

1. Office for Human Research Protections. Categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure. (Accessed February 1, 2008, at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>.)
2. Berwick DM. Developing and testing changes in delivery of care. *Ann Intern Med*. 1998;128:651-656.
3. Department of Health and Human Services Protection of Human Subjects, 45 CFR §46 (1991). Nelson EC, Splaine ME, Batalden PB, Plume SK. Building measurement and data collection into medical practice. *Ann Intern Med*. 1998;128:460-466.
4. Langley GJ, Nolan KM, Nolan TW, Norman CL, Pronovost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. San Francisco, Calif: Jossey-Bass; 1996.
5. Schmittiel J, Selby JV, Grumbach K, Quesenberry CPJ. Choice of a personal physician and patient satisfaction in a health maintenance organization. *JAMA*. 1997;278:1596-1599.
6. Goldberg HI. Ethical issues in administrative continuous improvement. *Med Care*. 1990;28:822-823.
7. Moore FD. Therapeutic innovation: ethical boundaries in the initial clinical trials of new drugs and surgical procedures. In: Freund PA, ed. *Experimentation With Human Subjects*. New York, NY: George Braziller; 1969.
8. Brett A, Grodin M. Ethical aspects of human experimentation in health services research. *JAMA*. 1991; 265:1854-1857.
9. Lynn J, Johnson J, Levine RJ. The ethical conduct of health services research: a case study of 55 institutions' applications to the SUPPORT project. *Clin Res*. 1994;42:3-10.
10. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York, NY: Oxford University Press; 1986.
11. Freedman B, Fuks A, Weijer C. Demarcating research and treatment: a systematic approach for the analysis of the ethics of clinical research. *Clin Res*. 1992;40:653-660.
12. Gawande A. A lifesaving checklist. *New York Times*. December 30, 2007:8.
13. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006;355:2725-32. [Erratum, *N Engl J Med*

2007;356:2660.]

14. Borror KC. Human research protections under federalwide assurances FWA-5752, FWA-287, AND FWA-3834. Rockville, MD: Office for Human Research Protections, July 19, 2007 (letter). (Accessed February 1,2008, at http://www.hhs.gov/ohrp/detrm_lettrs/YR07/jul07d.pdf.)
15. Kass N, Pronovost PJ, Sugarman J, Goeschel CA, Lubomski LH, Faden R. Controversy and Quality Improvement: Lingering Questions About Ethics, Oversight, and Patient safety Research. *Jt Comm J Qual Patient Saf*. Forum. 2008; 34(6):349-53

