Research in Developing Countries

Ethics: Bioethics (Fall 2014)

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Normative Enterprise: Clinical Research

- **Norms that do not fit**
  - Therapeutic practice
  - Marketplace

- **Investigational stance:** "responsibilities investigators and designers have toward those who participate in their studies" (Carse & Little)
  - **Differential between investigational stance & therapeutic stance**
    - Justifying studying, rather than treating

Normative Enterprise: Clinical Research

- **Public Health norms, aims** (need not be based in strict utilitarian)

- **Constraints on**
  - What benefits investigators can justifiably accrue
  - Using subjects for greater good, social utility
  - What community or individuals can justifiable undertake/accept

- **Worries about exploitation**
  - Taking unfair advantage of another's vulnerability
  - Taking advantage of vulnerabilities that one is charged to alleviate (in the name of public health norms)

Dignitary-Based Concerns

- **What does 'dignity' mean? How might it be used and interpreted differently?**
  - E.g., dignity of disability community, medical profession, Terri Schiavo, fetus, sex worker subjects in Guatemala

- **Matter of *not using someone as a mere means***
  - "your medical need may not be seen exclusively through the lens of its usefulness to my investigation" (C&L)
  - Researchers "must also indicate appreciation of the meaning those [health] needs carry for you" (ibid.)

Core Protections

1. Informed consent (positive & negative obligations)
2. Minimal risk, relative to importance of knowledge to be gained
3. Scientific validity
4. Equipoise
5. Minima of standard of care

Going Beyond Core Protections

- **Attending to current and emergent vulnerabilities**
  - In virtue of researcher-subject relationship
  - In virtue of other contextual factors
    - Those that exist before researcher arrives & those that arise in course of research
- **Justificatory burden**
  - Minimize burdens
  - Soften differential b/w IS & TS
  - Diminish “on behalf of others” proportion

How To

A. **Morally preferable:** Use world's best standard of care, inc. for control arm

B. **Next option, when can't do (A)**
   - Participants will likely (based on real, on-the-ground conditions) benefit from research
   - Will likely and sufficiently benefit those who are relevantly like subjects

Up Top: Research Approval

- Whether subjects will benefit based on actual affordability and accessibility – needs to be considered *before* research is approved

- "so that limited research funds are not wasted, and research subjects are not drawn from populations that will not be able to benefit from the research" (Glantz et al.)

Discussion Questions

- Do you think the criteria offered by these bioethicists are too stringent, too lax, or just right?
- How can researchers avoid complicity in injustices when conducting research based on less-than-ideal conditions?
- Is the recommendation made by Glantz et al. morally obligatory of IRBs and funding agencies?

Questions? Comments?