

Genome editing and the AMA Code of Medical Ethics

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An international team of researchers recently published, in the journal *Nature*, their study using genome editing to correct a heterozygous mutation in human preimplantation embryos using a technique called CRISPR-Cas9. This bench research, while far from bedside use, raises questions about the medical ethics of what could be considered “genetic engineering.” The *AMA Code of Medical Ethics* has guidance for physicians conducting research in this area.

What the Code says

In Opinion 7.3.6, “Research in Gene Therapy and Genetic Engineering,” the *Code* explains:

Gene therapy involves the replacement or modification of a genetic variant to restore or enhance cellular function or to improve response to nongenetic therapies. Genetic engineering involves the use of recombinant DNA techniques to introduce new characteristics or traits. In medicine, the goal of gene therapy and genetic engineering is to alleviate human suffering and disease. As with all therapies, this goal should be pursued only within the ethical traditions of the profession, which gives primacy to the welfare of the patient.

In general, genetic manipulation should be reserved for therapeutic purposes. Efforts to enhance “desirable” characteristics or to “improve” complex human traits are contrary to the ethical tradition of medicine. Because of the potential for abuse, genetic manipulation of nondisease traits or the eugenic development of offspring may never be justifiable.

Moreover, genetic manipulation can carry risks to both the individuals into whom modified genetic material is introduced and to future generations. Somatic cell gene therapy targets nongerm cells and thus does not carry risk to future generations. Germ-line therapy, in

which a genetic modification is introduced into the genome of human gametes or their precursors, is intended to result in the expression of the modified gene in the recipient's offspring and subsequent generations. Germ-line therapy thus may be associated with increased risk and the possibility of unpredictable and irreversible results that adversely affect the welfare of subsequent generations.

Thus, in addition to fundamental ethical requirements for the appropriate conduct of research with human participants, research in gene therapy or genetic engineering must put in place additional safeguards to vigorously protect the safety and well-being of participants and future generations.

Physicians should not engage in research involving gene therapy or genetic engineering with human participants unless the following conditions are met:

- (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.

AMA Principles of Medical Ethics: I,II,III,V

At the 2016 AMA Interim Meeting, the AMA House of Delegates adopted policy on genome editing and its potential clinical use. In the policy, the AMA “encourages continued research into the therapeutic use of genome editing” and also “urges continued development of consensus international principles, grounded in science and ethics, to determine permissible therapeutic applications of germline genome editing.”

More go-to guidance

Chapter 7 of the *Code*, “Opinions on Research & Innovation,” also features guidance on other research-related subjects, including informed consent, conflicts of interest, use of placebo controls, and the use of DNA databanks.

The *Code of Medical Ethics* is updated periodically to address the changing conditions of medicine. The new edition, adopted in June 2016, is the culmination of an eight-year project to comprehensively review, update and reorganize guidance to ensure that the *Code* remains timely and easy to use for physicians in teaching and in practice.

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