Present-day scientists involved in health care research have a code of ethical principles that must be applied to research involving both human and animal subjects.

With respect to human subjects, two of the most basic principles of ethical clinical research are:

1. to fully inform prospective participants about what the study procedures will entail, so that they can make an informed decision about whether or not to take part in the study
2. to do everything possible to minimize potential harm to study participants; this is derived from the Hippocratic Oath—to do no harm

Experimental studies are especially susceptible to ethical concerns because they involve direct intervention by the researcher in the lives or health of the participants. For this reason, the researcher is expected to make every effort to protect the human rights and well-being of the study’s participants.

Current standards for research ethics have been formalized since World War II. In the US, the Nuremberg Code (1947) and the Declaration of Helsinki (1964, revised in 1975) became the foundation for the formation of the National Commission for Protection of Human Subjects and Behavioral Research. This commission produced a document known as the Belmont Report, which is available online at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

The Belmont Report proposes that three core values should underlie all research endeavors: respect for persons, beneficence, and justice. The practical implications of each value are as follows:

**Respect for persons** refers to treating people as autonomous beings, with the right to make decisions based on their own interests or preferences. This value requires that people participate in research studies voluntarily, with adequate information regarding study procedures, and has resulted in the legal protections found in informed consent documents. People whose circumstances involve less autonomy, such as prisoners, children, or mentally challenged individuals, must receive special protections because they cannot give fully informed consent. For example, children participating in research must have a parent or guardian give consent in the child’s best interests.

**Beneficence** refers to the value of doing no harm. This concept obligates researchers to give thought to maximizing the potential benefits and minimizing the potential risks that might occur from participating in a research investigation. Researchers are required to
communicate an accurate assessment of the potential risks and benefits of participation, so that prospective subjects can decide for themselves whether the putative benefits outweigh the possible risks.

Beneficence underlies much public debate about exploring new areas of research, especially as new technologies expand the types of interventions that are possible.

**Justice** refers to the value of fairness in the distribution of the benefits and burdens associated with participation in research. In the 19th and 20th centuries, a disproportionate share of research participants came from poor, disenfranchised, and/or captive populations. The exploitation of Nazi prisoners in medical experiments is a particularly flagrant example of such injustice. While we might like to think that the abuse of research participants could never happen here or now, the need for justice remains current.

A disturbing example is found in recent US history. The Tuskegee Syphilis Study was initiated by the Public Health Service in 1932. Its subjects were rural black men diagnosed with syphilis, for which no effective treatments existed at the time; the study set out to observe the untreated natural course of the disease. The men were told that they were participating in a study of “bad blood.” When penicillin became available in 1943 the men were not offered this new treatment and the study was allowed to continue. Only when public health workers leaked the truth to the media, and the National Association for the Advancement of Colored People filed suit was the study stopped—in 1972. During the 40 years that the study was conducted, 28 men died directly as a result of the disease, 100 died from complications, and 40 wives and 19 children were infected. In 1997, former president Bill Clinton acknowledged publicly that the study had been morally reprehensible.

The value of justice leads to the expectation that researchers will assure that subjects or participants are solicited based on the requirements of the research question being asked, and that disadvantaged people are not disproportionately selected for a study because of their availability and vulnerability to exploitation.

One outgrowth of the Belmont Report was that the US government developed regulations requiring institutions conducting research to establish Institutional Review Boards (IRBs), the purpose of which is to act as ethics committees to safeguard the rights of study participants. IRBs consider the scientific merit of proposed projects, the competence of the investigators, and the suitability of all treatments and study procedures, in light of the study’s potential risks and benefits. IRBs also assess the procedures for selecting and recruiting participants, for ensuring appropriate informed consent, and for maintaining confidentiality of private health care information disclosed during the study. The IRB approves the proposed design of the study from the standpoint of whether its benefits outweigh its risks, and then monitors the conduct of the study as it progresses.
For case reports, IRB approval is not usually required. However, the informed consent of the patient or client is always required, and data should be de-identified to maintain confidentiality of health information. A sample consent form is included in the Learning Resources Community in the Forms and templates collection. While raw data can be easily de-identified, audio and videotaping of clients poses special challenges, and necessitates additional discussion with clients to be sure they understand that such recordings may be publically accessible. Care should be taken especially with videotaping to avoid showing the client's face unless specifically needed for demonstration of particular technique(s), and specific permission obtained.