CUTS THAT WILL NEVER HEAL: HOW THE NATIONAL INSTITUTES OF HEALTH CAN PROTECT CLINICAL TRIAL PARTICIPANTS FROM FUTURE FUNDING CUTS

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The Trump Administration's cuts to the National Institutes of Health (NIH) in 2025 laid bare the lack of protections clinical trial participants have when funding is terminated for policy purposes. This Comment demonstrates the importance of NIH's federally funded research, as well as how the agency has terminated funding in the past. It outlines the regulatory history of research with human subjects and how the Trump Administration's cuts do not align with current ethical guidelines. Further, it explains the challenges faced by patients who try to compel the agency to continue their study or recover monetarily from harm. Finally, this Comment proposes regulatory and legislative solutions to ensure clinical trial participants are better informed and protected in the future.

* J.D. Candidate, American University Washington College of Law (2027); B.A. in International Studies, American University (2020). This Comment is dedicated to my beloved grandfather and pediatric cancer research pioneer, Dr. Donald J. Fernbach, who passed away in 2013. In 1958, "Grampy" founded what is now the Texas Children's Cancer and Hematology Center. A passionate researcher, his team developed some of the first treatments for children with cancer, many of which are still used today. As a professor at Baylor College of Medicine, he published more than 160 articles, including the first textbook on pediatric oncology. Beyond his scholarly contributions, he co-founded the precursor to the Children's Oncology Group, a part of the National Cancer Institute's National Clinical Trials Network. Above all else, Grampy was a tireless advocate for the dignity and care of his patients. His legacy continues to inspire his grandchildren and his great-grandchildren. I would also like to thank Professor Jamie Abrams, Professor Mark Gross, and my editors, Kayla Keech and Ainnir O'Regan, for their invaluable feedback, guidance, and support.

INTRODUCTION

In 2011, Sue Scott, a patient in her mid-thirties, was diagnosed with stage 1B2 cervical cancer and prescribed a standard course of treatment.[1] Despite two-thirds of patients responding positively, Sue's cancer continued to grow, and her doctors told her she had less than a year to live.[2] Sue sought out a National Institutes of Health (NIH) clinical trial[3] as her only chance for

1. National Institutes of Health (NIH), *Women in Clinical Trials: Sue's Story*, YOUTUBE (May 10, 2016) [hereinafter *Sue's Story*], https://www.youtube.com/watch?v=pLqnD-iMP_g [https://perma.cc/QL5K-3SJE]; Kerry Sheridan, *How a Clinical Trial Cured Cancer—In Some Cases*, WHYY (July 16, 2021), https://whyy.org/segments/how-a-clinical-trial-cured-cancer-in-some-cases/ [https://perma.cc/K7GJ-7CPQ].

2. Sheridan, *supra* note 1; *Sue's Story*, *supra* note 1.

3. The NIH defines a clinical trial as "[a] research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or

survival.[4] Instead of spending her precious time left with friends and family, Sue underwent experimental chemotherapy and battled the intense side effects that came with it.[5] In just two months, the trial reduced her tumors and saved her life.[6] To Sue, participating in the clinical trial "ke[pt] that piece of hope alive."[7]

The NIH has long been nicknamed the National Institutes of Hope.[8] For many patients like Sue, the clinical research trials administered and funded by the NIH are their last hope for a cure.[9] Patients put their bodies on the line for the chance that researchers learn something that may improve future prognosis and treatment effectiveness.[10]

These clinical trials can also be ethically fraught.[11] Researchers and their institutions may take advantage of desperate patients and families, providing patients with false hope and subjecting them to greater risks than necessary.[12]

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behavioral outcomes." *NIH's Definition of a Clinical Trial*, NIH, GRANTS & FUNDING, https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition [https://perma.cc/P7D4-BC57] (last updated Jan. 29, 2026).

4. *Sue's Story*, *supra* note 1.

5. *See* Sheridan, *supra* note 1 (describing Sue's side-effects, which included losing her hair, intense nausea, and having to remain on oxygen).

6. *Id.* Out of nine women in the study, only two responded to treatment and survived. *Id.*

7. *Sue's Story*, *supra* note 1.

8. *See* Carolyn Y. Johnson, *His Custom Cancer Therapy is in an NIH Freezer. He May Not Get It in Time.*, WASH. POST (Aug. 18, 2025), https://www.washingtonpost.com/science/2025/06/18/nih-cancer-therapy-delay-staff-cuts/ [https://perma.cc/4XAM-75PU].

9. *See id.*; Rachel Leingang, *Woman's Life-Saving Treatment Delayed by Trump Cuts to NIH: 'Cancer Shouldn't Be Political,'* GUARDIAN (May 29, 2025), https://www.theguardian.com/us-news/2025/may/28/trump-cuts-nih-cancer-care [https://perma.cc/8US3-TZPC] (telling the story of a patient with stage 4 colorectal cancer who was "pleading for [her] life").

10. *See* Johnson, *supra* note 8; *see also* H E M van Luijn, N K Aaronson, R B Keus & A W Musschenga, *The Evaluation of the Risks and Benefits of Phase II Cancer Clinical Trials by Institutional Review Board (IRB) Members: A Case Study*, 32 J. MED. ETHICS 170, 171 (2006) (explaining that participants in a cancer clinical trial were expected to experience possible side effects such as "mucositis, infection, fertility problems/damage to offspring, bleeding, change of skin colour, high blood pressure, tremors, painful hands and feet, stomatitis, haematuria, genetic disturbances, and rejection of donor bone marrow").

11. *See* Valerie Gutmann Koch, *A Private Right of Action for Informed Consent in Research*, 45 SETON HALL L. REV. 173, 184 (2015) [hereinafter Koch, *Consent in Research*] (describing the Tuskegee Syphilis Study, a particularly notorious research scandal in the United States); Elizabeth R. Pike, *Recovering from Research: A No-Fault Proposal to Compensate Injured Research Participants*, 38 AM. J.L. & MED. 7, 12 (2012) ("[M]any elements of research . . . are contrary to good medical care.").

12. *See* Pike, *supra* note 11, at 12–13; Cecilia Nardini, *The Ethics of Clinical Trials*, ECANCERMEDICALSCIENCE, Jan. 16, 2014, at 1, 3 ("[T]he primary end of the trial is not that of treating trial participants but rather that of producing generalisable medical knowledge.").

This is why agency rules and regulations are imperative to keeping patients safe. Patients should not possess fewer rights in the research setting simply because they agreed to participate in a trial.[13] Patients should be able to trust that the government is regulating its own agencies and federal grant recipients responsibly and in accordance with its own ethics principles.

When the Trump Administration returned to office in January 2025, the Department of Government Efficiency (DOGE) issued guidance ordering sweeping and unprecedented cuts to the U.S. Department of Health and Human Services (HHS) and the NIH under the pretext of refocusing taxpayer dollars and "promoting efficiency in government."[14] First, the Acting Director of the Office of Management and Budget (OMB) circulated a memorandum instituting a temporary pause on disbursement of agency grants so the new Administration could review current recipients and their studies to ensure that they were aligned with President Trump's agenda to "Mak[e] America Healthy Again."[15] In the two months following that memorandum, the NIH terminated 780 research grants that referenced diversity, equity, and inclusion; LGBTQ+ patients; and COVID-19.[16] Next, agency officials issued a ban on NIH employee travel and placed a hiring freeze across the federal government.[17] Later, the NIH announced a 15% cap on indirect

13. *See* Valerie Gutmann Koch, *Reimaging Informed Consent: From Disclosure to Comprehension*, 14 U.C. IRVINE L. REV. 894, 897 (2024) [hereinafter Koch, *Reimagining Informed Consent*].

14. *See* Annie Waldman, *Trump's NIH Axed Research Grants Even After a Judge Blocked the Cuts, Internal Records Show*, PROPUBLICA (May 7, 2025, 5:10 PM), https://www.propublica.org/article/trump-nih-cuts-transgender-research-grants [https://perma.cc/22KE-ZMCC] (explaining that there is a dispute as to whether DOGE itself illegally issued terminations without proper authority); OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, OMB M-25-13, TEMPORARY PAUSE OF AGENCY GRANT, LOAN, AND OTHER FINANCIAL ASSISTANCE PROGRAMS (2025).

15. OFF. OF MGMT. & BUDGET, *supra* note 14.

16. *See* Sarah Owermohle, *Trump's Diversity Purge Freezes Hundreds of Millions in Medical Research at Universities Across the Country*, CNN (May 8, 2025, 9:00 AM), https://www.cnn.com/2025/05/08/politics/universities-medical-research-funding-frozen-trump-diversity-purge [https://perma.cc/6MAF-XNQ9]; Rae Ellen Bichell & Rachana Pradhan, *Beyond Ivy League, RFK Jr.'s NIH Slashed Science Funding Across States that Backed Trump*, KFF HEALTH NEWS (Apr. 17, 2025), https://kffhealthnews.org/news/article/nih-grant-cuts-red-states-science-research-vaccines-hiv-trump-rfk/ [https://perma.cc/D3SZ-U32B]. Many studies that were not centered around diversity, equity, and inclusion (DEI) but contained certain phrases such as "expression" were also terminated. Alander Rocha, *NIH Grant Cuts Throw Science into a 'Downward Spiral,' Researchers and Advocates Say*, GA. RECORDER (Sept. 16, 2025, 5:00 AM), https://georgiarecorder.com/2025/09/16/nih-grant-cuts-throw-science-into-a-downward-spiral-researchers-and-advocates-say/ [https://perma.cc/9WDV-YZ8D].

17. *See* Meredith Wadman & Jocelyn Kaiser, *Trump Hits NIH with 'Devastating' Freezes on Meetings, Travel, Communications, and Hiring*, SCIENCE (Jan. 22, 2025, 5:45 PM),

costs for grant recipients replacing the existing rates that were negotiated individually by each institution, many of which were much higher.[18] To circumvent court orders requiring the resumption of federal grant disbursement, HHS issued a memo prohibiting the NIH from publishing notices of meetings in the *Federal Register*, a required step in issuing new grants.[19] Finally, in April, over 1,200 NIH staff members were fired as part of a larger 10,000-person reduction in force (RIF) of HHS.[20] Together, these actions had life-altering effects on patients enrolled in clinical trials.[21]

States and other plaintiffs have challenged many of these actions in court alleging statutory and constitutional violations with varying success rates. For example, private research institutions, advocacy organizations, and states who receive NIH grant funding challenged the NIH's funding cuts under the Administrative Procedure Act (APA) as arbitrary and capricious in *NIH v. American Public Health Association*.[22] The Supreme Court allowed the termination of $783 million in NIH grants to proceed, and Justice Barrett noted in her concurrence that it was unclear whether the terminations were a final agency action that could be challenged pursuant to the APA.[23]

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https://www.science.org/content/article/trump-hits-nih-devastating-freezes-meetings-travel-communications-and-hiring [https://perma.cc/8HAU-P9QQ].

18. NAT'L INSTS. OF HEALTH, OFF. OF THE DIR., NOT-OD-25-068, SUPPLEMENTAL GUIDANCE TO THE 2024 NIH GRANTS POLICY STATEMENT: INDIRECT COST RATES (2025); *see* Ben Unglesbee, *'Self-Inflicted Wound': Widespread Alarm as Trump Administration Slashes NIH Funding*, HIGHER ED DIVE (Feb. 11, 2025), https://www.highereddive.com/news/nih-indirect-cost-rate-cap-funding-cut-ags-lawsuit/739735/ [https://perma.cc/BS6C-8UTL] (explaining that indirect costs include facilities and administrative costs).

19. *See* Judd Legum, *UPDATE: NIH Reimposes "DEI" Funding Freeze Despite Court Order*, POPULAR INFO. (Feb. 24, 2025), https://popular.info/p/update-nih-reimposes-dei-funding [https://perma.cc/XSF9-MYA2] (finding that preventing publication had "stalled" about 16,000 grant applications.); *see also* Nat'l Insts. of Health—Application of Impoundment Control Act to Availability of Funds for Grants, B-337203, 2025 WL 2238152 (Comp. Gen. Aug. 5, 2025) (finding the pause on publishing in the *Federal Register* was against the Impoundment and Control Act).

20. Erin Schumaker, Carmen Paun & Ruth Reader, *The Downside of RIFs at NIH*, POLITICO (Apr. 11, 2025, 2:00 PM), https://www.politico.com/newsletters/future-pulse/2025/04/11/the-downside-of-rifs-at-nih-00283243 [https://perma.cc/YFE9-8MJE] (reporting that 20% of NIH staff who were RIF'ed were reinstated after being mistakenly fired).

21. *See infra* text accompanying notes 29–39.

22. 145 S. Ct. 2658 (2025) (mem.).

23. *See id.* at 2662 (Barrett, J., concurring) ("[W]hether claims about the [terminations] in this case will succeed is another question. It is not obvious, for instance, that NIH's guidance is final agency action."); Dan McKay, *High Court Allows Trump Admin to Cancel $783M in NIH Grants*, LAW360 (Aug. 21, 2025, 5:30 PM), https://www.law360.com/healthcare-authority/articles/2379892/high-court-allows-trump-admin-to-cancel-783m-in-nih-grants [https://perma.cc/N4V3-L9GQ].

Plaintiffs have also filed lawsuits alleging that these actions are inconsistent with the U.S. Constitution. For instance, physicians in *American Association of Physicians for Human Rights, Inc. v. NIH*[24] argued that the targeting of LGBTQ+ people directly violated the Equal Protection and Due Process Clauses of the Fifth Amendment and multiple provisions of the APA.[25] And in *American Federation of Government Employees v. Trump*,[26] union members sued the Trump Administration, alleging that agency RIFs are an unlawful exercise of executive power and need congressional approval.[27] The Supreme Court, upon hearing an emergency application, stayed the lower courts' preliminary injunction and allowed the RIFs to continue as the case is adjudicated.[28]

While these lawsuits wind their way through the courts, critical research has been delayed, halted, or abandoned entirely.[29] These studies included lifesaving treatments for fighting cancer, HIV, substance abuse disorders, heart disease, Alzheimer's, and more.[30] It is estimated that more than 383

24. Complaint for Declaratory & Injunctive Relief, 8:25-CV-01620 (S.D. Md. filed May 20, 2025).

25. *See id.* at 1–2.

26. 784 F. Supp. 3d 1316 (N.D. Cal. 2025).

27. *See id.* at 1326–27.

28. Trump v. Am. Fed'n of Gov't Emps., 145 S. Ct. 2635, 2635 (2025) (mem.). The Supreme Court has repeatedly sided with the Trump Administration in striking down preliminary injunctions in cases regarding use of executive power, often without explanation. Alicia Bannon, *Supreme Court Must Explain Why It Keeps Ruling in Trump's Favor*, BRENNAN CTR. FOR JUST. (Aug. 14, 2025), https://www.brennancenter.org/our-work/analysis-opinion/supreme-court-must-explain-why-it-keeps-ruling-trumps-favor [https://perma.cc/336L-4EFC].

29. *See* Katherine J. Wu, *The NIH's Most Reckless Cuts Yet*, ATLANTIC (Mar. 27, 2025) [hereinafter Wu, *Reckless Cuts*], https://www.theatlantic.com/health/archive/2025/03/trump-nih-clinical-trials-patient-safey/682217/ [https://perma.cc/NV8H-UTER] (documenting the immediate impacts of continued RIFs on research).

30. *See id.*; Irena Hwang, Jon Huang, Emily Anthes, Blacki Migliozzi & Benjamin Mueller, *The Gutting of America's Medical Research: Here is Every Canceled or Delayed N.I.H. Grant*, N.Y. TIMES (June 5, 2025), https://www.nytimes.com/interactive/2025/06/04/health/trump-cuts-nih-grants-research.html [https://perma.cc/EA8D-LNLQ]. The NIH Clinical Center alone sees more than 10,000 patients every year. *Clinical Center (CC)*, NAT'L INSTS. OF HEALTH (June 13, 2025), https://www.nih.gov/about-nih/nih-almanac/clinical-center-cc [https://perma.cc/MGN7-AP9B]. Of the thirty-five NIH-funded Alzheimer's Disease Research Centers, fourteen had funding expire April 30, 2025. Allison Parshall, *Lifesaving Alzheimer's Research Delayed by Trump Funding Cuts*, SCI. AM. (Apr. 18, 2025), https://www.scientificamerican.com/article/lifesaving-alzheimers-research-delayed-by-trump-funding-cuts/ [https://perma.cc/52MB-6XS2] (finding that many had the word "diverse" in their study title).

clinical trials were terminated between February and November of 2025, affecting more than 74,000 study participants.[31]

A delay of any of these studies can have fatal consequences.[32] Richard Schlueter, an NIH patient with metastatic cancer, had his treatment postponed due to NIH staffing cuts.[33] With each day that passed without a physician to administer his specialized immune-cell therapy, his chances for survival and quality of life diminished.[34] Luckily for Richard, his physician was later rehired, and he was able to resume his treatments.[35] But not all patients have been as fortunate.[36] The delays or cancellations of behavioral health studies present alarming dangers.[37] For example, psychiatric drugs, such as those that treat anxiety, depression, bipolar disorder, and schizophrenia, require patients to be tapered off the medication to avoid symptoms of withdrawal and increased suicidality.[38] With no access to their experimental medication when a study is cancelled or delayed, and their physician fired as part of the RIF, vulnerable patients are left with few options for what to do next for treatment.[39]

Some researchers have received information from the NIH that emergency funding to complete a study may be available; however, they have not received any information on how they can apply for such funds.[40] Even so,

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31. Dan Vergano, *Halted NIH Clinical Trials List Reveals Slashed Treatments for Cancer, COVID and Minority Health*, SCI. AM. (Nov. 20, 2025), https://www.scientificamerican.com/article/halted-nih-clinical-trials-list-reveals-slashed-treatments-for-cancer-covid/ [https://perma.cc/4HDB-3XAA].

32. *See* Leingang, *supra* note 9 (explaining that if her clinical trial for colorectal cancer continues to be delayed, Natalie Phelps will likely die).

33. Johnson, *supra* note 8.

34. *See id.* (describing Richard's hip pain and his struggle to walk down the aisle to renew his vows as the cancer spread through his bones).

35. *Id.*

36. *See id.* (highlighting the risks to patients like Natalie Phelps who will have to restart chemotherapy in lieu of specialized clinical treatment).

37. *See* Wu, *Reckless Cuts*, *supra* note 29 (describing how patients may depend on the medical treatment or be monitored for adverse reactions to implanted devices).

38. *See id.*; Leslie Korn, *Tapering Psychotropic Medications: An Integrative Approach*, PSYCH. TODAY (Apr. 18, 2025), https://www.psychologytoday.com/us/blog/rhythms-of-recovery/202504/tapering-psychotropic-medications-an-integrative-approach (explaining the importance of working with a therapist and supportive health network to manage withdrawal from psychotropic medications).

39. *See* Wu, *Reckless Cuts*, *supra* note 29; Katherine J. Wu, *Inside the Collapse at NIH*, ATLANTIC (Feb. 28, 2025), https://www.theatlantic.com/health/archive/2025/02/nih-grant-freeze-biomedical-research/681853/ [https://perma.cc/R3NK-CXDC] ("[S]hould the pause continue . . . dozens of clinical trials for cancer patients—sometimes 'a patient's best chance for cure, and long-term survival,' . . . could be at risk of shutting down.").

40. Wu, *Reckless Cuts*, *supra* note 29.

restarting a study once it has been paused is not easy.[41] One researcher described the situation as "a fire in your store. It didn't destroy the store, but now you have to take inventory, order new supplies, repaint the inside . . . and hope your clients come back."[42] Maintaining trust between patients and researchers has always been a challenge, especially with underrepresented groups who have historically been victims of unethical research practices.[43] This trust is further challenged when research institutions have greater standing to sue the government for illegal funding cuts than the patients who are experiencing the serious and sometimes fatal physical harm themselves.[44]

Each presidential administration assumes office with different budgetary priorities and takes steps to enact them.[45] Patients like Sue and Richard should be protected regardless of what those priorities are. The actions by the Trump Administration, while dramatic and unprecedented, have revealed critical deficiencies in patient protections—protections that have not been substantially reviewed since 1979, when the Belmont Report set out the

41. *See id.* ("Many studies rely on collecting information at precise, regular intervals; miss just one data point, and an entire analysis can be thrown off."); Parshall, *supra* note 30; Marianne Guenot, *The Damage Done*, 31 NATURE MED. 3211, 3212 (2025) (explaining that research staff had already been laid off by the time funding was reinstated).

42. Parshall, *supra* note 30 (quoting Dr. Charles DeCarli, Director of the University of California Alzheimer's Disease Research Center).

43. *See* Pike, *supra* note 11, at 14 (noting the U.S. government's Tuskegee syphilis study as the most famous of these modern abuses); L L Wall, *The Medical Ethics of Dr. J. Marion Sims: A Fresh Look at the Historical Record*, 32 J. MED. ETHICS 346, 346 (2006) (explaining the unethical practices of Dr. J. Marion Sims who experimented on enslaved African American women, performing gynecologic surgeries without anesthesia or consent); Mike Stobbe, *Ugly Past of U.S. Human Experiments Uncovered*, NBC NEWS (Feb. 27, 2011, 6:14 PM), https://www.nbcnews.com/health/health-news/ugly-past-u-s-human-experiments-uncovered-flna1c9465329 [https://perma.cc/7L3N-JBYC] (detailing the U.S. government's use of prisoners and the mentally disabled as nonconsenting test subjects).

44. *See* Koch, *Consent in Research*, *supra* note 11, at 174–75 ("[N]o equivalent private right of action exists in the research context . . . ."); Kristen Underhill, *Righting Research Wrongs: An Empirical Study of How U.S. Institutions Resolve Grievances Involving Human Subjects*, YALE J. HEALTH POL'Y L. & ETHICS, Summer 2018, at 63, 75 (describing the power differential between patients who experienced misconduct and the legal sophistication of research institutions).

45. *Compare* Exec. Order No. 14,120, § 1, 89 Fed. Reg. 20,095, 20,095 (Mar. 21, 2024) (creating the Biden Administration's White House Initiative on Women's Health Research to accelerate research into conditions that uniquely affect women), *with* Exec. Order No. 13,435, § 1(a), 72 Fed. Reg. 34,591, 34,591 (June 22, 2007), *rev'd by* Exec. Order No. 13,505, § 3, 74 Fed. Reg. 10,667, 10,668 (Mar. 11, 2009) (providing strict ethical guidelines on stem cell research under President George W. Bush).

first ethical regulations for research with human subjects.[46] Historically, progress in expanding protection for patients participating in clinical trials has resulted from moments of great disruption; this moment should be no different.[47]

Part I of this Comment discusses the statutory basis for and the importance of federally funded clinical research, and how that funding has historically been structured.[48] Part II analyzes what rights patients have when they undergo clinical trials and the challenges that they face in recovering from harm caused by terminations in research funding.[49] Part III provides brief recommendations about how patients could be protected from federal funding cuts in future clinical trials.[50]

I. THE NIH AND FEDERALLY FUNDED CLINICAL RESEARCH

A. The History of the NIH and its Statutory Authority

The precursor to the NIH, the Laboratory of Hygiene (the Laboratory), was founded in 1887 as part of the Marine Hospital in Staten Island, New York.[51] The Laboratory was entrusted with researching "the origin and causes of epidemic diseases, especially yellow fever and cholera."[52] Four years later, the small research lab relocated to Washington, DC, and was tasked with investigating the causes of infectious diseases under the Public Health Service.[53] In 1930, Congress renamed it the National Institute of Health.[54] In the two decades that followed, the agency grew, and Congress expanded its research, prompting the agency to be renamed to the National *Institutes* of Health.[55]

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46. *See supra* text accompanying notes 14–20; Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192, 23,193 (Apr. 18, 1979).

47. *See generally* Pike, *supra* note 11, at 15–16 (describing the evolution of ethical guidelines in biomedical research in response to Nazi-era violations, the Tuskegee syphilis experiment, and the globalization of biomedical research).

48. *See infra* Part I.

49. *See infra* Part II.

50. *See infra* Part III.

51. Kavya Sekar, CONG. RSCH. SERV., R41705, THE NATIONAL INSTITUTES OF HEALTH (NIH): BACKGROUND AND CONGRESSIONAL ISSUES 2 (2025); *Chronology of Events*, NIH ALMANAC (Apr. 25, 2025), https://www.nih.gov/about-nih/nih-almanac/chronology-events [https://perma.cc/5ETK-DDCU].

52. *Chronology of Events*, *supra* note 51.

53. *Id.*; Sekar, *supra* note 51, at 2.

54. *Chronology of Events*, *supra* note 51; Sekar, *supra* note 51, at 2.

55. Sekar, *supra* note 51, at 2–3; *Chronology of Events*, *supra* note 51 (adding institutes like the National Heart Institute and National Institute of Dental Research).

The NIH draws most of its statutory authority from the Public Health Service Act of 1944 (the Act).[56] The Act established the NIH as an agency within the Public Health Service, a subdivision of HHS, and stipulated the leadership positions and responsibilities of the agency.[57] In 1985, Congress passed the Health Research Extension Act,[58] providing specific statutory authority to the NIH and requiring the Director to "encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences."[59] Congress continued to lay out its goals for the agency in the NIH Revitalization Act of 1993,[60] the NIH Reform Act of 2006,[61] and the 21st Century Cures Act of 2016.[62]

B. The Importance of the NIH and Federally Funded Research

Today, the NIH, a subagency of HHS, is the "world's largest public funder of biomedical research" with an annual budget of over $48 billion.[63] Consisting of twenty-seven research centers, Congress provided the agency with a mission to "support scientific discovery, enhance health, and lengthen life for Americans," while also protecting national security and maintaining the United States' global competitiveness in scientific research.[64] The agency issues around 60,000 "extramural" grants[65] annually to hospitals and universities while also conducting its own in-house "intramural" research.[66] The research the NIH funds differs substantially from that of the private sector in

56. Public Health Service Act of 1944, Pub. L. No. 78-410, 58 Stat. 682.

57. *Id.* §§ 201–02, 58 Stat. at 683.

58. Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820.

59. *Id.* § 405(b)(1)(A), 99 Stat. at 826; *see* Sekar, *supra* note 51, at 4–5.

60. NIH Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (requiring the inclusion of women and minorities in clinical research).

61. NIH Reform Act of 2006, Pub. L. No. 109-482, 120 Stat. 3675 (amending the Public Health Service Act to include that the NIH Director "shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans").

62. 21st Century Cures Act of 2016, Pub. L. No. 114-255, 130 Stat. 1033 (establishing the NIH Innovation Account); *see* Sekar, *supra* note 51, at 4–6.

63. Owermohle, *supra* note 16; *see* 42 U.S.C. § 281(a) (indicating that NIH is an agency of HHS).

64. U.S. DEP'T OF HEALTH & HUM. SERVS., FISCAL YEAR 2026 BUDGET IN BRIEF 21 (2025); *Institutes at NIH*, NIH, https://www.nih.gov/institutes-nih [https://perma.cc/TQT3-UDXX] (last updated Jan. 14, 2025).

65. Extramural grants include research and training grants, cooperative agreements, and contracts awarded to individual researchers based at universities and medical centers. Sekar, *supra* note 51, at 10.

66. Owermohle, *supra* note 16; Sekar, *supra* note 51, at 1. Intramural research is conducted by NIH employees at their Bethesda, Maryland campus and several off-campus sites. *Id.* at 18–19.

that its primary purpose is to increase the general body of scientific knowledge rather than serve practical applications.[67] This "basic research" can be used by others, creating a positive spillover effect that has led to breakthroughs—such as mRNA vaccines and GLP-1 weight loss drugs—as well as economic growth.[68]

While most publicly-funded clinical trials are funded at the federal level, state universities and colleges make up a large number of grant recipients.[69] Federal grants are an important source of revenue for these institutions and are economic drivers for states.[70] Institutions with prestigious research programs can attract top talent leading to a better educated workforce, which is more attractive to private company investment.[71] Additionally, indirect costs received from grants assist institutions with overhead costs from facilities maintenance to payroll.[72]

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67. NAT'L RSCH. COUNCIL, ASSESSMENT OF DEPARTMENT OF DEFENSE BASIC RESEARCH (2005).

68. *See* Neera Tanden, Ryan Mulholland & Adam Conner, *Attacks on the U.S. Innovation Ecosystem Are an Attack on a Wellspring of American Prosperity*, CTR. FOR AM. PROGRESS (July 17, 2025), https://www.americanprogress.org/article/attacks-on-the-u-s-innovation-ecosystem-are-an-attack-on-a-wellspring-of-american-prosperity/ [https://perma.cc/EQ6G-MYLJ]; Jacob Sweet, *How Just a Fishing Expedition Helped Lead to GLP-1*, HARV. GAZETTE (May 8, 2025), https://news.harvard.edu/gazette/story/2025/05/how-a-fishing-expedition-helped-lead-to-glp-1/ [https://perma.cc/Y96H-K629] (detailing how NIH funded research on hormones in anglerfish led to the discovery of GLP-1s); Mohammad S. Jalali & Zeynep Hasgül, *Proposed Cuts to NIH Funding Would Have Ripple Effects on Research that Could Hamper the US for Decades*, CONVERSATION (Sept. 12, 2025, 8:32 AM), https://theconversation.com/proposed-cuts-to-nih-funding-would-have-ripple-effects-on-research-that-could-hamper-the-us-for-decades-262419 [https://perma.cc/34C4-4C5N] (explaining NIH is also a major funder of preventative disease research which does not typically "attract private investment").

69. *See* Jason Cohn, *How Much Federal Funding Do Colleges and Universities Receive?*, URBAN WIRE (May 8, 2025), https://www.urban.org/urban-wire/how-much-federal-funding-do-colleges-and-universities-receive [https://perma.cc/93WM-ZLWC].

70. *See id.* (noting that the University of Alabama at Birmingham, University of Michigan-Ann Arbor, University of Hawaii at Manoa, and Montana State University all received more than 25% of their budget from federal sources); ADAM G. LEVIN & BEN LEUBSDORF, CONG. RSCH. SERV., IN12506, IMPACTS OF FEDERAL GRANTS AND OTHER FUNDS ON STATE AND LOCAL BUDGETS 1–3 (2025). The Bayh-Dole Act of 1980, also known as the Patent and Trademark Law Amendments Act, allowed research institutions to patent federally funded inventions. 35 U.S.C. § 200.

71. *See* Cohn, *supra* note 69; Sujai Shivakumar, Charles Wessner, Shruti Sharma & Chris Borges, *U.S. Universities: Engines of Economic Growth*, CTR. FOR STRATEGIC & INT'L STUDIES (Oct. 29, 2025), https://www.csis.org/analysis/us-universities-engines-economic-growth [https://perma.cc/SJG8-KV4D].

72. *See* Unglesbee, *supra* note 18.

Private researchers are already feeling the chilling effect of the Trump Administration's cuts.[73] NIH funded research has contributed to over 99% of drugs approved in the last decade.[74] Without public dollars driving innovation, new discoveries are likely to slow, potentially stunting the growth of medical research and treatments.[75] Additionally, physicians in the U.S. on work visas are facing the possibility of losing their legal status if they are laid off, contributing to a larger scientific brain drain.[76]

C. The NIH's Funding Structure

As of Fiscal Year 2025, the NIH manages a budget of $48 billion, of which 94% is distributed in research grants to universities, hospitals, and research institutions.[77] Section 282(m) of Title 42 requires that every six years the NIH develop a strategic plan, including a funding plan that identifies research priorities and objectives.[78] The NIH is mandated to "ensure that the resources of the [NIH] are sufficiently allocated for research projects identified in strategic plans."[79] The NIH also has statutory obligations to conduct specific research.[80] These areas include autoimmune diseases, muscular dystrophy, Parkinson's disease, osteoporosis, autism spectrum disorder, paralysis, pain, opioids, tick borne diseases, and more.[81]

Each of the NIH's twenty-seven institutes and centers (ICs) receive separate appropriations from Congress through the annual congressional budgetary process.[82] This budget is for their own intramural research as well as for the clinical research they fund across the country.[83] Once the ICs receive

73. *See* Rocha, *supra* note 16; Guenot, *supra* note 41.

74. Ekaterina Galkina Cleary, Matthew J. Jackson, Edward W. Zhou & Fred D. Ledley, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010–2019*, JAMA HEALTH F. (Apr. 28, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378 [https://perma.cc/VZS6-XRRR].

75. *See* Guenot, *supra* note 41.

76. *See id.*; Rocha, *supra* note 16 ("[T]here could be a 'lost generation of research,' where the pipeline of new scientists is disrupted and other countries become the leaders in scientific research." (quoting Amy Sharma, executive director of Science for Georgia)).

77. Tanden et al., *supra* note 68.

78. 42 U.S.C. § 282(m).

79. *Id.* § 282(b)(6).

80. *See id.* § 284(b)(1)(A) (directing the Secretary to encourage and support studies aimed at maintaining health, detecting, preventing, and rehabilitating human diseases, and expanding knowledge of human anatomy).

81. *Id.* §§ 284f–s.

82. *New to NIH*, NIH, GRANTS & FUNDING, https://grants.nih.gov/new-to-nih [https://perma.cc/ZM9B-6ZGR] (last updated Nov. 21, 2025).

83. *See id.*

their funds for the fiscal year, they consider and award grant applications based on "input from NIH staff, public health need, scientific opportunity, and the need to balance [their] scientific portfolio."[84]

The NIH has a rigorous grant application and review process to ensure the best use of federal funds.[85] Only around 20% of applications are approved.[86] The grant process is largely governed by the Public Health Service Act and its amendments, as well as the NIH Grants Policy Statement (GPS).[87] The Office of Policy for Extramural Research Administration (OPERA) is responsible for drafting and maintaining the GPS, which is routinely updated.[88] Grant applications are required to undergo two stages of peer review.[89] These reviews consider a number of criteria including the significance of the research, the approach, the level of innovation, and, significantly, if human subjects are adequately protected.[90] Additionally, grant recipients with human subjects must complete an educational program regarding the protection of human subjects before their application can be approved.[91] Section 8 of the GPS outlines administrative requirements for recipients including detailed processes for the closeout of a trial.[92] It does not, however, discuss early terminations of funding by the NIH for reasons other than noncompliance with agency policy.[93]

1. Terminations of Funding

Clinical research with human subjects is typically halted for only two reasons: mutual agreement between the researcher and the patient or if researchers and the Institutional Review Board (IRB), the ethics watchdog, determine that the treatment is doing more harm than good.[94] But even in these cases, the patients

84. *Id.*

85. *See id.*

86. *Id.*

87. *See* Public Health Service Act, 42 U.S.C. § 241(a); DEP'T OF HEALTH & HUM. SERVS. & NAT'L INSTS. OF HEALTH, NIH GRANTS POLICY STATEMENT (2024) [hereinafter NIH GRANTS POLICY STATEMENT]; *see also* Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 C.F.R. § 75 (2018).

88. NIH GRANTS POLICY STATEMENT, *supra* note 87, at iii.

89. 42 U.S.C. §§ 282(b)(9), 289a(a). The date for the second review must be published in the *Federal Register* at least fifteen days in advance of the meeting. 41 C.F.R. § 102-3.150(a) (2024).

90. NIH GRANTS POLICY STATEMENT, *supra* note 87, §§ 2.4.1.3–4.

91. *See id.* § 2.5.1.

92. *See id.* § 8.

93. *See id.* § 8.5.2.

94. 45 C.F.R. § 46.113 (2012); *see* Waldman, *supra* note 14.

are not simply abandoned.[95] Researchers will perform final follow-ups with patients and make a continuation of care plan.[96] Additionally, the IRB is required to submit a report to an HHS investigator explaining the basis for termination.[97]

Researchers can face these terminations of funding if there is evidence of misconduct or ethical concerns, such as violations of informed consent practices.[98] The threat of terminating funds incentivizes researchers and their institutions to comply with the guidelines of the Office of Human Research Protections (OHRP) and to mitigate the damage done to patients.[99] Therefore, the NIH will still provide the funds and ensure that patients are protected from any further risks to their health.[100] But the NIH rarely terminates funding.[101] Since 2012, there have been fewer than five terminations of grant funds due to noncompliance with agency regulations.[102]

When the NIH terminates a grant, it must notify the grant recipient, explain why the grant was terminated, and give the effective date of the termination.[103] Recipients then have the opportunity to object to the termination and to challenge the agency's reasoning to the official who signed off on the termination.[104] If the grant recipient is still unsatisfied with the outcome, the recipient can appeal the decision again to the Departmental Appeals Board.[105]

The Trump Administration justified its cuts to federal grants by relying on a federal regulation that provides that federal awards can be terminated if the purpose of the award "no longer effectuates the program goals or agency priorities."[106] Researchers reported that they no longer have funds to conduct close-out processes with their subjects, nor will the IRBs be able to submit a report at

95. *See* Wu, *Reckless Cuts*, *supra* note 29 ("[W]inding down a clinical trial safely can take months as researchers perform final check-ins with participants, collect additional data on safety, and in some cases help make arrangements for additional clinical care.").

96. *See id.*

97. 45 C.F.R. § 46.113 (2012).

98. *See* NIH GRANTS POLICY STATEMENT, *supra* note 87, § 8.5.2.

99. *See id.* § 4.1.15.4.

100. *See* Wu, *Reckless Cuts*, *supra* note 29 ("In the past, if an NIH-funded clinical trial needed to halt . . . the agency could be counted on to provide money and support to ensure that the study's participants wouldn't take on further risk . . . .").

101. *See* Waldman, *supra* note 14.

102. *Id.*

103. NIH GRANTS POLICY STATEMENT, *supra* note 87, § 12.13.3.

104. *Id.* § 8.7.

105. *See id.*; 45 C.F.R. § 16.3.

106. 2 C.F.R. § 200.340(2) (2024); Carolyn Y. Johnson & Joel Achenbach, *These 5 Words Have Killed Millions in Grants and Advanced Trump's Agenda*, WASH. POST (Mar. 27, 2025), https://www.washingtonpost.com/science/2025/03/27/trump-federal-grants-research-cuts/ [https://perma.cc/2TUT-RYFC].

their conclusion.[107] The OPERA issued a memorandum to grant recipients in July 2025 acknowledging that some grant recipients may not be able "to complete all closeout requirements within the timeframes provided in the revised Notice of Award."[108] This language seemed to suggest that HHS would not enforce the closeout regulations against institutions whose funding had been terminated.[109] The memorandum further stated that "in cases where a recipient has submitted an appeal, but has not yet received a response, NIH will not take action to initiate unilateral closeout while the appeal is under review."[110] The agency, however, did not provide guidance for intramural clinical trials where researchers were RIF'ed before completing closeout procedures or provide information on funding to complete the closeout procedures.[111]

2. Clinical Research Funding Under a Government Shutdown

OMB policy requires that emergency work involving the "safety of human life" be exempt from furloughs during a government shutdown.[112] In previous government shutdowns, the NIH has prioritized and provided uninterrupted care to human participants enrolled in its trials and diverting funds from other areas of research.[113] Trials involving patients with life-

107. *See* Wu, *Reckless Cuts*, *supra* note 29 ("Some [researchers] have sought funds from their department or university; some are turning to private donors or pharmaceutical companies, or dipping into money they've made as practicing physicians . . . even in a best-case scenario, they likely have just weeks or months of money left.").

108. NAT'L INSTS. OF HEALTH, NO. NOT-OD-25-128, GUIDANCE ON ENFORCEMENT OF CLOSEOUT REQUIREMENTS DURING THE APPEALS PROCESS (2025) [hereinafter NAT'L INSTS. OF HEALTH, NOT-OD-25-128]. A "Notice of Award" is a legal document issued from the NIH notifying the grant applicant of the funds they have been approved to receive as well as other relevant guidelines and conditions of the award. NIH GRANTS POLICY STATEMENT, *supra* note 87, § 5.

109. *See* NAT'L INSTS. OF HEALTH, NOT-OD-25-128, *supra* note 108.

110. *Id.*

111. *See id.*

112. OFF. OF PERS. MGMT., GUIDANCE FOR SHUTDOWN FURLOUGHS 1 (Dec. 2021).

113. *See* David Malakoff, *U.S. Scientists Brace for Looming Government Shutdown*, SCIENCE (Dec. 19, 2024, 12:50 PM), https://www.science.org/content/article/u-s-scientists-brace-looming-government-shutdown [https://perma.cc/FJ92-LP2M] (explaining 20,000 employees remained on duty to care for patients and research animals at the NIH Clinical Center and the agency's labs); *National Institutes of Health: Summary of Contingency Staffing Plan*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Sept. 25, 2025), https://www.hhs.gov/about/budget/fy-2026-nih-contingency-staffing-plan/index.html [https://perma.cc/4P4W-SQMY] ("Excepted NIH staff will continue to perform vital tasks related to imminent threats to human health or life, specifically by providing patient care."); Jocelyn Kaiser, *Tales from the Shutdown: ClinicalTrials.gov Gets Exemption*, SCIENCE (Oct. 4, 2013), https://www.science.org/content/article/tales-

threatening conditions commenced as planned, without any delays, due to ethics concerns.[114]

During the 2013 shutdown, a member of Congress lodged a complaint with HHS regarding a constituent who could not begin his clinical trial because the trial had not yet been entered into the ClinicalTrials.gov registry.[115] The complaint led to HHS bringing back a limited number of furloughed workers to maintain the database with "priority given to processing registrations of new trials and critical updates to existing entries."[116]

Shutdowns have had less of a direct effect on grant recipients.[117] Recipients are not affected by lapses in funding and can continue to draw on funds that were previously allocated.[118] However, grants processed before the funding lapse and set to be disbursed during the funding lapse will be postponed until funding is restored.[119]

II. PATIENTS' RIGHTS IN CLINICAL TRIALS

A. The Nuremberg Code

Clinical research with human participants has always had the potential for abuse.[120] After the horrific abuse at the hands of Nazi researchers was uncovered in 1947, a U.S. military court at the Palace of Justice in Nuremberg issued a landmark decision in *United States v. Brandt*[121] holding the doctors accountable for their crimes.[122] As part of its decision, the court included ten basic principles for ethical guidelines on acceptable risks to patients known

shutdown-clinicaltrialsgov-gets-exemption [https://perma.cc/3UE2-2M9F] (detailing how clinicaltrials.gov was brought back online during the 2013 shutdown).

114. *See* Kaiser, *supra* note 113.

115. *Id.*

116. *Id.*

117. *See* Malakoff, *supra* note 113.

118. NAT'L INSTS. OF HEALTH, NOT-OD-26-036, INFORMATION FOR THE NIH EXTRAMURAL COMMUNITY DURING THE LAPSE OF FEDERAL GOVERNMENT FUNDING (2026).

119. *See id.* ("For any awards processed before the funding lapse that have an issue date during the funding lapse, the awards will not be sent to the recipient on the issue date.").

120. *See* Pike, *supra* note 11, at 12, 15 ("The doctor-patient relationship is a fiduciary relationship, and patients are entitled to rely on doctors' learned judgments[;] . . . the same is not entirely true of the researcher-participant relationship.").

121. TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, VOLUME II (2017) (ebook) (part of the decision in *United States v. Brandt*, also referred to as the "Medical Trials" or the "Doctor's Trials," is colloquially called The Nuremberg Code).

122. *Id.* at 181–82.

as the Nuremberg Code.[123] The Nuremberg Code "set the standard for every subsequent attempt to regulate human experimentation" and created a foundational understanding of a researcher's duty to their patient.[124] The first principle set the groundwork for patient's informed consent in clinical trials.[125] It required that, among other precautions, the patient should be made aware of "all inconveniences and hazards reasonably to be expected" from participation in an experiment.[126] Additionally, the fourth principle called for experiments to be "conducted as to avoid all unnecessary physical and mental suffering and injury."[127] In 1964, the World Medical Association drew upon the principles of the Nuremberg Code when it published the Declaration of Helsinki to provide a clearer guide for physicians on research ethics.[128]

B. The Belmont Report and the Modern Era of Research Ethics

After the stunning abuses by American scientists in the 1970s' Tuskegee syphilis experiments,[129] Congress decided there needed to be a national policy governing human trials.[130] In 1974, Congress passed the National Research Act,[131] creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to identify "[t]he boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine" and "[t]he role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects."[132] The Commission later produced the Belmont Report establishing "an analytical framework [to] guide

123. *Id.* at 181–83. For a discussion of these principles in modern practice, see George J. Annas, *Beyond Nazi War Crimes Experiments: The Voluntary Consent Requirement of the Nuremberg Code at 70*, 108 AM. J. PUB. HEALTH, 42, 43 (2018).

124. *See* Annas, *supra* note 123, at 42.

125. *See* TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS, *supra* note 121, at 181–82.

126. *Id.* at 182.

127. *Id.*

128. *See Declaration of Helsinki*, WORLD MED. ASSEMBLY (June 1964), https://www.wma.net/wp-content/uploads/2018/07/DoH-Jun1964.pdf [https://perma.cc/LPE7-S9B4]; Pike, *supra* note 11, at 15.

129. *See* Pike, *supra* note 11, at 15; *see also About the Untreated Syphilis Study at Tuskegee*, CTRS. FOR DISEASE CONTROL (Sept. 4, 2024), https://www.cdc.gov/tuskegee/about/index.html [https://perma.cc/6AAH-6SFR] (explaining that subjects believed that they were receiving treatment for syphilis when in reality the scientists were studying how the disease progressed untreated).

130. Pub. L. No. 93-348, § 201, 88 Stat. 342, 348 (1974).

131. *Id.*

132. *Id.* § 202(a)(1)(B), 88 Stat. at 349; *see* Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192, 23,193 (Apr. 18, 1979).

the resolution of ethical problems arising from research involving human subjects."[133]

The Belmont Report set out three basic ethical principles for clinical research: respect for persons, beneficence, and justice.[134] Respect for persons relates to patients being treated as autonomous agents, incorporating elements of informed consent.[135] Beneficence incorporates two pillars: "(1) do not harm and (2) maximize possible benefits and minimize possible harms."[136] Lastly, justice entails that patients are not denied benefits or unduly burdened by research.[137]

1. Informed Consent and Institutional Review Boards (IRBs)

The Belmont Report formed the basis for HHS' Basic Policy for the Protection of Human Subjects, known as the "Common Rule," which governs federal research and how IRBs function.[138] An IRB's role is to ensure that risks to patients are minimized and are "reasonable in relation to anticipated benefits."[139] It also plays a vital role in ensuring that patients are well informed according to agency regulations when they consent to being enrolled in a study.[140] The Common Rule requires that federally funded institutions and federal agencies conducting research on human subjects have an IRB to approve and oversee studies as an ethical watchdog.[141] The IRBs are composed of at least five members with varying professional and personal backgrounds.[142] These requirements for informed consent include an explanation of the research, a description of reasonably foreseeable risks, possible

133. *See* Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. at 23,193.

134. *Id.* at 23,193–94.

135. *See id.* ("[R]espect for persons demands that subjects enter into the research voluntarily and with adequate information.").

136. *Id.* at 23,194 ("[I]nstitutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation.").

137. *See id.* ("An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.").

138. 45 C.F.R. § 46 (2012); *see* Pike, *supra* note 11, at 15–16.

139. 45 C.F.R. § 46.111.

140. *Id.* § 46.116. *But see* Russell T. Warne, *Stop Overregulating Research*, JAMES G. MARTIN CTR. FOR ACAD. RENEWAL (Jan. 22, 2025), https://jamesgmartin.center/2025/01/stop-overregulating-research/ [https://perma.cc/P8W9-6F9E] (arguing IRBs are inefficient, costly, and unconstitutional).

141. 45 C.F.R. § 46.01(b)(2).

142. *Id.* § 46.107 (stating IRBs ideally represent diverse perspectives to best protect the interests of all participants in a study).

benefits from participation, and other disclosures.[143] They do not require that participants be informed that funding for the study can be withdrawn without notice and all care will cease.[144]

C. Barriers to Patient Litigation

While the Common Rule is intended to protect patients, it is a regulation, not a statute, and does not provide patients with any avenues for seeking relief.[145] Patients who experience significant injuries or increases to their medical costs due to the termination or delay of their experimental treatment have no way of recovering monetary damages.[146] The APA,[147] the Federal Tort Claims Act (FTCA),[148] and the common law cause of action for lack of informed consent[149] also fall short of providing patients with adequate monetary or legal relief.[150]

1. The APA

Private citizens can bring claims pursuant to the APA if they are "adversely affected or aggrieved by agency action," however, they can only seek judicial review to compel an agency to act if the agency unlawfully withheld or unreasonably delayed an action required by statute.[151] While litigation continues as to whether the Trump Administration's cuts violated the Impoundment Control Act[152] or other provisions of the APA, the Supreme Court has allowed the terminations to remain in place, reasoning that the government would suffer irrevocable harm if they prevail and the funds had already been expended.[153] However, by the time a case reaches final adjudication and a court decides that funds should be released to restart a clinical trial, patients may no longer be eligible, may have sought out other treatments, or have died.[154] Researchers themselves may have been let go or

143. *Id.* § 46.116.

144. *See id.*

145. *See* Koch, *Consent in Research*, *supra* note 11, at 174 (highlighting that there is no private right of action to patients in clinical research trials).

146. *See id.* at 176.

147. 5 U.S.C. § 706.

148. Federal Tort Claims Act (FTCA), 28 U.S.C. § 2679.

149. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 791 (D.C. Cir. 1972).

150. *See infra* text accompanying notes 151–176.

151. 5 U.S.C. § 702.

152. 2 U.S.C. § 684(b).

153. Nat'l Insts. of Health v. Am. Pub. Health Ass'n, 145 S. Ct. 2658, 2660 (2025) (mem.).

154. *See* Parshall, *supra* note 30.

forced to move on to other projects with funding.[155] At this point, the APA's remedy, compelling the agency to release the funds, becomes moot and the APA does not allow for litigants to recover monetary damages for harms they have suffered.[156]

APA claims are also subject to other limitations. For example, a plaintiff can bring a claim only against a "final agency action."[157] Temporary pauses of federal grants are not considered a final agency action, and consequently, cannot be challenged under the statute.[158] Justice Barrett, in her concurrence in *NIH v. American Public Health Association*, stated that she was unsure whether even grant terminations, not just pauses, would be considered a final agency action, making the APA ill equipped to remedy patient harm.[159]

2. The FTCA and Sovereign Immunity

The principle of sovereign immunity holds that private citizens cannot sue the government for civil damages unless the government has consented to certain types of suits and remedies.[160] The FTCA waives sovereign immunity in specific circumstances.[161] Individuals can sue the federal government for negligent or wrongful acts committed by federal employees within the scope of their employment.[162] However, FTCA contains a number of exemptions that prevent courts from adjudicating claims, including barring liability from "the failure to exercise or perform a discretionary function or duty on the part of a federal agency."[163] A discretionary act is determined by whether the acting employee had a choice

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155. *Am. Pub. Health Ass'n*, 145 S. Ct. at 2676 (Jackson, J., concurring in part and dissenting in part).

156. 5 U.S.C. § 702.

157. *Id.* § 704.

158. *See id.* The Supreme Court has held that final agency action must satisfy two criteria: "First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Bennett v. Spear, 520 U.S. 154, 177–78 (1997) (citations omitted).

159. *Am. Pub. Health Ass'n*, 145 S. Ct. at 2662 (Barrett, J., concurring).

160. *See* Mark C. Niles, *"Nothing But Mischief": The Federal Tort Claims Act and the Scope of Discretionary Immunity*, 54 ADMIN. L. REV. 1275, 1290 (2002).

161. *See* FTCA, 28 U.S.C. § 2679(b)(1).

162. *Id.* For example, a car accident that occurs on government property while driving a government vehicle for National Guard training would be within the scope of employment, while an accident driving home from a federal job would not. *See* MICHAEL D. CONTINO & ANDREAS KUERSTEN, CONG. RSCH. SERV., R45732, FEDERAL TORT CLAIMS ACT (FTCA): A LEGAL OVERVIEW 11–12 (2023).

163. FTCA, 28 U.S.C. § 2680(a).

and whether that choice was a matter of public policy.[164] This exception broadly shields public policy decisions from liability to preserve government immunity in the function and operation of government and to prevent "'second-guessing' of legislative and administrative decisions."[165] Courts are likely to view terminations of grant funding as discretionary actions driven by a public policy undertaken by HHS and the broader Trump Administration, effectuated by employing a federal regulation.[166]

3. Informed Consent

Setting aside the issue of sovereign immunity, the tort system has generally provided patients with remedies for harm incurred during their treatment due to lack of informed consent.[167] Patients have a common law cause of action against physicians who violate the doctrine of informed consent by not disclosing certain information to patients that a reasonable person would need to inform their decision-making process.[168] Similar to a standard negligence claim, lack of informed consent requires a duty of care to the patient to inform them of risks, a breach of that duty by failing to disclose such risks, harm to the patient, and a causal relationship between the breach and the duty.[169]

Patient litigants in the research context face a unique challenge under the element of "duty."[170] By entering into an experimental study, patients are often viewed to "assume the risk" that accompanies the treatment.[171] It is for this reason that so little case law exists, and successful cases are rare.[172] Additionally, a researcher's duty is further distinguishable from a standard

164. *See* Berkovitz v. United States, 486 U.S. 531, 536–37 (1988).

165. Niles, *supra* note 160, at 1323; *see* Contino, *supra* note 162, at 18.

166. *See, e.g.*, Evans v. United States, 876 F.3d 375, 381 (1st Cir. 2017) ("The conduct of federal employees is generally held to be discretionary unless 'a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow.'" (quoting *Berkovitz*, 486 U.S. at 536)); *see* Pike, *supra* note 11, at 31 ("Courts have held the discretionary function exception to immunize the federal government from liability arising from the planning and execution of research.").

167. *See* Pike, *supra* note 11, at 23.

168. *See* Canterbury v. Spence, 464 F.2d 772, 791 (D.C. Cir. 1972).

169. Koch, *Consent in Research*, *supra* note 11, at 181–82.

170. *See id.* ("An individual claiming lack of informed consent must demonstrate that the physician failed to disclose information material to his or her decision to consent to a particular intervention.").

171. Pike, *supra* note 11, at 23–24.

172. *See id.* at 26 n.145.

physician by the federal regulations that govern their research.[173] The researcher's duty of informed consent has been fulfilled once the study has been approved by an IRB and satisfies the Common Rule's requirements.[174] Under the Common Rule, participants harmed by lack of informed consent are only protected by the loss of federal funding and suspension of research.[175] When the harm caused is the withdrawal of funding, there is no remedy.[176]

III. RECOMMENDATIONS

A. A More Informed Consent Process

Patients enrolling in clinical trials cannot provide informed consent unless they are informed of everything a reasonable person would need to know to decide whether to participate in that trial.[177] This should include information about the possibility of a cessation of treatment due to a block or withdrawal of funding.[178] HHS could alleviate this concern through a modification of the Common Rule § 46.116 through the notice-and-comment process under the APA.[179] Proposed language could follow subsection (8) and include the requirement of:

> A statement describing how the research is funded, the possibility of funding being withdrawn at any point during the study, and that patients will not be compensated for any harm resulting from a termination of funding.

This modification would add greater protection to patient decisionmaking and ensure that patients are not surprised when a funding cut happens. Patients would have the opportunity to make plans with their care teams outside of the research setting in the event of a grant termination.

While this recommendation would ensure a more informed consent process at the beginning of a clinical trial, it shifts responsibility away from the government and federal grant recipients, and onto the patient.[180] Patients

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173. *See id.* at 27–28 ("While doctors may be liable if they deviate from the generally accepted standard of care, research is an assessment of the effectiveness of those deviations from the standard of care.").

174. *See id.*

175. *See* 45 C.F.R. § 46.113 (2012); Koch, *Consent in Research*, *supra* note 11, at 175–76.

176. *See* Koch, *Consent in Research*, *supra* note 11, at 175–76.

177. *See* Canterbury v. Spence, 464 F.2d 772, 791 (D.C. Cir. 1972).

178. This information is not currently required by the Common Rule. *See* 45 C.F.R. § 46.116 (2012).

179. *See* 5 U.S.C. § 553.

180. *See* Koch, *Consent in Research*, *supra* note 11, at 212 ("[T]he standard for disclosure

who no longer have access to their experimental medications, or as a result of their treatment being halted have suffered severe bodily injury, still have no form of recourse because they have "assumed the risk."[181] This is a common criticism of informed consent in general that instead of protecting the patient it shifts liability away from the medical provider.[182] Ethical guardrails are not necessarily protections; however, they guide decisionmaking and are taken into consideration by researchers and IRBs.[183]

Additionally, duty in a case of lack of informed consent is often considered to be the federal requirements for informed consent.[184] If the Common Rule requires information on how funding can be terminated, patients have a better likelihood of success in proving the duty as an element of informed consent against non-government actors when they are not informed about a study's possible termination.

B. Emergency Funding Guidance

NIH leadership previously stated that certain studies could receive emergency funding if there are serious concerns about patient safety from the halting of the studies.[185] Despite this communication, the NIH released little guidance about how to apply for funding.[186] The Office for Extramural Research Administration routinely updates the NIH Grants Policy Statement to provide clarification and to implement new statutes and regulations.[187] The NIH could propose a regulation through the notice-and-comment process that could be incorporated into the GPS § 8.[188] This regulation could provide:

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must ensure that the informed consent process protects participants of research, rather than investigators and research institutions against potential liability."). *See generally* Koch, *Reimagining Informed Consent*, *supra* note 13, at 903–07 ("[I]nformed consent focuses almost exclusively on physician disclosures at the expense of ensuring that patients actually understand the risks, benefits, and alternatives that are being disclosed to them.").

181. *See supra* text accompanying note 171.

182. *See* Koch, *Reimagining Informed Consent*, *supra* note 13, at 903.

183. *See* Underhill, *supra* note 44, at 73–74 ("These [regulations] offer additional values that might be relevant to dispute systems design here, but no specific procedural guidance.").

184. *See supra* Part II.C.3.

185. Wu, *Reckless Cuts*, *supra* note 29 ("[A]gency officials were told to alert leadership if the halt on payments to certain studies might compromise patient safety, so that exceptions might be considered.").

186. *See id.* ("[T]he NIH's recent guidance on preserving patient safety has been murky at best . . . [an official was] not aware of any exceptions that had ever been made.").

187. NIH GRANTS POLICY STATEMENT, *supra* note 87, at iii.

188. *See* 5 U.S.C. § 553.

> *Terminations of Grants for Policy Reasons*: If a recipient's funds are terminated pursuant to 2 C.F.R. § 200.340(4)(a)(4), the recipient must complete closeout procedures in accordance with § 8.6 of the NIH Grants Policy Statement. If the early conclusion of a trial presents serious concerns about patient safety and possible loss of life, recipients can appeal to the Office of Human Research Protection via an online form for an emergency funding continuance. OHRP must respond to an application for emergency funds within ten business days. Additionally, OHRP must provide every grant recipient whose funds are terminated with funds to complete the closeout processes required by § 8.6 of the NIH Grants Policy Statement.

This regulation would protect patients from being abandoned by requiring a proper closeout process. By providing a mechanism for grant recipients to appeal, much like termination for failure to comply with agency regulations, it adds an additional safeguard. However, this safeguard still does nothing to improve patient rights and protect their autonomy.

C. Continuation of Care Plans as Part of the IRB Requirements

The core function of the IRB is to ensure risks to human research subjects are minimized.[189] To fulfill this function, there must be continuity of care plans built into the approval process rather than the closeout process.[190] Section 46.111 of the Common Rule outlines the criteria for the IRB's approval of research with human subjects.[191] HHS should propose a rule through the notice-and-comment process to add an additional requirement for the IRB's approval that includes:

> A continuation of care plan must be presented to each prospective subject outlining what type of treatment, if available, the plan should transition to in the event funding for the study or the researchers' employment is terminated during the research study.

This document would be included with informed consent materials and could be updated throughout the study. A continuation of care plan would allow patients to provide their primary care physicians or other specialists with the information to transfer them to non-experimental care. For terminal cancer patients, this may include a hospice-style plan. A continuation of care plan for behavioral health patients might include guidance about weaning off experimental drugs and transferring to a drug available in the general marketplace.

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189. 45 C.F.R. § 46.111 (2018).

190. *See supra* text accompanying note 96.

191. 45 C.F.R. § 46.111.

While this recommendation would ensure that many patients are not left completely abandoned when a study is terminated, it does not assist patients who are enrolled in trials for terminal illnesses in which no other treatments are available.

D. Insurance Requirement

Legal commentators have proposed requiring U.S. research institutions to carry insurance as a solution to compensating patients injured in clinical trials.[192] Insurance could also be a solution when federal funding is terminated. Some research institutions already carry insurance coverage to protect them from malpractice claims and to compensate injured participants even though it is not legally required.[193] Insurers could increase institutions' policies to cover the cost of continuing a study while the institution litigates whether funding should be restored; insurers could also cover the costs related to closing a study if a grant is terminated.

An insurance requirement could be imposed in two different ways. First, HHS' Policy for the Protection of Human Research Subjects allows department or agency heads to impose any additional conditions upon researchers they deem necessary for the protection of human subjects.[194] This insurance requirement could be incorporated into the NIH GPS through this provision.[195] Second, HHS could add an additional subsection to the Common Rule through the notice-and-comment process by providing:

> *46.XXX Insurance Requirement*: Each institution engaged in research that is covered by this policy and whose research is conducted or supported by a federal department or agency, shall carry insurance coverage to cover the cost of patient care deemed medically necessary through the closeout of the study in the event federal funds are not disbursed or are terminated due to agency policy changes.

An insurance requirement shifts the risks associated with grant terminations to the research institutions and away from the patients. This recommendation, however, does not protect patients participating in trials directly

192. *See* Pike, *supra* note 11, at 48.

193. *See Clinical Trials Insurance*, ALLIANZ, https://commercial.allianz.com/solutions/liability-insurance/clinical-trials-insurance.html [https://perma.cc/99FP-YLYQ] (last visited May 3, 2026). Many countries, including those of the European Union, require this type of insurance to conduct human trials. *See* Pike, *supra* note 11, at 39 ("Given the increasing globalization of research and the requirement that research conducted abroad comply with the laws of the host country, U.S.-sponsored research must increasingly comply with other countries' research regulations.").

194. 45 C.F.R. § 46.124 (2018).

195. *See id.*

administered by the NIH who are not covered by the NIH GPS. Additionally, adding an insurance requirement would increase already high costs of conducting a study with human subjects and could stifle research.[196] Insurers may be unwilling to take on the substantial risk associated with the unpredictability of congressional appropriations and agency policy.

E. Private Cause of Action

The solution that would provide the greatest amount of protection for patients in clinical trials is perhaps the most politically fraught and the hardest to achieve. Congress could create a cause of action for patients harmed in federally funded clinical trials because of the government's withdrawal of funds or for violations of their informed consent rights. This would eliminate the barrier of sovereign immunity and treat the government the same as a private actor with a duty to the patients under their care.[197] A private cause of action would provide patients and their families with some opportunity for monetary recovery, and importantly an admission of wrongdoing which would hopefully deter the government from making arbitrary cuts again.[198]

While this remedy would provide strong protection for patients, it is not without drawbacks. If each individual patient has a right to sue the government, it could force the government to litigate thousands of individual cases or possibly massive class actions that would be time-consuming and expensive for taxpayers.

F. Modeling the National Vaccine Injury Compensation Program

A more measured approach that would provide a compromise for patients and the government would be to model the National Vaccine Injury Compensation Program (VICP).[199] Congress created the VICP in 1986 to insulate vaccine manufacturers from vaccine injury lawsuits that would make it cost prohibitive to sell vaccines.[200] Congress recognized the public health

196. Regulations on research with human subjects "add[] to the cost of scientific progress" and "delay[] research projects," and requiring insurance could have a similar effect. *See* Warne, *supra* note 140.

197. *See supra* text accompanying note 160.

198. Private enforcement suits help to elevate personal experiences and can inform the public, lawmakers, and agencies about regulatory harms and power imbalances. *See* Luke P. Norris, *The Promise & Perils of Private Enforcement*, 108 VA. L. REV. 1483, 1489 (2022).

199. 42 U.S.C. § 300a-10.

200. *See About the National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/vaccine-compensation/about [https://perma.cc/CZ5T-U23M] (last updated May 2026).

necessity of compulsory vaccines as well as the right for patients and their families to recover from medical harm.[201] The VICP created a no-fault compensation system funded by the very drug companies that they were protecting from liability.[202] Under the VICP, those injured by vaccines file a petition with the U.S. Court of Federal Claims where a Special Master hears the case and decides whether the injury was caused by a covered vaccine.[203] Once the court decides the patient should be compensated, the Division of Injury Compensation Programs at HHS distributes compensation based on the Vaccine Injury Table.[204] This compensation is provided through the Vaccine Injury Compensation Trust Fund.[205] The fund is managed by the Department of the Treasury and financed by a $0.75 excise tax on each dose of childhood vaccines recommended by the Centers for Disease Control and Prevention.[206]

Congress could pass legislation to replicate this model, providing no-fault compensation to those who are harmed due to the termination of federally funded clinical research and granting statutory authority to a Special Master to hear the claims.[207] As with the VICP, patients would merely have to prove that they experienced physical harm due to the termination of their trial.[208] This would entitle them to compensation based on the severity of the injury, which could be determined by a Special Master, or by a compensation table.[209] To fund the program, drug companies could pay a $0.10 excise tax on the sale of any drug created as a result of federally funded research.[210] Whereas access to government research is provided at no cost, this would compensate the patients who take on the risks that enable private companies'

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201. *See id.*

202. *See id.*

203. *See* 42 U.S.C. §§ 300aa-11–300aa-13.

204. *See id.* § 300aa-14. The Secretary of HHS may modify the vaccine table through the notice-and-comment process. *Id.* § 300aa-14(c)(1).

205. *See id.* § 300aa-15(i)(2).

206. 26 U.S.C. §§ 9510(b), 4131(b)(1).

207. While not the focus of this comment, this recommendation has also been suggested by scholars to provide remedies for those injured in clinical trials. *See* Pike, *supra* note 11, at 50.

208. *See* 42 U.S.C. § 300aa-13(a)(1). Like the VICP, there would be no need to show negligence, only that the termination of the trial caused the injury. *See id.*

209. *See id.* § 300aa-14.

210. *See* 26 U.S.C. § 4131(b)(1). The total number of prescriptions dispensed in the U.S. in 2022 was 6.7 billion. *The Use of Medicines in the U.S. 2023*, IQVIA (May 2, 2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023 [https://perma.cc/5WJS-B37P]. With a $0.10 excise tax, the compensation fund would have received $670 million. *See id.* For a comparable model, see 42 U.S.C. § 300aa-13(a)(1).

profits.[211] However, like with the VICP excise tax, this cost would likely be passed on to the consumers of drugs and not borne by the drug companies.[212] With drug costs already too high for many American families, increasing those costs may be politically challenging.[213] Additionally, while the VICP has been largely successful, in recent years the program has struggled to keep up with the number of claims.[214] Without an expansion of the number of Special Masters, such a program is unlikely to resolve claims in a timely manner.[215]

CONCLUSION

If Sue Scott's clinical trial had taken place in 2025, rather than 2012, it likely would have been impacted by the NIH's expansive funding cuts.[216] Sue and her doctors would have known that the treatment was working, but would not have been able to continue it.[217] Her doctors may have been fired as part of the agency RIF, leaving her, like Richard Schlueter, with no way to access her treatment, even if the trial itself still had its funding.[218] Without access to her unique care, Sue would have likely died and her family would not have been able to do anything about it. The hope participating in the clinical trial gave her would have been false.[219]

It may be argued that the Trump Administration's funding cuts were the first of their kind; therefore, responding to a single event, the legality of which is still being determined by the courts, is unwarranted.[220] These actions, however, have revealed critical deficiencies in patient protections—

211. *See supra* text accompanying note 74.

212. *See* Pike, *supra* note 11, at 51.

213. *See* Atinuke Lardner, Grace Schuette & Evelyn Woo, *Tackling America's High Drug Prices*, REGUL. REV. (May 31, 2025), https://www.theregreview.org/2025/05/31/seminar-tackling-americas-high-drug-prices/ [https://perma.cc/3NFJ-4754].

214. Jon Wertheim, *Vaccine Court: Where Americans Who Suffer Rare Injury After Vaccination Can Take Their Claims*, 60 MINUTES (Oct. 5, 2025, 7:00 PM), https://www.cbsnews.com/news/vaccine-court-americans-who-suffer-rare-injury-after-vaccination-take-claims-60-minutes-transcript/ [https://perma.cc/7PM4-TK6R].

215. *See id.* ("The [Vaccine] court acknowledges the delays. Citing a backlog of more than 3,000 cases . . . [the court has] ask[ed] Congress for more resources four years running.").

216. *See* Sheridan, *supra* note 1. Cervical cancer affects women and research grants are often distributed under diversity, equity, and inclusion programs. *See generally* L. Vidal, Z. Dlamini, S. Qian, P. Rishi, M. Karmo, N. Joglekar, et al., *Equitable Inclusion of Diverse Populations in Oncology Clinical Trials: Deterrents and Drivers*, EUR. SOC'Y FOR MED. ONCOLOGY OPEN, May 2024, at 1, 2.

217. *See* Sheridan, *supra* note 1.

218. *See* Johnson, *supra* note 8.

219. *See Sue's Story*, *supra* note 1.

220. *See supra* text accompanying notes 22–28.

protections that it is high time that the government review and strengthen.[221] Additionally, the Supreme Court has expressed its opposition to nationwide temporary restraining orders, allowing harm to continue while the court weighs cases on their merits.[222] If patients have no way to recover for harm inflicted during that period, then they need to at least have some protections at the front end of the clinical trial process.[223]

Massive cuts to government spending can make it harder to discern how Americans are affected in a tangible way, but the government must care for the individuals that it puts at risk. The courts, Congress, and HHS have long recognized the importance of protecting human research subjects.[224] Each of these recommendations are in line with the Belmont Report's principles for ethical research of human subjects: respect for persons, beneficence, and justice.[225] Without them, however, justice for patients remains a concept on paper, and not in law. The drafting of the Belmont Report was a radical response to shocking patient harms.[226] Perhaps, at this moment, these recommendations are required to fulfill ethical and moral obligations to the patients that provide us with science's biggest breakthroughs.

221. Just as researchers continue to reexamine treatments, the government and its agencies should reexamine their regulations governing them. *See generally* Konstantinos Dean Boudoulas, Filippos Triposkiadis, Christodoulos Stefanadis & Harisios Boudoulas, *The Endlessness Evolution of Medicine, Continuous Increase in Life Expectancy and Constant Role of the Physician*, 58 HELLENIC J. CARDIOLOGY 322 (2017).

222. *See, e.g.*, Trump v. CASA, Inc., 145 S. Ct. 2540 (2025).

223. *See supra* Part II.

224. *See id.*

225. *See* Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Fed. Reg. 23,192, 23,193–94 (Apr. 18, 1979).

226. *See id.*