

Call to re-examine '14-day rule' limiting in vitro human-embryo research

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Human Embryo. Credit: Ed Uthman, MD/Wikipedia

Bioethicists from Case Western Reserve University School of Medicine and The Hastings Center, working with a research administrator at The Rockefeller University, are proposing a reexamination of an internationally recognized rule limiting in vitro research on human embryos to 14 days post-fertilization. Under the rule, such research is permitted before the cut-off date at 14 days and prohibited thereafter.

In a Comment piece published in the May 4, 2016 online edition of *Nature*, the authors say that what is known as the "14-day rule" has essentially been theoretical until now because scientists have been technologically incapable of moving past the 14-day threshold. But they also note that the rule has produced great benefit by demarcating a clear time period - "a legal and regulatory line in the sand" ? within which [research](#) could take place. Moreover, "[t]he alternatives at each extreme—banning embryo research altogether or imposing no restrictions on embryo use—would not have made for good public policy in a pluralistic society," the team writes.

The call for reappraisal comes as two research groups report sustaining human embryos in vitro up to 14 days. This is the first time anyone has reported culturing human embryos in vitro beyond nine days, and rarely have they been reported as being sustained for more than seven. Along with earlier stem cell work carried out at The Rockefeller University, the new achievements could provide scientists with unprecedented capacity to study early human development, say the authors. At the same time, the advances "are on a collision course with the rule that limits embryo research to the first two weeks."

"We understand that this issue raises profound moral questions and that people have different stances regarding this type of research," said the lead author Insoo Hyun, PhD, associate professor of bioethics and philosophy at Case Western Reserve University School of Medicine and director of the CWRU Stem Cell Ethics Center. "But it is important to

remind ourselves that the 14-day rule was never promoted as a fixed moral truth. Rather, it was designed to achieve a balance between allowing research and acknowledging opposing convictions on the part of many people. Therefore, as circumstances change, reconsideration of the existing limitations is legitimate."

At least twelve countries, including the United Kingdom, Canada, and Australia, have laws that restrict in vitro research on [human embryos](#) to the first 14 days of development. (Switzerland restricts human-embryo cultures to seven days.) In at least five others, including the United States, China, and India, nationally commissioned scientific guidelines stipulate the 14-day rule. Guidelines issued by the International Society for Stem Cell Research for the global research community also uphold the 14-day rule.

In preparing the 14-day rule, hundreds of medical and scientific associations submitted recommendations and dozens of public forums were held. "Any formal changes to the 14-day rule will require consensus-building involving scientists, policymakers and members of the general public," says co-author Amy Wilkerson, associate vice president for research support at The Rockefeller University. "The bioethical considerations are global so any reexamination of the rule should start at an international level. One goal should be to avoid a patchwork of guidelines and regulations that are impediments to collaborative international science."

Co-author Josephine Johnston, LLB, MBHL, director of research at The Hastings Center, notes that a reexamination of the rule need not lead to overturning it. "The 14-day rule was first developed more than 35 years ago, when both the science and the public discussion of embryo research were in different places than they are today. The passage of time alone suggests that a reexamination would be prudent," she says. "We should ask what the rule means for science and policy today, and consider

whether it still fulfills its dual purpose of delineating a space for valuable scientific research while respecting the deeply held views of a diverse society. We do not know where such a reexamination may lead, but we believe it is important to openly consider both the scientific merits of research beyond 14 days and the ethical concerns that such research would raise."

In closing, the authors call on scientists to play an educational role in any debate about the 14-day rule. "Researchers of human developmental biology should engage with the public about what they are doing and why it matters. And they should consider designing their experiments in a way that, while furthering discovery, also addresses people's moral concerns," they write, "to prevent a public backlash and the implementation of reactive, more restrictive limits on research."

More information: *Nature*, [DOI: 10.1038/533169a](https://doi.org/10.1038/533169a)

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