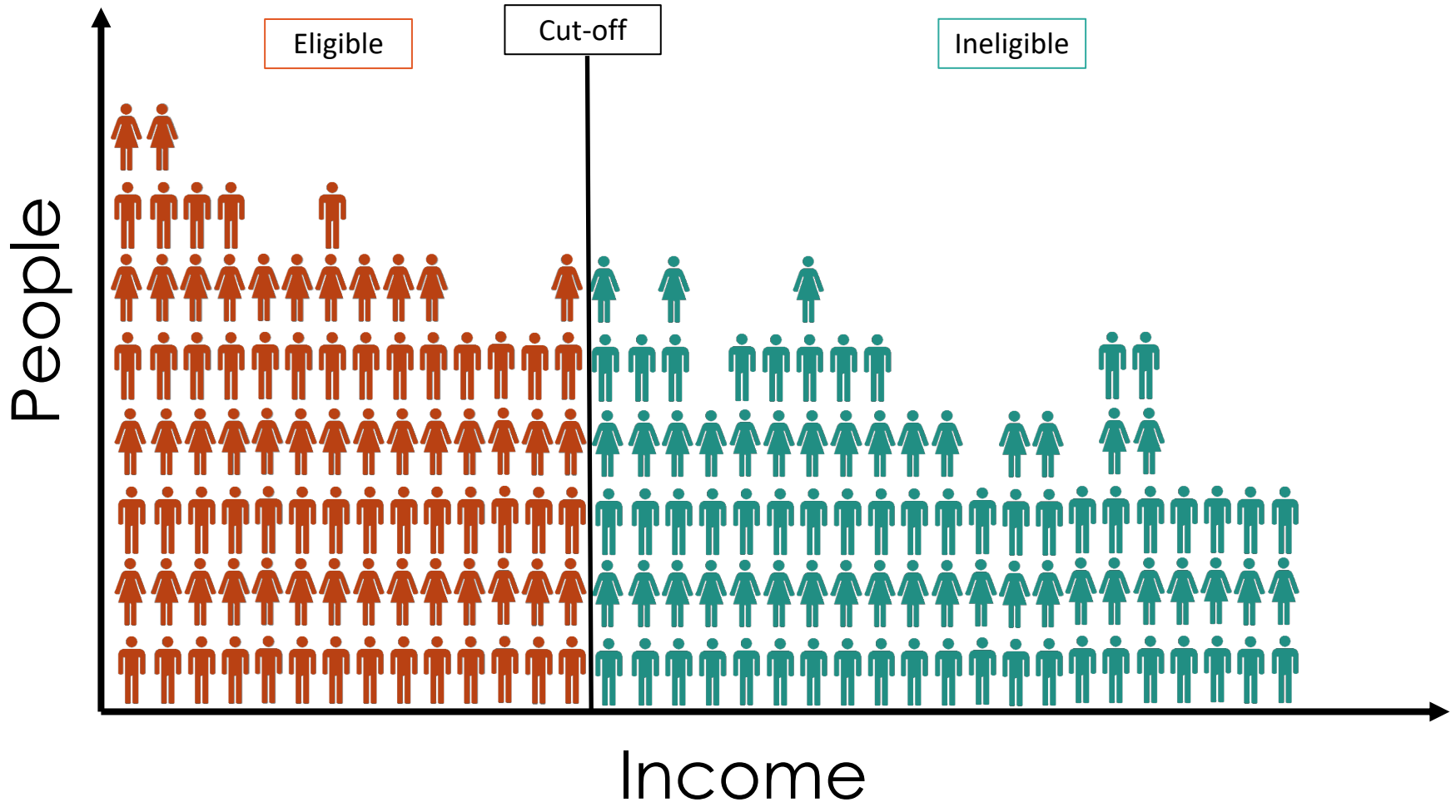
- How should we select among the eligible?
- "First-come, first-serve" may not ensure that those who are most in need would have access

What if we want to target resources to those most in need?

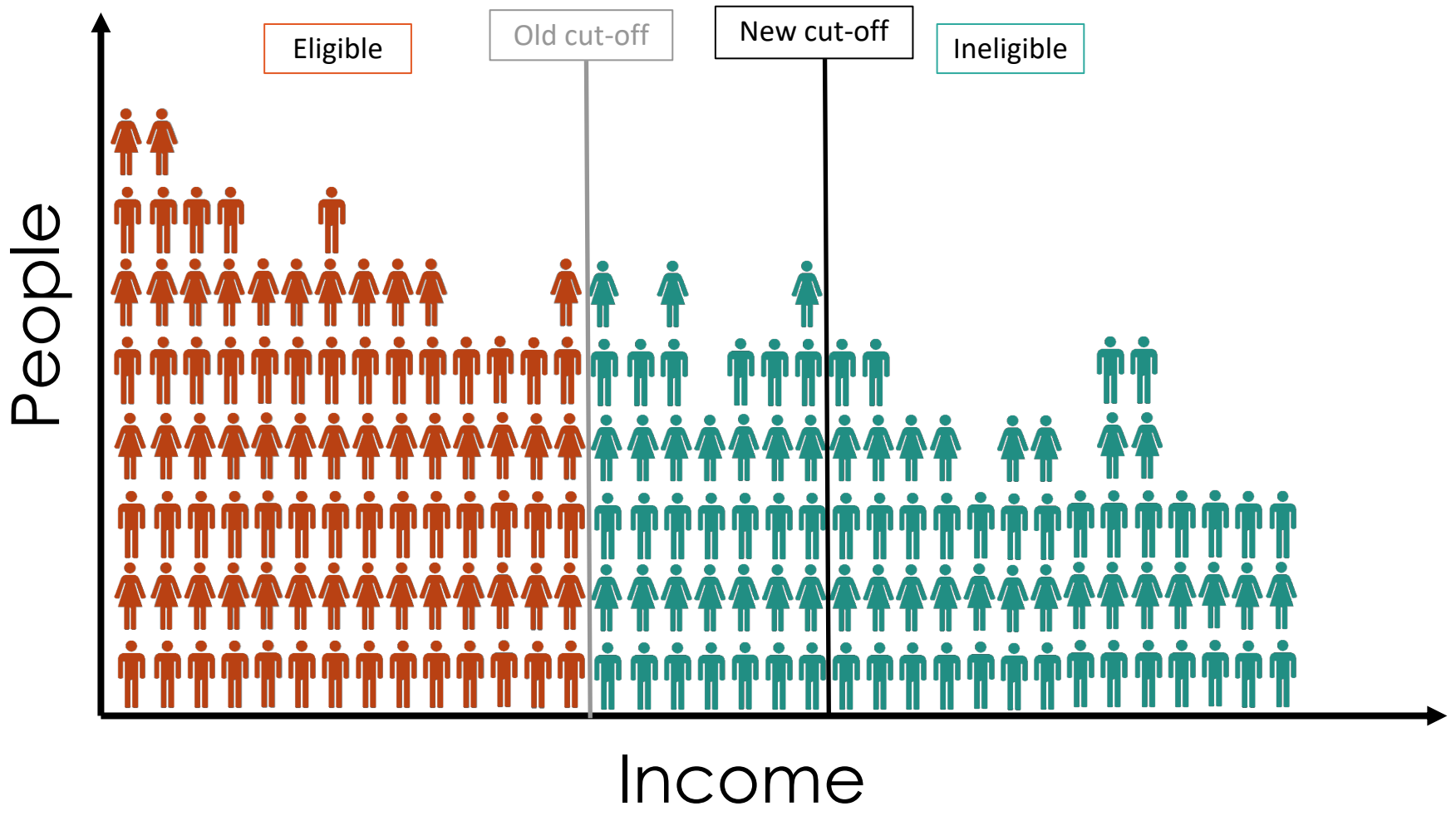
- Do we know how best to target program?
- Randomization design: create criterion for 'need,' admit everyone below some threshold and randomize everyone above.

Admit everyone below threshold, randomize above

Admit everyone below threshold, randomize above



Admit everyone below threshold, randomize above



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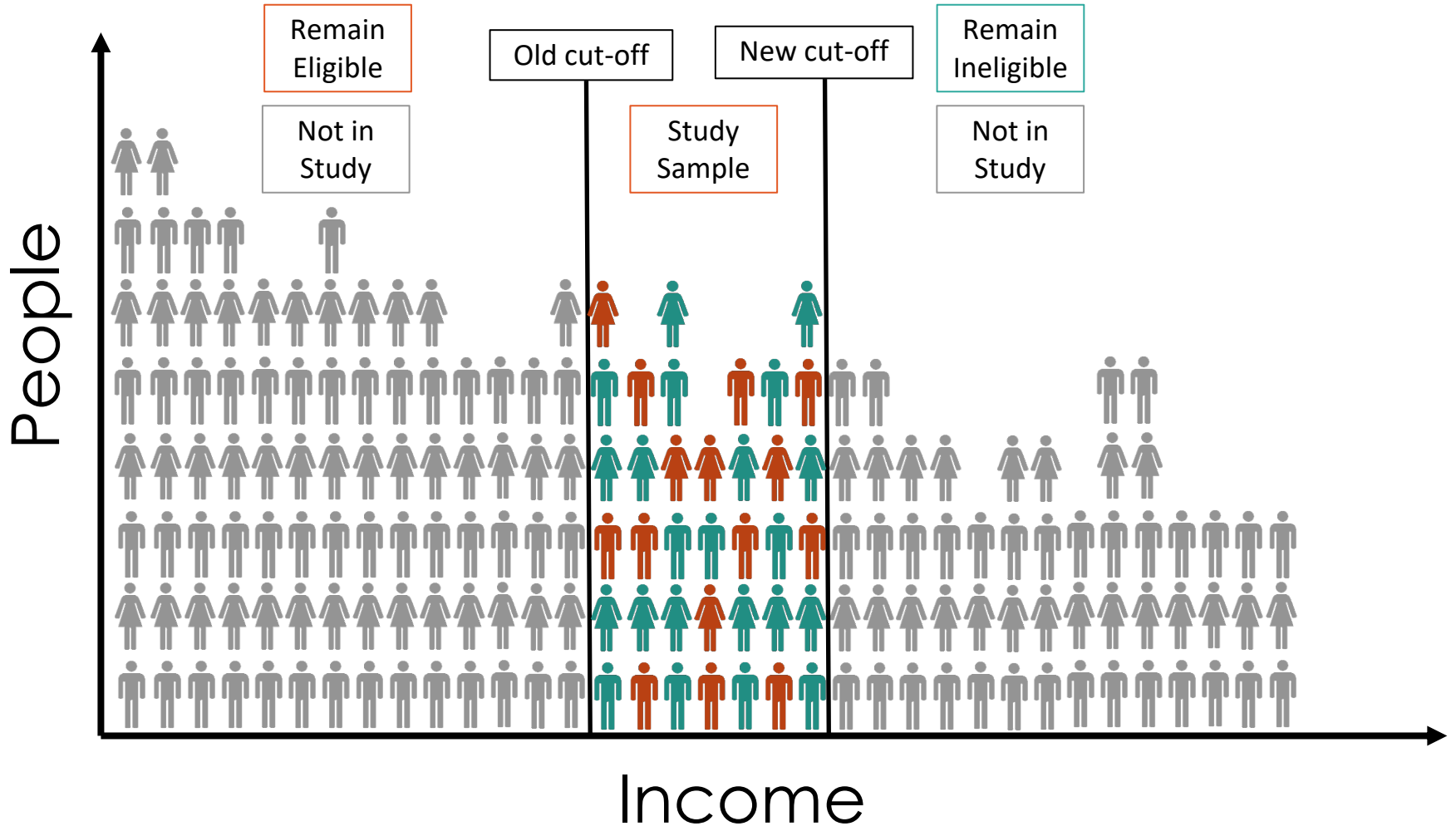

Justice and representativeness

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

FIRST OPINION

In the race for coronavirus vaccines, don't leave pregnant women behind

By CARLEIGH KRUBINER, RUTH R. FADEN, *and* RUTH A. KARRON / FEBRUARY 25, 2020

ADOBE

[Stat News article]

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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

IRBs review study protocol, risk assessment and all study-related documents

- Research objectives and purpose
- Research methods
- All materials subjects come in contact with:
  - questionnaires, recruitment flyers, apps, experimental tools, etc
- Study participants
  - Sample selection method, number of subjects
- Recruitment process and informed consent
- Assessment of risk (and justification, if applicable)
- Data confidentiality and participant privacy

Thank you! More Questions?

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 Laura Feeney with assistance from Stephanie Lin and Clare Sachsse.

Related research resources include…

- 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 ethic and principles

- Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
- The Markkula Center for Applied Ethics, Santa Clara University, specifically: https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/a-framework-for-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
- Rachel Glennerster and Shawn Powers (2016): Balancing Risk and Benefit: Ethical Tradeoffs in Running Randomized Evaluations.
- Glennerster, R. "Chapter 5 - The Practicalities of Running Randomized Evaluations: Partnerships, Measurement, Ethics, and Transparency." In Handbook of Economic Field Experiments, edited by Abhijit Vinayak Banerjee and Esther Duflo, 1:175–243. Handbook of Field Experiments. North-Holland, 2017. https://doi.org/10.1016/bs.hefe.2016.10.002.
- Macartan Humphreys (2015): Reflections on the Ethics of Social Experimentation.
- Harold Alderman, Jishnu Das and Vijayendra Rao (2013): Conducting Ethical Economic Research: Complications from the Field.
- Laura Feeney/J-PAL's resources on ethics and practicalities of informed consent: "Define intake and consent process"
- Bursztyn, Leonardo, Davide Cantoni, David Y. Yang, Naom Yuchtman, Y. Jane Zhang. (2019). "Persistent Political Engagement: Social Interactions and the Dynamics of Protest Movements." https://conference.nber.org/conf_papers/f126621.pdf
- Liu, K. A., & Mager, N. A. (2016). Women's involvement in clinical trials: historical perspective and future implications. Pharmacy practice, 14(1), 708. doi:10.18549/PharmPract.2016.01.708
- Ethics and communication: http://blogs.3ieimpact.org/not-lost-translation-ethical-research-communication-inform-decision-making/

References on prisoners as subjects

- Sarah Zhang. "Is Salt Bad? A Prison Study May Hold the Answer." Atlantic, May 17, 2018.
- Paul Christopher and Michael D. Stein (March 19 2019). "Should a Prison Salt Study be Federally Funded?" Annals of Internal Medicine.
- Allen M Hornblum (1997): They were cheap and available: prisoners as research subjects in twentieth century America.
- Common Rule regulations on research with prisoners as subjects: Subpart C, Title 45, Part 46, of the Code of Federal Regulations.
- HHS FAQs on research involving prisoners as subjects

References on compensation

- Emanuel, Ezekiel J. 2005. "Undue Inducement: Nonsense on Stilts?" *The American Journal of Bioethics* 5 (5): 9–13. https://doi.org/10.1080/15265160500244959
- **Discussion of compensation vs "undue influence" with useful bibliography:** Largent, Emily, and Holly Fernandez Lynch. 2017. "Paying Research Participants: The Outsized Influence of 'Undue Influence.'" Volume: 39, Issue: 4. The Hastings Center. https://www.thehastingscenter.org/irb_article/paying-research-participants-outsized-influence-undue-influence/
- Research Ethics Policy and Advisory Committee, University of Toronto. 2011. "Guidelines for Compensation and Reimbursement of Research Participants." http://www.research.utoronto.ca/wp-content/uploads/2010/01/Guidelines-for-Compensation-and-Reimbursement-of-Research-Participants-Approved-Feb-16-11.pdf
- U.S. Food and Drug Administration. Updated 7 Jul. 2018. "Payment and Reimbursement to Research Subjects - Information Sheet." https://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm
- Metropolitan State University of Denver. Accessed 1 Feb. 2019. "IRB Guidance on Compensation to Research Subjects." https://msudenver.edu/irb/guidance/compensationtosubjects/
- Committee for Protection of Human Subjects, University of California, Berkeley. 2017. "Compensation of Research Subjects." https://cphs.berkeley.edu/compensation.pdf