



The Role of Beneficence in Research Involving Vulnerable Humans

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Three Things:

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Three Things:

1. Autonomy and its limits

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2. Defining Beneficence

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3. The role of Beneficence in current guidelines



The Autonomy Paradigm

1947 Nuremburg Code, Article 1, “The voluntary consent of the human subject is absolutely essential.”

- legal capacity
- able to exercise “free power of choice”
- no element of force, fraud, deceit, duress or coercion
- sufficient knowledge and understanding

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The Limitations of Relying on the Autonomy Paradigm

- If no or limited capacity, how can we justify research?
- If capacity, but comprised (power relations), how can we justify research?
- If capacity, but irrational, how can we prohibit research?

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Beneficence (William Frankena, *Ethics*, 1973)

- One ought not to inflict evil or harm.
- One ought to prevent evil or harm.
- One ought to remove evil.
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Non-
Maleficence



Beneficence

- Intentionally doing good and avoiding harm through the application of duties that make all people's lives better, or at least not worse.



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Beneficence in Human Research

- Beneficence₁: Do Good
- Beneficence₂: Avoid Harm
- Beneficence₃: Proportional Benefit
- Beneficence₄: Special protection of the vulnerable



Beneficence in Human Research

- Beneficence₋₁: It is good to do biomedical research, so long as it is done in an ethical way, because progress in this field is good for human beings.



Beneficence in Human Research

- Beneficence₂: But, this research requires research on some human beings, which could be harmful to them. To ensure that they are not treated only as a means, first, risks and nonmoral harms should be minimized, the knowledge should not be obtainable by another means, and methods should be sound.



Beneficence in Human Research

- Beneficence₃: Second, there must be a benefit proportional to the remaining risks and nonmoral harms, and participants who are able to consent must do so with adequate information about these risks and benefits.



Beneficence in Human Research

- Beneficence₄: Where people are not fully able to consent, special protection should be given to ensure that there is either a direct proportionate benefit for the participant, or there is at least a proportionate benefit for those like him or her in some specific respect *and* there is very low risk for the participant. Furthermore, the consent of adequately informed guardians must be sought here too.

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Why is this important?

- 1) This research needs to be done
- 2) Provides a more elegant explanation than convoluted appeals to autonomy like *vicarious consent*
- 3) Opens the way to a case for the integrity of the researcher rather than proceduralism



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