

# Ethics in Clinical Research

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## Ethical Guidelines

The goal of clinical research is to develop generalizable knowledge that improves human health or increases understanding of human biology. People who participate in clinical research make it possible to secure that knowledge. The path to finding out if a new drug or treatment is safe or effective, for example, is to test it on patient volunteers. But by placing some people at risk of harm for the good of others, clinical research has the potential to exploit patient volunteers. The purpose of ethical guidelines is both to protect patient volunteers and to preserve the integrity of the science.

The ethical guidelines in place today were primarily a response to past abuses, the most notorious of which in America was an experiment in Tuskegee, Alabama, in which treatment was withheld from 400 African American men with syphilis so that scientists could study the course of the disease. Various ethical guidelines were developed in the 20th century in response to such studies.

Some of the influential codes of ethics and regulations that guide ethical clinical research include:

- 1. Nuremberg Code (1947)
- 2. Declaration of Helsinki (2000)
- 3. Belmont Report (1979)
- 4. CIOMS (2002)
- 5. U.S. Common Rule (1991)

Using these sources of guidance and others, seven main principles have been described as guiding the conduct of ethical research:

|                              |   |
|------------------------------|---|
| Social and clinical value    | + |
| Scientific validity          | + |
| Fair subject selection       | + |
| Favorable risk-benefit ratio | + |

|                                             |   |
|---------------------------------------------|---|
| Independent review                          | + |
| Informed consent                            | + |
| Respect for potential and enrolled subjects | + |

Sources:

For more information about what makes clinical research, we refer you to:

Ezekiel J. Emanuel, MD, PhD; David Wendler, PhD, and Christine Grady, PhD. "[What Makes Clinical Research Ethical?](#)" Journal of the American Medical Association, Vol. 283, No. 20, May 24, 2000, pp. 2701-2711.

Copy on this website is based largely on this article, on an interview with Dr. Grady, and on Dr. Emanuel's PowerPoint presentation, "What makes research ethical," available online: <http://www.bioethics.nih.gov/slides/10-29-03-Emmanuel.pdf> 

[Dr. Grady](#) is acting chief of the Bioethics Department and head of the Section on Human Subjects Research. [Dr. Wendler](#) heads the Unit on Vulnerable Populations. Dr. Emanuel was chief of the CC Bioethics Department 1996-2011.

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