

With in vitro model advances, group proposes refined legal definition of an embryo

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Human Embryo. Credit: Ed Uthman, MD/Wikipedia



Thanks to continuous advances in human stem cell research, studies that make use of embryo models are progressing quickly. This research offers both a scientific and ethical alternative to the use of embryos resulting from fertilized human eggs, and the appropriate ethical guidelines have been developed in parallel with the advances being made.

In a perspective in the August 17 issue of the journal *Cell*, a group of biologists and ethicists suggest additions to the current ethical framework that refine thinking about human embryology using embryo models to maximize benefits to society.

"Stem cell research has enabled the formation of models capable of organizing into structures that rudimentarily resemble embryos and reflect various degrees of completeness and developmental stages," says first author Nicolas Rivron, a development biologist at the Austrian Academy of Sciences.

"These new propositions are part of an effort to bring clarity to ongoing research—to better classify the types of structures formed in the laboratory, to refine the legal definition of human embryos, and to pinpoint what currently makes models and embryos different from the legal standpoint."

These new propositions build on the latest <u>formal guidelines</u> from the International Society for Stem Cell Research (ISSCR), which were issued in 2021 and dealt with emerging advances in the field, including stem cell-based embryo models, human embryo research, chimeras, organoids, and genome editing. Discussions about updated guidelines started after mouse embryo models were formed, in anticipation of major advances in human counterparts.



"It's important to frequently refine these ethical guidelines and gradually adapt ethical oversights as science advances," Rivron says. "Here, we propose a refined definition of the human embryo that focuses on what it can become rather than how it came to be. This definition allows us to think about the conditions under which models, if improved, might eventually pass a tipping point and be legally considered embryos."

The authors propose this definition to be "a group of human cells supported by elements fulfilling extra-embryonic and uterine functions that, combined, have the potential to form a fetus." They note that <u>current models</u> do not meet legal definitions, but that it's important to define how to evaluate whether they have passed that tipping point in the future.

Decisions about how to regulate embryo research are guided by <u>scientific societies</u> but are ultimately the responsibility of local authorities. "Some nations ask their ethical committees to adapt or implement the ethical guidelines as established by scientific societies without legislating, while others prefer to engrave decisions in a regulatory context, for example the UK's rule that restricts the culturing of embryos to 14 days," Rivron says. "Different approaches allow for a different level of flexibility as science progresses."

In addition, the authors also reiterate that, according to the ISSCR's Fundamental Principles, it is the duty of scientists to ensure accurate public understanding and perception of human embryology using embryo models.

"Appropriate, trustworthy, and timely public communication is necessary," Rivron says. For the structures currently being formed, the terms "embryo models," "embryonic models," and "stem cell-derived embryo models" are preferable to the term "synthetic embryos," which could imply that synthetic elements are being used, rather than the



natural cells and developmental programs that are at play.

"The reality is that these embryo models cannot form neonates, but they help us fill an important knowledge gap in our basic understanding of how humans form—something that is normally hidden in the womb," he says.

"We hope that in the future this knowledge will benefit society by supporting the development of medicines to combat infertility and early pregnancy loss and by leading to a better understanding of the origins of congenital malformations and diseases. The field is still in its infancy, but it is opening important and previously inaccessible avenues for science, ethics, and medicine."

More information: Nicolas C. Rivron, An ethical framework for human embryology with embryo models, *Cell* (2023). DOI: 10.1016/j.cell.2023.07.028. www.cell.com/cell/fulltext/S0092-8674(23)00807-3

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