

Vaccine trials & healthy volunteers

In the context of pandemic disease, developing a vaccine that will confer immunity and protect individuals and the community is an urgent matter, even as other measures are taken to reduce transmission and treat those who become infected. Vaccine trials of necessity recruit healthy volunteers and by design expose them to possible infection in addition to whatever risk the vaccine itself may pose.

Issues of trial design and informed consent take on particular ethical significance in these circumstances. The *AMA Code of Medical Ethics* provides guidance in Opinion 7.1.3, “Study Design & Sampling,” and Opinion 7.1.2, “Informed Consent in Research.”

Scientific value and validity are the foundation of ethically sound research involving human participants. Opinion 7.1.3 stresses physician-researchers’ ethical obligation to ensure that trials into which they recruit participants ask “research question(s) that will contribute meaningfully to medical knowledge and practice,” and that are “scientifically well designed to yield valid data” to answer those questions. This includes “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).” Like any clinical trial, a vaccine trial must minimize risks to participants to the greatest extent possible without compromising scientific integrity.

Vaccine trials ask healthy individuals to voluntarily and actively take on a risk that they might otherwise avoid and thus to be ethically acceptable require a robust process of informed consent. Opinion 7.1.2 provides, in the first instance that among prospective participants who meet inclusion criteria, physician-investigators should seek consent from individuals who have decision-making capacity. In the context of a vaccine trial, the ethical obligation to disclose “[a]ny known risks or foreseeable hazards” and the “nature of the research plan and implications for the participant” includes not only any risks posed by the candidate vaccine, but equally by the heightened risk of exposure to the pandemic disease. In all situations, physician-investigators should refrain from persuading the individual to enroll.

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.