Policy recommendations regarding reproductive technology

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Introduction

Here we list six policies that would help accelerate the development of novel assisted reproductive technologies. Such technologies include mitochondrial donation, in vitro gametogenesis (making eggs and sperm in the lab)[1], artificial wombs, and genetic engineering. These technologies could eventually enable millions of parents to have healthy children, when they otherwise would not be able to. The recommendations listed here are addressed to the United States, though many other jurisdictions could benefit from analogous policies.

CITES treaty

The CITES treaty is meant to protect endangered species by restricting exports (https://en.wikipedia.org/wiki/CITES)[2]. But it also applies to imports of stem cell lines derived from endangered species, which doesn't make sense: importing cell lines doesn't contribute to harming that species. Imports of cell lines to American researchers are key for research, and they are supposed to be approved. However, those imports often get stuck behind a year or more of needless bureaucratic delay.

Waive the CITES restrictions for cell lines, or ensure that cell line imports are automatically and speedily approved.

Ban on genetic modification research

Section 749 of the Consolidated Appropriations Act of 2016 (which was removed and then later restored) forbids the FDA to even allow an exemption for research purposes, for any research "in which a human embryo is intentionally created or modified to include a heritable genetic modification"[3][4]. Closing off all research is not an appropriate stance toward potentially highly beneficial areas, and it effectively bans the use of even well-tested assisted reproductive technologies such as mitochondrial donation. **We suggest that this rider be removed.** If problems arise in the future, regulators can subsequently implement restrictions that are informed by the actual science and technology.

[1] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy. In Vitro–Derived Human Gametes as a Reproductive Technology: Scientific, Ethical, and Regulatory Implications: Proceedings of a Workshop. Edited by Katherine Bowman, Chanel Matney, and Emily Packard Dawson. Washington (DC): National Academies Press (US), 2023. http://www.ncbi.nlm.nih.gov/books/NBK599671/.

[2] '50 CFR Part 23 – Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)'. Accessed 22 May 2025. https://www.ecfr.gov/current/title-50/part-23.

[3] Consolidated Appropriations Act, 2016, section 749. https://www.congress.gov/114/plaws/publ113/PLAW-114publ113.pdf.

[4] Matthews, Kirstin R W, and Daniel Morali. 'Can We Do That Here? An Analysis of US Federal and State Policies Guiding Human Embryo and Embryoid Research'. Journal of Law and the Biosciences 9, no. 1 (9 June 2022): lsac014. https://pmc.ncbi.nlm.nih.gov/articles/PMC9183789/.

Dickey-Wicker Amendment

Repeal the Dickey-Wicker rider[5], which prohibits federal funding for research on human embryos[6]. This research area is crucial to address fertility problems, and would be an excellent investment for the US.

The 14-day rule for embryos

In response to the first birth via IVF, a principle was put forward: embryos shouldn't be grown in vitro for longer than 14 days. This principle has turned into various laws in many countries, including some US states. However, the 14-day rule prevents research on the crucial third and fourth weeks of development. In order to assess the safety of assisted reproductive technologies, scientists have to study what development looks like in embryos created through simple IVF and through more novel technologies.

Recently it has been argued that the 14-day rule should be changed to the 28-day rule, allowing embryos to be grown up to four weeks in vitro[7]. Four-week embryos still lack the neural basis to feel pain, but exhibit scientifically important early developmental changes. The ISSCR's 2021 guidelines for stem cell research suggest that, with proper review, it may be worth it to extend the permitted culture length[8][9].

Change the 14-day rule for embryo research to the 28-day rule. There's no US federal ban on longer culturing, but some states restrict such research.

Proactive regulatory standards

The FDA is highly reactive when it comes to working with innovators. The FDA won't say "Here are broad conditions under which we could accept a novel assisted reproductive technology.". Instead they say "Come back when you've done some kind of study that you think should demonstrate safety, and then we'll tell you whether we think that study could possibly have demonstrated safety.". While it's understandable that the FDA can't talk to everyone under the sun about every hypothetical medical treatment, this is not a good environment for innovation. **We propose that the FDA institute a policy of proactively describing reasonable conditions for safety demonstrations**, whenever there is a substantial cohort of scientists and entrepreneurs who are working toward some novel treatment.

Primate research center

There are several primate research centers. For example, the US has seven National Primate Research Centers, doing research in a wide variety of areas, such as disease, drugs, somatic gene therapy, stem cell treatments, neuroscience, and behavior. The Oregon NPRC provides some research services in rhesus reproduction (https://www.ohsu.edu/onprc/assisted-reproductive-technology-art-core).

However, not much of NPRC research is aimed at making fast progress on reproductive science, and existing primate centers can't meet the needs of cutting edge reprotech research. That would require a readiness to quickly test and monitor novel assisted reproductive technologies. For example, in vitro oogenesis methods will have to be tested in primates to monitor for any developmental abnormalities. An especially neglected need is to build an epigenetic atlas of non-human primate embryos using single-cell RNA sequencing. Such an atlas would make it possible to compare the results of novel ARTs to a reference path of embryonic development.

We propose a new primate research center focused on studying primate reproduction and testing novel assisted reproductive technologies.

References

[5] '45 CFR Part 46 Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research'. Accessed 22 May 2025. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-B.

[6] Matthews, Kirstin R W, and Daniel Morali. 'Can We Do That Here? An Analysis of US Federal and State Policies Guiding Human Embryo and Embryoid Research'. Journal of Law and the Biosciences 9, no. 1 (9 June 2022): lsac014. https://pmc.ncbi.nlm.nih.gov/articles/PMC9183789/.

[7] Appleby, John B, and Annelien L Bredenoord. 'Should the 14-day Rule for Embryo Research Become the 28-day Rule?' EMBO Molecular Medicine 10, no. 9 (September 2018): e9437. https://pmc.ncbi.nlm.nih.gov/articles/PMC6127884/.

[8] Lovell-Badge, Robin, Eric Anthony, Roger A. Barker, Tania Bubela, Ali H. Brivanlou, Melissa Carpenter, R. Alta Charo, et al. 'ISSCR Guidelines for Stem Cell Research and Clinical Translation: The 2021 Update'. Stem Cell Reports 16, no. 6 (27 May 2021): 1398–1408. https://pmc.ncbi.nlm.nih.gov/articles/PMC8190668/.

[9] 'ISSCR Guidelines for Stem Cell Research and Clinical Translation, Version 1.1, May 2021', 2021. https://static1.squarespace.com/static/611faaa8fee682525ee16489/t/62ed69b184e2ed258e6eb7e4/1659726257773/isscr-guidelines-for-stem-cell-research-and-clinical-translation-2021.pdf, https://www.isscr.org/guidelines.