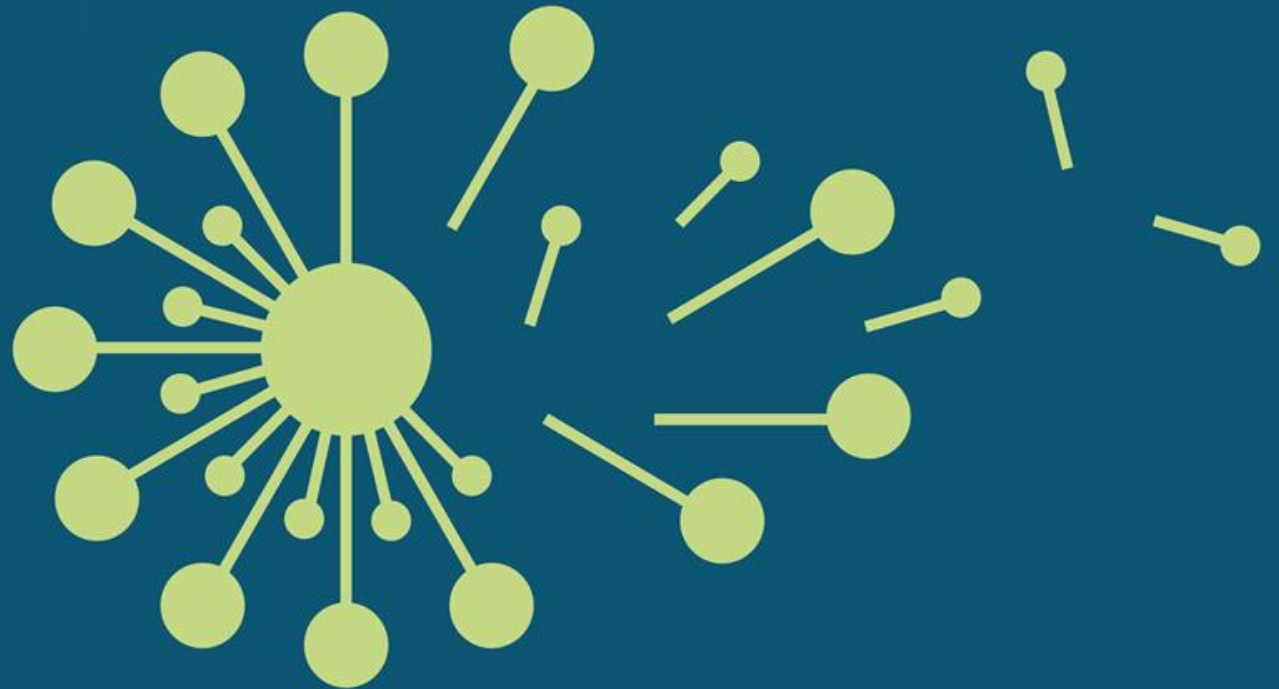


The garden of forking paths : *current regulation and implications of the Nuffield approach in the UK*

Pete Mills

Nuffield Council on Bioethics (UK)





OCTOBER 17-18, 2002
MEETING AGENDA

Hotel Monaco
700 F Street, NW
Washington, D.C. 20002

FRIDAY, OCTOBER 18

- 8:30 am Session 5: Regulation 8: International Models (United Kingdom).
Baroness Helena Kennedy QC, Chair, Human Genetics Commission (HGC).
- 10:00 am Break
- 10:20 am Session 6: Regulation 9: International Models (United Kingdom).
Suzi Leather, Chair, Human Fertilisation and Embryology Authority (HFEA).
- 11:50 am Break
- Noon Session 7: Regulation 10: General Discussion.
- 1:00 pm Adjournment

The President's Council on Bioethics

[Home](#) [Site Map](#) [Disclaimers](#) [Privacy Notice](#) [Accessibility](#) [NBAC](#) [HHS](#)





Why do we keep asking the wrong questions?

*'Why do we need germ
line genome editing?'*





MIT ON
TING

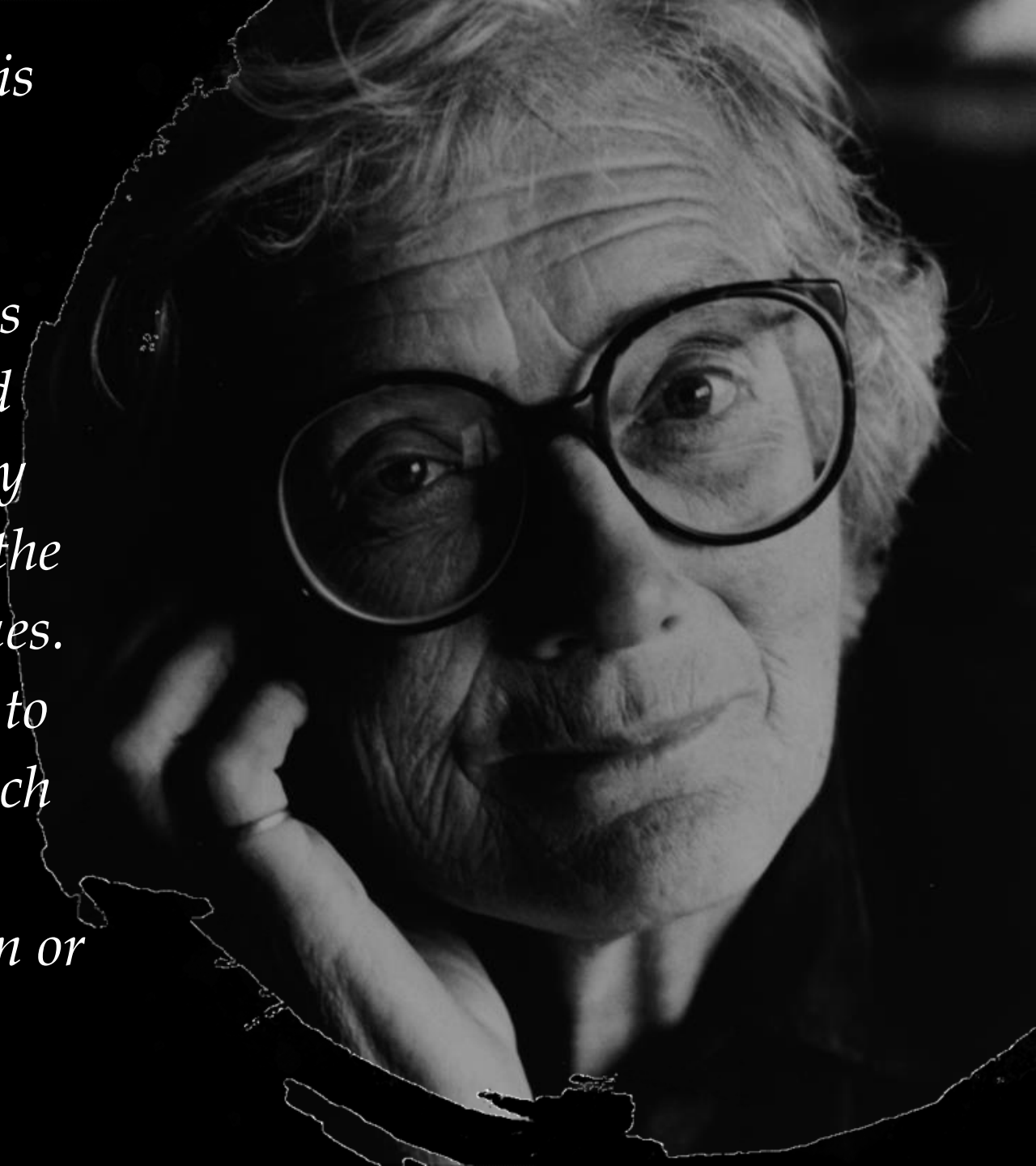
Convened by

OF MEDICINE

*'What might we do with
germ line genome
editing?'*

"...it would be idle to pretend that there is not a wide diversity in moral feelings, whether these arise from religious, philosophical or humanist beliefs. What is common (and this, too we have discovered with germ line genome editing) is that people generally edit principles or other to govern the development and use of the new techniques. There must be some barriers that are not to be crossed, some limits fixed, beyond which people must not be allowed to go. Nor is such a wish for containment a mere whim or fancy. The very existence of morality depends on it."

—Warnock Report (1984)



PETE



Human Fertilisation and Embryology Act 1990

CHAPTER 37

LONDON: HMSO

£5.85 net



Human Fertilisation and Embryology Act 1990

CHAPTER 37

ARRANGEMENT OF SECTIONS

Principal terms used

- Section
1. Meaning of "embryo", "gamete" and associated expressions.
 2. Other terms.

Activities governed by the Act

3. Prohibitions in connection with embryos.
4. Prohibitions in connection with gametes.

The Human Fertilisation and Embryology Authority, its functions and procedure

5. The Human Fertilisation and Embryology Authority.
6. Accounts and audit.
7. Reports to Secretary of State.
8. General functions of the Authority.
9. Licence committees and other committees.
10. Licensing procedure.

Scope of licences

11. Licences for treatment, storage and research.

Licence conditions

12. General conditions.
13. Conditions of licences for treatment.
14. Conditions of storage licences.
15. Conditions of research licences.

Grant, revocation and suspension of licences

16. Grant of licence.
17. The person responsible.
18. Revocation and variation of licence.
19. Procedure for refusal, variation or revocation of licence.



Code of practice

8th Edition

Edition 8.0
 First published October 2009
 Revised April 2010, April 2011,
 October 2011, April 2012,
 October 2013, October 2014,
 April 2015, October 2015, July
 2016, May 2017, October 2017

Human Fertilisation and
 Embryology Authority
 10 Spring Gardens
 London
 SW1A 2BU
 t. 020 7291 8200
 e. enquiries@hfea.gov.uk
 w. www.hfea.gov.uk

www.hfea.gov.uk

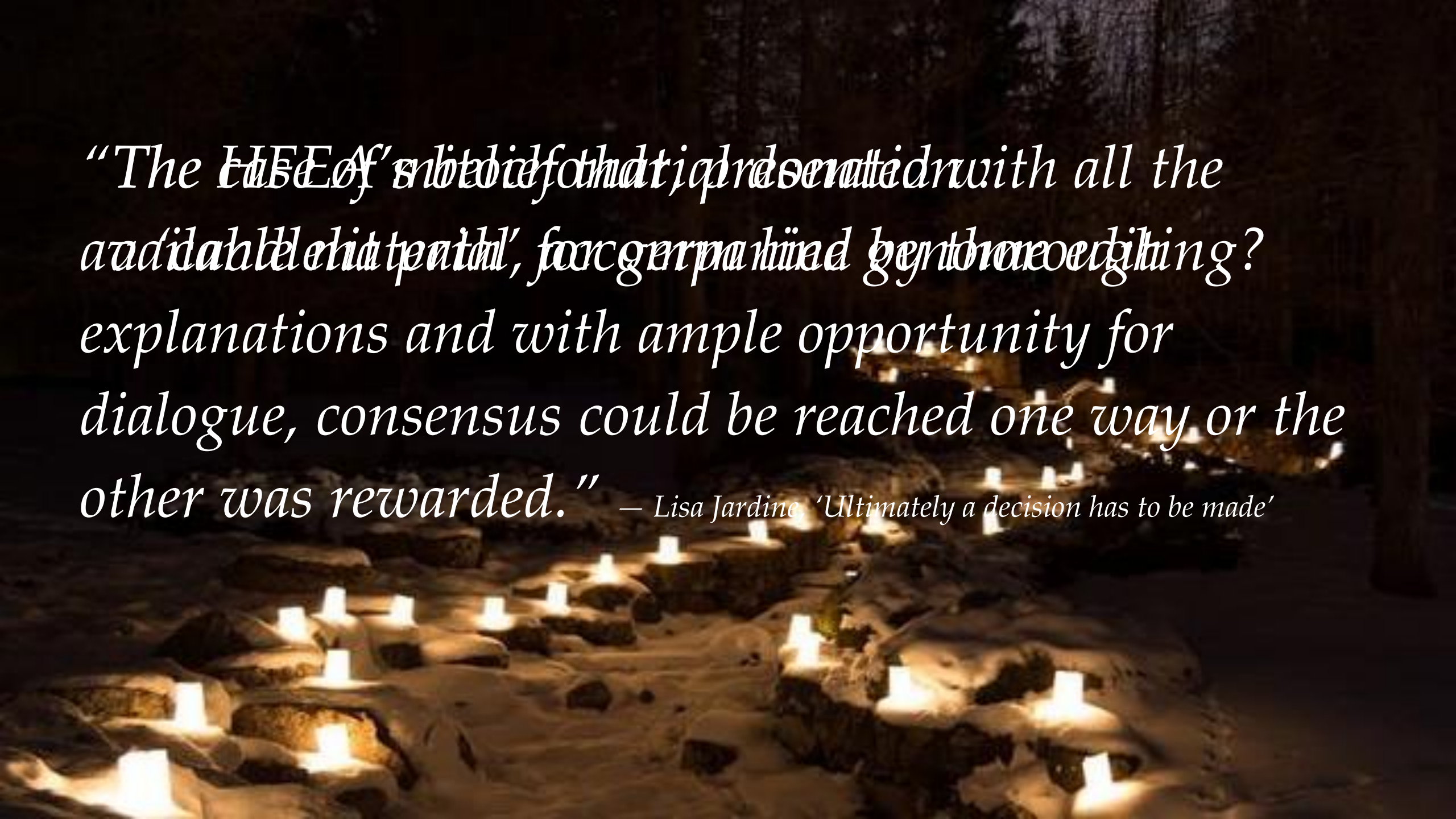
Contents (Version 7.0)

Human Fertilisation and Embryology Authority 13

Contents

Version 7.0

User guide	15
Regulatory principles for licensed centres	16
1. Person Responsible	19
2. Staff	23
3. Counselling	30
4. Information to be provided prior to consent	35
5. Consent to treatment, storage, donation, training and disclosure of information	41
6. Legal parenthood	63
7. Multiple births	91
8. Welfare of the child	94
9. Preimplantation genetic screening (PGS)	98
10. Embryo testing and sex selection	101
11. Donor recruitment, assessment and screening	112
12. Egg sharing arrangements	128
13. Payments for donors	136
14. Surrogacy	140
15. Procuring, processing and transporting gametes and embryos	145
16. Imports and exports	155
17. Storage of gametes and embryos	160
18. Witnessing and assuring patient and donor identification	176
19. Traceability	185
20. Donor assisted conception	189



"The ~~EE~~ of ~~en~~ ~~to~~ ~~ie~~ ~~fo~~ ~~th~~ ~~at~~ ~~i~~ ~~q~~ ~~u~~ ~~a~~ ~~r~~ ~~e~~ ~~s~~ ~~e~~ ~~r~~ ~~a~~ ~~t~~ ~~e~~ ~~d~~ ~~r~~ ~~w~~ ~~i~~ ~~t~~ ~~h~~ ~~a~~ ~~n~~ ~~d~~ ~~a~~ ~~n~~ ~~d~~ ~~a~~ ~~b~~ ~~l~~ ~~e~~ ~~h~~ ~~i~~ ~~t~~ ~~p~~ ~~e~~ ~~n~~ ~~t~~ ~~a~~ ~~n~~ ~~d~~ ~~f~~ ~~o~~ ~~r~~ ~~g~~ ~~e~~ ~~n~~ ~~e~~ ~~r~~ ~~a~~ ~~n~~ ~~n~~ ~~e~~ ~~d~~ ~~g~~ ~~e~~ ~~n~~ ~~t~~ ~~r~~ ~~e~~ ~~e~~ ~~d~~ ~~i~~ ~~n~~ ~~g~~ ~~?~~ explanations and with ample opportunity for dialogue, consensus could be reached one way or the other was rewarded." — Lisa Jardine, 'Ultimately a decision has to be made'

“Over the period of the consultation, both the expert groups and the general public moved from risk-averse anxiety to a clearly-expressed view that the benefits of mitochondrial replacement treatment, in allowing couples to avoid bearing children with



Wellcome Trust @wellcometrust · 3 Feb 2015

Brilliant day for British science. MPs vote in support of mitochondrial donation (382-128). Great news for @mitcresearch & @4lilyfoundation.

13

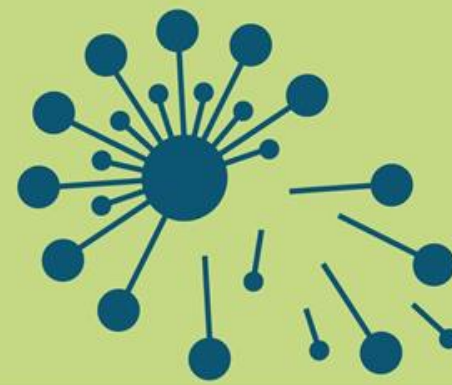
116

61

positions about any treatment involving human embryos came increasingly to look like outliers. They were not, of course, ignored, but were put in perspective by the increasingly steady assent of widely differing sectors of the community.”

— Lisa Jardine, ‘Ultimately a decision has to be made’

genome editing : *regulatory approaches in the UK*



NUFFIELD
COUNCIL ON
BIOETHICS

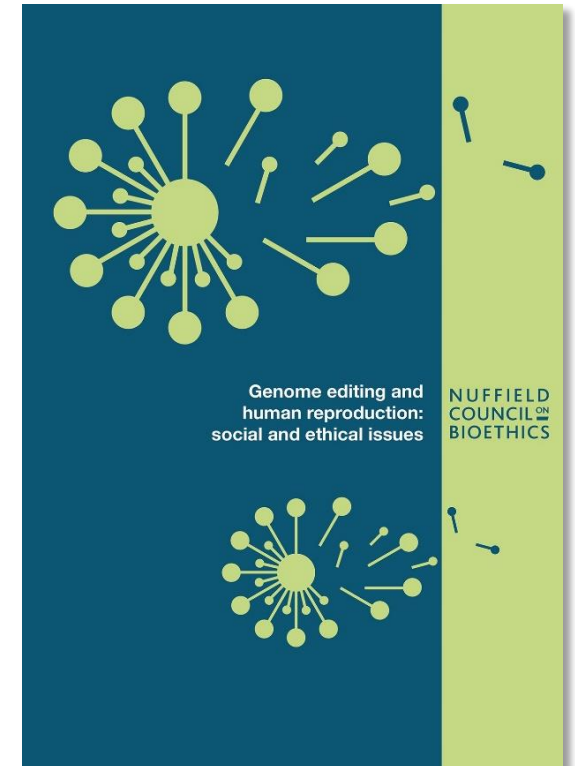
Nuffield Council on Bioethics (2018)

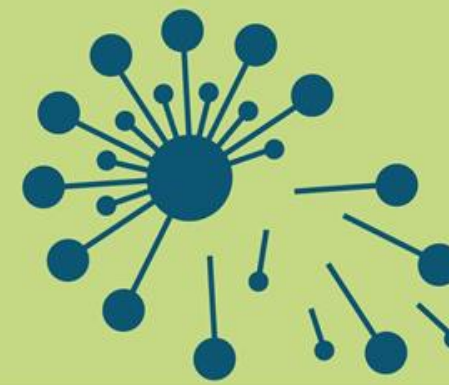
Principle 1: The welfare of the future person

Gametes or embryos that have been subject to genome editing procedures (or that are derived from cells that have been subject to such procedures) should be used only where the procedure is carried out in a manner and for a purpose that is intended to secure the welfare of and is consistent with the welfare of a person who may be born as a consequence of treatment using those cells.

Principle 2: Social justice and solidarity

The use of gametes or embryos that have been subject to genome editing procedures (or that are derived from cells that have been subject to such procedures) should be permitted only in circumstances in which it cannot reasonably be expected to produce or exacerbate social division or the unmitigated marginalisation or disadvantage of groups within society.





Nuffield Council on Bioethics (2018)

Recommendations for UK Government

Recommendation 3 We recommend that, before any move is made to amend UK legislation in order to permit heritable genome editing interventions, there should be sufficient opportunity for a broad and inclusive societal debate

Recommendation 4 We recommend that, without awaiting the opportunity for a thoroughgoing review of the framework legislation, the Secretary of State for Health and Social Care should give consideration to bringing within the scope of licensing any heritable genome editing interventions that currently fall outside that scope

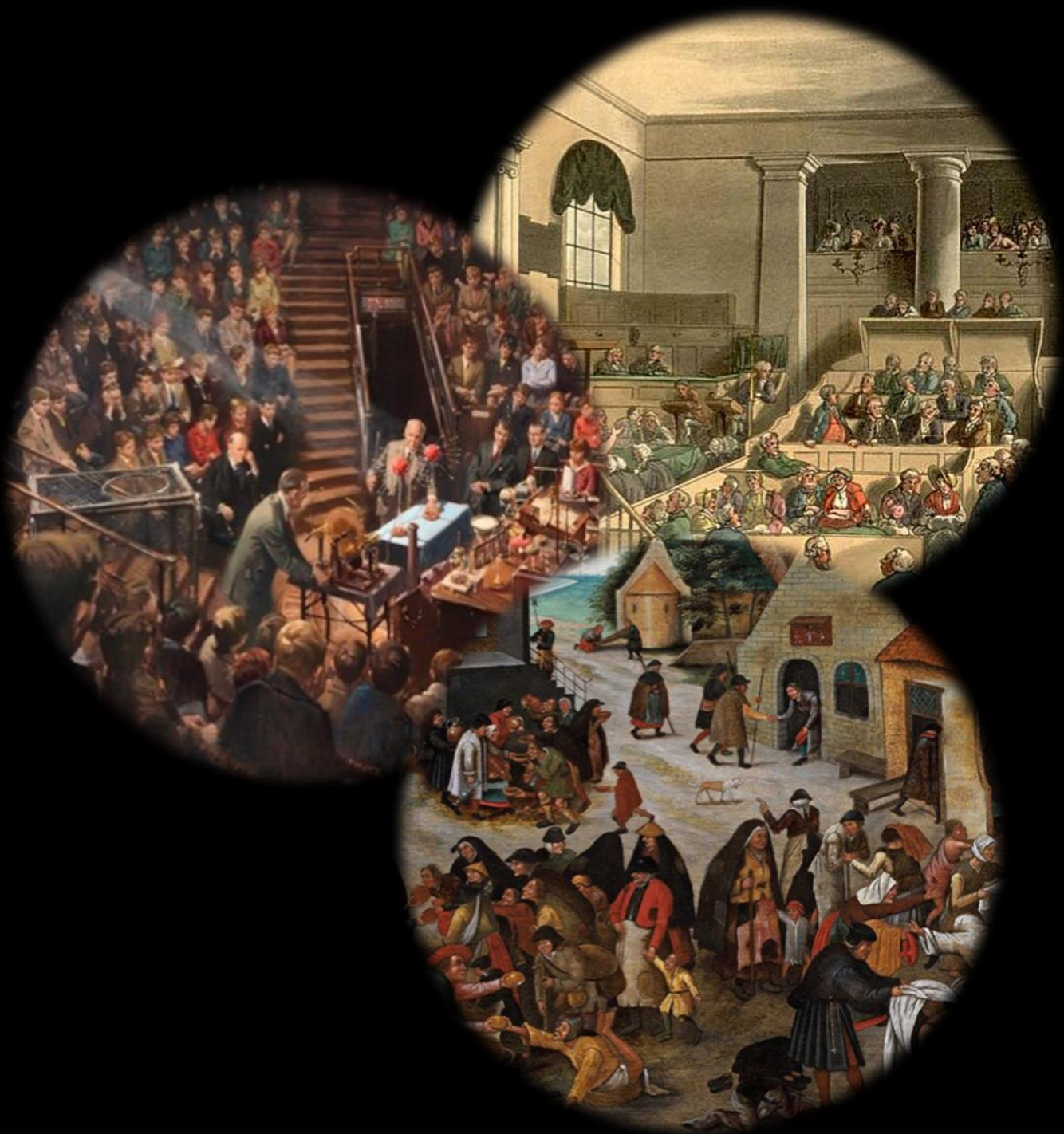
Recommendation 5 We recommend that heritable genome editing interventions should be permitted only provided that the impact on those whose vulnerability to adverse effects (including stigmatisation and discrimination) might thereby be increased has been assessed and mitigated (and, in any case, not without open and inclusive consultation with people in those positions)

Recommendation 6 We recommend that heritable genome editing interventions should only be permitted provided that arrangements are in place to monitor the effects on those whose interests may be collaterally affected and on society more generally, and provided that legitimate and effective mechanisms are in place to redress those effects and to revise relevant policy; this should include a clear regulatory measure to trigger a moratorium and a sunset provision, requiring review and an affirmative resolution to permit the practice to continue

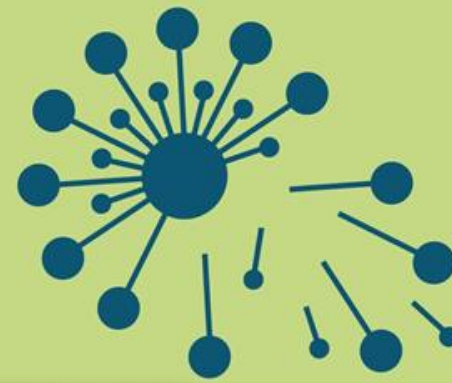
Recommendation 7 We recommend that consideration should be given to the establishment of a separate body or commission in the UK, independent of Government and independent of existing regulatory agencies, which would have the function of helping to identify and produce an understanding of public interest(s) through promotion of public debate, engagement with publics and monitoring the effects of relevant technological developments on the interests of potentially marginalised subjects and on social norms

*Governance as
ecology :*

*three venues of
'geo-ethics'*






genome editing : *regulatory approaches in the UK*



NUFFIELD
COUNCIL ON
BIOETHICS

Thank you.

-  www.nuffieldbioethics.org
-  [@nuffbioethics](https://twitter.com/nuffbioethics)
-  nuffieldbioethics.org/blog
-  pmills@nuffieldbioethics.org

