



Call for evidence: neural organoids (decision-making and governance)

Opens	12 July 2024
Closes	18 September 2024
Questions/submissions to	mindandbrain@nuffieldbioethics.org

The Nuffield Council on Bioethics (NCOB) is running an open call for evidence to inform its further work looking at neural organoids in research, following the publication of its policy [briefing note](#) earlier in the year.

Why we are calling for evidence

Our work to date, leading to the production of our policy briefing note in Spring 2024, has found that neural organoids are promising research tools that could have important applications in the future, and improve our understanding of a range of brain conditions and treatment options. At the same time, neural organoid research is still in its infancy and its potential is yet to be fully explored. There are a number of ethical and regulatory issues raised by neural organoids linked to:

- The uncertainties around benefits, limitations and possible future developments
- The implications of this research for both human and non-human animals
- The potential gaps in research governance and regulation
- The communication around the benefits and limitations of neural organoids and the implications for public perception
- The moral and legal status of neural organoids and neural organoid-based models, such as neural assembloids, biocomputing systems, organs-on-chips, and non-human animals who have had neural organoids transplanted into their brains

In its conclusions, the briefing note highlights **three unaddressed challenges for stakeholders in this sector**. These are:

- How regulation and governance of neural organoids can be proportionate and future proofed.
- What an informed consent process, able to account for fast-paced developments and an unpredictable direction of research, could look like.
- What current and possible future characteristics of neural organoids could have implications for their moral and legal significance, and so may warrant special ethical consideration.

We have developed this current call for evidence as part of an ongoing programme of work which builds on our briefing note, aimed at addressing these challenges and finding actionable solutions for researchers and policymakers.

We want to ensure that everyone who wants to contribute evidence has the opportunity to do so. We are especially interested to hear from those who carry out, fund and oversee neural organoid research (in both academia and industry), and from all those with expertise in the ethical and regulatory issues raised by the use of neural organoids in research. This evidence will be crucial to ensure our advice is robust and meaningful and that any recommendations we make are practically implementable.

What we are looking for

We welcome evidence of new developments in these areas since publication to further our understanding. More specifically, evidence that contributes to the discussion on (or seeks to answer) the below questions would be helpful. We are interested in evidence which covers all the latest developments in neural organoids and neural organoid-based models. These include, but are not limited to, neural assembloids, biocomputing systems, organs-on-chips, and non-human animals who have had neural organoids transplanted into their brains.

Please note that some questions may require specific subject matter expertise or experience to answer – there is no need to answer questions that fall outside your own professional, personal or academic scope.

Neural organoids and their status:

- Anatomical characteristics and/or functional capabilities that might, or should, affect a neural organoid's moral or legal significance or prompt 'consciousness' to be attributed to it
- Differences (if any) between neural organoids and other types of organoids (e.g., liver, kidney) that might, or should, affect how their moral or legal significance is viewed
- Differences (if any) between neural organoids and other types of neural cultures (e.g., human organotypic brain cultures, 2D stem cell cultures) that might, or should, affect how their moral or legal significance is viewed
- Changes to the anatomical and/or functional capabilities of neural organoids that might happen in the near future (next 5-10 years) in light of recent advances, and any resulting implications for moral and legal status
- Significance (if any) of the transplanting of *human* neural organoids, assembloids or other neural organoid-based models using neural tissue into non-human animal recipients, and whether (and how) significance would differ from the transplantation of disorganised human neural cells into non-human animals

Research processes and practices:

- Criteria and processes used to determine access to tissue by research teams, and any local/regional differences in processes or how they are followed
- Consent processes for donors, whether these are adapted to respond to changes in intended use of tissue and, if so, how

- Areas of practical challenge for researchers working with neural organoids and neural organoid-based models and views on how they might be effectively supported to resolve them
- Areas of practical challenge for decision-makers (research funders, biobanks, research ethics committees etc) when making decisions about neural organoid research, how these challenges are currently managed and what might be helpful in managing them in future
- Whether current guidance available for research and decision-makers on research using neural organoids and neural organoid-based models is adequate and sufficient for them to feel fully equipped to work and make decisions in this area, and reasons why
- Whether current guidance available for research and decision-makers on transplanting human neural organoids into non-human animals is adequate and sufficient for them to feel fully equipped to work and make decisions in this area, and reasons why

Regulation and governance:

- Gaps (if any) that can be identified in regulation and governance of neural organoids and other neural organoid-based models in the UK
- Any regulatory or governance gaps that may emerge in the near future (next 5-10 years) relating to neural organoids and other neural organoid-based models, in light of recent advances in the field and research directions
- Which extant regulatory body/bodies would be best-placed to oversee the storage, use and disposal of neural organoids – if any – and reasons why
- Whether legislative change would be needed to extend a regulatory body's powers to govern neural organoids and neural organoid-based models, and what that might look like
- Effectiveness of current regulatory processes that might be transferable to the governance of neural organoids
- Potential approaches to regulation and governance that may allow for rapid review and amendment in response to the fast pace of research
- Potential approaches to embedding stakeholder awareness and understanding of regulatory requirements where the regulation in question might be subject to regular change/edit

What we will do with the evidence

We will carefully consider and analyse all responses to the call for evidence. A summary of insights will be published on our website, and the themes and issues identified will inform our other research activities to be undertaken directly with stakeholders. We will only publish responses in full where you have given us explicit consent to do so.

Responding to the call for evidence

The call for evidence will be open for 10 weeks, from 12 July to 18 September 2024. Responses should be in the written word and sent as an email attachment to mindandbrain@nuffieldbioethics.org.

Please state clearly in your email if you are happy for us to publish your response in full, and, if so, whether you would like us to publish it under your/your organisation's name or anonymously.