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. Randomized Evaluation from Start to Finish
7. Threats & Analysis
8. Ethical Considerations
9. Applying & Generalizing Evidence

Learning objectives

1. Share a **guiding framework** for **ethical principles** in research

1. Discuss pertinent **ethical questions** and the **application** of these principles in practice

1. Understand the linkages between **ethical integrity** and **research quality**

Feedback & discussion

What ethical questions **do you have** or **have you faced** regarding human subject research?

I. Ethics principles
II. Case study: Nurse-Family Partnership
III. Ethical considerations in practice
IV. Ethical integrity & research quality

I. **Ethics principles**

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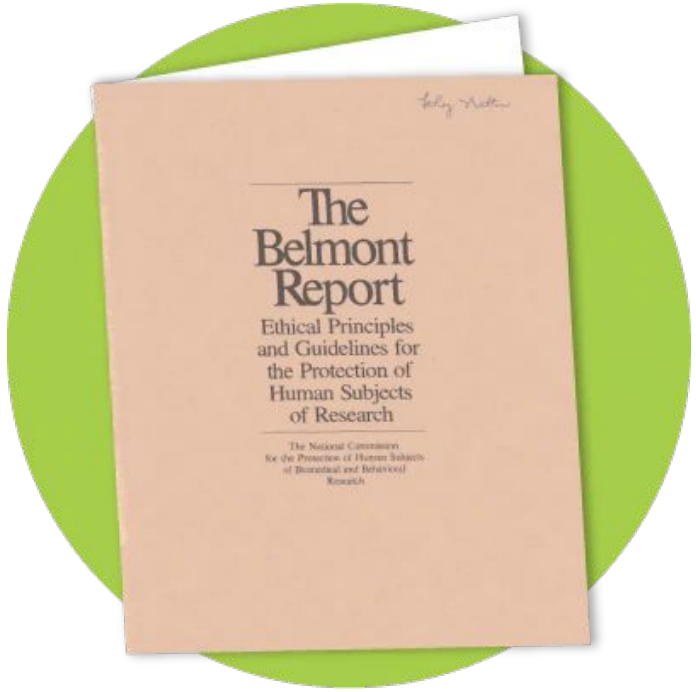
Belmont principles

ESP WORKBOOK

"The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (1978)

- Commissioned by the US government, prompted by the atrocities committed in the The Untreated Syphilis Study
- Principles are broadly applicable and build on prior international agreements
- Lays out three key ethical pillars:

  Respect for Persons, Beneficence, and Justice



Source: U.S. Department of Health and Human Services

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

Belmont principles

Respect for Persons

Beneficence

Justice

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

Respect for persons

- Individuals are **autonomous agents capable of making their own decisions**
- This requires that we seek **informed consent** for their participation in research

- Persons with **diminished autonomy** are entitled to **additional protection**
  - Consider **children**, **people in prison**, and **individuals with cognitive impairments**

Applying respect for persons in practice

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

- Individuals may be overly optimistic about potential benefits
- Recognize power dynamics between study team and study population

Logistics of documenting consent

- Are people familiar with or accustomed to signing forms?
- Different processes may be more protective (i.e. verbal consent)

Appropriate level of compensation

- High enough to offset the time and inconvenience of participation
- Not so high that it might undermine one's feeling of autonomy

Feedback & discussion

What might be a scenario where written consent is not appropriate?
How would you still uphold the respect for persons principle?

Belmont principles

Respect for Persons

Beneficence

Justice

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

Beneficence

"Do no harm"

- Do not administer a treatment that is **known to be harmful**
- Do not **withhold** a known benefit that would otherwise be available

Minimize risks	Maximize benefits
Potential adverse effects of the intervention and privacy violations **Psychological burden** of responding to (and administering) surveys Physical and safety **risks to staff**	**Knowledge gains** to society from learning what works Findings that are **credible** and **actionable** to inform policy decisions

Applying beneficence in practice

Protecting participants

- Consider the **time required** to participate
- Are you engaging **more people than necessary** to ensure your study is sufficiently powered?
- Would the **knowledge** that someone is **involved in the study** put them at risk?

Weighing risks and benefits

- **Plan in advance** to mitigate risks before they materialize
- **Challenging in practice** given genuine uncertainty about an intervention's benefit (and risks)

Feedback & discussion

What are some potential risks that might arise in this study context?
Potential learnings of the study?

Source: The Collegian student newspaper

Belmont principles

Respect for Persons

Beneficence

Justice

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

Justice

Justice requires fairness in the allocation of risks and benefits

- No one group should bear all the risk while another reaps all the benefits
- The study population should represent the population experiencing the challenge **and** the population that stands to benefit

Pregnant People's Paradox—Excluded From Vaccine Trials Despite Having a Higher Risk of COVID-19 Complications

Rita Rubin, MA

JAMA. 2021;325(11):1027-1028. doi:10.1001/jama.2021.2264

Article from Journal of the American Medical Association

"*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*

Applying justice in practice

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

- Balance between inclusion to ensure research is representative while putting appropriate protections in place

Is the study sample representative?

- Ease and convenience is not a valid justification for sample selection
- Important to consider heterogeneous effects
- Random sampling and assignment can be a way to eliminate some types of bias but won't address how the target population is selected

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Case Study

Impact evaluation of the Nurse-Family Partnership (NFP) program in South Carolina, USA

Randomized Evaluation of the Nurse Family Partnership in South Carolina evaluation summary

Intervention: Intensive nurse home visiting program

The Nurse-Family Partnership (NFP) aims to improve **maternal and neonatal health outcomes** for families with low incomes by providing **regular home visits** from early pregnancy through a child's 2nd birthday

Program eligibility:

- First-time birth mothers
- Less than 28 weeks pregnant at enrollment
- Eligible for Medicaid based on income

Implemented in South Carolina, US before and during the Covid-19 pandemic:

- Mothers enrolled between **2016** to **2020**
- Follow-up through **2021**

Source: Nurse Family Partnership

Evaluating impact on prenatal and birth outcomes

On-the-spot randomization of **5,670 individuals** at a **2:1** treatment to control ratio

- **Treatment group**: Offered NFP services
- **Comparison group**: Received standard of care and information on additional resources

Source: Social Finance

NFP staff and nurses conducted:

- Study enrollment
- Baseline survey
- Randomization

Administrative data from several sources to assess prenatal and birth outcomes

NFP's approach to respect for persons

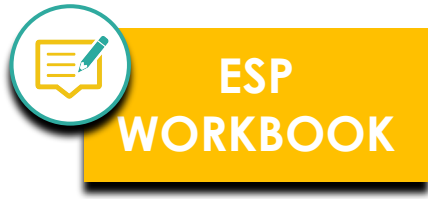
Consent process

- Nurses managed **informed consent**
  - Received training on ethics and informed consent process
- Consent form designed as an **FAQ**
  - Used concise, clear, and simple language
- Documentation through **electronic signatures**

Considerations

- Ensuring **comprehension** and **voluntariness**
- Restricted sample to persons over 14 years of age for whom consent could meaningful be obtained

NFP's approach to beneficence



Potential harms to participants

- Risk of **unintentional disclosure** of sensitive medical data
  - Extensive procedures to ensure data safety (separate server for study data)
- Time spent on research activities
  - Outcomes followed only in **administrative records**

Benefits from new knowledge gained

- **Changing context:** Mothers face different socioeconomic and public health conditions than 20 years ago when initial studies took place
- **Comprehensive life impacts**: Looks at linked outcomes on long time horizon
- **Expanded scale**: Includes broader population of Medicaid-eligible people

Beneficence for program and research staff

Concern about burden on nurses

- **Time burden** of study protocols and fatigue over the long enrollment period
- **Emotional burden** of communicating random assignment to the control group

Source: Social Finance

Ensuring the safety and protection of research staff

- Enforce and emphasize the importance of safety and security protocols
- Ensure staff receive appropriate training and can access support if needed

NFP's approach to justice

Special attention given to socially vulnerable groups

- NFP staff were encouraged to enroll people from **low income ZIP codes**
- Services were provided in **multiple languages** through bilingual nurses and translation services
- Analyzed impacts for **subgroups** that were considered socially vulnerable and for non-Hispanic black mothers
- Compared the control group to **similar people outside of the study** to understand whether the sample was representative of low-income new mothers in South Carolina

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Respect for societies

- Evaluations could affect local and large-scale **societal outcomes**
  - Those not part of sample but indirectly influenced **can't consent**

→ **Respect for societies holds that researchers are still ethically obligated to respect their rights and welfare**

- Consider the **tradeoff** between expected outcomes for individuals and for larger groups
- Consider how to **share results** with the communities involved in research
- **NFP study**: The research team made sure to support partner agencies and their community partners to explain the study and inform about study procedures

Potential for unintended consequences

- Some interventions may pose **unanticipated risks** beyond the outcomes of interest

> *Example*: A **conditional cash transfer program in Mexico** targeting women that aimed to promote child welfare also led to **increased incidences of domestic violence** for a subgroup of women who received large transfers

- It is **up to the research team** to decide how to **evaluate the probability and magnitude of risk** that an intervention may induce
  - It's important to establish protocols for addressing these issues and to communicate possible risks with participants

Feedback & discussion

What information do we need to evaluate the probability and magnitude of risk? Who should be responsible for this?

Beneficence and equipoise

Clinical equipoise: Genuine uncertainty within the expert community about the preferred treatment

Policy equipoise: Is there genuine uncertainty about treatment benefits versus the best policy alternative?

- Are participants in any treatment arm **predicted to be worse off** than they would be under the **counterfactual policy**?

Always look at **existing evidence (or lack thereof)**

- **NFP study**: Evidence gaps from past studies with policy implications in South Carolina for new mothers with low incomes

Feedback & discussion

What do we **owe to the comparison** group?

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

Beneficence and the comparison group

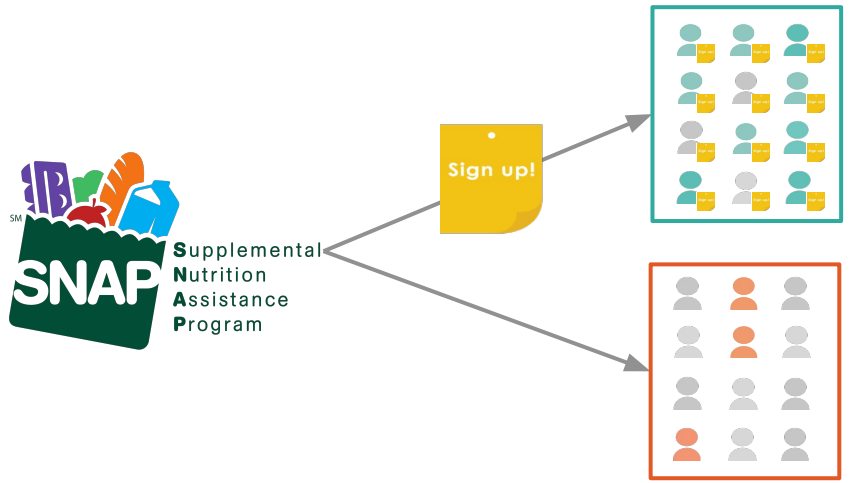
The comparison group is not offered the intervention offered to the treatment group. That does not mean they are denied services otherwise due.

- **Standard of care:** Comparison group receives already **available care**
  - **NFP study**: Comparison group received standard of care and information on additional resources

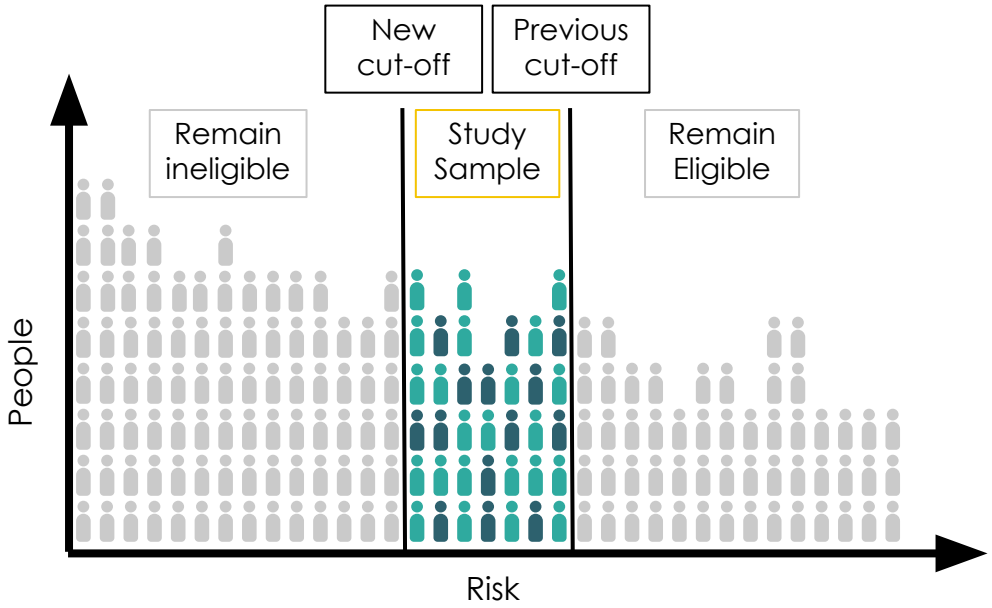
- If there are concerns about control group access to treatments, randomized evaluations can be designed in innovative ways!

Beneficence and the comparison group

Encouragement design: Maintains access to the existing program while encouraging take-up in treatment group



Expand eligibility: Maintains access for previously eligible individuals while introducing randomization among an expanded newly eligible group



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Ethical oversight

- Many countries, institutions, and funders require human subjects research to be overseen by an **independent body** that protects the rights and welfare of subjects
- Institutional Review Boards (IRBs) and Research Ethics Committees (RECs) operate within a **limited mandate**
  - Do not have scope to review "practice" in absence of research
  - Can only review based on the information provided
- **Researchers have primary responsibility** for ensuring an ethical study

→ don't outsource your ethics ←

What does the IRB NOT review?

- Policies that "**would have happened anyway**"
- Potential harm to **non-participants**
- Broader concerns around who is targeted for **inclusion**, **power** to detect heterogeneous treatment effects, etc.
- Potential **misuse of results**
- **Reputational risk**
- **Intellectual freedom** of researchers
- **Actual implementation** of protocols to protect participants

Massachusetts Institute of Technology
Committee on the Use of
Humans as Experimental Subjects
COUHES

COUHES Protocol #

APPLICATION FOR COMPREHENSIVE REVIEW

Please complete all questions and provide sufficient detail. Indicate 'N/A' if a question does not pertain to your research. An incomplete application will be rejected and returned for completion.

I. BASIC INFORMATION

1. Title of Study

2. Principal Investigator

Name:	Building and Room #:
Title:	Email:
Department:	Phone:

3. Funding

If the research is funded by an outside sponsor, please enclose one copy of the research proposal with your application. A draft of the research proposal is acceptable.

Do not leave this section blank. If your project is not funded, check No Funding in section C.

A. Sponsored Project Funding:

☐ Current Proposal Grant/Proposal # _____
Sponsor _____
Title _____

☐ Current Award Grant/Account # _____
Sponsor _____
Title _____

B. Institutional Funding:

☐ Gift ☐ Departmental Resources
☐ Other (explain) _____

C. No Funding

☐ This protocol will not be funded

4. Statement of Financial Interest

A. Does the investigator, study personnel, or their Family have a financial interest in a company or other organization involved in this study?
☐ Yes ☐ No

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Version 03/02/2021

Source: MIT COUHES Application for Comprehensive Review

Research ethics and research quality

IRB review cannot substitute for researchers' responsibility to consider the ethical implications of their research.

- Think carefully through the research design to **anticipate and understand** how participants will feel about the research
  - For policymakers, a thorough understanding of the research design is essential in effectively **advocating for communities** involved in the research
- Ask study participants as well as members of their broader communities if they are **comfortable with the research protocols**
- Following principles of **ethical** research in study procedures and implementation can lead to more **credible** research

More open discourse on ethical norms and challenges

Some researchers are calling for ethics appendices to enhance transparency and communication around ethical challenges (Asiedu et al.)

Topics to consider include:

- Policy equipoise and the counterfactual policy
- Role of researchers with respect to implementation
- Potential harms to participants and nonparticipants
- Financial and reputational conflicts of interest
- Feedback to participants or communities
- Foreseeable misuse of results

SPECIAL FEATURE: PERSPECTIVE

A call for structured ethics appendices in social science papers

Edward Asiedu[a], Dean Karlan[b,1], Monica Lambon-Quayefio[c], and Christopher Udry[d]

Edited by Paul J. Ferraro, Carey Business School and Department of Environmental Health and Engineering, Johns Hopkins University, Baltimore, MD, and accepted by Editorial Board Member Arun Agrawal June 2, 2021 (received for review January 22, 2021)

Ethics in social science experimentation and data collection are often discussed but rarely articulated in writing as part of research outputs. Although papers typically reference human subjects research approvals from relevant institutional review boards, most recognize that such boards do not carry out comprehensive ethical assessments. We propose a structured ethics appendix to provide details on the following: policy equipoise, role of the researcher, potential harms to participants and nonparticipants, conflicts of interest, intellectual freedom, feedback to participants, and foreseeable misuse of research results. We discuss each of these and some of the norms and challenging situations of each. We believe that discussing such issues explicitly in appendices of papers, even if briefly, will serve two purposes: more complete communication of ethics can improve discussions of papers and can clarify and improve the norms themselves.

ethics | randomized controlled trials | primary data collection | surveys | methodology

Social science researchers engaged in primary data collection often consider a range of ethical issues during planning but rarely discuss them in published articles. We believe that building explicit steps for considering and discussing ethical issues can lead to better research and better communications about research, and thus better impact of research as well. We propose a structured appendix to accompany social science papers that report on primary data collection efforts.

We believe that Sen's (1) capability approach provides a useful framework to inform a structured appendix, as it focuses on people's opportunities to set and achieve activities and goals for themselves. This framework, along with Rawls (2), is familiar to most social scientists and applies to both participants and affected nonparticipants. We acknowledge the diversity of life goals across people, but there is a higher-order common requirement to have the capabilities to set and pursue those goals. Ethical research should be designed to generate socially valuable information to advance these basic capabilities, while protecting the basic interests of participants. This requires research protocols not only be procedurally ethical as per international research standards but also ethical after considering specific contextual factors such as cultural, gender, and local institutional norms. London (3) starts from a principle of equal concern, that every participant is the moral equal of all members in the community, and derives several operational criteria that serve as guideposts for this paper and proposal. These include the avoidance of unnecessary risk, special concern for the basic interests of participants, and "social consistency." The latter requires that the sum of incremental risks to participants, minus their direct benefits (call this the net risk), must not be greater than the net risks faced by those in other socially sanctioned activities, like emergency workers. London (3) acknowledges that this calculation is difficult, but "the moral goal of such judgements is clear—the point is to ensure that there is a publicly available justification for the claim that each study participant is treated as the moral equal of every other participant . . . and of the community members in whose name research is conducted." These criteria motivate our proposal that authors include a structured ethics appendix in working

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This article contains supporting information online at https://www.pnas.org/lookup/suppl/doi:10.1073/pnas.2024570118/-/DCSupplemental.
Published July 12, 2021.

Asiedu, Edward, Dean Karlan, Monica Lambon-Quayefio and Christopher Udry. 2021. "A Call for Structured Ethics Appendices in Social Science Papers,"

To think about...

Did we address your questions and concerns coming into the lecture, and what are you still left contemplating?

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

References

Conducting ethical research

- The Belmont Report (1979)
- "A Framework for Ethical Decision Making" (Markkula Center for Applied Ethics 2015)
- "The Capability Approach" (Stanford Encyclopedia of Philosophy 2020)
- "Balancing Risk and Benefit: Ethical Tradeoffs in Running Randomized Evaluations" (Glennerster and Powers 2016)
- "The Practicalities of Running Randomized Evaluations" (Glennerster 2017)
- "How to make field experiments more ethical" (Humphreys 2014)
- "Reflections on the Ethics of Social Experimentation" (Humphreys 2015)
- "Government Policy Experiments and the Ethics of Randomization" (MacKay 2020)
- "How should we understand 'clinical equipoise' when doing RCTs in development" (McKenzie 2013)

Communicating about ethics

- "Reporting requirements for ethical considerations in economics RCTs" (Özler 2019)
- "A call for structured ethics appendices in social science papers" (Asiedu et al. 2021)

References

J-PAL Research Resources

- Ethical conduct of randomized evaluations
- Institutional Review Board (IRB) proposals
- Define intake and consent process
- Data security procedures for researchers

Ethical considerations in practice

- "Conducting Ethical Economic Research: Complications from the Field" (Alderman, Das, and Rao 2013)
- "From principles to practice: Methods to increase the transparency of research ethics in violent contexts" (Baron and Young 2021)
- "Practical Suggestions for More Ethical Social Science RCTs" (Evans 2021)
- "Do no harm? Field research in the Global South: Ethical challenges faced by research staff" (Kaplan et al. 2020)
- "Women's involvement in clinical trials: historical perspective and future implications" (Liu and Mager 2016)
- "Not lost in translation: Ethical research communication to inform decision making" (Rao 2018)

Reuse and citation

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