

Human Genome Editing

Principles of Governance and Summary of Recommendations

National Academies of Sciences,
Engineering, and Medicine

Principles for the Governance of Human Genome Editing

1. Promoting well-being: *The principle of promoting well-being supports providing benefit and preventing harm to those affected, often referred to in the bioethics literature as the principles of beneficence and nonmaleficence.*

Responsibilities that flow from adherence to this principle include (1) pursuing applications of human genome editing that promote the health and well-being of individuals, such as treating or preventing disease, while minimizing risk to individuals in early applications with a high degree of uncertainty; and (2) ensuring a reasonable balance of risk and benefit for any application of human genome editing.

2. Transparency: *The principle of transparency requires openness and sharing of information in ways that are accessible and understandable to stakeholders.*

Responsibilities that flow from adherence to this principle include (1) a commitment to disclosure of information to the fullest extent possible and in a timely manner, and (2) meaningful public input into the policy-making process related to human genome editing, as well as other novel and disruptive technologies.

These principles and recommendations are reprinted with permission from *Human Genome Editing: Science, Ethics, and Governance*, a report by the National Academies of Sciences, Engineering, and Medicine (Washington, DC: National Academies Press, 2017), doi: 10.18226/24623. The complete report is available at <https://www.nap.edu/catalog/24623/>. References to specific sections of the final report have been omitted from the reprinted text.

3. Due care: *The principle of due care for patients enrolled in research studies or receiving clinical care requires proceeding carefully and deliberately, and only when supported by sufficient and robust evidence.*

Responsibilities that flow from adherence to this principle include proceeding cautiously and incrementally, under appropriate supervision and in ways that allow for frequent reassessment in light of future advances and cultural opinions.

4. Responsible science: *The principle of responsible science underpins adherence to the highest standards of research, from bench to bedside, in accordance with international and professional norms.*

Responsibilities that flow from adherence to this principle include a commitment to (1) high-quality experimental design and analysis, (2) appropriate review and evaluation of protocols and resulting data, (3) transparency, and (4) correction of false or misleading data or analysis.

5. Respect for persons: *The principle of respect for persons requires recognition of the personal dignity of all individuals, acknowledgment of the centrality of personal choice, and respect for individual decisions. All people have equal moral value, regardless of their genetic qualities.*

Responsibilities that flow from adherence to this principle include (1) a commitment to the equal value of all individuals, (2) respect for and promotion of individual decision making, (3) a commitment to preventing recurrence of the abusive forms of eugenics practiced in the past, and (4) a commitment to destigmatizing disability.

6. Fairness: *The principle of fairness requires that like cases be treated alike, and that risks and benefits be equitably distributed (distributive justice).*

Responsibilities that flow from adherence to this principle include (1) equitable distribution of the burdens and benefits of research and (2) broad and equitable access to the benefits of resulting clinical applications of human genome editing.

7. Transnational cooperation: *The principle of transnational cooperation supports a commitment to collaborative approaches to research and governance while respecting different cultural contexts.*

Responsibilities that flow from adherence to this principle include (1) respect for differing national policies, (2) coordination of regulatory standards and procedures whenever possible, and (3) transnational collaboration and data sharing among different scientific communities and responsible regulatory authorities.

Oversight and Use of Human Gene Editing: Summary of Recommendations

Global Principles for Research and Clinical Use

Consider and apply the global principles in governance of human genome editing.

- Promoting well-being
- Transparency
- Due care
- Responsible science
- Respect for persons
- Fairness
- Transnational cooperation

Basic Laboratory Research

Use existing regulatory processes to oversee human genome editing laboratory research.

Somatic Genome Editing

Use existing regulatory processes for human gene therapy to oversee somatic human genome editing research and uses.

Limit clinical trials or therapies to treatment and prevention of disease or disability at this time.

Evaluate safety and efficacy in the context of risks and benefits of intended use. Require broad public input prior to extending uses.

Germline (Heritable) Genome Editing

Permit clinical research trials only for compelling purposes of treating or preventing serious disease or disabilities, and only if there is a stringent oversight system able to limit uses to specified criteria.

Enhancement

Do not proceed at this time with human genome editing for purposes other than treatment or prevention of disease and disability.

Encourage public discussion and policy debate with respect to somatic human genome editing for uses other than treatment or prevention of disease and disability.

Public Engagement

Public input should precede any clinical trials for an extension of human genome editing beyond disease treatment and prevention.

Ongoing reassessment and public participation should precede any clinical trials of heritable germline editing.

Incorporate public participation into the human genome editing policy process about “enhancement.”

When funding genome editing research, consider including research on strategies to improve public engagement and for long-term assessment of ethical, legal and social implications of human genome editing.