Ethical Considerations in Research Involving Children

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A May 17, 2012 Talk for the Presidential Commission for the Study of Bioethical Issues
What’s at stake

- Human research involves *using* human subjects.
- Often *imposes risks* on subjects.
- Much of the justification: PROSPECT FOR SIGNIFICANT BENEFIT TO SOCIETY
- Paramount *subject-centered* values:
  - SELF-DETERMINATION
  - WELL-BEING
Goals, rights, and protection from harm

- May understand these values in terms of goals, rights & protection from harm.

- Goal of societal benefit is undeniably valuable.

- But what means to this end are ethically permissible?

- Crucial factor in setting limits: rights of (prospective) subjects.
The rights of human subjects

- A RIGHT TO ADEQUATE PROTECTION FROM HARM

- Competent adults also have A RIGHT TO SELF-DETERMINATION.

- So, in a way, do children & adults w/compromised decision-making capacity.

- Rights as *side-constraints* or *trumps*.

- Rights are NOT to be balanced against goals of research.
Specifying the rights of minor subjects

- How should we think about the rights of children in research?

- First, bear in mind:
  - Their vulnerability to domination & exploitation by adults: parents, guardians, authority figures including researchers.
  - Their limited decision-making capacity.
Relevant decision-making standards

- Lexically ordered decision-making standards:
  - INFORMED CONSENT for competent adults or subjects determined to have (sufficient) decision-making capacity
  - BEST INTERESTS for children or adults who lack (sufficient) decision-making capacity.

- Factors complicating interpretation:
  - Children’s partial decision-making capacity
  - Ambiguity of “best interests”
Capacity & autonomy

- Informed-consent standard rests on DECISION-MAKING CAPACITY.

- This = capacity to make a decision (of the relevant kind) autonomously.

- Theoretical controversy over what AUTONOMOUS ACTION involves
Suggested analysis for informed consent

- Conditions for informed consent—(sufficiently) autonomous authorization—for participating in research:

  One provides valid (voluntary, informed) consent if & only if one consents to participate in a protocol

  (1) intentionally,

  (2) w/sufficient understanding of the nature of the study, its risks & possible benefits, and

  (3) sufficiently freely of (a) external constraints & (b) internal constraints.
The importance of children’s assent

- Some mature minors are probably capable of informed consent.

- All other minors are not. Tend to lack sufficient understanding and/or sufficient freedom from external & internal constraints.

- But autonomy & capacity come in degrees.

- So we should take a minor’s wishes into account.

- Common practice of requiring minor subjects’ *assent* (along w/ proxy permission) is sound. Exceptions are possible.
The BI standard applies to nearly all minors.

Generally understood to permit research on children when
- only minimal risk,
- “a minor increase over minimal risk” (if certain conditions are met), or
- direct medical benefit that compensates for the risk

Note: If we take “best interests” in literal, maximizing sense, BI standard will prohibit research on children whenever they face any risks not offset by prospect of benefits to them.

Suggestion: Don’t take “best interests” so literally.
Children’s essential interest in adequate protection from harm

- BI standard should be understood as protecting minor subjects’ *essential* interests.

- Extends idea that parents owe their children protection of their essential interests—including *adequate protection from harm*.

- But what constitutes adequate protection from harm in the context of pediatric research?
Recommended standard

- *Children may be involved in promising research that*
  
  - Offers direct medical benefit that compensates adequately for any risk; or
  
  - No direct medical benefit, but relatively minor risks compatible w/ protections responsible parents would afford their children.

- Pediatric research outside these categories violates children’s right to adequate protection from harm.