

Post-trial obligations to host communities

Joseph Millum, Ph.D.

Clinical Center Department of Bioethics/Fogarty
International Center – National Institutes of Health, USA

*Expert Conference on the Revision of the Declaration of
Helsinki, 6 December 2012*

Disclaimer

- The views expressed are my own and do not represent the views of the NIH, PHS, or DHHS
- But they do owe a debt to my colleagues at the Clinical Center Department of Bioethics (Christine Grady, Seema Shah, Dave Wendler)

Declaration of Helsinki (2008)

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

Exploitation

- A exploits B when A takes unfair advantage of B's situation (Wertheimer).
- E.g. price gouging

Responsiveness and exploitation

- The responsiveness requirement prevents exploitation by identifying a benefit which is sufficient to make the gains to host communities fair
- Analogy with health systems of high-income countries

A criticism of responsiveness

- Fairness is a matter of *how much* people receive, not what *type* of benefit they receive
- Clinical research can therefore be non-exploitative even if the benefits to participants and host communities are unrelated to the knowledge gained by the research (cf. Fair Benefits framework)

Two questions

1. *In principle*, what benefits should disadvantaged or vulnerable populations or communities receive after the completion of a research project?
2. *In practice*, what specific policies would result in disadvantaged or vulnerable populations or communities receiving these benefits?

Amending Paragraph 17

17. Medical research involving a disadvantaged or vulnerable population or community is only justified **if the population or community receives a fair level of benefits, for example,** if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit **sufficiently** from the results of the research.

Conclusions

- The responsiveness requirement is supposed to prevent exploitation
- Exploitation is taking unfair advantage of another's situation
- Exploitation can be prevented by ensuring that disadvantaged or vulnerable groups get a fair level of benefits
- Responsiveness is one way, but not the only way, to ensure that everyone gets a fair level of benefits.

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