Clinical research versus patient care: Conducting clinical trials

Search for effective treatments can move swiftly during a pandemic as researchers and institutions mount studies to test plausible therapies. Patients, and physicians on their behalf, may be tempted to overlook the “experimental” status of treatments under study and see enrollment in a clinical trial as a way to gain access to desperately hoped for therapy. In such circumstances, it’s all the more important to keep in mind the differences between clinical research and patient care.

Opinion 7.1.1, “Physician Involvement in Research,” in the AMA Code of Medical Ethics notes that 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.” Nonetheless, in coordination with institutional oversight, physicians who carry out research have a responsibility to “[d]emonstrate 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.”

Physicians-investigators should ensure that prospective participants receive the information they need about the nature of the research and potential harms, as well as their right to withdraw to make well-informed decisions to participate. Physicians should also “make all reasonable efforts” to ensure that prospective participants understand that the research is not intended to benefit them individually.

Opinion 7.1.3, “Study Design & Sampling,” instructs physicians to refer their patients only to studies that:

- address research questions “that will contribute meaningfully to medical knowledge and practice,”
- are “scientifically well designed to yield valid data” to answer those questions,
- minimize risks to participants, and
- do not “disproportionately recruit participants from historically disadvantaged populations or populations whose ability to provide fully voluntary consent is compromised.”

Further guidance on informed consent in the context of research is provided in Opinion 7.1.2, “Informed Consent in Research.”

**Additional ethics guidance in a pandemic**
The AMA offers an overview of foundational guidance regarding medical ethics for health care professionals and institutions responding to the COVID-19 pandemic.