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POLICY BRIEF

Reviewing the Ethics of Genome Editing

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Why this policy brief on Ethics of Genome Editing?

Genome editing (GE) modifies an organism's DNA by adding, removing, or replacing specific sequences using programmed proteins or protein/RNA complexes. CRISPR/Cas-based systems are widely used for this purpose, enabling efficient and targeted changes across various organisms. This technique offers applications in research, medicine, agriculture, and industry, with potential for heritable alterations and species-wide changes through technologies like gene drives. Research Ethics Committees (RECs) face a number of challenges when reviewing research projects involving GE. This policy brief highlights three key issues and provides recommendations for risk mitigation, specifically targeting ethics experts and members of Research Ethics Committees (RECs).

Current challenges

1. Distinguishing between diffent sub-categories of GE

Ethical questions raised by different subcategories of GE can vary greatly. Ethics experts may have difficulty distinguishing between somatic and heritable GE, although international guidelines clearly establish this difference. Somatic GE involves altering the genes of specific cells or tissues within an individual, while heritable GE pertains to making genetic changes in germline cells. The distinction between research (seeking to improve knowledge) and treatment (seeking to cure a particular patient) is not consistently enforced either. Lack of in-depth consideration of these distinctions may lead REC members to hastily allow disproportionately risky research or, on the contrary, to unintentionally hinder communities and individuals from accessing practical medical advantages.

2. Lack of policy alignment between countries

Ethical and legal deliberations on genetic engineering have been taking place for a long time, leading to numerous policy guidelines often dating

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back years or decades. Practical relevance of these guidelines to new GE technologies might be low, yet they create significantly different regulatory environments for GE. This lack of policy alignment between countries could allow scientists to evade constraints established in their home jurisdictions by 'exporting' their research elsewhere.

3. The difficult distinction between therapy and enhancement

While the question of purpose is a major factor in ethical reflection on GE, it is often difficult to make a distinction between therapy and enhancement. GE for therapy involves modifying genetic material to correct or prevent specific diseases or medical conditions in individuals, aiming to restore normal function and health. GE for enhancement is the result of individual desire and focuses on altering genetic traits to go beyond existing human capabilities or traits (intelligence, physical strength, etc.). Desire-driven GE for enhancement poses a range of ethical and societal challenges (e.g. unintended consequences or social discrimination), yet the border between therapy and enhancement is difficult to define in many practical cases.

Recommendations

1. Consistently train ethics experts to distinguish between different subcategories and applications of GE

To improve competence and to formulate relevant and operational recommendations for researchers, ethics experts should be trained on complex use cases to evaluate the relevance and limits of projecting human qualities, including moral values, on non-human biological systems. This particularly applies to projects involving plants and animals. Anthropomorphic projections may remain relevant for projects involving GE in animals if there exist of foreseeable future applications in humans ('animal models'). Ethics evaluators should be trained to consistently distinguish the applications of GE to different types of biological systems (plants, animals, or humans), between the types of GE (heritable or not), and the types of cells involved (somatic cells, stem cells, embryonic stem cells). Further, ethics evaluators should be trained to reflect on the complexity of moral 'gray zones' in research projects operating at the therapy/enhancement frontier.

2. Case-by-case approach to gene drive experiments

For the test of gene drive technologies, risk assessments should be carried out and risk management measures put in place to minimize potential adverse environmental effects. These procedures should be devised on a case-by-case basis depending on the purpose of research and the type of GE involved. In particular, organizations seeking to release gene drive organisms should obtain 'free, prior, and informed consent' (FPIC) from potentially affected communities, including for tests in the Global South. REC members should also consistently evaluate the accessibility of GE technologies striving for fair benefit sharing.

3. Highlight policy differences between countries, including EU member states

Both human GE and GE in plants or animals are regulated at the national level as well as at the international level, resulting in a lack of policy alignment between countries. While it is unrealistic to achieve a common international homogenous policy framework, ethics experts should be aware of the differences and of the risk of ethics dumping. When evaluating research projects, they should - whenever possible - apply a unified standard science-based approach based on standard use cases. If important differences arise because of regulatory discrepancies, ethics experts should explicitly inform researchers and policy makers about such differences.

What is Genome Editing?

Genome editing (GE) strategically changes the DNA of an organism, introducing new traits or suppressing unwanted ones. With the development of new techniques and tools, GE is cheaper and more effective than ever.

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Further Reading

The WHO framework for human genome editing
Governance framework by the World Health organization
https://www.who.int/publications/i/item/9789240030060

Opinion on the ethics of genome editing
By the European Group on Ethics in Science and New Technologies, Directorate-General for Research and Innovation, European Commission
https://data.europa.eu/doi/10.2777/659034

Revising EU rules on gene editing
Article published in *Science* (July 2023)
https://www.science.org/content/article/european-commission-proposes-loosening-rules-gene-edited-plant

The Nuffield Council on Bioethics' guide to ethics of gene editing (UK)
https://www.nuffieldbioethics.org/assets/pdfs/Genome-editing-an-ethical-review.pdf

How we did it

This policy brief is based on research conducted in *Task 2.2: Development of recommendations for addressing ethical challenges from research in new technologies*. Using desk research, expert consultation and a leadership roundtable, irecs identified ethical issues in GE as well as challenges faced by REC members and ethics appraisal experts. Recommendations were drafted with iterative input from irecs partners. The Stakeholder Advisory Board gave feedback and a dedicated focus group was organized by EUA to discuss and refine the recommendations.

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About irecs

"Improving Research Ethics Expertise and Competencies to Ensure Reliability and Trust in Science"

irecs aims to advance research ethics expertise and competences in new and emerging technologies. The project will focus on 4 emerging technologies (AI in health and healthcare; Extended reality; Genome editing (human/non-human); Biobanking) and will develop, implement and disseminate training material for research ethics reviewers and (early career) researchers.

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