

Ethics: Bioethics (Spring 2015)

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ESSENTIAL TEXTS IN BIOETHICS

DECLARATION OF HELSINKI

- ⦿ After Nuremberg, WMA Medical Ethics Committee proposed position paper, first finished in 1964
- ⦿ 2013 version highlights importance of
 - Duties of physicians as physicians
 - Informed consent
 - Research needs to have relatively good chances of being fruitful
 - Independent review
 - Careful balance of risks and benefits to individuals and society

DECLARATION OF HELSINKI

- ◎ “No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.”
 - Given revelations at Nuremberg...
 - How might this ethical requirement of the DoH pose problems for researchers in different social/cultural/legal contexts?
 - Is this requirement defensible?

HISTORY OF THE BELMONT REPORT

- ◎ Proximate US events leading up to the Belmont Report:
 - Thalidomide and infant deformities (1950s), Declaration of Helsinki (1964), Tuskegee syphilis study (1932-1972)
- ◎ National Research Act (1974) creates the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- ◎ Belmont Report written in 1978
 - Named after Belmont Conference Center—location of initial drafting of report
- ◎ Led to revisions of Code of Federal Regulations ([45 CFR 46](#))
 - Adopted by 14 other federal agencies in 1991 → the Common Rule



THE BELMONT REPORT

◎ Basic ethical principles

- Cut across moral philosophies
- No principle is always prioritized over the others.

➤ RESPECT FOR PERSONS

- “capable of deliberation about personal goals and acting under the direction of such deliberation” (5)
- 1) Respect autonomous agents; and 2) protect those with diminished autonomy

THE BELMONT REPORT

“To show a lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, **when there are no compelling reasons to do so**” (5).



PRIMA FACIE!

- What are some examples, in healthcare or research contexts, where there are compelling reasons to override someone’s autonomy in each of the three ways mentioned above? Are there any uncontroversial examples?

THE BELMONT REPORT

➤ BENEFICENCE

- 1) do no harm, and 2) maximize potential benefits and minimize potential harms
- Not just *supererogatory*, but a *strict obligation*

➤ JUSTICE

- Equals ought to be treated equally; fair distribution
- Prevent exploitation (taking unfair advantage of another's vulnerability)

RESPECT FOR AUTONOMY

- ◎ Autonomous choice:
 - Intentional
 - With understanding
 - Free of controlling interferences

- ◎ “Respect involves *respectful action*, not merely a *respect attitude*. It requires more than noninterference in others’ personal affairs. It includes, in some contexts, building up or maintaining others’ capacities” (103)

WHAT RESPECT FOR AUTONOMY DOES NOT DEMAND

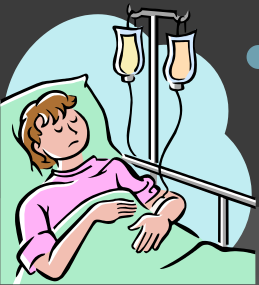
- ⊙ Rugged individualism or “Western” ideals
- ⊙ Ignoring or overriding all other ethical considerations
 - Does not necessarily trump other principles...
- ⊙ “correlative *right* to choose, not a mandatory *duty* to choose” (105)
 - Allow for transferring decisional authority to others; limiting what information or options are available

DISCUSSION QUESTIONS

- ⦿ Both the Declaration of Helsinki and Belmont Report warn against exploiting vulnerable populations. What are the competing ethical considerations with...
 - Including/excluding prisoners in research?
 - Including/excluding pregnant women in research?
- ⦿ If a research protocol carries minimal risk but does not have much potential to advance scientific knowledge (e.g., poor methodology, overdone study), should an ethics committee nonetheless approve the research?

DISCUSSION QUESTIONS

- ◎ How might the Declaration of Helsinki or Belmont Report prove helpful to ethical considerations *in the clinic*?
- ◎ Case to consider: Do you think that female patients at a teaching hospital have consented to pelvic exams by students while anesthetized, merely in virtue of having consented to treatment?
- If you were the student, how would you respond to being asked to participate in this lesson?



ADDITIONAL RESOURCES

- ◎ Kukla, Rebecca. “Autonomy.” *Intensive Bioethics Course*. Kennedy Institute of Ethics. Summer 2012.
- ◎ “25th Anniversary of the Belmont Report.” Office for Human Research Protections. Archive. 2008 November 13.
<http://www.hhs.gov/ohrp/archive/belmontArchive.html>
- ◎ “IRB Procedures: History of Ethics.” Claremont Graduate School.
<http://www.cgu.edu/pages/1722.asp>

QUESTIONS? COMMENTS?