Position on Human Genome Editing

Johnson & Johnson recognizes that advances in scientific technology have led to the development of a growing number of tools available to expand our understanding of human biology and to prevent and treat disease and disability. Genome editing tools are among these promising methods. Yet, the technical ability to edit the human genome has raised complex legal, ethical and social issues for consideration. Consistent with Our Credo, international guidance, scientific and ethical consensus, and current legal frameworks, J&J established a committee to review and oversee the bioethical, legal and social implications of human genome editing.

Genome editing research shall apply practices ensuring scientific rigor, data integrity and reproducibility, adherence to applicable regulatory frameworks, and internal oversight. Research involving human pluripotent stem cells shall adhere to the current <u>J&J Position on Human Pluripotent Stem Cell Research</u>.

Clinical application of human genome editing remains an active area of research, and the technical capabilities continue to evolve. The regulatory and legal frameworks, and what is socially acceptable for clinical genome editing are inconsistent; what is permissible in one jurisdiction may not be in another.

J&J has established the following internal guidelines for when a clinical genome editing activity should be brought for discussion to the J&J specialized committee:

Does <u>NOT</u> Require Committee Consultation

Situations where genome editing is recommended for the treatment or prevention of disease or disability in adults, including most applications of *ex vivo* genome editing.

Requires Committee Consultation

Any situation where there is ambiguity about the intent, including, but not limited to:

- Most applications of fetal, neonatal and pediatric genome editing.
- Clinical application of in vivo genome editing where there may be heritable consequences, as these are not recommended by current international consensus.^{1,2,3}

Application

This Position is relevant for the Johnson & Johnson Family of Companies, as detailed in our <u>governance</u> <u>materials</u>. We provide updates, where relevant, relating to anti-corruption in our annual <u>Health for Humanity Report</u>. Johnson & Johnson's Policies and Positions on these and other issues are available in full here.

Last updated: August 2025

- ¹ WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. 2021. Human Genome Editing: A Framework for Governance. Geneva: World Health Organization.
- ² National Academy of Medicine, National Academy of Sciences, and the Royal Society. 2020. Heritable Human Genome Editing. Washington, DC: National Academies Press. https://doi.org/10.17226/25665. https://nap.nationalacademies.org/catalog/25665/heritable-human-genome-editing.
- ³ National Academies of Sciences, Engineering, and Medicine. 2023. Third International Summit on Human Genome Editing: Expanding Capabilities, Participation, and Access: Proceedings of a Workshop in Brief. Washington, DC: The National Academies Press. https://doi.org/10.17226/27066.

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