Research Transparency and Ethics

THE WORLD BANK

SIEF
Strategic Impact Evaluation Fund
Agenda

Part I
- Are randomized evaluations ethical?

Part II
- Ethical treatment of Human Subjects

Part III
- Transparency in data analysis and research
Are randomized impact evaluations ethical?
We live in a world with limited resources

As a result programs often do not reach all beneficiaries at once

Programs are often phased-in to efficiently allocated limited resources
## Ethical considerations in impact evaluations

<table>
<thead>
<tr>
<th>Phase-in design</th>
<th>Randomized phase-in design</th>
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- **Phase I**
- **Phase II**
- **Phase III**

### Color Coding:
- **Green**: Phase I
- **Orange**: Phase II
- **Blue**: Phase III
Ethical treatment

• Evaluations should not dictate how benefits are assigned, but instead evaluations should be fitted in program assignment rules

  • Example: In a program that will be phased in over time, rollout can be done by randomly selecting the order in which equally deserving beneficiaries will receive the program

• From an ethical standpoint, all subjects that are equally eligible to participate in any type of social program should have the same chance of receiving the program
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Equal chance of treatment

• Can be obtained by a lottery (randomization)

• However, the process needs to be:

1. Fair
2. Simple
3. Transparent
Experimental Methods II

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Basic principles of research with human subjects

• In the US, basic principles set out in the Belmont Report, 1978.
  • Issued by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

• Provides the basis for decisions about the ethics of research funded by most federal departments or agencies

• Formulated in the US, but principles are reasonably general and are similar to the principles behind institutional review structures around the world
1. Respect for persons

• People should be treated as autonomous agents
  • Giving deference to a person’s judgement
  • Ensuring that the person is free to choose without interference

• Also recognizes that some individuals may not have full autonomy, such as children or prisoners, and research with these subjects need special precautions

• Two important mechanism for preserving respect and autonomy
  • Seek **free, informed** and **ongoing** consent
  • Protect **confidentiality of information**
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2. Welfare of others (Beneficence)

- Consideration of all aspects of subjects’ well-being
  - Physical, mental and spiritual health
  - Physical, economic and social circumstances

- Researchers should seek to maximize the benefits and minimize the risks to subjects from research
  - Should also avoid knowingly doing harm

- However, avoiding all risk of harm is unrealistic and would prevent the gains to society that come from research
  - Therefore, risk of harm needs to be weighed against likely benefits to society that could flow from the research
3. Justice

• Focuses on the distribution of costs and benefits of research

• Seeks to avoid a situation where one group of people bears the risks associated with research while another group receives the benefits
  • For example the poor, or prisoners bear the risks but the rich and non-prisoners receive the benefits

• Recognizes that the individuals who take on the risks of research may not be precisely those who reap the benefits
  • Instead it aims to ensure that research is conducted amongst the types of people who will benefit from it
Informed consent: Free, Informed, and Ongoing

Basic elements

1. General information about the study and the researchers
2. Purpose of the study
3. Information about study participants (subjects)
4. Information about study participation
5. Information about risks and benefits
6. Other options
7. Ending the study
8. Financial information
Confidentiality of information

How the data are handled?
Institutional Review Boards (IRBs)

Review boards or ethics committees regulate research involving human subjects

- Assess, approve, and monitor research studies
- With the primary goals of protecting the rights and promoting the welfare of all subjects
Institutional Review Boards (IRBs)

The basic principles of the U.S. law pertaining to the protection of human subjects are based on the historic Belmont Report and include ensuring that:

- Selection of subjects is equitable
- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Informed consent is sought from each prospective subject or his/her legal representative
- Adequate provisions are in place to protect the privacy of subjects and maintain confidentiality
- Additional safeguards are included to protect more vulnerable subjects such as children, prisoners, and the economically disadvantaged
Question

For an impact evaluation you are doing, you plan to do telephone surveys instead of in-person surveys. Do you still need informed consent?
Experimental Methods II

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You are an editor of a journal and you get two submissions…

1. We present results from a randomized evaluation of a nutrition program. We randomized a 5-day training about childhood nutrition supplemented with a monetary grant to a large representative sample of the population in rural Nepal. We measure impacts after two months, one year, and three year of the intervention. **Our results show that there were no short- or long-term gains from the nutrition program.**

2. We present results from a randomized evaluation of a nutrition program. We randomized a 5-day training about childhood nutrition supplemented with a monetary grant to a large representative sample of the population in rural Nepal. We measure impacts after two months, one year, and three year of the intervention. **Our results show that two months and one year after the program children in the treatment were less likely to be malnourished.** The impact after three years is also positive, but it is smaller and not statistically significant.
We evaluate a large scale teacher training program – more than 100,000 teachers. The overall program had no statistically significant impact on teacher motivation and student learning. However, when we look at the subsample of teachers who are male, bald, wear glasses and between ages of 30-45, we find that there is a large treatment impact.
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P-hacking and Publication bias

- P-hacking
- Publication bias
How to overcome issues of $p$-hacking and publication bias

- Power and sample size
- Trial registry
- Pre-analysis plans
- Statistical methods
  - Corrections for multiple hypothesis testing