

7.1.1 Physician Involvement in Research

Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients, rather than to the specific benefit of the individuals who participate as research subjects.

However, research involving human participants should be conducted in a manner that minimizes risks and avoids unnecessary suffering. Because research depends on the willingness of participants to accept risk, they must be able to make informed decisions about whether to participate or continue in a given protocol.

Physician researchers share their responsibility for the ethical conduct of research with the institution that carries out research. Institutions have an obligation to oversee the design, conduct, and dissemination of research to ensure that scientific, ethical, and legal standards are upheld. Institutional review boards (IRBs) as well as individual investigators should ensure that each participant has been appropriately informed and has given voluntary consent.

Physicians who are involved in any role in research with human participants have an ethical obligation to ensure that participants' interests are protected and to safeguard participants' welfare, safety, and comfort.

To fulfill these obligations, individually, physicians who are involved in research should:

- (a) Participate only in those studies for which they have relevant expertise.
- (b) Ensure that voluntary consent has been obtained from each participant or from the participant's legally authorized representative if the participant lacks the capacity to consent, in keeping with ethics guidance. This requires that:
 - (i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;
 - (ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;
 - (iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.
- (c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.
- (d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.
- (e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.
- (f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research.

Opinion 7.1.1, Physician involvement in research, compiles content from several previous opinions and associated background reports:

CEJA Report 3-I-00 Managing conflicts of interest in clinical trials

CEJA Report 3-I-98 Conflict of interest—biomedical research

CEJA Report 2-A-96 Ethical use of placebo controls in clinical trials

Report of the Judicial Council A-A-66 Declaration of Helsinki