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# Embryonic Personhood and Scientific Research Following the Alabama Supreme Court Decision on In Vitro Fertilization

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The Supreme Court of Alabama reached a landmark decision in *LePage, et al. v. Center for Reproductive Medicine*, affirming the legal personhood of embryos under Alabama law.<sup>[1]</sup> Among the consequences that might come from granting embryos legal personhood, commentators have focused on the effect of this decision on the practice of *in vitro* fertilization (IVF). Immediately following the decision, multiple IVF clinics announced the temporary cessation of services within Alabama, and state and federal legislators rushed to introduce legislation to protect IVF.<sup>[2]</sup> While analysis has understandably focused on access to IVF, the *LePage* ruling and the subsequent political attention to embryonic personhood also has the potential to significantly affect scientific research that relies on IVF-derived embryos, such as for the creation of human stem cell lines. Those involved in

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human embryonic research should keep abreast of legal updates and take appropriate steps to remain compliant with evolving law, as discussed below.

## Legal Context

In *LePage*, plaintiffs sought relief for negligence related to the accidental destruction of their cryopreserved IVF-derived embryos. Plaintiffs sought relief under Alabama’s Wrongful Death of a Minor Act, which the court previously had held to apply to fetuses *in utero*, even prior to viability.<sup>[3]</sup> In the *LePage* decision, the court held that an “extrauterine” embryo, fertilized *in vitro*, stored frozen, and never implanted likewise constitutes a minor child subject to protection under this act. The court noted that it was unwilling to draw boundaries on personhood based on whether an embryo is or is not *in utero*.<sup>[4]</sup>

Alabama is the first state to see landmark litigation affirming embryonic personhood, but various other states have related laws defining embryonic personhood. Louisiana, for example, statutorily defines an IVF-derived embryo as a “juridical person until such time as . . . [it] is implanted in the womb,” which “shall not be intentionally destroyed.”<sup>[5]</sup> An IVF-derived embryo unclaimed by parents in Louisiana should, under these statutes, receive the guardianship of a physician or a court-appointed curator.<sup>[6]</sup> In fact, prior to the *LePage* ruling, Louisiana was cited by at least one court as the only state in which parents who pay for embryonic cryopreservation do not necessarily have the ultimate right to determine how those embryos are disposed.<sup>[7]</sup>

Some state laws have limited definitions of embryonic personhood that allow safe harbors for IVF and embryonic research. One example is Arizona’s public health statutes, which define a human embryo as a “living organism of the species homo sapiens . . . excluding any time during which its development has been suspended.”<sup>[8]</sup> Similarly, Massachusetts law prohibiting experimentation on live human fetuses includes embryos in this category, but does not include pre-implantation embryos, such as those created by IVF.<sup>[9]</sup>

Lastly, some states have explicitly disclaimed embryonic personhood. Tennessee, for instance, has held that early-stage embryos are neither persons nor property, but occupy an “interim category.”<sup>[10]</sup> Ohio has gone further and held that frozen embryos are property.<sup>[11]</sup> Illinois, as well as other states, has heard a case closely analogous to *LePage* but ruled opposite to the Alabama decision, holding that cryopreserved early-stage embryos do not constitute persons in the context of wrongful death lawsuits.<sup>[12]</sup>

In the federal context, the U.S. Supreme Court has ruled in favor of exemptions to mandatory employer health insurance coverage of contraceptives based on personal beliefs including those regarding embryonic personhood but has not ruled on the matter of embryonic personhood itself.<sup>[13]</sup> As the ruling in *Dobbs v. Jackson Women’s Health Organization* left authority over abortion law to the states, the question of embryonic personhood has likewise been left to the states so far.<sup>[14]</sup>

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## Research Regulations

Federal regulations on human subjects research, known colloquially as the Common Rule, apply to research involving human subjects conducted or supported by most federal departments and agencies. These regulations define a “human subject” as a “living individual about whom an investigator . . . obtains information or biospecimens through intervention or interaction with the individual . . . or . . . obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”<sup>[15]</sup> These regulations do not include embryos under the definition of “human subject.” The George W. Bush administration took steps towards doing so, and then-current Department of Health and Human Services (HHS) guidance referenced that some research involving embryonic cells could constitute human subjects research.<sup>[16]</sup> However, HHS shifted away from this characterization in 2002 to the current stance, in which parent donors of an embryo or a patient recipient of embryonic cells may be considered a human subject, but not an embryo itself.<sup>[17]</sup>

Notably, federal funds may not be used for research that destroys an embryo or subjects it to “risk of injury or death greater than that allowed for research on fetuses in utero,” which leans towards personhood.<sup>[18]</sup> This does not, however, speak directly to the treatment of an embryo under the Common Rule, which instead would fall under OHRP’s 2002 guidance discussed above.

HHS maintains additional regulations on human subjects research involving pregnant women, fetuses, and neonates (Subpart B).<sup>[19]</sup> There are no references to embryos in Subpart B, and fetuses are defined in the regulations as “the product of conception from implantation to delivery.”<sup>[20]</sup> IVF-derived extrauterine embryos, therefore, are not subject to Subpart B protections as human subjects.<sup>[21]</sup> Indeed, while these regulations provide specific rules for research involving a living fetus *in utero* and also reference research involving material derived from a dead fetus post-delivery, the regulations do not account for the legal or biological possibility of a “living” extrauterine embryo or fetus.

Beyond federal regulations, the National Institutes of Health (NIH) and the National Academies of Science provide guidelines for embryonic stem cell research, both of which operate under the assumption that adults, with informed consent, can freely donate for research purposes any embryos that were created using IVF that are no longer needed for reproduction.<sup>[22]</sup> Neither of these sets of guidelines consider the possibility of legal embryonic personhood.

## Effect on Research

The Defendants in *LePage* unsuccessfully argued that extrauterine embryos should be considered property, claiming that this was implied by the contracts that the Plaintiffs had

executed with the IVF clinic.<sup>[23]</sup> Federal research regulations operate under a similar assumption; that embryos created by IVF which are no longer needed for reproductive purposes may be used for research purposes with informed consent of the parent(s). Research that relies on human embryo donations, such as the creation of new human embryonic stem cell lines, also relies on these assumptions. The *LePage* ruling casts these assumptions into question.

Researchers and institutions that work with embryonic tissue within Alabama or that source embryonic tissue from Alabama may determine that it is prudent to cease doing so, at least temporarily, as several IVF clinics did with respect to the creation of embryos. Under the *LePage* ruling, destruction of a donated embryo for research purposes may constitute the death of a child, with the potential for legal consequences. Contractual agreements and consent forms to donate embryos also will have to be reconsidered, as the *LePage* ruling demonstrates that legal documents treating embryos as property are not necessarily compliant with the new legal regime in Alabama.

In response to *LePage*, the Alabama legislature has acted rapidly to protect IVF. A newly enacted Alabama law immunizes persons and entities from civil or criminal action for damage to or death of an embryo “when providing or receiving goods or services related to in vitro fertilization.”<sup>[24]</sup> This law does not mention embryonic research, nor whether research involving IVF-derived and donated embryos would fall under the umbrella of “related to in vitro fertilization.”<sup>[25]</sup> This omission leaves researchers and research institutions potentially vulnerable to suit under the *LePage* precedent. Beyond Alabama, other states, particularly those with embryonic personhood laws (such as Louisiana), also may see litigation- or legislative-based challenges to the donation and use of human embryos in research. Federal human subjects research regulations would not immunize researchers against this, as these regulations do not preempt state law and, in fact, mandate compliance with applicable state laws.<sup>[26]</sup>

## Recommendations for Researchers

Researchers making use of human embryonic tissue should prepare for potential constraints on embryonic tissue sourcing as legal regimes and health care providers react to *LePage*. Research institutions should keep abreast of evolving state laws regarding embryonic personhood and should revisit their current procurement practices, contractual agreements, and consent forms to determine whether any immediate adjustments are needed. Institutions should consider potential legal risks to themselves, their researchers, and their donors, including applicable tolerance for such risk. Researchers and research institutions engaged in work with embryonic tissue also should prepare for the possibility of reputational harms and ideological challenges to their research as courts and legislatures consider and debate embryonic personhood.

## About the Authors

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<sup>[1]</sup> *LePage v. Ctr. Reprod. Med.*, No. SC-2022-0515, 22 (Ala. 2024).

<sup>[2]</sup> Aria Bendix, *Three Alabama Clinics Pause IVF Services after Court Rules that Embryos are Children*, NBC NEWS (Feb. 22, 2024), <https://www.nbcnews.com/health/health-news/university-alabama-pauses-ivf-services-court-rules-embryos-are-children-rcna139846>; S.B 159, 2024 Reg. Sess. (Ala. 2024) (having been signed into law by the Governor on March 6, 2024); Nomia Iqbal & Alex Lederman, *Alabama's Legislature Pushes to Protect IVF after Court Ruling*, BBC NEWS (Feb. 27, 2024), <https://www.bbc.com/news/world-us-canada-68414148>; Alice Ollstein, *Senate Dems Set Up IVF Showdown*, POLITICO (Feb. 27, 2024), <https://www.politico.com/news/2024/02/27/senate-democrats-ivf-tammy-duckworth-00143535>.

<sup>[3]</sup> ALA. CODE § 6-5-391; *Mack v. Carmack*, 79 So. 3d 597, 611 (Ala. 2011).

<sup>[4]</sup> *LePage*, No. SC-2022-0515, 18–21 (Ala. 2024) (noting, however, that the court's ruling does not extend the state's homicide statutes to embryos).

<sup>[5]</sup> LA. REV. STAT. §§ 9:123 & 9:129.

<sup>[6]</sup> LA. REV. STAT. § 9:126.

<sup>[7]</sup> *In re Estate of Desta*, No. PR-12-2856-1, 2014 WL 12837825, at \*3 & \*3 n.5 (Tex. Prob. Ct.).

<sup>[8]</sup> ARIZ. REV. STAT. § 36-2311(3).



- <sup>[9]</sup> MASS. GEN. LAWS ch. 111L § 2 and ch. 112 § 12J(a)(I).
- <sup>[10]</sup> *Davis v. Davis*, 842 S.W. 2d. 588, 594 (Tenn. 1992).
- <sup>[11]</sup> *Kotkowski-Paul v. Paul*, 204 N.E. 3d. 66, 76 (Ohio App. Ct. 2022).
- <sup>[12]</sup> *Miller v. Am. Infertility Grp.*, 6 Ill. App. 3d 141, 144 (Ill. App. Ct. 2008).
- <sup>[13]</sup> See, e.g., *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 724 (2014).
- <sup>[14]</sup> *Dobbs v. Jackson Women’s Health Organization*, 142 S. Ct. 2228 (2022).
- <sup>[15]</sup> 45 C.F.R. § 46.102(e).
- <sup>[16]</sup> Marlene Cimon, *Embryos To Be Treated As Human Subjects*, 8(12) NATURE MED. 1338 (2002); DEP’T HEALTH HUMAN SERVS., GUIDANCE FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS REGARDING RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS (Nov. 16, 2001), <https://www.hhs.gov/ohrp/sites/default/files/ohrp/archive/references/HESCGuidance.pdf>.
- <sup>[17]</sup> DEP’T HEALTH HUMAN SERVS., HUMAN EMBRYONIC STEM CELLS: OHRP GUIDANCE (2002), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html> (noting that research on cells with information linking them to their donors is considered human subjects research due to the involvement of “identifiable private information,” thus making the donors human subjects).
- <sup>[18]</sup> Pub. L. No. 117-328, § 508, 136 Stat. 4909 (2022) (renewing the Dickey-Wicker Amendment restricting federal funding for embryo research, which has continued to appear on appropriations bills since 1996); NAT’L INST. HEALTH, 4.2.5 HUMAN EMBRYO RESEARCH AND CLONING BAN, [https://grants.nih.gov/grants/policy/nihgps/html5/section\\_4/4.2.5\\_human\\_embryo\\_research\\_and\\_cloning\\_ban.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.2.5_human_embryo_research_and_cloning_ban.htm) (last visited Feb. 29, 2024); HEALTH HUMAN SERVS., OHRP GUIDANCE (2002), *supra* note 17.
- <sup>[19]</sup> 45 C.F.R. Part 46, Subpart B.
- <sup>[20]</sup> 45 C.F.R. § 46.202(c).
- <sup>[21]</sup> 45 C.F.R. § 46.202. See also 66 Fed. Reg. 56775, 56777 (Nov. 13, 2001) (regarding public comments on the Common Rule, noting that HHS is apparently satisfied with the current status of embryos in the context of human subjects research: “[C]ommenters stated that language from HHS appropriations statutes regarding research involving embryos should be incorporated into the regulations and that either a definition of ‘embryo’ should be added to the regulations or the definition of ‘fetus’ should be revised . . . The Department finds that the current definition of fetus contained in the regulations appropriately includes embryos in utero, and that research involving embryos is otherwise adequately addressed by existing statutory requirements.”).
- <sup>[22]</sup> See NAT’L INST. HEALTH, NIH GUIDELINES FOR HUMAN STEM CELL RESEARCH, <https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research> (last visited Feb. 26, 2024); NAT’L RSCH. COUNCIL., FINAL REPORT OF THE NATIONAL ACADEMIES’ HUMAN EMBRYONIC STEM CELL RESEARCH ADVISORY COMMITTEE 10 & 11 (2010).
- <sup>[23]</sup> *LePage*, No. SC-2022-0515, 23–24 (Ala. 2024).
- <sup>[24]</sup> See S.B 159, 2024 Reg. Sess. (Ala. 2024) (having been signed into law by the Governor on March 6, 2024); see also Iqbal & Lederman, *supra* note 2.
- <sup>[25]</sup> S.B 159, 2024 Reg. Sess. (Ala. 2024). See also Lauren Mascarenhas & Isabel Rosales, *Alabama Clinics Resume Treatment Under New IVF Law*, CNN (Mar. 7, 2024), <https://www.cnn.com/2024/03/06/us/alabama-ivf-fertility-protection/index.html> (quoting multiple Alabama legislators, as well as the Governor, as stating that the law is a “temporary” and incomplete response to the issue of embryonic personhood).
- <sup>[26]</sup> 45 C.F.R. §§ 46.101(f) & 46.206.