



AMGA Statement on Human Subjects Research

Human subject research for medical progress has expanded our understanding and capability to improve healthcare delivery, treat serious diseases, and achieve major improvements in population health. However, research with humans must consider all of the ethical dimensions for the conduct of research and follow proper procedural steps to ensure results reflect good science.

Protecting human participants through the ethical conduct of research is a priority for AMGA. AMGA research involving human subjects is guided by the fundamental ethical [principles set forth in *The Belmont Report*](#). These principles are (1) respect for persons; (2) beneficence; and (3) justice. All affiliated or collaborating personnel, co-investigators, and investigators involved in the conduct and oversight of human research under the auspices of AMGA shall abide by this ethical foundation.

Respect for Persons: Embodies informed consent from individuals to enter a research study voluntarily and that they be given sufficient information with which to make this decision. Investigators will seek voluntary, informed consent by ensuring potential subjects are given assurances of the voluntary nature of their participation. Information about the study and its potential impact will be provided in easy-to-understand language. Potential subjects will be free from coercion or undue influence from researchers or others who may benefit from their participation. Respect also honors an individual's privacy by maintaining confidentiality when appropriate. In the case of immature or incapacitated persons, investigators will take additional precautions to protect them during the conduct of the research based upon the risks and benefits.

Beneficence: Requires that expected benefits to subjects are maximized and potential risks of harm are minimized. Possible benefits—whether for participants, for science, for society, or for development of new knowledge—should always outweigh the risks. Assessments of potential harm will consider the probability and magnitude of psychological, physical, legal, social, and economic harms as well as the risks and benefits of research alternatives. Investigators shall weigh the reasonableness of seeking certain benefits, despite the risks involved, to determine when potential benefits may not sufficiently justify the risks.

Justice: Means those who bear the burdens of research (i.e., those who are exposed to discomforts, inconveniences, and risks) should receive benefits in equal measure to the burdens. Subjects should be fairly selected and the risks and benefits distributed equitably among subjects. Care should be taken not to systematically target particular classes (e.g., the poor, racial and ethnic minorities, or persons confined to institutions) because of ease of access, compromised position, manipulability, or the convenience of investigators. Sample populations will be selected for reasons directly related to the research. Publicly funded research that leads to therapeutic and other improvements in care will neither provide advantages to more affluent populations nor unduly involve persons from groups least likely to benefit.

Institutional Review Board: To ensure ethical acceptability of AMGA research proposals, AMGA has entered a Master Services Agreement with the [WCG-IRB](#), an independent, external board that provides ethical (IRB) review of protocol and informed consent for human subject protections. WCG IRB is a trusted partner to more than 3,300 research institutions in the United States.

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