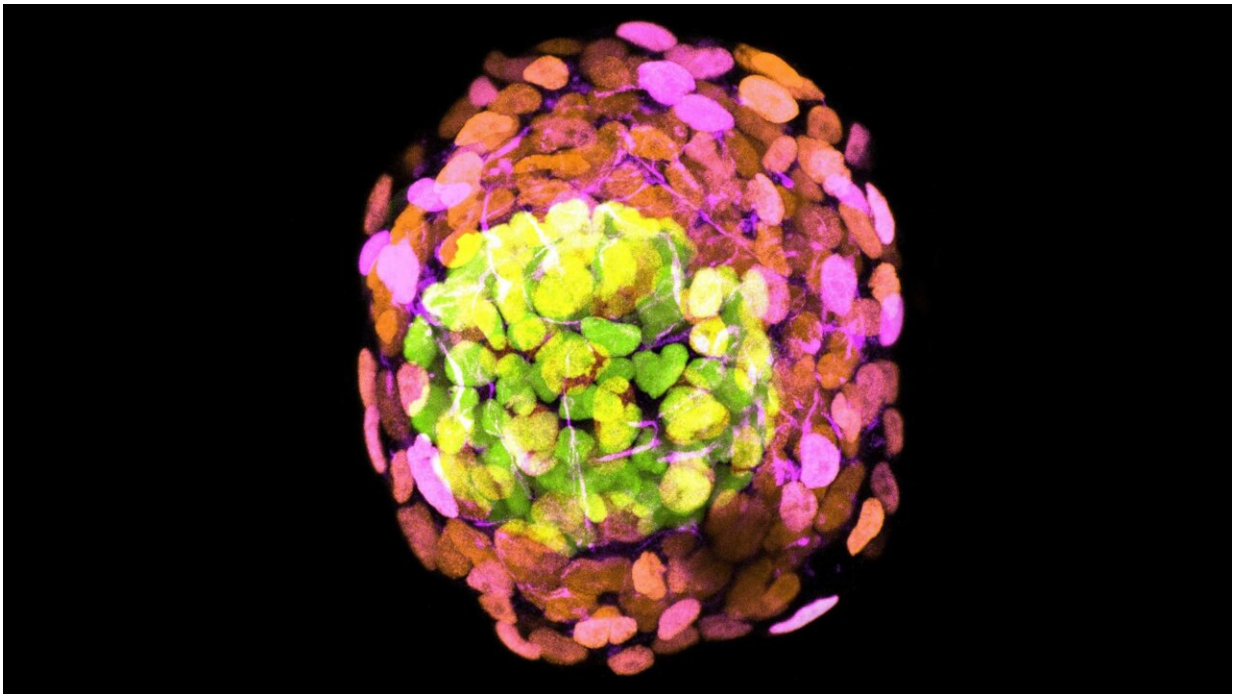


# Q&A: Research with embryo models needs legal clarity

July 24 2023, by Fabio Bergamin

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Caltech and University of Cambridge professor Magdalena Zernicka-Goetz's human embryo model on day 4. Credit: University of Cambridge

Science often runs ahead of legislation—and this is now also true for research on embryo-like cell aggregates from human stem cells. Bioethicist Alessandro Blasimme of ETH Zurich explains why this controversial topic calls for legal clarity.

As publicly announced in June, three research teams from the U.K., the U.S. and Israel have independently succeeded in developing cell aggregates from human stem cells that very closely resemble the early human embryo.

These cell aggregates are considered the most faithful embryo models ever created. What's new about them is that human embryonic development can be initiated using cells other than gametes (ova and sperm); these embryo models are created from a single person's stem cells. Now the question is whether they should be used in research.

After all, research on real human embryos is ethically controversial and tightly restricted in many countries. Research on these new models, on the other hand, is not yet regulated by law in many countries. Ethicist Alessandro Blasimme of ETH Zurich has been studying ethical issues in biomedicine for years. In a recent study published in the journal *Cell Stem Cell*, he specifically addressed the new embryo models derived from human stem cells.

## **ETH News: Why are these embryo models significant to science?**

Alessandro Blasimme: We still know very little about the first phases of human embryonic development. Since research in this field is highly regulated in many countries, embryo models offer scientists a close alternative for studying embryonic development and also relevant problems that may occur in early pregnancy.

For instance, how does an embryo implant in the uterus, and why are spontaneous miscarriages relatively common during this stage of pregnancy? Ultimately, such research could also lead to treatments for couples who are otherwise unable to have children. These extremely

accurate models enable scientists to study embryonic life in a way that was simply not possible before.

**In some countries, researchers are allowed to use real human embryos up to 14 days old. So far, the novel embryo models haven't been kept in culture for more than 14 days either. What's the benefit of these models when you can also do research on real embryos?**

The researchers who developed human embryo models kept them in culture up to eight days probably due to current experimental limitations. Presumably, however, such embryo models will soon permit researchers to observe much later stages of embryogenesis.

Two of the research groups involved in these experiments, were recently able to generate mouse embryo models from stem cells up to the organogenesis, meaning that they were able to observe a [beating heart](#) develop and a brain emerge in these models. A further benefit is that while natural human embryos are created using ova harvested from women, embryo models don't require human egg cells.

**Is it currently legal in Switzerland to work with human embryo models beyond the 14-day limit?**

Research with embryos is not forbidden in Switzerland but it is strictly regulated. The limit here is seven rather than 14 days. However, the legal definition of what constitutes an embryo in Switzerland is very narrow. The new embryo models are not likely to be included. This means that at the moment working with such models is largely unregulated in Switzerland.

There are different methods for creating such embryo models. In some cases, [human stem cells](#) are genetically modified before being aggregated to form an embryo model. This would likely be prohibited in Switzerland. But there are also methods that don't require genetic engineering.

## **And in other European countries?**

The legal situation—and in particular the definition of an embryo—varies from country to country. The legislation in Austria and Belgium, for example, defines embryos in a broad way that could also cover the new models. This means that the rules that apply to research with human embryo may be interpreted to apply also to embryo models derived from stem cells. In most countries, however, there are significant legal loopholes.

## **What does that mean for science?**

Uncertain frameworks don't produce good science. It would harm publicly funded research if scientists were to exploit legal loopholes. That's all the more true in such a controversial field. Let's not forget that society has been debating the moral and legal status of embryos for decades. And while each country has achieved its own legal framework, the controversy is far from settled.

Legal clarity is important for research. Each country now has to ask itself whether it wants to allow embryo model research. National parliaments need to discuss the issue and then legislate accordingly.

## **What role can your field, bioethics, play here?**

As a society, we need to answer practical questions: Should the law treat

embryo models the same as embryos or not? And should research on these models be allowed and within what boundaries? One of the reasons why we published our study was to stimulate this discussion.

The task of us ethicists is to explore the reasons for and against using such embryo models for research and propose rules that are coherent and acceptable even if there is no definitive societal consensus on the topic. Legal loopholes hurt science. I personally think we should permit [scientific research](#), but with rules that have been publicly discussed and can be accepted by society.

## **What is your opinion? Should the models be treated like real embryos?**

The models are indeed very similar to natural human embryos. And both ethics and legal logic suggest treating like things alike. This doesn't necessarily mean extending existing rules and limitations also to embryo models. But the latest scientific developments are a good opportunity to also reflect on and to clarify existing rules.

**More information:** Alessandro Blasimme et al, Human stem cell-derived embryo models: Toward ethically appropriate regulations and policies, *Cell Stem Cell* (2023). [DOI: 10.1016/j.stem.2023.06.007](https://doi.org/10.1016/j.stem.2023.06.007)

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