The Ethics of Policy RCTs: The Need for a Field

Douglas MacKay, PhD, Associate Professor, Department of Public Policy
Core Faculty Member, Philosophy, Politics, and Economics Program
Core Faculty Member, Center for Bioethics
University of North Carolina at Chapel Hill
Policy RCTs and Ethics

- Policy RCTs pose numerous, complicated ethical challenges for policymakers and investigators.

- But significant lack of concepts and principles to address them and limited sustained discussion – e.g. a literature.

- Contrast with Clinical Research Ethics is stark.
Policy Research Ethics as a *Field of Research*

- A shared and inclusive intellectual space for the discussion of ethical challenges posed by policy research and possible solutions.
  - Scholarly journals, edited volumes, blogs, conferences, and workshops as venues.
  - Understanding of research ethics as a sphere of intellectual inquiry, not merely a space for uncritical application of norms and codes.
  - Development of shared – but contested – set of concepts and principles to organize debate and discussion.
Informed Consent


• Broader Question: When is informed consent necessary for ethical policy research?

• Puzzle: Informed consent in clinical research is necessary since researchers have no authority over what participants put in their bodies…but governments do have authority over policy (MacKay and Chakrabarti 2019).
Social Value

• Social Value: Human subjects research is costly and exposes participants to risk. To be permissible, it must be sufficiently valuable to society.

• Broader Question: How should we understand the principle of “social value” in policy experimentation? Do policy RCTs satisfy this principle?

• Challenges:
  • Generalizability/External Validity: Will the results of a well-designed RCT apply elsewhere? (Deaton and Cartwright 2018).
  • Knowledge Gaps: Is the knowledge produced by RCTs useful for policymakers? (Ravallion 2020).
  • The “whims” of political actors.
“Standard of Care”

• Standard of Care: The level of medical care to which patients are entitled, and which clinical research participants ought to be guaranteed.

• Broader Question: What is the “standard of care” for participants in policy RCTs? What are the criteria for identifying the interventions to which people are entitled?

Randomization and Distributive Justice

• Random assignment is desirable for epistemic reasons but is also a way of allocating access to an intervention.

• Broader Question: When is it permissible to allocate access to an intervention by means of a lottery (MacKay 2020)?
  • Equipoise?
  • Fair allocation of a scarce benefit?

• Challenge: Conditions when lottery is fair may be quite limited.
Community Engagement

• Concerns regarding:
  • Well-funded international organizations bypassing local governments.
  • Lack of buy-in and understanding regarding use of randomization.

• Broader Question: Is “community engagement” a necessary condition of ethical policy research? What are the appropriate roles for international organizations, local governments, and communities in identifying research questions and research design?
Summing Up

- Policy research raises a number of ethical challenges and sustained, systematic ethical reflection is necessary to address them.

- Current Initiative: *Oxford Handbook of Research Ethics* (edited by Ana Iltis and Douglas MacKay)

- Would love to hear perspectives of practitioners and think tankers – what am I missing?