

## Research ethics in a public health crisis

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Scientifically-grounded knowledge is essential for responding to a pandemic when the lives of so many are at stake. Bench research to characterize the pathogen is critically important as a foundation for innovations in prevention and treatment. Epidemiological research to understand the mode and rate of transmission is fundamental to implementing sound public health interventions (Opinion 8.3, "Physician Responsibilities for Disaster Response & Preparedness"; Opinion 8.4, "Ethical Use of Quarantine & Isolation").

Clinical research is key to evaluating the safety and efficacy of therapeutic interventions. Time is of the essence, but the pressure to act does not justify relaxing the standards for ethically conducted research.

The *AMA Code of Medical Ethics* articulates core standards for research that involves human participants in Opinion 7.1.1, "Physician Involvement in Research"; Opinion 7.1.2, "Informed Consent in Research"; Opinion 7.1.3, "Study Design & Sampling"; and Opinion 7.2.1., "Principles for Disseminating Research Results." Opinion 7.1.1 reminds us that research is intended primarily to advance knowledge and benefit future patients. It calls on physicians to participate only in scientifically sound protocols and only in areas in which they have relevant expertise. Research should be carried out "in a manner that minimizes risk and avoids unnecessary suffering."

Opinion 7.1.2 sets out the requirements for informed consent in the context of research, including the nature of the research protocol and its implications for the participant, the risks it poses and the likelihood of direct benefit to the individual. This opinion charges physicians to make clear to prospective participants "(t)he differences between the physician's responsibilities as a researcher and as the patient's treating physician."

Opinion 7.1.3 delineates essential characteristics of ethically sound design in research with human participants. The study must ask a research question that will "contribute meaningfully to medical knowledge and practice," and must be "scientifically well designed to yield valid data" to answer that question—for example, it must use appropriate controls and inclusion/exclusion criteria, as well as "a statistically sound plan for data collection and analysis." In times of urgent need, it can be ethically justifiable to use an alternative to the "gold standard" randomized controlled clinical trial, such as an

adaptive trial design, that adheres to the guidance set out in Opinion 7.1.3.

Finally, Opinion 7.2.1 articulates physician-investigators' responsibility to share research findings, including negative findings, "for the ultimate benefit of patients." The duty to report results in a timely, transparent manner includes responsibility to "(r)eport the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis."

## **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.