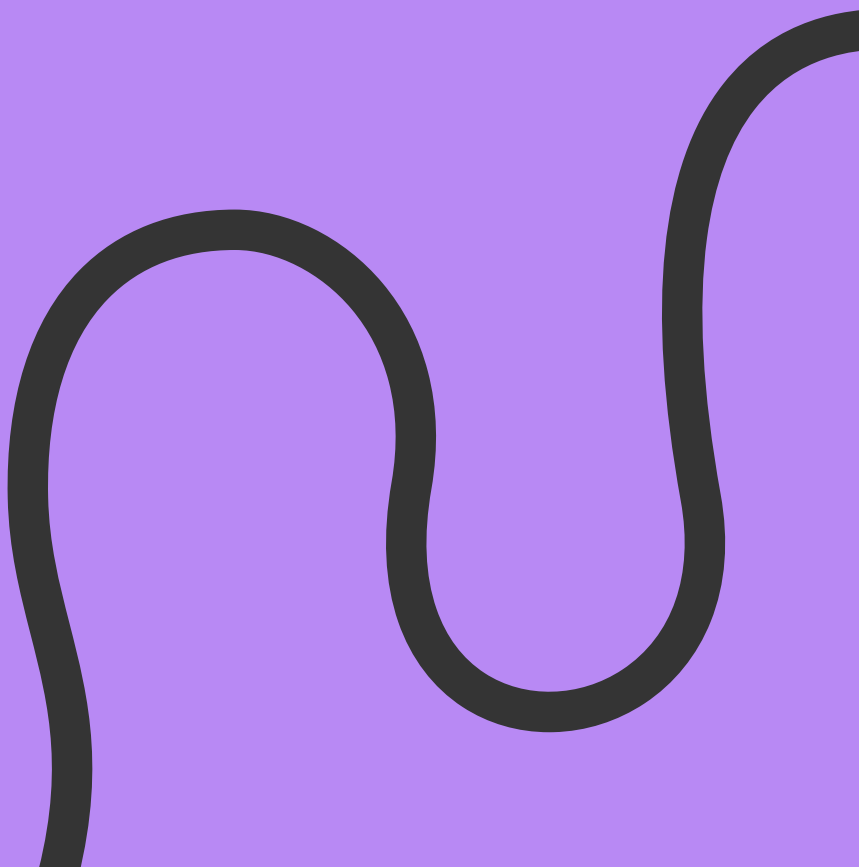
Nuffield Council on Bioethics

Neural organoids

Ethical and governance considerations



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Foreword

Emerging biotechnologies present many challenges for decision makers. The pace of scientific advancement, combined with uncertainties about the trajectory of future research, make it difficult to envisage what effective and proportionate regulatory mechanisms might look like – which allow for research and innovation, protect people and animals, and inspire public trust in research.

This report is the product of the Working Group's mandate to identify and recommend such an approach in relation to neural organoids (and similar models) in research.

We had the dubious luxury of a relatively blank canvas as a starting point. Neural organoids, despite being created from human cells, fall into a regulatory lacuna. The remit of the Human Tissue Act 2004 does not extend to anything made from human cells or tissue outside of the human body – thus excluding neural organoids and similar models (as well as other stem-cell based models and organoids). This gap is not surprising. The Act was introduced in order to improve informed consent practices in the wake of organ retention scandals. In 2004, the legislature had no reason to contemplate the future creation and use of neural organoids.

Why is it important to start to fill this governance gap? As the science advances, so too may the complexity of neural organoids. Advances in the functioning or complexity of neural organoids are potentially significant, given the role of the brain in the development of sentience, and our belief in the centrality of our brains to 'who we are'. Although there has not yet been any public engagement work about neural organoids in the UK (something we suggest is remedied as part of our recommendations), insights from research in other jurisdictions suggests that there may be particular public concern about neural organoid research. This, in turn, makes it important to ensure that tissue donors' broad or generic consent is sufficiently informed.

Other important ethical challenges arise in relation to the use of non-human animals in research. Neural organoids and similar models are one of the technologies which the UK government hopes will hasten the replacement of non-human animals in research. While this is to be welcomed, human neural organoids can also be transplanted into non-human animals, in order to overcome some of the models'

current limitations, such as the lack of vascularisation and interaction with their environment. It is therefore important to ensure that animals used in these new ways are properly protected.

Fortunately, we are not the only ones thinking about the future of neural organoid research governance. A collective of eminent neuroscientists, ethicists and lawyers published a call to action in November 2025, setting out a need for a "continuing international process to watch, and to guide, the progress of this field" in light of the pace of scientific advancement and the ethical and social questions it raises.[1] The needs they highlight – for greater centralisation of oversight, the production of field-specific guidance that is responsive to developments, and a collaborative approach to engaging with the public – also underpin our recommendations. Although our remit was to consider the UK context, we are conscious that much neural organoid research takes place across international borders. We therefore hope that our recommendations for domestic change are aligned with these calls for a global approach, and will facilitate the UK's meaningful contribution to such initiatives.

A number of thanks are owed to the many contributors who made this report possible. Our work has been shaped by candid and generous input from a range of people and institutions including research scientists, institutional decision makers, regulators, funders, stem cell and tissue banks, ethicists and policymakers. All of their contributions were vitally important. We were very fortunate to benefit from the wisdom of expert reviewers, who generously commented on an earlier draft of this report. On a personal note, I would also like to thank my fellow Working Group members for their hard work, collegiality and thoughtfulness. Finally, my very grateful thanks are due to the members of the Nuffield Council on Bioethics, and the Executive, particularly Claudia Corradi, Natalie Michaux, and Martin Davies, with whom the Working Group developed this report.

Professor Emily Jackson
Working Group Chair

1 Pașca SP, Arlotta P, Campbell P, *et al* (2025) The need for a global effort to attend to human neural organoid and assembloid research *Science* **390(6773)**: 574-7.

Executive summary

As with many emerging biotechnologies, neural organoids can be useful research tools, generating valuable insights into the brain and its development, and in the future potentially leading to therapeutic or other practical applications.

Neural organoids – and organoids more generally – are also of growing interest, including to the UK Government, as a potential means of reducing or replacing the use of animals in research.[2]

As neural organoid research progresses, however, they are increasing in complexity, which is raising questions about their potential future similarity to actual brains (or parts of brains), and how they might responsibly be developed, used and regulated in the light of this.

In this report, we set out the present state of the science and projected future developments relating to neural organoids and similar models and analyse the current and likely ethical and governance challenges arising from them. Informed by the evidence we gathered and the deliberations of our expert Working Group, we then make recommendations for change based on those deliberations.

What are neural organoids?

Neural organoids are small, three-dimensional tissue cultures developed in the laboratory to model human brain tissue. They provide scientists with opportunities to study aspects of the brain in ways that may not otherwise be possible, given the challenges associated with accessing living brain tissue inside the human body.

2 Department for Science, Innovation & Technology, Home Office, Department for Environment, Food & Rural Affairs (November 2025) *Replacing animals in science: A strategy to support the development, validation and uptake of alternative methods*, available at: https://www.gov.uk/government/publications/replacing-animals-in-science-strategy/replacing-animals-in-science-a-strategy-to-support-the-development-validation-and-uptake-of-alternative-methods.

Since reports of early 3D models of neural tissue (described as 'rosettes') in the early 2000s[3], the field has advanced rapidly. The development of 3D cerebral cortical tissues and neural retina in 2008 and 2011[4] were followed by multi-region brain tissues that were first referred to as organoids in 2013[5], giving rise to new models that can be used to explore many different questions about how the brain develops and functions. These models include "assembloids" which are created by fusing two or more organoids, and which can be used to study interactions between different brain regions and/or between the brain and other body systems.[6] Another example is "chimeroids", in which cells from different individuals – and potentially, in the future, from different species – co-develop within a single organoid.[7] Neural organoids, assembloids and chimeroids can also be transplanted into non-human animal brains, or linked to computational systems to create biocomputing systems.[8] **We use the term 'neural organoids and similar models' throughout this report to be inclusive of all such models.**

This report focuses on human neural organoids. Any reference to neural organoids in the text presupposes that they are made from human cells, unless indicated otherwise.

A note on nomenclature and terminology

Over the past decade, a wide range of terms and classifications have been used – sometimes inconsistently – to describe neural organoids and other neural tissue modelling systems, complicating communication both within and beyond the scientific community.

In recent years, a group of leading experts has developed a classification framework and working guidelines for the field.[9] In their 2022 consensus paper, organoids are

Continued >>

3 Zhang SC, Wernig M, Duncan ID, Brüstle O, and Thomson JA (2001) In vitro differentiation of transplantable neural precursors from human embryonic stem cells *Nature Biotechnology* **9(12)**: 1129-33.

4 Eiraku M, Watanabe K, Matsuo-Takasaki M, *et al* (2008) Self-organized formation of polarized cortical tissues from ESCs and its active manipulation by extrinsic signals *Cell Stem Cell* **3(5)**: 519-32; and Eiraku M, Takata N, Ishibashi H, *et al* (2011) Self-organizing optic-cup morphogenesis in three-dimensional culture *Nature* **472(7341)**: 51-6.

5 Lancaster MA, Renner M, Martin CA, *et al* (2013) Cerebral organoids model human brain development and microcephaly *Nature* **501(7467)**: 373-79.

6 See, for example: Bagley JA, Reumann D, Bian S, Lévi-Strauss, and Knoblich J (2017) Fused cerebral organoids model interactions between brain regions Nature Methods **14**: 743–51; and Andersen J, Revah O, Miura Y, *et al* (2020) Generation of functional human 3D cortico-motor assembloids *Cell* **183(7)**: 1913-29.

7 Antón-Bolaños N, Faravelli I, Faits T, *et al* (2024) Brain Chimeroids reveal individual susceptibility to neurotoxic triggers *Nature* **631**: 142-9.

8 Smirnova L, Caffo BS, Gracias DH, *et al* (2023) Organoid intelligence (OI): the new frontier in biocomputing and intelligence-in-a-dish *Frontiers in Science* **1**.

9 Paşca SP, Arlotta P, Bateup HS, *et al* (2022) A nomenclature consensus for nervous system organoids and assembloids *Nature* **609(7929)**: 907-10.

defined as *"in vitro-generated cellular systems that emerge by self-organization, include multiple cell types, and exhibit some cytoarchitectural and functional features reminiscent of an organ or organ region"*[10] (in the case of neural organoids, the brain). The key feature of neural organoids and similar models, therefore, lies in the ability of organoids *to self-organise* in a manner that may more faithfully represent early brain development in vivo.

The Working Group is supportive of attempts to establish a consensus nomenclature and adopts the term *neural organoids*, which, in our view, accurately reflects the purpose of these models – namely, to model the brain or specific regions of it. In recognition of the importance of consistency across formal frameworks and guidelines, the Working Group has adopted the term *neural organoids* and related terms agreed upon in the 2022 consensus paper throughout this report. We acknowledge, however, that terminology in this rapidly evolving field continues to develop, and we encourage members of the scientific community to continue to engage actively in ongoing discussions about appropriate terminology.

What ethical issues do neural organoids raise?

Sentience and consciousness

The brain's central role in establishing sentience and consciousness means that ethical challenges arise in relation to whether neural organoids and similar models could be capable of developing these features, and if so, how they might be appropriately protected.

Animal welfare

It is unclear what the impact of neural organoid research will be on non-human animals. Some have claimed that it has the potential to reduce or replace the use of laboratory animals.[11] However, others have raised concerns that interest in the transplantation of human neural organoids into animal brains may increase demand for laboratory animals.[12] There are also concerns about how such transplantation might affect animals' welfare and integrity (see **section 2.2**).

10 Ibid.

11 Park G, Rim YA, Sohn Y, Nam Y, and Ju YH (2024) Replacing animal testing with stem cell-organoids: advantages and limitations *Stem Cell Reviews and Reports* **20**: 1375-86.

12 Pichl A, Ranisch R, Altinok OA, *et al* (2023) Ethical, legal and social aspects of human cerebral organoids and their governance in Germany, the United Kingdom and the United States *Frontiers in Cell and Developmental Biology* **11**.

Consent

Neural organoids and similar models are created from human stem cells and informed consent is provided by cell/tissue donors at the time of donation. Because stem cells can be stored for extended periods, they may in practice be used in ways that could not have been foreseen when consent was originally obtained. Generic consent models (i.e. those which seek consent for a broad range of unspecified research purposes) are common in stem cell donation, but it is important to ensure that donors have enough information about what might be done with their samples to make an informed choice.

Responsible communication

Communication about neural organoids and similar models – both in academic literature and the public-facing media – has at times been criticised for being misleading.[13] Examples include exaggerating the likelihood that models will develop sentience and other morally significant capacities, or that they will result in treatments for brain disorders in the very near future. As scientific communication can influence donor and patient expectations and affect public trust in science, it is important to ensure that it is accurate and responsible.

Emerging gaps in regulation and governance

The current regulatory landscape for neural organoid research in the UK – as for many emerging biotechnologies – is fragmented and incomplete. Although there are statutory mechanisms to regulate elements of the research pathway – including the collection and storage of stem cells and the protection of laboratory animals – human tissue legislation does not include oversight of material created from human cells outside of the body. This means that the creation and use of neural organoids and similar models are not subject to legislative control, and are not squarely within the remit of any existing regulatory authority.

In practice, this means that much of the day-to-day decision making about research involving neural organoids and similar models happens at a local level, with minimal guidance available to support researchers or institutions. While allowing for flexibility as science rapidly progresses, this lack of structure to guide decision making risks inconsistency and insufficient clarity in managing complex emerging issues.

There is a clear public interest in neural organoid-related research, given its potential for improving the health and wellbeing of people living with brain-related conditions, and much of it is publicly funded. Moreover, the special status of the brain – and its close association with identity, cognition, and emotional experience – may intensify

13 Kataoka M, Gyngell C, Savulescu J and Sawai T (2023) The importance of accurate representation of human brain organoid research *Trends in Biotechnology* **41(8)**: 985-7.

public concern and interest in such research. It would therefore be beneficial to ensure that options for future regulation can take account of public perceptions. While some studies exploring public views have been undertaken in other jurisdictions, none has yet been undertaken with UK publics. Findings from other jurisdictions may not be directly transferable to the UK context; sociocultural differences, regulatory traditions, and public trust in science and governance may influence how this research is perceived.

Recommendations

Although considerable scientific advances have been made in terms of the structure and functioning of neural organoids and similar models, they currently lack the biological complexity that might indicate a capacity for sentience. We are not aware of any additional evidence which indicates a current need for statutory protection or oversight. Our view, at the time of writing, is that neural organoids amount to *models of the brain and its parts*, and are not actual brains, and nor are they sufficiently similar to brains to require immediate legislative protection. As such, **amending primary legislation to include neural organoids and similar models within statutory regulation would currently be premature, and a disproportionate response to the challenges faced by the sector.** The pace of development, however, means this should be kept under ongoing review.

Alongside ongoing review of the need for legislative change, we recommend that **Government scope a range of potential future approaches to bring such technologies into the scope of regulation**. As gaps in regulation and governance are common across a range of emerging biotechnologies, being able to address these gaps in a more responsive way would likely be of broad benefit.

Until statuatory regulation becomes appropriate, the rest of our recommendations focus on **'soft' regulation as a more proportionate approach**. As research progresses and models increase in complexity, it becomes increasingly challenging for individual institutions and local ethics bodies to assess emerging trade-offs between scientific benefit and ethical risk without a shared framework to guide judgement. We therefore recommend that **best practice guidance is produced to help those involved in research navigate its complexities**. We suggest that this is developed by an interdisciplinary alliance, to reflect the fragmented nature of neural organoid-related research and account for the diffuse responsibilities across the research landscape. We have also recommended that **existing Home Office guidance on the use of non-human animals in research should be updated** in order to account for scientific developments in relation to the use of neural organoids and similar models, and in line with the introduction of the Animal Welfare (Sentience) Act 2025.

There is, currently, insufficient understanding of the neural organoid research landscape as a whole and how it is evolving. Even within institutions, the details of neural organoid-related research may not be consistently recorded. This means that understanding the overall direction of research – and ongoing review of

whether regulation is proportionate – is challenging. Accordingly, we have recommended that **individual research institutions should keep records of all neural organoid-related research**.

There would be clear advantages to having information on how the field is developing collected together. There are a range of practical barriers to such an initiative, however. There is no obvious 'home' for this information at present, and the scope and specifics of the data to be collected would need careful consideration. We therefore recommend that **relevant biobanks, research institutions and regulators convene to discuss pragmatic and proportionate approaches to the collection of data on neural organoid research.**

An understanding of UK public perspectives will also help in informing appropriate future regulatory mechanisms. We therefore recommend **that public engagement work is undertaken in order to understand more about public perspectives on neural organoid-related research.**

We recommend that **consent processes are reviewed to determine whether further information could be provided to tissue donors.** This would account for neural organoids and similar models becoming more complex and, given the gap between donation and future uses, to try to futureproof the informed consent process**.** In order to respect tissue donors' consent, we also recommend that **tissue banks should decline requests for use from outside the UK where they consider that the intended use would not meet UK legal or ethical standards**.

Finally, we recognise the importance of proportionate and appropriate communication and its impact on public trust in science – particularly in relation to research which is likely to elicit considerable public interest. We therefore recommend that **scientists involved in communicating about neural organoids and similar models adhere to standard nomenclature, and ensure that their communications align with the UK Committee on Research Integrity (UKCORI) concordat on research integrity.**[14] 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.

14 UK Committee on Research Integrity (2025) *The concordat to support research integrity,* available at: https://ukcori.org/wp-content/uploads/2025/12/The-Concordat-to-Support-Research-Integrity-2025.pdf.

Introduction

In 2024, the Nuffield Council on Bioethics published its briefing note 'Neural organoids in research: ethical considerations'.[15] This provided an overview of this fast-paced research field, and the main ethical and governance questions it raises. It also highlighted questions that required more detailed examination. These included:

- Is specific regulation of neural organoids and similar models needed and, if so, what might future-looking and proportionate regulation look like?
- What criteria, if any, might be used to attribute sentience to neural organoids and similar models and what might be the implications of these models acquiring sentience?
- How can consent processes appropriately account for rapid scientific developments and uncertain future research trajectories?

Following the publication of the briefing note, the Nuffield Council on Bioethics undertook further work to explore these questions in greater depth. This report is the outcome of that programme of research.

An expert Working Group was established in May 2025 to discuss and analyse the issues raised by neural organoids and similar models, and to develop evidence-based recommendations for the regulation and governance of this sort of research in the UK. This, in turn, built on evidence-gathering activities, including a literature review, a workshop, a call for evidence, and a roundtable stakeholder meeting. The Working Group met seven times between August 2025 and February 2026, including an evidence session with expert stakeholders and academics.

15 Nuffield Council on Bioethics (2024) *Neural organoids in research: ethical considerations,* available at: https://cdn.nuffieldbioethics.org/wp-content/uploads/Neural-Organoids-in-Research-Briefing-FINAL.pdf.

Report structure

The report is organised into four main sections:

- **Section 1** ("The scientific context") summarises the evidence gathered on the state of the science.
- **Section 2** ("Ethical considerations") sets out the ethical considerations arising from current research and its potential future applications.
- **Section 3** ("Governance") identifies key challenges for the governance of neural organoids and similar models.
- **Section 4** ("Recommendations") makes recommendations through which key governance challenges might be addressed.

Definitions of key terms and descriptions of different neural organoids and similar models – which appear first in bold – are provided in the **Appendix Glossary.**

1 The scientific context: uses, bottlenecks and future directions

Key messages

- Neural organoids are small, three-dimensional tissue cultures that are created in the laboratory to model aspects of the human brain (such as specific processes or regions).
- They are made from donated tissue – most commonly **pluripotent stem cells** – and, more rarely, from fetal tissue. They are genetically identical to the donated tissue.
- Neural organoids can be fused together – creating assembloids – or be transplanted into the brain of non-human animals. They can also be developed using cells from different individuals which co-develop within a single organoid.
- They can be used to study different aspects of the brain in ways that were not previously possible, because of the practical and ethical challenges associated with accessing ***in vivo* brain tissue**.
- To date, they have mainly been used in basic science – to model adult and fetal brain tissue – and in pre-clinical research, for example to test new drugs.
- In the future, it is possible that neural organoids and similar models will have clinical applications, such as in personalised medicine. The development of patient-specific neural organoids (or similar models) could then be used to support personalised drug screening, modelling of disease progression, or to predict how well an individual might respond to different treatments.
- Neural organoids and similar models face a number of limitations, for example linked to their limited size and inability to grow and mature.
- Some recent research efforts have focused on overcoming these limitations by transplanting neural organoids into the brain of non-human animals, or creating more complex, multi-part assembloids, or by linking neural organoids or assembloids to computer systems.

This section outlines the current state of the science. It begins with an overview of neural organoids and similar models and their uses to date, before describing in greater detail how neural organoids are generated, and the types of cells and tissues required for their development. We then consider emerging applications and potential future uses of these models, and identify the key scientific challenges and bottlenecks that remain.

1.1 What are neural organoids and similar model and what are they used for?

Human neural organoids are small, three-dimensional tissues **cultured** in the laboratory to model aspects of the human brain, for example specific processes or regions. They are small 'balls' of tissue, typically the size of a lentil, and are made up of several million brain cells.[16] Once created, neural organoids can be maintained indefinitely in culture, provided they receive the necessary nutrients, although their physical growth and complexity is limited to a few millimetres in diameter. This is because the absence of a **vascular system** leads to the death of the cells that are in the middle of the organoid, as they cease to be in contact with the nutrients provided by the **culture medium**.[17]

Different types of neural organoids can be generated. 'Guided organoids' model specific brain regions, such as the **cerebral cortex**, **hippocampus**, or **cerebellum**, while 'unguided' organoids develop a broader range of brain regions simultaneously. (Please see **Appendix 2** for further information about the human nervous system and its main regions).[18]

Both guided and unguided organoids provide scientists with the opportunity to study different aspects of the brain in ways that were not previously possible, given the practical difficulties and ethical challenges associated with accessing *in vivo* brain tissue, and limits on what can be learned from studying post-mortem brain tissue. By providing a more human-relevant platform for research, neural organoids and similar models may offer a means to address some of the existing limitations in brain research.[19] The need to rely on animal models has long constrained research and

16 National Academies of Sciences, Engineering and Medicine (2021) *The emerging field of human neural organoids, transplants, and chimeras: science, ethics, and governance*, available at: https://www.ncbi.nlm.nih.gov/books/NBK569428/.

17 Giandomenico SL, Sutcliffe M and Lancaster MA (2021) Generation and long-term culture of advanced cerebral organoids for studying later stages of neural development *Nature protocols* **16(2)**: 579-602. The 'oldest' documented neural organoids have been cultured for five years. More insights into how neural organoids grow and mature over time can be found in this preprint: Faravelli I, Antón-Bolaños N, Wei A, *et al* (2025) Human brain organoids record the passage of time over multiple years in culture *BioRxiv* 679721.

18 Paşca SP, Arlotta P, Bateup HS, *et al* (2022) A nomenclature consensus for nervous system organoids and assembloids *Nature* **609(7929)**: 907-10.

19 Luo J and Li P (2021) Human pluripotent stem cell-derived brain organoids as in vitro models for studying neural disorders and cancer *Cell & Bioscience* **11(99)**.

hindered the development of effective treatments for brain-related conditions.[20] Often, drugs that appear promising in animal studies – and particularly in mental health and other brain-related research – fail in human trials, in part because of fundamental differences between human and non-human animal brains and their responses to disease.[21]

Basic science research

Neural organoids and similar models have been particularly useful in developmental neuroscience, which focuses on understanding how the nervous system develops and changes over its lifespan, particularly early developmental stages. As neural organoids grow in culture and their cells mature, they acquire cellular and molecular characteristics that resemble those of a fetus a few months after conception.[22] This makes neural organoids and similar models a valuable tool for studying neurodevelopmental processes that normally occur in utero, as well as conditions that arise during pregnancy. For example, researchers have used neural organoids to model a rare form of **microcephaly** and to study the effects of the **Zika virus** infection during pregnancy.[23]

Neural organoids and similar models have also been used to study rare genetic disorders, including Timothy Syndrome, a serious condition causing different cardiac, neurological, and other physical symptoms. Using assembloids, researchers observed abnormalities in neuronal migration – the process by which neurons migrate from their place of origin to their final position during brain development – and were able to identify possible causal mechanisms of these abnormalities.[24] These results would have been very difficult, if not impossible, to obtain without using an organoid model as it is currently not possible to observe abnormalities in brain formation as they occur in the uterus. Following this, researchers were then able to test a drug that restored normal migration patterns within the assembloids. This drug is currently undergoing safety testing in animals in preparation for clinical trials.[25]

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20 Arlotta P and Gage FH (2023) Neural organoids and the quest to understand and treat psychiatric disease *Biological Psychiatry* **93 (7)**: 588-9.

21 Stanford SC (2020) Some reasons why preclinical studies of psychiatric disorders fail to translate: what can be rescued from the misunderstanding and misuse of animal 'models'? *Alternatives to Laboratory Animals* **48(3)**: 106-15.

22 There are reports of neural organoids which have been cultured for many years and have acquired some characteristics similar to those of a newborn brain. However, most neural organoids currently in use exhibit characteristics similar to the fetal brain a few months after conception. See: The New York Times (6 November 2025) *What we can learn from brain organoids*, available at: https://www.nytimes.com/2025/11/06/science/brain-organoids-neurons.html.

23 See Lancaster MA, Renner M, Martin CA, *et al* (2013) Cerebral organoids model human brain development and microcephaly *Nature* **501(7467)**: 373-9; and Qian X, Nguyen HN, Jacob F, Song H, and Ming GL (2017) Using brain organoids to understand Zika virus-induced microcephaly *Development* **144(6)**: 952-7.

24 Birey F, Andersen J, Makinson CD, *et al* (2017) Assembly of functionally integrated human forebrain spheroids *Nature* **545(7652)**: 54-9; Fikri Birey, Min-Yin Li, Aaron Gordon, *et al* (2022) Dissecting the molecular basis of human interneuron migration in forebrain assembloids from Timothy syndrome *Cell Stem Cell* **29 (2)**: 248-64.

25 The New York Times (6 November 2025) *What we can learn from brain organoids*, available at: https://www.nytimes.com/2025/11/06/science/brain-organoids-neurons.html.

While neural organoids most closely model the fetal brain, studies suggest they may also help to investigate conditions affecting the adult brain and inform treatment strategies. Using patient-derived stem cells, scientists have generated organoids to model glioblastoma, a form of brain cancer, and study its development and progression.[26] Neural organoids and similar models are also being used to model neurodegenerative disorders, such as Parkinson's disease.[27] Neuropsychiatric research using organoids is still in its early stages, but studies are beginning to explore the physiological mechanisms underlying schizophrenia, depression, and bipolar disorder.[28] Researchers caution that it is still too early to determine how accurately organoids can model adult conditions, particularly age-related neurodegenerative diseases, and findings should be interpreted with care.[29]

Scientists are also using neural organoids and similar models to study brain evolution, identify species-unique features and compare brain development between human and non-human animals, including primates. For example, neural organoids derived from different ape species have been compared to human neural organoids to identify cells and molecules that may explain differences in brain growth and neuron numbers.[30]

Pre-clinical research

While neural organoids and similar models have primarily been used in basic science research to study how organisms and biological processes work, they also hold potential for pre-clinical applications. For example, new drugs could be tested on organoids derived from the stem cells of individuals with specific conditions to understand how they may respond to specific treatments.[31] This would be valuable because a high number of neuroscience drugs that reach clinical trials ultimately fail, often because traditional animal models do not accurately reflect human biology.[32]

Current studies are investigating the suitability of neural organoids and similar models as experimental models for evaluating the effects of potential therapeutics.

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26 Hubert, CG, Rivera M, Spangler LC, *et al* (2016) A three-dimensional organoid culture system derived from human glioblastomas recapitulates the hypoxic gradients and cancer stem cell heterogeneity of tumors found in vivo *Cancer Research* **76**: 2465–77; and Bian Z, Repic M, Guo Z, *et al* (2018) Genetically engineered cerebral organoids model brain tumor formation *Nature Methods* **15**: 631-9.

27 See for example: Kim H, Park HJ, Choi H, *et al* (2019) Modeling G2019S-LRRK2 Sporadic Parkinson's Disease in 3D *Midbrain Organoids Stem Cell Reports* **12(3)**: 518-31.

28 Villanueva R (2023) Advances in the knowledge and therapeutics of schizophrenia, major depression disorder, and bipolar disorder from human brain organoid research *Frontiers in Psychiatry* **14**.

29 Andrews MG and Kriegstein AR (2022) Challenges of organoid research *Annual Review of Neuroscience* **45**: 23-39.

30 Otani T, Marchetto MC, Gage FH, Simons BD, Livesey FJ (2016) 2D and 3D stem cell models of primate cortical development identify species-specific differences in progenitor behavior contributing to brain size *Cell Stem cell* **18(4)**: 467-80.

31 Guy B, Zhang JS, Duncan LH, and Johnston Jr RJ (2021) Human neural organoids: Models for developmental neurobiology and disease *Developmental biology* **478**: 102-21.

32 Stanford SC (2020) Some reasons why preclinical studies of psychiatric disorders fail to translate: what can be rescued from the misunderstanding and misuse of animal 'models'? *Alternatives to Laboratory Animals* **48(3)**: 106-15.

For example, neural organoids derived from individuals with Alzheimer's disease have been used to screen drugs – originally developed for other conditions – that might also alleviate Alzheimer's symptoms.[33] This highlights how neural organoids and similar models could therefore help improve the success rate of clinical trials by providing more human-relevant data earlier in the research process.

1.2 Origins of neural organoids and similar models

The first study to describe human neural organoid tissue and formally refer to these structures as "neural organoids" was published in 2013.[34] Prior to this, early 3D models of stem cell-derived human neural tissue – referred to as "rosettes" – had been developed in the early 2000s.[35] These pioneering models laid the groundwork for subsequent advances, including the generation of 3D cerebral cortical tissue and neural retina models in 2008 and 2011, respectively.[36] This led to the development of what are now referred to as human neural organoids in 2013.[37] In the 2013 study, researchers cultured pluripotent stem cells in the lab and observed them self-organising, mimicking the formation of a rudimentary central nervous system. They also observed the formation of distinct regions similar to specific brain areas, including structures resembling the dorsal cortex, midbrain, hindbrain, and retina (see **Appendix 2** of this report for a description of the central nervous system's main structures and regions).[38] Since 2013, numerous **protocols** have been developed to generate organoids for different scientific purposes and to improve their longevity, reproducibility, and scalability.[39] Neural organoids have now been developed to resemble specific regions, including the **cerebral cortex, spinal cord, cerebellum, thalamus and midbrain** (see **Appendix 2** for a description of the central nervous system's main structures and regions).

Organoids of specific regions have also been fused together to create neural assembloids. Assembloids enable researchers to examine how distinct brain regions interact and how neural circuits form. The first examples of assembloids were

33 Par, JC, Jang SY, Lee D, *et al* (2021) A logical network-based drug-screening platform for Alzheimer's disease representing pathological features of human brain organoids *Nature Communications* **12**: 280.

34 Lancaster MA, Renner M, Martin CA, *et al* (2013) Cerebral organoids model human brain development and microcephaly *Nature* **501(7467)**: 373-79.

35 Zhang SC, Wernig M, Duncan ID, Brüstle O, and Thomson JA (2001) In vitro differentiation of transplantable neural precursors from human embryonic stem cells *Nature Biotechnology* **9(12)**: 1129-33.

36 Eiraku M, Watanabe K, Matsuo-Takasaki M, *et al* Self-organized formation of polarized cortical tissues from ESCs and its active manipulation by extrinsic signals (2008) *Cell Stem Cell* **3(5)**:519-32; and Eiraku M, Takata N, Ishibashi H, *et al* (2011) Self-organizing optic-cup morphogenesis in three-dimensional culture *Nature* **472(7341)**: 51-6.

37 Lancaster MA, Renner M, Martin CA, *et al* (2013) Cerebral organoids model human brain development and microcephaly *Nature* **501(7467)**: 373-9.

38 Ibid.

39 Mayhew CN and Singhania R (2023) A review of protocols for brain organoids and applications for disease modelling *STAR Protocols* **4(1)**: 101860.

created in 2017 by different research groups.[40] In two of these experiments, dorsal and ventral organoids were combined to model the dorsal-ventral axis of the brain.[41] All these experiments provided a platform for investigating how human neurons develop and migrate during early brain formation, allowing researchers to observe neurons moving between regions in patterns similar to those seen during fetal brain development.

Chimeroids, sometimes referred to as multi-donor organoids, have also been developed. In chimeroids, cells from different individuals co-develop within a single organoid.[42] One way in which chimeroids have been used is to explore how the impacts of exposure to toxic substances vary between individuals.[43]

1.3 Types of tissue used to make neural organoids and similar models

The stem cells needed to make neural organoids and similar models are sourced from donated tissue. During organoid formation, stem cells self-assemble into brain-like structures with the support of nutrients and growth factors supplied by researchers.[44]

Embryonic and induced pluripotent stem cells

Two main types of pluripotent stem cells are used to generate neural organoids and similar models: embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs).

ESCs are derived from donated embryos created via *in vitro* fertilisation (IVF).[45] UK researchers can request approval and access ESC lines via the UK Stem Cell Bank (UKSCB).[46]

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40 Birey F, Andersen J, Makinson CD, *et al* (2017) Assembly of functionally integrated human forebrain spheroids *Nature* **545(7652)**: 54-9; Bagley JA, Reumann D, Bian S, *et al* (2017) Fused cerebral organoids model interactions between brain regions *Nature Methods* **14**: 743–51; and Xiang Y, Tanaka Y, Patterson B, *et al* (2017) Fusion of regionally specified hPSC-derived organoids models human brain development and interneuron migration *Cell Stem Cell* **21(3)**: 383-98.

41 Birey F, Andersen J, Makinson CD, *et al* (2017) Assembly of functionally integrated human forebrain spheroids *Nature* **545(7652)**: 54-9; and Bagley JA, Reumann D, Bian S, *et al* (2017) Fused cerebral organoids model interactions between brain regions *Nature Methods* **14**: 743-51.

42 Antón-Bolaños N, Faravelli I, Faits T, *et al* (2024) Brain Chimeroids reveal individual susceptibility to neurotoxic triggers *Nature* **631**: 142-49.

43 Ibid.

44 Benito-Kwiecinski S and Lancaster M (2020) Brain organoids: human neurodevelopment in a dish *Cold Spring Harbor Perspectives in Biology* **12**.

45 They may also, under the HFE Act 1990 (as amended), be derived from embryos created for research purposes or created by somatic cell nuclear transfer, although this is not a common source of human ESCs.

46 Created in 2003, the UKSCB is funded by the National Institute for Health Research (NIHR). All ESCs developed in the UK must be deposited in the UKSCB as a condition of the Human Fertilisation and Embryology Authority (HFEA) research licences.

iPSCs are created from donated adult somatic cells – typically from skin, hair, or blood – which can be reprogrammed to become pluripotent, acquiring properties similar to ESCs.[47] Using iPSCs can be advantageous because adult tissue may be easier to obtain than embryonic or fetal tissue, and, for some, may not evoke the same ethical concerns as the use of embryos.[48] iPSC reprogramming technology is relatively accessible for specialist laboratories, though it can be technically challenging and time-consuming. Commercial kits are available for purchase.[49] Researchers can obtain iPSC lines from **biorepositories** such as the European Bank for induced pluripotent Stem Cells (EBiSC)[50], which store and distribute iPSCs generated from donors through initiatives such as the Human Induced Pluripotent Stem Cell Initiative (HipSci).[51] They can also make iPSC lines themselves using cells directly obtained from human donors.

Fetal tissue

Neural organoids and similar models can also be derived from fetal tissue.[52] These neural organoids are generated from tissue donated following pregnancy termination, culturing small fragments of the fetal brain from different regions of the central nervous system. To date, fetal brain organoids have been derived from fetuses up to 12-15 weeks gestation (corresponding to early to mid-**neurogenesis** stages).[53]

Respondents to our call for evidence and our engagement with stakeholders highlighted that interest is increasing in the use of fetal tissue for the purpose of developing neural organoids and similar models. This is because fetal tissue-derived organoids may more faithfully model fetal brain development than organoids derived from reprogrammed cells.[54]

47 Takahashi K, and Yamanaka S (2006) Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors *Cell* **126:4**: 663-76; and Takahashi K, Tanabe K, Ohnuki M, *et al* (2007) Induction of pluripotent stem cells from adult human fibroblasts by defined factors *Cell* **131:5**: 861-72.

48 Zheng YL (2016) Some ethical concerns about human induced pluripotent stem cells *Science and engineering ethics* **22(5)**: 1277-84.

49 See, for example, Thermo Fisher (2024) *Stem cell reprogramming tools,* available at: https://www.thermofisher.com/uk/en/home/life-science/stem-cell-research/stem-cell-engineering-reprogramming.html.

50 See: https://ebisc.org/.

51 See HipSci (2024) Human induced pluripotent stem cell initiative, available at: https://www.hipsci.org/.

52 Hendriks D, Pagliaro A, Andreatta F, *et al* (2024) Human fetal brain self-organizes into long-term expanding organoids *Cell* **187(3)**: 712-32.

53 Ibid.

54 Respondents to our call for evidence.

1.4 Limitations and scientific challenges

Growth, maturity and complexity

Despite their potential to advance basic and pre-clinical research, neural organoids and similar models continue to face significant scientific limitations. Current models remain developmentally immature, are constrained in size, and lack a functional vascular system.[55]

The absence of a vascular system in particular imposes a fundamental constraint on organoid growth. In culture, organoids cannot currently be grown beyond a few millimetres in diameter, as nutrients and oxygen cannot be efficiently delivered throughout the tissue. As increasing number of neurons are produced, cells at the core of the organoid are deprived of the resources necessary for survival, leading to progressive cell death and limiting further maturation.[56]

A further major challenge concerns biological complexity. The development of assembloids has represented an important advance, enabling the study of interactions between different brain regions. However, these models are still much simpler than the human brain, which involves highly complex and coordinated activity, both within the brain itself and in its interactions with the rest of the body. Because of this, current assembloids remain limited in their ability to fully replicate or model how the human brain functions.[57]

Reproducibility of experiments

Neural organoids and similar models face challenges when it comes to how reliably experiments can be reproduced in different labs.[58] These challenges affect how reliable the models are and how useful they are in research. Studies have struggled to intentionally reproduce size, structure and appearance.[59] The scientific community is taking steps to create standardised procedures (covering how these models are created, assessed for quality, and reported in scientific studies).[60] A 2025 consensus paper highlighted the need for guidance and advice on designing, conducting and

55 Andrews MG and Kriegstein AR (2022) Challenges of organoid research *Annual Review of Neuroscience* **45(1)**: 23-39.

56 Giandomenico SL, Sutcliffe M and Lancaster MA (2021) Generation and long-term culture of advanced cerebral organoids for studying later stages of neural development *Nature protocols* **16(2)**: 579-602.

57 Andrews MG and Kriegstein AR (2022) Challenges of organoid research *Annual Review of Neuroscience* **45(1)**: 23-39.

58 Sandoval SO, Cappuccio G, Kruth K, *et al* (2024) Rigor and reproducibility in human brain organoid research: Where we are and where we need to go *Stem Cell Reports* **19(6)**: 796-816.

59 Ibid.

60 Paşca, SP, Arlotta P, Bateup HS, *et al* (2025) A framework for neural organoids, assembloids and transplantation studies *Nature* **639**: 315-20; and Castiglione H, Madrange L, Baquerre C, *et al* (2025) Towards a quality control framework for cerebral cortical organoids *Scientific Reports* **15**.

reporting experiments to increase the reproducibility and utility of these models.[61] The authors also called for published studies to include detailed information about the **cell lines** and culture conditions used, so that other researchers can accurately replicate the experiments.[62]

Validating neural organoids and similar models

A further challenge lies in validating models – that is, confirming how well they reflect real human brain development. As noted in earlier sections, although neural organoids and similar models share many features with the developing human brain, there are also important differences. Comparing organoids with normal human brain development is therefore essential to ensure that research findings based on these models are reliable.[63] Validation is difficult because access to human brain tissue is limited. Researchers may therefore rely on a combination of sources, such as post-mortem tissue, surgically-removed brain tissue, clinical and neuroimaging data, fetal samples from post-mortem examinations, and animal models.

1.5 Overcoming limitations: creating more sophisticated models

Scientists are exploring a range of approaches to address these limitations and generate larger and more mature organoids, introduce vascular-like structures, and incorporate previously missing cell types through improved scientific protocols.[64] These efforts include the transplantation of neural organoids and similar models into non-human animals and the use of **organ-on-chip technologies**, as well as the development of more complex assembloids that incorporate multiple brain regions.

Transplantation into non-human animals

Transplantation of human neural organoids into the brains of living non-human animals may be carried out in order to create conditions conducive to more complex organoid development. These include providing the organoids with a vascular system; giving them an environment to support their growth and maturation; enabling their interactions with other brain regions and with the rest of the body; and providing the opportunity to interact with the external environment through input and output mechanisms.

61 Paşca, SP, Arlotta P, Bateup HS, *et al* (2025) A framework for neural organoids, assembloids and transplantation studies *Nature* **639**: 315-20.

62 Ibid.

63 Di Lullo E and Kriegstein AR (2017) The use of brain organoids to investigate neural development and disease *Nature Reviews Neuroscience* **18**: 573-84.

64 Chen H, Song H, and Ming G (2019) Applications of human brain organoids to clinical problems *Developmental Dynamics* **248**: 53-64.

In 2018, human neural organoids were transplanted into the brains of adult mice and, in 2022, into newborn rats.[65] In these experiments, the human organoids matured and formed both vascular and neural connections with the host brain. Integration was more pronounced in newborn rather than in adult rats. Researchers reported that activity within the organoids could influence the newborn rats' behaviour and that the organoids could react to stimulation. This suggested a higher level of functional interaction between human organoid tissue and the host nervous system when transplantation is performed during early stages of development.

To date, neural organoids have been transplanted mostly in rodents, but in at least one study they have been transplanted into non-human primates.[66]

Organs-on-chips

Another strategy to address the limitations of vascularisation involves combining organoid with organ-on-chip (OOC) technologies. OOCs are **microfluidic devices** containing cultured tissue, with channels that allow precise control of fluids and the cellular environment.[67] Integrating neural organoids and similar models with OOCs could mimic blood-like circulation, deliver oxygen and nutrients and provide a more physiologically-realistic environment for growth and maturation. This approach could have pharmaceutical applications, and has recently been used to closely observe how prenatal nicotine exposure affects brain development.[68] Microfluidic devices may also facilitate the creation of more complex assembloids. Looking further ahead, researchers hope to link multiple OOCs to connect distinct organoids, forming multi-assembloid-on-chip systems that replicate interactions between different organs and more sophisticated neural networks.[69] In a recent study, researchers used organ-on-chip technology to develop a system composed of neural organoids, motor neuron spheroids and muscle bundle to model Parkinson's disease and evaluate responses to drugs.[70]

65 Mansour AA, Gonçalves JT, Bloyd CW, *et al* (2018) An in vivo model of functional and vascularized human brain organoids *Nature biotechnology* **36(5)**:432-44; and Revah O, Gore F, Kelley KW, *et al* (2022) Maturation and circuit integration of transplanted human cortical organoids *Nature,* **610(7931)**: 319-26.

66 Kitahara T, Sakaguchi H, Morizane A, *et al* (2020) Axonal extensions along corticospinal tracts from transplanted human cerebral organoids *Stem Cell Reports* **15**: 476-81.

67 Castiglione H, Vigneron PA, Baquerre C, *et al* (2022) Human brain organoids-on-chip: advances, challenges, and perspectives for preclinical applications *Pharmaceutics,* **14(11)**: 2301.

68 Wang Y, Wang L, Zhu Y, and Qin J (2018) Human brain organoid-on-a-chip to model prenatal nicotine exposure *Lab on a Chip* **18(6)**: 851-60.

69 Castiglione H, Vigneron PA, Baquerre C, *et al* (2022) Human brain organoids-on-chip: advances, challenges, and perspectives for preclinical applications *Pharmaceutics,* **14(11)**: 2301.

70 Shin M, Ha T, Lim L, *et al* (2024) Human motor system based biohybrid robot on a chip for drug evaluation of neurodegenerative disease *Advanced Science* **11**: 4.

Multi-region assembloids

In recent years, assembloids have become more complex, incorporating three or more organoids. For example, assembloids connecting cortical and muscle organoids have been used to study neural circuits controlling voluntary movement, where stimulation of the cortical region triggered muscle twitching.[71] More recently, four-part assembloids were created that integrated somatosensory, spinal, thalamic and cortical organoids to better understand how sensory information – for example about pain and touch – is conveyed from peripheral organs to the nervous system[72] (see **Appendix 2** for a description of the central nervous system's main structures and regions).

Advances in specifying multiple regions of the nervous system in 3D cultures and refining culture conditions are likely to support the creation of assembloids consisting of many integrated regions, further expanding their complexity.[73] Such models could provide ways to more closely model different aspects and capacities of the human brain and human neurological disease, as well as its interactions with different organs and tissues of the body.

1.6 New trajectories and future directions

Medical applications

Advances in assembloids, OOC technologies, and transplantation into animals are making neural organoids and similar models increasingly complex, mature, and more representative of human physiology. As these models improve, they may become more widely used in pre-clinical studies, for example to assess the efficacy and toxicity of new medicines. By using iPSCs from individuals with specific health conditions, researchers may also be able to develop personalised organoid models that mirror a patient's genetic background. These patient-derived systems could support personalised drug screening, modelling of disease progression, and predictions of how well an individual might respond to different treatments.[74]

Looking further ahead, transplanting neural organoids into humans for therapeutic purposes may also become possible. As organoids possess the capacity for self-renewal and self-organisation, they might be able to replace damaged neural tissue in conditions such as Parkinson's disease or spinal muscular atrophy or following a

71 Andersen J, Revah O, Miura Y, *et al* (2020) Generation of functional human 3D cortico-motor assembloids *Cell* **183(7)**: 1913-29.

72 Kim J, Imaizumi K, Jurjuț O, *et al* (2025) Human assembloid model of the ascending neural sensory pathway *Nature* **642**: 143-53.

73 Kanton S and Paşca SP (2022) Human assembloids *Development* **149(20)**.

74 Guy B, Zhang JS, Duncan LH, Johnston RJ, *et al* (2021) Human neural organoids: models for developmental neurobiology and disease *Developmental biology* **478**: 102-21.

stroke.[75] Compared with traditional neural stem cell therapy, organoids may survive more effectively and form more appropriate connections with host brains due to their structural organisation and cellular diversity.[76] This hypothesis was supported by a 2023 study in mice, in which transplanted human neural organoids repaired stroke-induced brain lesions and restored lost brain function.[77] When researchers repeated the procedure using dissociated single cells from the same organoids, the cells did not repair the damage, suggesting that intact organoids may offer unique therapeutic advantages.[78]

Therapeutic transplantation into human brains is, however, a distant prospect and as such, we have chosen to focus this report on the more pressing contemporary ethical and governance challenges arising from neural organoid-related research.

Biocomputing

Potential applications of neural organoids and similar models extend beyond clinical research. Several groups are investigating how organoids might be integrated with computers as part of the emerging area of "biocomputing" technology.[79] This involves connecting neural organoids and similar models to sensors and output devices and continuously training them to respond to electrical stimulation using AI, machine learning, and related methods. In these systems, neural activity is recorded through microelectrodes, processed computationally, and then fed back into the organoid through stimulation, enabling the organoid to adapt its activity over time.[80] Scientists working in the field envision biocomputing systems that could improve our understanding of brain development, learning and memory and eventually surpass conventional computers or overcome some of the current AI limitations.[81]

Research in this area remains at an early stage, and significant advances in organoid biology, big data tools, and AI will be required before such systems can be fully realised.[82] However, proof-of-concept efforts have begun and companies are already investing in this technology. In the US the National Science Foundation (NSF) has

75 Wei N, Quan Z, Tang H, Zhu JH (2017) Three-dimensional organoid system transplantation technologies in future treatment of central nervous system diseases S*tem Cells International* **2017(1)**.

76 Ibid.

77 Cao SY, Yang D, Huang ZQ, *et al* (2023) Cerebral organoids transplantation repairs infarcted cortex and restores impaired function after stroke *Npj Regenerative Medicine* **8(27)**.

78 Ibid.

79 Smirnova L, Caffo BS, Gracias DH, *et al* (2023) Organoid intelligence (OI): the new frontier in biocomputing and intelligence-in-a-dish *Frontiers in Science* **1**.

80 Ibid.

81 Ibid.

82 Hartung T, Smirnova L, Morales Pantoja IE, *et al* (2023) The Baltimore declaration toward the exploration of organoid intelligence *Frontiers in Science* **1**: 1068159.

invested millions of dollars in projects involving research and development of biocomputing systems in recent years.[83]

A 2022 paper reported on an early version of a biocomputing system that used 2D neural cell culture rather than 3D organoids.[84] Other studies have involved 3D organoids. For example, in one experiment, researchers tested whether neural organoids could distinguish Braille letters: a robot scanned each letter, converted the tactile information into distinct electrical stimulation patterns, and delivered these to the organoids. The organoids produced neural activity patterns that varied depending on the input, and machine-learning models were able to classify the letters with an accuracy of about 61% for a single organoid and 83% when data from more organoids were combined.[85]

Because of their commercial potential, several companies now offer remote access to neural cultures to enable researchers to control their neural activity at a distance. The Swiss company FinalSparks provides access via their Neuroplatform[86] which allows for code to be uploaded to electrically stimulate the cultures. Researchers then receive the cultures' responses to this stimulation in the form of activity patterns – typically electrophysiological signals – in real time. Researchers can access the Neuroplatform for a monthly fee of around USD 1,000, with free access available to selected research groups.[87] Users are not required to disclose how they intend to use the organoids.[88] Another company, Cortical Labs, offers online access to neural cultures and sells what it describes as the world's first biological computer, the CL1, for approximately USD 35,000.[89] The device combines connected **wells** of cultured neurons with an interface that enables users to run experiments and analyse electrical signals.[90]

Some have used the term "organoid intelligence" to refer to neural organoid-related biocomputing,[91] describing it as "an emerging field working to develop biological computing using 3D cultures of human brain cells (brain organoids) and brain–machine interface technologies".[92]

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83 US National Science Foundation (30 August 2024) *NSF invests $14M in bioengineered systems and ethical biocomputing research*, available at: https://www.nsf.gov/news/nsf-invests-14m-bioengineered-systems-ethical-biocomputing.

84 Kagan B, Kitchen AC, Tran NT, *et al* (2022) In vitro neurons learn and exhibit sentience when embodied in a simulated game-world *Neuron* **110(23)**: 3952-69.

85 Liu, T., Philamore, H. and Ward-Cherrier, B. (2025) Encoding tactile stimuli for Braille recognition with organoids (preprint) *arXiv*.

86 For example, see: https://finalspark.com/neuroplatform/.

87 Ibid.

88 Nature News (11 November 2025) *The computers that run on human brain cells*, available at: https://www.nature.com/articles/d41586-025-03633-0.

89 Ibid.

90 Ibid.

91 Smirnova L, Caffo BS, Gracias DH, *et al* (2023) Organoid intelligence (OI): the new frontier in biocomputing and intelligence-in-a-dish *Frontiers in Science* **1**: 1017235.

92 Ibid.

This area of research has generated significant controversy. Some scientists argue that terms such as "sentience" and "organoid intelligence" are scientifically unsupported and risk misleading the public.[93] Others have concerns that exaggerated or speculative claims could provoke a public backlash that results in overly broad and disproportionately restrictive regulation, potentially impeding other areas of research involving organoids.[94] Some have also argued that building organoid-based computing systems that meaningfully complement AI is unlikely to succeed in the near future.[95]

93 Balci F, Hamed Sb, Boraud T, *et al* (2023) A response to claims of emergent intelligence and sentience in a dish *Neuron* **111(5)**: 604-5.

94 Nature News (11 November 2025) *The computers that run on human brain cells*, available at: https://www.nature.com/articles/d41586-025-03633-0.

95 Ibid.

2 Ethical considerations

Key messages

- Neural organoids and similar models arguably present greater ethical challenges than organoids modelling other organs because of their relationship to the brain.
- There is broad scientific consensus that current neural organoids and similar models differ from human brains and the brains of other non-human animals, and they are not currently capable of acquiring sentience (or even a rudimentary form of it).
- However, recent advances indicate that neural organoids and similar models are becoming increasingly complex and sophisticated, raising the possibility that they might acquire characteristics such as sentience in the future.
- This scenario would raise difficult questions about how complex these models should be allowed to become in the future. Consensus on how to identify thresholds or 'hallmarks' of sentience would also be needed.
- Research involving neural organoids and similar models may have impacts – both positive and negative – on non-human animals. More widespread use of neural organoids and similar models could help reduce the use of non-human animals in research, although this is not a universally accepted view.
- Transplanting human neural organoids into the brain of non-human animals may be seen as ethically problematic for multiple reasons, including violation of the integrity of the non-human animals used in this research, the potential suffering caused, and the possibility that the human and non-human tissue might hybridise cognitively in ways that are difficult to predict.
- Neural organoids are created from cells donated by individuals and therefore retain a biological and genetic link to the donor. This raises questions about whether existing broad informed consent models will remain adequate as the science advances, and whether donors will need more information about possible uses of their tissue.

In this section, we set out a range of ethical considerations that have shaped our deliberations throughout the project, and that have informed the development of our recommendations.

In some instances, the issues raised by neural organoids and similar models are commonly encountered across research ethics contexts – and, in particular, in relation to research with other emerging biotechnologies. These include honesty, clarity and transparency in obtaining informed consent to tissue use; integrity in knowledge production and communication; and translation of research into practice. We elaborate on how these apply to neural organoid-related research throughout this section, and have sought to highlight where they may have impacts beyond those seen in other research contexts.

In other instances, the issues raised are novel to the development and use of neural organoids and similar models (and, in some circumstances, other stem cell-based models) in research. These largely centre around the potential future capacities of such models to develop sentience, and the implications of transplanting human neural organoid models into the brains of non-human animals. We also discuss these issues in more depth within this section.

Our analysis draws on relevant academic, legal and policy literature, as well as discussions with scientists, ethicists, legal scholars and other members of the wider scientific community with whom we have engaged in the course of this work.

2.1 Sentience in neural organoids and similar models

Defining key terms

The possibility that neural organoids and similar models might acquire sentience has featured heavily in ethical debates ever since the first neural organoids were developed, and remains at the centre of discussion around governance and regulation.

The concept of sentience has been debated by philosophers for centuries and, more recently, by neuroscientists. There is a lack of consensus on how sentience should be defined, understood and applied in scientific and policy contexts. However, broadly speaking, experts in animal ethics, moral philosophy and philosophy of mind have described sentience as any capacity for feeling – meaning that there is "something it is like" to be that entity (sometimes also described as " phenomenal consciousness")[96] – and the ability to perceive positive and negative states, such as pleasure and pain.[97]

96 Block N (1995) On a confusion about a function of consciousness *Behavioral and brain sciences* **18(2)**: 227-47.

97 Nagel T (1974) *What is it like to be a bat?* Philosophical Review **83(4)**: 435; Birch J (2024) *The edge of sentience: risk and precaution in humans, other animals, and AI* (Oxford: Oxford University Press).

For the purposes of this report, we have decided to adopt a broad definition of sentience – i.e. the capacity to experience feelings such as pain, pleasure, sadness or joy – in line with prominent definitions in animal welfare and science.[98]

Current capabilities and future trajectories

In the literature, neural organoids and similar models are widely regarded as presenting greater ethical challenges than organoids modelling other organs because of their relationship to the human brain.[99] As these models become more complex, mature, and organised, some have expressed concerns that it may become increasingly difficult to identify a clear boundary between resemblance and equivalence to the actual living brain.[100]

The brain is the source of a range of distinctive mental abilities, including our ability to perceive pain and pleasure, experience a range of emotions and to make decisions. Across cultures, it is also viewed as the centre of identity and individuality, and thus as warranting special moral consideration. The little evidence there is about public attitudes towards neural organoids suggests that because of their link to the human brain, neural organoids and similar models might evoke particularly strong symbolic and moral responses. For example, a US-based study of public attitudes towards neural organoid research found that some participants considered that a metaphysical "connection" remained between a tissue donor and the neural organoids that were created from their cells.[101]

At present, there is broad scientific consensus that organoids and similar models currently neither look, nor act, like human brains. They remain relatively simple and lack the biological complexity that would be required for them to develop features associated with sentience.

At the same time, recent advances indicate that the field is developing rapidly towards greater biological complexity with efforts aimed at overcoming these limitations. For example, a recent paper describes highly complex assembloids integrating multiple brain areas.[102]

98 Birch J, Burn C, Schnell A, Browning H, and Crump A (November 2021) *Review of the evidence of sentience in cephalopods molluscs and decapod crustaceans*, available at: Sentience-in-Cephalopod-Molluscs-and-Decapod-Crustaceans-Final-Report-November-2021.pdf.

99 Nuffield Council on Bioethics (2024) *Neural organoids in research: ethical considerations*, available at: https://cdn.nuffieldbioethics.org/wp-content/uploads/Neural-Organoids-in-Research-Briefing-FINAL.pdf.

100 Greely HT (2020) Human brain surrogates research: the onrushing ethical dilemma *The American Journal of Bioethics* **21(1)**: 34-45.

101 Evans JH (2024) *Disembodied brains: understanding our intuitions on neuro-chimeras and human brain organoids* (Oxford: Oxford University Press).

102 Kshirsagar A, Mnatsakanyan H, Kulkarni S, *et al* (2025) Multi-region brain organoids integrating cerebral, mid-hindbrain, and endothelial systems *Advanced Science* **12(33)**: e03768.

As the authors of the paper note, while these models still lack complete vascular networks, long-range axonal projections, and a functional blood-brain barrier, they still display high cellular diversity and increasingly realistic architecture when compared to that of embryonic neural tissue.[103]

Concerns around sentience are also based on evidence that organoids can form neural networks, exhibit spontaneous electrical activity, and respond to stimulation when provided with appropriate input and output mechanisms.[104] For example, they have been observed to respond to light when connected with retinal tissue.[105] Further debate has been prompted by at least one report of some organoids displaying neural oscillations (a type of activity found in functioning brains of a number of species, from flies to humans).[106]

Identifying thresholds and 'hallmarks' of sentience

Assessing whether neural organoids and similar models could become sentient is complicated by the lack of consensus on how to identify anatomical or functional 'hallmarks' of sentience.[107] While this subject has been widely discussed in philosophical and scientific contexts, there is no widespread agreement on hallmarks of the conscious brain that could be used as criteria for the attribution of sentience.[108] While current models may not replicate the full complexity of the human brain, it is reasonable to anticipate that, in the future, they might become sufficiently complex to push at the boundaries of ethical acceptability – to become "sentience candidates".[109] In this scenario, there might be difficult trade-offs between the benefits of research and the complexity that these models should be permitted to develop in the future.

It is worth noting that similar challenges exist in defining and measuring sentience in non-human animals, especially in animals with considerably different nervous systems and behaviours to humans. However, there are frameworks that have sought to address this issue. For example, an approach that evaluated evidence of sentience in decapod crustaceans and cephalopod molluscs used eight criteria – some looking at the possession of certain neural structures, others looking for the presence of

103 Ibid.

104 See for example: Andersen J, Revah O, Miura Y, *et al* (2020) Generation of functional human 3D cortico-motor assembloids *Cell* **183(7)**: 1913-9.

105 Quadrato G, Nguyen, Macosko EZ, *et al* (2017) Cell diversity and network dynamics in photosensitive human brain organoids *Nature* **545(7652)**: 48-53.

106 Trujillo CA, Gao R, Negraes PD, *et al* (2019) Complex oscillatory waves emerging from cortical organoids model early human brain network development *Cell Stem Cell* **25(4)**: 558-69.

107 Diner S (2023) Potential consciousness of human cerebral organoids: on similarity-based views in precautionary discourse *Neuroethics* **16**.

108 Ibid.

109 For a clarification of the concept of "sentience candidacy", see Birch J (2024) *The edge of sentience: risk and precaution in humans, other animals, and AI* (Oxford: Oxford University Press).

certain behaviours.[110] Underpinning the framework is the precautionary principle, and the view that "we should not allow uncertainties about the sentience of some animals to delay the adoption of proportionate measures to protect those animals from severe welfare threats".[111] This approach influenced the introduction of statutory protection for decapod crustaceans and cephalopod molluscs.[112]

In relation to neural organoids specifically, the suggestions include bringing organoids into the remit of legislation around use of animals in research[113] or regulating them based on 'gestational age' analogous with fetal development.[114]

We believe that, in light of these uncertainties, researchers would benefit from a framework to identify where models may have (or be likely to develop) morally relevant characteristics – or, as it has been described, 'sentience candidacy'.[115] This framework would need to be developed collaboratively between a range of stakeholders to ensure it reflects the realities of contemporary and future research. It could act as a prompt for additional mandatory ethical review beyond normal institutional/funder requirements, or other further scrutiny, so that a proportionate approach can be taken to ethical and practical challenges posed by the research.

A number of factors may affect the likelihood of sentience candidacy in neural organoids and similar models. One could be the features of the models being developed or used (i.e. if they have increased biological complexity, comparable to that of humans or protected non-human animals). Another may be the environments and methods used to study them; for example, if they are connected to biological or computational systems which enable interaction or integration with external environments, or if they are implanted into non-human animals at an embryonic or other sensitive developmental stage. The aims or intended outcomes of research may also be relevant factors, such as transplantation for the purpose of cognitive enhancement, or replication of pain responses.

110 Birch J, Burn C, Schnell A, Browning H, and Crump A (November 2021) *Review of the evidence of sentience in cephalopods molluscs and decapod crustaceans,* available at: Sentience-in-Cephalopod-Molluscs-and-Decapod-Crustaceans-Final-Report-November-2021.pdf.

111 Birch J and Browning H (2021) Neural organoids and the precautionary principle *The American Journal of Bioethics* **21(1)**: 56-8.

112 Gov UK (19 November 2021) *Lobsters, octopus and crabs recognised as sentient beings*, available at: Lobsters, octopus and crabs recognised as sentient beings – GOV.UK.

113 Birch J and Browning H (2021) Neural organoids and the precautionary principle *The American Journal of Bioethics* **21(1)**: 56-8.

114 Koplin JJ and Savulescu J (2020) Moral limits of brain organoid research *The Journal of Law, Medicine and Ethics* **47(4)**: 760-7.

115 Birch J (2024) *The edge of sentience: risk and precaution in humans, other animals, and AI* (Oxford: Oxford University Press).

2.2 Ethical considerations in the transplantation of human neural organoids into non-human animals

The introduction of human cells – including neural cells – into other animal species is not new. Human tissue has been transplanted into mice, rats, non-human primates, and other animals (including into their brains) for decades.[116] Such transplants are typically undertaken to create models that more closely replicate aspects of the human brain (as compared to unmodified animals of the same species), or to test the safety and efficacy of new drugs using these hybrid models.[117]

The transplantation of larger portions of human brain tissue – such as neural organoids and similar models – into non-human animals could be seen as ethically problematic for a number of reasons.[118] For example, the alteration of basic physiological processes as a result of human tissue transplant could be painful, possibly in novel ways. As a result, the non-human animals used might experience more acute pain, discomfort or stress, and in a way that might be difficult to detect.[119] Because of this possibility, some have recommended that scientists conducting experiments that involve transplanting human tissue into animals should systematically monitor the behaviour of non-human animals used in experiments so that any novel changes can be detected and reported.[120]

As research progresses, concerns have also been raised over the possibility that large human neural organoids grown in animal hosts could hybridise cognitively in unpredictable ways.[121] There are concerns that such modified animals might develop cognitive and emotional capacities that differ from those of their non-modified counterparts in a morally significant way (for example, in their capacity to suffer or experience pleasure), resulting in them having different welfare needs which require protection.[122]

116 Behringer RR (2007) Human-animal chimeras in biomedical research *Cell Stem Cell* **1(3)**: 259-62.

117 Johnston J, Hyun I, Neuhaus CP, *et al* (2022) Clarifying the ethics and oversight of chimeric research *Hastings Center Report* **52**: 2-23.

118 Kataoka M, Gyngell C, Savulescu J, Sawai T (2023) The ethics of human brain organoid transplantation in animals *Neuroethics* **16(3)**: 27.

119 Johnston J, Hyun I, Neuhaus CP, *et al* (2022) Clarifying the ethics and oversight of chimeric research *Hastings Center Report* **52**: 2-23.

120 Ibid.

121 Lavazza A (2020) Human cerebral organoids and consciousness: a double-edged sword *Monash Bioethics Review* **38(2)**: 105-28.

122 Koplin JJ and Savulescu J (2019) Time to rethink the law on part-human chimeras *Journal of Law and the Biosciences* **6(1)**: 37-50.

Ethical considerations can also arise in relation to the concept of animal integrity. Multiple definitions of the term exist but, broadly speaking, it refers to the animal's "wholeness, intactness and species-specific balance"[123] and its ability to exist and have experiences in accordance with its species norms.

Proponents of animal integrity may consider that the animal's existence in accordance with species norms – its 'right' to exist as it is – has not been respected. Integrity-based concerns have been raised about the application of emerging biotechnologies to non-human animals, including in relation to gene editing.[124] Attention has been drawn to the absence of integrity considerations from UK policymaking, with claims that relying solely on animal welfare risks only partly accounting for public concern about animal interests.[125] Calls have therefore been made for the inclusion of integrity considerations alongside the harm-benefit analyses conducted when authorising research involving non-human animals.[126]

To date, experiments involving the transplantation of human neural organoids into non-human animals have been mostly limited to rodents. However the use of other animals, for example those with brain and developmental trajectories closer to those of humans, could increase the likelihood of extensive integration and growth of human neural tissue – particularly if transplanted in the early stages of neurodevelopment.[127] The Academy of Medical Sciences' 2011 report *Animals containing human material* provides some guidance on mitigating the risk of integration of human tissue in research involving non-human primates, although it does not refer to neural organoids and similar models specifically.[128] It cites a list of factors from a 2005 paper which it suggests should be taken into consideration when considering the risk of integration in non-human primates. These include the proportion of human neural cells transplanted, the animal host species, brain size, site of integration and the stage of neurodevelopment.[129]

123 Rutgers B and Heeger R (1999) Inherent worth and respect for animal integrity, in *Recognizing the intrinsic value of nature* (Van Gorcum) at page 41-53.

124 De Graeff N, Jongsma KR, Johnson J, *et al* (2019) The ethics of genome editing in non-human animals: a systematic review of reasons reported in the academic literature. *Philosophical Transactions of the Royal Society of Biology* **374 (1772)**: 20180106.

125 Yeates JW, Rocklinsburg H and Gjerris M (2011) Is welfare all that matters? A discussion of what should be included in policy-making regarding animals *Animal Welfare* **20**: 423-32.

126 Röcklinsberg H, Gamborg C, Gjerris M (2014) A case for integrity: gains from including more than animal welfare in animal ethics committee deliberations *Laboratory Animals* **48(1)**: 61-71.

127 Chen HI, Wolf JA, Blue R, *et al* (2019) Transplantation of human brain organoids: Revisiting the science and ethics of brain chimeras *Cell Stem Cell* **25(4)**: 462-72.

128 Academy of Medical Sciences (2011) *Animals containing human material*, available at: https://acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material.

129 Greene M, Schill K, Takahashi S, *et al* (2005) Moral issues of human-non-human primate neural grafting *Science* **309(5733)**: 385-6.

The potential role of organoids in reducing the use of non-human animals in research

Research involving neural organoids and similar models may have impacts – both positive and negative – on non-human animals.

One potential positive impact is in reducing the use of non-human animals in research.[130] For example, testing drugs on organoids first could help to narrow down a smaller group of compounds to be tested on non-human animals, and therefore reduce the number of non-human animals needed in experiments.[131] Advances in organoid research have generally been welcomed as a means of replacing (or, at least, significantly reducing) non-human animal testing, and therefore the potential for animal suffering.[132] This is in line with the statutory animal research ethics principles of reduction, refinement, and replacement.[133] The Animal Welfare (Sentience) Act 2022 also established the Animal Sentience Committee, which has the power to review the impact of government policy on animal welfare.[134] In 2025, the UK Government committed to incentivise the development and adoption of alternative methods, including organoid technologies, in its strategy for replacing the use of animals in science.[135]

Evidence from public engagement research in other jurisdictions suggests that the potential to reduce animal use could be a significant driver of public support for organoid research.[136]

However, the extent to which neural organoids and similar models are likely to reduce animal use in research remains contested. Some argue that current limitations mean that organoids are not yet suitable replacements for animals, and therefore replacement of animal use in research will not be realisable in the near future.[137] It has also been suggested that developments in neural organoid technology – and particularly the transplantation of human neural organoids into the brains of non-human animals –

130 Pichl A, *et al* (2023) Ethical, legal and social aspects of human cerebral organoids and their governance in Germany, the United Kingdom and the United States *Frontiers in Cell and Developmental Biology* **11**: 1194706.

131 Park G, Rim YA, Sohn Y, Nam Y, Ju H (2024) Replacing animal testing with stem cell-organoids: advantages and limitations *Stem Cell Reviews and Reports* **20**: 1375-86.

132 Lee CJ, Nam Y, Rim YA, and Ju JH (2025). Advanced animal replacement testing strategies using stem cell and organoids *International journal of stem cells* **18(2)**: 107-25.

133 Animals (Scientific Procedures) Act 1986 (ASPA), s. 2(1); 3(1); 10(2).

134 Animal Welfare (Sentience) Act 2022.

135 Department for Science, Innovation & Technology, Home Office, Department for Environment, Food & Rural Affairs (November 2025) *Replacing animals in science: A strategy to support the development, validation and uptake of alternative methods*, available at: https://www.gov.uk/government/publications/replacing-animals-in-science-strategy/replacing-animals-in-science-a-strategy-to-support-the-development-validation-and-uptake-of-alternative-methods.

136 Ravn T, Sørensen MP, Capulli E, *et al* (2023) Public perceptions and expectations: disentangling the hope and hype of organoid research *Stem Cell Reports* **18(4)**: 841-52.

137 Bredenoord AL, Clevers H, and Knoblich JA (2017) Human tissues in a dish: the research and ethical implications of organoid technology *Science* **355(6322)**.

may instead lead to an increased overall demand for laboratory animals.[138] As seen earlier in this report (**section 1.5**), there are a number of advantages to be gained from transplanting human neural organoids into non-human animals which may make them more appealing options for researchers.

Additional factors may be relevant when assessing the overall impact of neural organoid-related research on non-human animals, including the use of animal-derived substances to culture neural organoids and similar models. For example, one substance, Matrigel, is derived from mouse sarcoma cells. Studies suggest that one mouse is needed for every 6.3 ml of Matrigel produced,[139] which is enough to generate between 64 and 192 organoids, depending on the method employed.[140]

Public views on transplanting neural organoids into non-human animals

A few empirical studies have explored public views on transplanting human neural organoids into non-human animals. A US-based study – mentioned earlier in this report (**section 2.1**) – found some ethical unease in relation to the crossing of perceived species boundaries and violating the foundational divide between humans and animals.[141] That study also suggests that the terminology used in these contexts can be important. Participants tended to be less supportive of such research when non-human animals were described as "humanised", suggesting that the term evokes a sense of boundary violation.[142]

As has been found with other emerging or controversial biotechnologies, such as genome editing,[143] engaging with the public on these issues is important to open a dialogue on what this research involves and hopes to achieve, understanding what drives unease, and identifying what governance measures might help to ensure public trust.[144]

138 Pichl A, *et al* (2023) Ethical, legal and social aspects of human cerebral organoids and their governance in Germany, the United Kingdom and the United States *Frontiers in Cell and Developmental Biology* **11**: 1194706.

139 Gallimore Godkin Laboratory (2026) *Replacement of Matrigel in organoid culture*, available at: https://www.cancerimmunology.co.uk/nc3r.

140 Participants in our evidence-gathering programme.

141 Evans JH (2024) *Disembodied brains: understanding our intuitions on neuro-chimeras and human brain organoids* (Oxford: Oxford University Press).

142 Ibid.

143 Morrison M and de Saille S (2019) CRISPR in context: towards a socially responsible debate on embryo editing *Palgrave Communications* **5(1)**.

144 Basis Social with the NCOB, BBSRC, and Sciencewise (October 2022) *Public dialogue on genome editing in farmed animals*, available at: https://cdn.nuffieldbioethics.org/wp-content/uploads/NCOB-BBSRC-Sciencewise-Genome-editing-and-farmed-animals-dialogue-Oct-2022.pdf.

2.3 Consent

Challenges have been raised in relation to obtaining informed consent for neural organoid-related research.

Empirical research conducted in the US suggests that some people may attribute personal meaning to donated tissue.[145] In a qualitative study, some participants viewed neural organoids as an extension of the donor.[146] This resonates with some earlier research exploring public views on organ transplantation, which show that some recipients may believe that an organ carries something of the donor's 'essence'.[147] It is important to ensure that potential donors who hold such views can make informed choices about donation as any other potential donor, despite the challenges discussed earlier in this section.

Donors' views on these connections, and on the extent of control they wish to retain over the use of their tissue, are likely to vary. Our 2011 report, which covered bodily donation, considered generic consent acceptable for future research uses, provided that donors are informed of the range of possible applications and are given the opportunity to express preferences and place limits.[148] However, providing information about the range of potential applications in the context of neural organoid research is challenging because of the pace and unpredictability of advances – current applications including biocomputing and organs-on-chips would have been difficult to anticipate even a few years ago. Because neural organoids and similar models can be kept in culture for years, it is possible that they could be used in ways that could not have been anticipated when consent was sought. In our evidence gathering, we heard that biobanks tend to use generic consent models to account for varied potential research uses, and generally do not contain reference to specific research projects.

Unlike broad or generic forms of consent, "dynamic" and "tiered" consent allow for continuous interactions between biobanks and donors, enabling donors to consent to specific uses of their cells and tissue. Dynamic consent models are designed to enable ongoing communication between researchers and tissue donors (enabling participants to regularly update their consent choices in response to new uses of their material, for example). In the case of tiered consent, donors are provided with different 'tiers' of participation and/or potential tissue uses that they can choose between. These consent models could therefore allow for greater flexibility and ongoing communication, but they also present a range of practical challenges, including costs and the administrative burden of ongoing contact. In addition, some

145 Bollinger J, May E, Mathews D, *et al* (2021) "Patients' perspectives on the derivation and use of organoids *Stem Cell Reports* **16(8)**: 1874-83.

146 Evans JH (2024) *Disembodied brains: understanding our intuitions on neuro-chimeras and human brain organoids* (Oxford: Oxford University Press).

147 Fox RC and Swazey JP (1992) *Spare Parts: Organ Replacement in American Society* (Oxford: Oxford University Press).

148 Nuffield Council on Bioethics (2011*) Human bodies: donation for medicine and research*, available at: https://www.nuffieldbioethics.org/publications/human-bodies-donation-for-medicine-and-research.

donors may prefer not to be recontacted.[149] A public dialogue exercise carried out in 2017 on behalf of the Human Tissue Authority (HTA) and Health Research Authority (HRA) about consent to use of human tissue found that some participants considered that limits on generic consent, such as those used in dynamic and tiered consent models, could present barriers to their participation.[150] Evidence about consent preferences, however, is mixed. In a public engagement exercise conducted across several European countries, participants expressed the view that consent information should be clear, understandable, and precise, and include information about the purpose and use of tissue, its ownership, and the distribution of profits.[151] While recognising the difficulties in finding a proper balance, the majority of participants expressed a preference for some restrictions to be imposed on existing forms of broad consent (for example in the form of tiered or dynamic consent).[152]

2.4 Communication

Understanding of, and engagement with, neural organoids and similar models is dependent on balanced, clear, and factual information about what they are, their capabilities and limitations, and their likely future potential.

However, communication about neural organoids and similar models has sometimes drawn criticism for being misleading, for example by exaggerating the models' capability to develop sentience and other human-like characteristics or overstating their potential to lead to a range of medical applications in the near future.[153]

Some media articles have portrayed brain organoids as already experiencing some kind of mental state.[154] As an example, a study of organoids with optical cups that are sensitive to light stimulus was reported with the headline "Tiny human brain grown in lab has eye-like structures that 'see' light", suggesting that neural organoids have the capacity for sight.[155] Another example concerned media reports of a study where researchers constructed brain-computer interfaces using brain organoids and electrodes that both read electrical signals from the brain and sent electrical

149 Ipsos MORI (July 2018) *Consent to use human tissue and linked health data in health research: A public dialogue for Health Research Authority and Human Tissue Authority*, available at: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Consent_to_use_human_tissue_and_linked_health_data_in_health_research_FINAL.pdf.

150 Ipsos MORI (July 2018) *Consent to use human tissue and linked health data in health research: A public dialogue for Health Research Authority and Human Tissue Authority*, available at: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Consent_to_use_human_tissue_and_linked_health_data_in_health_research_FINAL.pdf.

151 Ravn T, Sørensen MP, Capulli E, *et al* (2023). Public perceptions and expectations: disentangling the hope and hype of organoid research *Stem Cell Reports* **18(4)**: 841-52.

152 Ibid.

153 Kataoka M, Gyngell C, Savulescu J and Sawai T (2023) The importance of accurate representation of human brain organoid research *Trends in Biotechnology* **41(8)**: 985-7.

154 Ibid.

155 New Scientist (17 August 2021) *Tiny human brain grown in lab has eye-like structures that 'see' light*, available at: https://www.newscientist.com/article/2287207-tiny-human-brain-grown-in-lab-has-eye-like-structures-that-see-light/.

stimulation back to them. This was reported as creating "Frankenstein robots" and of neural organoids "controlling intelligent robots in the lab."[156]

Misleading claims about new technologies – including organoids – may risk leaving individuals feeling unnecessarily threatened or fearful, but it may also lead to unrealistic expectations of potential treatments among patients with serious conditions.[157] A 2022 analysis of global media reporting on neural organoids found that while the majority of articles analysed had a neutral tone, there was a tendency towards polarised misleading narratives in the remainder, alternating between alarmist portrayals and exaggerated optimism about therapeutic potential.[158] For example, while neural organoids only seem to have very limited – albeit important – utility for understanding autism spectrum disorder (ASD) at present, a recent study was reported with the headline "Gene edited brain organoids are unlocking the secrets of autism", clearly exaggerating the current role of neural organoids in ASD research.[159]

Inaccurate representations of neural organoid-related research do not come from the media alone; scientists have also been criticised for misleading communication of their research, for example by the use of the word "intelligence" in describing organoids.[160]

Prominent experts within the scientific community have also expressed concerns about the use of metaphors – such as "mini-brains" or "intelligence in a dish" – and have suggested that these terms should not be used to describe neural organoids and similar models.[161] They do not accurately describe what organoids and similar models are, and could give the non-expert reader misleading impressions about their capabilities and resemblance to the human brain. There are calls within the scientific community to agree on appropriate terminology to be used in neural organoid-related research. Experts in the field have come together to set out a tentative consensus nomenclature for the field.[162]

156 See, for example: Futura Sciences (26 December 2025) *Mini human brains are now controlling intelligent robots in the lab*, available at: https://www.futura-sciences.com/en/mini-human-brains-are-now-controlling-intelligent-robots-in-the-lab_22535/; and The Science Times (3 July 2024) *Robot with human brain created by Chinese researchers; how does human-on-chip system work?*, available at: https://www.sciencetimes.com/articles/51064/20240703/robot-human-brain-organoid-human-on-chip-system.htm.

157 Nuffield Council on Bioethics (2013) *Novel neurotechnologies: intervening in the brain*, available at: https://www.nuffieldbioethics.org/publication/novel-neurotechnologies-intervening-in-the-brain/.

158 Presley A, Samsa LA and Dubljević V (2022) Media portrayal of ethical and social issues in brain organoid research *Philosophy Ethics and Humanity in Medicine* **17:8**.

159 Wired (21 February 2022) *Gene-edited brain organoids are unlocking the secrets of autism*, available at: https://www.wired.com/story/gene-edited-brain-organoids-are-unlocking-the-secrets-of-autism/.

160 Ibid.

161 Paşca SP, Arlotta P, Bateup HS, *et al* (2022) A nomenclature consensus for nervous system organoids and assembloids *Nature* **609(7929)**: 907-10.

162 Ibid.

3 Governance

Key messages

- Neural organoids and similar models are not regulated by any UK legislation or regulatory authority. Statutory mechanisms only regulate specific elements of the research pathway.
- The stem cells and tissue used to create neural organoids and similar models are subject to regulatory mechanisms, i.e. the Human Fertilisation and Embryology Act 1990, as amended, administered by the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Act 2004, administered by the Human Tissue Authority (HTA).
- However, neural organoids are excluded from the HTA's regulatory remit because they are created outside of the human body. The remit of the HFEA ceases once the embryo has been dissociated and embryonic stem cell lines have been created from it.
- While there is general guidance on the use of stem cells in research – such as the International Society for Stem Cell Research (ISSRC)'s Guidelines for Stem Cell Research and Clinical Translation – there is no specific guidance addressing the development and use of neural organoids in the UK.
- Research involving living non-human protected animals is regulated under the Animals (Scientific Procedures) Act 1986 (ASPA). Researchers wanting to undertake research under ASPA must apply for licences from the Animals in Science Regulation Unit (ASRU) – part of the Home Office.
- Guidance on the use of human material in animals is provided by the Academy of Medical Sciences, and endorsed by the Home Office. However the guidance, published in 2011, does not cover neural organoids and similar models and their transplantation into non-human animals.
- In the future, neural organoids and similar models may have a range of medical applications including in relation to drug discovery, and personalised medicine. In this scenario, the HTA, the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA) are all likely to have authority over different aspects of the creation and use of medicinal products made from human material, and clinical trials.

In this section, we map the current governance landscape relevant to neural organoids and similar models in the UK; the key issues raised by the gaps or limitations in existing mechanisms; and the potential future governance implications of the scientific and ethical developments mentioned in previous sections.

We differentiate between broad 'governance' and narrower 'regulation', which is a subset of governance involving oversight by regulatory bodies, often based on legal authority. We also differentiate between 'hard law' by which we mean binding legal obligations, and 'soft law' which means principles, guidelines and codes which are not legally binding, but which can nevertheless exert considerable practical control over behaviour. As much of the research in this area is collaborative and cross-jurisdictional, we looked at the approach to neural organoid research in other countries (Germany, the US and China) and the mechanisms they have in place – a summary of the approaches taken in these jurisdictions is provided at the end of this section.[163]

Neural organoids and similar models themselves are not regulated by any UK legislation or regulatory authority. This governance gap has practical consequences. The absence of clear national guidance means that the responsibility for assessing and managing the ethical dimensions of neural organoid research largely falls to institutional research ethics committees, biobanks, funders, and other local decision makers. This creates the risks of inconsistency, uncertainty, and a lack of confidence in managing complex and ethically sensitive research trajectories.

3.1 The UK governance and regulatory landscape

Creation

The stem cells and tissue used to create neural organoids and similar models are subject to different regulatory mechanisms depending on the types of tissue used. However, the creation and use of neural organoids and similar models itself is not regulated.

Embryonic stem cell (ESC) lines

Research on embryos is governed by the Human Fertilisation and Embryology Act 1990 (as amended), but its remit ceases once the embryo has been dissociated and embryonic stem cell lines are created from it.[164] The 1990 Act is administered by the Human Fertilisation and Embryology Authority (HFEA).

163 We commissioned Dr David Lawrence from the University of Durham to carry out a comparative exercise, mapping the governance mechanisms in Germany and the US and identifying lessons for the UK. The comparative exercise is available at: https://www.nuffieldbioethics.org/wp-content/uploads/Nuffield-Neural-Organoids-Comparative-Report-Final.pdf.

164 Human Fertilisation and Embryology Act 1990, s.1(1)(a); see also HTA (2026) *Regulating human embryonic stem cell lines for human application*, available at: https://www.hta.gov.uk/guidance-professionals/guidance-sector/human-application/regulating-human-embryonic-stem-cell-lines.

ESCs, once created, are therefore considered to be distinct from embryos and fall within the remit of the UK Stem Cell Bank (UKSCB). Research involving ESCs is subject to approval by the UKSCB's independent Steering Committee, which is guided by the principles set out in its 2010 Code of Practice.[165] The Steering Committee is responsible for ensuring that appropriate donor consents, ethical approvals, licences and authorisations are in place for all deposited lines and for projects receiving cell lines from the Bank.

The UKSCB is not a statutory regulator and therefore compliance with its mechanisms is not mandatory, however researchers using ESCs can voluntarily comply with the 2010 Code of Practice.

Once approval for research has been given by the UKSCB, no further approval, such as that from an NHS Research Ethics Committee (REC), is required.[166]

Induced pluripotent stem cells (iPSCs)

The removal, storage and use of the cells used to make iPSCs is governed in England, Wales and Northern Ireland by the Human Tissue Act 2004, and the Authority responsible for implementing it – the Human Tissue Authority (HTA).[167] Under the Act, the HTA regulates and licences establishments that remove, store and use 'relevant material' for research purposes. 'Relevant material' for the purposes of the Act is defined as material, other than gametes, which consists of, or includes, human cells.[168]

The creation of iPSC lines falls outside the HTA's regulatory remit, however, as material created *outside* the human body consisting of, or including, human cells is explicitly excluded by the Act, and treated as 'not relevant material'.[169] Neural organoids and similar models created from iPSC lines therefore also fall outside of the HTA's regulatory remit.

In Scotland, the Human Tissue (Scotland) Act 2006 sets out provisions for the removal, storage and use of human tissue from the deceased. Collection, storage and use of tissue (including that obtained from consenting, living donors) is governed by NHS Research Scotland, which independently accredits tissue banks using criteria comparable to those used by the HTA[170].

Unlike ESCs, there is no requirement to deposit iPSC lines with the UKSCB, and their use falls outside the remit of the UKSCB Steering Committee.

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165 UKSCB (April 2010) *Code of practice for the use of human stem cell lines*, available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1182116/Code_of_Practice_for_the_Use_of_Human_Stem_Cell_Lines_-_2010_-_amended_August_2023.pdf.

166 Ibid.

167 Human Tissue Act 2004, s.1(1) a; and Human Tissue Act 2004, s.13-15.

168 Human Tissue Act 2004, s.53(1).

169 Human Tissue Act 2004, s.53(2); and HTA Code of Practice E (Research) para 26.

170 NHS Research Scotland (2026) Overview of the biorepository network, available at: https://www.nhsresearchscotland.org.uk/research-in-scotland/facilities/biorepositories-and-tissue-services/overview.

Fetal tissue

With consent, fetal stem cells can be extracted from donated fetuses, usually following termination of pregnancy. These are stored by a number of tissue banks, including local banks in hospital settings and the Human Developmental Biology Resource (HDBR), which serves as an international tissue bank. These tissue banks operate under licence from the HTA. As with iPSC lines, the HTA's regulatory remit explicitly excludes material created outside the human body consisting of, or including, human cells; this means that once cell lines have been created from the extracted stem cells, they are outside the HTA's jurisdiction. Neural organoids and similar models created from fetal tissue therefore also fall outside of the HTA's regulatory remit.

Use of neural organoids and similar models

Inconsistencies persist after neural organoids and similar models have been created and begin to be used for research purposes.

Consent

There is no standard consent form model in the UK for donors to consent to the use of their cells or tissue for neural organoid-related research.

The Human Tissue Act 2004 requires that 'appropriate consent' is obtained for the storage and use of relevant material for 'scheduled purposes[171]. The sourcing of human cells and tissue, from which the cell lines to create neural organoids and similar models are formed, amounts to a scheduled purpose under the Act ('research in connection with disorders, or the functioning, of the human body'[172]), and therefore 'appropriate consent' is required. For a living adult donor, consent must be the donor's own, and cannot be presumed or deemed.[173] Usually, a generic form of consent is sought so that the donor's material can be used for a range of future research purposes, although there are examples of consent forms which are more specific in describing possible ways in which a donor's tissue might be used in the future.[174] The Medical Research Council has advised researchers that, when seeking generic consent, they should think about the amount of information a donor might need to understand enough about how samples might be used in future.[175]

As discussed in **section 2.3**, a number of ethical and practical challenges arise as a result of the gaps in existing consent processes, as well as when considering what

171 Human Tissue Act 2004, s. 1(1).

172 Human Tissue Act 2004, Sch.1, para.6.

173 Human Tissue Act 2004, s. 45(1-2).

174 See, for example, the ISSCR *Somatic cell donation stem cell research*, available at: https://www.isscr.org/guidelines/appendices.

175 Medical Research Council (2019) *Research and the Human Tissue Act 2004*, available at: https://www.ukri.org/wp-content/uploads/2021/11/MRC-301121-ResearchHumanTissueAct2004-ConsentSummary-May2019.pdf.

alternatives might look like. The Working Group's discussions have focused upon the appropriateness of obtaining generic consent from tissue donors, and what information donors need before giving generic consent.

The 2010 UK Stem Cell Bank's Code of Practice says that obtaining consent from potential participants should – where possible – be explicit about the range of *possible* ways in which donors' tissue might be used in the future so that the participant can make an informed choice.[176] Reasons to seek specific consent may include where risks of involvement are significant or unknown, where participants may be identifiable or where the research in question is particularly sensitive or controversial.

Practical challenges arise in obtaining specific consent. As mentioned earlier (**section 1.1**), stem cell lines used to create neural organoids and similar models can be stored and used indefinitely following donation. Combined with the rapid pace of research, this makes it potentially impossible to tell donors about all future research applications in a meaningful way at the point of donation. This is affirmed by Medical Research Council advice to consider seeking generic consent in order to futureproof derived cell lines for a broad range of potential uses.[177] The possibility of tissue being used a long time after donation might make it difficult to go back to donors in order to obtain specific consent for new uses. Although neural organoids and similar models can never be truly anonymised because of their genetic identity with the original tissue donor, information about the source of tissue used to derive stem cell lines is not routinely held and so identification and tracing of donors would be complex and costly. Some have also noted that, even where tracing of donors was possible, being recontacted may conflict with their wishes about future involvement.[178]

Withdrawal of consent presents another challenge, both practically and ethically. While theoretically donors may exercise their right to withdraw consent to use and storage of their tissue, in practice, it may not be actionable if their tissue has already been used to derive cell lines and biotechnological products.[179] This, and other issues relating to the withdrawal of consent, have been highlighted in a report from the HYBRIDA project, a European Union research initiative which ran from 2021 to 2024 and which explored the ethical, conceptual and regulatory challenges arising from organoid research.[180]

176 UKSCB (April 2010) *Code of practice for the use of human stem cell lines*, available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1182116/Code_of_Practice_for_the_Use_of_Human_Stem_Cell_Lines_-_2010_-_amended_August_2023.pdf.

177 MRC (2024) *Guidance: ethics and approvals*, available at: https://www.ukri.org/publications/mrc-guidance-for-applicants/ethics-and-approvals/.

178 Ipsos MORI (2018) Consent to use human tissue and linked health data in health research: A public dialogue for Health Research Authority and Human Tissue Authority, available at: Consent_to_use_human_tissue_and_linked_health_data_in_health_research_FINAL.pdf.

179 HTA (June 2023) *Code of practice and standards: code E*, available at: https://www.hta.gov.uk/sites/default/files/2023-06/Code%20E%20-%20Research.pdf.

180 The HYBRIDA reports are available at: https://hybrida-project.eu/deliverables/.

Guidance for researchers

In the UK, there is no specific guidance addressing the development and use of neural organoids. There is, however, guidance on the use of stem cell lines, which includes neural organoids and organoids more generally.

One of the most comprehensive sets of ethical recommendations and guidance for the use of stem cells in research is provided by the International Society for Stem Cell Research (ISSCR), a leading international scientific organisation in stem cell research.[181] Its guidelines include a series of statements on neural organoids and organoids more generally, and conclude that while there is currently no evidence to suggest any "issues of concern" – for example, in relation to neural organoids developing "consciousness or pain perception" – researchers "should be aware of any ethical issues that may arise in the future as organoid models become more complex through long-term maturation or through the assembly of multiple organoids".[182]

Use of human tissue and cells for therapeutic purposes

As discussed earlier (**section 1.6**), neural organoids and similar models may have significant potential for medical applications including in relation to drug discovery, and personalised medicine. However, the absence of a single regulatory authority creates challenges for using human tissues and cells in therapeutic contexts. The HTA licenses and monitors the procurement, testing, processing, storage, and distribution of human material for human application. While the collection of material for Advanced Therapy Medicinal Products (ATMPs) falls under the HTA's remit, further processing, storage, and distribution are overseen by the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA and the Health Research Authority (HRA) regulate clinical trials involving ATMPs, but only the MHRA licenses their manufacture and trade in the UK. This fragmented regulatory landscape complicates the pathway to clinical translation.

Research involving the use of non-human animals

Research involving living non-human vertebrates and cephalopods ("protected animals") is regulated under the Animals (Scientific Procedures) Act 1986 (ASPA).[183] Any research falling under ASPA must comply with the 3R principles – replacement, reduction and refinement. In 2022, the Animal Welfare (Sentience) Act established the Animal Sentience Committee[184], which has the power to review the impact of government policy on animal welfare.[185] The Act also broadened the legal recognition

181 ISSCR (2025) Guidelines for Stem Cell Research and Clinical Translation, available at: https://www.isscr.org/guidelines.

182 Ibid.

183 Animals (Scientific Procedures) Act 1986 (ASPA), s. 2(1); 3(1); 10(2).

184 Gov UK (2026) *Animal Sentience Committee*, available at: https://www.gov.uk/government/groups/animal-sentience-committee.

185 Animal Welfare (Sentience) Act 2022.

of sentience, to include certain invertebrates such as decapod crustaceans and cephalopod molluscs.[186]

In England, Scotland and Wales, researchers must apply for licences from the Animals in Science Regulation Unit (ASRU) – part of the Home Office – to be able to undertake research under ASPA.[187] Both the establishment and the researcher must hold valid licenses, in addition to the licensing of the specific project. In Northern Ireland, licences are issued by the Department of Health.[188]

The project must have been reviewed by an Animal Welfare & Ethical Review Body (AWERB) at a licenced establishment before it can be granted a project licence. The Home Office provides guidance on establishing an AWERB,[189] and operational and best practice guidance for established AWERBs has been issued by third party organisations with an interest in animal welfare such as the Royal Society for the Prevention of Cruelty to Animals (RSPCA)[190].

As highlighted earlier (**section 2.2**), guidance on the use of human material in animals was published by the Academy of Medical Sciences in 2011 and endorsed by the Home Office in 2016.[191] The 2011 report proposed three categories for research projects involving the use of human material in animals based on the scientific justification and ethical concerns generated by the work:

- Category 1 – lowest risk and licensable under ASPA;
- Category 2 – medium risk and licensable under ASPA subject to a positive harm/benefit assessment and specialist scrutiny by an expert body; and
- Category 3 – lacking compelling scientific justification or raising very strong ethical concerns.[192]

Category 2 includes research which may modify an animal's brain to make it function in a more 'human-like' way, though what is meant by 'human-like' remains undefined. The Academy recommends that proposed studies of this nature should

186 Ibid.

187 Home Office (March 2013) *Research and testing using animals: licences and compliance*, available at: https://www.gov.uk/guidance/research-and-testing-using-animals.

188 Home Office (March 2014) *Guidance on the operation of the Animals (Scientific Procedures) Act 1986*, available at: https://assets.publishing.service.gov.uk/media/66e0233ab1a8879e443282a0/Guidance_on_the_operation_of_ASPA_-_December_2023.pdf.

189 Ibid.

190 RSPCA (January 2026) *Guiding principles on good practice for Animal Welfare and Ethical Review Bodies*, available at: https://science.rspca.org.uk/documents/d/science/guiding-principles-on-good-practice-for-awerbs.

191 See Academy of Medical Sciences (July 2011) *Animals containing human material*, available at: https://acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material; and Home office (2016); Home Office (February 2016) Guidance on the use of human material in animals, available at: https://www.gov.uk/government/publications/guidance-on-the-use-of-human-material-in-animals.

192 See Academy of Medical Sciences (July 2011) Animals containing human material, available at: https://acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material.

be assessed on a case-by-case basis "at least until experience allows the formulation of guidelines".[193]

As research in this area progresses, an important question to answer will be whether transplanting human neural organoids and similar models into non-human animals, as opposed to isolated human neural stem cells, could increase the chances of significantly altering the behaviour and cognitive abilities of the animal host. There could be questions, for example, as to whether human neural organoid transplantation could modify non-human animals' capacity to suffer or experience pleasure and, if this happens, what a proportionate regulatory mechanism that adequately protects animal welfare might look like.

Patenting

The Patents Act 1977 governs the granting of patents in the UK. This Act was amended to implement the European Directive 98/44/EC on the patentability of biotechnological innovations in domestic legislation. Article 6(2)(c) of this Directive sets out that inventions are unpatentable "where their commercial exploitation would be contrary to *ordre public* or morality". European case law, namely the *Brüstle* decision, ruled that human embryos – as organisms "capable of commencing the process of development of a human being" – are not patentable.[194] UK authorities have clarified that uses of human embryos for commercial purposes (including for processes of obtaining stem cells from embryos) and inventions that require the destruction of human embryos cannot be patented.[195] Inventions which are for therapeutic or diagnostic purposes applied to, and useful to, the human embryo are not excluded from patentability.[196] It is not clear whether a neural organoid derived from an already-existing ESC line (i.e. where no sourcing of ESCs would be required to create the organoid) would be patentable.

Neural organoids and similar models derived from iPSC lines, however, may be patented. Guidance from the UK Intellectual Property Office, issued following the *Brüstle* decision, set out that patents for inventions concerning human stem cells not derived from embryos, such as iPSCs and adult stem cells, can be patented if they fulfil the criteria set out in the Patents Act 1977.[197] To be a patentable invention under the Act, it must be new, involve an inventive step, be capable of industrial application, not be otherwise excluded from the Act or have a commercial use that would run contrary to public policy or morality.

193 Ibid.

194 *Oliver Brüstle v Greenpeace* [2011] Case C-34/10.

195 Intellectual Property Office (March 2015) *Inventions involving human embryonic stem cells*, available at: https://www.gov.uk/government/publications/inventions-involving-human-embryonic-stem-cells-25-march-2015/inventions-involving-human-embryonic-stem-cells-25-march-2015.

196 Ibid.

197 Ibid.

Gaps therefore exist in UK patent protections for neural organoids and similar models. Those derived from iPSCs are patentable, and those derived from already-existing ESC lines are potentially patentable, but not those where ESC lines have been created for the purpose of creating the neural organoid. The inconsistency around patentability of organoids more generally was cited as potentially problematic for attracting investment in European research and product development.[198]

3.2 Governance and regulation in other jurisdictions

We looked at other jurisdictions in order to see how they are responding to the ethical and regulatory challenges raised by neural organoid-based research. In particular, we looked at Germany, the US and China as examples of different nations where neural organoid research is ongoing, in order to explore the mechanisms they have in place.[199]

Germany

In Germany, the regulation of embryonic stem cell lines is particularly stringent and shaped by two key federal statutes: the Embryo Protection Act (ESchG, 1990)[200] and the Stem Cell Act (StZG, 2002; amended 2008).[201]

The ESchG criminalises the creation of embryos for research and prohibits embryo-level research. This definition excludes iPSCs, which are not governed by the same restrictions. The StZG permits only the import and use of human embryonic stem cell (hESC) lines derived before 1 May 2007. The Robert Koch Institute (RKI) – with advisory input from the Central Ethics Commission for Stem Cell Research (ZES) – evaluates each project and decides whether or not to licence the use of hECS derived before May 2007.[202]

The approval of animal research follows the Animal Welfare Act (TierSchG), updated in line with EU Directive 2010/63/EU, with prohibitions on research involving great apes.[203] The Leopoldina (National Academy of Sciences) considers current in vitro neural organoid research to be adequately regulated but recommends ongoing

198 Lewis J & Holm S. (2023) *Regulating organoid and organoid-related activities: an analysis of the regulatory gaps and areas of over-regulation*, available at: https://hybrida-project.eu/deliverables/.

199 We commissioned Dr David Lawrence from the University of Durham to carry out a comparative exercise, mapping the governance mechanisms in Germany and the US and identifying lessons for the UK. The comparative exercise is available at: https://www.nuffieldbioethics.org/wp-content/uploads/Nuffield-Neural-Organoids-Comparative-Report-Final.pdf.

200 Embryonenschutzgesetz (Embryo Protection Act, 1990).

201 Stammzellgesetz (Stem Cell Act, 2002; amended 2008) (StZG).

202 Ibid.

203 Tierschutzgesetz (Animal Welfare Act, 1998).

monitoring of advances and specialised ethics review for transplantation into the brain of non-human animals.[204]

United States

In the United States, regulation of neural organoid research is more fragmented than the German model, with a mix of federal funder policies, institutional oversight, and variable state laws. The Dickey-Wicker Amendment restricts federally funded research involving the creation or destruction of embryos but does not directly address the creation of organoids.[205] Research guidelines from the National Institutes of Health (NIH) primarily apply to the sourcing of hESCs, stipulating that only lines derived from surplus IVF embryos, with proper consent and without inducement, are eligible for federal funding.[206] The NIH Registry lists these eligible hESC lines.[207] iPSC-derived organoids are largely unregulated at the federal level.

Research funded through the NIH follows rigorous oversight through Institutional Review Boards (IRBs), Stem Cell Research Oversight Committees (SCROs), and Institutional Animal Care and Use Committees (IACUCs). The Animal Welfare Act (AWA) and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals govern animal procedures.[208] While publicly funded neural organoid research is subject to some federal restrictions, private funding and permissive state laws allow for a wider range of research activities that federal funds will not support, creating a dual-track regulatory environment.[209]

Despite the lack of a clear federal statute on organoid research, NIH guidelines and IRBs ensure that human stem cell-based organoid research adheres to ethical principles, particularly regarding consent and respect for privacy.[210] Research involving organoid transplantation into animals is often reviewed by IACUCs on a case-by-case basis, with institutions responsible for ensuring compliance with ethical standards.[211]

204 Leopoldina (May 2023) *Brain organoids – model systems of the human brain: Statement*, available at: https://levana.leopoldina.org/receive/leopoldina_mods_00778.

205 Dickey–Wicker Amendment, s. 509 (a).

206 NIH (July 2009) *Guidelines for human stem cell research*, available at: https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research.

207 NIH (2023) *NIH Human Embryonic Stem Cell Registry*, available at: https://stemcells.nih.gov/registry/eligible-to-use-lines.

208 Animal Welfare Act 1996, to be read accompanied by the Implementing Regulations; and U.S. Department of Health and Human Services & NIH (2015) PHS Policy on humane care and use of laboratory animals, available at: https://olaw.nih.gov/policies-laws/phs-policy.htm.

209 Lawrence DL (2026) Comparative mapping exercise – governance of neural organoids, available at: https://www.nuffieldbioethics.org/wp-content/uploads/Nuffield-Neural-Organoids-Comparative-Report-Final.pdf.

210 Ibid.

211 Ibid.

China

At the time of writing, the only existing guidance which specifically addresses neural organoids and similar models is the 'Human Organoid Research Ethical Guidelines' issued by China's National Science and Technology Ethics Committee (Life Science Ethics Subcommittee) in April 2025.[212]

To the best of the Working Group's knowledge, these are the first ethics guidelines anywhere that focus specifically on organoid research. While they apply to all organoids, they place particular emphasis on neural organoids, embryo-like models, and the transplantation of human organoids into animals. The guidance itself is currently only available in Chinese. An accompanying commentary on the guidelines is provided in English and it is this commentary on which we based our discussions and analysis.[213]

The guidelines set out eight broad requirements, including the creation of specialised research ethics committees with relevant expertise, stricter rules for storing and sharing biological materials, and the use of dynamic consent processes that allow donors to opt in again when research takes an unexpected new direction. They also introduce special safeguards for neural organoids, such as limits on mixing human and animal cells in transplantation experiments, and the use of multiple methods to monitor signs of emerging consciousness. These include organoid neural activity monitoring via electroencephalogram (EEG) and cross-checks using other biological markers.[214]

As the authors of the commentary paper note, these provisions have not yet been accompanied by any quantitative thresholds (such as upper limits to the proportion of human cells that can be transplanted into non-human animals) which might be necessary to facilitate compliance with the guidelines.[215]

212 **The guidance is currently only available in Chinese. A commentary on the Guidelines in English is provided in a paper that accompanied the publication of the Guidelines in 2025. We based our discussions and analysis on the English commentary.** See: Zhou LB, Lei YT and Han XX (2025) Charting bioethical frontiers: China's human organoid guidelines in a global context *Military Medical Research* **12**.

213 Zhou LB, Lei YT and Han XX (2025) Charting bioethical frontiers: China's human organoid guidelines in a global context *Military Medical Research* **12**.

214 Zhou LB, Lei YT and Han XX (2025) Charting bioethical frontiers: China's human organoid guidelines in a global context *Military Medical Research* **12**.

215 Ibid.

Calls for international governance and oversight

In November 2025, a group of eminent neuroscientists, ethicists and lawyers published an article with a call to action on the future governance of neural organoids and similar models.[216]

The article sets out a need for a "continuing international process to watch, and to guide, the progress of this field". The authors note that much research in this area takes place collaboratively between institutions in different jurisdictions, and therefore suggest that greater centralisation of oversight would allow for appropriate monitoring of (and response to) any ethically significant developments in neural organoid-related research.

They also suggest a need for production of field-specific guidance that can be responsive to the rapid pace of scientific advancement, in order to provide support to both researchers and other stakeholders in making consistent decisions and managing risk effectively. The authors also advocate a collaborative approach to public engagement, so that public perspectives can be taken into account in shaping future research and governance trajectories.

216 Pașca SP, Arlotta P, Campbell P, *et al* (2025) The need for a global effort to attend to human neural organoid and assembloid research *Science* **390(6773)**: 574-7.

4 Recommendations

We discussed in **section 3** how neural organoids and similar models are not subject to dedicated legislative oversight, nor do they fall clearly within the remit of any single regulatory authority. In the absence of centralised governance mechanisms, oversight of neural organoid research is primarily undertaken at a local level, with decision making left to individual researchers, institutional research ethics committees (RECs), biobanks, and research funders. This creates the potential for uncertainty and inconsistency across the sector. As part of our evidence gathering, we heard that those making decisions about neural organoid research do not always feel confident in doing so as a result of these governance gaps.

As research progresses, increasingly complex models may be developed that have a greater resemblance to the human brain, which may lead to more complex ethical issues arising. Similarly, the extent to which non-human animals may be adversely affected – for example, by transplantation of human neural tissue – may also increase. In the absence of a common understanding of what is ethically acceptable, there is a need to define clear ethical boundaries to guide scientists, biobanks, local ethics research committees and other involved in neural organoid-related research to ensure scientific advances in this area remain trustworthy.

Research perceived to proceed without robust ethical safeguards could lead to a loss of trust in science governance and create potential reputational risks for research institutions and others involved in neural organoid research, leaving them open to criticism that could damage public trust in science. Such criticism could trigger reactive or disproportionate regulatory responses by policymakers – and possibly unnecessarily limit the progress of research with great potential public benefit – or fuel alarmist media coverage, further eroding public confidence.

These potential impacts are not unique to the UK context, and the interdisciplinary and increasingly cross-jurisdictional nature of neural organoid-related research has prompted the international calls to action described above (**section 3.2**).[217] We fully support these calls and the need for greater discussion internationally on the oversight of neural organoid research. Though our remit in this report is limited to the UK context, we hope our recommendations will help to ensure that the UK can participate meaningfully in any future collaborative governance efforts.

217 Pașca SP, Arlotta P, Campbell P, *et al* (2025) The need for a global effort to attend to human neural organoid and assembloid research *Science* **390(6773)**: 574-7.

4.1 To legislate or not to legislate?

In considering how best to fill existing governance gaps, we have considered a range of approaches, including 'hard' and 'soft' regulatory mechanisms. Although considerable scientific advances have been made in terms of the structure and functioning of neural organoids and similar models, they currently lack the biological complexity that may indicate an emergent capacity for sentience – and it is difficult to predict if, or when, they may develop it. Outside of this, we are not aware of additional evidence which indicates a current need for statutory protection. Our view is that, at the time of writing, they amount to *models of the brain tissue and its parts*, and are not actual brains. As such, governance via primary legislation would be premature, and a disproportionate response to the challenges faced by the sector at present.

Models may never reach a stage of complexity which will require legislative change to regulate them, and it remains unclear how their biological complexity may develop in the future, or how other factors might influence a need to legislate. This uncertainty means that the need for legislative change around the governance of neural organoids should be kept under regular review as research advances. If neural organoids and similar models develop in complexity such that they might begin to display evidence of emerging sentience, or if other reasons to introduce statutory regulation emerge, the current approach and current legislation will be insufficient.

The Human Tissue Authority can helpfully contribute to ongoing review of the need for legislative reform via its regular horizon-scanning and monitoring of the scope of the Human Tissue Act 2004. The Act, introduced primarily to address public concern about the retention and use of human tissue without appropriate consent, did not foresee or account for advances in stem cell science which make it possible for such complex entities to be created from human tissue outside the body. Although these advances raise concerns that, in some respects, echo those that motivated the Act, they are not covered by UK human tissue regulation and this may become unsustainable over the longer term.

4.2 Future legislative approaches to new biotechnologies

Governance issues are not unique to neural organoids and similar models. Other biotechnologies are also developing at pace and emerging into a legislative landscape that may be unequipped to regulate them – either partly or wholly.[218]

Not all emerging biotechnologies will require statutory regulation immediately; often, non-binding, soft governance approaches may be more proportionate – particularly

218 Nuffield Council on Bioethics (November 2024) *Human stem cell-based embryo models: a review of ethical and governance questions*, available at: https://cdn.nuffieldbioethics.org/wp-content/uploads/NCOB-SCBEM-Full-Report-Final.pdf.

before a plausible pathway to clinical application can be realised. This is the case at present for neural organoids and similar models. However, if evidence emerges of a current or future need for statutory regulation, decision makers need to be able to act quickly and appropriately.

This raises the question of what an appropriate approach to introducing statutory regulation might look like, and this is complicated by the mismatched pace of scientific progress and legal change. Law reform is a slow and lengthy process and statute is, by nature, relatively inflexible. Scientific advancement, by contrast, is often rapid and non-linear. Introducing new (or amending existing) primary legislation specifically to regulate an individual new biotechnology therefore runs the risk of being rendered obsolete or inadequate by the pace and unforeseen trajectories of research. A piecemeal, 'technology-by-technology' approach to legislative change may also risk inadvertently excluding other, related technologies on the horizon that pose similar ethical and governance challenges. Approaches to legislative change that enable agility – such as enshrining frameworks or criteria for introducing statutory regulation that could be applied to a range of similar biotechnologies – may allow for much-needed flexibility and speed.

Equally crucial is when to scope options for future statutory regulation, and when to introduce them. Introducing regulation at an early stage of biotechnological development may result in placing limitations that are disproportionate to any risks. Waiting until a later stage may result in uncertainty amongst scientists about what is (or should be) permitted, which could in turn stifle innovation. Without clear guardrails, there is also a risk that concerning scientific practices might damage public trust and result in emergency 'knee-jerk' legislation.[219] An anticipatory approach to statutory regulation is therefore needed so that appropriate regulation can be introduced in a timely way.

It is unlikely that a one-size-fits-all approach to legislation will work for the regulation of all possible emerging biotechnologies, although those posing similar risks may benefit from a **technology-neutral approach**. Accordingly, it is essential that Government builds upon existing work taking place, including through the Regulatory Innovation Office, to scope a range of proportionate approaches to the future statutory regulation of new biotechnologies; ones which balance the need for responsiveness with the need for regulatory stability and clarity. The aim should be to ensure that when evidence emerges for a need to move towards statutory regulation of a biotechnology, this can be acted upon swiftly, so that risks can be identified and mitigated and the benefits of innovation can be realised by society in a safe and timely manner.

219 For example, our 2024 report on stem cell-based embryo models (SCBEMs), available at: https://cdn.nuffieldbioethics.org/wp-content/uploads/NCOB-SCBEM-Full-Report-Final.pdf, highlighted the possibility that, if they become more sophisticated, developments or events that raise public or parliamentary concern could trigger a reactive decision to regulate the models as embryos, which would be inappropriate, burdensome and insufficiently target those SCBEMs that pose ethical concerns.

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.

4.3 'Soft' regulation as a proportionate approach

Some scientific efforts – both in the UK and internationally – are explicitly directed towards increasing the complexity and sophistication of neural organoids and similar models -including their anatomical and functional resemblance to the brain – in order to maximise their usefulness in research. As this advances, it becomes increasingly difficult for individual institutions and local ethics committees to assess emerging trade-offs without a shared framework to guide judgement. There is, therefore, a pressing need for centralised (and co-ordinated) guidance in the UK that can evolve alongside the science, anticipate likely developments based on available evidence, and support consistent and proportionate decision making. This guidance should account for differences in legislation, regulatory policy and practice between the devolved nations of the UK. Crucially, we believe it will provide institutions with advice and direction, help fill the governance gap and give some reassurance to the public, and to the scientists themselves, that neural organoid research operates within defined parameters and controls. We note that an increasing amount of research involving neural organoids and similar models is taking place in the private sector (i.e. outside academic institutions), and such research may not necessarily have the benefit of established ethics review mechanisms. It is therefore important that any best practice guidance is both applicable and useful to the private sector, as well as to academic research.

A key component of best practice guidance should be the identification of markers or proximal indicators of sentience, to advise decision makers – such as RECs, tissue banks, research institutions and funders – on characteristics that may warrant heightened ethical scrutiny. The presence of indicators should not be interpreted as implying that a particular line of research is inherently unethical or should be halted, but instead should act as a trigger for more in-depth ethical scrutiny.

In **section 2.1**, we outlined examples of research involving neural organoids and similar models that might have, or acquire, morally relevant characteristics, including

features indicative of increased proximity to sentience. We consider that determining morally significant characteristics – and any associated red lines – will require input from a broad range of expertise, including public, patient and donor perspectives in the UK. The intention is for this initial, non-exhaustive set of features to serve as a starting point to guide further discussion.

4.4 The importance of interdisciplinary collaboration

Throughout the course of our evidence gathering, we heard from a variety of different stakeholders. All made valuable contributions, and shed light on how governance gaps in the sector might most usefully be filled. Increasingly, research is interdisciplinary and collaborative between institutions and jurisdictions. Each discipline and institution has its own challenges, which run the risk of remaining unresolved without a collaborative approach to problem-solving.

The fragmented nature of neural organoid research means that there is no single authority with agency for addressing the challenges we heard about. Decision points are diffuse, with groups and organisations having influence over different parts of the research pathway. Our second recommendation is therefore to **bring together all stakeholders in an interdisciplinary alliance to produce best practice guidance for the sector.** As part of this process, the alliance should consider whether to provide criteria for the ethics review of research involving neural organoids and similar models.

The Nuffield Council on Bioethics is committed to further engagement on this issue and will contribute to this initiative as appropriate.

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;

Continued >>

- 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.

4.5 Use of UK tissue overseas

We have seen in **section 3.1** how the absence of clear national guidance leaves local institutions with the responsibility of making day-to-day decisions about research involving the development and use of neural organoids and similar models. One area in which decision making may be challenging is when tissue banks receive requests for material from outside the UK. For example, we heard of concerns that UK-based tissue banks might receive requests from researchers working in jurisdictions where animal welfare standards are either unknown or known to be lower than in the UK. At present, we heard that tissue banks may feel they cannot justify a refusal to transfer human tissue on this basis, even where the proposed research would raise significant ethical concerns in the UK. **Although there are limitations on what tissue banks can know about how the tissue will be used in the future, they should decline requests from overseas where the stated intended purpose would not comply with accepted UK ethical standards or would be unlawful in the UK**.

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.

4.6 Engaging with the public

Future guidance on the development, use, and transplantation of neural organoids and similar models should consider societal values. Neural organoid research has considerable potential for improving the health and wellbeing of people living with brain-related conditions, and much of it is publicly funded. Moreover, the special status of the brain – and its close association with identity, cognition, and emotional experience – is likely to intensify public concern and interest in research involving neural tissue.

Public perspectives should, therefore, play a meaningful role in shaping both research practice and governance. While some studies have explored public perceptions of neural organoids in other jurisdictions, the findings may not be directly transferable to the UK context, and no comparable work has been done in the UK. Sociocultural differences, regulatory traditions, and public trust in science and governance are likely to influence how this research is perceived. **Any changes to the governance of neural organoids and similar models research would benefit from UK public engagement, and a clear understanding of public attitudes, including the views of current and prospective patients and tissue donors**.

Neural organoids and similar models have already been developed to study a wide range of brain-related conditions, including neurodevelopmental, neurodegenerative, and neuropsychiatric conditions. Engagement with people with lived experience will therefore be particularly important. Limited evidence from outside the UK suggests that patients and the public may differ in how they assess the benefits, risks, and acceptability of organoid research.

Recommendation four

Funders of research involving neural organoids and similar models (such as UKRI[220], 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;

Continued >>

220 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.

- 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.

4.7 Research monitoring

There is currently no means to systematically monitor developments in neural organoid research. At a local level, while many projects are reviewed at the point of applying for funding, researchers are not required to register basic research within their research institutions, which limits awareness of ongoing work. Given the rapid pace of research trajectories aimed at developing more complex models, there is a risk that effective horizon scanning and identification of future ethical challenges could be hindered. In turn, if such challenges are not identified, studies could inadvertently cross boundaries, with reputational implications. **We therefore propose that research institutions introduce a requirement to record and log all projects involving neural organoids and similar models.**

Beyond this, we believe there is also a strong case for more centralised data collection at a national level in the form of a register. This would help to develop a good understanding of the broader research picture, monitor developments and provide valuable insights to inform ongoing review of the need for legislative change. A similar approach to data collection has been proposed for stem cell-based embryo models (SCBEMs) to enable appropriate oversight of a sensitive and rapidly progressing research field, while enabling ongoing learning about risks, benefits, and capabilities.[221] Careful consideration would need to be given to the scope of research (including the complexity of models) to be included in a register, and the level of data to be collected to ensure that compliance is not overly burdensome or disproportionate when compared with similar research.

221 Cambridge Reproduction (July 2024) *Code of practice for the generation and use of human stem cell-based embryo models*, available at: https://www.repro.cam.ac.uk/files/240704_scbem_code_of_practice.pdf; and Nuffield Council on Bioethics (November 2024) *Human stem cell-based embryo models: a review of ethical and governance questions*, available at: https://cdn.nuffieldbioethics.org/wp-content/uploads/NCOB-SCBEM-Full-Report-Final.pdf.

However, collating research data at a national level presents a number of challenges. Without legislative change to bring neural organoids and similar models within the scope of statutory regulation, there is no obvious 'home' for a centralised register of research, and no way of mandating submission of relevant data to it. It would therefore need to be voluntarily established by an appropriate organisation, and would require a significant commitment of funding and administrative resources.

Nevertheless, we believe that there is merit in exploring the feasibility and practicalities of co-ordinating data collection. We therefore recommend that **relevant biobanks, research institutions, research funders and regulators convene to discuss pragmatic and proportionate approaches to the collection of neural organoid research data.**

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.

4.8 Impacts on non-human animals

As discussed in **section 2.2**, there is optimism (though not universally shared) that increased use of neural organoids and similar models could help to reduce the use of non-human animals in research.

At the same time, significant animal welfare (and other) concerns may arise where neural organoids or related models are transplanted into the brains of non-human animals. While the transplantation of human neural cells into animal brains predates the development of neural organoids, the transplantation of human neural organoids into non-human animals may be seen as more problematic. This is due to the increased potential for pain, ambiguities around moral status and uncertainties about the impact on cognitive capacity and the animals' welfare needs.

Existing regulatory frameworks governing animal research do not specifically address developments in neural organoid transplantation and chimeric models. Current UK practice is largely informed by the Home Office's *Guidance on the use of human material in animals* (2016), which in turn builds on the Academy of Medical Sciences' 2011 report *Animals containing human material*. Since the publication of that report, there have been substantial advances in the ability to generate complex neural organoids and to transplant them into the brains of a range of mammalian species at different developmental stages. There have also been considerable legislative and regulatory changes relevant to matters of animal welfare and sentience, following the introduction of the Animal Welfare (Sentience) Act 2022 and its establishment of the Animal Sentience Committee.

There is therefore **a need to update this guidance to account for such developments and protect the interests of non-human animals**.

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.

4.9 Informed consent

Developments in neural organoid research raise important questions about whether existing informed consent models will remain adequate.

We heard during this project that tissue donors give generic consent to the future potential use(s) of their donated tissue (and are told, for example, that tissue "may be used to create cell lines", and can be given information about the use of stem cell lines to create different types of tissue). This allows for tissue to be used for a variety of research purposes without requiring additional consent to be obtained for specific uses. If models become more complex in the future, donors may wish to have more information about new ways in which their tissue might be used. The evidence on whether tissue donors would welcome dynamic consent, in which they are recontacted about future possible uses, is decidedly mixed[222] and so more research on this question would be valuable. However, even in the absence of further evidence, we consider that **research institutions and biobanks should review and, where appropriate, update their consent policies and practices to account for developments in neural organoid-related research.**

Consistent with the UK Stem Cell Bank's Code of Practice, we advise that consent for the creation and use of stem cell lines should, where possible, be explicit about the nature of the research and cover areas that donors may find particularly salient or concerning.[223] These include potential commercial use, genetic analysis, use in animal research (including transplantation of human material into non-humans), and possible clinical applications. As noted earlier in this report, there are examples of good practice in the development of consent forms which are available to the community.[224]

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.

222 See, for example: Ipsos MORI (July 2018) *Consent to use human tissue and linked health data in health research: A public dialogue for Health Research Authority and Human Tissue Authority*, available at: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Consent_to_use_human_tissue_and_linked_health_data_in_health_research_FINAL.pdf; and Ravn T, Sørensen MP, Capulli E, *et al* (2023). Public perceptions and expectations: disentangling the hope and hype of organoid research *Stem Cell Reports* **18(4)**: 841-52.

223 UKSCB (April 2010) *Code of practice for the use of human stem cell lines*, available at: ??

224 See, for example, the ISSCR Sample research consent form for somatic cell donation for induced pluripotent stem cell research, available at: https://www.isscr.org/guidelines/appendices.

4.10 Responsible science communication

Our work has highlighted the importance of providing the public with clear and factual information about what neural organoids and similar models are and what they are not, their capabilities and limitations, and their scientific value **(section 2.4)**. Examples exist of scientists' and media communication about neural organoids and similar models coming under criticism for being misleading.

Inconsistency of language and the lack of standard nomenclature may sometimes contribute to misunderstandings and confusion about this field of research. We believe, as with all communication about scientific research, it is essential for the scientific community to uphold "the values of honesty, rigour, transparency and open communication" (as set out in UK CORI's concordat on research integrity)[225] when communicating about research involving the development and use of neural organoids and similar models. We also consider that the scientific community should adhere to standard nomenclature for neural organoids and similar models, as proposed in the 2022 consensus paper. The Science Media Centre has an important role in encouraging accurate and responsible scientific reporting.[226]

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.

225 UK Committee on Research Integrity (2025) *The Concordat to support research integrity*, available at: https://ukcori.org/wp-content/uploads/2025/12/The-Concordat-to-Support-Research-Integrity-2025.pdf.

226 Paşca SP, Arlotta P, Bateup HS, *et al* (2022) A nomenclature consensus for nervous system organoids and assembloids *Nature* **609(7929)**: 907-10.

Appendix 1 Glossary

Axonal projections: The process by which neurons send out a long extension called an axon to connect with other neurons or target cells in the body

Biorepositories: Facilities that safely stores biological samples (including, for example, tissue, blood and urine) collected from different living organisms so they can be used for scientific and medical research

Blood brain barrier: A protective barrier around the brain that controls what substances can pass from the bloodstream into the brain

Cell lines: A group of cells grown in culture outside the human body that can be expanded for prolonged periods by making more copies of themselves and have the potential to give rise to any cell type in the human body

Culture: cells grown and developed in a clinic or laboratory for research, such as in a dish or flask

Culture medium: The substance which provides necessary nutrients and environment to support cell growth and direct cell development in vitro

In vivo brain tissue: Brain tissue within a living body

Microcephaly: A rare lifelong condition in which a baby is born with a smaller-than-usual head, and which can cause a range of neurological symptoms

Microfluidic devices: Tiny lab tools that can control and move very small amounts of liquids through tiny channels

Neurogenesis: The process of creation, placement, and specialisation of new brain cells in a developing brain before birth

Organ-on-chip technologies: Microfluidic devices containing cultured tissue, with channels that allow precise control of fluids and the cellular environment

Pluripotent stem cells: Cells with the unique ability to divide and/or differentiate into any type of cell of the future body, including other stem cells. Unlike somatic cells, pluripotent stem cells have the ability to self-organise into 3-D structures mimicking embryonic development

Protocols (scientific): Detailed, step-by-step instructions that explain how to carry out a scientific experiment or procedure

Technology-neutral approach: An approach that can be equally applied to a variety of technologies and it is not specific of one technology only

Vascular system: The network of blood vessels that circulates blood throughout the body

Wells: Small containers in a lab plate used to hold samples or liquids for experiments

Zika virus: A virus spread mainly by mosquitoes that can affect a developing fetus if a pregnant person becomes infected

Appendix 2 The nervous system and its main structures and regions

The nervous system – composed of central and peripheral nervous system – operates in a complex way, with most functions arising from interactions across multiple regions rather than being localised to a single area. While significant gaps remain in our understanding of how the nervous system and its individual components operate, ongoing advances in neuroscience continue to expand this knowledge.

The **brain** is a central organ of the nervous system, responsible for regulating thought, memory, emotion, sensory perception, motor function, and vital physiological processes such as breathing, body temperature, and hunger. Together with the spinal cord, they make up the central nervous system, or CNS. The brain carries out these functions by sending and receiving chemical and electrical signals throughout the body. This communication depends on billions of specialised nerve cells, known as **neurons**. At a broad level, the brain is commonly divided into four main regions: the **cerebrum**, the **diencephalon**, the **brainstem**, and the **cerebellum**.

The **cerebrum** is the largest part of the brain, and it is considered to be central to a variety of important brain functions. The complexity of the cerebrum is different across vertebrate species. In humans, many of what are sometimes called 'higher' neurological functions – such as memory, emotion, and problem solving – are the result of cerebral function. Examples of other important cerebellar functions include sensory perception, voluntary control of movement, and language. The cerebrum is made of an **outer grey matter** (**cerebral cortex**) overlying **white matter** and it is divided into left and right cerebral hemispheres which communicate with each other through a structure called the **corpus callosum**. The cerebrum is composed of frontal, parietal, temporal and occipital lobes. Still within the cerebrum, there is the limbic system, a group of structures that are known for being implicated in emotions, memory and motivation: these includes the hippocampus – which is thought to have a major role in emotion and memory – the amygdala – which has a primary role in detecting and processing threat and attaching emotional significance to memories –

and the cingulate gyrus – which is mainly involved in information processing for decision-making and planning, but also interprets pain as being unpleasant.

The **diencephalon** is located beneath the cerebrum and contains important structures, for example the thalamus and the hypothalamus. Some of the main functions performed by the structures included in the diencephalon include: control of the autonomic nervous system (and therefore of those centres in the brain that regulate things like heart rate and blood pressure) control of emotional responses in association with the limbic system, basic functions such as regulation of body temperature, hunger and thirst, and control of the release of certain hormones. The epithalamus includes the pineal gland, which responds to light and dark and secretes melatonin, which regulates circadian rhythms and the sleep-wake cycle.

The **brainstem** is located in the middle of the brain and it connects the cerebrum with the spinal cord. Its main areas are the **midbrain** (also called mesencephalon), the **pons** and the **medulla**. The midbrain contributes to regulate a number of functions linked to hearing and movement. The midbrain also contains the substantia nigra, an area affected by Parkinson's disease, which enables movement and coordination. The pons plays an important role in the regulation of the respiratory system and it is the origin for four of the 12 cranial nerves, which enable a range of activities such as tear production, chewing, blinking, focusing vision, balance, hearing and facial expression. The medulla is a portion of the brainstem and the lowest anatomical part of the brain, and is the last division of the brain before it becomes the spinal cord at the bottom of the brainstem. Essential to survival, it plays a critical role in transmitting signals between the spinal cord and the higher parts of the brain and in controlling autonomic activities, such as heartbeat and respiration.

The **spinal cord** extends from the bottom of the medulla and through a large opening in the bottom of the skull. Supported by the vertebrae, the spinal cord carries messages to and from the brain and the rest of the body.

The **cerebellum** is located at the back of the head. The cerebellum is mainly known for role in coordinating voluntary muscle movements and to maintain posture, balance and equilibrium. New studies are, however, also exploring the cerebellum's roles in thought, emotions and social behaviour, as well as its possible involvement in addiction, autism and schizophrenia.

Appendix 3
Acknowledgements

Between July and September 2024 we ran a call for evidence, seeking expert opinion on the ethical and governance challenges raised by neural organoids and similar models. We also invited input on three further occasions:

- In July 2024, we hosted a workshop in London, bringing together expertise around the current science, law and governance, and ethical issues
- In September 2024, we held a roundtable to discuss possible solutions and next steps to ensure that appropriate governance mechanisms are in place for research involving neural organoids
- In September 2025, a small group of expert stakeholders attended one of our Working Group meetings to provide insights into the governance of neural organoid research

Participants in our evidence-gathering activities included:

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