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ORIGINAL ARTICLE

From Cells to Organoids: Sociological Considerations for the Bioengineering of Human Models

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ABSTRACT

By examining the laboratory practices behind designing and crafting organoids—miniature, three-dimensional cellular structures that replicate organ functions—we highlight a critical shift in biomedical research. Over the past 16 years, advances in stem cell research have transitioned from generating stem cells to utilising these cells in building sophisticated organ models and bioengineered tissues. This transition represents a significant move from the 'what' of cell creation to the 'how' of constructing and interpreting three-dimensional human models. Through ethnographic research (including observations and interviews) in Europe and North America, we explore how organoids are constructed and the underlying logic driving their development. Our analysis underscores the growing importance of these in vitro models for human health, urging a sociological examination of their 'near human' status. We argue that understanding the implications of this shift—particularly how it influences perceptions of human representation and diversity in biomedical research—requires critical scrutiny from sociologists of health and illness. This paper aims to address the urgent need to investigate not just the experimental challenges but also the socio-political dimensions of using organoids as proxies for human physiology.

1 | Introduction

In the ever-evolving landscape of biomedical research, a new way to model human disease and development has emerged: the creation of organoids—miniature, rudimentary three-dimensional models of human organs made from living stem cells. These multicellular structures offer new windows into understanding of human disease and development. They also, as we will argue here, challenge us to consider what it means to replicate human health, physiology and disease processes in the lab.

The promise of stem cell science and its outcomes, such as regenerating damaged organs, treating disease, and extending the boundaries of what is medically possible has, over the last quarter of a century, been juxtaposed with different moral, legal, and societal dimensions that have impacted research possibilities and shaped a range of government policies (Thompson 2013; Benjamin 2013; H. Landecker 2007; Waldby 2002). In 2007, Shinya Yamanaka (Takahashi et al. 2007) and his colleagues ushered in a milestone in the history of stem cell research by pioneering discovery of induced pluripotent stem (iPS) cells. By reprogramming adult cells, such as skin cells taken from a biopsy, to regain pluripotency, iPS cells have offered new pathways for scientists and clinicians because they do not involve the use of human embryos. With more than 16 years of iPS cell reprogramming providing foundational tools for research, the field of stem cell science is undergoing a profound shift from the isolation and creation of iPS cells to now using these cells to build and model complex multicellular structures such as organs and tissues (Kim, Koo, and Knoblich 2020).

In exploring the design and making of organoid technologies we draw on the anthropologist Svendsen's (2021) recent book, *Near Human: Border Zones of Species, Life, and Belonging*. In this book, she proposes a way to study biomedical research and innovation through the concept of nearness. Svendsen argues that 'nearness' allows us to delve into the border zones of biomedical research, where various animals and entities serve as substitutes for humans in experimentation. In our study, we employ this idea of the 'near human' to examine different experimental and professional environments dedicated to bioengineering organoids.

This paper makes a novel conceptual contribution by advancing sociological engagement with the emerging field of organoid research. It builds on previous work that shows how 'the humanness of organoid model systems are not a given but are enacted with and through a variety of scientific practices' (Hinterberger and Bea 2023, 1). Our ethnographic account critically examines how organoid technologies blur traditional boundaries between human and nonhuman entities, offering a new perspective on the process of 'nearing the human' in vitro. Our analysis reveals that organoids are not merely biological models but are socially and politically constructed tools that embody broader tensions within biomedical science, particularly around issues of representation, inclusivity, and translational potential. By focussing on the labour and uncertainties involved in crafting these models, we argue that organoid research is reshaping our understanding of human health, ethics, and the politics of bioengineering in ways that require deeper sociological inquiry.

Throughout, the article is grounded by our sense that first, as stem cell research continues to expand its significance, sociologists of health and medicine are called upon to delve deeper into these emerging trajectories which are moving beyond traditional stem cell research; second, the sociological implications of bioengineering human models extend beyond the laboratory. By constructing organoids that mimic human physiology, researchers are reshaping our understanding of human health and disease. This shift challenges traditional boundaries between human and nonhuman entities, raising ethical questions about the 'near human' status of these models. Moreover, as we will show, the development and use of organoids prompt critical reflections on issues of inclusivity and diversity in biomedical research.

1.1 | New Human Models of Disease and Development

The power and impact of the emerging frontiers of stem cell science is demonstrated by the US Federal Drug and Administration (FDA) Modernisation Act 2.0 which was brought into law on 29 December 2022. The passing of this Act marks a juncture in the mandated animal testing required by the FDA for the pharmaceutical drug approval process (FDA 2021). The new law recognises the limitations of animal testing for drug research and provides more opportunities for researchers to use nonanimal methods—these methods include the use of human organoids, and other human tissue-based technologies.

The driving idea here is that as opposed to testing drugs on animals, such as mice, which have very different physiology to humans, these new cellular technologies offer better and more accurate methods to model human biology. As detailed by Adashi, O'Mahony, and Glenn Cohen (2023, 853) the new law amends previous rules by authorising sponsors of novel drugs to make use of 'certain alternatives to animal testing, including cell-based assays and computer models, to obtain an exemption from the Food and Drug Administration to investigate the safety and effectiveness of a drug'. Animal rights supporters, and groups that seek to advocate for the reduction, refinement and replacement of animals used in research have welcomed this change in law (PETA 2022). However, other responses and engagements with the new legal changes highlight that the move to nonanimal technologies is neither simple nor straightforward (EARA 2023). This is because the emergence of nonanimal drug testing technology, of which organoids and other multicellular technologies are part, have opened new questions about human biology.

As we will demonstrate in our multi-sited ethnography, a major query confronting researchers engaged in the development of bioengineered organoids is: How can they ensure that the processes occurring in the organoid they have constructed accurately mirror those taking place in the human body? In other words, just because the organoid is built of cells from human origin, how can that structure be validated and checked against the biology of a living human-being (without opening and experimenting on the human, that is, being modelled)? In the three main ethnographic vignettes that follow, we track and illuminate how these questions are addressed and managed by researchers.

Our first vignette explores the meticulous experimental processes involved in creating a novel human organoid at a UK lab, specifically a kidney ureter, highlighting the technical challenges and labour-intensive nature of the work. In contrast, vignette 2 examines a collaborative effort at a different lab, located in southwestern Europe, working to bioengineer kidney organoids to model diabetes, emphasising the translational efforts and interdisciplinary interactions that drive the development of these emerging disease models. The third vignette contrasts the lab work with the articulations of organoids in a US conference that delves into the approximation of human population differences in organoids by exploring concepts of inclusion and diversity. This vignette underscores the imperative of addressing health disparities and promoting inclusivity in bioengineering by emphasising the importance of diverse human models and ethical considerations.

Taken together the three vignettes show how the task of 'nearing the human' in organoid research extends beyond experimental challenges to encompass significant socio-political considerations. Researchers must continuously confront the uncertainty that their in vitro models might not accurately represent the complexity of human biology. However, this process is not just about achieving biological nearness, it also necessitates asking which humans these models are designed to approximate. We will show that, in their pursuit of nearness, researchers are struggling with how to conceptualise human

difference and diversity, along with how to incorporate these aspects into their models. Will the organoids of tomorrow be sufficiently representative of different human populations, or will they reflect a narrow subset? In this context, we highlight that the question of representation in organoids remains an open and pressing challenge, and a sociological perspective can provide valuable insights into how these models address human diversity, in what way, and why.

In exploring these and other dilemmas faced by researchers, we draw on previous work in medical sociology that engages with the pre-clinical spaces of translational research on health and disease (Thompson 2013; Franklin 2013). For example, we continue the tradition and emphasis on 'socially embedded accounts' (Wainwright et al. 2006, 732) of controversial and innovative technologies that can often be discussed in decontextualised manners in ethical and legal reviews (Wainwright et al. 2006; Benjamin 2013). We further draw on the distinctions developed in Morrison's (2019, 56) work on the differences between embryonic stem cells and induced pluripotent stem cells, which contribute to shaping the various ways that calculations of value (both moral, social and economic) are brought into research practices: 'Where the process of deriving hESC [human embryonic stem cells] remains morally and politically contentious, hiPSC (human induced pluripotent stem cells) are regarded by many groups as being ethically acceptable to make and use. This manifests itself in a willingness of companies and governments, including the EU (the UK and USA), to invest in hiPSC technologies'. As his work shows, due to the investments of both public and private funders, researchers now have available to them a plethora of different iPS cell-based research tools that help support the making of organoids.

While our article focuses on the kinds of research made possible by induced pluripotent stem cells, it's important to underscore that their emergence has not rendered embryonic stem (ES) cells obsolete. Both iPS and ES cells continue to play significant roles in scientific investigations each offering different advantages and considerations. There is no line to draw in stem cell research as if it has moved on from the ethically fraught area of the human embryo. Instead of resolving debates about the human embryo, the use of iPS cells has given rise to new questions and discussions, particularly surrounding the embryo-like models that are being made with iPS cells (H. L. Landecker and Clark 2023). Our paper engages with these notable shifts and examines the sociological aspects of manipulating cells to create novel biological entities.

2 | Methods

The purpose of our paper is to illuminate the new cellular landscapes that are emerging in biomedical research, with an eye to their significance for the sociology of health and illness. Drawing on laboratory ethnography, interviews and observations of conferences and expert workshops, we will trace out some of the biomedical, social scientific, bioethical and public discussions around organoids, to locate their social and political significance.

2.1 | Study Design and Data Collection

Our project employed a multi-sited ethnographic approach to investigate the emerging landscape of bioengineered stem cell models of disease and development. The study was conducted by the Biomedical Research and the Politics of the Human research team (Sara Bea, project postdoctoral researcher and Amy Hinterberger, project PI), and it involved immersive engagement with the communities and spaces such as the laboratory and expert conferences where we could track this evolving area of research.

We conducted ethnographic fieldwork in Europe, along with a series of different academic and research settings in the USA. While organoid research is a global endeavour, our study specifically examines practices and discourses within the UK, southwestern Europe, and the USA, providing insights into the dynamics of bioengineering and inclusion within these regions. During these visits, which took place between 2021 and 2022, we observed and interacted with researchers, technicians and other key actors involved in the bioengineering of stem cell models. Sara Bea conducted ethnographic work at the two labs and Amy Hinterberger met with researchers from the lab and provided ethical consultation and observed public engagement activities conducted by lab group members.

In addition to laboratory visits, we attended a series of national and international conferences related to stem cell research, disease modelling, and bioengineering. At some of these conferences we were observers and others we were invited as speakers by our project participants. We use these conferences to discuss broader discourses within the field, as currently formal regulation and policy guidance are emerging and not yet formalised.

2.2 | Data Analysis

We collected different forms of data through a combination of field notes, audio recordings and photographs, enriching our understanding of organoid research practices. Simultaneously, themes emerged from the analysis of the collected data by employing the qualitative software NVivo to code the different perspectives captured. In laboratory visits and interviews, participants presented different ways of discussing organoid technologies, reflecting the different practices and reasons for the creation of human organoids. This research study adhered to ethical guidelines, including informed consent for interviews and observations. Pseudonyms were assigned to individuals and organisations mentioned in the study to protect their confidentiality.

In our analysis we paid particular attention to understanding the researchers' own perspectives. This is important because while the goal of some organoid researchers is to scale up organoid research, with the cultivation and validation techniques currently available this is not yet possible. Our account enables us to provide a description of the type of professional work and personal demands associated with the pursuit of making these human models. Secondly, by tracking the

everyday scientific practices and practitioners' narratives of human organoids, we highlight the paramount role of accommodating uncertainties and the social and political implications emerging from the translational ethos that dominates biomedicine today.

3 | Findings

3.1 | Building Ureter Organoids: Growing Rudimentary Organ-Like Structures

From the outside the university medical building looks old and unassuming. This UK lab housed over two corridors works in developmental biology, particularly developing kidneys, with a focus on tissue engineering. The lab group has generated kidney organoids. Notably, the lab specialises in using approaches that minimise animal use and in translating basic research into improved medical care. The long-term goal is to develop transplantable kidneys from human stem cells. The PI of this lab had helped to arrange that we would learn how a senior researcher in the lab conducted her day-to-day activities growing human organoids. This senior researcher, Farah, had designed a successful protocol to grow kidney organoids with human iPSC during her early research, and now she was embarking on a challenging next step: building human ureter organoids in vitro for the first time. The tubes that carry urine from our kidneys to the bladder are ureters—thus the creation of kidney organoid system includes the ureters.

The way to go about building a ureter consisted in trying out different human and nonhuman cell combinations in an organoid. Farah combined well-known mouse embryonic stem cells (mESCs), as she put it, the reliable gold standard in biomedical research, with established mouse tissue-derived cells, and then added less standardised and hence more variable human iPSCs. The idea was that they would integrate in the growing 3D structure which would not go beyond a few millimetres. She showed video footage of what this looks like: a group of muscle cells contracting harmoniously in a dish.

It was an arduously experimental process, and one that progressively incorporated more human materials and less mouse cells and tissue in the organoid. We draw on Svendsen's analytical lens of the near human to explore how in the stem cell science lab the human and the nonhuman are interdependent. Following Farah's everyday work at the lab with organoids helps us unpack the process of '*nearing the human*'. We map the interplay between both distance and proximity that compound the challenges of nearing the human in vitro.

The cultures combined mouse and human cells; thus, their chimaerism complicated the experiments with interspecies differences such as cell timing. For example, because human cell cultures take longer to self-assemble than mouse cells, sometimes, the interspecies organoid could be ruined if mouse cultures started dying. The reason behind the interspecies approach to validation was because a human-to-human comparison would involve using human tissue or ESCs. Farah explained it would be difficult to justify and unlikely that she would obtain ESCs for this research purpose. Thus, her work with human iPSCs requires her to use animal embryonic tissue that she extracts herself from mouse embryos and grows in culture so she can have a control to check if ureter organoids are growing as they would do in vivo. In this context, Farah considers a mouse embryo to be the closest available entity to a human embryo for validating organoid models, highlighting a key justification for using animal tissue samples. This approach is based on the developmental similarities between mouse embryos and human embryos, which are crucial for assessing the organoids' progress. However, the use of mouse tissue also underscores the inherent species differences, which introduces an element of distance from human biology. Therefore, researchers must continuously validate their organoid cultures against these animal tissue samples, balancing the developmental similarities with species-specific variations.

The iPSCs that Farah uses are obtained with a visit to a vaulted door in the basement where there are large liquid nitrogen freezers. In terms of the materials needed to conduct her experiments, some are living and from human origin and some are not. In narrating her research, she referred to 'my cells, my medium, my Matrigel, my pipette', and 'my animals' referring to the mice specimens in the animal house destined for her experiments. Back at the lab, and once the iPSCs have defrosted and are ready to be cultured, Farah prepares the media which is different to the one she uses to culture mouse ESCs. It has no animal-derived serum, she tells me, 'They like to complicate things for the human, for mouse the cheapest and easiest'. This is because, as she asserts, when growing human cultures, it is paramount to use well-defined growth factors to achieve increased consistency between organoids. In short, it helps with reproducibility and that is crucial if organoids are to become translational tools that go beyond basic research and into the clinical setting as reliable near-human models.

Every day Farah checks which cultures need to have their spent medium changed and the cells split. Cell density is the criterion she monitors to ascertain that cells are progressing as they would inside the body, growing into more complex 3D structures. She gets two petri dishes and with the microscope she shows the difference between human cultures, with a pink hue to them resulting from the colour marker used to differentiate them, and the mouse cultures that look see-through as they are only suspended in gelatine and simple medium. Besides colour, they look different, human cultures appear as well-defined colonies with visible black nuclei of iPSCs, whereas mouse cultures look generally crowded more densely populated throughout the petri dish. Once satisfied that the difference has been appreciated, she puts the cultures back in the fridge. This is something she does repeatedly every day, taking things in and out of different containers and controlling temperatures and timings with calculated precision. Cells need defrosting, medium thawed, everything is to be restored to working function and primed prior to putting together in an experiment. It is a herculean task to balance the right temperatures and synchronicity to find the right equilibrium. At this lab, the process of nearing the human with organoids hinges upon simulating the closest thing to a human body environment that will guide the desired growth of the human cultures.

Disinfection is always a must; the cell culture hood is generously spread with alcohol solution before and after each use. It is not because of COVID-19, it is business as usual in a wet lab where contamination is to be kept at bay from living cell cultures. Farah meticulously and silently tends her living cells; they determine her schedule. In the afternoon, if the cells let her, she takes her kids to the pool; later, if her husband is home, she goes back to the lab to check if her cells need feeding and cleaning. 'Changing nappies at home and changing mediums in the lab' she joked. However, once cells' daily checks had been done, there was not a lot of lab action to observe, cells were left to themselves, and Farah sat in the office and worked away at her computer. On these occasions, growing near human organoids was about proximity and similarity, cultured human cells were effortlessly differentiating in vitro as they would do in vivo, following the same path as inside a developing human body.

Once the cells have self-organised and differentiated in culture, it is time to flood them with fixating agent prior to staining them. The staining kills the cells but preserves them ready to be studied under the confocal microscope. Any organoid generated needs to be validated, the near humanness or similarity with its human in vivo counterpart cannot be taken for granted and requires monitoring. To do that, Farah checks whether the proteins expressed in the organoid correspond to those of a ureter in vivo. Now Farah can work outside the hood with her cultures without worrying about damage or contamination; they have become nonliving entities. She picks up the two-mm organoid with tiny forceps and places it on a glass sample holder ready for the microscope. Farah does not use the term organoid; before staining, they are her cultures, and after, they become her samples. Organoid is a term that she only uses at the publication stage because, as she states, to her an organoid should be something closer to the human organ than what she is working with. The ureter organoid she attempts to build is to her not near-human enough. Distance is the dimension that she emphasises when assessing the validity of her organoid, it does not yet qualify as a substitute for a human ureter.

Results day has arrived, Farah sits by the confocal microscope in a dark room adjacent to the wet lab. A quick glimpse at the screen and Farah flatly declares, the results are negative. The protein expression results indicate the organoid does not match with what would be expected for a human ureter in vivo. It is neither a surprise nor a disappointment to her. She is compelled to explain that it is not because something she did went wrong, or something was not accurately designed. Rather, getting negative results is part and parcel of her challenging pursuit. After all, she is growing human ureter organoids without known protocols or any external guidance. Farah's verbatim expression is: 'It is not a good result, but I am building this from scratch, there is no human ureter organoid protocol, I am working in the dark, I am used to it, you keep going and do it again, and again until it works'. Her next step is to keep working on optimising the protein expression of her cultures, which she will try with different growth factors in the future. Farah's solitary and relentless work at the stem cell lab will continue to combine human and nonhuman cellular material, intertwined and inseparable, both similar and different, in the experimental process of nearing the human in vitro.

3.2 | Human Disease in a Dish: Using Bioengineered Human Models

This research institute, located in southwestern Europe, strategically sits within a campus that boasts a state-of-the-art science park and several life sciences university buildings. The impression was of a high-tech research-intensive setting with public and private partnerships. The lab occupied a modern building that bustled with activity and was dotted with inviting communal areas. The atmosphere was one of collegiality, people chatting informally along the corridors where many languages could be heard at once. Early on in designing and planning the project we had consulted with the PI of this lab who had done cutting edge research in stem cell bioengineering. These researchers worked with several human organoid systems, but mostly with kidney and heart. The lab uses human iPSCs, especially patient-derived, for disease modelling and drug testing. The ethos is highly translational with the aim to leverage the potential of stem cell science and translate it into the clinic with novel cell-based therapies. Broadly, this lab works on organ regeneration and pursues a long-term trajectory towards human iPSC-based autologous transplantation as the future of regenerative medicine. There are various research lines that address chronic diseases with high incidence like diabetes, hypertension, and cardiopathies, as well as infectious diseases like COVID-19. In what follows we present a vignette that differs from the UK basic research lab where Farah was the solitary scientist culturing stem cells. In this research institute, the work is highly collaborative, interdisciplinary and above all translational, with an eye on the clinic.

One of the researchers is developing hydrogels to be used in organoid culture. She explains that she starts with a human or pig kidney that is then decellularized. Once the DNA has been removed, the cellular matrix is frozen, and it is then converted into a gelatine which is the hydrogel in question. This is used to culture kidney organoids, and it helps by providing the signals required to differentiate as would happen in a kidney in vivo. The minuscule kidney organoid, once it is built measures a few millimetres, is then saturated with glucose, and it becomes a model to study diabetes in stem cell lines derived from male and female donors, respectively. To study human disease, this researcher explains, you need a platform with human genetic identity, a mouse model will simply not do the job. In this lab, unlike at Farah's, mice's nearness to the human is articulated by referring to the distance between, in this researcher's words—'intrinsically different species'. On this occasion, the justification of the humanness of organoids is achieved by emphasising the genetic differences between human and mice as species.

Ongoing experiments at the lab involved creating a range of 'sweet' and 'savoury' organoids. To replicate kidney hypertension, researchers added sodium chloride, salt, and compared them to a control with mannitol, sugar, to study the kidney's regulation of osmosis. This work is translational in its intent and the idea is to bring closer to the lab the clinic, disease, and patients. This is done by using any data that could be available to triangulate and validate the organoid data. For example, data from human ESCs, patients' ex vivo samples, epidemiological data, genetic databases, or data from animal models as human

proxies. The latter is essential because human organoids remain embryonic in the model stage. This means the researchers need to include data from animal material to model adult tissue. Besides using male and female lines, they also use genome editing technology, CRISPR-Cas9, to reproduce patient-specific genetic mutations in the organoid. They then bioengineer a healthy control to compare with, that is, a human organoid without the mutation. This, they stress, is simply impossible with a sick patient, you can never have what they call 'a wild type' to compare with and model the disease. This team employs standardised protocols to produce large numbers of organoids for study, which is in contrast with Farah's more experimental approach in the first vignette, where she utilises a trial-and-error method to develop a ureter organoid from scratch.

As mentioned above, the lab works with genome editing technologies to recapitulate disease states in a dish. The CRISPR-Cas9 expert at the lab explains that this is done by introducing a patient's genetic mutation associated with the given disease in the organoid platform. In detailing her experimental work, she declares, that in bioengineering it is always the case that 'the cells are the ones that rule, not us'. Like her, the rest of the team's work is punctuated by the challenge of dealing with unpredictable living systems liable to contamination, corruption and death. During project lab visits, the lab staff talk about what they call the lab's 'black period'. At one point, the lab's experiments kept failing. Organoids would either not grow properly or die prematurely. It was very disconcerting and despite adapting their interventions, like changing the starter cells, media or growth factors used, it went on for weeks. Eventually, the mystery was dispelled after a lab inspection: something was wrong with the carbon dioxide levels of the culturing hood. They might use all the bioengineering tools at their disposal, but the team emphasise, much like Farah, the unpredictability of stem cells in culture.

The sentiment of laborious work and uncertain results resonates Farah's phrase 'working in the dark'. And much like in the UK lab, it is expressed in an academic setting that has produced prominent research with a privileged position in the landscape of stem cell technologies. For example, the lab succeeded in using kidney organoids to understand how Sars-Cov-2 infected human cells and proved that a specific protein was able to inhibit the entrance of the virus leading to phase one clinical trials for a drug. These studies involved wide international collaboration, the organoids were grown in the institute and later shipped to another country to be infected with the virus. Organoids travelled in a test tube, measuring a few millimetres, and suspended in medium. Key to this process was to keep samples of the same organoids in the lab, once they reached the other lab, the data would then be validated vis-a-vis the original organoids. It did not always work, sometimes organoids did not survive the trip. Other times, the organoids became something else, and the protein expression data would differ vastly to that of the control organoid at the lab. Hence, the researcher emphasises, 'We need to check that it is what it is meant to be, or if it still is what it is meant to be'. This vignette about this southwestern European research institute helps us to unpack the making of bioengineered organoids as an intricate and fallible process of nearing the human. A challenging and precarious achievement that brings together both difference and similarity to and from the human subject.

3.3 | Bioengineering and Inclusion: Moving Beyond a 'One Size Fits All' Approach

The conference took place online, still under pandemic restrictions. It was hosted at a US institution with the aim to bring together scientists working at the intersection of biology and engineering. The theme was the emergence of a vast array of multicellular engineered living systems, from organoids to embryo models and miniaturised biological robots. Conference attendees were from interdisciplinary fields drawing from developmental biology, bioengineering, biofabrication, biomaterials, tissue engineering, synthetic biology, systems biology and computational modelling.

We offer this US conference vignette as a complement to the previous sections that focused on a basic research lab at the UK and a bioengineering research institute in southwestern Europe. In the labs, we saw how researchers' work with organoids blurs the boundaries between human and nonhuman animals amidst the complexities of nearing the human with in vitro models. Contrastingly, at the conference, organoids were heralded as breakthrough models for their uniquely human purchase vis-à-vis the inadequacies of nonhuman animal models. Many presenters started their talks by emphasising that now that they have obtained 'truly human' living systems in a dish, it is possible to circumvent the inadequacies of animal models. One presenting neuroscientist explained that with rodent models they could not go very far because mice failed to capture the human specific features and complex genetics of neurodevelopmental disease. Organoids might only be reductionist models of the human brain, she cautioned, nevertheless their use can answer longstanding questions about complex and polygenic neurological disorders. Many diseases with a diverse population pose challenges in the preclinical stage. One of these challenges for this researcher is determining how many stem cell donors are needed to include diversity of genetic backgrounds. To do this, she explained, an organoid can effectively become a 'village-in-a-dish' and include a thousand patients in the same model. And at the same time, organoids derived from a specific patient's blood sample can usher in precision medicine, acting as a clinical surrogate to screen the individual's response to a drug or a tailored treatment. But as the presenter remarked, bioengineering solutions are needed to address the challenges posed by these goals:

> The elephant in the room that precludes use of organoids to understand brain disease is that every organoid we make is very different to the other, whereas not in culture but in vivo, every brain develops following the same pathway, unlike organoids that vary from one to the other.
>
> (Professor of Stem Cell and Regenerative Medicine).

The road to more robust organoids, they agreed during the Q&A, lies in stronger and more interdisciplinary collaborations to develop protocols for enhanced reproducibility. The idea here is that when organoids become consistent, they will perform better as highly reliable human models and enable better therapeutics and accelerate drug discovery.

A biomedical engineer at the conference explained that complex human models can help cross 'the valley of death'. Here she means the problem of the current drug discovery paradigm, which she cited as having a failure rate of 50%. Drugs' poor efficacy and toxicity problems are pinned down to the lack of congruence between animal models and human diseases. Stem cell-based human models, she continues, promise to address the disparity in disease incidence and outcomes, moving beyond the 'one size fits all' approach and delving deep into human specificities and differences across the population. She uses organoids to understand the higher incidence of African Americans and Hispanics that suffer a stroke, almost doubled in black women, as well as health disparities in chronic diseases like diabetes and cancer. Organoids offer unprecedented access to specific patient populations with a variety of genetic backgrounds and consequently, as another presenter puts it, improve the representation of underserved populations in drug screening:

> Multicellular organoid modelling to date has largely relied upon the average cell, not reflecting underlying genetic differences, but that diversity can be modelled for personalised applications. This community has a leadership opportunity to shape standards of how diversity is leveraged in iPSC-based platforms.
>
> (Professor of Bioengineering).

This researcher suggested that organoid models, achievable through machine learning and computational modelling, could thus combat medical research's insufficient inclusion of race and ethnicity The aim, she urged, is to build applications that meet societal needs: designing 'a societal melting pot on a plate' to bring forth the possibility to democratise the drug development pipeline.

Another recurrent theme that punctuated many presentations was the translational leap from organoids as models to therapeutic organs for human transplant. The stem cell technologies of today, participants asserted, can with advanced biomanufacturing technologies pave the way for long awaited clinical applications in regenerative medicine. The plan at hand is to develop human tissue structures that can be implanted into experimental animals to assess their integration and functionality. Nevertheless, to speed up the process the speaker urged the community to bridge the gap from animal to human host, and to design with biomaterials that will work in the human body. The point, the presenter insisted, was to reflect on the fact that building human cell-based systems in vitro requires validating their correspondence in vivo at the cellular level. Doing that exposes the knowledge gaps in human biology. Organoids might be articulated as 'truly human' by presenters, but the community acknowledged that to their translational power will be determined by their near humanness:

> What should these living systems even look like, at the cellular and molecular level?
> Do we even know what we are trying to build? What is the blueprint? How close are we to it?
>
> (Associate Professor of Bioengineering).

This presenter's final point was to build models thoughtfully, thinking of human biology, and not forgetting that they are not developing for a 'person in a box' but for the very diverse US population. Overall, the community gathered shared the aspiration to advance what they referred to as 'ethical bioengineering', and ample space was given to discussions on the ramifications in science and in society. The stress was on designing cell-based technologies with proper representation of population diversity, sex differences as well as ethnicity. Doing that, requires, as it was noted during the conference, an adequate involvement of public and stakeholders. The final exhortation to the scientific community was that to design for social justice, and to advance morally responsible bioengineering, ethical questions about accessibility need to be addressed early in the design process.

4 | Discussion: Navigating Experimental Challenges and Socio-Political Implications

In the preceding sections, we have explored how advancements from embryonic stem (ES) cells to induced pluripotent stem (iPS) cells have catalysed a transformative shift in biomedical research. This new era, marked using cellular technologies, has opened up innovative avenues for modelling human disease and development through organoids. However, as researchers navigate this evolving landscape, they face not only the technical challenges of constructing accurate models but also significant socio-political questions about the use and representation of human tissues and cells in their research. This interplay of experimental and socio-political considerations underscores the need for sociological consideration of how these models are crafted and how they may impact our broader perceptions of human identity and diversity.

4.1 | The Craft of Balancing Emergence and Engineering

Bioengineering organoids is a demanding work. It requires researchers' utmost attention to the organoids growing in vitro, and a calculated precision in all their interventions to coax the cells to self-assemble and differentiate as they would inside the human body. The sociological work of Meskus (2018) is helpful to understand the prerogative of the researchers' toils with human iPS cells that she fittingly describes in her book '*Craft in Biomedical Research*'. Meskus' work builds upon Landecker's (2007) concept of 'culturing life' or how novel possibilities of culturing cells in the laboratory effectively turn cells into technologies and alter notions of what it means to be biological that in turn impinge on notions of humanness.

Our ethnographic work at the UK and southwestern European labs also brings forward the notion of craft. Growing organoids

is indeed a craft that requires professional skilfulness and patience. As the researcher at the institute put it, 'the cells are the ones that rule, not us'. The challenges at the lab revolve around providing an environment that can mimic a living organism in which cells would grow, assemble and differentiate accordingly. Thus, and building on Meskus' (2018) biomedical craft framework, we draw on our empirical materials that unpack the craft of nearing the human to understand the work of building human organoids. The uncertainties that researchers grapple with can sometimes be due to the cultures becoming contaminated, as in the 'black period' in the institute with the malfunctioning hood. More often, however, it is because of stem cells' intrinsic variability which leads to the pressing problem of organoids' compromised reproducibility. This is the 'elephant in the room', as described in the conference when pointing to a key obstacle in using organoids as reliable and consistent human models. Our study resonates with Eriksson's (2012) work on human embryonic stem cells (hESCs) and the distinction between the public 'discursive' stem cell—found in scientific journals and media—and the private 'material' backstage stem cell—as experienced in laboratories. Whereas the 'discursive' stem cells were enacted as stable and compliant entities, the 'material' hESCs' capricious variability punctuated the experimental labour in the lab. An experimental variability that, as noted by Eriksson and Webster (2015), is being addressed by concerted efforts to develop scientific standards to enable regulatory approval. The aim of this work of 'bio-identification' is to render hESC 'bio-identical' and comparable across laboratories and cell lines to accelerate prospective clinical applications.

The ethnographic vignettes above bring forward the challenge of stem cells' variability in lab practice. In the UK's basic research lab, Farah's difficulties are more pronounced as she is pioneering human ureter organoids with no existing protocols from scratch. This expression resonates with other kinds of stem cell work, such as the practices of making stem cells and turning them into egg or sperm cells explored by Merleau-Ponty (2021). The situation at the European institute is similar. However, this collaborative group has an approach to emergence that involves a more dominant focus on bioengineering. They are without doubt experts in engineering, and they have several tools at their disposal such as genome editing technologies and hydrogels. However, the success of their bioengineering also depends on respecting and working with the cells' autonomous emergence. Work with organoids rests on a delicate balance between a bottom-up biological approach (emergence), and a top-down engineering approach (engineering). Such balance is not easily achieved, as showed by Calvert's (2024) longstanding ethnographic study of synthetic biologists. In our multi-sited ethnography, show that the delicate work of balancing emergence and engineering underpins the feeling of precariousness expressed by researchers' accounts and practices in the lab. As Eriksson and Webster put it: 'while it is vital to control vitality, this is rarely done once and for all. Standardising is an ongoing and provisional process' (2015, 86).

The experimental work of growing organoids in the lab can be aptly described as scientific practices of knowledge and control. This is similarly reflected in Hilgartner's (2017) work on the transformative scientific change brought about by genomics and the scientists' capacity to 'reorder life'. Similarly, it resonates with other social studies that critically discuss biomedicine's drive to know, change and control the very fabric of life (Franklin and Lock 2003; Kelz 2019; Nowotny and Testa 2011). Nevertheless, the researchers in this study cannot be said to be limitless engineers of life (Carlson 2011). As shown in previous ethnographic sections, the limits of control materialise when engineering needs to adapt to cells' emergence.

4.2 | The Politics of Inclusion in Preclinical and Translational Research

Our multi-sited ethnographic account can help to unpack how researchers define the biological objects that they work with. Going beyond 'the average cell' and a 'one size fits all' approach is about accounting for human diversity within the population. It is also about increasing the inclusion of underrepresented and underserved populations, as well as modelling specific disease states and the 'patient in a dish' of precision medicine. Bioengineers themselves recognise the importance of inclusivity in developing human-engineered tissues. For example, a group of bioengineers writing in *Nature Review Materials* recently argued that 'to develop tools and platforms that benefit the entire human population, we must consider the ancestry of cells and intentionally diversify the cells we use in our designs' (Moore et al. 2022, 2; see also Co et al. 2023).

However, our ethnographic accounts show that there is not yet a clear coordinated approach or framework across research platforms for systematically considering diversity and inclusion in these new in vitro models. The emerging research practices and accompanying discourses on justice and inclusion we describe here raise pressing questions about how human differences, especially categories such as race, ethnicity and gender are brought into new model systems both within organoids, but also more broadly into computational and automated systems (Lensink et al. 2020; Schelenz 2022; Galasso 2023). Here we turn to the work of sociologist Williams (2022) who conducts research in another domain of stem cell research—her work explores stem cell donation for cancer treatments (cells sourced from bone marrow or blood). She explores how it is characterised in the UK by increasing minoritised donors on the stem cell registry. In reflecting on her ethnographic research, she explores how a focus on increasing diversity through categories of race and ethnicity in donor drives often cannot account for the systemic problems that have led to this strategic focus in the first place: 'the establishment of a system that for years did not do enough to recruit amongst minoritised donors and that operates in a state that has led minoritised people to feel a legitimate sense of concern about where and to what use their data might be put' (Hollin and Williams 2022, 4; see also Williams 2022).

This issue is also highlighted in a recent policy forum in *Science* where the authors call for the development of an ethics of inclusion in precision medicine because 'people must believe that there is value in providing information about themselves and their families, and that their participation will translate into equitable distribution of benefits' (Lee et al. 2019, 941). Indeed,

Epstein's (2008) sociological analysis of inclusion strategies in US-based clinical research demonstrated how attempts to address systemic discrimination and lack of representation in clinical trials, resulted in a series of unintended consequences directly affecting the health of the targeted groups. These included potentially overlooking how health risks are distributed across society, valorising some forms of identity but concealing others, and encouraging the erroneous belief that categories such as race are themselves biological (Epstein 2008, 11). Striving for diversity and inclusion without critical reflection and consideration of factors such as ancestry may lead to unintended consequences, perpetuate existing inequalities, and neglect marginalised groups and communities. Our ethnographic exploration of bioengineered human models highlights how the field is grappling with the social and political implications of their work, such as navigating the intersection of race, ethnicity and gender in model systems in order to ensure that biomedical innovations contribute to fair and equitable healthcare outcomes.

4.3 | Nearing the Human

In medical sociology, much attention has been devoted to understanding and managing uncertainty in healthcare (Mackintosh and Armstrong 2020), Oor how uncertainty comes to define genomic research and the cancer clinic in the clinicians' 'ethos of modest, and persistent inquiry' (Kerr et al. 2019, 236). Countering inevitable uncertainties also becomes part of the work of bioengineering human models. As Hogle (2022, 547) has explained, both human organoids and cultured meat are variously enacted as 'the real thing'. The organoids' authenticity as analogue is accomplished through material and discursive means embedded in knowledge practices, governance regimes and political interests.

The scientific practices of caring for organoids are directed at optimising their reliability as human models. The notion of near-human models helps us to problematise narratives of authenticity, as elucidated by Hogle (2022). The ethnographic vignettes highlight the diverse ways scientists articulate and justify their assessments of nearness to the human. These justifications vary depending on the context and the criteria used. For example, Farah assesses proximity based on developmental stage, noting that a mouse embryo is the closest analogue to a human embryo. In other instances, nearness is justified by the origin of the starter cells, such as using human donor cells. Scientists also employ different indices of comparison when emphasising the distance from human tissue, including genetic identity, as seen in the southwestern European institute, or the variability in organoid development, referred to as the 'elephant in the room' at the US conference.

Importantly, focussing on how researchers accommodate uncertainties brings into relief the limits of these models and the processes of moving between in vitro and in vivo forms of experimentation, a dynamic captured in the changing relationship between bodies and engineered biomaterials described by Coren (2020, 170) as 'life inter vivos'. The researchers growing organoids in the lab, as shown in our multi-sited ethnography, deal with and accommodate the uncertainties emerging from working with unpredictable multicellular living systems.

For example, the lab observations show that the human cultures Farah was growing were indeed markedly different than those of mouse origin; they look different, and they required different protocols and products. This is because the starter cells come from human tissue donors, hence their near human proximity. Yet, Farah's efforts in growing human ureters also enact the human as disentangled from its human provenance, as a research material at the lab. This distance from donors to cell-based technologies is what Waldby and Mitchell (2006, 60) refer to as 'disentanglement' in their work on human stem cells whereby ties are cut with the tissue donors to enable a circulation of 'tissue economies'. Similarly, Boers et al. (2019, 134), also discuss the process of disentanglement to explore the notion of organoids as 'hybrids', both with subject-like and object-like values. Disentanglement, Boers et al. (2019, 135) explain, albeit necessary to enable the creation of useful tools for biomedical research, can also erode the moral and instrumental value of organoids. Another perspective on disentanglement, and one that closely resonates with our observations at the lab, is articulated in Dam and Green's (2022, 8–13) ethnography of 'caring for organoids' in translational research. The authors follow the work of laboratory researchers with personal cancer models that intimately engage with and care for organoids whilst simultaneously caring for patients in the clinic through practices of avoidance and exclusion. Disengagement and distance rather than depersonalising organoids, or reducing them to a thing, is a way to enact patient personhood by folding patient and organoid as a pair (Dam and Green 2022, 17).

In revisiting Mette Svendsen's concept of the 'near human', our study underscores the relevance of her framework in the context of contemporary bioengineering practices. Svendsen's idea of 'nearness' to navigate the border zones between human and nonhuman entities resonates with our findings on organoid research. Our ethnographic investigation reveals how the pursuit of near-human models involves not only technical challenges but also significant socio-political considerations, echoing Svendsen's exploration of how biomedical research grapples with notions of human similarity and difference. As Green (2024) also argues 'our ambiguous relationship with animals in science therefore also brings into question what it means to be human'. By examining the diverse ways scientists assess and justify the nearness of organoids to human physiology, we illuminate the complexities of creating and interpreting these models. Future research should continue to explore these dynamics, building on Svendsen's insights to address the evolving challenges and implications of bioengineering human-like models.

5 | Conclusion

The multi-sited ethnographic research presented in this paper reveals the growing sociological significance of in vitro models in crafting human tissues and organs for advancing human health. Our findings show how a translational ethos shapes contemporary biomedicine, particularly within stem cell

science (Harrington and Hauskeller 2014). This ethos is amplified by U.S. research funding policies, such as the FDA's fast-track designation for drugs tested in stem cell-based human models (FDA 2021) and the NIH's support for multicellular stem cell technologies aimed at accelerating precision medicine (NIH 2020).

Ultimately, the scientific community is driven to leverage the power of stem cells to get 'more treatments for all people more quickly' (NIH 2021).

Through our ethnographic investigation of organoids, we argue for the critical importance of employing a sociological lens to interrogate the landscapes of health and illness that these 'near-human' models embody. This paper contributes conceptually by reframing organoids not simply as technical achievements, but as socio-political artefacts shaped by the labour, uncertainties, and translational pressures in the field. By focussing on the making of human organoids, we uncover the ways in which the development of these models mirrors broader tensions in biomedicine, especially regarding the ethics of 'nearing the human' in vitro.

Organoids represent a fundamental shift towards human-specific models that aspire to more closely replicate human biology than traditional animal models. As these technologies become mainstream, the socio-political questions of representation, diversity, and inclusivity within these models grow in relevance. This paper underscores the need for a deeper sociological engagement with how organoids are constructed, asking who is included in these models, under what conditions, and for what purposes. Ultimately, our analysis reveals that the transition from generating stem cells to engineering complex multicellular structures not only reorients human health research but also calls into question the boundaries of human physiology, challenging researchers to reconsider how life is modelled and represented both inside and outside the lab.

Author Contributions

Sara Bea: conceptualization (equal), data curation (lead), methodology (equal), writing–original draft (equal), writing–review & editing (equal). **Amy Hinterberger:** conceptualization (equal), funding acquisition (lead), investigation (equal), methodology (equal), project administration (lead), supervision (lead), writing–original draft (equal), writing–review & editing (equal).

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

References

Adashi, E. Y., D. P. O'Mahony, and I. Glenn Cohen. 2023. "The FDA Modernization Act 2.0: Drug Testing in Animals Is Rendered Optional." *American Journal of Medicine* 136, no. 9: 853–854. https://doi.org/10.1016/j.amjmed.2023.03.033.

Benjamin, R. 2013. *People's Science: Bodies and Rights on the Stem Cell Frontier*. Stanford, CA: Stanford University Press.

Boers, S. N., J. J. M. van Delden, and A. L. Bredenoord. 2019. "Organoids as Hybrids: Ethical Implications for the Exchange of Human Tissues." *Journal of Medical Ethics*, [online] 45, no. 2: 131–139. https://doi.org/10.1136/medethics-2018-104846.

Calvert, J. 2024. *A Place for Science and Technology Studies: Observation, Intervention, and Collaboration*. Cambridge, MA: MIT Press.

Carlson, R. H. 2011. *Biology Is Technology: The Promise, Peril, and New Business of Engineering Life*. Cambridge, MA: Harvard University Press.

Co, J. Y., J. A. Klein, S. Kang, and K. A. Homan. 2023. "Toward Inclusivity in Preclinical Drug Development: A Proposition to Start With Intestinal Organoids." *Advanced Biology* 7, no. 12: 2200333. https://doi.org/10.1002/adbi.202200333.

Coren, G. G. 2020. "Life Inter Vivos: Modeling Regeneration in the Relation Between Bodies and Biomaterials." *BioSocieties* 17, no. 2: 169–202. https://doi.org/10.1057/s41292-020-00206-4.

Dam, M. S., and S. Green. 2022. "Caring for Organoids: Patient Personhood and the Ethics of Avoidance in Translational Cancer Research." *Science, Technology & Human Values*: 0162243922114320. https://doi.org/10.1177/0162243922114320.

Epstein, S. 2008. *Inclusion: The Politics of Difference in Medical Research*. Chicago, USA: University of Chicago Press.

Eriksson, L. 2012. "Pluripotent Promises: Configurations of a Bio-Object." In *Bio-Objects: Life in the 21st Century*, edited by N. Vermeulen, S. Tamminen, and A. Webster, 27–42. Burlington, VT: Ashgate.

Eriksson, L., and A. Webster. 2015. "Standardizing Work as a Recursive Process: Shaping the Embryonic Stem Cell Field." *New Genetics & Society* 34, no. 1: 72–88. https://doi.org/10.1080/14636778.2014.998818.

European Animal Research Association, EARA. 2023. "FDA Modernization Act 2.0 – What, If Anything, Has Changed in US Regulations?" [online]. https://www.eara.eu/post/fda-modernization-act-2-0-what-if-anything-has-changed-in-us-regulations.

FDA. 2021. "FDA Modernization Act of 2021." https://www.congress.gov/bill/117th-congress/house-bill/2565?r=33%26s.

Franklin, S. 2013. *Biological Relatives: IVF, Stem Cells, and the Future of Kinship*. Durham: Duke University Press.

Franklin, S., and M. M. Lock. 2003. *Remaking Life and Death: Towards an Anthropology of the Biosciences*. Santa Fe, USA: James Currey.

Galasso, I. 2023. "Precision Medicine for Whom? Public Health Outputs From 'Genomics England' and 'All of Us' to Make Up for Upstream and Downstream Exclusion." *American Journal of Bioethics* 24, no. 3: 1–15. https://doi.org/10.1080/15265161.2023.2180108.

Green, S. 2024. *Animal Models of Human Disease*. Cambridge, UK: Cambridge University Press.

Harrington, J., and C. Hauskeller. 2014. "Translational Research: An Imperative Shaping the Spaces in Biomedicine." *Tecnoscienza–Italian Journal of Science & Technology Studies* 5, no. 1: 191–201.

Hilgartner, S. 2017. *Reordering Life: Knowledge and Control in the Genomics Revolution*. Cambridge, MA: MIT Press.

Hinterberger, A., and S. Bea. 2023. "How Do Scientists Model Humanness? A Qualitative Study of Human Organoids in Biomedical Research." *Social Science & Medicine* 320: 115676. https://doi.org/10.1016/j.socscimed.2023.115676.

Hogle, L. F. 2022. "Enacting Authenticity: Changing Ontologies of Biological Entities." In *The Palgrave Handbook of the Anthropology of Technology*, edited by M. Hojer Bruun, A. Wahlberg, R. Douglas-Jones, et al., 547–568. Singapore: Palgrave Macmillan. https://doi.org/10.1007/978-981-16-7084-8_28.

Hollin, G., and R. Williams. 2022. "Complicity: Methodologies of Power, Politics and the Ethics of Knowledge Production." Supplement,

Sociology of Health & Illness 44, no. S1: 1–21. https://doi.org/10.1111/1467-9566.13575.

Kelz, R. 2019. "Genome Editing Animals and the Promise of Control in a (Post-) Anthropocentric World." *Body & Society* 26, no. 1: 3–25. https://doi.org/10.1177/1357034x19882762.

Kerr, A., J. Swallow, C. K. Chekar, and S. Cunningham-Burley. 2019. "Genomic Research and the Cancer Clinic: Uncertainty and Expectations in Professional Accounts." *New Genetics & Society*, [online] 38, no. 2: 222–239. https://doi.org/10.1080/14636778.2019.1586525.

Kim, J., B.-K. Koo, and J. A. Knoblich. 2020. "Human Organoids: Model Systems for Human Biology and Medicine." *Nature Reviews Molecular Cell Biology* 21, no. 10: 571–584. https://doi.org/10.1038/s41580-020-0259-3.

Landecker, H. 2007. *Culturing Life: How Cells Became Technologies*. Cambridge, MA: Harvard University Press.

Landecker, H. L., and A. T. Clark. 2023. "Human Embryo Models Made From Pluripotent Stem Cells Are Not Synthetic; They Aren't Embryos, Either." *Cell Stem Cell*, [online] 30, no. 10: 1290–1293. https://doi.org/10.1016/j.stem.2023.09.006.

Lee, S. S.-J., S. M. Fullerton, A. Saperstein, and J. K. Shim. 2019. "Ethics of Inclusion: Cultivate Trust in Precision Medicine." *Science*, [online] 364, no. 6444: 941–942. https://doi.org/10.1126/science.aaw8299.

Lensink, M. A., K. R. Jongsma, S. N. Boers, J. J. Noordhoek, J. M. Beekman, and A. L. Bredenoord. 2020. "Responsible Use of Organoids in Precision Medicine: The Need for Active Participant Involvement." *Development* 147, no. 7. https://doi.org/10.1242/dev.177972.

Mackintosh, N., and N. Armstrong. 2020. "Understanding and Managing Uncertainty in Health Care: Revisiting and Advancing Sociological Contributions." Supplement, *Sociology of Health & Illness* 42, no. S1: 1–20. https://doi.org/10.1111/1467-9566.13160.

Merleau-Ponty, N. 2021. "Sociology as Technology: A Toolkit for Studying In Vitro Gametogenesis." In *Sociology as Technology: A Toolkit for Studying in Vitro Gametogenesis*, edited by R. Davis-Floyd, 77–89. London: Routledge.

Meskus, M. 2018. *Craft in Biomedical Research: The iPS Cell Technology and the Future of Stem Cell Science*. New York: Palgrave Macmillan.

Moore, E., J. B. Allen, C. J. Mulligan, and E. C. Wayne. 2022. "Ancestry of Cells Must Be Considered in Bioengineering." *Nature Reviews Materials* 7, no. 1: 2–4. https://doi.org/10.1038/s41578-021-00397-7.

Morrison, M. 2019. "Making Cells Worthwhile: Calculations of Value in a European Consortium for Induced Pluripotent Stem Cell Banking." *Science as Culture* 28, no. 1: 46–69. https://doi.org/10.1080/09505431.2018.1538331.

NIH. 2020. "NIH Wide Strategic Plan: Fiscal Years 2021–2025." [online] *National Institutes of Health*, 1–64. https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf.

NIH National Center for Advancing Translational Sciences. 2021. "Director's Message Series: NCATS' Bold Goals." [online]. https://ncats.nih.gov/about/director/ncats-bold-goals.

Nowotny, H., and G. Testa. 2011. *Naked Genes: Reinventing the Human in the Molecular Age*. Cambridge, MA: MIT Press.

PETA. 2022. "Victory! President Signs Groundbreaking FDA Modernization Act 2.0." [online]. https://www.peta.org/action/action-alerts/victory-congress-passes-groundbreaking-fda-modernization-act-2-0/.

Schelenz, L. 2022. "Diversity Concepts in Computer Science and Technology Development: A Critique." *Science, Technology & Human Values* 48, no. 5: 1054–1079. https://doi.org/10.1177/01622439221122549.

Svendsen, M. 2021. *Near Human: Border Zones of Species, Life, and Belonging*. New Jersey, USA: Rutgers University Press.

Takahashi, K., K. Tanabe, M. Ohnuki, et al. 2007. "Induction of Pluripotent Stem Cells From Adult Human Fibroblasts by Defined Factors." *Obstetrical & Gynecological Survey* 131, no. 5: 861–872. https://doi.org/10.1097/01.ogx.0000305204.97355.0d.

Thompson, C. 2013. *Good Science*. Cambridge: MIT Press.

Wainwright, S. P., C. Williams, M. Michael, B. Farsides, and A. Cribb. 2006. "Ethical Boundary-Work in the Embryonic Stem Cell Laboratory." *Sociology of Health & Illness* 28, no. 6: 732–748. https://doi.org/10.1111/j.1467-9566.2006.00539.x.

Waldby, C. 2002. "Stem Cells, Tissue Cultures and the Production of Biovalue." *Health* 6, no. 3: 305–323. https://doi.org/10.1177/136345930200600304.

Waldby, C., and R. Mitchell. 2006. *Tissue Economies: Blood, Organs and Cell Lines in Late Capitalism*. Durham: Duke University Press.

Williams, R. 2022. "Improving the Odds for Everybody': Narrative and Media in Stem Cell Donor Recruitment Patient Appeals, and the Work to Redress Racial Inequity." *Sociology of Health & Illness* 44, no. 7: 1114–1131. https://doi.org/10.1111/1467-9566.13505.