

AMA Code of Medical Ethics

7.1.3 Study Design & Sampling

To be ethically justifiable, biomedical and health research that involves human subjects must uphold fundamental principles of respect for persons, beneficence, and justice. These principles apply not only to the conduct of research, but equally to the selection of research topics and study design.

Well-designed, ethically sound research aligns with the goals of medicine, addresses questions relevant to the population among whom the study will be carried out, balances the potential for benefit against the potential for harm, employs study designs that will yield scientifically valid and significant data, and generates useful knowledge. For example, research to develop biological or chemical weapons is antithetical to the goals of the medical profession, whereas research to develop defenses against such weapons can be ethically justifiable.

Physicians who engage in biomedical or health research with human participants thus have an ethical obligation to ensure that any study with which they are involved:

- (a) Is consistent with the goals and fundamental values of the medical profession.
- (b) Addresses research question(s) that will contribute meaningfully to medical knowledge and practice.
- (c) Is scientifically well designed to yield valid data to answer the research question(s), including using appropriate population and sampling controls, clear and appropriate inclusion/exclusion criteria, a statistically sound plan for data collection and analysis, appropriate controls, and when applicable, criteria for discontinuing the study (stopping rules).
- (d) Minimizes risks to participants, including risks associated with recruitment and data collection activities, without compromising scientific integrity.
- (e) Provides mechanisms to safeguard confidentiality.
- (f) Does not disproportionately recruit participants from historically disadvantaged populations or populations whose ability to provide fully voluntary consent is compromised. Participants who otherwise meet inclusion/exclusion criteria should be recruited without regard to race, ethnicity, gender, or economic status.
- (g) Recruits participants who lack the capacity to give informed consent only when the study stands to benefit that class of participants and participants with capacity would not yield valid results. In this event, assent should be sought from the participant and consent should be obtained from the prospective participant's legally authorized representative, in keeping with ethics guidance.
- (h) Has been reviewed and approved by appropriate oversight bodies.

AMA Principles of Medical Ethics: I,II,III,V,VII