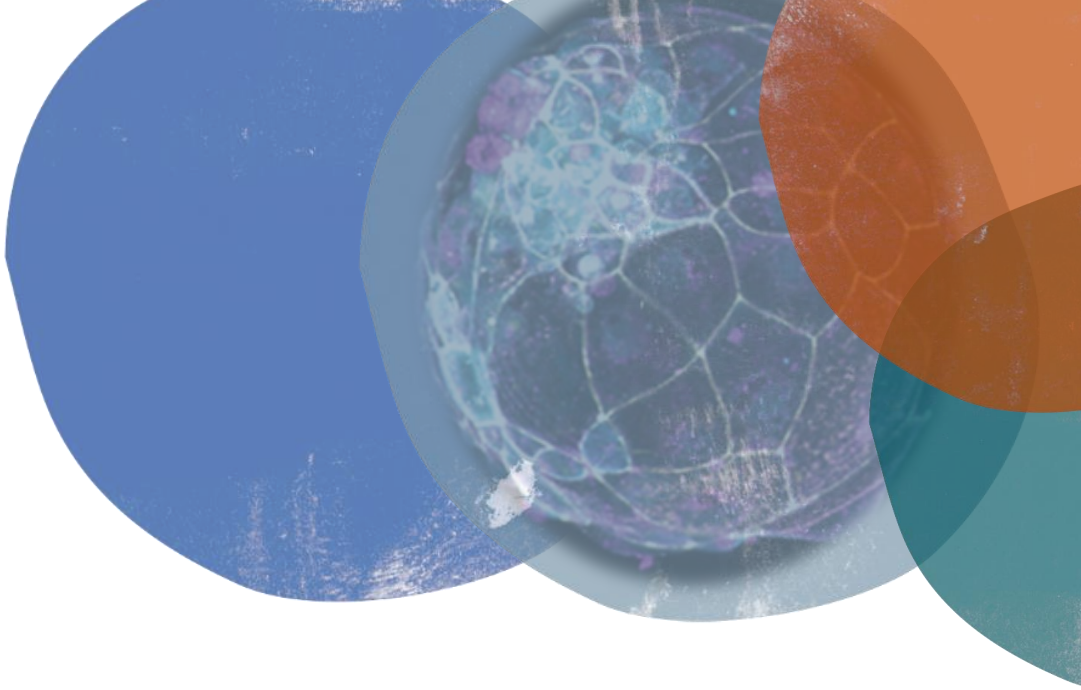

Addressing the governance gap

A public dialogue on the governance of research involving stem cell-based embryo models

Full report

Hopkins Van Mil
April 2024

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Contents

Foreword

Stem cell-based embryo models (SCBEMs, referred to in this report simply as “embryo models”) are, as the term suggests, similar to embryos in some respects but different from embryos in other respects. This is what makes embryo models so fascinating and useful in research, but this is also what makes them challenging to think about. Adding to the challenge is the existence of a large (and growing) variety of embryo models, which can differ considerably in their nature and extent of similarity to human embryos.

Perhaps unsurprisingly, the question of how best to categorise different embryo models and assess their most significant attributes is not fully settled. Arriving at a satisfactory answer to this question involves an interplay between scientific, ethical, regulatory and other considerations that is as subtle, in its way, as the interplay between biological phenomena that enables scientists to create embryo models in the first place.

All of this has led to some uncertainty regarding what rules should apply to research involving embryo models, and whether established rules are sufficient or whether new rules are called for. It became increasingly apparent to both of us, and to the organisations where we work – respectively Cambridge Reproduction (an interdisciplinary initiative that brings together researchers across Cambridge) and the Progress Educational Trust (PET, a charity that improves choices for people affected by infertility and genetic conditions) – that there is a need for clearer guidance on the way embryo models can, and should, be used in UK research.

This need became particularly apparent at two workshops that were organised by Cambridge Reproduction in 2022, at which key figures from a wide variety of disciplines suggested that there should be some form of dedicated governance for embryo model-related research in the UK. A major concern expressed at those workshops was that failure to establish dedicated governance would jeopardise research on (at least) two fronts – it threatened to undermine public trust in research, and it was already undermining the confidence of researchers themselves, who wanted to know the boundaries within which they could pursue their work.

In order to address this pressing need for governance, Cambridge Reproduction and PET collaborated in 2023 to launch a project called Governance of Stem Cell-Based Embryo Models (G-SCBEM). For the past year, this project has been developing a Code of Practice for UK research involving embryo models.

Work on the Code of Practice is drawing upon the insights of experts and practitioners from various areas of science, law and ethics, both within the UK and overseas. This sort of input is necessary, if the G-SCBEM Code of Practice is to be robust and credible, but it is not sufficient. A vital element that has to be included is the contribution of the general public.

The G-SCBEM Code of Practice will set out things that researchers ought to do – and ought *not* to do – so as to meet ethical standards, demonstrate responsibility and transparency, and take account of public hopes, concerns and sensitivities. If these stipulations are to be meaningful, then the Code of Practice must be informed by an accurate sense of how people understand the relevant ethical considerations,

what people think is adequate in relation to demonstrating transparency, and what people's hopes, concerns and sensitivities actually are.

For all of these reasons and more, we were delighted to receive support from Sciencewise and from the Biotechnology and Biological Sciences Research Council (BBSRC), and to collaborate with Hopkins Van Mil and other colleagues on the public dialogue whose content and findings are described in the following report.

Although this public dialogue concerns embryo models, all of its participants had previously participated in a 2023 public dialogue about human embryo research, conducted by Hopkins Van Mil as part of the Human Developmental Biology Initiative (HDBI). This meant that participants had already had occasion to reflect in depth on the science and ethics of research involving human embryos. This left them well-placed to consider whether, and in what respects, research involving embryo models should be regarded differently.

Of course, public views are liable to evolve and the science is developing rapidly, so the G-SCBEM Code of Practice will be revised periodically to take account of the latest developments. But we are keen that the views of the wider public, as well as the views of the other stakeholders in our orbit, should inform the Code of Practice at the very outset. It is thanks to this public dialogue that we will be able to ensure that this is the case.

A growing number of projects, besides ours, are exploring ethical and policy dimensions of embryo models. In the UK, there has been a recent briefing on the subject by the Parliamentary Office of Science and Technology[1], and there is also a project underway from the Nuffield Council on Bioethics[2]. Elsewhere, public perceptions of embryo models have recently been explored in the Netherlands[3], while the International Society for Stem Cell Research is building on its important earlier guidance in this area. We hope that the publication of this public dialogue report, and the imminent publication of the G-SCBEM Code of Practice, will help to establish a clearer context for all of these discussions.

Finally, we wish to conclude by expressing our heartfelt gratitude to the participants in the SCBEM public dialogue. As you will read in the following pages, these participants were asked to consider some of the most cutting-edge achievements and conundrums in present-day research and policy, thinking through and weighing up both the related opportunities and the related risks. This was no easy task, but the insights that they offered in response were – and are – invaluable.

Christina Rozeik, Programme Manager, Cambridge Reproduction
Sandy Starr, Deputy Director, Progress Educational Trust

[1] https://doi.org/10.58248/PN716
[2] https://www.nuffieldbioethics.org/publications/stem-cell-based-embryo-models
[3] https://doi.org/10.1007/s11673-023-10325-9

Executive summary

The purpose of this public dialogue

This public dialogue aims to inform a Code of Practice currently being developed by the Governance of Stem Cell-Based Embryo Models (G-SCBEM) project, which is led by Cambridge Reproduction in partnership with the Progress Educational Trust. The Code of Practice is intended to help scientists conducting research involving stem cell-based embryo models (embryo models) to work responsibly, accountably and transparently, in a way that sustains and builds public trust. Currently, no such dedicated guidance exists for UK research involving embryo models.

Who was involved as a participant in the dialogue?

38 participants took part in this dialogue. They were recruited from the 70 members of the public who took part in the 2023 Human Developmental Biology Initiative (HDBI)'s public dialogue on early human embryo research[4]. This meant that participants were already aware of embryo models and the wider context of embryo research and regulation, including the 14 day/primitive streak rule. Participants were a cross section of UK society, with a range of ages, ethnicities, socioeconomic statuses and attitudes to embryo research, see page 15 for more detail.

The dialogue process

This public dialogue used Zoom video-conferencing workshops and a dedicated online space during two weeks in January 2024. Figure 1 below summarises the process. It was commissioned by Cambridge Reproduction and co funded by UKRI Sciencewise programme and BBSRC Impact Acceleration fund. We believe that this has been one of the first public dialogues in the world where public participants, scientists, legal experts and ethicists have spent several hours over a number of weeks exploring the subject of research involving stem cell-based embryo models.

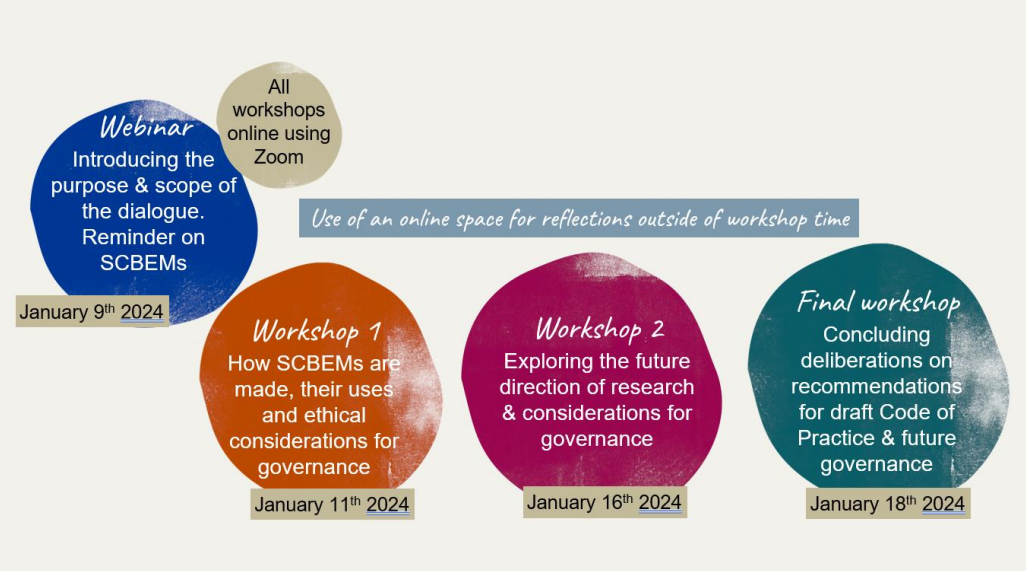
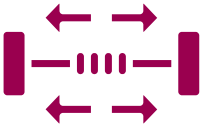


Figure 1: The dialogue process

[4] https://hdbi.org/public-dialogue

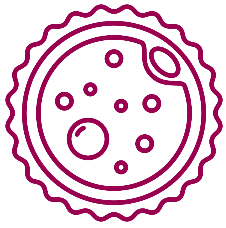
The dialogue findings



Tensions that emerged from the dialogue discussions: similarities and differences between embryo models and human embryos, limits, types of governance

The dialogue discussions explored the nature of embryo models, their use in research and the different ways that such research could be governed, including voluntary and legislative approaches. Several tensions emerged from these discussions, most notably:

Similarity with a human embryo		
Embryo models that are considered to be like a human embryo: Ethics of use: a potential baby?	vs	**Embryo models that are considered to be unlike a human embryo**: What research benefits can they bring?
Type of governance		
Legislative governance: Too restrictive, slow, cumbersome but needed to prevent malpractice?	vs	**Voluntary governance:** Lacks meaningful deterrents but responsive to scientific developments and quick to implement
Time/developmental limits on embryo model research		
Enable important research discovery	vs	Protect an embryo model if it could potentially develop into a sentient lifeform
Oversight Committee membership		
Involving lay members alongside scientists, ethicists etc to ensure a broad range of perspectives	vs	The need for detailed scrutiny of embryo model research



Status of embryo models: Views differed, but most participants see them as different from human embryos

Views on the status of embryo models differed among participants. Many concluded that embryo models are distinctly different from human embryos, or different enough, that they do not pose the same moral concerns as human embryo research. Their reasoning related to:

- the differences in how embryo models are created (e.g. from stem cells rather than an egg and a sperm)

- the differences in how embryo models develop (e.g. skipping stages of development)
- the fact that embryo models are created for human research rather than human reproductive purposes and may not be transferred to a womb
- some models' incomplete structure (e.g. some but not all tissues/organs present)

Some participants expressed concerns that embryo models have the potential to be like human embryos, particularly when they learnt about an embryo model that had formed what resembled a primitive streak. Participants worry that more complete embryo models could become so like human embryos that it would not be possible to differentiate between the two. For these reasons, some participants want to see a robust, legislative approach to governance.

Perceived benefits and harms of research uses of embryo models

Benefits – an exciting and amazing area of research Participants welcome research innovation to:	*Harms – stepping into the unknown without guardrails* Participants are worried about harms from:
• improve IVF success rates • better understand the causes of miscarriage and reducing its occurrence • understand and find new treatments for disease and genetic conditions • study early human development and hope that embryo models could be used, where possible for research, rather than human embryos	• what is unknown and uncertain about future uses of embryo models • a lack of clarity about potential outcomes and research ambitions which could lead to public mistrust • research which over-reaches and over time goes beyond what society currently understands to be acceptable • commercial interests being prioritised • misuse of the embryo model and the research data

Governance of embryo model research: a voluntary code of practice as a short-term stepping stone to legislation

Participants are very surprised by the current governance gap. They believe that because embryo models are formed from human cells and because of the wide range of types of models and their uses, governance is vital. Voluntary governance is seen as swifter and more flexible, but

potentially lacking teeth. Legislation is largely seen as inevitable and necessary in the medium to long term but raises questions of how it can avoid impeding research discoveries by being too inflexible.

Many participants see a voluntary code of practice as a short-term stepping stone to legislation in the medium to long term.

Participants spoke frequently about the importance of governance being regularly reviewed to ensure it is keeping up with the science and learning from it and what society wants from it.

Time or physical development milestone limits on embryo model research are of significant interest to participants. The 2023 HDBI public dialogue on early human embryo research that the participants had taken part in had spent considerable time exploring if the current 14 day/primitive streak limit should be extended. These earlier discussions were among the many considerations that informed participants' thinking about time or developmental limits for embryo model research.

Most participants believe such limits are necessary for several reasons, including to ensure no harm is done to embryo models which may develop some form of sentience and physical resemblance to a human embryo. There was a lot of discussion, but no consensus, about whether the same limits should be applied to all types of embryo models or whether limits should be considered on a case-by-case basis, or by placing embryo models in particular classes. Participants want to see more work done on classifying embryo models and determining how similar and different they are to human embryos. There is widespread agreement with the Code's prohibition on the use of embryo models for reproduction.

Participants hope that an Oversight Committee will review embryo model research and be the eyes and ears of the Code of Practice. They would like a broad range of perspectives to be included on this committee: scientists, legal experts, ethicists, clinicians, people with lived experience of health conditions and members of the public, including young adults. Having a range of generations is important to some participants because they see them providing different perspectives. As well as reviewing the research proposals, participants have hopes that the committee will play a role in making the science better known to the wider public.

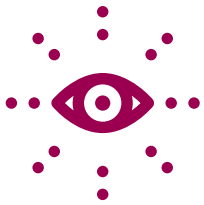
The draft Code of Practice graphic summary: instils confidence but lacks limits on when research should end

Participants' first reactions to reading the graphic summary were mostly very positive. Several participants used words such as 'confident' and 'reassured'.

The aspect of the Code of Practice, presented in the graphic summary, that generated greatest interest concerned the consequences of not following the code. Participants are split into two camps: those who think the possible consequences of not following the Code, such as not getting funding and potentially losing a job within a research institution, will likely ensure that almost all scientists conduct research that follows its recommendations; and those who think a legal footing is necessary with prosecution routes available for those who break rules.

Participants think that a time or physical developmental limit that makes clear when embryo model research should stop is missing. Participants strongly endorse the need for regular reviews of the Code. They would like to see these reviews explained in greater detailed in the published Code of Practice than they were in the graphic summary.

Communication and engagement: embryo model research needs public awareness and acceptance to thrive



There is a strong belief that this field of research will need public awareness and acceptability to thrive in the future: the wider public will need to see that scientists are working ethically and with good intent.

The terminology of ‘stem cell-based embryo model’ was discussed. Participants explored existing terms and generated their own. No single term emerged as a clear preference. Participants tend to favour either a ‘keep it simple’ e.g. embryo model or embryo-like structure or a ‘say exactly what it is’ approach e.g. stem cell-based embryo model or, as some participants suggested, stem cell research models containing human tissue.

Five considerations participants would like the authors of the draft Code of Practice to be mindful of as they progress their work

1. **Time or developmental limits on embryo model research: more consideration is needed**

   Almost all participants wish to see time or developmental limits on embryo model research, but they believe that more work is needed on the design and implementation of these limits.

2. **Code of Practice as a stepping stone to legislation**

   Participants see the merits of a Code of Practice that fills a current governance gap in a matter of months rather than several years. But there is a view that in the longer term embryo model research should be addressed by legislation, particularly around limits in law that would help to prevent certain outcomes, such as researchers culturing models with a developed nervous system.

3. **Regular reviews of the science and governance**

   The rapid progress of embryo model research in recent years makes regular reviews of governance vital for participants. They want to see more specific commitments in the Code for how reviews are carried out, and how often, but expect them to be annual or three-yearly or linked to significant developments in the field.

4. **Public involvement in governance and greater public awareness of the science**

   Many participants see embryo models as fascinating and complex. Their use in research has significant implications for understanding miscarriage and in vitro fertilisation (IVF), human development and

finding ways to prevent or cure diseases. Some participants also foresee more dystopian possibilities, such as changing the way in which human life is created. Participants believe that greater public involvement in, and awareness of, research and its governance will be essential to earning public trust in embryo model research.

5. **Research benefits clearly described and shared**

As fascinating as the science is, participants believe that there need to be clearer descriptions of what research involving embryo models is trying to achieve. Participants hope to see benefits from this research, such as improved IVF techniques and new treatments for health conditions, made available to those that need them, not just to those able to afford them.

Section 1: Setting the Scene

1. Introduction

1.1 How did this public dialogue come about?

Stem cell-based embryo models (embryo models) are a relatively new innovation in biomedical science. Currently there is no dedicated regulatory framework addressing research involving embryo models, although existing UK law seeks to prohibit them from being transferred into a human womb. Embryo models have been developed to help scientists understand early human development and to supplement the scarce supply of human embryos for research.

This public dialogue was commissioned to inform a draft Code of Practice for research involving embryo models. The commissioners are Cambridge Reproduction[5] and UK Research and Innovation's (UKRI) Sciencewise[6] programme. Cambridge Reproduction is an interdisciplinary research initiative that 'explores the urgent challenges posed by reproduction today'. Sciencewise is a public engagement programme that enables policy makers to develop socially informed policy with a particular emphasis on science and technology.

The lack of clear, transparent guidance in this area hinders research and risks damaging public confidence. A tangible example is that some scientists working in this area limit their research to the equivalent of 14 days of development in a human embryo or at the first sign of the primitive streak (the current legal limit for human embryo culture regulated by the Human Fertilisation & Embryology Authority (HFEA)[7]). In March 2023, Cambridge Reproduction launched a project to develop the first governance framework for research involving embryo models in the UK.

The Governance of Stem Cell-Based Embryo Models (G-SCBEM) project is led in partnership with the Progress Educational Trust[8]. It brings together scientists, legal scholars and bioethics experts and major research funders and regulators. In November 2023, social research agency Hopkins Van Mil (HVM) was commissioned to design, facilitate and report on this public dialogue. HVM was commissioned as a follow-up to its work on the Early Human Embryo Research Public Dialogue[9]. This latest dialogue involved 38 participants who had taken part in the dialogue process on early human embryo research.

1.2 What did the dialogue aim to do?

This public dialogue on the governance of research involving embryo models aims to inform the G-SCBEM project with the views of members of the public, who through the dialogue learnt about the research area. Their hopes, fears and expectations for how research involving embryo models is conducted will inform future governance. This will help scientists to conduct their research responsibly, transparently and in a way that garners public trust.

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[5] https://www.repro.cam.ac.uk/
[6] https://sciencewise.org.uk/about-sciencewise/
[7] https://www.hfea.gov.uk/
[8] PET is an independent charity that improves choices for people affected by infertility and genetic conditions https://www.progress.org.uk/
[9] https://hdbi.org/public-dialogue

1.3 What is a public dialogue?

Public dialogue is a process during which members of the public interact with scientists, stakeholders and policy makers to deliberate on issues relevant to future decisions.

Public dialogue enables constructive conversations amongst diverse groups of citizens on topics which are often complex or controversial. Not only does it provide an in-depth insight into public opinion, it also offers a window into understanding people's reasoning. This public dialogue, unlike a Citizen's Jury or Assembly, did not aim to reach a consensus on set of recommendations. Instead, it focused on surfacing and exploring a range of views from a small but diverse group.

Public dialogue was chosen as the format for this research to ensure that participants were given time and a level playing field to discuss the issues that matter to individuals, to communities and to society. Public dialogue is:

- informed – evidence is provided on what embryo models are, how they are created and why they are used in research so that participants can give their opinions on future governance; participants have access to specialists in their field
- two way – participants, scientists, legal and ethical specialists all give something to and take something away from the process
- facilitated – the process is carefully structured to ensure that participants receive the right amount and detail of information, a diverse range of views are heard and taken into account and the discussion is not dominated by particular individuals or issues
- deliberative – participants develop their views on an issue through conversation with other participants and specialists

HVM works within and promotes Sciencewise principles and quality framework[10]. The HVM team has extensive experience in designing, delivering and reporting on the outcomes of public dialogue.

1.4 What was the scope of the dialogue?

The focus of this dialogue was on research involving stem cell-based embryo models and how this research should be governed in the future.

The dialogue's objectives were to:

- gain a deeper understanding of public views on, and around the value and potential risks of, research involving embryo models
- understand whether and/or how public participants expect embryo models to be regulated in future, including legal and governance structures
- enable scientists and public participants to engage in a constructive dialogue to hear, reflect, consider and respond to issues around the research
- reflect on the draft Code of Practice and how this might be strengthened, including identifying any missing themes or issues

[10] https://sciencewise.org.uk/about-sciencewise/our-guiding-principles/

- identify participants' views about specific proposals or recommendations in the draft Code of Practice
- ensure dialogue findings inform subsequent drafts of the Code of Practice and other relevant decisions, activities and guidance

The research questions that informed the design of the dialogue were:

- what do participants perceive to be societal implications of research with embryo models?
- what ethical questions do participants raise around research with embryo models?
- what implications / applications of research with embryo models are most important to participants?
- should we impose limits on any areas of embryo model research and use?
- how can researchers maintain public trust in this area of research?
- what do participants think about the trade-offs for possible medical / healthcare implications of this research, where do the red lines exist, how does the 14 day rule factor into their thinking about possible outcomes and how does their knowledge of early human embryo research affect their views?
- what regulatory questions do participants raise around embryo model research, how should we strike the right balance between ensuring that this sensitive area of research is adequately overseen and enabling scientists the freedom to make new discoveries?
- how do the recommendations in the draft Code of Practice meet the participants' hopes and concerns for embryo model research?

2. Methodology

2.1 How the project was designed and managed

HVM collaborated with Cambridge Reproduction, Progress Educational Trust, Sciencewise and the evaluator Ursus Consulting[11] to design, recruit, facilitate and report on this public dialogue. This project team met weekly between November 2023 and February 2024. This timescale was set to enable the dialogue to feed into the G-SCBEM project which aims to publish its Code of Practice in Spring 2024.

In line with Sciencewise good practice, an Oversight Group was set up to help guide the dialogue design and reporting. This group of scientists, ethicists, historians and writers met three times, in the design phase, early reporting and final reporting stages. Those involved in this work are listed in Appendix A.

The dialogue process took place in three phases:

- planning, recruitment and design: November-December 2023
- fieldwork delivery: January 2024
- coding, analysis and report writing: February 2023.

2.2 Who were the participants who took part?

The 38 participants in this dialogue were recruited from the 70 members of the public who took part in the 2023 Human Developmental Biology Initiative (HDBI)'s public dialogue on early human embryo research[12]. The reason for recruiting these previous dialogue participants was that they were already aware of embryo models and the wider context of human embryo research and regulation. This meant that less time would be needed in building awareness and understanding of embryo models – an important factor given the modest budget for this dialogue and the tight timeframe.

When the 70 participants from the early human embryo research dialogue were approached about taking part in this follow up project, almost all expressed interest. The 38 participants were selected to achieve a range of ages, genders, ethnicities, locations and views on embryo research.

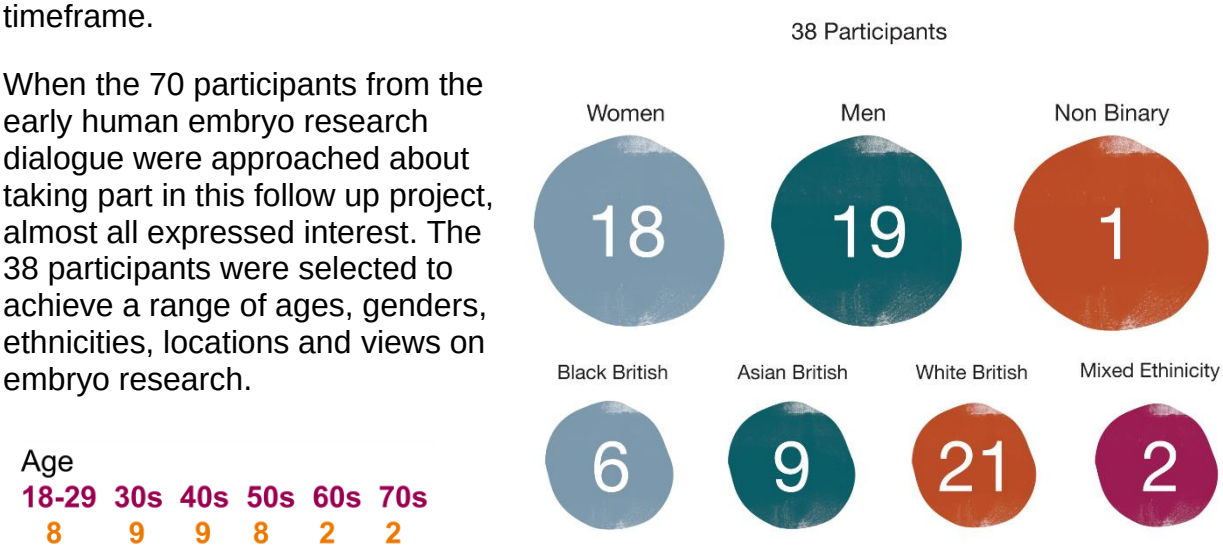


Figure 2 Participant backgrounds

[11] Ursus Consulting were commissioned by Sciencewise to evaluate the impact of this dialogue on future policy development https://www.ursusconsulting.co.uk/
[12] https://hdbi.org/public-dialogue

Participants' views on early human embryo and embryo model research ranged from strongly supportive to believing it should be banned. Appendix C lists participant demographics.

2.3 What did participants in the dialogue do?

This public dialogue used Zoom video-conferencing workshops and a dedicated online space (Recollective) during two weeks in January 2024. Before joining the first session, participants were emailed a welcome pack. This pack included the purpose of the dialogue, brief profiles of the organisations involved and how participants' data would be used and kept secure. The online space gave participants access to materials to remind them of their earlier dialogue involvement and add to their knowledge of embryo models. This included the early human embryo dialogue report section on embryo models[13] and a link to a BBC News[14] item on embryo models.

The webinar was a 90 minute session where participants were reminded of what embryo models are and given information on the focus of the dialogue on future governance. Participants asked questions of the speakers: Christina Rozeik, G-SCBEM Project Manager, Roger Sturmey, Professor of Reproductive Medicine at the Hull York Medical School and Chair of the G-SCBEM Guidelines Working Group, and Stephen Wilkinson, Professor of Bioethics at Lancaster University.

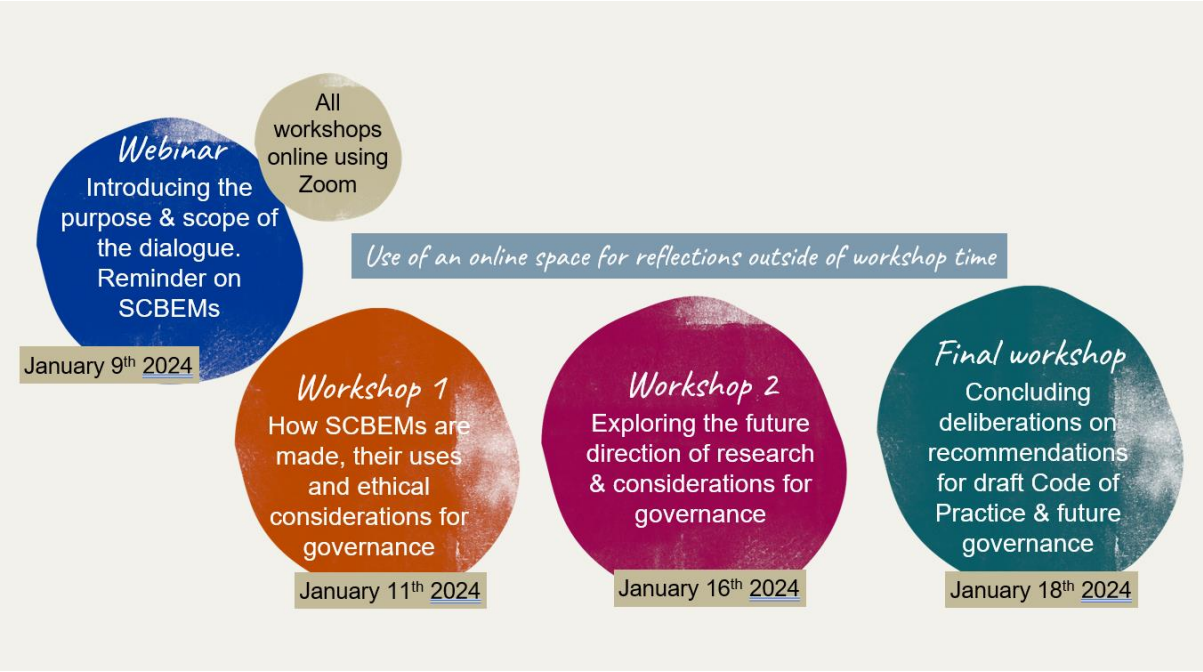


Figure 3 Dialogue process

The three 2.5 hour workshops that followed the webinar included plenary presentations, a panel discussion, question and answer sessions, mini-briefings on ethical provocations and facilitated small group discussions.

The first workshop focused on how embryo models are created and what they are used for in research. The second workshop looked at potential future uses of embryo models and considerations for governance. In the final workshop participants

[13] Early Human Embryo Research Public Dialogue Report
[14] Scientists grow whole model of human embryo, without sperm or egg – BBC News (youtube.com)

discussed a graphic summary of the draft Code of Practice for embryo models and wider issues of governance and priorities for research. A list of all speakers and contributors is in Appendix B.

Between the workshops, participants used the online space to re-watch presentations, watch and read new materials and share views on discussion boards.

A list of materials used during the dialogue are in Appendix D. Facilitator process plans are in Appendix E.

2.4 How we developed the findings in this report

Public dialogue reports are qualitative in nature. As such we do not report on the number of times something was said, but rather the strength of feeling expressed across the methods used. Strength is determined by the kind of language used and the extent to which participants raise, review and return to an issue.

The workshops were recorded and transcribed. These transcriptions, along with the comments shared in the online space Recollective and on the visual voting tool Mentimeter, were thematically coded using the analysis software NVivo.

For this project we used grounded theory[15], which means we read, and re-read, the transcripts many times. We collated what was said into key themes and used those themes to draw out meaning from the discussions. We chose this approach to ensure the findings are rooted in what participants tell us, guided by the dialogue objectives and the research questions, rather than looking for confirmation of preconceived ideas.

As such we use the following quantifiers in the report:

- ‘many’ or ‘most’ when it is clear that all or almost all participants shared a similar view
- ‘some’ when a reasonable number of participants shared a similar view
- ‘a few’ when a small number of participants shared a similar view

Bullet points are used to summarise key points made. These mostly reflect areas of agreement and where points were made by many participants across many groups. Anonymised quotations are used to illustrate points made by participants and to underline points made by a range of people. They also highlight points of particular significance to participants. Quotations are drawn from across the small group transcripts to ensure that a wide range of voices are heard throughout this report.

Interpreting and extrapolating findings

Public dialogues are a well-respected, robust approach for engaging the public with complex policy issues in a meaningful and informed way. As with any research method, it is important to consider what the approach means for interpreting or extrapolating findings:

- people interested in a topic are more likely to sign up and attend workshops such as these, but, unlike open public meetings, participants

[15] https://doi.org/10.1080/14780887.2020.1780357

are paid for their time and recruited to reflect society and not based on their interest in an area
- this report is a snapshot in time, people's views may change in the future
- the dialogue was a qualitative exercise, which did not aim to be representative of the UK population. As such, findings are not intended to be statistically representative or generalisable across the wider public, for these reasons we do not use terms such as 'majority' or 'minority'

Reading this report

Those reading this report will find:

Chapter summaries: key messages

Are presented throughout the findings section of the report in text boxes with a coloured frame like this one. They highlight key points made on the topic being described in the chapter.

> *"**Quotes** set out like this. Quotes are used throughout the report to illustrate points, not replace narrative. These are provided verbatim in participants' own words, we remove filler words, but do not make changes to spelling or grammar so as not to distort the participants' meaning".*

We use the following language: we use the term 'embryo model' as shorthand for stem cell-based embryo model. We use the term 'human embryo' when discussing a human embryo created through direct bi-parental fertilisation involving eggs and sperm.

Section 2 Findings

- Embryo models: how participants understand and view them
- Research uses of embryo models: potential benefits and harms
- Governance of embryo model research
  - Voluntary vs legislative
  - Limits for research
  - Oversight Committee
- Responses to the draft Code of Practice graphic summary
- Engagement with and communication of stem cell-based embryo models

3. Embryo models: how participants understand and view them

What you will find in this chapter

In this chapter you will learn about participants' views on the status of embryo models and how different or similar participants feel they are to human embryos.

Over the course of the dialogue, many participants concluded that embryo models are distinctly different from human embryos, or different enough, that they do not pose the same moral concerns as human embryo research, because of:

- the difference in how embryo models are created (e.g. from stem cells rather than an egg and a sperm)
- the difference in how embryo models develop (e.g. skipping stages of development)
- the fact that they are created for human research rather than human reproductive purposes and cannot be implanted in a womb
- some models' incomplete structure (e.g. some but not all tissues/organs present)

However, some participants expressed concerns that embryo models have the potential to be like human embryos, particularly when they learnt about an embryo model that had formed what resembled a primitive streak. They also worry that it may be difficult to tell whether an embryo model is the same as a human embryo. For these reasons, they want to see a robust legislative ethical and regulatory framework.

A tension emerged between some participants being reassured from an ethical perspective that models are different from embryo models, whilst at the same time questioning whether they are similar enough to be useful for research. The reasons why embryo models raise fewer ethical concerns for some (e.g. skipping developmental stages, not being created from an egg and a sperm), are also the reasons why some participants are doubtful about the efficacy of medicines and treatments that result from the findings of research involving embryo models.

A few participants call for there to be ongoing attention paid to understanding how similar or different embryo models are becoming to real human embryos. They see this as important from both an ethical perspective (e.g. they should not feel pain, are they real humans?) and a practical perspective (e.g. the validity and usefulness of the research findings).

3.1 Perspectives on the status of embryo models

During the discussions, participants shared their perspectives on the status of embryo models, what they think and feel about them, and what they see as the differences and similarities between embryo models and human embryos.

As the dialogue progressed, most participants increasingly felt that embryo models, particularly those that are less complete, are different from human embryos, or different enough that they pose fewer ethical concerns than human embryo research. However, some participants expressed concerns that some embryo models, particularly those that are more complete in terms of tissues, organs and development, may acquire the potential to be like human embryos and should therefore be governed by a similar ethical and regulatory framework.

Figure 4 depicts the range of views that participants held towards the moral status of embryo models over the course of the dialogue.

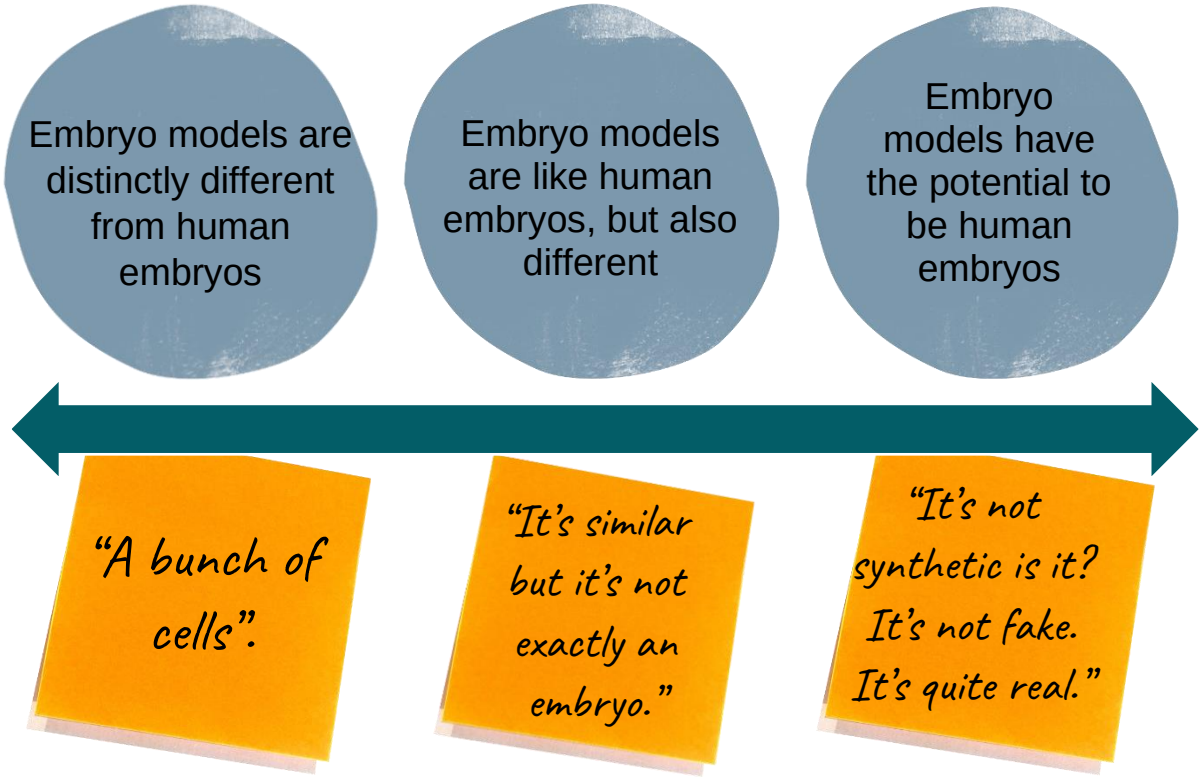


Figure 4: Range of views on moral status of embryo models

Embryo models are different from human embryos

Many participants see embryo models as being distinctly different from human embryos and therefore not human. Some participants see embryo models as "cells in a pot" that are created purely for scientific purposes and will never result in a human baby. For this reason, many participants have fewer concerns ethically about research involving embryo models than research involving human embryos.

Participants described embryo models as being "fake", or "not real", because they are not created or developed in the same way as human embryos.

> *"I don't think there is going to be the same ethical challenges of culture, because if I'm right, it's man-made, it's grown, it's not an embryo at all."*

Reflecting on what they had heard from the presenters during the public dialogue, participants highlighted what they see as important differences between how embryo models are created and develop and the development of human embryos.

Embryo model and human embryo differences

- Embryo models are created from stem cells.
- Embryo models are not created from the joining of gametes (sperm and egg) from two separate individuals, but rather can be derived from a single cellular source.
- Embryo models are created in a lab for research purposes not reproductive purposes.
- Some embryo models may skip developmental stages.
- Embryo models are used to study specific parts of embryo development and therefore may not model a complete embryo.
- Unlike embryo development in human pregnancy, embryo model development is shaped by external research factors (e.g. research objectives)'.

> *"They're grown in a lab, they're not going to be exactly the same as human embryos. It's a completely separate thing for me. It's just purely for research purposes, and science purposes. I don't associate that with a human, even though it might have human material in it."*

Because of these distinctions between embryo models and human embryos, some participants believe that embryo models wouldn't be able to progress to a fetus.

> *"... from what I understand is that it doesn't have the potential to develop into a fetus because it is being modified. First of all, it jumps several stages. It doesn't come from the union of a sperm and an egg. There are only parts. The research is modified that only some parts are accentuated in that sense and researched upon, so it would never really progress."*

Some participants discussed how they place greater emotional and moral importance on human embryos than on embryo models. One participant explained how they have a different emotional response to embryo models; they don't feel they need to protect the embryo model, whereas they had many more ethical concerns when participating in the previous dialogue about research involving human embryos. Some participants also argue that human embryos have souls unlike embryo models.

> *"Embryo has a soul. I see it very differently as to a ball of cells. I don't have the same feelings around them."*

When reaching the conclusion that embryo models do not have the potential to become indistinguishable from human embryos or feel pain, some participants argue

that research involving embryo models should progress with fewer restrictions than those placed on human embryos. Another reason that some participants are reassured about research involving embryo models is that UK law seeks to prohibit the transfer of an embryo model into a human's womb. They also note that gestation hasn't been successful, so far, in animal research involving embryo models.

Embryo models are similar but different from human embryos

When participants learnt more about embryo models and how they are created and developed, some continued to see the similarities with human embryos while at the same time feeling they are different enough for there to be fewer ethical concerns. They acknowledged that embryo models have been created from human cells but highlighted the technical differences between them and human embryos.

> *"I think even though they're made from actual human cells, there seems to be a lot of missed stages and it's embryo-like, it's not an embryo, it's similar but it's not exactly an embryo. I think that's reduced my concern about misuse."*

One participant highlighted the importance of having a precise understanding of how embryo models deviate from human embryos. They call for the HFEA to define this distinction.

> *"I think a key piece of understanding needed is the difference in performance of actual human embryos, and stem cell-based models. The models should be thoroughly used to more fully understand early embryonic processes, but a precise definition of where they deviate from actual embryos is essential. As I understand it the HFEA acts as a regulatory body in the area. it should be developing detailed protocols that define this distinction in research."*

Embryo models have the potential to be indistinguishable from human embryos

Some participants, when thinking about the status of embryo models, worry that they have the potential to become indistinguishable from human embryos. They are concerned about how difficult it will be to tell the difference between embryo models and human embryos.

> *"The process of the embryo developing looks incredibly similar to the point where people can't always tell the difference."*

Some participants became more concerned about the potential for embryo models to be like a human embryo when they heard a scientist talk about seeing a model that had developed a primitive streak. This made them see the model as more than a

"bunch of cells" and instead something that is "coming very close to a human embryo."

> *"When [scientist] said, "I had to look at it with a microscope, because the pictures were very small and I noticed a primitive streak on the embryo model." Now, I didn't expect to see a primitive streak on an embryo model. That sort of said to me, well, it would know what's up and down, if you get what I mean? It's not just a bunch of cells. It would know the makeup of the baby in effect. That's coming very close to a human embryo."*

A few participants feel there is uncertainty about how an embryo model will develop if it is allowed to extend beyond the equivalent of 14 days of development and the appearance of the primitive streak. They argue that it would be some kind of 'humanoid' and they worry whether it would feel pain.

When one participant realised that an embryo model is made from human material, it changed their perspective and they no longer saw it as a model.

> *"Embryo models that contain entirely or partly human material; I wasn't aware that an embryo model could contain human material... it changes everything to me. An embryo model entirely human is so not a model but an embryo; and using embryos (that are) partly human would be in my opinion inhuman because of copying endlessly."*

Another participant described human life as precious and argues that embryo models should be governed by a similar ethical and moral framework.

> *"I just think human life is precious. Even though these are models made of human entities, I still think that they really do need to be adhered to as ethically and morally as best as possible... It's just making sure that life and the precious status are there."*

Another participant posed the question: what life is and whose definition of life should be used when thinking about embryo models? From their perspective "a cell is a life in and of itself" and they want to see the definition expanded beyond human embryos, as they argue that "you wouldn't have an embryo without the cells".

3.2 Usefulness for research on human development

A tension emerged during the dialogue between participants feeling reassured from an ethical perspective that models are different from human embryos, whilst at the

same time questioning whether they are similar enough to human embryos to be useful in research on early human development.

> *"This seems a more ethical way of research, however how will it help disease identification as it's not a real embryo? Also, how can you trust any of the findings regarding implantation, as in essence it's a foreign body?"*

They question whether the results of research involving embryo models can give an accurate picture of how an embryo develops because of how they have been created (e.g. stem cells rather than a sperm and an egg) and how they develop (e.g. components missing and skipped developmental stages).

> *"If they're missing out vital components, vital parts of that process, how are they interpreting from the models what may happen in that human reproductive process? ... To me it doesn't sound like it could ever work in a way that's going to give a true understanding of the human reproductive process because you're thinking about two human beings, two individuals, the sperm and the egg."*

Some participants particularly struggle to see how research involving embryo models can shed light on fertility and IVF, given the differences.

Some assume that embryo models created from embryonic stem cells, because of their perceived closer link to an embryo, are likely to be more useful to fertility research than models developed from adult stem cells.

> *"If you're taking fetal cells, they're in that stage of development, and it will probably give more indicators as to why something is happening or not happening than adult cells."*

Participants question whether embryo model research that looks beyond the 14 day equivalent would be valid, given that human embryo research in the UK isn't currently permitted beyond this stage. They argue that it wouldn't be possible to assess how accurately the embryo model is replicating an actual human embryo after 14 days/appearance of the primitive streak.

> *"I realise, with last week it was not a definite time when those models are created so they can't exactly know when the 14 days goes over. Even if we did go over the 14 days, we wouldn't know whether that was right or if the model was replicated correctly or anything like that because we haven't moved past the 14 days for normal embryos."*

Some participants doubt they would have confidence in medicine or interventions that have been developed from research involving embryo models. They would want further evidence to give them confidence in their safety and efficacy.

> *"Would I use medicine that was tested on an embryo model? I'm not sure. I would need more evidence of its success as it's not been tested on a live embryo. More research on this would need to be done to persuade us to use the medicine and give confidence in its safety."*

Some participants emphasise the importance of monitoring via governance how closely models are matching a human embryo, in order for people to have confidence in the usefulness of the research.

> *"I think we need a clear focus on how close or how different the model is from a real human embryo, because the further away the model gets from how real human embryos actually are, the less valuable it might be... Some kind of attention to how the model matches the reality is a very important part of the governance that needs to be built in."*

Rather than questioning their usefulness, some participants are keen to understand how embryo models have already helped to research human development, incurable diseases, miscarriage or infertility and what applications models have been used for either in the UK or abroad.

4. Research uses of embryo models

What you can expect to find in this chapter

In this chapter we share what participants state are the harms and benefits of the use of stem cell-based embryo models for research.

Benefits – an exciting and amazing area of research

Participants welcome research innovation to:

- improve IVF success rates
- better understand the causes of miscarriage and reducing its occurrence
- understand and find new treatments for disease and genetic conditions
- study early human development and hope that embryo models could be used, where possible for research, rather than human embryos

Harms – stepping into the unknown without guardrails

Participants are worried about harms from:

- what is unknown and uncertain about future uses of stem cell-based embryo models
- a lack of clarity about potential outcomes and research ambitions which could lead to public mistrust
- research which over-reaches and over time goes beyond what society currently understands to be acceptable
- commercial interests being prioritised
- misuse of the embryo model and the research data

4.1 Potential benefits

The "exciting" potential of embryo model research

For many participants involved in the dialogue the benefits of the research and its future potential outweigh any concerns they have. The words 'exciting' and 'amazing' were used often in Recollective, on Menti and in workshop discussions to describe participants' feelings towards the research and its potential to bring significant societal benefits.

Addressing issues such as low IVF success rates, and recurrent miscarriage as well as improving health outcomes, exploring treatments and cures for heritable diseases are all seen as part of this exciting and amazing future.

> *"How amazing this science is, how fast things are progressing. I remember when the first IVF baby was born. Just think how fast things are progressing. It's about my children's future, and my grandchildren. It's just mind-blowing really."*

The fact that such research developments are happening now, in the lifetime of participants is seen as genuinely thrilling. A step forward in scientific discovery and technology that should be celebrated.

> *"I want to say I'm very excited about this. I want to actually see some development and breakthroughs. It's an exciting time, and it is happening in my lifetime."*

We saw in the previous chapter that some participants raised concerns about what we do not know yet about the future of this research and what it might result in. However, participants equally see that this unknown potential could bring great benefits for society, even if we are not sure precisely what all those benefits will be in the future.

> *"It really makes you wonder about what is next. And from my point of view in a totally positive way. This is a step towards "The future is now." What is going to come out of this research? Who knows! Will the people in the future come to rely on it? Probably!"*

For these participants the potential benefits, such as understanding human development and the origins of conditions such as childhood cancers, outweigh any further potential harms.

> *"The benefits I think outweigh the harms. That's what we've got to look at because there's a potential for greater human development and for our future, like the childhood cancers, so much can be discovered. It's a good time now because the technology is there now. There are further advancements in the future too."*

Benefits articulated by participants include:

- enabling fundamental and blue sky research
- exploring what is possible to improve health and reproductive outcomes
- going further into ensuring that innovation in research is not stifled and to enable further benefits to be identified in the future

Improving IVF success, understanding and preventing miscarriage

Research involving embryo models is seen by participants to have important benefits for understanding human reproduction and development. Across the workshops this was raised as a significant benefit that participants feel should be more widely understood across society. Participants welcome the possibilities for this research in:

- improving understanding of human reproductive and early developmental processes
- improving IVF success rates
- reducing the number of miscarriages
- unlocking the so called 'black box'[16] period of embryo development, which cannot currently be studied in the lab using human embryos, to understand why embryo implantation fails
- enabling people who would have previously been unable to conceive to have children
- giving answers to people who have had problems with fertility.

> *"We can (use this research) to unlock the mysteries around implantation failure and prevent heartache to millions of wannabe parents."*

For some participants improving IVF success rates is the most significant benefit that they see for the research.

> *"I think the potential benefit is more towards the IVF because the current IVF success rate is not too much. If we can know more about the embryo model, it can make the success rate go a lot higher and help a lot of people."*

Understanding and preventing disease and genetic conditions

For many participants using the research to develop our understanding of diseases and their causes is of great importance and an area of research with significant potential. A hope is expressed that the research can help improve understanding of genetic conditions which predominate in certain ethnic groups. They hope this will counter issues in research where not enough samples come from minoritised ethnic communities and there is insufficient research done to develop treatments and address these conditions.

> *"I hope there will be more knowledge in regard to ethnicity. Could this widen the research into certain diseases that only affect certain communities?"*

Using embryo models to replace human embryos for research

Using embryo models in research is seen by many participants as more acceptable than using human embryos. Some relate this to their own principles and values, whilst others apply this thinking to what they perceive others in society will find more acceptable.

[16] https://www.scientificamerican.com/article/new-human-embryo-models-spark-needless-controversy/

> *"I think using models will come across as more palatable for anyone who has a moral stance on embryo development."*

They describe the embryo models as 'valuable' in this regard. Seeing them as a more appropriate means of uncovering the mysteries of human reproduction and the early development of diseases in embryos than using actual human embryos – because they are models, not embryos.

> *"There's a huge sensitivity about experimenting on actual embryos, understandable sensitivity. If the model can give us a lot more information and a lot more knowledge about what's going on, that's thoroughly valuable."*

The potential for embryo models to enable the fundamental exploration of human development without using a human embryo is seen as a significant benefit for many. These participants proposed that using an embryo model gives researchers the freedom to develop their knowledge and improve scientific understanding of the current key challenges in embryo development.

> *"This gives researchers the freedom to acquire a huge amount more knowledge about how the whole mechanism works. I'm very much in favour of expansion of the use of models for that purpose, to give them that freedom."*

Another benefit mentioned by some participants is that human embryos are a scarce resource in research, whereas embryo models can be developed at scale. The potential for embryo models to enable more research in this area to be conducted is welcomed by participants.

4.2 Potential harms

Concern for future unknowns and research over-reach

A recognition amongst participants that research involving embryo models is relatively new, and is moving at pace, gives rise to concerns that the full scale of possibilities from the research is not yet understood. They want to ensure that there is monitoring of these future possibilities.

> *"This is still very, very new science, very new technology. There are people thinking about ideas that could be very, very upsetting and very socially dangerous as part of the progress of this. I think that we need to watch the future."*

This is linked to a concern that if society does not know enough about where this research could lead, and no boundaries are set around what is possible, anything could happen. A few participants expressed concern that the exciting nature of the research, and its potential for good, could lead some researchers to over-reach their

public good remit and go too far. This could be in allowing the models to develop into a potential life, or other areas which are not yet known by scientists. This links to a potential harm raised by a few participants as a result of the science and technology developing at such a pace that the Code of Practice, and any subsequent legislation cannot keep up with the speed of development, giving a window for wrongdoing.

Participants want to know that researchers are clear about why they are doing their research, that they have agreement on what their objectives are and what they expect the outcomes to be.

> *"There is a concern that if we don't know what researchers want from doing this research anything is possible. We don't know what the end game is."*

In Recollective and in the workshop discussions participants sometimes drew on dystopian visions of the future and science fiction to describe potential future uses for embryo models which raise concern. These include:

- the modification of how human embryos develop, fundamentally altering what a human is
- creating spare body parts from clones
- research which leads to 'perfect' humans with genetic conditions eradicated

For some participants this kind of research might over time change society's understanding of what it means to be human. They are also concerned that as the science develops it could normalise or enable unacceptable ideas including eugenics.

> *"When you are actually talking about human life and stuff like that, eugenics and all of those kinds of things, people have got crazy ideas and they'll use those crazy ideas to propagate ideas and beliefs about what a human is and what that's supposed to be."*

Red lines emerged for participants during these discussions. Many made it clear that research used to identify an ideal in human development should be prohibited. They use the terms 'eugenics', 'cloning' and 'designer babies' in this context:

> *"Eugenics and designer babies. Where people are using this new technology to create designer babies, the perfect human is worrying for society."*

Many participants are pleased to see that the draft Code of Practice prohibits the transfer of an embryo model to a human womb. This gives them reassurance on an issue that some believe is of grave concern, with potential for babies to be born which have not developed from a human sperm and egg.

> *"When it comes to implanting these into humans then I think that would be dangerous and unethical."*

Participants want to ensure that there are boundaries in place around what is and what is not acceptable. Such concerns justify a belief widely held in the dialogue that there is a need for some form of regulation. According to many participants the research is only a concern if it is given free rein without such a regulatory framework.

> *"Embryo models must be highly regulated, or we could be producing alien beings. This is concerning."*

Commercial interests

Some participants assume that the research will inevitably, over time, involve those with commercial as well as public sector interests. This gives rise, in their view, to a potential harm from a profit motive. They see a risk in commercial interests, for example private clinics offering enhanced IVF techniques developed through research involving embryo models for a higher fee, private medical practices treating cancer, or private research laboratories dominating the research agenda because they have the funds. They see this as potentially undermining a public sector research ethos focused on addressing key issues for all society by making the discoveries from research involving embryo models available only to those who can afford them.

> *"Make sure this doesn't go crazy and people don't lose their minds just for the benefit of profits for laboratory use. In the end it is the pharmaceutical industry who are going to rule the money, and also the support for everything. They're going to have profits and benefits from this, but make sure that things don't get out of control."*

A few participants voiced the concern that a market might open up for the sale of either stem cells for the purpose of making embryo models, or a market for the models themselves at various stages of development.

> *"If these stem cells get in the wrong hands there'll be a private market where if you've got enough money you can commission a lab to create designer babies or even a clone. It's all possible if you think about it if it's unregulated."*

A very few participants also expressed a concern that only rich nations will be able to conduct and benefit from the research, further exacerbating global inequalities.

> *"It's like science is trying to usurp natural functions of nature for money. This really only benefits a minority of the world population."*

A misuse of the models and research data

Misuse of embryo models was a concern voiced frequently and a term used when participants described their concerns about the research being used for profit rather

than public benefit. They also used it when describing 'rogue' elements. By this they meant researchers who try to use embryo models for unacceptable purposes, such as creating a baby, or others using legitimate research data for potentially harmful reasons. Some participants do not see this as a far-fetched proposition. These participants remember reading about the He Jiankui scandal in the early human embryo research public dialogue and apply that example as a possibility for embryo models.[17]

> *"The harm that comes to mind is just misuse, which is, it could be a rogue (scientist), someone who's got the knowledge, like the scientist in China, tries to go forward with it, tries to create life, tries to play God."*

Creating a baby from embryo models, if not possible now, is seen as a future risk in the development of this research area. Some cite this as the reason they find the research potentially 'scary', because of a future potential to create life.

> *"The fact that stem cell models could potentially be used to create a baby whether animal or human scares me. The potential for using the models for all the wrong reasons springs to mind."*

There is also a concern for some that even if the research is well-regulated there are those that will work outside the framework, as He Jiankui did.

> *"There's always going to be someone who goes a bit further. Something like, I don't know, create life. It is possible that something happens and you actually end up with a baby. And that's not desirable at all."*

An interesting dilemma arises for some participants who at the same time as believing that research involving embryo models goes against their principles of faith, or their understanding of order in the world, they nevertheless think the research is worthwhile.

> *"All very interesting stuff and food for thought. I will admit I find the subject difficult to align with my own personal views on 'life' etc., but nevertheless I do respect this work is being undertaken."*

Some participants suggest that the mooted benefits of embryo model research, such as improving IVF techniques, are a 'trojan horse' for expanding embryo model research in ways that could be unacceptable to society. They worry that the shorter term benefits of better IVF treatments may be a distraction from bigger, longer term threats to humankind.

[17] Scientists who edited babies' genes says he acted 'too quickly' The Guardian, 4 Feb, 2023. This article was shared with participants during the previous dialogue on early human embryo research.

> *"I see tons of mentions of IVF and I feel a lot of the responses towards pushing forward with testing and based on personal experiences rather than the bigger picture for humanity. This worries me as we cannot allow one potential outcome of testing to outweigh any other and IVF is the part that worries me most about people crossing the line."*

The closer the resemblance to a human embryo – the greater the concern

The closer the models come to mirroring a human embryo, the more concerns are raised by participants. Some participants believe that closeness to a human embryo makes it more likely that models could, in the future, be used to create a living baby. As such they believe that greater caution should be exercised with research involving more sophisticated embryo models. They fear that researchers will become accustomed to extending their research and would no longer be able to critically evaluate the potential harms.

> *"Once you start getting down to the realms of absolutely resembling something that could carry on under its own steam, I think that's a serious red line for me. Before we know it, you've got, not Dolly the sheep, but Dolly the daughter."*

5. Governance of embryo model research

What you can expect to find in this chapter

In the previous chapters we have seen what participants think about the status of embryo models and how they are involved in research. In this chapter we explore what participants think about the form of governance for research involving embryo models.

The starting point is what participants think about the current 'governance gap'. For them, this is a surprise. Participants believe that because the research involves 'human cells' and because of the wide range of types of models and their uses, governance is vital.

Participants have clear expectations for the role they think governance should play. This includes encouraging beneficial and hindering harmful research, giving clear guidelines for scientists and anticipating the future direction of research.

Voluntary or legislative approaches are explored for their pros and cons. Voluntary measures are seen as swifter and more flexible, but potentially lacking teeth. Legislation is largely seen as inevitable and necessary in the medium to long term but raises questions about how it can avoid impeding research discoveries by being too inflexible.

Many participants see a voluntary code of practice as a short-term stepping stone to legislation in the medium to long term.

Participants spoke frequently about the importance of governance that is regularly reviewed to ensure it keeps pace with science, learns from its developments and what society wants from these.

Governance needs to factor in who is involved in embryo model research and participants believe that commercial organisations will soon be working in this field extensively. They want this to factor into the design of governance.

A topic of strong interest for participants is time/developmental limits on embryo model research. Most participants believe such limits are necessary for several reasons, including: to ensure no harm is done to embryo models which develop some form of sentience; and to ensure that models are only used for research and not for reproduction. There was a great deal of discussion, but no consensus, about whether there should be a single time/developmental limit for all types of embryo models (more and less complete) or if time/developmental limits should be case-by-case or stratified.

Participants hope that an Oversight Committee will review embryo model research and be the eyes and ears of the Code of Practice. They would like a broad range of perspectives to work on this committee: scientists, legal experts, ethicists, clinicians, people with lived experience of health conditions and members of the public, including young people. As well as reviewing the science, they have hopes that more effort will be made to make the science better known to the wider public.

5.1 Views on the current situation: surprise at lack of governance

Participants were very surprised and concerned when they heard that in the UK there are no laws and regulations governing embryo model research specifically, aside from the stipulation in the Human Fertilisation and Embryology Act 1990 (as amended)[18] that 'No person shall place in a woman... an embryo other than a permitted embryo'.

Some participants said that because embryo models are created using human materials, they would have expected there to be more regulation around them.

> *"What's really surprised me is the guidance and the regulations differ quite significantly between embryos and embryo model. I thought there was more regulation around the models too, just because purely it still comes from human."*

Participants were relieved to hear that the current convention among many scientists conducting research with embryo models is to be guided by the 14 day/primitive streak limit that exists for human embryo research in the UK.

> *"I'm also a bit shocked that there are no laws. Well, I knew there were no laws, but I never thought there is nothing in place. I'm very happy to hear that a lot of scientists still use and abide by the laws for the human embryos."*

Several participants are supportive of research on embryo models not being conducted beyond a '14 day rule' equivalent until guidance and regulation are in place.

Some worry that a lack of a governance of embryo models means that it will not be known if there are scientists who are already 'going too far' and experimenting on embryo models over too long a timeframe.

> *"I have a concern. It doesn't seem to be any laws or regulations in place at the moment with regards to the embryo models, how long they can do tests and experiments on them. How do we know that some scientists aren't going to take it too far?"*

Many participants are reassured to hear that a code of practice is under development and consider that will help ensure that research involving embryo models is ethical.

[18] https://www.legislation.gov.uk/ukpga/1990/37/section/3

"It is quite reassuring to hear that there are protocols being put in place to ensure ethical side of the embryo [model] research is protected."

5.2 Why have governance of embryo model research?

As described above, the current situation of a 'governance gap' for research involving embryo models is not acceptable to many participants. Before exploring views on the type of governance participants favour and the reasons why, we look at the expectations participants have for what governance should aim to do. These expectations are wide ranging:

Benefits and harms to society

- Encouraging research that benefits society.
- Reducing the likelihood of research that is harmful to society.
- Recognising that this research is important and has practical application for human beings.

How scientists work

- Encouraging responsible and ethical conduct by scientists.
- Giving scientists clear guidance on what they can and can't do.
- Creating consistency through standards for research that can be applied not just in the UK but in other countries where embryo model research is taking place.
- Ensuring that science is not working in its own "little bubble".
- Encouraging scientific collaboration and avoiding duplication of research activity.
- Preventing abuse of power and information.

Future focused

- Keeping up with the fast-moving nature of this area of science.
- Striking the right balance between enabling scientific progress and accounting for the fact that "we don't know what they (embryo models) could develop into potentially".
- Based on a strong foundation that has looked at the different directions that embryo model research could go in.
- Recognising that commercial applications are inevitable and ensuring they are guided by public benefit and acceptability.

5.3 What is an appropriate model of governance for embryo model research?

The question of how embryo model research should be governed was explored throughout the dialogue process. Many participants see a voluntary code of practice as a short-term stepping stone to legislation in the medium to long-term. However, the terms 'voluntary' and 'legislative' are problematic for many participants. In the early stages of the dialogue process governance that is 'voluntary' was seen by some as too loose and 'lacking teeth'. As will be seen, participant thinking on this evolved when the draft Code of Practice was shared before the final workshop and

they saw the consequences that researchers could face if they did not follow the Code (e.g. not receiving funding, not being employed by a university or not having their research published). Some feel these would be highly likely to influence scientists to work within the guidelines, without being enshrined in law.

A legislative approach, whilst seen as desirable by many participants in the medium to long term for reasons outlined below, is seen in the short term as problematic for being too inflexible and too time consuming to implement. Laws could be outdated by the time they are enacted. There are hopes that future regulation could be designed to be flexible and updated frequently.

5.4 Reasons for favouring a non-legislative approach to governance: timing, flexibility and encouraging collaboration

Some participants believe that embryo models are too new, and it is too early in the life of this scientific field to legislate effectively now.

Hope for what scientific discovery could tell us is a key consideration for several participants. They believe that a voluntary model of governance at this point would be more flexible and responsive to new scientific developments and so would do a better job of advancing rather than stifling discoveries.

> *"Please do not make the research guidelines too restrictive as this will impact a blue skies approach."*

The likelihood of a long legislative lead time concerns some participants. They worry that embryo model research and potential scientific discoveries could be held back if this field of science has to wait for legislation to be drawn up and introduced.

> *"It's quite groundbreaking science and we want to be cracking on with what we're able to. If it did go through to a law, how long could that take? Will it delay things even more?"*

Another reason for preferring guidelines at this point is wanting to see a collaborative approach that could encourage open relationships with and between scientists. Rather than forcing scientists to comply with reporting requirements and information disclosure through legislation, working to a set of commonly agreed standards could foster sharing, collaboration and openness.

When thinking about approaches to governance, some participants draw a comparison with what is in place for human embryos. Many participants see embryo models as different from human embryos and in need of less strict governance.

> *"It seems to me that one of the objectives of models is to open up the scope of gaining more knowledge and understanding, but I didn't want it to have the same limits as real human embryos, because I think there's less need for control if it is a model and it's not an actual embryo."*

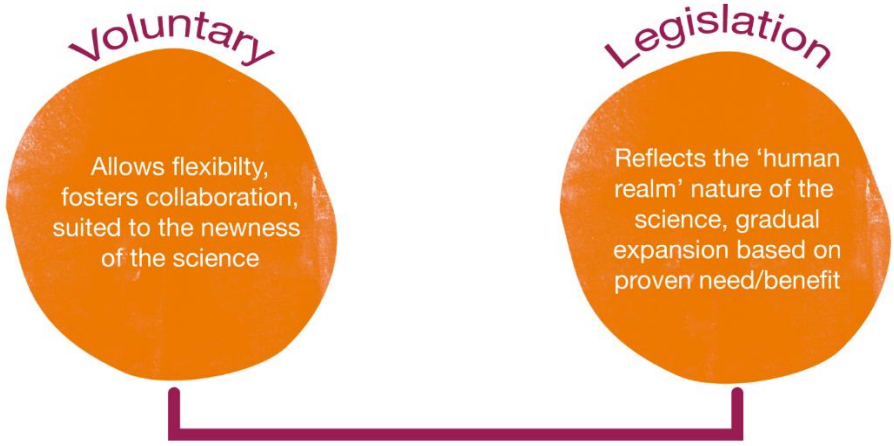
5.5 Reasons for a legislative approach to governance: an important scientific field in "the human realm"

Governance similar to what is in place for human embryo research, but 'more flexible' was suggested by some participants. This view was influenced by seeing embryo model research as being in "the human realm" and having important implications for human beings. Therefore, the governance of embryo model research is too important and high stakes to be left to a voluntary model.

For these participants, addressing embryo models in legislation is a clear statement of what society expects and the importance it places on this field of science. The 'more flexible' qualifier was informed by the participants' understanding of the legislation of early human embryo research and that the 14 day rule has remained unchanged for more than three decades. The more complex and fast-moving nature of embryo model research led to many participants calling for governance – be it voluntary or legislative – to have regular reviews and mechanisms for revision designed in.

> "One of the important things we need to build into this whole governance thing is a periodic review time so that it's not just set the rules and they're there but that the rules need checking and checking and checking because the science is developing so rapidly."

A few participants want to see governance take a 'start strict and gradually relax when there is proven need or benefit' approach. They want embryo model research to be closely monitored and controlled and only expand its remit when there are clear needs or potential benefits. These participants are concerned about a 'free-for-all' situation in which scientists lack ethical guidance and legislated boundaries that make it clear where they can and can't work. Some also feel that the fast-moving nature of the science is not a reason to shy away from legislation, but a reason for closer control of what should and should not be permitted in research.



5.6 How to strike the right balance between freedom to discover and regulatory restrictions

Getting the balance right between enabling scientific progress and guarding against causing societal harm is an important feature of a governance system for many participants.

> "One of my concerns, that would be there are too many rules and regulations that it just wouldn't end up providing any decent or scientific results from it if they get too tight on the regulations. At the same time, there needs to be, I'm contradicting myself, some sort of regulation in there. I don't want to go too extreme."

Some participants' caution about embryo model research is rooted in uncertainty. What could this research lead to in the future? What could the models become? How could they be used? How might this change the beginnings of human life and development in the future?

> "I think it is real, it's human tissue. I think we've heard about we don't know the potential for what these models can do, what they can develop into potentially. I think that's why I use the words caution and I think that's why I feel I'm excited by it. I think we need to press forward. I think we need to be considered with that and informed."

Some participants fear a governance model that requires scientists to work to tightly defined questions and does not permit them to stray beyond these may lead to missed opportunities or discoveries.

> "In terms of the research, and the research goals and the research question. I think that sometimes it can be restrictive to have a very narrow and focused question...Sometimes science can be quite serendipitous in the results that it finds so research, the questions shouldn't necessarily be so restrictive."

For many participants a way of achieving a balance of scientific progress that fits with society's hopes and expectations is to have a governance system that has built in regular reviews. The review process would need to be reflective and responsive and not lead to a 'stop-start' approach that brings research to a juddering halt.

> "Having an easy process of making the changes to the Code of Practice. They shouldn't be waiting until there's a large group of scientists raising the same issue about the change that should be made. They should view the changes that should be made if there's

one or two scientists that might have raised that, or if there's a public concern as well."

5.6 Who's involved in this research

During the dialogue participants asked questions about the types of organisations involved in embryo model research and where this research is taking place. Participants were told that most of the research is currently taking place in universities and institutes in the UK, United States, continental Europe and Israel.

In general, participants feel that scientists working in universities and institutes are trustworthy. They are seen to be more publicly accountable and more likely to be at least partly public or third sector funded. However, some participants think that there will be, as in many sectors of society, rogue operators who would reject any limitations on their work. They think that these individuals would ignore any governance, whether it be guidance or legislation.

"I expect (research) to be regulated, but there's always going to be somebody who disregards that regulation. Even if it's very heavily regulated, there's always the chance that someone would go rogue with it."

Commercial involvement in embryo model research is expected by many participants to be just a matter of time. Many believe that it is important that a governance system takes account of this. Concerns among some participants about the implications of commercial involvement include:

- could pharmaceutical companies try to influence what research is done to protect their products, for example, discouraging or suppressing research that might lead to reduced demand for a drug or therapy?
- could companies use embryo models in research in ways that don't follow ethical guidelines and create high-cost health treatments only available to people with the ability to pay for them?
- could commercial organisations use embryo model research, if it lacks regulation, to progress science in directions that many participants believe are unethical, such as human cloning and 'designer babies'?

When discussing the possible consequences for not following the proposed Code of Practice, some participants raised concerns that those listed in the graphic summary would not be disincentives for commercial organisations. They said that not being funded, not being employed by universities and not being published were either irrelevant or would be disregarded if a profitable outcome of embryo model research was in prospect.

"We've talked a lot about universities like governmental institutions. What if somebody comes up with an (Elon) Musk-type thing with loads of money, how are we going to deal with that? Are we going to control that?"

The global nature of research is significant for some participants. If there are countries with less regulation of scientific research, a few participants think that scientists would be drawn to work there and lead to a reduction of the talent pool in the UK.

> *"Not only collaborating on the science but also collaborating on the governance and regulation because if you have some countries that are more liberal with what they allow and some are more strict, then you'll just get a tidal flow of scientists in the wrong direction."*

Some participants hope to see Cambridge Reproduction involve the international scientific community in the drafting of the Code of Practice and that when published it would exert influence or be adopted across the world.

> *"I would like to think that the international community would comment and would give good feedback on this code of conduct, but also they could then use this code of conduct once it's been developed and copy and paste it across the world so that you have an international standard of research."*

5.7 Time or developmental limits and restrictions for embryo model research

Almost all participants believe that it is very important that embryo model research has some restrictions on what it does and limits that make clear when research must stop. However, in comparison to other discussions where there was a great deal of confidence and certainty, such as on the involvement of the public in oversight, discussions on limits were often caveated with 'I'm not sure, I don't know, I'm not an expert'.

> *"I think there needs to be a debate as to how long. I'm not sure. It needs to be looked into and the various factors involved in terms of when the spinal cord and nervous system process, all of that, the consideration needs to take into place."*

This uncertainty comes from:

- knowing that there are many different types of embryo models that develop in different ways
- the ethical tension between progressing research that could be beneficial to humankind, and protecting an embryo model if it could potentially develop into a human being

Several forms of limits and restrictions were discussed during the dialogue:

- limits based on the nature of the research (case-by-case basis)
- limits for duration of culture, comparable with those applied to human embryos (e.g. 14 days/primitive streak)

- the restrictions concerning how embryo models are used in research (e.g. not transferring to a woman's womb)
- the physical characteristics of the models
- different limits for complete and less complete/partial embryo models

Discussions on limits emphasise the importance of giving clarity to scientists about when they must stop their research. Several participants believe that the current lack of guidance on limits is probably hampering research.

> *"Guidance needs to be clearer to progress research. I understand there needs to be acceptable limits in terms of how far research is allowed to go."*

The human aspect of some embryo model research makes it distinct from other technological developments. Time or developmental limits are often seen as essential protection for the future of the concept of 'human life'.

In small group discussions in workshop 2, participants discussed a range of scenarios on how embryo model research should be governed in the future:

- No limits or governance
- Case-by-case review
- Same as human embryos e.g. 14 day rule, each embryo approved
- Complete ban
- Not sure

Limits based on the nature of the research: case-by-case

Several participants see merit in a case-by-case approach for governance. They see merit because: this is a new field of research, there are many types of models that develop in ways different from human embryos and there are many avenues that research could explore, some of which could be ethically questionable. There is also the sense that it strikes the right balance between managing ethical concerns but not hindering research progress.

A case-by-case approach for some participants has the benefit of scrutinising the research that is taking place in a systematic way and therefore increasing knowledge of how the research is taking place and what it hopes to achieve. Case-by-case also gives the option of approving some research and perhaps refusing or restricting other studies, based on the outcomes they hope to achieve. A groundbreaking new drug treatment was offered as an example of an outcome that needed a flexible approach to ensure the opportunity wasn't delayed or denied.

> *"When you have a case-by-case basis, then you are looking at everything. You're not imposing a blanket ban, neither are you going*

> *fast and loose with the governance. You'd have the flexibility, you'd have best of both worlds."*

The wide range of 'types' of embryo models is suited to a case-by-case governance approach in the minds of some participants. The difficulty of applying limits of days, such as the 14 day rule for human embryos is a factor in their thinking here, as is the uncertainty around how embryo models actually develop, in different ways to human embryos.

> *"I think it has to be case-by-case because they're all going to develop at different stages and you can't really just put an exact number on that."*

That this is a relatively new field of science is a reason for some participants to favour a case-by-case style of governance. They believe it will help to spotlight how the science is evolving and what learning is emerging.

> *"I think that a case-by-case review is important because we still don't know what's going to happen after the 14 days of that stem cell, is it going to develop differently? What kind of changes? Then if each one is looked at, then those findings can be recorded, and then progression made on that."*

In contrast, some participants lean away from a case-by-case approach to governance as they feel it could be too bureaucratic and delay research and scientific breakthroughs.

> *"There's a point where we don't hold it back because there needs to be a balance between research progressing, but also governance and not taking up too much time to continuously be asking for permission."*

Governance that is similar to that for human embryo research

Participants in this dialogue are familiar with the regulations surrounding human embryo research, given their involvement in the public dialogue on early human embryo research in the summer of 2023. For many participants in that dialogue, the regulation of early human embryo research is robust and trustworthy because of its mechanisms for oversight, monitoring and clear limits. Favouring governance of embryo model research that is similar to that for human embryo research is not necessarily linked to the 14 day rule. Rather it stems from respect for the structures, expertise and oversight that is in place to regulate this field of research. Some see the human embryo research system of governance as a good 'benchmark' from which to start. A few participants believe the same sort of expertise and approach may be needed for the governance of embryo model research as for human embryo research.

> *"I do think there has to be control over both the human embryo and the embryo model and I think it should be joined together so that they are running under similar governance. I don't mean that the embryo model needs to be under as strict governance as the human embryo, but I think it would be safer if you like under the same umbrella."*

Another reason for supporting a governance approach that is similar to human embryo research is that some participants believe that as research into embryo models develops in the future, the models may become increasingly similar to human embryos and therefore may merit being regulated in the same way. Chapter 3 included the expectation from some participants that the HFEA have a role in defining how different or similar embryo models are to human embryos. This extends to expectations for governance.

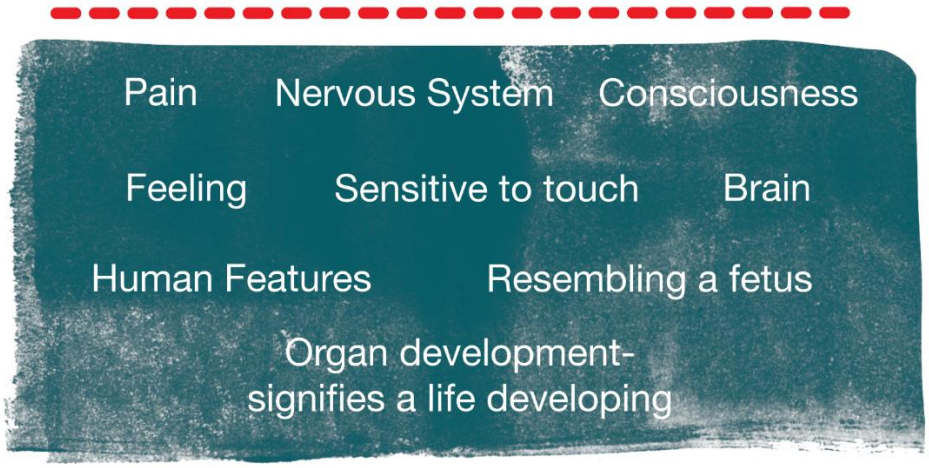
> *"I would like to see regulation in line with human embryo research because as time goes by, I think the lines of the scenarios will get blurred and potentially in the future we won't be able to tell the difference between human or embryo models."*

Limits for embryo model research based on developmental milestones: pain and appearance matter

The different ways in which embryo models develop, compared to human embryo development, is a cause of concern and anxiety when discussing milestones for when research should stop. The concept of embryo models 'jumping' to different stages of development prompts questions from many participants about how can we know if they feel pain or have some form of consciousness/sensitivity?

> *"I think it's just the uncertainty. The fact it can jump or we're not sure how many days after, I'm not sure how happy I feel once it develops organs or the heartbeat, et cetera. Because we're not sure how many days before that starts, so I think that's where the uncertainty is for me."*

The milestones and features that participants emphasise as being a definite limit for research are:



"I imagine all of us have a horror of one of these models developing some nervous system or awareness and therefore the possibility of experiencing pain. That must give us the real shudders of saying, "Oh, no, stop, stop, stop, gone much too far."

A video used in the dialogue showed embryo models pulsating. Several participants found this sobering to watch. It shifted their view of models as a passive 'bunch of cells' to something with the potential for life.

"I think, even though it's fascinating, like seeing cells having a pulse, it makes me feel a little bit uneasy that there's testing being done on these cells that they look like they have a pulse. I don't know why, it just makes me feel a bit uneasy. Also with the brain cells, could they potentially feel pain? I don't know."

So whilst many participants see embryo models as being different from human embryos, they talk about many of the same physical milestone limits for both fields of research.

Equivalent day limits 14, 20, 28 etc. days

During the dialogue process, participants heard about how embryo models differ from human embryos in both the way they are created and how they develop. That some models can 'skip' some stages and jump to later stages, such as post-implantation models that 'skip all the earliest stages and jump straight to post-implantation stages' and post-gastrulation models that 'jump straight to post-gastrulation (day 14+) stages'[19].

However, the 14 day/primitive streak rule for early human embryo research was an important milestone for many participants. They believe that embryo model research should be allowed to work beyond that equivalent limit[20] to enable scientific

[19] Workshop 1 Presentation, Dr Naomi Moris, Francis Crick Institute: Case studies and current uses of embryo models
[20] For instance, limiting research to a stage of development that looks like a 14 day embryo.

breakthroughs in IVF treatment, understanding miscarriage and diagnosing, preventing and treating genetic and congenital diseases. This view is also based on seeing the embryo models as not human, more akin to a 'bunch of cells', as described in chapter 3. It is also based on the view that embryo models cannot and will not implant and develop beyond this early state.

> "Thinking about how similar the embryo stem cell model is to an actual embryo and actually thinking about the potential for life. The stem cell-based model at the moment doesn't really have the potential to be a real human because they're having issues with implantation, et cetera. That's one of the things for me, which I think that it's actually perfect for research, as it shouldn't be limited to 14 days."

Some participants do feel strongly that 'older', more developed and more complete embryos that have a greater likelihood of becoming a human life should be subject to tighter governance.

> "There still should be governance but at different levels. The older it gets, the more stringent the requirement is."

In discussions that echoed conversations in the early human embryo research dialogue, participants spoke about extending a time limit on embryo model research incrementally, in stages based on potential for breakthroughs and discoveries. Some participants also think that the staged approach should not only be based on the developmental stage, but also on the type of research being conducted.

> "If extended to 28 days it should not be a licence to do everything. I think it should be step-by-step, instead of just making the law of 28. I think it should be a proposal, but actually build it progressively, because different laboratories are also going to do different types of research. Some IVF, some other things, so I think these governance people would be invigilating and looking after what is actually happening and how far people are going."

Participants also drew on their knowledge of the 14-28 day 'black box' in early human embryo research (where little is known about human development because of the 14 day rule at one end and the availability of material from abortions post 28 days). This feels to several participants as a relevant and logical time period for embryo model research to help unlock and understand.

> "I feel like extending it to where the black box ends will be more beneficial. I'm not sure, as I understand the embryo wouldn't have feelings, hearts, or anything like human embryos do, but still it can help more in the long-term run."

One participant referred to the time limit for abortions as a potential comparison point for establishing a time limit for embryo model research.

> "To go beyond where we are today, we need to go beyond the time limit as well. If you look at the abortion law in the UK, there is a set time limit to do an abortion. I think as far as I know, you can go up to the four month and sometimes five months. When you can go up to that limit to have an abortion, then why not? You can go over the 14 days rule. Okay, not over the three months."

Transfer of embryo models into a human womb is a red line for many, but not all participants

Many participants feel reassured that UK legislation seeks to prohibit embryo models from being transferred to a human womb. This is an important existing legislative barrier that gives participants confidence that embryo models are entities for research and not destined for reproduction. However, a small number of participants think this should be a red line for now, but one that should also be reviewed in the future, because transferring models into a womb could lead to discoveries that benefit IVF or the ability to cure diseases.

> "If there's going to be potential for those experiments to be done ethically and implantation, for example, I don't know under what circumstances could be useful, then maybe that's something that needs review. I'm not saying it should happen, but I'm saying it needs to be reviewed."

No limits because embryo models are not human

As noted in Chapter 3, a very few participants said that they do not think there should be any time or transfer limits on embryo model research. This is because they do not see them as human in any way and because they think limits will stymie research progress and be a barrier to discoveries that will benefit many.

> "Maybe there shouldn't be any restrictions because it's never going to make a human, it's never going to have feelings or feel pain. It's just made me think, you're right actually. If it's never going to be like a baby, then, go for it. No limitations, go wild."

5.8 Types of models and completeness and how this should be factored into governance

There are several ways of categorising different types of embryo models which were discussed during the dialogue process for their implications on the governance of research. These were either prompted or emerged organically. They include:

- what the embryo models are made of:
    - induced pluripotent stem cells: e.g. from reprogrammed adult skin cells
    - embryonic stem cells: from embryos donated to or created for research

- how ‘complete’ the embryo model is, also described as ‘integrated’ and ‘non-integrated’:
    - participants largely characterised this in their minds as being how similar a model was to a complete embryo – with potential to become a fetus or whether it would acquire specific organs or processes e.g. a spine or blood system

- how ‘developed’ the embryo model is – similar to how ‘complete’ – but also includes temporal considerations such as developments in physical appearance, viability and sensations such as feeling pain

- what research the embryo model will be used for: e.g. IVF, understanding human development or investigating genetic conditions

Participants had many questions around why embryo models are created using different sources of stem cells. They wondered if embryonic stem cells created different models or different research outcomes than induced pluripotent stem cells. Several feel more accepting of models created from induced pluripotent cells, for example from adult skin cells, because they feel embryos are a precious resource that merit a high degree of protection. This concern about the original source material did not clearly translate into calls for different governance – but it was a grey area that participants felt uncertain about and wanted more information to guide their views on implications for governance.

> *“If it’s using your skin cells, hair cells, those kind of things to induce the embryo model, that makes it a bit less concerning to use, or it’s all easier to think of that more as a thing than it’s not harming any human cells, if that makes sense.”*

Some participants said it made no difference to them what human materials embryo models are made of. What mattered to them was what the models would become and how they would be used.

In all the small groups, participants keenly discussed the question of whether different types of models should be treated differently in a Code of Practice.

Views largely fell into two camps:

One governance approach for all embryo models	Different governance for different types of embryo models
• Scientists don't know enough about the different types of models at this stage. • Scientists could claim a model is simple when it is in fact complex. • Different rules for different models could tie research up in red-tape and delay discoveries. • Start with a 'blanket' approach and review and diversify as more is learnt about model types and their potential.	• To be clearer – research involving different embryo model types would have better defined routes for review. • More precise governance doesn't hinder research unnecessarily: having one approach could limit the range of research that could be done for simpler embryos, if applying the same limits that are in place for more complex embryos. • To allow for different time frames for research: e.g. 'black box' timeframe – up to (the equivalent of) 28 days for complex models, longer perhaps for simpler models. • To allow for considerations about the type of research proposed: e.g. understanding human development, genetic conditions, IVF and others.

The 'type' of model that most participants believe merit more governance scrutiny is models closest to human embryos in terms of their potential to become a fetus and further development. In short: could they become a baby?

5.9 Oversight Committee

Discussions on the role of oversight in the governance of embryo model research began during workshop 2 and expanded during workshop 3. An Oversight Committee is seen as an important part of a governance structure. The main areas of interest and importance for participants are around membership, independence, transparency, guidance and the regularity and pace of reviewing research.

Role of an Oversight Committee

Participants see several roles for an Oversight Committee. These go beyond reviewing research study applications to ensure they comply with the Code of Practice. They include:

- reviewing the potential risks of research at each new stage and taking decisions on whether the research can progress
- reviewing legal and ethical requirements
- dealing with any breaches of the Code of Practice

- linking with an independent body that audits laboratories, including spot checks that the research study is being carried out as described in their approved application
- having a role in growing public understanding of embryo model research

> *"A committee that someone has to present each case to who then sign off on the risks. If they want to take it a bit further, then those risks are looked at and they're assessed, then they're signed off by a committee of scientists or whoever else could be part of that."*

Many want an Oversight Committee to also have a longer-term perspective on the field of embryo model research. This could be in following research studies, their outcomes and their implications for future decision making by the Committee. For example, in the future should some types of research be subject to higher or lower levels of scrutiny?

> *"A committee to actually follow the progress and the failures of what is being done, actually before, to create a final law. As we get results, positives or negatives, things would somehow be adapted for where can go."*

Membership that includes a range of backgrounds and perspectives, but doesn't slow down research

Many participants are keen to see an Oversight Committee with members drawn from a range of backgrounds. This is to ensure that the research is not just reviewed by fellow scientists, which some participants feel could lead to a system of mutual research approval. This is thought to be a particular risk in a scientific field as specialised as this. Diverse committee membership would also ensure that a wide range of perspectives are available to review the research and put forward different considerations.

The types of people that participants hope to see on an Oversight Committee are:

Scientists working in embryo model research

To bring their understanding of the science

Ethicists

To ask deeper questions about impact on society, future implications of the research

Legal experts

To understand how the research fits within the current legal and regulatory framework

People with lived experience

For example people who have donated cells or embryos to research, with experience of IVF, and with genetic conditions

To involve those who have experience of the consent process or whose lives/people like them in the future could be changed by the research

Healthcare professionals

To consider if/ how the research might translate into clinical practice/ patient impact

Members of the public

Range of ages including young people to take into account generational differences

To have a diverse set of perspectives from wider society

Public Engagement / Communicators

To ensure this field of research gains higher awareness and is better understood by society e.g. by helping scientists describe their work

> *"It's quite commonplace that lay members are part of research committees and I think their value is really spotting the obvious if there's anything that seems really out of place, but also from a medical and moral perspective, what the reaction of the general public would be like as well, which I think that maybe sometimes scientists could possibly be cocooned because a lot of the time I know that scientists can be in their bubble."*

Some participants think that a Committee with diverse membership could slow down research studies and expressed their hope that a range of perspectives could be achieved with efficiency.

> *"I think it would be reassuring to know that there's a panel or a board of people who will be, reviewing it within a time frame, but from all backgrounds, like we've been interacting with ethicists and lawyers and scientists, but I think it's really important to get people from lots of backgrounds and different age groups, and, people from everywhere to just have a review of this."*

A few participants said that members of the public should not be included on an Oversight Committee. They believe that the public should be involved in shaping the governance framework and future of embryo model research, but not on the Oversight Committee itself, because they said they would lack specialist knowledge and expertise.

In response to these concerns, some participants suggested that lay members of the Oversight Committee could be given training to help them understand the science and research context, so they could feel confident in their role.

Membership that is regularly refreshed is also important to participants. They fear that if people sit on committees for several years or decades that they will become overly involved in the area. This could lead to them losing sight of wider public opinion and not asking fundamental questions about the research. Some suggest a portion of the Committee is replaced every few years – to maintain some consistency, but also draw in different perspectives.

> *"If you have a fixed term, a little bit like a jury service, but a longer period of time, whether it's three years or something, so you can get your teeth into it and get understanding."*

Independence and transparency are important features of an Oversight Committee – with an expectation of statutory powers in the future

Participants do not want to see party politics involved in the work of an Oversight Committee. Many said that they want the Committee to be independent of government, but in the future, expect it to have some statutory powers. In the

meantime, they see a Committee helping to uphold a Code of Practice and that its decisions will influence the wider scientific community, including academic and institutional employers and funders.

> *"I suppose, any sort of Oversight Committee if we've got legislation down the line, then that could be a statutory committee, but not necessarily controlled by the government. Independent, but statutory."*

A Committee should not work behind closed doors. For the sake of public confidence in embryo model research, participants believe that it should work transparently. Who is on the committee, summaries of the research they are reviewing and the decisions they make should be publicly available.

> *"The important thing for me is that every decision that the committee made and the reason why they made that decision was public information. Not necessarily the applications that they didn't approve, but the applications that they do approve are able to be read publicly, or at least within the scientific community or something like that. Because I feel that holds the committee a bit more accountable for the decisions that they're making."*

6. Responses to the draft Code of Practice graphic summary

What you can expect to find in this chapter

In this chapter we share how participants responded to a graphic summary of an early draft of the Code of Practice that outlined how the Code would work and what some of its key recommendations are. It explores responses to both the content and language in the graphic summary.

It begins with participants' first reactions to reading the graphic summary, which are mostly very positive. Several participants use words such as 'confident' and 'reassured'.

It continues by exploring the section of the graphic summary of greatest interest: consequences of not following the Code. Participants are split into two camps: those who think the possible consequences of not following the Code, such as not getting funding, will likely ensure that almost all scientists conduct research that follows its recommendations and those who think a legal footing is necessary with prosecution routes available for those who break rules.

This is followed by sections on where more clarity is needed: such as why animal embryo models are excluded and what participants think is missing from the Code, which, most importantly, is a limit that makes clear when embryo model research should stop. The chapter ends with participants' strong endorsement on the need for regular reviews of the Code of Practice, which many want to see explained more specifically.

Figure 5: Draft Code of Practice graphic summary

Cambridge Reproduction created a graphic summary of the draft Code of Practice that outlined how the Code would work and what some of its key recommendations are for participants to review on Recollective. It was shared and comments were invited before the final workshop and then discussed in detail there.

Figure 6: Snapshot from Recollective online space introducing the graphic summary

Graphic summary a concise and confidence building encapsulation of the draft Code of Practice

Seeing a summary of a draft Code of Practice was a significant moment in the dialogue for many participants. Some used words such as “reassured”, “more confident” and “secure” to describe their first responses. The aspects that contributed to this were the description of the possible consequences for scientists if they don’t follow the Code, the plans for an Oversight Committee, the guidance for scientists on what to do and not do and the assurance that the Code will be regularly reviewed. Many participants particularly like the use of graphics and concise language in the graphic summary. Some think that a document such as this could play a role in building understanding for this emerging field of science.

> *“I feel more confident now that I’ve seen what they can do, what they can’t do.”*

Penalties: influential but are they a sufficiently strong deterrent?

The page of the graphic summary that attracted most participant attention was ‘How will we make sure people follow the rules’. Two lines of thought are evident from the discussions. The first is that the consequences set out here – research not being published, researchers not getting funding or being able to work in major research institutions etc. – are meaningful and would ensure adherence from the majority of scientists. The second is that stronger, legal penalties would be necessary to guarantee broad adherence.

The participants had confidence in the consequences set out in the graphic summary of the draft Code because they believe that being funded, collaborating and being recognised for their work are strong motivators for scientists. Some also said they thought that the media focuses excessively on the behaviours of ‘rogue scientists’. They said that this creates the impression that science is more corrupt than in reality. They feel that the suggested consequences recognise that most scientists want to work ethically and be seen to work ethically.

> *"I think, as a society, people tend to look at the scary stuff and the media also focuses on that. Scientists are really about making sure that their reputation is upheld and their work is being respected so they don't want to do unethical things, so they want to be respected and their papers be published."*

Some also said they like the fact that the proposed consequences are not just financial, such as fines. They feel that some scientists working for commercial organisations might see a fine as 'a cost of doing business' and ignore them. But these participants think that the prospect of never being published and never being recognised by your peers are 'quite harsh blows'.

> *"These were real personal things, rather than – "Pay us £2 billion," and they're like, "Sure.""*

Those that want to see stronger repercussions want to have penalties based in law. They used words such as 'prosecuted', 'harsh punishment', 'penalised' and 'imprisoned'. They said they could not have confidence that the governance system would work unless scientists could be found criminally responsible, fined and/or imprisoned if their work ignores restrictions and limits. This desire for stronger punishments than are currently in the Code stems from the nature of the science: dealing with fundamental aspects of human life and development and therefore scientists being in a position of trust, in a similar way to clinicians. It also stems from a belief that the consequences of not getting funding or not being published are meaningless to those who have their own funding source, access to technology and for whom ethics are irrelevant to their research goal.

> *"Whatever's on that page doesn't matter. They don't care if their work's published or they're able to get funding. Maybe they want to do something on their own and they've got access to that technology, they've got the money. If they were found out, what would be the repercussions?"*

A few participants discussed the concept of scientists working in fields such as embryo model research being regulated through a system of registration, in a similar way to nurses, doctors and social workers. They wondered if indeed they were and if so, think that signing up to the Code of Practice should be part of their registration. This would mean that if they broke any aspect of the Code they could have their registration reviewed by a 'board' and withdrawn.

> ***Participant:*** *"Social work, doctors, nurses, vet nurses, vets, they have to apply for their registration, and you get your disclosure checked and you get everything done, and you get your registration number. When you then are perceived to do anything that breaks your code of practice, you then have to go in front of the board to*

talk to them about if you have or you haven't. If they find you have, they can take that registration and you won't be able to work without it again. That's a huge deterrent, especially in the social care field."

Facilitator *"Do you think scientists then, should have to sign up to this code of practice?"*

Participant: *"Yes, I think so, it gives more faith and peace of mind that they know what they're talking about. Yes, it's something you should have to do, definitely."*

Where more clarity is needed: why animals and organoids are excluded, why some elements are 'must' and others 'should' and 'least complex embryo models'?

Some sections of the draft Code graphic summary left some participants feeling confused or concerned, notably the section 'What does the Code of Practice cover'. Several are concerned that if animal embryo models are excluded, could this mean that animal embryo models are completely unregulated and that animals could be being poorly and unethically treated. During the workshop 3 Q&A session, participants were told that animal research is regulated elsewhere. They feel that this information is important to include in both the full and summary Code of Practice.

A few participants also want more information on why organoids are excluded, particularly because they believe there will be significant growth in this area of science in the future.

Seeing that human embryos are not included in the Code of Practice prompted a few participants to discuss the merits of human embryo regulations and embryo model governance being connected in some way if the 14 day rule is extended to 28 days. They believe that researchers will work with both embryo models and human embryos. They foresee researchers conducting early stage experiments with the more plentiful embryo models and then using human embryos to validate their work.

"I think there needs to be some joined-up part between embryo models and human embryo governance because my understanding that the human embryo, they want to extend it to 28 days. I understand that the embryo model potentially could have thousands, to test on. You narrow it down to what will and what won't work. Then you can try that test then on a human embryo, of which you haven't got very many. I can't see how they're really going to run separately."

Several participants noted the wording on the second page of Key Recommendations: 'Researcher must use the least complex embryo model possible

to achieve their aims'. They think that this needs to be reviewed as they worry that it means that the Code will not cover more complex models. They think that the Code needs to be explicit about how more complex models will be governed and what processes scientists would need to follow.

> *"It's simpler models that it's talking about, but it needs something then to say" If you do go on to use more complex models, then this is what we're going to have to look at. That's what we're going to have to consider for you to be able to take that research further by using these more complex models."*

In the Key Recommendations section, the draft Code uses the word 'must' eight times and the word 'should' twice. Participants are concerned that 'should' makes the action optional and feels less compelling and enforceable than 'must'. They wonder why this is applied to the recommendations around experiment design and implementation and clear names and terminology. The latter feels particularly important to participants. They fear that unethical scientists could use complex language to bamboozle the public and scientific community about the nature and intent of their research.

> *"The very last point about the language and the names and terminology, that's the bit where it could fall down on. You could potentially either mislead intentionally the public or unintentionally."*

What's missing: a cut-off point, research reporting and committee decision making

A timeline, milestone or 'cut off point' on the culture of embryo models in research is a missing element from the draft Code of Practice that is an important and worrying omission for many participants. Chapter 5 explores the types of temporal or developmental limits that participants considered. There is no clear consensus among participants on what the limit should be, but there is widespread belief that the Code of Practice needs to include some form of temporal or developmental limit. Many participants think it is important to establish boundaries or different levels of governance and scrutiny depending on how developed the model is.

> *"How far do you go before it's deemed as actually being life, or a sentient being, that sort of thing? There needs to be some time limit on that. I think that would maybe worry people as well, how far they're going to be able to go by looking at these guidelines."*

Some participants see regular reviews of the Code and the research that it governs playing an important part in the decisions around 'cut off points'.

> *"That's a good thing about this being reviewed regularly. It's going to be reviewed on the findings of the scientists, because what they*

find, they might have to change the code of practice, to add in other things, things like that."

Several participants want to see the Code of Practice include reporting on the type of research that is taking place and who is funding it. They think this is important to help understand how this new field of science is developing, who is involved in it and the aspects that are generating most interest and funding.

"If everyone doing the research or every university, every whatever it is, sends an annual or biannual report back saying, actually, we are looking at X, Y, Z, and we've had A, B, C amount spent on that."

A few participants wanted to see more information about embryo model research Oversight Committee's ability to reject a research application.

"If applications fall short of credibility of ethical necessity, can it be disallowed by a code of practice board for example?"

Regular reviews of the Code of Practice are essential and need to be a clearer commitment

Throughout the dialogue, participants discussed the fast-moving nature of this field of science. They see it as absolutely vital that governance is designed to take account of how embryo models and their use in research is developing. Participants want to see this learning applied swiftly and effectively to the way in which the research is governed.

"I think that's something that is needed because this is very new science. There's going to be a lot changing. There's going to be things come up that we can't foresee at the moment and it's developing very rapidly."

Some participants believe the development of other technologies, such as artificial intelligence and computer models, should also be included in these reviews. This is because they foresee that computer models could replace the need for physical embryo models in research in the future.

"Instead of doing research with embryo models, they may be able to do it with computer modelling... They know very often what the embryo models do. If that gets put into a computer and it'll translate, in effect, what the probable outcome will be if they take the embryo model further ahead, rather than the need to actually, in fact, do the research."

Because this review aspect is so important to participants, they want to see more specific commitments to how ‘regular reviews’ will happen, for example how often and what circumstances would trigger a review. Some participants suggest annual reviews, others three-yearly or whenever there are significant development in the field.

> *“What are the timescales for review and under what circumstances? For example, would you say it’ll be reviewed annually and under this specific circumstance, if this happens, if A happens, B happens, or C happens, we review, and annually at a minimum.”*

7. Engagement with and communication of stem cell-based embryo models

What you can expect to find in this chapter

This final chapter of findings focuses on what participants said about how embryo model research should be communicated and engaged with in the future. There is a strong belief that this field of research will need greater public awareness and acceptance to thrive in the coming years: the wider public will need to see that scientists are working ethically and with good intent.

The term 'stem cell-based embryo model' was discussed. Participants tend to favour either a 'keep it simple' e.g. embryo model or embryo-like structure or a 'say exactly what it is' approach e.g. stem cell-based embryo model or stem cell research models containing human tissue. Some feel the immediate association with the word embryo is a 'baby' and so including this could draw negative reactions – but many think it is a necessary term to include. The term 'stembryo' is seen by many to trivialise an important field of science.

7.1 Communicating with public, acting with transparency

Having been involved in two public dialogues in embryology research in the last year participants are eager for people across society to know about research involving stem cell-based embryo models. Some participants consider, despite press reports during 2023, that more coverage is needed to ensure that people across society understand that:

- embryo models are used in research, and they are distinct from early human embryos
- such research is happening in leading UK universities, with research labs receiving public funding at the forefront of current innovation
- ethical considerations are in researchers' minds as they undertake this work given that human stem cells are used in the development of the models

Many participants believe that there should be much more awareness of the research, its implications and its potential. Without this awareness some participants suggest that the research will be seen as somehow hidden away from public view and lacking in transparency. If this perception continues, they fear it will give rise to a sense of unease about the research, and a lack of trust in the science and the researchers who undertake it.

> *"It is important to make the whole process of research transparent. The public should be made aware of why that research is being carried out and how it will benefit someone, otherwise all the positive benefits could be undermined if people don't trust them."*

It is understood by participants that this area of research is complex, and difficult to explain to a lay audience. Nonetheless they feel that researchers and the communication teams they work with should be doing more to give regular updates on the kind of science that is being done and what outcomes are expected from it.

> *"The idea of embryo research is difficult. The idea of an embryo model is profoundly difficult to understand. Let's push it back to the scientists and call for the information to be out there in the way that the public can understand."*

As a governance model is agreed, and the Code of Practice is implemented, participants want to be kept informed. They feel that people across society should know that there are rules in place to ensure that ethical standards are met by researchers. If Research Ethics Committees are involved in approving research on embryo models, then the public should know that and understand the importance of it to ensure acceptable uses of the models in research are monitored and assured. This will ensure that the Committees approving the work are also accountable to public scrutiny.

Participants believe that bringing the research into the open and communicating the Code of Practice and the governance structures in place will give people the tools to trust the research. They believe understanding the motivations of researchers and the assurances that the research is being done to high standards for the public good will ensure that more people can benefit from the research findings.

> *"It will give the public more confidence and trust in the process of the research."*

The reason most participants are keen for the research to be explained is that they believe that this research will only progress and flourish if it is widely supported by the public. That means understanding the difference that research involving embryo models can make.

> *"This dialogue that we're in at the moment is a helpful step in the right direction, but I think they need to do a lot more explanation of what they're doing, what they mean by their terms, and how these terms relate to the real world."*

7.2 Terminology: Ideas for most appropriate terms

This brings us to reflections on the terminology used to describe the models. Given the desire by participants for embryo model research to be better understood, they believe that the terms used to describe the models should be clear, concise and precise. In workshop 3 each of the small groups discussed which words should be used for the models. No consensus was sought or obtained for this terminology, but some useful indications of criteria to be applied when deciding on the appropriate language is summarised in figure 7.

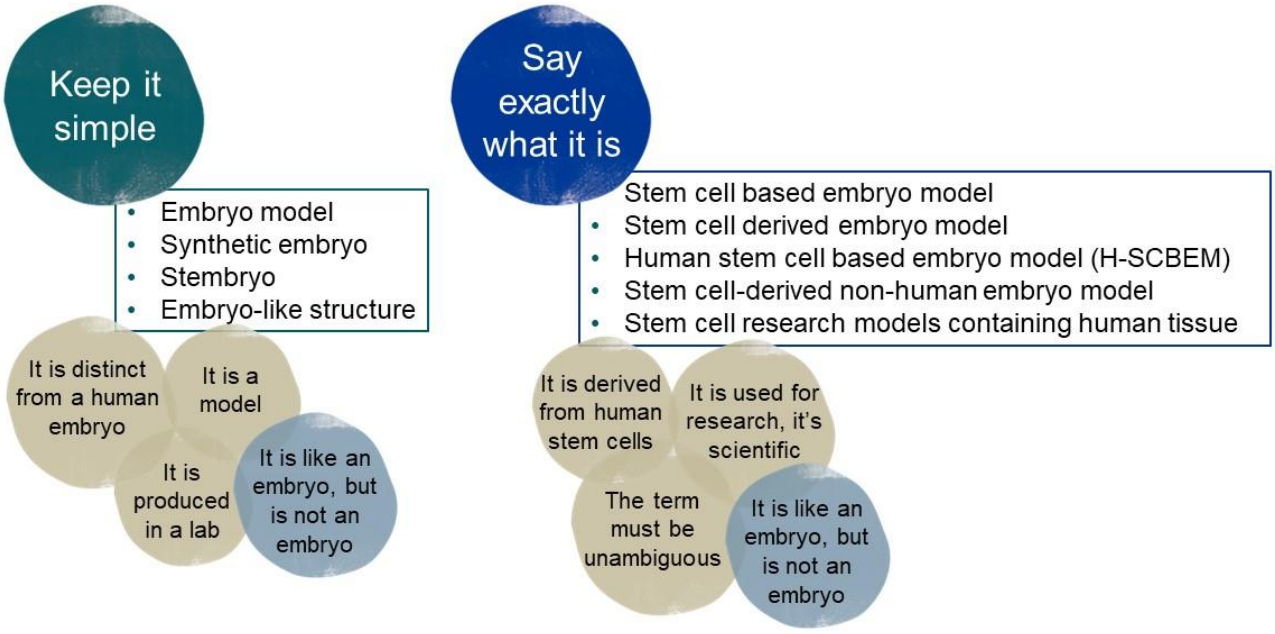


Figure 7: a summary of the terms and why they are preferred

All participants want it made clear, whichever terms are used, that these are models. They also want to be explicit that the models are embryo-like, but they are not a human embryo.

However, participants divide roughly into two groups: 'keep it simple' and 'say exactly what it is'. For those who prefer simplicity, shorter terminology is preferred. These participants think that words such as, "embryo model" make it clear enough that these models are not formed from donated eggs and sperm, but rather are constructed in a lab from stem cells.

> *"Embryo models. It's nice and to the point. I could imagine a shop dummy. One is a human and then standing next to it is a shop dummy. The dummy is the embryo model."*

Other participants want the terminology to be precise and unambiguous. They think that to achieve this it is important to use as many words as necessary (and related acronyms) to describe a model. For some this means including the word 'human' as they want to stress that human stem cells form the basis of the model, rather than animal stem cells or a material constructed by humans.

> *"I would definitely prefer to have some note of human in there. You can't have the model without human stem cells to start off with. I think it is important to be explicit about that."*

Participants suggest that using more words which explicitly mention the process through which the models are created is transparent. It makes it clear that this work is done by scientists in a research lab. For this group of participants clarity is essential.

> *"I just like the term stem cell-derived embryo model because there is no uncertainty and it's very, very clear. Although it's quite a long term you can use the acronym which is perfect."*

7.3 Terminology: avoid misleading a public audience

Many participants want to ensure that whatever terminology is used it cannot be misinterpreted, or potentially mislead a public audience. This led some participants to question whether the word 'embryo' should be used in this context at all. They explain that 'embryo' is a sensitive word which should be used with caution and always in association with 'model', so that people are clear that the models are distinct from human embryos.

> *"Using the word 'embryo' could raise concerns. It is quite a delicate word. A precious word. I'm thinking that the public reaction to that. They are not going to stop and think, "Is that the same thing (as an embryo)?" They're going to instantly think it is. A wee bit of understanding is needed to make that difference."*

One participant suggested using 'stem cell research models containing human tissue', which they said was too long, but at least avoided using the word embryo. For a few participants including the word 'embryo' could be seen to engender fear in a public audience about what researchers are doing with embryos in the lab and exacerbate concerns about early human embryo research unnecessarily. They suggested the key word is 'cells' which cannot be confused with 'embryo' with it's potential to become a baby.

A few participants think using the word 'synthetic' in the descriptor for the models could also be misleading. It suggests to them that the models are constructed in the lab from human-made material like plastic, like a 3D-printed model.

> *"I think synthetic embryo is perhaps a bit misleading because that potentially sounds too far removed from actually being derived from a human, because it's still derived from human cells. When I think 'synthetic' I would think of something completely unrelated to people."*

For those participants in the ‘say exactly what it is’ group it could also be seen as misleading to use terms which are vague, or open to misinterpretation. The term ‘embryo-like’ falls into this camp for these participants as it could suggest a number of things to people.

Some participants also suggest that terms should only be used if they are ‘serious’. There is a concern that combining terms into one word like ‘stembryo’ could be considered as belittling the science. They feel this would be a mistake, trivialising an area of research which could have significant implications for humanity.

> *“I think this word (stembryo) takes the edge off actually what they’re doing. This is serious research. It’s got the potential to change the course of human history really. That’s got to be highly respected.”*

Whichever terms are used, participants are united in wanting to ensure that the research is clear to participants, that it doesn’t mislead and that the research, and the Code of Practice, are understood widely. Such transparency, in their view, will give more confidence in the research across society and enable researchers to work in their field without having to be defensive about their practice.

> *“Whatever they’re doing in the code of conduct, if you put that in a library somebody should be able to pick that up and understand exactly what researchers are doing. That they are doing A and B, the intention is C and it’s made up of these processes.”*

Section 3

Considerations for future governance of embryo model research

Dialogue process reflections

8. Considerations for the future governance of embryo model research

What you can expect to find in this chapter

This final chapter summarises five considerations that participants of the public dialogue would like the authors of the draft Code of Practice to be mindful of as they progress their work.

1. **Timescale/ developmental limits for embryo research: more consideration is needed**
   Almost all participants wish to see timescale or developmental limits on embryo model research but more work is needed on the design and implementation of these limits.

2. **Code of Practice as a stepping stone to legislation**
   Participants see the merits of a Code of Practice that fills a current governance gap in a matter of months rather than several years. But there is a view that in the longer term embryo model research should be addressed by legislation, particularly around limits in law that would help to prevent certain outcomes, such as researchers culturing models with a developed nervous system.

3. **Regular reviews of the science and governance**
   The rapid progress of embryo model research in recent years makes regular reviews of governance vital for participants. They want to see more specific commitments for how and how often in the Code but expect reviews to be annual or three-yearly or linked to significant developments in the field.

4. **Public involvement in governance and greater public awareness of the science**
   Many participants see embryo models as fascinating and complex. Their use in research has significant implications for understanding miscarriage and IVF, human development and finding ways to prevent or cure diseases. Some participants also foresee more dystopian possibilities, such as changing the way in which human life is created. Participants believe that greater public involvement in, and awareness of research and its governance will be essential to earning public trust in embryo model research.

5. **Research benefits clearly described and shared**

   As fascinating as the science is, participants believe that there need to be clearer descriptions of what research involving embryo models is trying to achieve. Participants hope to see benefits from this research, such as improved IVF techniques and new treatments for health conditions, available to those that need them, not just to those able to afford them.

8.1 Limits for embryo model research: more consideration is needed

Almost all participants wish to see time or developmental limits on embryo model research, but many believe more work is needed on how these are designed and implemented.

Many participants believe that regulating embryo models in the same way as human embryos would be too restrictive. They understand that the 14 day rule could not apply because of the different ways in which embryo models are created and develop compared to human embryos. The absolute red line that many participants have for research involving embryo models is developmental: when a model could feel pain.

> *"I would put an absolute barrier on the survival of the models to the point of any kind of sentient nervous system or brain development. That should not be permitted, I think."*

Several participants look to a 28-day equivalent limit, because they have heard of the 14-28 day 'black box', after which some embryo material is available from abortions. It should be noted that participants heard about the use of embryo material from abortions being used by scientists for understanding human development beyond 28 days, but their potential usefulness compared to embryo models was not discussed in any depth.

Many participants lean towards a staged approach to governance and limits: with greater limits and scrutiny on models that are more developed.

8.2 Code of Practice as a stepping stone to legislation

Participants see the merits of a Code of Practice that fills a current governance gap in a matter of months rather than years. But there is a medium to longer term view that embryo model research should be included in legislation. This is rooted in the belief that there should be limits in law that would prevent what participants see as unethical research outcomes, such as the use of models in research when they have the potential to feel pain.

One group of participants discussed the idea of whether or not there would be legislation on embryo models in 10 years' time. This group strongly believe there should be.

> *"I would hope that this would be acting as a preliminary to legislation in parliament."*
>
> *"I think that it's (the Code of Practice) a good step and it's a much needed step, but we really need legislation. I think 10 years is a long time. I would really like the legislation to be there a lot sooner."*

8.3 Regular reviews of the science and governance of embryo model research

The rapid progress of embryo model research in recent years makes regular reviews of governance vital in the eyes of participants. They want to see more specific commitments for how and how often reviews take place written into the Code. Many participants expect to see annual reviews, with flexibility for interim reviews if there are significant developments in the field.

There are hopes that these regular governance reviews will be done in a way that will help ensure that ethical research can progress without being hindered. In contrast, a few participants prefer to see all research paused until full governance is reviewed and updated.

8.4 Public involvement in governance and greater public awareness of the science

Many participants see embryo models as fascinating and complex. Their use in research has significant implications for understanding miscarriage and IVF, human development and finding ways to prevent or cure disease. Some participants also foresee more dystopian possibilities, such as changing the way in which human life is created. Participants believe that public involvement in, and awareness of, future research and its governance will be essential to earning public trust in embryo model research.

Almost all participants think that lay members should be involved in the oversight of embryo model research. This means:

- involving people of different ages, backgrounds and beliefs to ensure society's views are brought into governance
- involving people with lived experience, such as those with experience of genetic conditions, miscarriage or IVF
- supporting people, through training and information on the science, so they feel confident in their role
- ensuring that membership of an Oversight Committee is refreshed every few years to prevent over-familiarity leading to a lack of perspective

Participants also want to see more efforts made to grow public awareness of embryo model research, including featuring them in education at school.

8.5 Research benefits clearly described and shared

As fascinating as the science is, participants believe that the Code of Practice should include an expectation that researchers provide clear (and publicly accessible) descriptions of what the research involving embryo models is trying to achieve, that it is ethical and fits with society's hopes, and that benefits will be available to those that need them, not just those who can afford them.

Participants also hope that scientists working in this field collaborate wherever possible. They believe that collaboration will help to prevent duplication of effort and allow one group of scientists to build on another group's work and potentially find solutions to problems that halted the work of a previous group.

> *"I think that's something the public really like to see, to read, because then they can see why this Code of Practise is in place and how valuable it is, because this is what they've found by using these models. They're very beneficial to the research, and I think that's a good thing to give the public more confidence and trust."*

9. Dialogue process reflections

We believe that this has been one of the first public dialogues in the world where public participants, scientists, legal experts and ethicists have spent several hours over a number of weeks exploring the subject of research involving stem cell-based embryo models. Therefore as the facilitators of this dialogue, we believe it will be helpful to share our reflections on potential learnings to help inform future public involvement in this area of science.

9.1 The start of a longer conversation

Whilst this has been one of the first public dialogues on embryo model research, it should, we believe, be the first of several in the years to come. The dialogue was convened quite rapidly at the start of 2024 for two reasons: to inform the development of the draft Code of Practice on Embryo Model research due for publication in Spring 2024 and to capitalise on the opportunity and on the knowledge of embryo research gained by participants from the 2023 HDBI Public Dialogue.

As the report has hopefully demonstrated, participants grasped many of the potential benefits, harms and tensions that exist in this field of science. However, there are topics that merit further exploration such as how embryo models are created, how they differ from other research material such as tissue from abortions and why and what differences there are in the use of both pluripotent stem cells and embryonic stem cells to create embryo models.

This fast moving field of science will inevitably generate new discoveries. These will need to be explored by members of the public, scientists, lawmakers, ethicists and others for their implications for society and fed into an ongoing review of how embryo models are governed, particularly if there are moves towards legislation.

9.2 Considerations for the content of future public dialogues on embryo models

Allow time and space for understanding what stem cell-based embryo models are and how they are created e.g. recapping on the basic facts

That an embryo model can be created not through sperm and egg fertilisation but by stimulating stem cells is astounding for participants. It changes the way they view how ‘life’ is formed and what ‘life’ is. It was extremely helpful to re-connect with the participants from the early human embryo research public dialogue. Their understanding of human embryo research and regulation and the existence of embryo models was a key factor in the dialogue being able to explore governance questions relatively quickly. However a small number of participants understood only quite late in the process that the embryo models we were discussing contained human cells. So re-capping on key facts will need to be an important feature of deliberative processes on this topic.

Exactly what is done to stem cells to lead them to form an embryo model was not explored in depth in this process. This wasn’t a large stumbling block because there were so many other dimensions to explore, but creating accessible materials that

explain how stem cells are stimulated to become embryo models will be helpful to public understanding.

In a similar vein, participants learnt about different types of embryo models, but for the most part discussions simplified these to ‘more complete – and like a human embryo’ and ‘less complete – more like specific organs or body functions’. Potentially creating categories of embryo models will help a more specific understanding.

In this report we note the tension between seeing embryo models as different to human embryos and the concern that models might be so different that they can’t be trusted to tell us about human development or diagnosis and treatments for diseases. Clear explanations of how different models with different degrees of completeness and specialisation can be used in ways applicable to human beings will be extremely helpful in building public understanding.

Understanding how embryo models compare to human embryos, animal/human mixed embryos and material from abortions

Participants understood that embryo models are a relatively new area of research and therefore there are many unknowns and uncertainties. Going forward, it will be helpful for future public involvement to be able to compare embryo models to other research materials such as human embryos, combinations of human and animal materials and material from abortions. This will help members of the public to understand why researchers use these different materials and explore the pros and cons of each. Participants are also interested in the potential to use computer models in the future to work alongside or replace these physical materials.

Understanding what might be appropriate limits for research involving embryo models: equivalence?

The 14 day rule/ primitive streak for human embryo research is a simple and clear limit. Participants understood that because embryo models are created differently and can skip stages, the number of days / appearance of physical traits, could not easily be applied to embryo models. If a future public deliberation explores the issue of temporal or developmental limits for embryo model research, more time will need to be spent on what the potential development indicators might be for embryo models that could be used as limits for research.

Acknowledgements

Hopkins Van Mil is immensely grateful to all those who took part in the dialogue. We were delighted to see the willingness of participants from the 2023 Human Development Biology Initiative's early human embryo research dialogue to take part in discussions on this even more complex topic. It was evident from the very start of the process that they were deeply interested in the how and why of embryo models and their future governance.

Specialists are essential to meaningful public dialogue. This dialogue involved leading figures in science, law and ethics. We are very grateful for the time they spent preparing materials specifically for this dialogue and for answering participants questions thoughtfully and clearly.

A huge thank you also to the members of the Oversight Group. Their thoughts helped shape both the dialogue process – particularly how much time we gave to exploring embryo models and to understanding approaches to governance – and this report.

Appendices

Appendix A – List of dialogue Oversight Group members

Name **Chair of the group*	**Role(s)**	**Organisation(s)**
Suzannah Lansdell*	Dialogue and Engagement Specialist	Sciencewise
Anna Middleton	Associate Director, Engagement and Society	Wellcome, Sanger Institute
Christina Rozeik	Coordinator	Cambridge Reproduction
Dina Halai	Head of Regulatory Policy	Human Fertilisation and Embryology Authority
Julian Hitchcock	Legal Counsel	Biolawgy
Naomi Moris	Group Leader, Developmental Models Laboratory	The Francis Crick Institute
Nick Hopwood	Professor of History of Science and Medicine	University of Cambridge
Ran Svenning Berg	Research and Policy Manager	Nuffield Council on Bioethics
Roger Sturmey	Professor of Reproductive Medicine	Hull York Medical School and University of Manchester
Sandy Starr	Deputy Director	Progress Educational Trust
Steve Wilkinson	Professor of Bioethics	Lancaster University
Subhadra Das	Writer, Historian, Curator	Independent
Anna MacGillivray	Dialogue Evaluator	Ursus Consulting

Appendix B – List of specialist speakers and contributors

Speaker	Organisation	Topic
Webinar		
Christina Rozeik	Coordinator, Cambridge Reproduction	What is the Governance of Embryo Models Project?
Roger Sturmey	Professor of Reproductive Medicine, Hull York Medical School	Reminders and updates about embryo models
Steve Wilkinson	Professor Bioethics, Lancaster University	Ethical reflections on embryo models and regulation
Workshop 1		
Peter Rugg-Gunn	Professor and Group Leader, Babraham Institute	Embryo models: Origins, materials and differences/similarities to human embryos
Naomi Moris	Group Leader, Developmental Models Laboratory, Francis Crick Institute	Case studies of uses of embryo models
Steve Wilkinson	Professor Bioethics, Lancaster University	Ethical reflections on embryo models
Workshop 2		
Philip Ball	Science writer and previous editor at the journal Nature	Speaker panel chair
Rosamund Scott	Professor of Medical Law and Ethics, Kings College London	Governance and regulatory options available for embryo models and speaker panel contributor
Kathleen Liddell	Professor of Law, University of Cambridge	Contributor on regulation – speaker panel
Nienke De Graeff	Asst Professor, Department of Ethics and Law, Leiden University Medical Centre, Netherlands	Contributor on regulation and ethics – speaker panel
Peter Rugg-Gunn	Professor and Group Leader, Babraham Institute	Contributor on scientific research – speaker panel
Workshop 3		
Christina Rozeik	Coordinator, Cambridge Reproduction	Draft Code of Practice
Peter Rugg-Gunn	The Babraham Institute	Short reflections
Kathleen Liddell	Director of the Centre for Law, Medicine and Life Sciences, University of Cambridge	Short reflections
Steve Wilkinson	Professor of Bioethics, Lancaster University	Short reflections

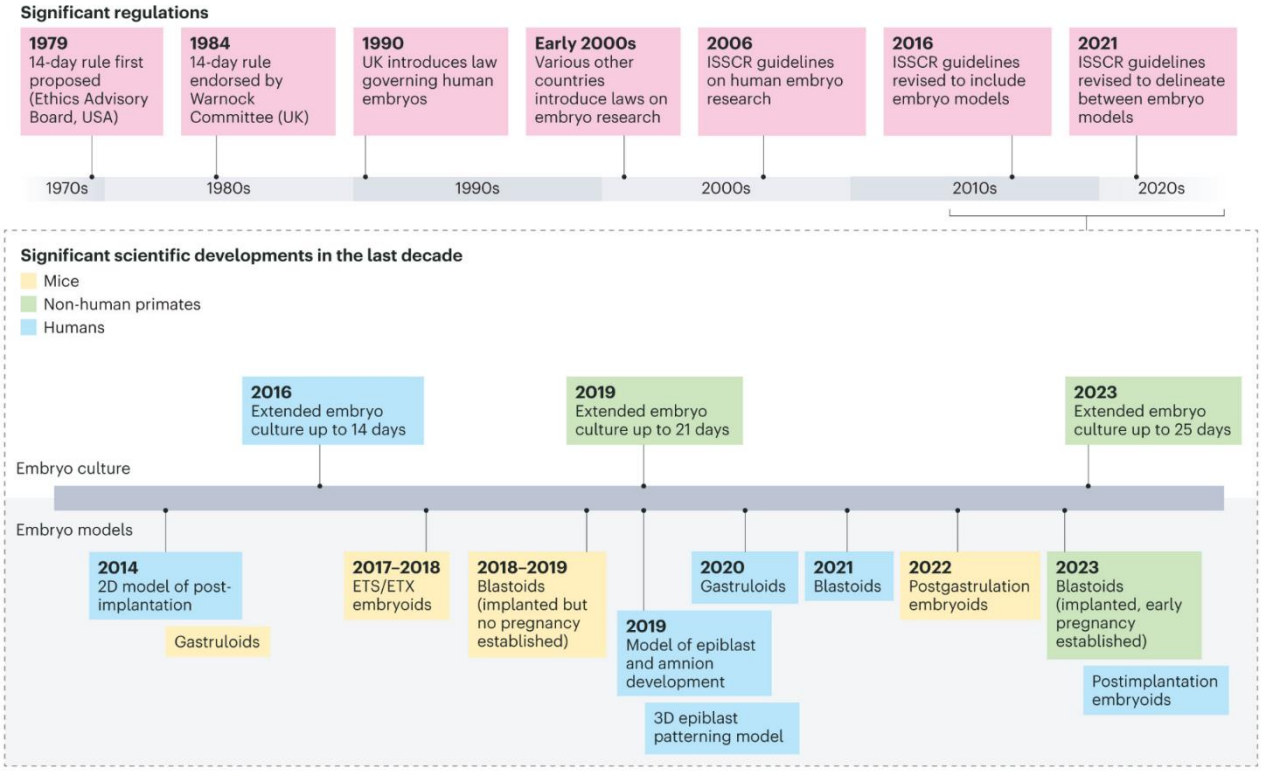
Appendix C – Participant demographics

Demographic	Number
Gender	
Female	18
Male	19
Non-Binary	1
Age group	
18-29 years	8
30-39 years	9
40-49 years	9
50-59 years	8
60-69 years	2
70+ years	2
Country	
England	31
Scotland	6
Northern Ireland	1
Ethnic background	
Asian/Asian British	9
Black/Black British/Caribbean/African	6
Mixed/multiple ethnicities	2
White	21
Religion	
Buddhism	1
Christianity	7
Hinduism	5
Islam	1
Judaism	3
None/Atheist	12
N/A	9
Support for Early Human Embryo Research	
Strongly oppose	2
Oppose	6
Neither support nor oppose	9
Support	7
Strongly support	9
N/A	5

Appendix D – List of specialist presentations and stimulus materials

Summary of online activities

Task	Description
1. Watch – Early Human Embryo Research Public Dialogue Film	Participants were asked to review a film from the previous public dialogue on Early Human Embryo Research.
2. Watch – BBC segment on Stem Cell Based Embryo Models	Participants were asked to watch a short segment from BBC News covering the successful creation of a Stem Cell Based Embryo Model.
3. Read – Stem Cell Embryo Models Section of the Early Human Embryo Research Public Dialogue	In the previous public dialogue on Early Human Embryo Research there was a section on Stem Cell Based Embryo Models. Participants were asked to review this section to refresh their memory.
4. Read – Jargon Buster	Participants were asked to review a jargon buster which defined the key terms that would be used throughout the dialogue.
5. Embryo Models: Research and regulation timeline	This task involved looking at a timeline detailing the history of Embryo models. Shown in detail below.
6. Watch – Webinar Presentations	This activity gave participants the opportunity to watch the presentations that were shown in the webinar.
7. Review – the Jamboards from workshop 1	Participants were given the option to review the jamboard facilitator notes from the other groups in Workshop 1.
8. Review – Draft Code of Practice Graphic Summary	This activity involved a graphic summary of the draft code of practice for research using embryo models.
9. Watch – Workshop 2 Panel Discussion and Presentation	Participants were given the option to review the panel discussion and presentation from Workshop 2.
10. Watch this recap of the Public Dialogue	This short film recapped some of the presentations that participants had seen over the course of the dialogue.



Activity 5. Timeline of embryo model research and regulation. Source: de Graeff, N., De Proost, L. & Munsie, M. 'Ceci n'est pas un embryon?' The ethics of human embryo model research. *Nat Methods* **20**, 1863–1867 (2023).[21]

[21] https://doi.org/10.1038/s41592-023-02066-9

Appendix E – Facilitator process plans

Webinar – 6-7:30pm Tuesday 9th January 2024

Time	Agenda	Process	Expected Outcomes
6:00-6:15 (15 mins)	Introduction to this webinar and the overall dialogue programme	Warm welcome to our first session together. This is an introductory webinar to get us into a space where – over the next two weeks – we can discuss stem cell based embryo models, with a focus on how they are governed in the future. We briefly discussed these embryo models in the previous dialogue you took part in. It will **not** run in the same way as our other workshops which will be a lot more interactive and give lots of space for discussion in small groups and time to listen and respond to specialists in the room. The purpose of this webinar is to give you initial information to start thinking about our topic. You don't need to know anything about this in advance. 1. HVM team introduce themselves 2. Observers/ speakers present introduce themselves 3. Evaluator to introduce themselves and the evaluation process **1. Introduction to the Dialogue** We will be discussing stem cell based embryo models in this dialogue – with a particular focus on how they are governed in the future. This is a topic that is right at the cutting edge of science. We want you to know there is support for you in this dialogue – 3 main ways: Sharing questions/ concerns/ anything you are worried about with the facilitation team Referring to the handbook where we've listed organisations that can give advice, help and support on issues related to this topic You can take time out at any point if you need a breather – turn off your mic/ camera. We'll check in with you after a bit though to make sure you are ok. Note from LF – as I'm speaking please put any questions you have about the dialogue and what we are doing together in the Chat. Then LF	People are clear: Who is in the room and why; who they will be working with What support is available. What we will be doing together What the scope of the discussion is How we will work together and how the findings from the deliberation will be used

Time	Agenda	Process	Expected Outcomes
		• Refers to the consent already signed before attending – and that consent is active and ongoing and can be withdrawn at any stage...temporarily or permanently. • Explains what we'll be doing this evening • Explains how Recollective works in combination with the workshops – and a reminder of what we've already shared there • Explains the handbook – and that there is key contact info there, practical guidance e.g. how to use Zoom and information on our topic • Shares who has commissioned the dialogue and its purpose, the partners – you'll hear more about 'why this dialogue' in our speaker presentations later • Shows visual of the whole programme • Shares how participants were selected from all the other HDBI dialogue applicants • Shares the points to help the discussion – highlighting using the chat to ask questions/ comments • Shares today's programme – where we will be setting the context of our deliberations • How/ why we'll capture what is said this evening • Mention the final report and its purpose	
6:15-6:25 (10 mins)	Menti	QM1: Share where in the UK you are zooming in from QM2: When I say the word 'governance' what comes to your mind?	Beginning to think about the content
6:25-6:30 (5 mins)	Chat questions	Participants asked to share questions they have in the chat about the purpose of the dialogue. Quick points of clarification. LF to answer questions directly related to the dialogue process. Questions more related to our topic will be covered in the next Q&A we have after our next presentations.	Immediate dialogue questions answered
6:30-6:45 (15 mins)	An introduction to the G-SCBEM project	**2. Presentation: What is the SCBEM Governance Project?: Christina Rozeik**: Coordinator, Cambridge Reproduction; G-SCBEM project manager An introduction: more info on SCBEMs and governance and regulation will be shared in future workshops Why a review of governance is needed	Understand who is commissioning this dialogue and why

Time	Agenda	Process	Expected Outcomes
		Existing relevant governance and guidance e.g. legislation that outlaws implanting SCBEM into a human / ISCCR guidelines Who's involved in the G-SCBEM project Scope of the project e.g. UK only Output of the project: why a code of practice vs other forms of governance/regulation Project timeline: when will the CoP be published	
6:45-6:55 (10 mins)	Chat questions	Participants asked to share questions they have in the chat about the SCBEM governance project. **Christina** to answer questions as directed by LF. LF confirmation that this is an introduction to embryo models, their use in research and their governance. We'll be learning more as we go along.	Immediate/ front of mind dialogue topic questions answered. Early areas of uncertainty cleared up.
6:55-7:05 (10 mins)	A reminder and update on SCBEMs	LF to introduce Roger Sturmey, Professor in Reproductive Medicine at Hull Medical School who will share slides you saw in the previous dialogue and some recent updates. **3. Presentation: Reminders and updates about SCBEMs: Roger Sturmey** What is a stem cell and its features How models are made and what from What models help to understand Why models vs embryos Key differences between models and embryos	A reminder of key things to know about SCBEMs
7:05-7:20 (15 mins)	Chat questions	Roger and other speakers to answer questions prioritised by the LF. LF confirmation that this is our first introduction to these topics. We'll be learning more as we go along.	Understanding the questions people raise first on this subject
7:20-7:25 (5 mins)	Ethical reflections for consideration	LF introduces Steve Wilkinson, Professor of Bioethics, University of Lancaster Steve shares 3-4 brief ethical reflections on what he's heard this evening – focusing on questions/ comments in the chat – and helpful points for participants to consider ahead of the first full workshop e.g. how there are different forms of governance/regulation/legislation and their role in society.	First ethical considerations
7:25-7:30 (5 mins)	Menti.com – online polling	QM3: One thing that you have learnt or has particularly interested you this evening Wrap up and close	Summing up what's been discussed. An understanding of key points and highlights.

Time	Agenda	Process	Expected Outcomes
In own time	Online community space activities for next time	Review the speaker presentations from this evening, add any questions you have Review international context: SCBEMs around the world: Film by Robin Lovell-Badge	Completion of/ reflection on this workshop's activities. Preparing for the next workshop.

Workshop 1

Time	Agenda	Process	Expected Outcomes
6:00-6:10 (10 mins)	Introduction to this workshop and the overall dialogue programme	Warm welcome to our full workshop session together. The purpose of this workshop is to share more information about stem cell based embryo models. 1. HVM team introduce themselves 2. Observers/ speakers present introduce themselves 3. Evaluator to introduce themselves and the evaluation process Introduction to the workshop • Explains what we'll be doing this evening • Shows visual of the whole programme • Shares the points to help the discussion • How/ why we'll capture what is said this evening • What support is available • Mention the final report and its purpose	People are clear: Who is in the room and why; what they will be doing and who they will be working with What support is available.
6:10-6:15 (5 mins)	Menti questions	**Participants asked to get menti.com on their phones/ another tab on their device.** QM1: One thing you remember from Tuesday's webinar…	Continuing to think about the content
TS to open breakout rooms on LF's instructions			
6:15-6:35 (20 mins)	Small Group Discussion:	Let's start by introducing ourselves to each other	Small group get to know each other and first

Time	Agenda	Process	Expected Outcomes
6:15-6:25 (10 mins) 6:25-6:35 (10 mins)	Introductions and first thoughts	**Q1: Share your name, where you are zooming in from and one thing that's on your mind about this dialogue since the webinar.** Participants answer in turn. Encourage participants to stay off mute unless they have background noise. **Q2: What aspects of this dialogue on the future governance of research involving embryo models interest you most and why?**	perspectives shared on SCBEMs
TS to close breakout rooms at 6:35			
6:35-6:50 **(15 mins)**	Presentation: Origins and formation of SCBEMs	LF introduces first speaker: Peter Rugg-Gunn, Group Leader, Babraham Institute. **1. Presentation: SCBEMs: Origins, materials and differences / similarities to human embryos** When and where they first began Why they were developed What materials they are made from: e.g. embryonic stem cells and human derived pluripotent stem cells: why and what differences How they differ and are similar to human embryos e.g. no point of fertilisation, different developmental processes and timescales.	
TS to open breakout rooms on LF's instructions			
6:50-7:00 **(10 mins)** 6:50-6:58 (8 mins) 7:58-7:00 (2 mins)	Question gathering in small groups	Given what we've heard from Peter, 10 mins for a gathering of questions **Q3: What questions or reflections do you have about what Peter said about SCBEMs? Or what else would you like to know?** **Q4: Which two questions do we want to raise this evening?** • **Note that those we don't get to ask tonight will be shared with the speakers to answer later**	Gather questions on what SCBEM are and where they came from
TS to closes breakout rooms at 7:00			
7:00-7:15 **(15 mins)**	Q&A Session on SCBEM: origins and types	LF asks each of the five group's facilitators to share one question each from their Jamboards. Second question shared if time. Fs chose different questions if same/similar question is asked by others. LF shares questions with Peter and other speakers for short responses	Knowledge increased on SCBEMs
7:15-7:25 Break: turn off camera and put yourself on mute			

Time	Agenda	Process	Expected Outcomes
7:25-7:35 (10 mins)	SCBEM Case Studies	LF introduces Naomi Moris, Group Leader, Francis Crick Institute. Reminder to take notes as we listen as we'll go into our groups straight after and gather our questions and thoughts. **2. Presentation: Case studies of uses of embryo models** Range of uses currently Examples of: ○ Understanding human development ○ Understanding causes of miscarriage ○ Others E.g. likely affect of infection on embryo development (COVID)	Understand range of uses of SCBEMs
7:35: TS to open breakout rooms on LF's instructions			
7:35-7:45 (10 mins) 7:35-7:43 (8 mins) 7:43-7:45 (2 mins)	Question gathering in small groups	Given what we've heard from Naomi, 10 mins for a gathering of questions **Q5: What questions or reflections do you have about what Naomi told us about the uses of SCBEMs? Or what else would you like to know?** **Q6: Which question do we want to raise this evening?** • **Note that those we don't get to ask tonight will be shared with the speakers to answer later**	Gather questions on uses of SCBEM
TS to closes breakout rooms at 7:45			
7:45-8:00 (15 mins)	Q&A Session on SCBEM: origins and types	LF asks each of the five groups' facilitators to share one question each from their Jamboards. Fs chose different questions if same/similar question is asked by others. LF shares questions with Naomi and other speakers for short responses	Questions answered
8:00-8:05	Ethical briefing	LF asks Steve Wilkinson, Professor of Bioethics, University of Lancaster to share ethical prompts on considerations for the moral status of SCBEMs vs human embryos, following up on discussions and presentations this evening.	
TS to open breakout rooms on LF's instructions			
8:05-8:25 (20 mins) **8:05-8:15 (10 mins)**	Discussion on uses of SCBEMs and how they	This is our last discussion of the evening. **Q7: What are your hopes and/or concerns about the uses of stem cell based embryo models that you have heard about this evening?**	

Time	Agenda	Process	Expected Outcomes
8:15-8:25 (10 mins)	differ/similar to embryos	**Q8: What to you makes embryo models similar to or different from human embryos and how does this change how you view them?**	
TS to close breakout rooms at 8:25			
8:25-8:30 (5 mins)	Menti.com – online polling Wrap up and close	QM2: One thing that you have learnt or has particularly interested you from what you've heard this evening	Summing up what's been discussed. An understanding of what's coming up.
In own time	Online community space activities for next time	Review the speaker presentations from this evening, add any questions you have Watch PRG video on future scenarios for SCBEMs	Completion of/ reflection on this workshop's activities. Preparing for the next workshop.

Workshop 2

Time	Agenda	Process	Expected Outcomes
6:00-6:10 (10 mins)	Introduction to this workshop and the overall dialogue programme	Warm welcome to our second workshop session. The purpose of this workshop is to explore the future of stem cell based embryo models. We will look at how they could develop and be used in the future and how they might be governed, taking learnings from other fields. 1. HVM team introduce themselves 2. Observers/ speakers present introduce themselves 3. Evaluator to introduce themselves and the evaluation process Introduction to the workshop • Explains what we'll be doing this evening • Shows visual of the whole programme and what we've covered so far, including on Recollective • Shares the points to help the discussion • How/ why we'll capture what is said this evening • What support is available • Mention the final report and its purpose	People are clear: Who is in the room and why; what they will be doing and who they will be working with

Time	Agenda	Process	Expected Outcomes
TS to open breakout rooms on LF's instructions			
6:10-6:25 (15 mins) 6:10-6:25 (15 mins)	Small Group Discussion: Reflections on homework and future of SCBEMs	F Welcome everyone to the small group, we'll be together in this group this evening, the same group as W1. QM1: You watched a video of Peter Rugg-Gunn talking about future scenarios for stem cell based embryo model research and outcomes – having watched this and from what you've heard so far in the dialogue, where would you put yourself on this scale of how stem cell based embryo models research should be governed: No limits or governance…..Case by case review…..Same as human embryos (e.g. currently not beyond 14 days)…Complete ban….. Not sure Where did you put yourself on this scale and why? What is it about stem cell based embryo models that influenced your choice?	Understand where participants are at in their thinking about stem cell based embryo models and their governance.
TS to close breakout rooms at 6:25			
6:25-6:50 6:25-6:30 (5 mins) 6:30-6:50 (20 mins)	Panel discussion on future of embryo models led by Philip Ball	**Panel Discussion:** LF introduces Philip Ball who will host this panel discussion and the other new speakers: Nienke and Rosamund, they'll be joined by Roger and Peter who you have already met. The focus of this discussion is 'the future of stem cell based embryo models'. They will talk about the questions/points below for 20 mins and then we'll open it up for your reflections/questions to the panel. Encourage participants to take notes as they listen.	More perspectives shared on the future of SCBEMs and considerations for how they are governed
6:50-7:05 (15 mins)	Panel Q&A	Philip opens up for participants to share their reflections or questions in the chat or by raising their hand. Philip to chair Q&A session, with LF feeding in questions from the chat as necessary.	Questions/ reflections on future of SCBEMs and their governance shared
7:05-7:15 Break: turn off camera and put yourself on mute			
7:15-7:20 (5 mins)	Intro to small group discussion 1	LF welcomes participants back. Our first small group discussion this evening we will share our thoughts on what we've heard about the future of embryo models	Small group discussion introduced
7:20: TS to open breakout rooms on LF's instructions			

Time	Agenda	Process	Expected Outcomes
7:20-7:55 (35 mins) 7:20-7:40 (20 mins) 7:40-7:55 (15mins)	Small group discussion 1: Discussing the future: benefits & harms and thoughts on governance	We have heard some views on the future of embryo models and how they are/could be used in research… **Q2: What benefits and/or harms do you see from the future of research with embryo models? Why?** **Q3: What needs to be in place to help to maximise the benefits and minimise/prevent the harms? How might this change in the future?**	Consider the future uses of embryo models and factors for their future governance
7:55: TS to close breakout rooms			
7:55-8:15 (20 mins) 8:00-8:15 (15 mins)	Presentation 1: Thinking about governance: current situation; range of options; learnings from other areas of science.	LF Introduces Rosamund Scott to speak about governance in this field of science – participants reminded to take notes and put questions/reflections in the chat **Presentation 1: Governance** The range of governance and regulatory options that are available (self-reg to legislation) and considerations for why some may be more suitable than others for SCBEMs Existing regulations/legislation in this space (e.g. HFEA Act: law against implanting embryos used in research) Governance models in similar contexts: e.g. Stem Cells	
8:15-8:25 (10 mins)	Q&A Session on governance	LF invites questions/reflections from the participants. Speakers/observers to indicate which questions/reflections they would like to respond to.	Questions answered
8:25-8:30 (5 mins)	Menti.com – online polling Wrap up and close	QM2: One thing that you have learnt or has particularly interested you from what you've heard this evening. QM3: One hope you have for embryo model research? QM4: One concern you have for embryo model research?	Summing up what's been discussed.
In own time	Online community space activities for next time	Review the speaker presentations from this evening, add any questions you have Watch Suzannah's summary film of information shared so far Simple summary version of Code of Practice	Completion of/ reflection on this workshop's activities. Preparing for the final workshop.

Workshop 3

Time	Agenda	Process	Expected Outcomes
6:00-6:10 (10 mins)	Introduction to this final workshop	Warm welcome to our third and final workshop session. The purpose of this workshop is to discuss our considerations and expectations for the governance of stem cell based embryo models. 1. HVM team introduce themselves 2. Observers/ speakers present introduce themselves 3. Evaluator to introduce themselves and reminder of the evaluation process Introduction to the workshop • Explains what we'll be doing this evening • Shows visual of the whole programme and what we've covered so far, including on Recollective • Shares the points to help the discussion • How/ why we'll capture what is said this evening • What support is available • Mention the final report and its purpose	People are clear: Who is in the room and why; what they will be doing and who they will be working with
6:10-6:25 (15 mins) 6:10-6:15 (5 mins) 6:15-6:25 (10 mins)	Presentation 1: Draft Code of Practice	LF re-introduces Christina Rozeik, co-ordinator for the G-SCBEM project. Remind participants to take notes and share any questions in the chat. Christina will share: Reminder of the role and status of the **draft** Code of Practice e.g. first step in governing Embryo Models Overall structure and areas that most need public input e.g. 1. What if any limits should be imposed on embryo model research? 2. Redlines for research 3. How to balance freedom of research and overseeing a sensitive area of science 4. Role and membership of an Oversight Committee Opportunity for participants to ask questions for clarification about the draft Code of Practice.	Status, content and key input needed for Code of Practice understood
TS to open breakout rooms on LF's instructions			

Time	Agenda	Process	Expected Outcomes
6:25-6.55 (30 mins) 6:25-6:30 (5mins) 6:30-6:55 (25mins)	Small Group Discussion 1: Code of Practice	Welcome to our small group, we'll be together as a group for this workshop. We have mixed up the group so that you can hear different experiences and perspectives. Briefly introduce yourself: name, where you live. **Q1: Having read the graphic summary of the draft code of practice, are you more or less confident in how embryo models could be governed in the future than you were beforehand – or no change in view?**	Understand spontaneous reactions to the draft CoP graphic summary
6:55-7:10 (15 mins)	Speaker Panel reflections for final deliberations	LF asks Peter RG, Kathy Liddell and Steve Wilkinson to share reflections / provocations with participants as they prepare for their concluding discussions. 5 minutes each	
7:10-7:20 Break: turn off camera and put yourself on mute			
7:20-7:22 (2 mins)	Intro to concluding discussions	LF introduces our final discussions: underlining this opportunity to bring your experience, views, values and knowledge gained to contribute to the draft CoP.	Ready to share considerations
TS to open breakout rooms on LF's instructions			
7:22-8:20 (58 mins) 7:22-7:37 (15 mins) 7:37-7:47 (10 mins) 7:47-8:20 (33 mins)	Small group discussion 2: Code of Practice and considerations for governance	Welcome to our final small group discussion. **Q2: You have heard about different types of embryo models: those that are more like a complete embryo and supporting structures (e.g. amniotic sac) and those that are more like a collection of human cells. How should the Code of Practice account for these different types? Why?** **Q3: Thinking about the term: 'Stem Cell Based Embryo Models': given all that you've heard during the dialogue, which term feels most appropriate to you and why? Which are the least appropriate and why? What other terms do you suggest?** **Q4: As a group, let's finish by compiling 5-7 considerations we would like the group working on the Code of Practice for governance of embryo model research to hear: considerations might include:**	

Time	Agenda	Process	Expected Outcomes
		Individually spend 3-5mins writing down what you'd like to say to the working group Now let's share our considerations and agree 5-7 that we'd like to put forward and briefly explain why they are important.	
8:20 TS to close breakout rooms			
8:20-8:25 (5 mins)	Reflections from G-SCBEM team	Christina shares reflections on what she's heard during the dialogue, how the report will be used to shape the Code of Practice alongside other inputs, timing and next steps	Next steps understood
8:25-8:30 (5 mins)	Menti question and final practical points	Two Menti questions to end our workshop. The first revisits a question we asked in workshop 2: **QM 1: Share one piece of advice for the G-SCBEM team as they finalise the Code of Practice for research.**	Final thoughts shared, evaluation and payment process understood.
8:30 Workshop ends: facilitators, evaluator and speakers/observers stay on zoom for a brief wash up			

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