

Written evidence from Nuffield Council on Bioethics (ENB0004)

Introduction

The [Nuffield Council on Bioethics](#) (NCOB) is a leading independent policy and research centre, and the foremost bioethics body in the UK. We identify, analyse, and advise on ethical issues in biomedicine and health so that decisions in these areas benefit people and society.

Our vision is for ethics to be at the centre of decision-making. Our new strategy, '[Making ethics matter](#)' sets out the steps we will take to ensure that decision-makers will have access to rigorous and timely ethical analysis and advice to inform key decisions that affect us all.

The NCOB welcomes this inquiry and hopes to provide helpful responses with a focus on the ethical, regulatory, and safety implications of rapid developments in the field.

While it is an exciting time scientifically to be able to explore and solve some of society's critical issues through engineering biology, we need to ensure that the developments are fair, equitable, accessible, and mitigate unintended consequences.

Ethical considerations cannot be confined to one-off processes of review, nor can they be considered in a vacuum. Ethical implications unfortunately are often identified too late and once impact has already occurred. Ethics should be embedded in frameworks, regulation, policy, and research.

Being ethically aware can help policymakers get closer to the best choices.

NCOB submission

In 2012, the NCOB published *Emerging biotechnologies: technology, choice and the public good*¹. This report recommended that when framing science policy through societal challenges, a 'public ethics' approach should be taken to avoid an overemphasis on technological rather than social solutions to problems with substantial social dimensions. Furthermore, the report argues that in all cases in which technical advice is sought by policymakers, there should be a demonstrable attempt to avoid sole reliance on a limited range of established experts in particular fields. This ability to prevent the premature establishment of orthodoxies

¹ [Emerging biotechnologies - The Nuffield Council on Bioethics \(nuffieldbioethics.org\)](#)

in fields characterised by uncertainty and rapid technological advancement remains important.

Industry and wider government should work with NCOB to create a framework that incorporates ethical considerations in future engineering biology policy, not just as a measure to ensure it adheres to regulatory parameters, but for societal benefit and to aid the development of ethically conscious legislation.

Within the recently published *UK Science and Technology Framework*², DSIT emphasises that the agenda for this framework will only be delivered if the public sector, civil society, academia, industry and private sector, and international partners work together, and the public is continually engaged. They list several intended outcomes they are striving for by 2030. Below is a selection of these where we would welcome involvement as the government develops its thinking:

1. Using government horizon-scanning and futures capability to support regulators and key decision-makers to further consider how emerging technologies could become critical technologies. NCOB's expertise could be harnessed to support this. Our horizon scanning and foresight work provides a unique ethics lens that others do not always incorporate in their future focus.
2. Improved knowledge, talent, and resource sharing within government, between the public sector, academia, and businesses; training government leaders to raise their awareness. The NCOB could provide a multi-disciplinary approach and an ethical dimension to this knowledge exchange and training. We will work with decision-makers so the UK can harness the many benefits of engineering biology whilst ensuring ethical consideration.
3. Lead international efforts to shape standards and regulations for critical technologies. The NCOB has international networks and collaboration with the global ethics community; these partnerships could be used to ensure ethical considerations are taken into account during the development of standards and regulations.

The Government's vision that ethical responsible innovation is a part of this sector means NCOB, as the UK's independent national bioethics body, has a vital role to play in supporting this. *We are calling for an increased and continued role working with the Government to ensure that ethical considerations are always part of the regulatory and legislative process.*

Q: What early warning systems are in place, both nationally and internationally, to monitor whether engineering biology is being misused?

² [The UK Science and Technology Framework: taking a systems approach to UK science and technology \(publishing.service.gov.uk\)](https://www.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/671112/uk-science-and-technology-framework.pdf)

A: Global place

The government should work with equivalent international regulatory bodies and legislators to ensure a coordinated approach to the governance of new technologies. Historically, the UK has played an important role in the regulation of emerging biotechnologies. A key example is the use of mitochondrial DNA transfer techniques for couples at risk of having children with severe, inherited mitochondrial disorders. Our 2012 report³ concluded that the use of these techniques could be an ethical treatment option provided those seeking the treatment met all the requirements for eligibility and helped inform the eventual legislation. This is a direct example of where ethics and public dialogue wasn't just 'red tape', but helped bring about changes to the legislation to allow groundbreaking innovation to happen in ways that were carefully considered and had garnered public support. Embedding ethics into the co-design of technology should not be seen as a barrier to innovation, it is an enabler.

The UK has the expertise and infrastructure in place to work with the international community to both showcase our innovation and build future, fruitful collaborations. These collaborations can also work together to monitor risks or if engineering biology is being misused. This will be an important part of maintaining our place on the global stage and increasing international recognition of the UK's strengths and ambitions in science and technology. Demonstrating the benefits of investment and collaboration with the UK. International industry and governments should *embed ethical questions and considerations into regulatory sandbox exercises to test implications, risks, and benefits in application before society is impacted.*

Q: What more can the Government do to foster public understanding of engineering biology?

A: Public engagement and building trust

The NCOB, in partnership with the Biotechnology and Biological Sciences Research Council (BBSRC), with support from Sciencewise, recently (2022) undertook a public dialogue on genome editing and farmed animals⁴. This dialogue is a good example of how public dialogue should be designed, carried out, and used to inform wider bodies of work, policy decisions, and legislation. We also recently published a report on *Genome editing and farmed animal breeding: social and ethical issues*⁵, this report is highly regarded and helped inform the Genetic Technology (Precision

³ [Mitochondrial DNA disorders - The Nuffield Council on Bioethics \(nuffieldbioethics.org\)](https://www.nuffieldbioethics.org/mtdna-disorders)

⁴ [Public dialogue on genome editing and farmed animals - The Nuffield Council on Bioethics \(nuffieldbioethics.org\)](https://www.nuffieldbioethics.org/public-dialogue-on-genome-editing-and-farmed-animals)

⁵ [Genome-editing-and-farmed-animal-breeding-FINAL-WEB-PDF.pdf \(nuffieldbioethics.org\)](https://www.nuffieldbioethics.org/genome-editing-and-farmed-animal-breeding-final-web-pdf)

Breeding) Act 2023⁶. In the report, we highlighted distinctive ethical issues from the previous iteration of the legislation that needed exploration, particularly concerning farmed animals. That many of our recommendations were responded to within the legislation demonstrates the value of involving an organisation that examines and places ethics at its heart.

Public engagement and participatory methods need to be at the heart of engineering biology and its applications to help society make informed decisions and build trust and transparency about how developments affect people and communities.

Q: What are the risks posed to society by engineering biology?

- **There are regulatory, ethical, and safety concerns that go along with any dual-use technology, particularly in the case of gene-editing. What are the major areas of concern?**

The beneficial use of this technology is the proposed ability to correct mutations to treat severely life-limiting disorders, improve crop resistance to pests and diseases, improve our food and farming systems, and develop more precise/effective treatments for cancer. However, whilst there is a myriad of proposed benefits, there are risks to balance. These could include creating genome-edited offspring with selected traits that could exacerbate inequalities or using the technology to develop biological weapons.

In its [Genome UK strategy](#), the Government committed to establishing a gold standard UK model for how to apply strong and consistent ethical and regulatory standards, while [recognising](#) the need for more discussion on how to achieve this in a meaningful way.

Developing a UK best practice approach – or 'gold standard model' – for ethics in genomics healthcare and research could help those working in the field negotiate ethical issues, promote consistency of approach, and, ultimately, create better, more equitable experiences for patients and research participants.

Since 2022 we have partnered with the Office for Life Sciences (OLS) to support the government's commitment. Full information about this work can be found in our 2023 report '[Ethics in genomics healthcare and research: building connections and sharing best practice](#)' and our 2024 report '[Towards a gold standard of ethics across genomic healthcare and research: where are we?](#)' The second report concluded that a coordination function is required and we are now working to set this up.

⁶ [Genetic Technology \(Precision Breeding\) Act \(legislation.gov.uk\)](#)

Q. How are the ethical, safety, and national security concerns raised in Q5 addressed under current regulations? Are regulators sufficiently independent from Government and from industry?

A: We have not had cause to be concerned the regulatory agencies that we work with are not sufficiently independent from Government and industry. In our experience, they work collaboratively with parties to unpick ethical considerations and build in safeguards where evidenced. However, some of our current work is identifying where issues around human stem-cell-based embryo models, and neural organoids raise ethical questions and fall within regulatory gaps.

Embryo model & neural organoid research

We have started a [rapid review project](#) to assess and advise on the ethical and regulatory issues raised by research using human stem cell-based embryo models.

An interdisciplinary working group, which will include a representative from the [Human Fertilisation and Embryology Authority](#) (HFEA) will lead our work. Our insights will build upon, and contribute to, the considerations that have been, and continue to be, discussed by experienced researchers, policy makers, and other UK and international experts. Embryo models are not explicitly covered in UK laws or regulations.

We have recently published a [policy briefing note](#) identifying key ethical considerations⁷ raised by neural organoid research and areas where further ethical guidance, policy, and regulatory decisions could be needed. We now intend to facilitate further discussions with policymakers, scientists, ethicists, and the public to shed more light on the most pressing challenges in this area of research and what is needed to tackle them.

We believe there is benefit in exploring the ethical and legal implications of neural organoids further. Issues could include changes in moral status as research progresses (for example, where the organoids could be considered to have developed sentience); gaining informed consent for research; and proportionate regulation.

In conclusion

The UK has a strong history in science policy and regulation that both facilitates innovation and is trusted by the public, such as the regulation of research on human embryos. Perhaps one of the most significant factors that must be highlighted and reiterated is how important ethical

⁷ [Neural-Organoids-in-Research-Briefing-FINAL.pdf \(nuffieldbioethics.org\)](#)

mapping and participatory approaches are to the design of these technologies as well as their application. A good example of this, because it speaks to scientific advancement, ethical consideration, and public engagement for a policy decision, is that of mitochondrial replacement therapy (MRT).

The UK was the first country to approve the use of MRT and this was only after extensive engagement with the research, innovation, ethics sectors, and crucially, the public. In this case, public trust was garnered through exploring and engaging with citizens on the scientific and ethical issues involved. The findings of this work were subsequently used to inform policy decisions, meaning that they truly reflected public values and could be trusted.

In an area as prominent as engineering biology, it is reassuring UK policymakers are examining the parameters and potential of this transformative field.

At the NCOB, undertaking horizon scanning helps us identify emerging issues early, allowing us to map and address competing concerns effectively. This mapping of the ethics identifies different ethical principles and interests involved which helps shape ethically informed public deliberation in an impartial and balanced way.

We are currently developing approaches that aim to help decision-makers incorporate ethics earlier and more overtly into their horizon scanning and future thinking work. Designing tools and making recommendations that reflect values, and protect interests to ensure policy is ethically sensitive.

Thank you for considering our submission to the Committee's inquiry on engineering biology. If the Committee would like to hear more about embedding ethics in science, technology, and innovations, we would be happy and available to provide oral evidence.

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