Editorial governance in germline gene editing

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Editor-in-Chief, *Nature* and Nature publications

Academies summit, Washington DC 2 December 2015

The editorial landscape

In research publishing:

- Thousands of journals published by private for-profit companies, not-for-profit organisations, and learned societies funded by government and/or members.
- Within these organisations are internal and external – usually academic – editors and Editors-in-Chief.
- Editors-in-Chief make the final decisions as to what to publish. They have substantial freedom - ‘editorial independence’ is a key principle – but they are accountable to readerships and authorships and reviewers, who can vote with their feet.

The editorial landscape (cont.)

In research publishing:

- There are ways in which editorial norms are developed – see later.
- Editorial collaborations between journals and publishers include policies for dual-use assessment, reproducibility, data-access, author contributions reporting, peer review cascades…. By and large, editors do not use these axes competitively.

Some journals, in effect assisting governance, also use non-research content to deliberately foster discussion within and beyond the global research community…….

SPECIAL

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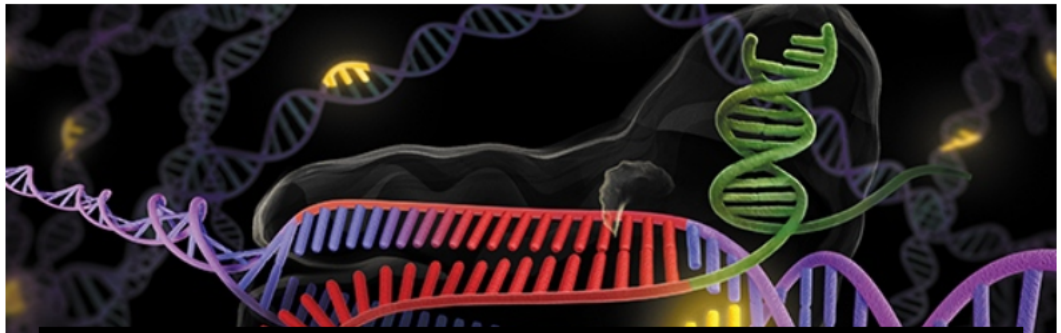

CRISPR: THE GOOD, THE BAD AND THE UNKNOWN

A DNA-editing technology called CRISPR has rapidly become one of the most popular ways to alter genomes. Concerns about its risks temper excitement about its usefulness. It has already been used to modify human embryos, and the technology could alter wild animal populations; it works in everything from wheat to mice. *Nature* brings together research, reporting and expert opinion on gene-editing and its implications.

Image credit: K.C. Roeyer

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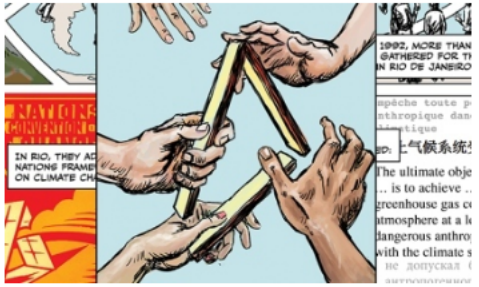
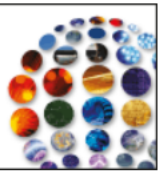
Climate comic



The fragile framework

The 25-year quest for a climate treaty. Can nations unite to save Earth's climate?



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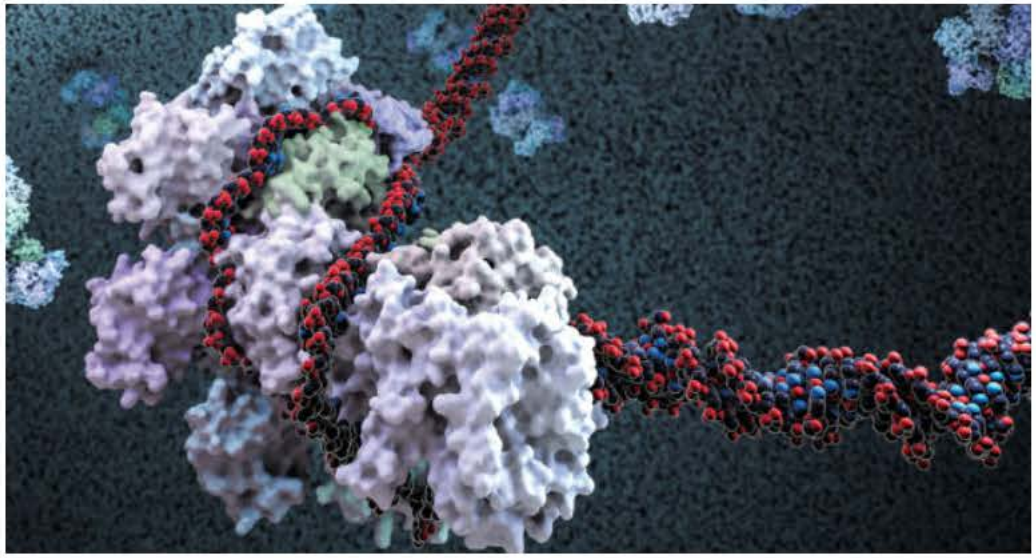


Val Altounian/*Science*

Precision gene editing paves way for transgenic monkeys

Despite political challenges, engineered primates could be better disease models than mice.

Nature (06 November 2013)

COMMENTARY

CRISPR: A path through the thicket

As various advisory bodies, scientific organizations and funding agencies deliberate on genome editing in humans, Debra J. H. Mathews, Robin Lovell-Badge and colleagues lay out some key points for consideration.

Nature (10 November 2015)

CRISPR: Science can't solve it

Democratically weighing up the benefits and risks of gene editing and artificial intelligence is a political endeavour, not an academic one, says Daniel Sarewitz.

Nature (23 June 2015)

Regulate gene editing in wild animals

The use of genome-modification tools in wild species must be properly governed to avoid irreversible damage to ecosystems, says Jeantine Lunshof.

Nature (12 May 2015)

CRISPR germline engineering — the community speaks

Nature Biotechnology talks to 26 influential researchers about the ethics of genetically editing human reproductive cells.

Nature Biotechnology (12 May 2015)

Don't edit the human germ line

Heritable human genetic modifications pose serious risks, and the therapeutic benefits are tenuous, warn Edward Lanphier, Fyodor Urnov and colleagues.

Nature (12 March 2015)

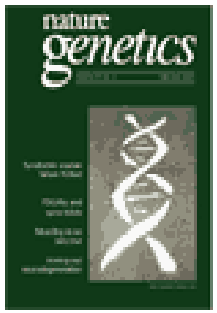
RESEARCH FROM NATURE JOURNALS

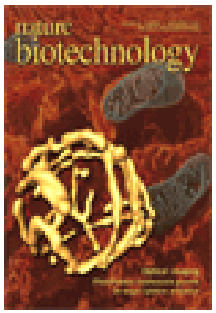
Criteria that influence editors

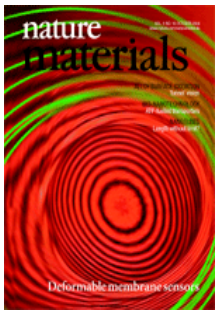
- Significance of resource or insight
- Significance of application
- Ethical integrity
- Technical integrity
- Community or societal norms

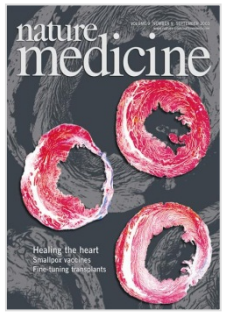
Nature & Nature research journals

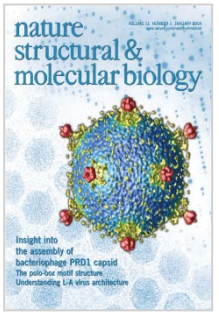
(The print versions - *Nature Plants*, *Nature Energy*, *Nature Microbiology* are online only)

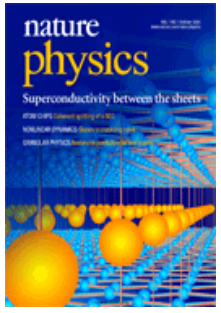


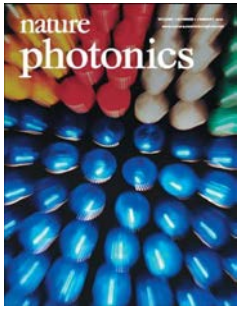












Internal discussions that influence Nature group editors

- *Nature* and Nature-journal staff editors have always had the final say over what their journal publishes, informed by referees' advice.
- Each journal is editorially independent, but subject to group policy.
- Journal teams discuss their manuscripts.
- Multi-journal subject groups meet regularly to discuss scientific trends and standards.
- Internal policy forum including journal Chief Editors, Head of Editorial Policy, Editor-in-Chief (who has final sign-off on policy)
- Human germline editing policy review group

External processes that influence editors, Nature group included

- Community discussions eg Hinxton, ISSCR, academies
- Committee on Publication Ethics (which focuses on the ethical decisions within the publishing processes, eg on handling misconduct and retractions)
- Proactive informal discussions with researchers, funders and editors of other publications.
- Formal discussions eg in National Scientific Advisory Board for Biosecurity (NSABB)
- Discussions in journals and blogs

Nature group's public policy on human germline editing

- In deciding whether to publish papers describing modifications of the human germline, we will be guided by safety considerations, compliance with applicable regulations, as well as the status of the societal debate on the implications of such modifications for future generations.
- We have established an editorial monitoring group to oversee the consideration of these concerns. (The monitoring group includes the Editor-in-Chief of Nature publications, the Nature Editorial Director, the Head of Editorial Policy, Nature Journals and the Executive Editor, Life Sciences.)
- **This group will also seek advice from regulatory experts to ensure that the study was conducted according to the relevant local and national regulations.**
- **In this evaluation, we will be strongly guided by the guidance issued by the International Society for Stem Cell Research: Guidelines for the Conduct of Human Embryonic Stem Cell Research (http://www.isscr.org/home/publications/guide-clintrans).**
- Regulatory advice will usually be sought in parallel with the technical peer review process. As always, the decision whether to publish the paper is the responsibility of the Chief Editor of the Nature journal concerned.

Nature group's experience of human germline editing papers

- Individual submissions are confidential
- Several papers received by several journals
- All so far rejected either because of technical inadequacies or because of non-compliance with local regulations or both.

Required: compliance with local regulations

- Regulations vary between regions, so we may publish a paper from one country which we would reject from another, or from a company which we would reject from a government-funded lab.
- Eg derivation of embryos for research: regulations vary between countries
- Co-authorship may involve several regions with varying regulations – author contributions are relevant.
- Need local ethical expertise to ensure compliance and that the appropriate committees have given approval.

Editors are not in a societal or research community vacuum

- We have consistently advocated public inclusiveness in the setting of societal framings and goals within which science is supported and regulated. So the outcome of such a discussion will have a substantial influence on our thinking.

- And where there is a clear set of standards established by a community, we will respect them. The evolving ISSCR guidelines and prohibitions are particularly important.

What might independence require of editors?

- Community discussions and consensus' are important but may be outpaced by developments in the science or technology or their context. Thus a submitted paper may use HGE in a way that goes beyond the consensus in unanticipated ways.
- Editors will always seek advice, but the ultimate decision may involve editors going beyond the boundaries of the HGE consensus (without breaching laws or long-established fundamental guidelines), ie reaching our/their own scientific and ethical judgement as to what to publish.

Where have we had to take our own decision amidst researcher and societal debate?

Example: H5N1 flu gain-of-function – initial advice of NSABB against full publication

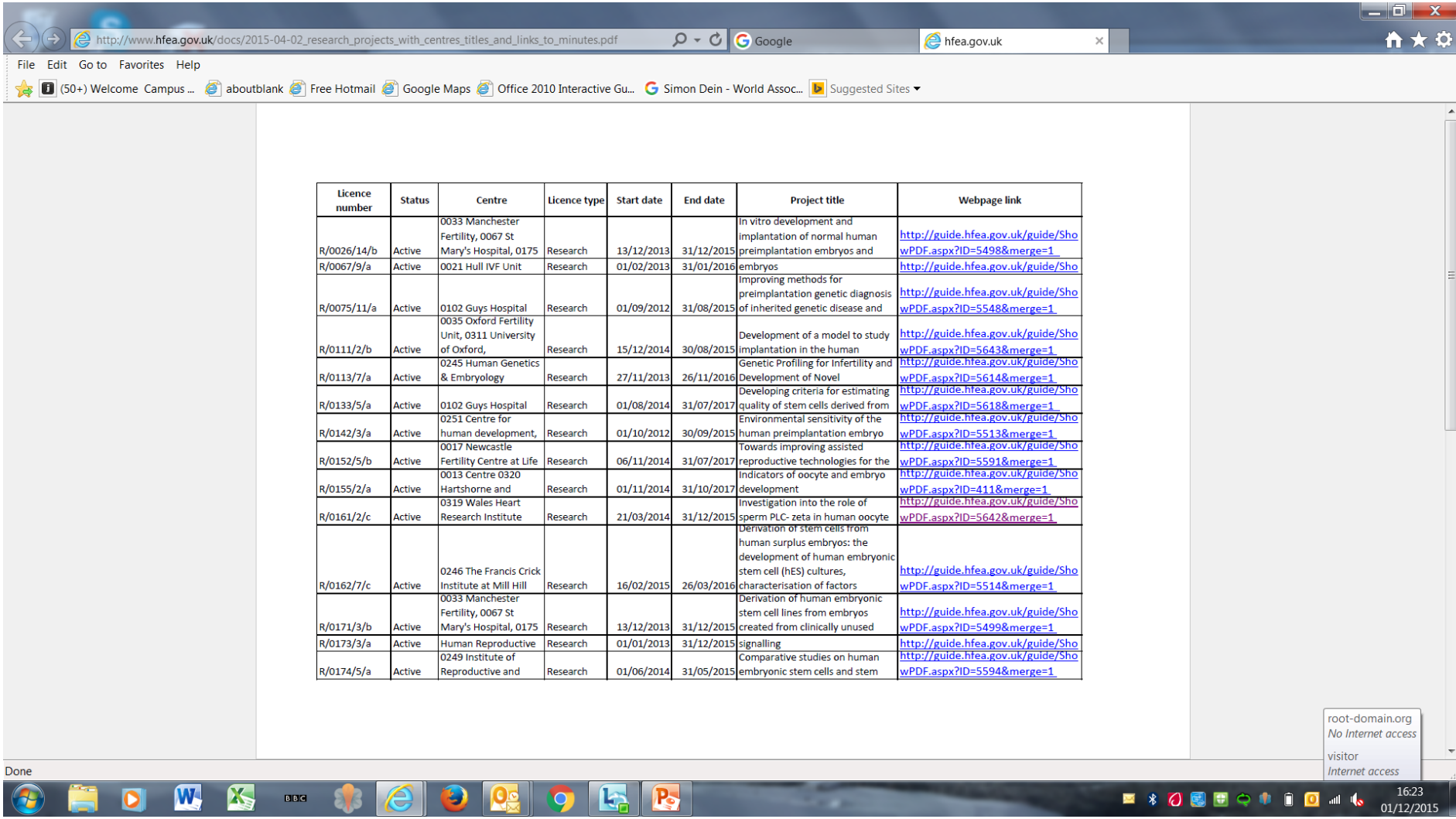
We eventually decided that we would publish the outcomes of gain-of-function flu research without redaction.

Given the differences of opinion within and around NSABB, we might well have decided to publish if the NSABB had advised against, not least because our own dual-use biosecurity procedures (which are exactly analogous to our HGE ethical process) had unequivocally advised in favour.

What do I hope for in the academies' deliberations?

- Inclusiveness from the outset in societal input, including attention to clinical potential, alternative treatments, disability/ability perspectives and social justice.
- An assessment of predictability of intergenerational impacts of interventions, and case studies of genetic risks and benefits.
- An explicit formulation of whether/how the interests of future generations are to be accounted for, in place of informed consent.
- Some sort of moratorium seems the only way to give due respect to the discussions that are needed.
- And in the meantime, for relevant experiments,…..

…transparency of experiments, licensing, and consent (eg UK HFEA)



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Licence number	Status	Centre	Licence type	Start date	End date	Project title	Webpage link
R/0026/14/b	Active	0033 Manchester Fertility, 0067 St Mary's Hospital, 0175	Research	13/12/2013	31/12/2015	In vitro development and implantation of normal human preimplantation embryos and	http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5498&merge=1
R/0067/9/a	Active	0021 Hull IVF Unit	Research	01/02/2013	31/01/2016	embryos	http://guide.hfea.gov.uk/guide/Sho
R/0075/11/a	Active	0102 Guys Hospital	Research	01/09/2012	31/08/2015	Improving methods for preimplantation genetic diagnosis of inherited genetic disease and	http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5548&merge=1
R/0111/2/b	Active	0035 Oxford Fertility Unit, 0311 University of Oxford,	Research	15/12/2014	30/08/2015	Development of a model to study implantation in the human	http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5643&merge=1
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R/0152/5/b	Active	0017 Newcastle Fertility Centre at Life	Research	06/11/2014	31/07/2017	Towards improving assisted reproductive technologies for the	http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5591&merge=1
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R/0162/7/c	Active	0246 The Francis Crick Institute at Mill Hill	Research	16/02/2015	26/03/2016	Derivation of stem cells from human surplus embryos: the development of human embryonic stem cell (hES) cultures, characterisation of factors	http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5514&merge=1
R/0171/3/b	Active	0033 Manchester Fertility, 0067 St Mary's Hospital, 0175	Research	13/12/2013	31/12/2015	Derivation of human embryonic stem cell lines from embryos created from clinically unused	http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5499&merge=1
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