

HUMAN SUBJECTS RESEARCH

KEY CONCEPTS

Respect: this means treating those persons upon whom research is being conducted—or being proposed to be conducted—as autonomous agents. Their participation must be both voluntary and adequately informed. In cases for which the persons upon whom research is being conducted—or being proposed to be conducted—have diminished agency or autonomy, they may still be able to ethically participate in research, but in doing so must be granted special and extensive protections.

Beneficence: the first rule of beneficence is not to cause harm to participants in order to secure benefits for others. The second rule is to maximize possible benefits and minimize possible harms both inside the context of the study—for participants—and outside it—for non-participants, for knowledge, for future tech, for society at large, etc.

Justice: this requires incorporating notions of equality, equity, and fairness, along with the concept of desert (pronounced "dessert"); all with respect to the distribution of the efforts, burdens, and fruits of the (proposed) research.

TEXTBOOKS & REPORTS

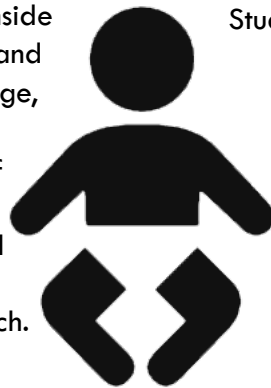
- *Preserving Public Trust* (The National Academies Press 2001; free at nap.edu)

ASSOCIATED ARTICLES

- Brandt's (1978) "Racism and Research... Tuskegee Syphilis Study" *Hastings Cent Rep* 21–29.
- Aronowitz' (2014) "Screening for Prostate Cancer in... Skid Row" *Am J Public Health* 104(1): 70–76.

CASES IN THE NEWS

- Using Inmates in Drug Trails—see Ian Urbina (2006) writing for *The New York Times*



DISCUSSION QUESTIONS

1. What tradeoffs amongst respect, beneficence, and justice are most commonly or significantly required by **Human Subjects Research (HSR)** in your experience?
2. How should reviewers of proposed HSR rank respect, beneficence, and justice with respect to one another—in order to adjudicate cases of conflict?
3. How could your institution's HSR review process be improved? Consider what additions, removals, or alterations you think ought to be made to the process.
4. What does the history of apparent violations of ethical considerations in HSR mean for your research? What about the reputation of research in general?
5. What is the legacy of, e.g., the Tuskegee Syphilis Study? What does this legacy mean for science?

POLICY & REPORTING

The **1979 Belmont Report** identified three principles necessary for ethically conducting HSR in the US: respect, beneficence, justice.

Members of **Institutional Review Boards (IRBs)** across the country assess investigators' proposals to engage in HSR, and—among other procedural and institutional factors—these committees approve or deny proposals based on consideration of "the Belmont trio."

Each of these three moral commitments is generally honored by engaging in related, specific research practices. The commitment to respect for persons is usually honored via the practice of obtaining informed consent. Beneficence requires consideration of risks and benefits. Finally, justice is typically honored via the proper, equitable selection of research subjects.

The **1991 Common Rule** established many key IRB procedures and was updated via the **2017 Final Rule**.

FINE PRINT

In 1992–3, the National Academy of Sciences (NAS) published a pair of reports on *Responsible Science* (Vol. 1–2), and those reports ushered in an era of ethical oversight centered around the concept of the Responsible Conduct of Research (RCR) at federally-funded American research institutions across the nation. By 2009, the National Institutes of Health (NIH) had mandated that "all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research" (NOT-OD-10-019). The National Science Foundation (NSF) recommends—though does not require—something similar. Both agencies suggest that satisfactory RCR instruction tends to cover: research misconduct; conflict of interest; human subjects research; animal subjects research; collaboration and interdisciplinarity; data acquisition and management; authorship, peer review, and publication; mentoring and being mentored; and the relationship between science and society.

This handout introduces the topic of **human subjects research**.