

Human subjects

This core area addresses issues important in conducting research involving human subjects. This includes topics such as the definition of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality and privacy of data and patient records, risks and benefits, preparation of a research protocol, institutional review boards, adherence to study protocol, proper conduct of the study, and special protections for targeted populations, e.g., children, minorities, and the elderly.

Publications on the topic:

Bulger, R. E., Heitman, E., & Reiser, S. J. (1993). The ethical dimensions of the biological sciences (Part VI, pp. 143-172). New York: Cambridge University Press.

Ellis, G. (1999). Keeping research subjects out of harm's way. Journal of the American Medical Association, 283, 1963-1965.

Ellis, G. (1999). Protecting the rights and welfare of human research subjects. Academic Medicine, 74, 1008-1009.

Frankel, M. S., & Siang, S. (1999). Ethical and legal aspects of human subjects research on the internet: A report of a workshop. American Association for the Advancement of Science. (hard copy available in ORC office, also available online at <http://www.aaas.org/spp/dspp/sfrr/projects/intres/main.htm>)

Kahn, P. (1996). Coming to grips with genes and risk. Science, 274, 496-498.

Marshall, E. (1996). The Genome Project's conscience. Science, 274, 488-490.

Rothman, D. J. (1987). Ethics and human experimentation: Henry Beecher revisited. New England Journal of Medicine, 317, 1195-1199.

Shuster, E. (1997). Fifty years later: The significance of the Nuremberg Code. New England Journal of Medicine, 337, 1436-1440.

Swerdlow, P. (2000). Use of humans in biomedical experimentation. In F. L. Macrina (Ed.), Scientific Integrity (2nd ed., pp. 137-151). Washington, DC: ASM Press.

Online resources:

- Love, C. B., Thomson, E. J., & Royal, C. D. (1999, May). Ethical issues in research involving human participants: Current bibliographies in medicine (4650 citations). National Library of Medicine, U. S. Department of Health and Human Services. Covers January 1989 through November 1998. Available online at http://www.nlm.nih.gov/pubs/cbm/hum_exp.html
- Office for Human Research Protections: <http://www.hhs.gov/ohrp/>