



# Neural organoids: Ethical and governance considerations

## Recommendations from the report

The Nuffield Council on Bioethics (NCOB) has published a report on the ethical and governance issues arising from neural organoid research.

This is a fast-developing area of science that uses stem cells to make small, three-dimensional models able to mimic aspects of brain function and development.

The report was overseen by a multi-disciplinary expert working group and was informed by contributions from a wide range of people, including an open call for evidence.

The full report is available [here](#). It makes nine recommendations which are listed below.

### Recommendation one

Government (via the Department of Science & Technology and the Department of Health & Social Care) should scope approaches for the future statutory regulation of emerging biotechnologies, working closely with the Regulatory Innovation Office (RIO) to map and develop options.

Approaches should allow for flexibility to avoid or mitigate the risks posed by the mismatched pace of scientific development and legislative reform and should have public benefit (both in terms of safety and benefitting from innovation) as their primary goal.

## Recommendation two

An alliance of key stakeholders – including tissue banks (such as UKSCB and HDBR), relevant regulators (HTA, HRA, MHRA, the Home Office and the Animals in Science Committee), journal editors and groups with expertise in neuroscience (such as the British Neuroscience Association) ) and major research funders (such as UKRI, Wellcome, and the NC3Rs) – should collaborate to develop best practice guidance for human neural organoid research. The guidance should:

- develop a shared definition of what is meant by sentience in the context of neural organoids and similar models;
- ensure that differences in regulatory policy and practice between devolved nations are accounted for, and be applicable and useful to research taking place in both the public and private sectors;
- identify model characteristics and experimental steps, or research features, that may indicate development of sentience;
- articulate best practice on informed consent in relation to neural organoids and similar models, including where long-term storage and potential future uses are anticipated; and
- articulate best practice on animal welfare in neural organoid-related research – considering the wider impacts of this research on non-human animal species – and particularly in relation to the transplantation of human organoids into non-human animals.

It will also be important to ensure that there are direct lines of communication between the alliance and the Department of Health & Social Care (DHSC) and the Department for Science & Technology (DSIT), as part of their regulatory horizon scanning functions.

## Recommendation three

Tissue banks should not grant access to tissue for research projects outside the UK where the intended use would not be permitted under UK law or does not comply with accepted UK ethical standards.

## Recommendation four

Funders of research involving neural organoids and similar models (such as UKRI<sup>1</sup>, Wellcome, and NC3R) should prioritise funding of robust public engagement to explore UK public attitudes towards neural organoid-related research. In particular, engagement activities should seek to understand public perspectives on:

- the values that should underpin research involving neural organoid and assembloid models;
- ways in which different publics think these models should be used to deliver benefits;
- the level of information they would want in order to be able to consent to tissue donation, where that donation would or may be used for neural organoid-related research;
- which aspects of these models and their applications are perceived to be ethically problematic, and why; and
- whether there are any perceived “red lines” or limits that should not be crossed as this research develops.

Engagement should include a range of publics – including people with lived experience of brain conditions and tissue donors – to ensure a plurality of perspectives are available to underpin future guidance and oversight.

## Recommendation five

Research institutions in the UK (including both academic and commercial) should require that all projects involving the development and use of neural organoids and similar models are logged with their institutional research governance teams, so that summary details of research can be centrally recorded. If research plans change, for example due to unexpected findings, researchers should update detail accordingly.

## Recommendation six

Biobanks, research institutions, research funders and regulators should convene to discuss pragmatic and proportionate approaches to the centralised collection of data on neural organoid research. A central record of data would facilitate:

- the ongoing assessment of the need for legislative change; and
- the updating of best practice guidance and horizon scanning for potential risks as appropriate.

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<sup>1</sup> We have identified UKRI as the umbrella body under which a number of research councils sit (BBSRC, MRC, EPSRC, ESRC, AHRC) that may all fund, or part-fund, neural organoid-related research given its interdisciplinary nature.

## Recommendation seven

The UK Home Office, advised by the Animals in Science Committee, should update its 2016 guidance on the use of human material in animals to reflect advances in neural organoid research and changes to the wider ethical and regulatory landscape relating to animal sentience. It should consider what – and if – any additional protections may be required.

In order to produce this guidance, the Home Office will need to work closely with the relevant research funders and regulators to ensure coherence between animal research oversight, relevant best practice guidance, and broader monitoring and horizon-scanning activities.

## Recommendation eight

Research institutions and biobanks should review and update informed consent policies and practices for the donation of human fetal, embryonic, and adult tissue used in stem cell and organoid research. In particular, information about possible uses of donated tissue in neural organoids and similar models should be included in consent forms, where those uses can realistically be envisaged.

## Recommendation nine

All those involved in scientific communication about neural organoids and similar models (for example editors of scientific journals and scientists themselves) should adhere to UK CORI's concordat on research integrity; and standard nomenclature when describing neural organoids and similar models.

We also encourage media outlets to engage in responsible and sensible communication when reporting about neural organoids and similar models, recognising the importance of accurate scientific media reporting for keeping the public informed about developments in this field of research.