The contemporary protections for human subjects of research are based on three founding documents: the Nuremberg Code (1949), the Declaration of Helsinki (1964), and the Belmont Report (1979). Ethical principles set forth in these founding documents should be upheld during the conduct, review, and oversight of research by investigators, research coordinators, key personnel, employees, students, organizational officials, IRB members, and IRB staff. Short overviews of these principles are provided below. For a history of these principles, please visit the Institutional Review Board tutorial available on the Human Research Protection Program (HRPP) website.

In addition, clinical human subject research may also follow the International Conference on Harmonisation – Guidelines for Good Clinical Practice (E6) (ICH GCP). The ICH GCP (E6) provides international guidelines for the conduct of clinical trials. For more information on ICH GCP (E6), see the HRPP Manual 2-4 “International Conference on Harmonization Good Clinical Practice (E6).”

**The Nuremberg Code - 1949**
The Nuremberg Code was developed out of the trials of Nazi war criminals, including those involved in medical experiments. The Nuremberg Code was adopted by the United Nations General Assembly and is considered international “common law.”

The Nuremberg Code includes the following principles:
- Voluntary consent
- Freedom from coercion
- Ability to withdraw at any time
- Appropriate research design
- Consideration of risk/benefit
- Qualified investigators

**The Declaration of Helsinki - 1964**
The Declaration of Helsinki was adopted by the World Medical Assembly (WMA) in Helsinki, Finland in 1964 and is periodically amended by the WMA. It is a statement of ethical principles for medical human subject research and discusses research versus clinical care.

The Declaration of Helsinki includes principles such as:
• Health of patient is first consideration
• Well-being of subject takes precedence over interests of science and society
• Refusal of patient to participate in research must never interfere with physician-patient relationship

The Belmont Report - 1979
The Belmont Report was produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and became the foundation of U.S. human subject protection. Michigan State University (MSU) applies the ethical principles found in the Belmont Report to all of its activities related to human subject research, regardless of funding. The principles found in the Belmont Report are summarized as follows:

Respect for Persons: Individuals should be treated as autonomous agents. They should voluntarily enter into research by being adequately informed. Special protection should be given to individuals with diminished autonomy and/or of special circumstances since they may not be able to make a considered judgment even if they are adequately informed. One group entitled to special protections is prisoners who may be subtly coerced or unduly influenced.

Beneficence: Researchers are obligated to do no harm by maximizing possible benefits and reducing possible risks to subjects. In some cases where research may pose risk to individual subjects with no direct benefit to them the principle of beneficence requires careful assessment of the benefits to others or to society.

Justice: The risks of research should be equally distributed and should not unduly involve persons from groups unlikely to be among the beneficiaries of the research. Selection of individuals or classes of individuals should be fair. Vulnerable classes of subjects should be given special protection and not be unduly selected as research subjects due to their ready availability or dependent status.