

INSERM

FOSTERING RESPONSIBLE RESEARCH WITH CRISPR- Cas9

External Experts Meeting

March 16th, 2016

Biopark, Paris

The Position of the Nuffield Council on Bioethics

Pete Mills, Assistant Director



Exploring ethical issues in biology and medicine

www.nuffieldbioethics.org

Terms of reference

1. To identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern
2. To make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion;
3. To publish reports; and to make representations, as the Council may judge appropriate.



The Nuffield Council



“We are a bioethics council, not a council of bioethicists.”

— Professor Albert Weale, former Chair



Genome editing: opening gambits

- **Don't rock the boat** (don't carry out research on human embryos, e.g. Lanphier, E. *et al. Nature* **519**, 410–411 (12 March 2015))
- **Self-denying ordinance** (voluntary moratorium on clinical use of human embryos, e.g. Baltimore D. *et al. Science* 19 March 2015; ISSCR 27 April 2015)
- **Control via funding** (of research on human embryos, e.g. NIH, 29 April 2015)
- **Formal moratorium with oversight** (UNESCO IBC)
- **A 'global consensus' or 'go-it-alone'?** (Hinxton Group, September 2015? *Nature Biotechnology* **33**(5): 478-486, May 2015; NAS/NAM?; Liang *et al. Protein & Cell* **6**(5): 363-72, May 2015)
- **Proceed with caution** (UK research organisations, 2 September 2015; NAS/RS/CAS Global summit, 3 December 2015)
- **A 'starting point' for democratic debate** (Council of Europe Bioethics Committee, 3 December 2015)

Germ line modification: an area of global consensus?

- Structural integrity of the ‘human genome’
- Integrity of lines of descent/ inheritance

“The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity” (Universal Declaration on the Human Genome and Human Rights, Art.1)

“In the fields of medicine and biology...the prohibition of eugenic practices, in particular those aiming at the selection of persons” must be respected (EU Charter of Fundamental Rights, Art.3(2))

“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 Convention, Art. 13)



Human germ line modification lawful in UK

“We feel that it is appropriate to call PNT and MST ‘germline therapies’ because they would have germline effects.” (NCoB, June 2012)

Although...

“...genetic modification involves the germ-line modification of nuclear DNA (in the chromosomes) that can be passed on to future generations.”

(Earl Howe, *Hansard*, 5 February 2015)

Draft Regulations laid before Parliament under section 45(4) of the Human Fertilisation and Embryology Act 1990, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2015 No. 0000

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015

Made - - - - -
Coming into force - - - - - 29th October 2015

These Regulations are made by the Secretary of State in exercise of the powers conferred by sections 3ZA(5) and (6), 31ZA(2)(a), 35A and 45(1) and (3A) of the Human Fertilisation and Embryology Act 1990(a).

A draft of this instrument has been approved by resolution of each House of Parliament pursuant to section 45(4) of that Act.

PART 1 Introductory Provisions

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 and shall come into force on 29th October 2015.

Interpretation

2.—(1) In these Regulations “the Act” means the Human Fertilisation and Embryology Act 1990.

(2) In these Regulations “polar body nuclear DNA” means any nuclear DNA located in a polar body.

(3) In these Regulations a reference to the removal of any nuclear DNA (including polar body nuclear DNA) includes a reference to the removal of any material which is necessarily removed along with that DNA, and such material may include any associated organelles.

(4) For the purposes of these Regulations, the following are to be treated as removed from an egg—

(a) 1990 c. 37. Sections 3ZA(5) and (6), 31ZA(2)(a), 35A and 45(3A) were inserted by sections 3(3), 24, 26 and 30 of the Human Fertilisation and Embryology Act 2008 (c. 23) (“the 2008 Act”). Section 3ZA(6) is cited for the meaning of “prescribed”.



Three kinds of question

1. What is the basis of public interest in different uses of genome editing (and to what extent does this apply to *research*)?
 - momentum; mission creep; slippery slope
2. How can we delineate what is unacceptable (should be prohibited) / acceptable (should be permitted) / desirable (should be promoted)
 - somatic/germline; prevention/preference; therapy/enhancement
3. What is the appropriate jurisdiction?
 - global consensus? nation state? republic of science?



Emerging approaches

- **Trust the scientists?** (e.g. George Church, “Gene editing: Bring it on,” *New Scientist*, 26 September 2015)
- **Trust the market?** (e.g. Steven Pinker, “The moral imperative for bioethics”, *Boston Globe*, 1 August 2015)
- **Trust the law?** (e.g. Council of Europe, statement of 3 December 2015)
- **Trust the public?** (e.g. Jasanoff, Sheila, J. Benjamin Hurlbut, and Krishanu Saha. "CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation." *Issues in Science and Technology* 32, no. 1 (Fall 2015).)



Nuffield genome editing project

Two part project:

- Core working group – ‘platform’ report (→ mid 2016)

Part 1 will address conceptual and descriptive issues relating to the impact of genome editing technology, and the prioritisation of issues for consideration

- One or more ‘applications’ working parties (→ end 2016/early 2017)

Part 2 will address practical and normative issues for a particular domain of problems (e.g. control of insect disease vectors, organ (xeno)transplantation, avoidance of inherited disease)

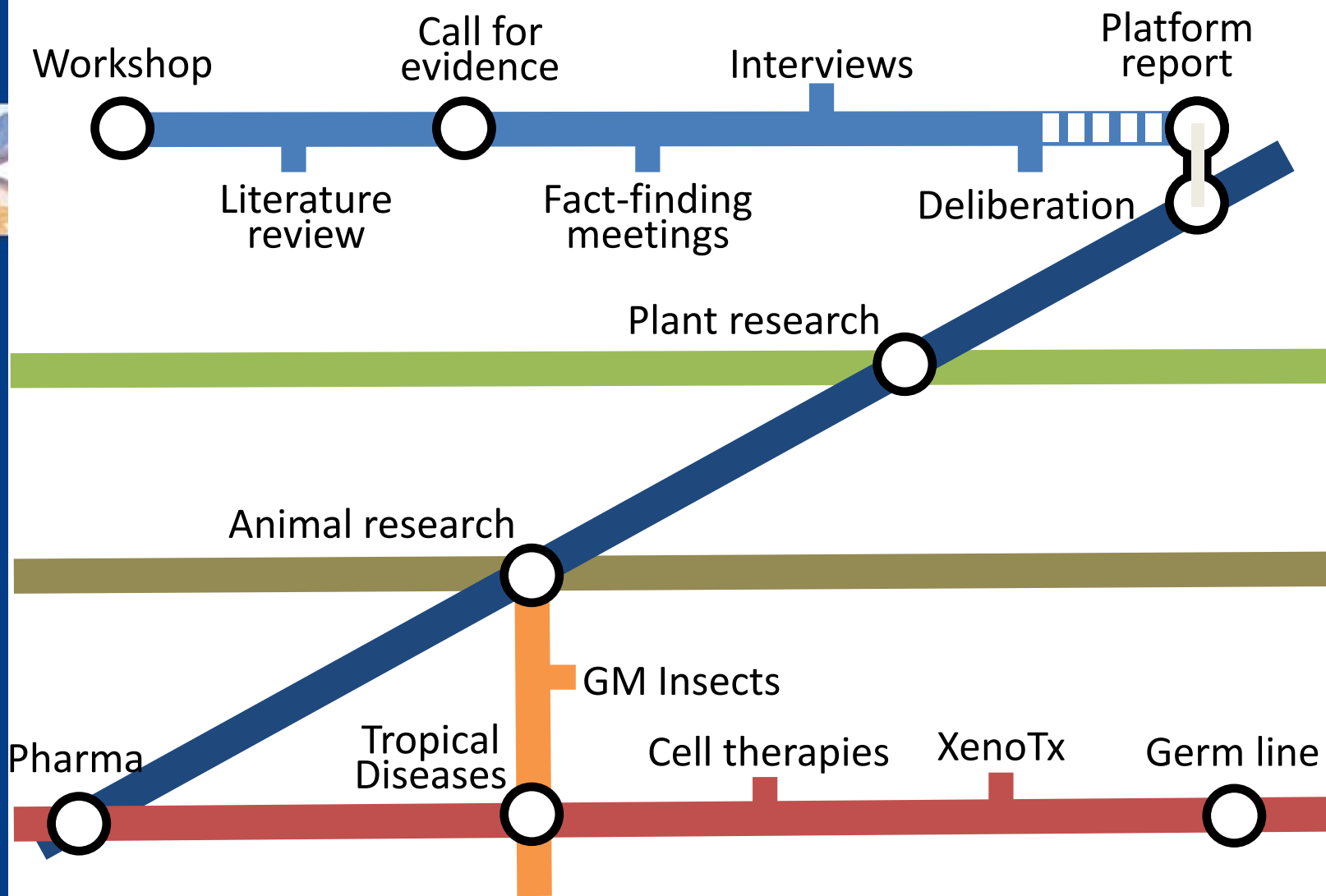
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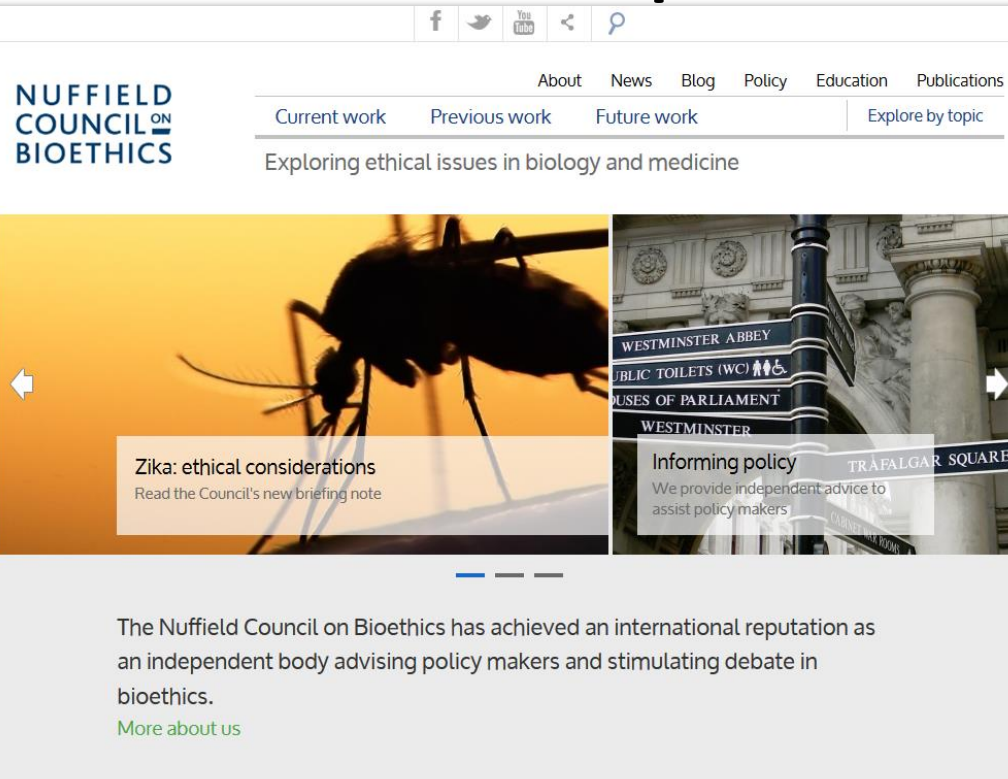
**NUFFIELD
COUNCIL ON
BIOETHICS**



Process and progress



Watch this space...



The screenshot shows the Nuffield Council on Bioethics website. At the top, there are social media icons for Facebook, Twitter, YouTube, and a search icon. Below these are navigation links: About, News, Blog, Policy, Education, and Publications. A secondary navigation bar includes Current work, Previous work, Future work, and Explore by topic. The main heading reads "Exploring ethical issues in biology and medicine". The central banner features two images: a mosquito on the left and a street sign for Westminster on the right. The mosquito image is titled "Zika: ethical considerations" with a subtext "Read the Council's new briefing note". The street sign image is titled "Informing policy" with a subtext "We provide independent advice to assist policy makers". Below the banner, a paragraph states: "The Nuffield Council on Bioethics has achieved an international reputation as an independent body advising policy makers and stimulating debate in bioethics." followed by a green link "More about us".

NUFFIELD COUNCIL ON BIOETHICS

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Published reports

FEATURED



Mitochondrial DNA disorders
Published: June 2012



Biological and health data
Published: February 2015



The culture of scientific research
Published: December 2014

TRENDING

Thank you



wellcometrust



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