Ethical and Legal Obligations for Research Involving Pregnant Persons in a Post-*Dobbs* Context

Richard M. Weinmeyer,[1,2] *Seema K. Shah,*[2,3] *and Michelle L. McGowan*[4]

1: DEPAUL UNIVERSITY COLLEGE OF LAW, CHICAGO, IL, USA; 2: NORTHWESTERN UNIVERSITY, CHICAGO, IL, USA; 3: LURIE CHILDREN'S HOSPITAL, CHICAGO, IL, USA; 4: MAYO CLINIC, ROCHESTER, MN, USA.

Keywords: Research Ethics and Regulation, Abortion, Pregnancy, Human Subjects Research, and Health Law

Abstract: In light of a history of categorical exclusion, it is critical that pregnant people are included in research to help improve the knowledge base and interventions needed to address public health. Yet the volatile legal landscape around reproductive rights in the United States threatens to undue recent progress made toward the greater inclusion of pregnant people in research. We offer ethical and practical guidance for researchers, sponsors, and institutional review boards to take specific steps to minimize legal risks and ensure the ethical conduct of research with pregnant people in an evolving legal environment.

Introduction

Even before *Dobbs v. Jackson Women's Health Organization* eliminated the right to abortion under the U.S. Constitution, states actively regulated reproduction. Some states enacted pernicious laws and reinterpreted existing criminal codes to punish pregnant people and those who have lost a pregnancy, often based on tenuous theories connecting substance use during pregnancy to fetal demise, as other articles in this symposium explore.[1] While a growing body of scholarship explores the instability generated by *Dobbs*, there has been insufficient focus on the decision's effects on research with pregnant people.

Although research is unlikely to be top of mind for lawmakers and judges restricting reproductive rights, their actions have an undeniable impact on research activities that include women and people capable of pregnancy. Women were almost entirely excluded from biomedical research for decades, and while significant gains have been made in recent years, pregnant people have been kept at arm's length from the research enterprise.[4] Now the precarity of reproductive rights and greater focus on fetal life (sometimes prioritized over maternal health) threatens the movement towards greater research inclusion. No one is rendered immune from diseases simply because they are pregnant, and for many serious conditions, treatment is the best approach for both the pregnant per-

Richard M. Weinmeyer, J.D., Ph.D., *is with DePaul University College of Law and Northwestern University;* **Seema K. Shah, J.D.**, *is with Lurie Children's Hospital and Northwestern University;* **Michelle L. McGowan, Ph.D.**, *is with the Mayo Clinic.*

The Journal of Law, Medicine & Ethics, 51 (2023): 504-510. © 2023 The Author(s)
DOI: 10.1017/jme.2023.95

son and the fetus. In fact, most people take at least one medication during pregnancy.[5] However, pregnancy causes the body to process some therapies in radically different ways, and some medications have teratogenic effects.[6] Yet from 2000–2010, 97.7% of drugs approved by the FDA had "undetermined" risk of causing harm to the fetus, and over 70% had no safety data about their use in pregnancy.[7] Including pregnant people in research can increase our understanding of the impact of medications and licit and illicit substances used during pregnancy. But in a nation where law and policy are radically altering how maternal health and safety are balanced with fetal life, how to include pregnant people in research without exposing them to heightened legal risk has become much less clear.

This article is intended to provide guidance to researchers, sponsors, and institutional review boards (IRBs). Part I provides an overview of the history of research with pregnant people, highlighting recent progress towards greater inclusion. Part II discusses the evolving ethical and legal implications that researchers face. Here we provide an example of a multi-state study that is conducting research with pregnant people, and the dangers that lie ahead for researchers navigating a rapidly evolving legal landscape. In Part III, we provide four recommendations for the ethical conduct of research in this evolving legal landscape.

The ongoing legal battle over reproductive rights could have several immediate implications for research. Scientists, research participants, and the research ethics and compliance community face increasingly complex scenarios in which to study pregnant persons, and the heightened possibility of liability and even criminal prosecution for abortion and fetal harm may chill important scientific advancements. This is especially true for research with pregnant people that may involve highly sensitive topics, like substance abuse or criminal conduct, but that are nonetheless important to study. Therefore, it is incumbent upon these parties to prepare for the ethical and legal challenges that lie ahead in an uncertain political landscape, while recognizing that research with pregnant people is sorely needed.

This article is intended to provide guidance to researchers, sponsors, and institutional review boards (IRBs). Part I provides an overview of the history of research with pregnant people, highlighting recent progress towards greater inclusion. Part II discusses the evolving ethical and legal implications that researchers face. Here we provide an example of a multi-state study that is conducting research with pregnant people, and the dangers that lie ahead for researchers navigating a rapidly evolving legal landscape. In Part III, we provide four recommendations for the ethical conduct of research in this in this legal environment.

I. Research and Pregnancy

For much of U.S. history, women of reproductive age and pregnant people have been categorically excluded from participating in research.[8] This is both because of a presumed universalization of the "normal" male body in biomedical research,[9] but also because of several tragedies. In the late 1950s, the drug Thalidomide was sold internationally to ease morning sickness symptoms.[10] But by 1961, the drug was pulled from the marketplace after over 10,000 children globally were born with birth defects, linked to thalidomide use by women during their pregnancies.[11] Similarly, from 1940 to 1971, doctors prescribed Diethylstilbestrol (DES) to millions of pregnant women because the synthetic nonsteroidal estrogen was believed to lower the risk of pregnancy complications and miscarriages. Tragically, the daughters of women who had taken DES while pregnant have increased risk for developing rare cervical and vaginal cancers, reproductive tract deformities, ectopic pregnancies, pre-term deliveries, and infertility.[12] The horror of thalidomide and DES fed into an already cautious culture surrounding enrolling pregnant people in research.

This hesitancy ultimately endangers pregnant people, however, by failing to consider what is necessary to protect them as a group. Without appropriate data on and insight into the physiological state of the pregnant body, researchers, clinicians, and pregnant

The Journal of Law, Medicine & Ethics, 51 (2023): 504-510. © 2023 The Author(s)

patients are forced to make decisions about interventions without evidence. Public health emergencies have laid bare this fact. After September 11th and the anthrax attacks that followed, the American College of Obstetrics and Gynecologists (ACOG) recommended that pregnant women take amoxicillin as post-exposure prophylaxis.[13] A 2007 study revealed that the ACOG-recommended dose of the antibiotic would have been unachievable in pregnant people because of the increased metabolism of the drug during pregnancy.[14] In the COVID-19 pandemic, pregnant people were excluded from the initial vaccine research, resulting in confusing and contradictory guidance on whether pregnant people should be vaccinated.[15] This likely led to higher rates of morbidity and mortality in pregnant people and fetuses.[16]

For several years, bioethicists have urged the importance of realizing the principle of justice in research with respect to pregnant people, in part by providing sorely-needed benefits from research for this population.[17] In particular, Lyerly and colleagues have explained that three conceptual shifts are needed for pregnant people in research: (1) seeing pregnant people as "complex" instead of "vulnerable," (2) protecting them *through* research rather than *from* research, and (3) shifting the default of presumptive exclusion to fair inclusion.[18] They point out that, unlike children and adults with serious cognitive disabilities, pregnant people have the capacity to consent. They are not categorically more vulnerable to exploitation or coercion, unlike people who are incarcerated. Thus, the classic protections for vulnerable populations are unhelpful for considering the inclusion of pregnant people in research.

This work has had tremendous impact. Lawmakers have taken proactive steps to address research inequities. In 2016, the World Health Organization's Council for International Organizations for Medical Sciences issued new ethical guidelines that stopped using the term "vulnerable" to characterize pregnant people.[19] Around the same time, the 21st Century Cures Act created a Task Force on Research Specific to Pregnant Women and Lactating Women. The task force was established to advise the Secretary of the Department of Health and Human Services on "identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women."[20] Fifteen recommendations were published by the Task Force in 2018. These included reducing liability to expand the evidence base for the development of therapeutics for people who are, or may become, pregnant, and developing programs to support research on conditions specific to pregnant and lactating people.[21] Furthermore, in 2018, revisions to the Common Rule resulted in pregnant participants no longer being deemed a vulnerable population.[22] Ultimately, conceptual shifts undergirding more inclusive approaches to regulation of research will likely lead to better health outcomes for pregnant people and children.

II. Ethical & Legal Implications for Research with Pregnant People

In general, researchers have ethical obligations based on the ethical principle of beneficence, the obligation to act to benefit others and prevent harm to them.[23] In research, beneficence is typically understood to require that researchers minimize risks for participants and communities and enhance research benefits.[24] Some scholars have operationalized ethical principles related to research by providing benchmarks that require community engagement, ensuring the research has social value, selecting participants fairly, treating them with respect, and offering them a reasonable risk/benefit ratio in research.[25] As part of the obligation to ensure research risks are reasonable, international ethical guidance states that research on interventions that could harm fetuses should only be conducted in places where abortion is legal and safe.[26] Thus, conducting clinical trials in states that ban or severely restrict abortion could violate international ethical standards, unless researchers find ways to ensure participants are informed about how to access safe and legal abortion and are able to do so.

In the current legal environment, it is important to note that these ethical obligations to participants may be triggered in any studies enrolling people who might become pregnant. For example, phase I studies that test for safety in humans typically exclude pregnant people and administer frequent pregnancy tests. These studies are not designed to benefit participants, but rather to produce data to help future patients. One advantage of testing for pregnancy frequently in phase I studies would be to provide participants with time to make reproductive choices. Yet researchers may have to grapple with state laws that require reporting intent to terminate a pregnancy.[27] Data from studies with regular pregnancy testing could be subpoenaed as evidence that a person had an abortion in states where this is now a crime.[28]

Laws restricting reproductive freedom are likely to have an even greater impact on research focused on pregnancy that actively seeks to include pregnant people. One prominent example of such a study is the HEALthy Brain and Child Development (HBCD) study funded by the National Institutes of Health

The Journal of Law, Medicine & Ethics, 51 (2023): 504-510. © 2023 The Author(s)

and led by the National Institute of Drug Abuse.[29] The HBCD study is designed to build a longitudinal cohort of pregnant people and their children to understand how prenatal substance use and other adverse exposures may affect brain development for children through age ten. And the myriad challenges HBCD has faced are illustrative of the legal and ethical considerations researchers, sponsors, and IRBs could encounter in other studies.

HBCD consists of a large network of sites across the United States, including in states with restrictive laws governing substance use in pregnancy. The study team has taken several steps to protect participants in this changing legal landscape that may be instructive for other researchers. For example, researchers initially worked on community engagement plans that included a variety of stakeholders. This included efforts to develop relationships and enter into Memoranda of Understanding with state agencies and prosecutors to ensure the information gathered in the study would remain confidential. It quickly became clear that in states with punitive orientations, reaching out to prosecutors and state officials could backfire by informing them that the study was collecting information that could be of value in a criminal prosecution. Thus, in states where this kind of collaboration could be most helpful for protecting participants, it was too risky to pursue.

Even screening prospective participants for eligibility for the study became ethically and legally fraught. To determine eligibility for HBCD, researchers must determine whether pregnant people will be able to remain engaged and bring their child to study visits over several years. Robust recruitment and retention are necessary to ensure the study will be able to collect representative and generalizable data that has value for society. Eligibility screening questions could reveal that a potential participant was planning to seek an abortion. Accordingly, the HBCD study developed screening questions that simply asked whether people would be willing to remain in the study with their child over time, along with a warning not to reveal too much in states that instituted requirements to report abortions. Study coordinators are also not asking people their reasons for declining to participate to avoid having participants reveal intent to seek an abortion. Not asking these questions could hamper recruitment efforts going forward, as the study will be unable to identify and address common barriers to participation.

Determining eligibility for people who have used substances in pregnancy is also challenging. In most states, if a patient or research participant reports substance use to their doctor or a member of the research team, this admission does not have to be reported to state officials. Furthermore, unless reporting of information is mandatory, the Certificate of Confidentiality for the study that was automatically issued by the NIH requires that researchers keep this information confidential.[30] Accordingly, to build a sample of pregnant people who have used substances in pregnancy, the HBCD study relied on self-reporting in most states, even though that is less reliable than testing for substances directly.

Nevertheless, some states require that study investigators report substance use during pregnancy however the information is learned. In states with punitive approaches to substance use, mandatory reporting requirements could result in incarceration and loss of child custody, rather than access to addiction treatment. In those states, participants for the part of the cohort that have used substances in pregnancy are recruited from addiction treatment centers, as reporting has already occurred and will not need to be repeated.

Additionally, many researchers initially felt an obligation to provide ancillary care to participants who need addiction treatment.[31] However, if researchers were also acting as clinicians, this could generate new reporting requirements related to substance use. To maintain trust, demonstrate respect, and ensure pregnant people who use substances have access to the care they need and are often highly motivated to seek, HBCD developed a robust referral network of providers and places that provide treatment for pregnant people using substances. This strategy of providing referrals and warm hand-offs to other services fulfilled the ancillary care obligations of beneficence that researchers have, while also decreasing legal risk of participation in a research study. If participants are in treatment already, states typically do not require reporting substance use as a form of abuse or neglect.

Protecting the confidentiality of the sensitive data in HBCD requires multiple levels of security. For example, toxicology and biospecimen assays for substances will be collected from participants at their respective study sites, but samples will be tested at a centralized location and de-identified, meaning that individual results will not be reported back to the participants nor the local study sites. While this system strengthens confidentiality protections, it makes it difficult for participants to receive information that may benefit them. By adapting study design to accommodate punitive state laws around substance use in pregnancy, the benefits to research participants may be diminished and the study's findings less robust.

The Journal of Law, Medicine & Ethics, 51 (2023): 504-510. © 2023 The Author(s)

Pilar Ossorio, an HBCD researcher,[32] reviewed state laws where study sites are located — an uncommon task for research that is not explicitly or implicitly about law.[33] While NIH has issued a Certificate of Confidentiality (CoC) for this study, understanding the legal limits of CoCs post-*Dobbs* is also important, as they do not protect information if it is legally compelled or the research participant has given consent to share it, making it important to craft informed consent documents carefully so participants do not inadvertently sign away privacy protections. This understanding of state- and federal-level law and policy is necessary to comprehend the potential risks that might be associated with laws on substance use and pregnancy, child abuse, newborn toxicology screenings, and the reporting requirements of researchers. Using this review to make decisions about modifying the study design can help protect participants from legal jeopardy. Additionally, safety monitoring approaches were carefully designed to help determine whether a study could no longer be safely conducted within a particular jurisdiction over time.

The experiences of HBCD investigators are illustrative of the obstacles researchers and institutions will undoubtedly face moving forward in the post-*Dobbs* era. Despite the potential public health benefits of this research, it presents risks for the participants and the research team that are challenging to navigate. Investigators recruiting pregnant people may struggle to find willing participants and develop adequate protections for them when laws take a punitive approach to abortion, particularly if substance use during pregnancy and any negative pregnancy outcomes could potentially be traced to maternal behavior.

The experiences of HBCD investigators are illustrative of the obstacles researchers and institutions will undoubtedly face moving forward in the post-*Dobbs* era. Despite the potential public health benefits of this research, it presents risks for the participants and the research team that are challenging to navigate, as investigators recruiting pregnant people may struggle to find willing participants and develop adequate protections for them when laws take a punitive approach to abortion, substance use during pregnancy, and any negative pregnancy outcomes that could potentially be traced to maternal behavior.

III. Recommendations

First, research teams and institutions should work to understand the strengths and limits of confidentiality protections under existing federal research regulations. Researchers have many tools to help protect research participants from potential legal jeopardy. For example, investigators can apply to obtain CoCs to prohibit the disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or if compelled by law.[34] NIH has strengthened CoCs in recent years and issued them automatically for studies collecting identifiable, sensitive information. However, these protections are not ironclad, nor have they been tested in light of the current reproductive regulatory context.

Leslie Wolf and colleagues have emphasized the importance of working with university counsel and other parties involved in the IRB process to strengthen existing confidentiality protections.[35] They recommend involving and educating relevant parties as to the benefits and limits of CoCs to ensure the study is able to take full advantage of the protections afforded by CoCs. Whenever possible, if data may not be entirely protected, those questions should be raised in advance of initiating research. This type of knowledge can prevent scenarios in which researchers inadvertently waive CoC protections, such as when a member of the research team is asked to confirm whether a specific person is participating in a study. Furthermore, if researchers are asked to supply any data in response to a legal request, they should consult with institutional counsel before responding, and ensure they provide the minimal amount of information required by law. Research teams should be prepared for legal demands

The Journal of Law, Medicine & Ethics, 51 (2023): 504-510. © 2023 The Author(s)

for human subject research data and have a reasonable strategy in place to address those inquiries.

Second, the research team should understand the legal environment in which a study is conducted. Although a study situated at a university may have a supportive and mutually beneficial relationship with its surrounding community, that may not be the case when a study enters a space with which it does not have longstanding ties; tensions may arise between community members, institutions, or prospective participants about the study. As has been the case with HBCD, engaging with communities about the research has facilitated relationships with organizations and local authorities to benefit not only the science but also the community members participating in the research. Whether through the creation of Memoranda of Understanding with local prosecutors when it is reasonable to do so, or by developing strong referral networks for participants to access care or services outside of the research, taking proactive steps to appreciate the state or local circumstances should make for a safer and more effective research environment. For some jurisdictions, however, such steps may not be realistic.

Indeed, in some situations, conducting research involving pregnant persons may raise the level of risk substantially, perhaps even beyond what is permissible in the federal regulations governing research or international guidelines for protecting human subjects. This brings us to a third recommendation: the research environment must be monitored throughout the duration of the research, and it may be necessary to determine whether some settings are simply too risky to undertake or continue research.

As noted above and in the symposium articles by Bach and Carroll et al., some states have histories of prosecuting people who have experienced miscarriages or stillbirths, or obtained abortions, particularly in situations in which substance use was suspected or confirmed. As states enact abortion bans, the risks of criminal punishment could potentially increase. Therefore, researchers must remain aware of ongoing political circumstances, as the threat of legal action in one state may differ from another.

Researchers, funders, and institutions should also prepare to deal with political attacks and campaigns by activists who may seek to discredit research, compromise scientific integrity, or imperil participants' safety. While manufactured controversy is not novel, it could have a newly destabilizing effect on ongoing and future studies and erode public trust in research. Researchers should establish a mechanism, such as an oversight committee with bioethics, clinical, and legal expertise, or an observational or data safety monitoring board, to assess the legal environment at a study site and determine when the environment may prove too risky for pregnant research participants, the study team, or both.

Finally, researchers must be stewards of change and advocate for the populations with which they work. For instance, researchers who study substance use during pregnancy are better positioned than legislators to understand the evidentiary bases for substance exposure harming a developing fetus, and which approaches to addressing substance use are most likely to help affected families and their children. As laws governing substance use do not necessarily follow evidence, researchers can use their expertise to promote public, maternal, and child health.[36] If lawmakers are concerned about protecting children and supporting families, punitive approaches to substance use in pregnancy are likely to be counterproductive.[37] Moreover, access to safe and legal abortion care is critical for respecting the rights of pregnant people, protecting their health,[38] and promoting the health of their families.[39]

Conclusion

The story of research including pregnant people was near total exclusion, and the uncertainty and harms it has perpetuated are inexcusable in a country that proclaims to venerate parenthood, pregnancy, children, and life. Despite recent commitments toward inclusion of pregnant people in research, ongoing legal change may sabotage recent progress. Researchers' ethical duties to promote beneficence and justice necessitate preparing for evolving legal risks and providing prospective and enrolled participants with the protection, information, care, and respect they deserve.

Note

The authors have no conflicts to disclose. Dr. Weinmeyer's work was funded in part by Agency for Healthcare Research and Quality (AHRQ) University of Chicago and Northwestern University Predoctoral Health Services Research Program T32 HS000084 (Konetzka and Meltzer), and the Mary and Michael Jaharis Health Law Institute at the DePaul University College of Law. Professor Shah's work was funded by grants R34DA050266 (Wakschlag) and U01DA55355 (Norton & Wakschlag) from the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH). Dr. McGowan's work was funded by NIDA and the National Institute of Biomedical Imaging and Bioengineering U01A055342 (Merhar and Vannest). The content in this article is the responsibility of authors and does not necessarily represent the official views of their funders.

Acknowledgements

The authors would like to thank the participants at the 2023 Jaharis Health Law Symposium at DePaul University's College of Law for their thoughts and feedback on this piece.

The Journal of Law, Medicine & Ethics, 51 (2023): 504-510. © 2023 The Author(s)

References

1. C. Aspinwall et al., "They Lost Pregnancies for Unclear Reasons. Then They were Prosecuted." *Washington Post*, September 1, 2022.
2. Transcript of Oral Argument at 49, *Dobbs v. Jackson, Women's Health Org.*, 597 U.S. ___ (No. 19-1392).
3. L. R. Fowler and M. Ulrich, "Femtechnodystopia," *Stanford Law Review* 75 (forthcoming 2023), *available at* <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4099764> (last visited November 9, 2022).
4. A.D. Lyerly et al., "The Second Wave: Toward Responsible Inclusion of Pregnant Women in Research," *International Journal of Feminist Approaches to Bioethics* 1, no. 2 (2008): 5–22.
5. A. A. Mitchell et al., "Medication use During Pregnancy, with Particular Focus on Prescription Drugs: 1976-2008," *American Journal of Obstetrics and Gynecology* 205, no. 1 (2008): 51.e1–51.e8.
6. Food and Drug Administration, "Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials," (Rockville, MD, April 2018), *available at* <https://www.fda.gov/media/112195/download> (last visited February 15, 2022).
7. M. P. Adam et al., "Evolving Knowledge of the Teratogenicity of Medications in Human Pregnancy," *American Journal of Medical Genetics* 157C, no. 3 (2011): 175–182.
8. Lyerly et al., *supra* note 4.
9. National Academies of Sciences, Engineering, and Medicine, "Women's Health Research: Progress, Pitfalls, and Promise," (Washington, DC: The National Academies Press, 2010): at 16
10. M. E. Franks et al., "Thalidomide," *The Lancet* 363 (2004): 1802–1811.
11. *Id.*
12. R. N. Hoover et al., "Adverse Health Outcomes in Women Exposed in Utero to Diethylstilbestrol," *New England Journal of Medicine* 365, no. 14 (2011): 1304–1314.
13. "ACOG Committee Opinion No. 268: Management of Asymptomatic Pregnancy or Lactating Women Exposed to Anthrax," *Obstetrics and Gynecology* 99, no. 2 (2002): 366–368.
14. M. A. Andrew et al., "Amoxicillin Pharmacokinetics in Pregnant Women: Modeling and Simulations of Dosage Strategies," *Clinical Pharmacology and Therapeutics* 81, no. 4 (2007): 547–556.
15. D. W. Bianchi et al., "Involving Pregnant Individuals in Clinical Research on COVID-19 Vaccines," *JAMA* 325, no. 11 (2021): 1041–1042.
16. See National Institutes of Health, *NIH Begins Study of COVID-19 Vaccination During Pregnancy and Postpartum*, National Institutes of Health New Releases, June 23, 2021, *available at* <https://www.nih.gov/news-events/news-releases/nih-begins-study-covid-19-vaccination-during-pregnancy-postpartum> (last visited November 10, 2022).
17. C. B. Krubiner et al., "Pregnant Women & Vaccines against Emerging Epidemic Threats: Ethics Guidance for Preparedness, Research, and Response," *Vaccine* 39 (2021): 85–120,.
18. D. Lyerly et al., "Ending the Evidence Gap for Pregnancy, HIV and Co-Infections: Ethics Guidance from the PHASES Project," *Journal of the International AIDS Society* 24, no. 12 (2021): 1–7.
19. Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Health-related Research Involving Humans*, CIOMS website, *available at* <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (last visited November 10, 2022).
20. Pub. L. 114–255, div. A, title II, §2041, Dec. 13, 2016, 130 Stat. 1070; National Institute for Child Health and Human Development, *Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)*, PRGLAC Task Force website, *available at* <https://www.nichd.nih.gov/about/advisory/PRGLAC> (last visited November 10, 2022).
21. Task Force on Research Specific to Pregnant Women and Lactating Women, "Report to the Secretary of Health and Human Services and Congress," September 2018, *available at* <https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf> (last visited November 10, 2022).
22. 45 C.F.R. 46 § 46.204 (2018).
23. T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, 2009).
24. Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Subjects in Human Subjects Research* (December 2011), *available at* <https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/Moral%20Science%20June%202012.pdf> (last visited February 16, 2023).
25. E. J. Emanuel et al., "What Makes Clinical Research Ethical?" *JAMA* 283, no. 20 (2000): 2701–2711.
26. *International Ethical Guidelines for Health-related Research Involving Humans*, *supra* note 19.
27. A. Brennan, "Subject, not Suspect: The New Hazards of Conducting Clinical Research in the Dobbs Era," *STAT Plus*, September 26, 2022, *available at* <https://www.statnews.com/2022/09/26/new-hazards-conducting-clinical-research-dobbs-era/> (last visited February 17, 2023).
28. *Id.*; C. M. Klapperich, "How the Dobbs Decision Changed my Research on Reproductive Health Technology," *STAT*, June 30, 2022, *available at* <https://www.statnews.com/2022/06/30/dobbs-decision-changing-research-reproductive-health-technology/> (last visited February 17, 2023).
29. National Institutes of Health, *HEALthy Brain and Child Development Study (HBCD)*, HBCD website, *available at* <https://heal.nih.gov/research/infants-and-children/healthy-brain> (last visited February 17, 2023).
30. National Institutes of Health, *Information Protected by a CoC*, National Institutes of Health Grants and Funding website, *available at* <https://grants.nih.gov/policy/humansubjects/coc/information-protected-coc.htm> (last visited February 17, 2023).
31. N. W. Olson, "Medical Researchers' Ancillary Care Obligations: The Relationship-Based Approach," *Bioethics* 30, no. 5 (2016): 317–324.
32. University of Wisconsin Law School, *Pilar Ossorio*, Faculty Profile website, *available at* <https://secure.law.wisc.edu/profiles/pnossorio@wisc.edu> (last visited February 17, 2023).
33. Morgridge Institute for Research, *Infants with Prenatal Substance Exposure*, Morgridge Institute for Research website, *available at* <https://morgridge.org/research/bioethics/prenatal-substance-exposure/> (last visited February 16, 2023).
34. National Institutes of Health, *Information Protected by a CoC*, National Institutes of Health Grants and Funding website, *available at* <https://grants.nih.gov/policy/humansubjects/coc/information-protected-coc.htm> (last visited February 17, 2023).
35. L. E. Wolf et al., "Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice," *Journal of Law, Medicine & Ethics* 43, no. 3 (2016): 594–609.
36. M. F. Marshall et al., "Perinatal Substance Abuse and Human Subjects Research: Are Privacy Protections Adequate?" *Mental Retardation and Developmental Disabilities Research Reviews* 9, no. 1 (2003): 54–59.
37. K. Hui et al., "Criminalizing Substance use in Pregnancy: Misplaced Priorities," *Addiction* 112, no. 7 (2017): 1123–1125.
38. C. Gerdts et al., "Side Effects, Physical Health Consequences, and Mortality Associated with Abortion and Birth after an Unwanted Pregnancy," *Women's Health Issues* 26, no. 1 (2016): 55–59.
39. D. G. Foster et al., "Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children," *Journal of Pediatrics* 205 (2019): 183–189.

The Journal of Law, Medicine & Ethics, 51 (2023): 504-510. © 2023 The Author(s)