

What are embryo models and what are their main ethical issues?

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CHANGER Training | 21 October 2026



Overview

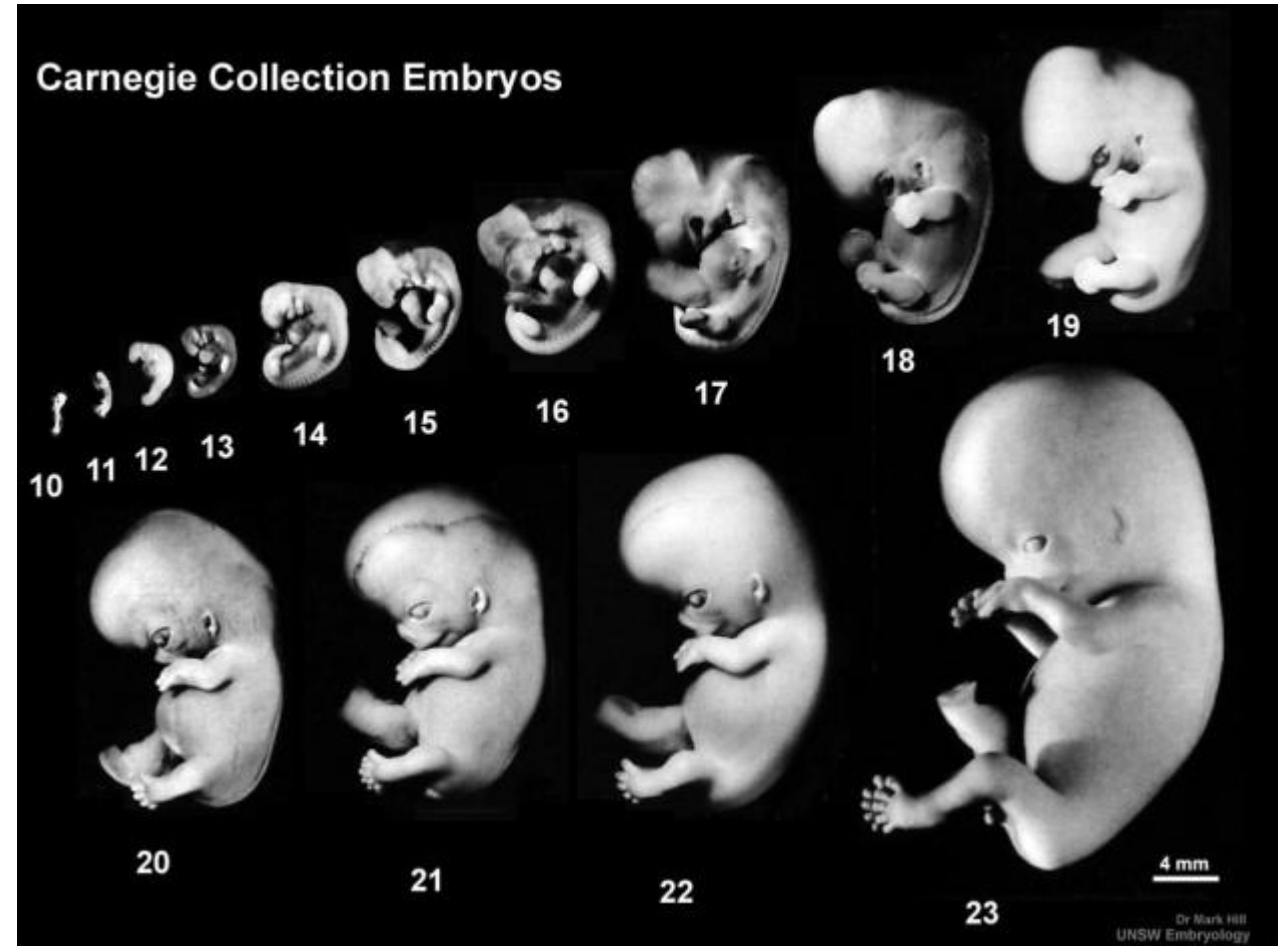
Part 1. Understanding stem cell-based embryo models

- Scientific background: What are SCBEMs, their applications and limitations?
- Ethical challenges: Cell sources, informed consent, moral status and terminology
- Governance: Research limits, prohibitions, ISSCR guidelines and ethical oversight, public engagement

Part 2. Case study and practical application

Why is early human development difficult to study?

- Implantation, gastrulation and early pregnancy loss remain insufficiently understood
- Limited availability of human embryos for research
- Ethical and legal restrictions
- Limitations of animal models



Carnegie stages 10-23

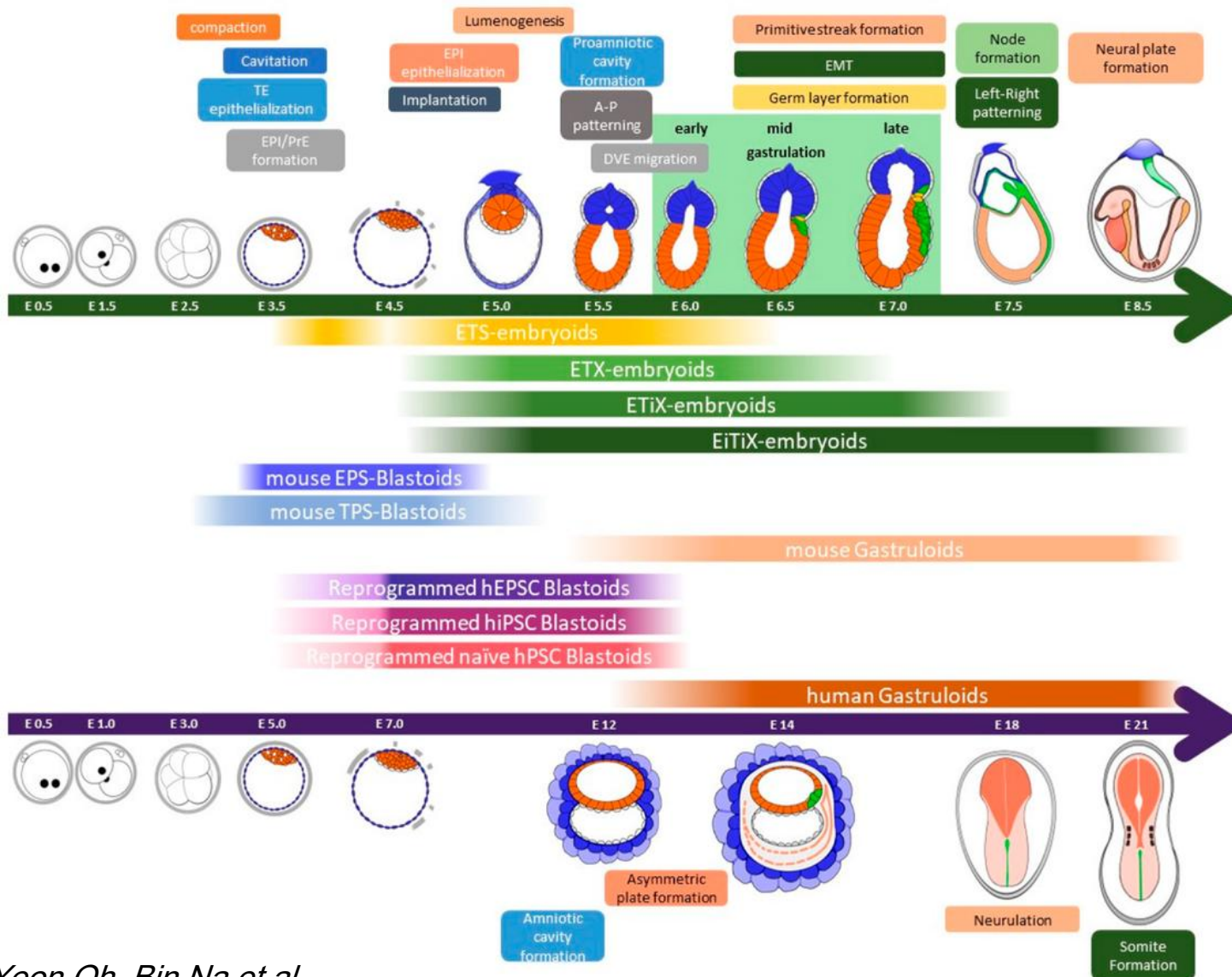
What are stem cell-based embryo models?

SCBEMs are stem cell-derived structures that recapitulate selected aspects of early human embryonic development.

- Generated *in vitro* from stem cells
- Not created by fertilization
- Vary in complexity, organisation and developmental features
- Self-organisation



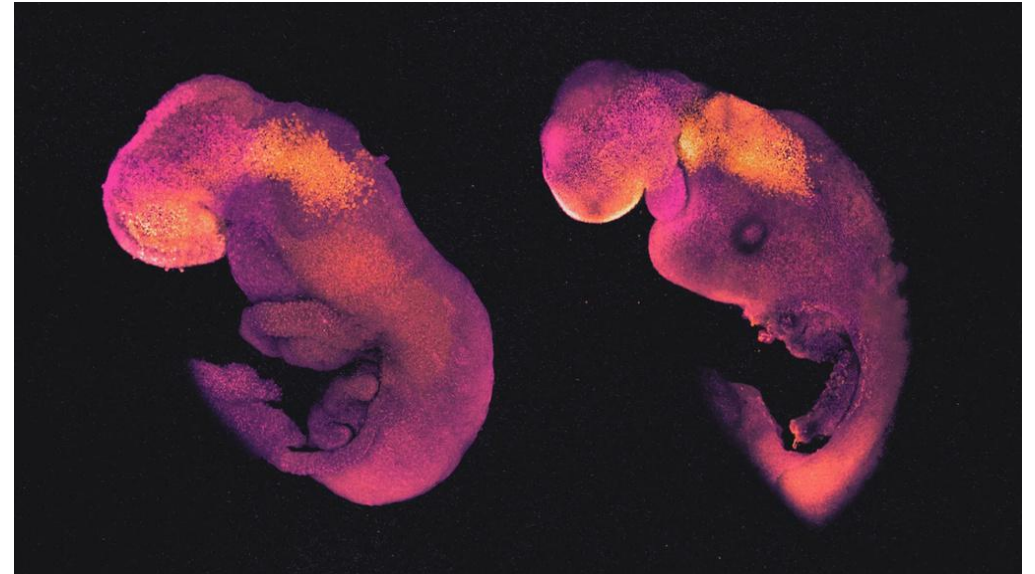
One term, several different models



- **Blastoids:** Model aspects of the blastocyst stage
- **Peri-implantation models:** Model developmental processes around implantation
- **Gastruloids:** Model gastrulation and early body axis formation

Why are scientists interested in SCBEMs?

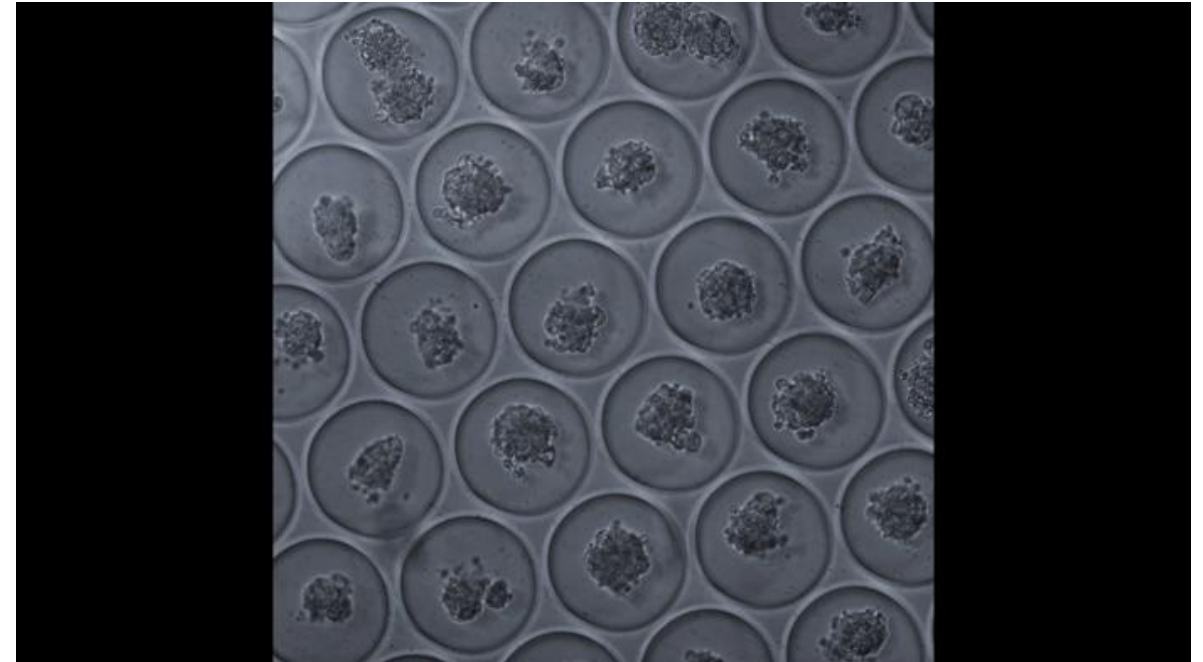
- Understanding early human development
- Investigating implantation failure and pregnancy loss
- Studying genetic and developmental disorders
- Drug and toxicity testing
- Potential applications in reproductive medicine



University of Cambridge

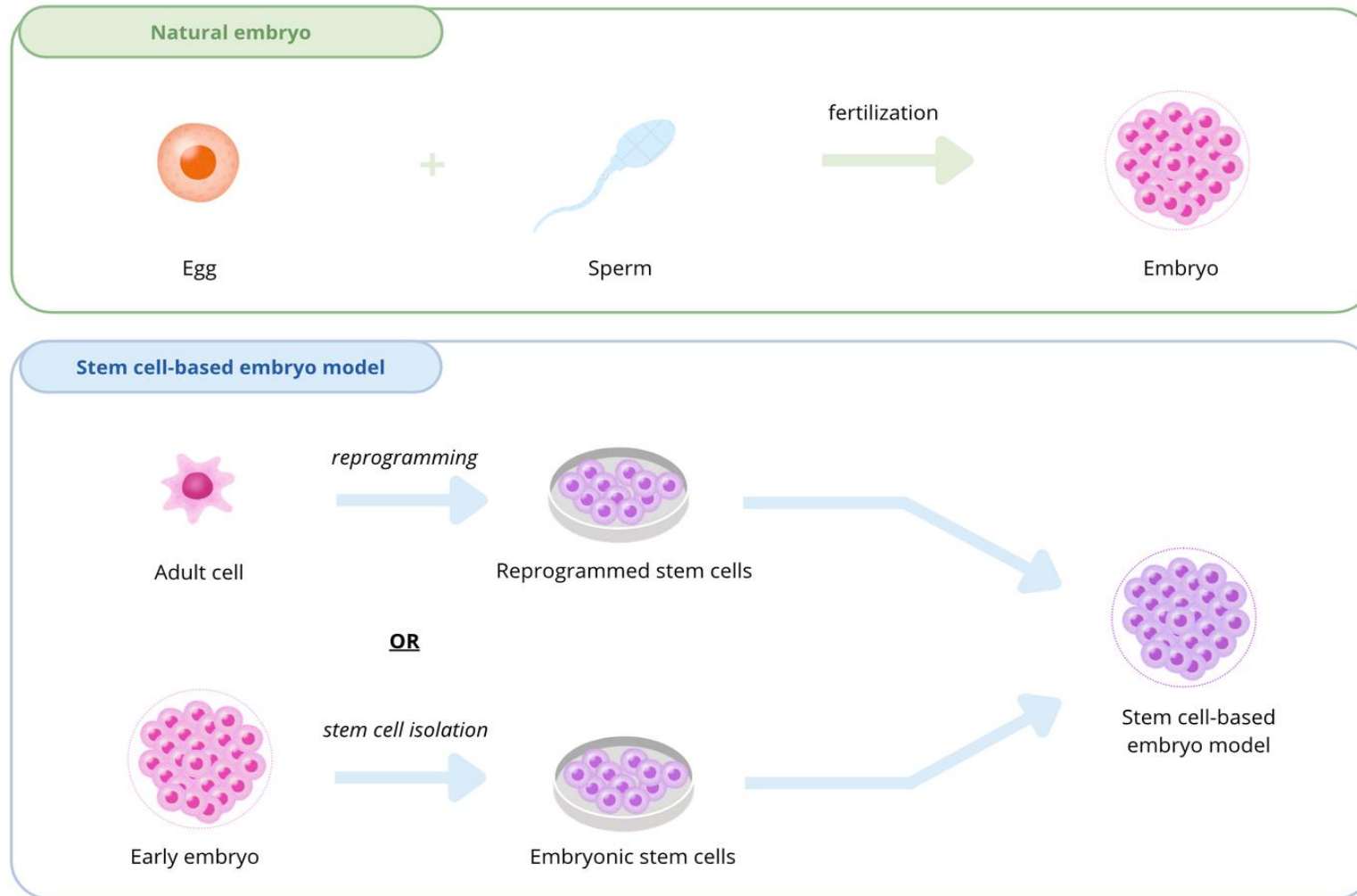
Scientific usefulness does not mean biological equivalence

- Incomplete representation of human embryos
- Missing or abnormal cell populations
- Variability and reproducibility challenges
- Limited developmental potential
- Continued need for validation against human embryos and other models



*Kagawa et al.,
2021*

Where do the cells come from?



Informed consent

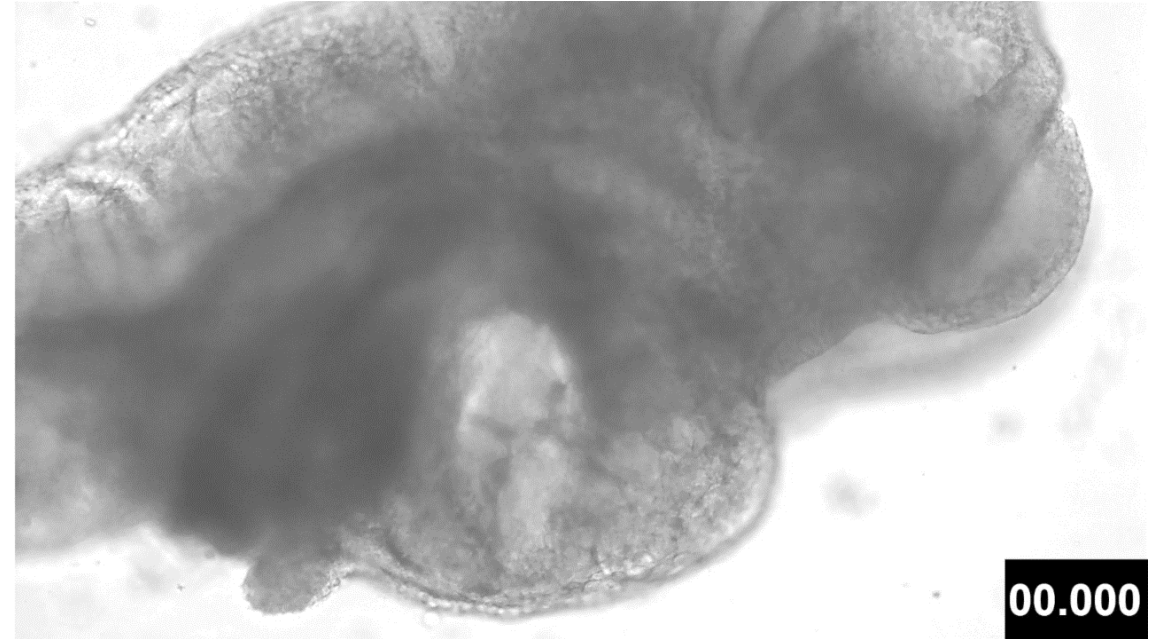


The 2-step informed consent tool: A manual.



Should SCBEMs receive moral protection?

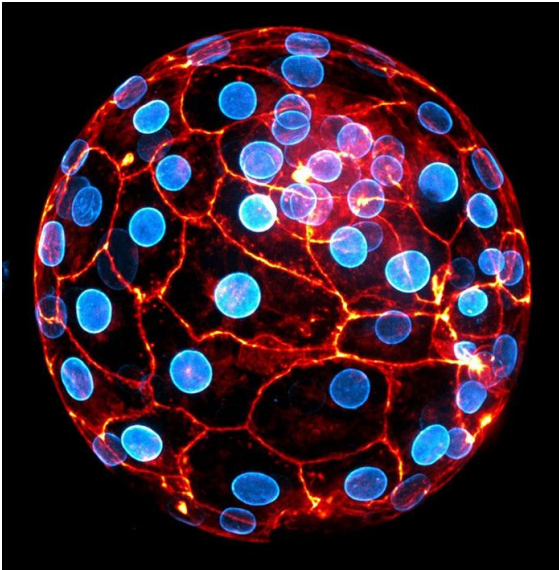
- Human origin and resemblance to embryos
- Developmental potential
- Organismal integration and biological complexity
- Potential emergence of morally relevant capacities
- Different views on moral status and proportionate protection



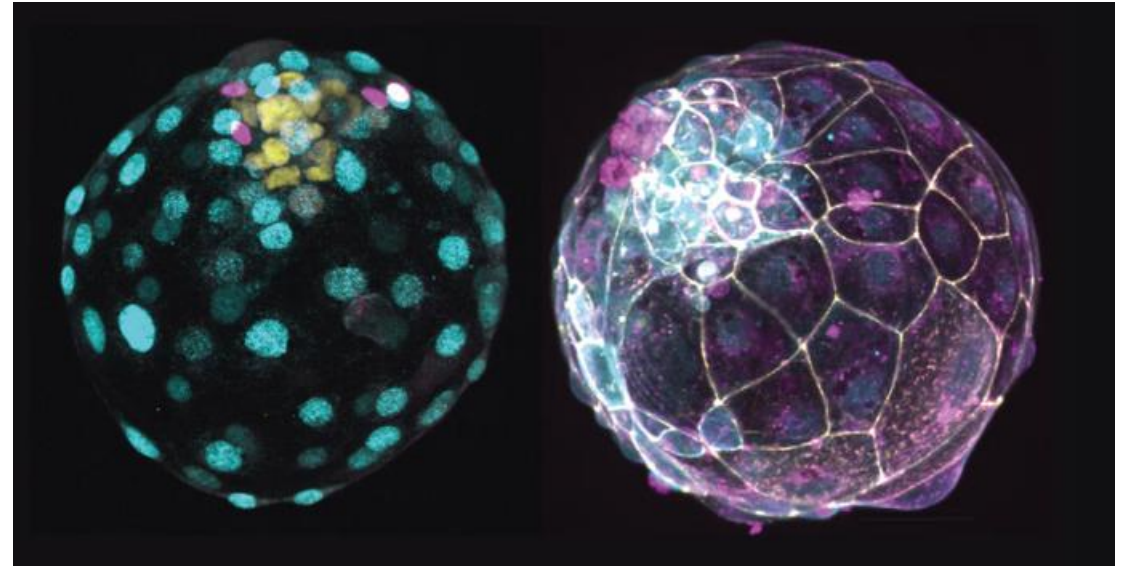
*Lau et al.,
2022*

Terminology

- Preferred term: Stem cell-based embryo models (SCBEMs)
- Different ethical and legal interpretations
- Some frameworks distinguish models from embryos; others may classify particular models as embryos



Natural human embryo



Stem cell-based embryo models

Why do SCBEMs require specific governance?

- Rapid technological advances
- Existing embryo legislation does not always clearly apply
- Regulatory uncertainty and legal gaps
- Risk of disproportionate restrictions or insufficient oversight
- Need for adaptive governance

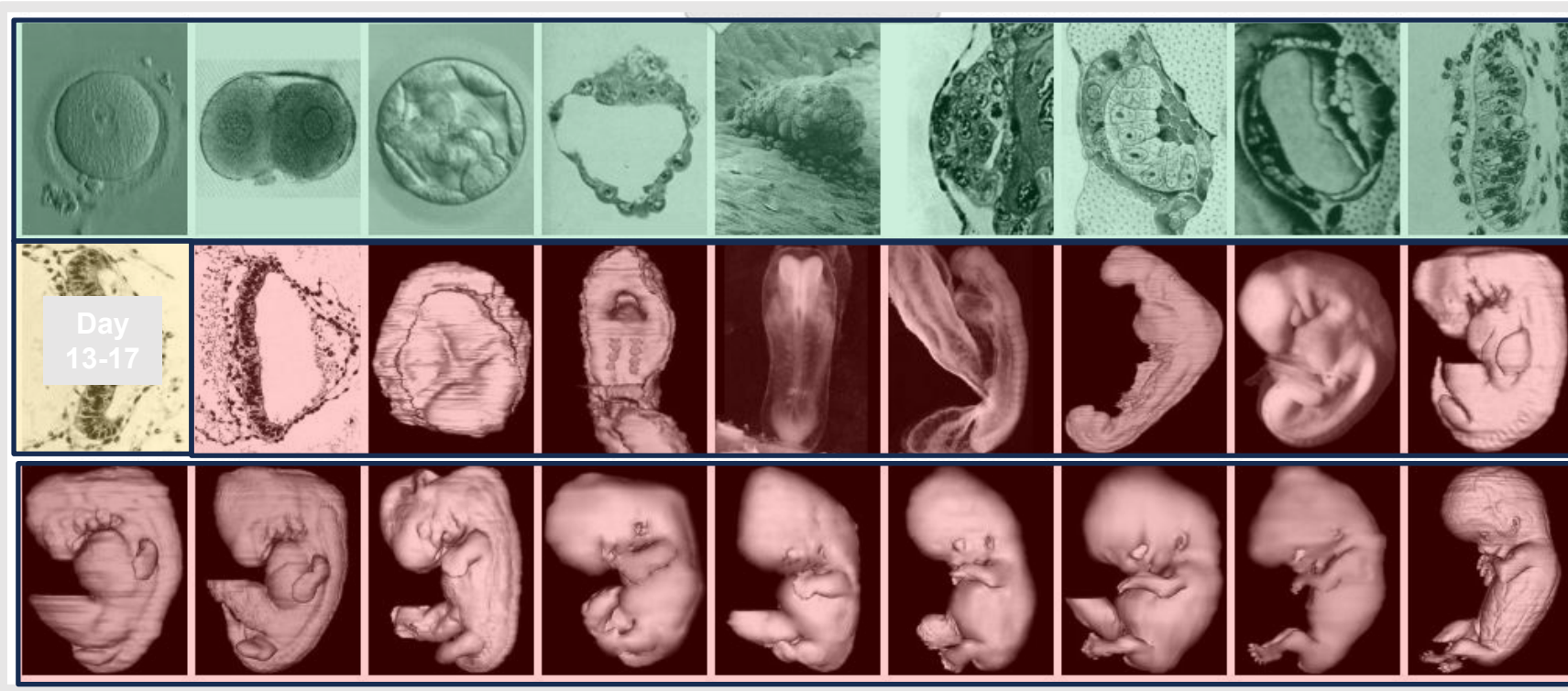


How are SCBEMs currently governed?

- National legislation and regulatory frameworks
- ISSCR: International Society for Stem Cell Research
- 2021 revision and 2025 update
- International guidelines do not replace national legislation

INTERNATIONAL (7)							US (1)	UK (2)	BELGIUM (1)	FRANCE (2)	PORTUGAL (1)	NETHERLANDS (2)	SWEDEN (1)	EAU (1)	BRAZIL (1)	AUSTRALIA (1)			
																			
ISSCR Guidelines (2016, 2021, 2025)			HYBRIDA (2024)	UNESCO IBC (2021)	ESHRE (2024)	EBCOG (2020)	ASNTR (2025)	Code of Practice (2024)	NCOB Report (2024)	BeSSCR (2025)	Agence de la biomédecine (2023)	INSERM (2019)	CNECV (2023)	Derde Evaluatie Embryowet (2021)	Veertiendagen- grens (2023)	SMER (2024)	Abu Dhabi (2025)	ABTCel-Gen Statement (2025)	NHMRC (2021)

Research limits: How far should SCBEM research go?



Virtual Human Embryo Project (adapted by Charlotte Clarke-Slakey)

Three approaches:

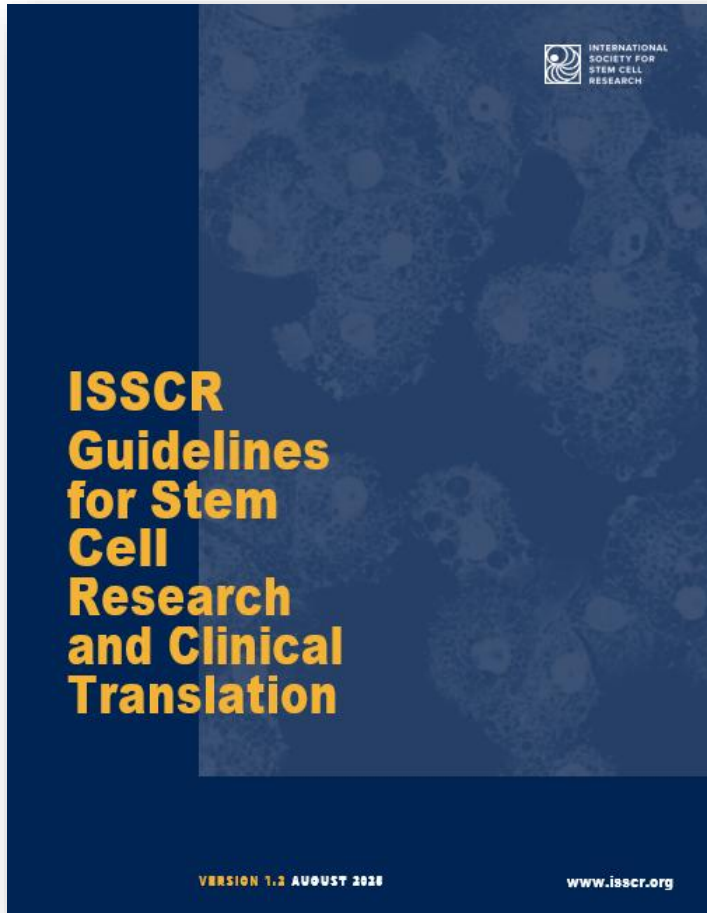
- Embryo-equivalent limits
 - Extended developmental limits
 - Model-specific limits
-
- Key question: Which developmental stages should be permitted, under which conditions?

Research boundaries: What should not be allowed?

- Gestational transfer
- Ectogenesis towards viability
- Increasing developmental complexity raises additional ethical questions
- Sentience, consciousness and capacity to experience pain



Ethical oversight: What changed in the ISSCR 2025 Guidelines?



Category	Oversight
1A	Exempt from specialized review
1B	Reportable
2	Specialized scientific and ethical review
3	Research that should not be undertaken

- Previously: Integrated versus non-integrated models
- Integrated: Embryonic and extraembryonic tissues
- Non-integrated: Specific parts or processes of embryonic development
- 2025 update: Distinction removed for oversight purposes
- All spatially organized 3D human SCBEMs: Category 2

Who should oversee SCBEM research?

- Scientific self-governance
- Research Ethics Committees and specialized oversight bodies
- Multidisciplinary expertise
- Independence and management of conflicts of interest



Public dialogue: Why should society be involved?

- Public values and concerns
- Transparency and responsible communication
- Risks of normalization, misunderstanding and public backlash

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CENTRE FOR BIOMEDICAL ETHICS & LAW KU LEUVEN

This study has been approved by the Social and Societal Ethics Committee of KU Leuven (SMEC), file number C-2025-XXXX.

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Do not litter on public roads.

Thank you! Questions?



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PART 2. Case study



- Case study: SCBEMs in implantation research
- Your task: Evaluate the ethical acceptability of the project

The proposed research

A multidisciplinary team wants to understand implantation failure.

Aim

Understand mechanisms behind unsuccessful implantation and very early pregnancy loss.

Models

Human blastoids and other pluripotent stem cell-based embryo models.

Experimental approach

Culture selected models through early post-implantation-like stages.

Submitted to a Research Ethics Committee for approval

The biological material and consent

Different cell lines, different histories

Lines used

iPSC lines from adult donors and ESC lines initially derived from surplus IVF embryos.

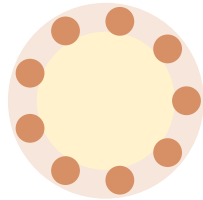
Where they come from

Commercial suppliers and local collaborations with fertility clinics.

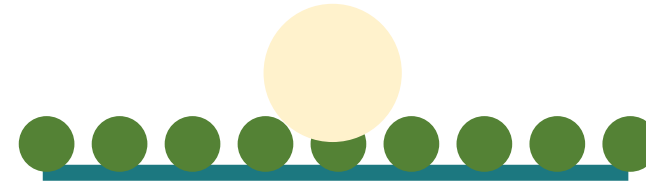
Donors gave broad research consent, sometimes years before SCBEM research existed.

What will the team actually do?

The protocol includes a combination of experimental systems.



Blastoids



Co-culture with endometrial organoids

The ISSCR 2025 approach

Category 2 SCBEM research requires specialised scientific and ethics review.

1

Justify the model

Why this model and not a less complex alternative?

2

Set the endpoint

Which developmental milestones and maximum culture period?

3

Review iteratively

What will be reported, monitored or resubmitted?

A practical REC checklist

Adapted from the CHANGER guidance document

● Scientific justification

Is this model necessary and suitable?

● Developmental scope

How is complexity monitored and bounded?

● Responsible communication

Are claims accurate and proportionate?

● Cell provenance & consent

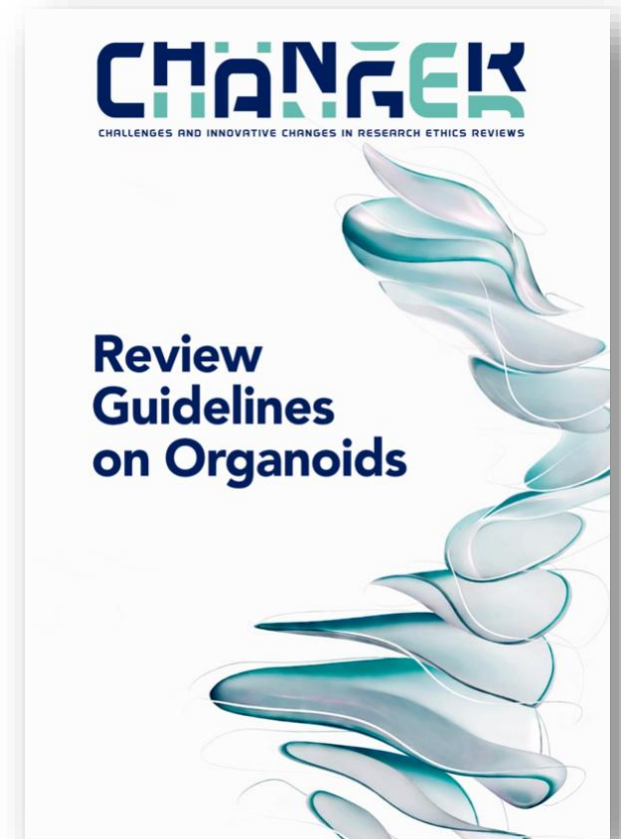
What permissions and restrictions apply?

● Governance & responsibility

Who reviews changes and oversees sharing?

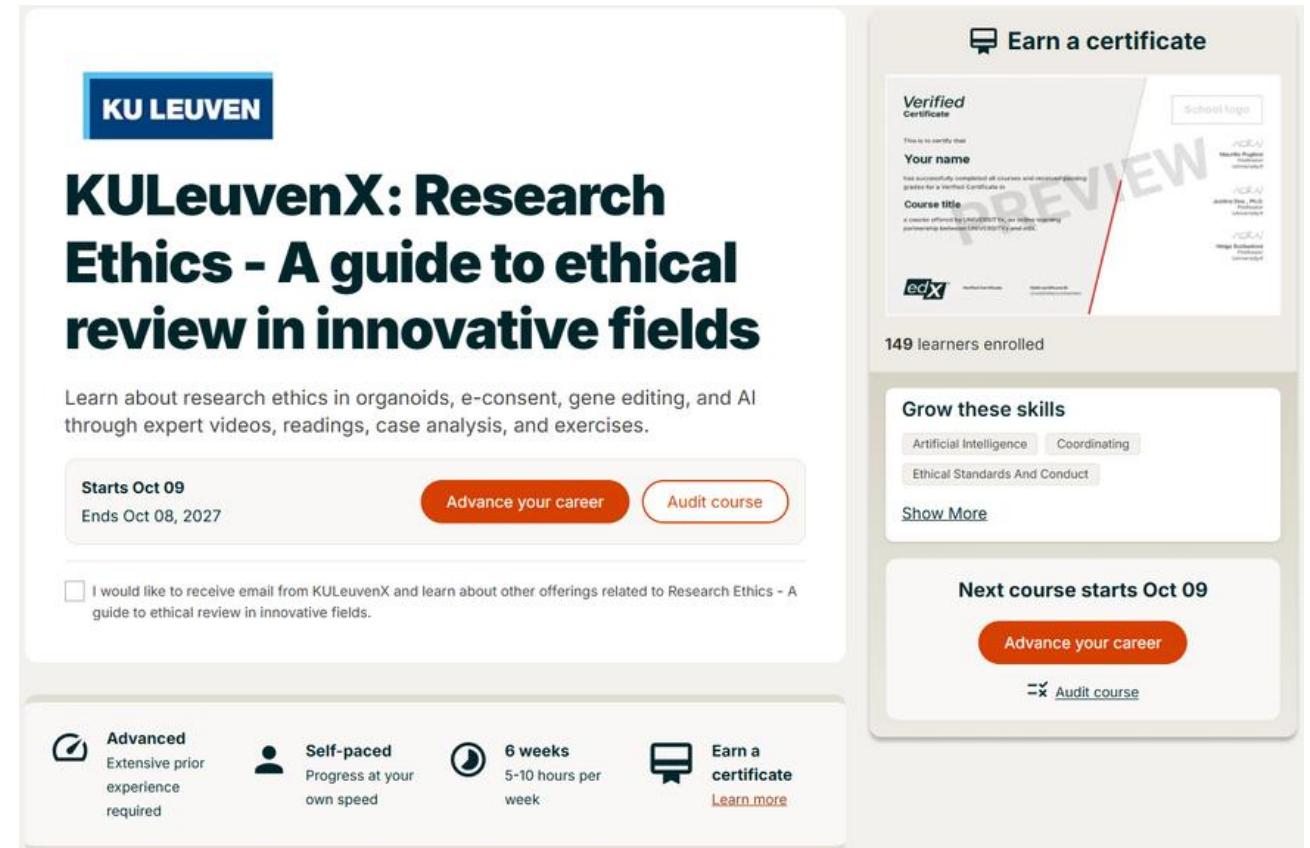
● Public & societal perspectives

How are relevant concerns considered?



Recommendations: Responsible research practices

- Scientific integrity and reproducibility
- Standardization and appropriate validation
- Transparency about model limitations
- Responsible communication without hype
- Commercial interests and conflicts of interest
- Clear institutional responsibilities



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Breakout rooms: You are the REC

01 Scientific justification

Are the model and developmental scope justified?

02 Consent and provenance

Are the donor permissions and cell histories adequate?

03 Governance and safeguards

What is missing for co-culture, sharing and oversight?

04 Decision

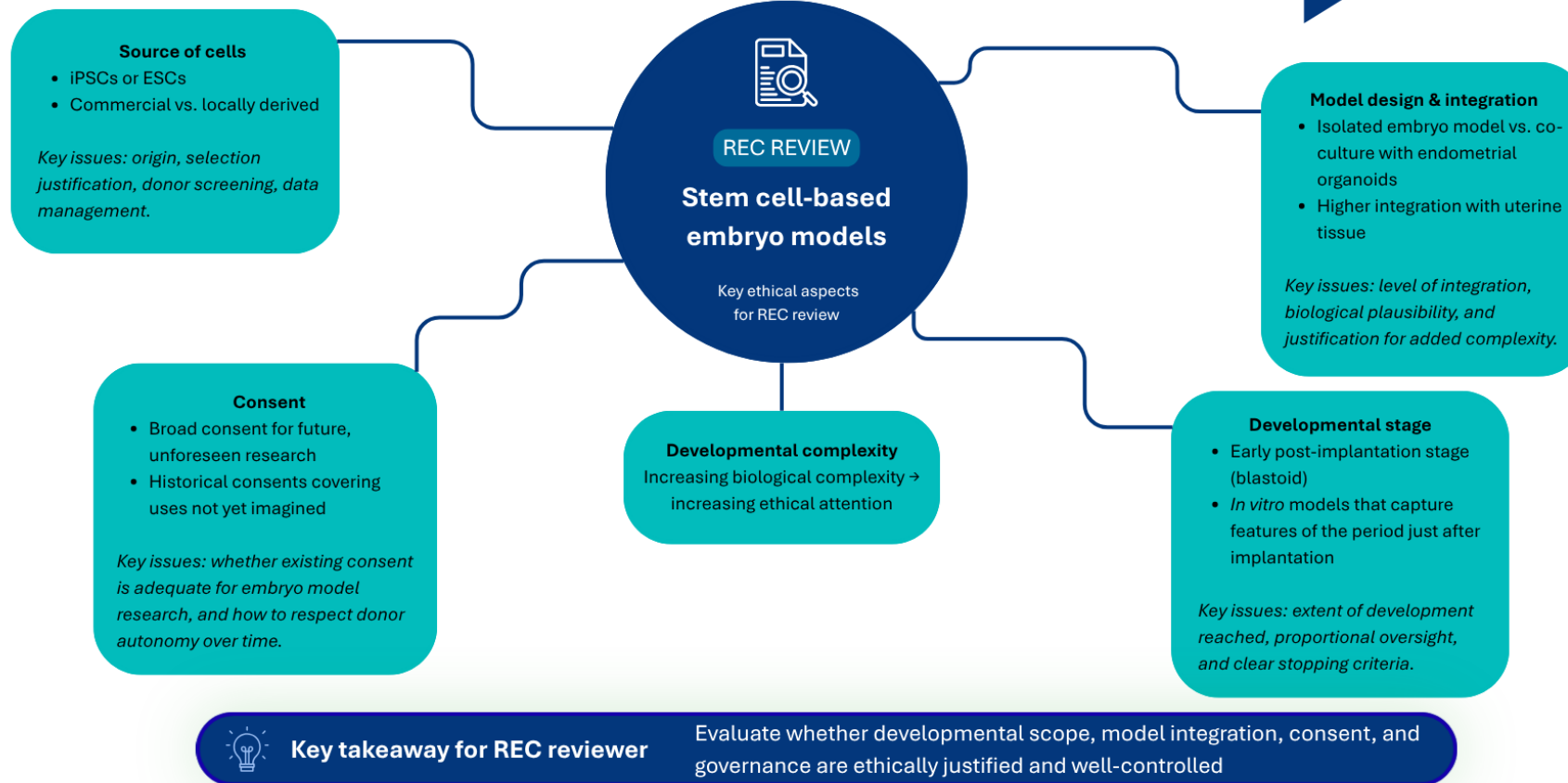
Approve, approve with conditions, request revisions, or reject?

See you in 20 minutes!

Plenary discussion: What would your REC decide?

Human pluripotent stem cells are used to model early post-implantation development

Increasing developmental complexity & ethical attention



- Main ethical concerns identified
- Additional information required
- Recommended safeguards
- Differences between groups

Take-home messages

Responsible oversight means informed, proportionate and revisable review.

- **Know the model** Biological resemblance is not the same as full equivalence.
- **Know the source** Provenance and donor permissions remain relevant after distribution.
- **Know the limits** Justified endpoints and monitoring are essential.
- **Know the pathway** Coordinate specialist oversight, REC review and legal duties.

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