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Review of Ethics positions, reports,
documents published on gene editing by
other groups and institutions

Biotechnology. A prudent path forward for
genomic engineering and germline gene
modification

Baltimore D, Berg P, Botchan M, Carroll D, Charo RA, Church G, Corn JE, Daley GQ, Doudna JA, Fenner M, Greely HT, Jinek M, Martin GS, Penhoet E, Puck J, Sternberg SH, Weissman JS, Yamamoto KR.

**Biotechnology. A prudent path forward
for genomic engineering and germline
gene modification**

- Science. 2015 Apr 3;348(6230):36-8

Oviedo

Ratified by:

Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus,
Czech Republic, Denmark, Estonia, Finlandia, France, Georgia,
Greece, Hungary, Island, Latvia, Lithuania,
Montenegro, Norway, Portugal, Moldova, Romania,
San Marino, Serbia, Slovakia, Slovenia, Spain,
Switzerland, Macedonia, Turkey

Signed: Italy, Luxembourg, Netherlands, Poland, Sweden, Ukraine

Not signed: Andorra, Armenia, Austria, Azerbaijan,
Belgium, Germany, Ireland, Liechtenstein, Malta, Monaco
Russian Federation, United Kingdom,

Oviedo

- Article 13 – Interventions on the human genome
- An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Oviedo

Article 18 – Research on embryos in vitro

1 Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

2 The creation of human embryos for research purposes is prohibited. (Mitalipov paper)

Sykora and Caplan “The Council of Europe should not reaffirm the ban on germline genome editing in humans” EMBO Reports

European Parliamentary Assembly – 5 steps

Petra de Sutter – Oct. 12/ Recommendation 2015

- Member states should be urged to ratify the Oviedo Convention or at least implement ban on pregnancy with a modified embryo
- A broad and informed public debate should be fostered
- Council of Europe Committee on Bioethics should assess the ethical and legal challenges

European Parliamentary Assembly – 5 steps

- A common regulatory and legal framework should be developed
- Member states should develop a clear national position on use of new genetic technologies “setting the limits and promoting good practices”

European Group on Ethics in Science and New Technologies (former)

- Inclusive debate on “acceptability and desirability” extending to civil society not limited to safety issues, potential health risks and health benefits
- Dignity, justice, equity, proportionality and autonomy
- 3 different opinions in group: prohibit; continued research justified;

International Bioethics Committee

UNESCO - Report of the IBC on Updating
Its Reflection on the Human Genome and
Human Rights. 2015

Moratorium on germline editing

Worked for genetic engineering; not a good
idea – delay not a solution (our paper) ”not
appropriate to promote good research
practice and adequate safeguards”

Chneiweiss et al.

Fostering responsible research with genome editing technologies: a European perspective

Foster research to assess feasibility, efficacy & safety

Reassess ban on all germline modifications of the nuclear genome

Prevent hijacking by extremists (mitochondrial replacement!) , avoid misleading the public

Raise awareness on distinction between treatment and enhancement

INSERM

- Response to request by INSERM director to present, discuss and advise on issues...
- French/English
- A technical barrier is no more a response to an ethical question than technological success is an ethical blank check.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

REPORT

Human Genome Editing

**SCIENCE,
ETHICS,
AND
GOVERNANCE**

NATIONAL ACADEMY OF SCIENCES
NATIONAL ACADEMY OF MEDICINE

PDF] [Genome editing: an ethical review - Nuffield Bioethics](https://www.nuffieldbioethics.org/wp-content/uploads/Genome-editing-an-ethical-review.pdf)
[nuffieldbioethics.org/wp-content/uploads/Genome-editing-an-ethical-review.pdf](https://www.nuffieldbioethics.org/wp-content/uploads/Genome-editing-an-ethical-review.pdf)

Human Genome editing Science, ethics, and Governance

- absence of reasonable alternatives;
- restriction to editing genes that have been convincingly demonstrated to cause or strongly predispose to a serious disease or condition;
- credible pre-clinical and/or clinical data on risks and potential health benefits;

Human Genome editing Science, ethics, and Governance

- ongoing, rigorous oversight during clinical trials;
- comprehensive plans for long-term multigenerational follow-up; and
- continued reassessment of both health and societal benefits and risks, with wide-ranging, ongoing input from the public.

American Society of Human Genetics position statement

- Inappropriate to perform editing if culminates in pregnancy
- No reason to prohibit editing on human embryos and gametes
- Clinical application in future should not proceed unless a) compelling medical rationale b) evidence base supporting use c) ethical justification d) transparent public process

European Academies Science Advisory Council

- **Genome editing: scientific opportunities, public interests and policy options in the European Union**
- Basic and clinical research should proceed
- **Germline interventions “It would be irresponsible to proceed unless and until the relevant scientific, ethical, safety and efficacy issues have been resolved and there is broad societal consensus”**

Deutscher Ethikrat

- Keimbahneingriffe an menschlichen Embryo: Deutscher Ethikrat fordert globalen politischen Diskurs und internationale Regulierung
- Discussion in United Nations suggested
- Comment on NAS/NAM – from do not allow until risks are better understood to allow when they can be evaluated better

Human Genome Surgery

- Berlin-Brandenburg Academy of Sciences and Humanities – English and German
- Call for debate which is to lead to broader social discussion

Federation of European Academies of Medicine

- Human Genome Editing in the EU

HUGO Committee of Ethics, Law and Society

Ethical issues of CRISPR Technology and
gene editing through the lens of solidarity

Restraint on experimentation on human
germ cells

Leopoldina

- The opportunities and limits of genome editing German/English
- “It must be clear under what circumstances intervention in the germline is acceptable”
- Moratorium on all forms of human genome engineering that could have an impact on the genome of the offspring

Schweizer Ethikrat

- Short document in German
- Divided – maintain ban on germline editing, reflect on need for continuing a moratorium, and allow work on germline editing

Italian

- Public debate including not only technical problems but also ethical consequences of introducing germline modifications;
- Divided on whether research on embryos/gametes should take place

Hinxton group

- Value of basic scientific research
- Prospect of human genome editing for reproductive purposes
- 3 categories of embryos (non-viable, supernumerary, created for the experiment)
- International and regional debate required
- Justice, equity
- Governance, meaningful engagement

Opinion Group of the Bioethics and Law Observatory, University of Barcelona

- Declaration on Bioethics and Gene Editing in Humans (December 2016)
- De Lecuona et al. Gene Editing in Humans: Towards a Global and Inclusive Debate for Responsible Research (Yale Journal of Biology and Medicine 90(2017)673.) – review of several documents

Human germline gene editing: Recommendations of ESHG and ESHRE

:

- de Wert G, Pennings G, Clarke A, Eichenlaub-Ritter U, van El CG, Forzano F, Goddijn M, Heindryckx B, Howard HC, Radojkovic D, Rial-Sebbag E, Tarlatzis BC, Cornel MC; European Society of **Human** Genetics and the European Society of **Human** Reproduction and Embryology. Eur J Hum Genet. 2018 Jan 12. doi: 10.1038/s41431-017-0076-0.

Human germline gene editing: Recommendations of ESHG and ESHR
E.

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-

One small edit for humans, one giant edit for humankind.

- **Howard et al. on behalf of Public and Professional Policy Committee of the ESHG; Eur. Journal of Human Genetics (2018) 26:1-11**
- **Conducting careful scientific research and disseminating results**
- **ELSI research**
- **„meaningful stakeholder research, education and dialogue”**

OECD report.

March 22, 2018

„Gene editing in an international context
Scientific, economic and social issues
across sectors”

What must be addressed

How to engage the public in a discussion

GENETIC ALLIANCE UK/Progress Educational Trust/Wellcome – Basic understanding of genome editing

Media

What about the germline? – Oviedo

Ethical trials – watch for several generations? (Cwik, NEJM)

Acceptability of germline interventions (Church, 2017; Steffann et al., 2018)

How to do GLOBAL regulation ?????

Nature March 22, 2018

Editorial – How to get public engagement right

3 interesting publications:

1) A global observatory for gene editing

Sheila Jasanoff and J. Benjamin Hurlbut call for an international network of scholars and organizations to support a new kind of conversation.

Nature March 22, 2018

2) Rethink public engagement for gene editing

The breadth of social and moral questions raised requires a new architecture for democratic debate, insists Simon Burall.

Nature March 22, 2018

3) How human embryonic stem cells sparked a revolution

After 20 years of hope, promise and controversy, human embryonic stem cells are reshaping biological concepts and starting to move into the clinic.

David Cyranoski