LEGAL AND REGULATORY CONSIDERATIONS FOR POST-TRIAL ACCESS TO MAINTENANCE OF BENEFICIAL INVESTIGATIONAL NEURAL DEVICES*

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This Article examines the ethical, legal, and policy imperatives of guaranteeing post-trial access to those implanted with beneficial investigational neural devices. As neural implant research expands and delivers transformative benefits for people with severe, treatment-resistant conditions, trial participants routinely lose access to essential maintenance, programming, clinical follow-up, and hardware replacements once studies end. We argue that post-trial access disputes over brain implants are sui generis: the devices are invasive, lifelong, and dependence-creating; withdrawal of support can precipitate rapid clinical deterioration, rebound effects, psychosocial harm, and safety risks from abandoned or obsolete hardware.

Part I surveys the science, applications, and distinctive risk profile of implanted neural devices. Part II analyzes the U.S. legal landscape and shows that courts have—so far—refused to recognize any freestanding right to investigational access and typically reject post-trial claims against sponsors. This is true even as funders, industry policies, and international ethics guidance increasingly require prospective post-trial access planning and disclosure. Part III contends that robust, predictable post-trial access is essential to protect uniquely vulnerable

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participants, sustain public trust in neurotechnology research, and enable responsible innovation.

INTRODUCTION

Implantable neural devices like deep-brain stimulation systems and brain-computer interfaces offer therapeutic promise for patients who have exhausted conventional treatments. Major investments in neurotechnology have led to the development of devices that can successfully target—with incredible precision—which brain activity to record and which brain regions to stimulate, to many different ends. The focus of this Article is the medical applications for these devices. These applications are primarily aimed at managing the symptoms of treatment-resistant conditions, like Parkinson's disease and depression, or they are aimed at improving functional impairments, like acquired blindness or paralysis.

In many trials, most people with severe, treatment-resistant conditions who resort to implantable neural devices benefit from doing so. And for some,

neural implants can provide dramatic improvements—like restoring lost abilities or reducing symptoms to the point of remission. The transformative impact of these devices is especially significant because these participants have long endured debilitating symptoms and the disappointment of failed treatment after failed treatment.

Yet, after undergoing neurosurgery and being implanted with a brain device that changed the course of their lives, these participants almost always lose access to device maintenance and care after the clinical trial ends. Device companies and research teams that sponsor these trials typically have no long-term plan in place for devices that are intended to remain in the brain for the duration of a patient's life. When companies do offer support after the trial's end, it is often temporary in duration and limited in scope. Essential services, such as programming, follow-up care, and hardware replacements (like replacing batteries), are not guaranteed after the trial ends.

The lapses in maintenance that can result from this neglect or abandonment can abruptly reverse benefits, leading to the recurrence of debilitating motor or neuropsychiatric symptoms.[1] The stress from this medical and financial uncertainty can cause significant physical and psychological harm. Because these devices are investigational, insurers frequently deny coverage for maintenance and related clinical appointments, shifting prohibitive costs to patients and prompting ad hoc workarounds by researchers and clinicians.

Although post-trial access disputes are nothing new, this Article highlights why post-trial access disputes in the context of clinical trials involving brain implants are sui generis and should be a primary focus of stakeholders in this promising field.

I. BRAIN IMPLANT BASICS

Implantable neural devices promise improvement to patients with hard-to-treat neurological and psychiatric conditions and impaired or reduced functions, such as sight, speech, and movement. This Part will cover the basics. Section I.A starts with an explanation of which neural devices implicating post-trial access concerns matter for our purposes and their most relevant applications. Then, Section I.B turns to trends in clinical research exploring

1. Cessation of deep brain stimulation (for example, battery depletion or powering off the system) leads to a rebound of symptoms, which at times, can be worse than before stimulation. A.K. Vora, H. Ward, K.D. Foote, W.K. Goodman & M.S. Okun, *Rebound Symptoms Following Battery Depletion in the NIH OCD DBS Cohort: Clinical and Reimbursement Issues*, 5 BRAIN STIMUL. 599, 603–04 (2012); Pieter Ooms, Matthijs Blankers, Martijn Figee, Mariska Mantione, Pepijn van den Munckhof, P. Richard Schuurman & Damiaan Denys, *Rebound of Affective Symptoms Following Acute Cessation of Deep Brain Stimulation in Obsessive-Compulsive Disorder*, 7 BRAIN STIMUL. 727, 730 (2014); Sarah S. Cooper, Benjamin I. Ferleger, Andrew L. Ko, Jeffrey A. Herron & Howard J. Chizeck, *Rebound Effect in Deep Brain Stimulation for Essential Tremor and Symptom Severity Estimation from Neural Data*, 2020 ANN. INT'L CONF. IEEE ENG'G MED. & BIOL. SOC'Y 3621, 3621.

new applications for these devices. Last, Section I.C highlights some of the risks and vulnerabilities that those implanted with these investigational devices face, especially because these interventions are often successful in providing relief to treatment-resistant subjects when all else fails.

A. *Medical Applications of Neural Implant Devices*

Some neural implant devices have transitioned from experimental tools to emerging or established therapeutic options that fundamentally alter how we manage certain neurological and psychiatric conditions.

These devices come in different forms. The phrase "implantable neural devices" might refer to brain-computer interfaces ("BCIs"),[2] deep brain stimulation ("DBS") systems, or cochlear implants,[3] all of which stimulate brain targets. Increasingly, as we explore herein, these systems are integrating sensing capabilities that allow the systems to record neural activity and modify stimulation based on this activity.

They are implanted throughout the nervous system to different ends. Keeping it simple, one could think of the nervous system in two parts: the central nervous system and the peripheral nervous system.[4] A peripheral system of nerves and ganglia gathers sensory information, and this information is collected and processed by our brain and spinal cord—that is, the central nervous system.[5] Depending on the intended therapeutic end, neural devices are placed somewhere along the nervous system to stimulate specific areas associated with symptoms or functional impairment, including the spinal cord and specific brain regions, and to record and decode signals from these areas.[6]

2. BCIs are what Neuralink and Synchron have popularized. *See* NEURALINK, https://neuralink.com/ [https://perma.cc/93DS-EUWS]; SYNCHRON, https://synchron.com/ [https://perma.cc/L9QM-D627].

3. Gabriel Lázaro-Muñoz, Michelle T. Pham, Katrina A. Muñoz, Kristin Kostick-Quenet, Clarissa E. Sanchez, Laura Torgerson, Jill Robinson, Stacey Pereira, Simon Outram, Barbara A. Koenig, Philip A. Starr, Aysegul Gunduz, Kelly D. Foote, Michael S. Okun, Wayne Goodman, Amy L. McGuire & Peter Zuk, *Post-Trial Access in Implanted Neural Device Research: Device Maintenance, Abandonment, and Cost*, 15 BRAIN STIMUL. 1029, 1030 (2022) [hereinafter Lázaro-Muñoz et al., *Device Maintenance, Abandonment, and Cost*], https://www.brainstimjrnl.com/action/showPdf?pii=S1935-861X%2822%2900169-3 [https://perma.cc/Z7RQ-S3PQ (staff-uploaded archive)]; Thomas J. Buell, Alexander Ksendzovsky, Binit B. Shah, Bradley W. Kesser & W. Jeffrey Elias, *Deep Brain Stimulation in the Setting of Cochlear Implants: Case Report and Literature Review*, 93 STEREOTACT. & FUNCT. NEUROSURG. 245, 245 (2015).

4. Kadir A. Yildiz, Alexander Y. Shin & Kenton R. Kaufman, *Interfaces with the Peripheral Nervous System for the Control of a Neuroprosthetic Limb: A Review*, at 1, *in* 17 J. NEUROENG. REHAB. art. 43 (2020), https://link.springer.com/content/pdf/10.1186/s12984-020-00667-5.pdf [https://perma.cc/5KCL-MGK7].

5. *Id.* at 2.

6. *See* Younguk Cho, Sanghoon Park, Juyoung Lee & Ki Jun Yu, *Emerging Materials and Technologies with Applications in Flexible Neural Implants: A Comprehensive Review of Current Issues with Neural Devices*, at 1, *in* 33 ADV. MATERS. art. 2005786 (2021), https://advanced.onlinelibrary.wiley.com/doi/epdf/10.1002/adma.202005786 [https://perma.cc/5BLM-8KXH (staff-uploaded archive)].

A DBS system is a type of neural implant device with recognized therapeutic applications. The Food and Drug Administration ("FDA") has approved DBS to treat movement disorders, particularly Parkinson's disease and essential tremor.[7] The FDA has authorized a humanitarian device exemption ("HDE") for DBS for dystonia starting in children at age seven.[8] In those with Parkinson's disease and other movement disorders, DBS intervention can significantly improve motor symptoms, reduce reliance on medication, and enhance a patient's quality of life.[9] DBS is also available under an HDE for treatment-resistant obsessive-compulsive disorder ("OCD"),[10] while DBS targeting the anterior nucleus of the thalamus is approved for epilepsy.[11] Studies are actively investigating DBS for a range of other conditions, too. Among these targets are treatment-resistant major depression, chronic pain syndromes, Alzheimer's disease, Tourette syndrome, post-traumatic stress disorder, obesity, addiction, and traumatic brain injury.[12]

DBS works by targeting and electrically stimulating specific areas of the brain. In DBS, electrodes are surgically implanted into specific brain targets (like the subthalamic nucleus or globus pallidus), delivering electrical signals

7. Michelle T. Pham, Tiffany A. Campbell, Natalie Dorfman, Laura Torgerson, Kristin Kostick-Quenet, Jennifer Blumenthal-Barby, Eric A. Storch & Gabriel Lázaro-Muñoz, C*linician Perspectives on Levels of Evidence and Oversight for Deep Brain Stimulation for Treatment-Resistant Childhood OCD*, at 1, *in* 39 J. OBSESSIVE-COMPULS. & RELAT. DISORDS. art. 100830 (2023), https://www.clinicalkey.com/service/content/pdf/watermarked/1-s2.0-S2211364923000519.pdf?locale=enUS&searchIndex= [https://perma.cc/K5FR-HAWL (staff-uploaded, dark archive)].

8. *Humanitarian Device Exemption (HDE)*: *Medtronic Activa Deep Brain Stimulation (DBS) System*, U.S. FOOD & DRUG ADMIN. (Apr. 15, 2003), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=375511 [https://perma.cc/D37D-2DRQ (staff-uploaded archive)].

9. *See* S.J. Groiss, L. Wojtecki, M. Sudmeyer & A. Schnitzler, *Deep Brain Stimulation in Parkinson's Disease*, 2 THER. ADVS. NEUROL. DISORDS. 379, 382–83 (2009), https://journals.sagepub.com/doi/epdf/10.1177/1756285609339382 [https://perma.cc/R72E-K72Z (staff-uploaded archive)].

10. Saskia Hendriks, Christine Grady, Khara M. Ramos, Winston Chiong, Joseph J. Fins, Paul Ford, Sara Goering, Henry T. Greely, Katrina Hutchinson, Michael L. Kelly, Scott Y.H. Kim, Eran Klein, Sarah Lisanby, Heleb Mayberg, Hannah Maslen, Franklin G. Miller, Karen Rommelfanger, Sameer S. Sheth & Anna Wexler, *Ethical Challenges of Risk, Informed Consent, and Posttrial Responsibilities in Human Research with Neural Devices: A Review*, 76 J. AM. MED. ASS'N NEUROL. 1506, 1507 (2019) [hereinafter Hendriks et al., *Ethical Challenges*]. A humanitarian exception is a regulatory pathway that allows the FDA to approve a Class III medical device for a rare disease or condition affecting fewer than 8,000 people in the United States each year. *See Humanitarian Device Exemption*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/humanitarian-device-exemption [https://perma.cc/C8B4-795Y (staff-uploaded archive)] (last updated Jan. 13, 2025).

11. *See* Ricardo Costa-Gertrudes, Diogo Simão, Ana Franco, Carlos Morgado, Ana Rita Peralta, José Pimentel, António Gonçalves-Ferreira, Carla Bentes & Alexandre Rainha Campos, *Anterior Nucleus of Thalamus Deep Brain Stimulation: A Clinical-Based Analysis of the Ideal Target in Drug-Resistant Epilepsy*, 100 STEREOTACT. & FUNCT. NEUROSURG. 108, 108 (2022).

12. *See, e.g.*, Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1507.

that modulate dysfunctional neural circuits.[13] Typically, DBS systems have been what scientists call "open-loop" systems.[14] This means that the systems provide continuous, constant electrical stimulation to the brain, which can lead to more pronounced side effects; neural habituation; and battery depletion, which requires surgical replacement.[15] Recent technological advances, however, have achieved a significant step forward in personalizing the neuromodulation achieved by these systems. We now have available "closed-loop" or "adaptive" DBS systems, which incorporate real-time sensing of neural activity to automatically adjust stimulation parameters.[16] The FDA has already approved next-generation adaptive devices to manage Parkinson's disease (for example, Medtronic's BrainSense),[17] and the hope is that adaptive devices can optimize therapeutic efficacy, minimize side effects, and adapt to fluctuations in disease state.[18]

Vagus nerve stimulation ("VNS") systems are another type of neural implant. VNS treatments involve the implantation of a device that delivers intermittent electrical stimulation to the vagus nerve in the neck, modulating brain excitability.[19] VNS has transformed epilepsy care because it has proven efficacious in reducing seizure frequency, particularly for patients with drug-resistant or refractory epilepsy who are not candidates for surgical resection[20] and patients with treatment-resistant depression.[21]

13. *See, e.g.*, Wolf-Julian Neumann, Roee Gilron, Simon Little & Gerd Tinkhauser, *Adaptive Deep Brain Stimulation: From Experimental Evidence Toward Practical Implementation*, 38 MOV. DISORDS. 937, 938 (2023), https://movementdisorders.onlinelibrary.wiley.com/doi/epdf/10.1002/mds.29415 [https://perma.cc/JN9A-FQPZ (staff-uploaded archive)].

14. Mahboubeh Parastarfeizabadi & Abbas Z. Kouzani, *Advances in Closed-Loop Deep Brain Stimulation Devices*, at 1, *in* 14 J. NEUROENG. & REHAB. art. 79 (2017), https://link.springer.com/content/pdf/10.1186/s12984-017-0295-1.pdf [https://perma.cc/BTS6-3Q4S].

15. *See id.* at 1–2.

16. *Id.* at 1; Neumann et al., *supra* note 13, at 938.

17. *FDA Approves New Adaptive DBS System*, AM. PARKINSON DISEASE ASS'N (Feb. 28, 2025), https://www.apdaparkinson.org/article/fda-approves-new-adaptive-dbs-system/ [https://perma.cc/8LAX-76J9].

18. Neumann et al., *supra* note 13, at 938; Parastarfeizabadi & Kouzani, *supra* note 14, at 1–2.

19. Hernán F.J. González, Aaron Yengo-Kahn & Dario J. Englot, *Vagus Nerve Stimulation for the Treatment of Epilepsy*, 30 NEUROSURG. CLINS. N. AM. 219, 219 (2019).

20. *See id.* at 223–25 (citing Dario J. Englot, John D. Rolston, Clinton W. Wright, Kevin H. Hassnain & Edward F. Chang, *Rates and Predictors of Seizure Freedom with Vagus Nerve Stimulation for Intractable Epilepsy*, 79 NEUROSURGERY 345, 345–50 (2016)). Surgical resection means removing a part of the patient's brain that is causing the seizures.

21. Dario J. Englot, Edward F. Chang & Kurtis I. Auguste, *Vagus Nerve Stimulation for Epilepsy: A Meta-Analysis of Efficacy and Predictors of Response*, 115 J. NEUROSURG. 1248, 1248 (2011); Lim Mervyn Jun Rui, Fong Khi Yung, Zheng Yilong, Chua Christopher Yuan Kit, Samuel Miny, Jeremy Bingyuan Lin, Vincent Diong Weng Nga, Hian Tat Ong, Rahul Rathakrishnan & Tseng Tsai Yeo, *Vagus Nerve Stimulation for Treatment of Drug-Resistant Epilepsy: A Systematic Review and Meta-Analysis*, 45 NEUROSURG. REV. 2361, 2364–65 (2022).

Responsive neurostimulation ("RNS") is a more recent advance in this field: this fully implanted, closed-loop system continuously monitors electrocorticographic activity via electrodes in the skull.[22] The system detects abnormal electrical activity in the brain, and as it does, it delivers targeted electrical pulses.[23] These electrical impulses abort or attenuate seizures in real time.[24] Clinical trials have shown that these modalities reduce seizure frequency and severity, improve quality of life, and offer hope to patients who have exhausted other treatment options.[25]

BCIs—like Neuralink—are another major therapeutic application of neural implants.[26] BCIs are particularly useful for those with severe paralysis due to conditions such as amyotrophic lateral sclerosis ("ALS"), spinal cord injury, or brainstem stroke.[27] Intracortical BCIs involve the implantation of microelectrode arrays into the motor cortex, and these allow for the decoding of neural signals associated with intended movement or communication.[28] BCI systems let paralyzed patients control computer cursors, type text via imagined handwriting, and even decode basic speech directly from neural activity.[29] Neural interfaces can also be coupled to robotic prostheses or computer-based

22. Beata Jarosiewicz & Martha Morrell, *The RNS System: Brain-Responsive Neurostimulation for the Treatment of Epilepsy*, 18 EXPERT REV. MED. DEVICES 129, 130 (2021).

23. *See id.* at 2.

24. *See, e.g.*, NEUROPACE, https://www.neuropace.com/ [https://perma.cc/Y8RK-8RHW] ("There's a smarter way to treat epilepsy."); *see also* Felice T. Sun & Martha J. Morrell, *The RNS System: Responsive Cortical Stimulation for the Treatment of Refractory Partial Epilepsy*, 11 EXPERT REV. MED. DEVICES 563, 564 (2014); Tara L. Skarpaas, Beata Jarosiewicz & Martha J. Morrell, *Brain-Responsive Neurostimulation for Epilepsy (RNS System)*, 153 EPILEPSY RSCH. 68, 68 (2019), https://www.clinicalkey.com/service/content/pdf/watermarked/1-s2.0-S0920121118305758.pdf?locale=en_US&searchIndex= [https://perma.cc/U9JY-X6K7 (staff-uploaded archive)].

25. *See* Sun & Morrell, *supra* note 24, at 569.

26. *See* Jamie F.M. Brannigan, Kishan Liyanage, Hugo Layard Horsfall, Luke Brashford, William Muirhead & Adam Fry, *Patient Preferences for Brain-Computer Interfaces: A Systematic Review*, at 1, *in* 21 J. NEURAL ENG'G art. 061005 (2024), https://iopscience.iop.org/article/10.1088/1741-2552/ad94a6/pdf [https://perma.cc/FX7P-5U2D (staff-uploaded archive)].

27. *Id.*

28. *See id.*; David A. Moses, Sean L. Metzger, Jessie R. Liu, Gopala K. Anumanchipalli, Joseph G. Makin, Pengfei F. Sun, Josh Chartier, Maximilian E. Dougherty, Patricia M. Liu, Gary M. Abrams, Adelyn Tu-Chan, Karunesh Ganguly & Edward F. Chang, *Neuroprosthesis for Decoding Speech in a Paralyzed Person with Anarthria*, 385 NEW ENG. J. MED. 217, 218 (2021), https://www.nejm.org/doi/pdf/10.1056/NEJMoa2027540 [https://perma.cc/968P-FCCX (staff-uploaded archive)]; Francis R. Willett, Erin M. Kunz, Chaofei Fan, Donald T. Avansino, Guy H. Wilson, Eun Young Choi, Foram Kamdar, Matthew F. Glasser, Leigh R. Hochberg, Shaul Druckmann, Krishna V. Shenoy & Jaimie M. Henderson, *A High-Performance Speech Neuroprosthesis*, 620 NATURE 1031, 1031 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10468393/pdf/41586_2023_Article_6377.pdf [https://perma.cc/9MH3-SSEE (staff-uploaded archive)].

29. *See* Brannigan et al., *supra* note 26, at 1–2, 8–9; Willett et al., *supra* note 28, at 1035.

assistive devices, restoring a person's motor functions, like their ability to reach or grasp.[30]

These developments are paving the way for broader clinical adoption and the realization of precision medicine in neuromodulation.

B. *Trends in Neural Device Research over a Decade*

Now that we have covered where the brain implant clinical landscape is today, let us take a step back and explore how we got here and why.

Interest in clinical research involving brain implants has grown significantly over the last ten years. For example, the number of scientific publications related to implantable devices has more than doubled, with annual publications indexed in the Web of Science database increasing from "415 in 2015 to 981 in 2024," representing a compound annual growth rate of approximately ten percent.[31] Compare this to publications about cancer research, which "steadily increased by about 3% to 5% per year on average" between 2005 and 2025.[32] This surge in research output highlights the global momentum in both basic and translational studies of neural implants.

The scope of clinical trials has also broadened. In a recent international survey looking at post-trial access to care in neural device trials, investigators reported a wide diversity of device types and clinical indications under investigation. These included DBS systems, spinal cord stimulation, BCIs and sensory prostheses, among others.[33] Over half (fifty-four percent) of the surveyed trials focused on DBS for new or understudied indications, while twenty-three percent explored implants not yet approved for any indication.[34] First-in-human or early feasibility trials represented thirty-five percent of surveyed trials, reflecting the field's commitment to innovation and translation.[35]

The clinical research landscape is now international and collaborative. Trials are conducted across North America, Europe, Asia, and Oceania, with government grants funding nearly half of recent studies and commercial or

30. Brannigan et al., *supra* note 26, at 1–2.

31. *See* Jonghyun Lee, Sung Yong Han & Young Woo Kwon, *Technological Advances and Medical Applications of Implantable Electronic Devices: From the Heart, Brain, and Skin to Gastrointestinal Organs*, at 2, *in* 15 BIOSENSORS art. 543 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12384755/pdf/biosensors-15-00543.pdf [https://perma.cc/PB6D-8GL3 (staff-uploaded archive)].

32. *Fastest Growing Cancer Research Over 20 Years? 2005–2025*, ONCODAILY: ONCOLIBRARY (Aug. 17, 2025, at 11:54 ET), https://oncodaily.com/oncolibrary/cancer-research-trends-2005-2025 [https://perma.cc/8RH7-X5AM].

33. Nathan Higgins, John Gardner, Anna Wexler, Philipp Kellmeyer, Kerry O'Brien & Adrian Carter, *Post-Trial Access to Implantable Neural Devices: An Exploratory International Survey*, at 4 tbl. 1, *in* BMJ SURG. INTERV. & HEALTH TECHS. art. 262 (2024), https://iopscience.iop.org/article/10.1088/1741-2552/ad94a6/pdf [https://perma.cc/FX7P-5U2D (staff-uploaded archive)].

34. *Id.*

35. *Id.* at 4 tbl. 2.

industry funding most of the rest.[36] Multicenter and multinational studies are increasingly common,[37] enabling larger sample sizes and more robust data.

Technological advances have driven this growth. The development of adaptive and closed-loop neuromodulation systems; wireless power and data transmission; and miniaturized, biocompatible materials now allows for more sophisticated and durable devices.[38] These innovations facilitated the transition from laboratory-based research to long-term, home-based clinical studies, which have collectively accumulated tens of thousands of days of implant data and demonstrated real-world functional benefits for participants.[39]

The COVID-19 pandemic also deserves some credit. Because of its consequences in terms of the ways we interacted during that time, researchers focused on remote monitoring, telemedicine integration, and digital health solutions for neural device users.[40] Now, the field is characterized by a dynamic interplay between engineering, clinical neuroscience, and patient-centered care, with research output and clinical trial activity at an all-time high.[41]

C. *The Risks of Brain Implant Clinical Research*

With clinical trial activity at an all-time high, it is important to understand the risks that come along with that activity. Clinical research involving neural implant devices presents a complex risk landscape, reflecting both the inherent challenges of neurosurgical intervention and the unique features of brain-targeted technologies.

36. *Id.*

37. *See id.* at 4.

38. *See* Ryan M Neely, David K Piech, Samantha R Santacruz, Michel M Maharbiz & Jose M Carmena, *Recent Advances in Neural Dust: Towards a Neural Interface Platform*, 50 CURR. OP. NEUROBIOL. 64, 64–65 (2018).

39. *See* Lee et al., *supra* note 31, at 12; *see also* Daniel B. Rubin, A. Bolu Ajiboye, Laurie Barefoot, Marguerite Bowker, Sydney S. Cash, David Chen, John P. Donoghue, Emad N. Eskandar, Gerhard Friehs, Carol Grant, Jaimie M. Henderson, Robert F. Kirsch, Rose Marujo, Maryam Masood, Stephen T. Mernoff, Jonathan P. Miller, Jon A. Mukand, Richard D. Penn, Jeremy Shefner, Krishna V. Shenoy, John D. Simeral, Jennifer A. Sweet, Benjamin L. Walter, Ziv M. Williams & Leigh R. Hochberg, *Interim Safety Profile from the Feasibility Study of the BrainGate Neural Interface System*, 100 NEUROLOGY e1177, e1177 (2023); Peter Mitchell, Sarah C.M. Lee, Peter E. Yoo, Andrew Morokoff, Rahul P. Sharma, Daryl L. Williams, Christopher MacIsaac, Mark E. Howard, Lou Irving, Ivan Vrljic, Cameron Williams, Steven Bush, Anna H. Balabanski, Katharine J. Drummond, Patricia Desmond, Douglas Weber, Timothy Denison, Susan Mathers, Terence J. O'Brien, J. Mocco, David B. Grayden, David S. Liebeskind, Nicholas L. Opie, Thomas J. Oxley & Bruce C.V. Campbell, *Assessment of Safety of a Fully Implanted Endovascular Brain-Computer Interface for Severe Paralysis in 4 Patients: The Stentrode with Thought-Controlled Digital Switch (SWITCH) Study*, 80 J. AM. MED. ASS'N NEUROLOGY 270, 270 (2023).

40. *See* Lee et al., *supra* note 31, at 2.

41. *See* Irene E. Harmsen, Gavin J.B. Elias, Michelle E. Beyn, Alexandre Boutet, Aditya Pancholi, Jürgen Germann, Alireza Mansouri, Christopher S. Lozano & Andres M. Lozano, *Clinical Trials for Deep Brain Stimulation: Current State of Affairs*, 13 BRAIN STIMUL. 378, 382–83 (2020).

Undoubtedly, research into such devices is high-risk.[42] There are relatively few Class I (lowest risk) neurological devices, such as anvils used to form skull plates.[43] "Most neurological devices are classified as class II (moderate risk) or class III (high risk) devices."[44] Class II devices include certain neurostimulators, aneurysm clips, and blood clot retrievers; deep brain stimulators and medical devices for the treatment of brain tumors are Class III devices.[45]

The risks can be broadly (though not exclusively) categorized into five domains: surgical risks; hardware-related risks; stimulation-related risks; privacy and security risks; and research-specific risks, including the lack of post-trial maintenance and care. We will address each in turn, ending with the risk that is this Article's main focus: the aftermath of losing access to device care and maintenance after a trial ends.

1. Surgical Risks

Implanting neural devices implicates invasive neurosurgical procedures, which always carry risks, such as "intracranial hemorrhage, stroke, infection, and seizures."[46] To be sure, the incidence of severe complications around the operation is relatively low.[47] But the consequences—including deep vein thrombosis, pulmonary embolism, or adverse effects of anesthesia—can nonetheless be significant even if rare.[48] Device explantation (or the removal of the device through surgery), when required, also poses surgical risks, and the decision to remove or retain a device must balance these risks against ongoing

42. These risks are not theoretical. *See* Ishan Dasgupta, Eran Klein, Laura Y. Cabrera, Winston Chiong, Ashley Feinsinger, Joseph J. Fins, Tobias Haeusermann, Saskia Hendriks, Gabriel Lázaro-Muñoz, Cynthia Kubu, Helen Mayberg, Khara Ramos, Adina Roskies, Lauren Sankary, Ashley Walton, Alik S. Widge & Sara Goering, *What Happens After a Neural Implant Study? Neuroethics Expert Workshop on Post-Trial Obligations*, at 2–3, *in* 17 NEUROETHICS art. 22 (2024), https://link.springer.com/article/10.1007/s12152-024-09549-2 [https://perma.cc/MY8N-VL87 (staff-uploaded, dark archive)]; Sara Goering, Andrew I. Brown & Eran Klein, *Brain Pioneers and Moral Entanglement: An Argument for Post-Trial Responsibilities in Neural-Device Trials*, HASTINGS CTR. REP., Jan.–Feb. 2024, at 24, 27.

43. *Regulatory Overview for Neurological Devices*, U.S. FOOD & DRUG ADMIN. (Apr. 22, 2024), https://www.fda.gov/medical-devices/neurological-devices/regulatory-overview-neurological-devices [https://perma.cc/W23L-AH6E (staff-uploaded archive)].

44. *Id.*

45. *Id.*

46. Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1507.

47. *Id.* ("General perioperative complications are uncommon but can be severe.").

48. *See id.* (citing Albert J. Fenoy & Richard K. Simpson Jr., *Risks of Common Complications in Deep Brain Stimulation Surgery: Management and Avoidance*, 120 J. NEUROSURG. 132, 132–39 (2014)).

clinical needs.[49] In short, "[t]he positioning and purpose of these devices give rise to profound risks."[50]

2. Hardware-Related Risks

Once implanted, there can be hardware complications that come up, such as infection caused by the implanted parts, device malfunction, and erosion of device components.[51] The person implanted might then need more surgeries to fix or replace the problematic hardware, and sometimes, device failure might result in exposure to new health risks or the sudden loss of any therapeutic benefit.[52] Meeting these needs can be difficult once research funding for the study runs out, especially when manufacturers have no plans for ongoing device support. As time passes, the ability for patients to manage their devices over the long term will become more complicated and sometimes impossible.[53] This risk increases as the neurotechnology market grows and the implantable devices become more sophisticated, rendering older versions of the neurotechnology obsolete.[54] Because outdated technology becomes more difficult and expensive to maintain, this will likely increasingly lead to device abandonment.[55]

3. Stimulation-Related Risks

Neural implants electrically stimulate the nervous system, and this stimulation can cause a range of what research clinicians call adverse effects. These include headaches, speech disturbances, numbness in different parts of the body, and disruptions of affective or cognitive function.[56] Which of these adverse events affects a person and how depends on the implanted device's stimulation parameters and the anatomical target.[57] Less commonly, stimulation may even induce behavioral changes, like prompting increased impulsivity,

49. *See* Demetrio Sierra-Mercado, Peter Zuk, Michael S. Beauchamp, Sameer A. Sheth, Daniel Yosher, Wayne K. Goodman, Amy L. McGuire & Gabriel Lázaro-Muñoz, *Device Removal Following Brain Implant Research*, 103 NEURON 759, 759–60 (2019).

50. A. Rotenberg, M. Gunning, R. Magistro Nadler, Z.H.T. Kiss & J. Illes, *A Liability Framework for High-Risk Neural Devices*, 388 SCIENCE 1136, 1136 (2025).

51. Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1507; *see* Sierra-Mercado et al., *supra* note 49, at 759–60.

52. Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1507.

53. *See* Michael S. Okun, Timothy Marjenin, Jinendra Ekanayake, Frederic Gilbert, Sean P. Doherty, Jack Pilkington, Jennifer French, Cynthia Kubu, Gabriel Lázaro-Muñoz, Timothy Denison & James Giordano, *Definition of Implanted Neurological Device Abandonment*, at 1–2, *in* 7 J. AM. MED. ASS'N NETW. OPEN art. 4 (2024).

54. *Id.*; *see infra* Subsection III.A.3.

55. Okun et al., *supra* note 53, at 1–2; *see* Sierra-Mercado et al., *supra* note 49, at 759–60.

56. *See* Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1508.

57. *See id.*

affecting people's moods, or changing their perceptions of identity and agency—effects that are often unpredictable.[58]

4. Privacy and Security Risks

Neural devices often collect and transmit sensitive brain data,[59] which raises a host of other significant risks. Most poignantly, there are significant privacy and cybersecurity concerns that accompany data collection of this type.[60] As with all data, the aggregation and analysis of neural data may inadvertently disclose private information about participants, but unlike most data sets, these data might encode information about a person's thoughts, feelings, or behaviors.[61] Especially as technology in this space improves, wireless data transmission introduces the risk of unauthorized access or hacking, which could compromise both data privacy and device function.[62]

5. Research-Specific Risks and Lack of Post-Trial Care

What happens to research participants after a neural implant trial ends varies and is rarely determined by the trial participant. Some—often at the sponsors' behest—keep the device on and functioning until the battery or the device stops working.[63] Some keep the device on and continue receiving support for their devices (for example, battery and component replacements, ongoing device adjustment appointments, and the like).[64] Others have their neural implants removed through surgical explantation.[65] Still others, indeed most, continue to live with a deactivated neural implant embedded in their body once the trial ends.[66] The proportion of participants who opt to continue using the

58. *Id.* These changes are not always harmful. But because we do not understand them well, they are nevertheless exceedingly risky. *See id.* (citing Longfei Wu, Xiaojiang Du, Mohsen Guizani & Amr Mohamed, *Access Control Schemes for Implantable Medical Devices: A Survey*, 4 IEEE INTERNET THINGS J. 1272, 1280 (2017)).

59. Sjors Ligthart, Marcello Ienca, Gerben Meynen, Fruzsina Molnar-Gabor, Roberto Andorno, Christoph Bublitz, Paul Catley, Lisa Claydon, Thomas Douglas, Nita Farahany, Joseph J. Fins, Sara Goering, Pim Haselager, Fabrice Jotterand, Andrea Lavazza, Allan McCay, Abel Wajnerman Paz, Stephen Rainey, Jesper Ryberg & Philipp Kellmeyer, *Minding Rights: Mapping Ethical and Legal Foundations of "Neurorights*,*"* 32 CAMBRIDGE Q. HEALTHC. ETHICS 461, 463–64 (2023).

60. *See, e.g.*, Dimitris Angelakis, Errikos Ventouras, Spyros Kostopoulos & Pantelis Asvestas, *Cybersecurity Issues in Brain-Computer Interfaces: Analysis of Existing Bluetooth Vulnerabilities*, 3 DIGIT. TECH. RSCH. & APPLICATIONS 92, 97–98 (2024); Tamara Denning, Yoky Matsuoka & Tadayoshi Kohno, *Neurosecurity: Security and Privacy for Neural Devices*, at 1–2, *in* 27 NEUROSURG. FOCUS art. 7 (2009), https://thejns.org/focus/view/journals/neurosurg-focus/27/1/article-pE7.xml [https://perma.cc/J2YZ-2Q56].

61. *See* Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1508.

62. *See* Denning et al., *supra* note 60, at 1–2; Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1508.

63. *See* Dasgupta et al., *supra* note 42, at 3.

64. *Id.*

65. *See* Higgins et al., *supra* note 33, at 2.

66. *See id.*

devices can vary widely depending on factors such as the effectiveness of the device and the risks associated with explantation.[67]

Significant financial and logistical harms to trial participants sometimes follow the end of a trial. Because many neural devices remain investigational, health insurance often does not cover maintenance appointments, new batteries, or explantation, leaving participants responsible for substantial out-of-pocket costs.[68] The discontinuation of device support by manufacturers—whether due to lack of planning, business failure, or product obsolescence—can leave participants with unsupported, malfunctioning, or even hazardous implants.[69]

The lack of clear post-trial care plans and the patchwork nature of the U.S. healthcare system exacerbate these risks, particularly for vulnerable or economically disadvantaged participants.[70]

Additionally, the abrupt withdrawal of device support can lead to a recurrence of the treatment-resistant condition. As a former trial participant who received deep-brain stimulation for depression described: "If this turns off, I get sick again. Like, I'm not cured. This is a treatment that absolutely works, but only as long as I've got a working device."[71]

Neuromodulation is a promising therapeutic avenue for treatment-resistant conditions, but it does not cure or fix the neural circuits underlying the pathology of depression, OCD, or other neurological conditions.[72] Those

67. *Id.*

68. Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1508; *see* Dasgupta et al., *supra* note 42, at 10.

69. *See* Dasgupta et al., *supra* note 42, at 2–3; Saskia Hendriks, Nina Hsu, Andrea C. Beckel-Mitchener, John Ngai & Christine Grady, *Continuing Trial Responsibilities for Implantable Neural Devices*, 111 NEURON 3143, 3144 (2023) [hereinafter Hendriks et al., *Continuing Trial Responsibilities*].

70. These defective implants can be quite common in trials like those for DBS where high-symptom burden prior to trial enrollment often makes finding employment very difficult and where many participants' only income is from social security and disability benefits. *See* Hendriks et al., *Continuing Trial Responsibilities*, *supra* note 69, at 3144–45; *see also* Goering et al., *supra* note 42, at 31; Liam Drew, *"Like Taking Away a Part of Myself"—Life After a Neural Implant Trial*, 26 NAT. MED. 1154, 1156 (2020).

71. Laura Ungar, *NIH Cuts Spotlight a Hidden Crisis Facing Patients with Experimental Brain Implants*, CBS8, https://www.cbs8.com/article/news/nation-world/nih-cuts-experimental-brain-implant-concerns/507-47e1d106-3ea5-4298-bbc3-773a7f7641de [https://perma.cc/C78S-A43P] (last updated July 28, 2025, at 05:15 PT).

72. *See* Vinata Vedam-Mai, Karl Deisseroth, James Giordano, Gabriel Lázaro-Muñoz, Winston Chiong, Nanthia Suthana, Jean-Philippe Langevin, Jay Gill, Wayne Goodman, Nicole R. Provenza, Casey H. Halpern, Rajat S. Shivacharan, Tricia N. Cunningham, Sameer A. Sheth, Nader Pouratian, Katherine W. Scangos, Helen S. Mayberg, Andreas Horn, Kara A. Johnson, Christopher R. Butson, Ro'ee Gilron, Coralie de Hemptinne, Robert Wilt, Maria Yaroshinsky, Simon Little, Philip Starr, Greg Worrell, Prasad Shirvalkar, Edward Chang, Jens Volkmann, Muthuraman Muthuraman, Sergiu Groppa, Andrea A. Kühn, Luming Li, Matthew Johnson, Kevin J. Otto, Robert Raike, Steve Goetz, Chengyuan Wu, Peter Silburn, Binith Cheeran, Yagna J. Pathak, Mahsa Malekmohammadi, Aysegul Gunduz, Joshua K. Wong, Stephanie Cernera, Aparna Wagle Shukla, Adolfo Ramirez-Zamora,

who lose access to their devices often experience a sense of abandonment and a loss of newly gained abilities.[73] Symptoms can even return to a degree that exceeds pretrial baseline in what are called "rebound effects."[74] Participants have described the loss of device function as akin to losing a part of themselves, underscoring the depth of the psychosocial impact.[75]

Unless something changes, the scale of this post-trial access problem will continue to grow as more people access these devices through clinical trials.

II. THE LEGAL LANDSCAPE OF ACCESS TO POST-TRIAL CARE

Despite the widely acknowledged risks that accompany the loss of post-trial access to device maintenance, there are no clear post-trial maintenance plans for participants in neural implant research. Major stakeholders in this field appear to largely agree that access to post-trial care is necessary, yet no one entity has taken charge of ensuring that such care is provided.[76] Consequently, research participants enroll in studies with no promise of any care after the trial ends.[77] This problem is an old one, even though the technology of interest to us here is novel.

In this Part, we explore the history and legal landscape of post-trial access disputes that would likely govern any legal battle in U.S. courts over harms caused by a person's lack of access to post-trial care after participating in a clinical trial assessing a neural implant device.

A. *Variations on a Theme*

As others have recognized, disputes about post-trial access to care are not new. For decades, our courts, ethicists, regulators, and industry stakeholders have wrestled with recurring conflicts about whether, when, and how

Wissam Deeb, Addie Patterson, Kelly D. Foote & Michael S. Okun, *Proceedings of the Eighth Annual Deep Brain Stimulation Think Tank: Advances in Optogenetics, Ethical Issues Affecting DBS Research, Neuromodulatory Approaches for Depression, Adaptive Neurostimulation, and Emerging DBS Technologies*, at 6, *in* 15 FRONT. HUM. NEUROSCI. art. 644593 (2021), https://www.frontiersin.org/journals/human-neuroscience/articles/10.3389/fnhum.2021.644593/full [https://perma.cc/59TN-U2LU (staff-uploaded archive)].

73. *See* Dasgupta et al., *supra* note 42, at 6; Goering et al., *supra* note 42, at 31.

74. Ooms et al., *supra* note 1, at 727–28.

75. *See* Dasgupta et al., *supra* note 42, at 2–4; Goering et al., *supra* note 42, at 31.

76. Higgins et al., *supra* note 33, at 8; Lázaro-Muñoz et al., *Device Maintenance, Abandonment, and Cost*, *supra* note 3, at 1035. In many trials, consent forms often describe that if the participant wants to maintain the device, they must talk to their insurance companies, and if their insurance companies do not cover the necessary costs, then the patients are responsible for covering the cost. *See* Gabriel Lázaro-Muñoz, Daniel Yoshor, Michael S. Beauchamp, Wayne K. Goodman & Amy L. McGuire, *Continued Access to Investigational Brain Implants*, 19 NAT. REV. NEUROSCI. 317, 317 (2018) [hereinafter Lázaro-Muñoz et al., *Continued Access*].

77. *See* Lázaro-Muñoz et al., *Continued Access*, *supra* note 76, at 317 (suggesting a path toward post-treatment care).

individuals should access investigational or newly proven interventions once a clinical study ends—and with who must pay for and manage that access.[78]

Indeed, the template for today's fights was set by earlier access battles over investigational products outside trials, which largely concluded that there is no fundamentally guaranteed right to access investigational treatments. These early cases entrenched a legal baseline—no freestanding right to experimental products—that has repeatedly shaped post-trial contests.

Back in 1979, the Supreme Court held in *United States v. Rutherford*[79] that terminally ill cancer patients had no right to access amygdalin (Laetrile), a now discredited treatment, for which an application for clinical testing was pending before the FDA when the patients filed suit.[80] The *Rutherford* plaintiffs argued that the Food, Drug, and Cosmetics Act[81] ("FDCA") should not bar them from obtaining Laetrile for personal use because the statute did not apply to drugs intended solely for the terminally ill.[82] The Court rejected this argument because the FDCA's requirements for safety and efficacy applied universally,[83] regardless of the patient's prognosis or the drug's intended use.[84] The Court emphasized that Congress had entrusted the FDA with the responsibility to determine which drugs could be marketed and that judicially created exceptions for specific patient populations would undermine the regulatory scheme.[85]

In 2007, the D.C. Circuit rejected a constitutional right to experimental drugs in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*.[86] There, the court addressed an argument that terminally ill patients possess a constitutional right to access experimental drugs after completion of Phase I clinical trials but before full FDA approval.[87] According to the plaintiffs, the U.S. Constitution's Fourteenth Amendment Due Process Clause protects their respective liberties to seek potentially life-saving investigational treatments when no other options remain.[88] The circuit court, sitting en banc, disagreed. It rejected the plaintiffs' arguments because the nation's history and tradition reflect a longstanding commitment to rigorous drug regulation rather

78. *See, e.g.*, Richard S. Saver, *At the End of the Clinical Trial: Does Access to Investigational Technology End as Well?*, 31 W. NEW ENG. L. REV. 411, 413–14 (2009) (tracing the history of such disputes).

79. 442 U.S. 544 (1979).

80. *Id.* at 546–59.

81. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i).

82. *Rutherford*, 442 U.S. at 348–51.

83. Drug Amendments of 1962, Pub. L. No. 87-781, sec. 102(a)(1), (b), §§ 201(p)(1), 505(b), 76 Stat. 780, 781 (codified as amended at 21 U.S.C. §§ 321(p)(1), 355(b)).

84. *Rutherford*, 442 U.S. at 351–59.

85. *Id.*

86. 495 F.3d 695, 701–07 (D.C. Cir. 2007) (en banc), *cert. denied*, 552 U.S. 1159 (2008).

87. *Id.*

88. *Id.*

than unfettered individual access.[89] The court found no "fundamental right" to experimental drugs, reasoning (1) that the risks associated with unproven therapies justified the FDA's cautious approach, (2) that recognizing such a right would disrupt the regulatory balance struck by Congress and the FDA, and (3) that policy arguments about risk and autonomy were more appropriately addressed to the legislative branch.[90]

More recently, since at least the early 2000s, post-trial disputes have surfaced in waves, and they look strikingly similar across settings. In a series of suits brought by Parkinson's subjects against Amgen, multiple courts refused to order continued access after trial termination, finding no enforceable promise in consent documents, no fiduciary duty running from sponsor to subjects, and no viable tort or contract theory to compel resumed supply.[91] And the Sixth Circuit admonished Institutional Review Boards ("IRBs")—committees that protect the rights and welfare of human research subjects by reviewing and approving research protocols—to ensure research institutions and those running clinical trials clearly communicate to subjects that they may be denied continued treatment.[92]

In *Abney v. Amgen*,[93] the Sixth Circuit affirmed the denial of a preliminary injunction that would have compelled Amgen, the clinical-trial sponsor, to continue supplying an investigational biologic after study termination.[94] The Sixth Circuit concluded that the subjects showed neither a likelihood of success on the merits nor entitlement on the remaining injunction factors.[95] The appellate court held there was no enforceable contract because Amgen was not a party to the informed consent agreement and because the clinical trial agreement (executed with the university and investigators) expressly preserved the institution's independent-contractor status and Amgen's right to terminate, defeating any privity or agency theory.[96] Promissory estoppel likewise failed for want of a "clear promise" by Amgen; any assurances by investigators could not bind the sponsor absent actual or apparent authority.[97] Nor did Amgen owe a fiduciary duty to act primarily for the individual subjects' benefits; the court emphasized that under the federal scheme, investigators and IRBs—not

89. *Id.*

90. Ultimately, the Supreme Court denied certiorari, leaving intact the principle that access to investigational drugs is governed by regulatory—not constitutional—mandate. *Id.*

91. Abney v. Amgen, Inc., 443 F.3d 540, 547–53 (6th Cir. 2006); Suthers v. Amgen, Inc. (*Suthers I*), 372 F. Supp. 2d 416, 424–30 (S.D.N.Y. 2005); Suthers v. Amgen, Inc. (*Suthers II*), 441 F. Supp. 2d 478, 482–85 (S.D.N.Y. 2006).

92. Vinion v. Amgen, Inc., 272 F. App'x 582, 583–85 (9th Cir. 2008).

93. 443 F.3d 540 (6th Cir. 2006).

94. *Id.* at 542.

95. *Id.* at 547 (affirming denial of preliminary injunction).

96. *Id.* at 547–49.

97. *Id.* at 549–50.

sponsors—bear primary responsibility for subject protection, and it even urged IRBs to clarify ex ante that post-trial access may be denied.[98] On the remaining factors, the panel found no irreparable harm given contested safety (primate cerebellar lesions; neutralizing antibodies) and equivocal efficacy data. The panel determined that the public interest favored preserving the FDA's gatekeeping role and avoiding disincentives for sponsors to conduct trials, rather than judicially mandating "compassionate use" outside that framework.[99]

And in *Vinion v. Amgen*,[100] the Ninth Circuit affirmed the dismissal of the plaintiffs' breach of contract claims, likewise affirming the dismissal of various agency claims against Amgen for failing to provide the study drug following termination of the clinical trial.[101]

As is typically the case, the courts lag behind bioethics literature, which has wrestled with the problem of lack of post-trial access for more than two decades. By the early 2000s, scholars around the world urged enforceable post-trial obligations in research to avoid exploitation and to align with evolving guidance under the Declaration of Helsinki and other international guidelines.[102] Academic publications have extensively cataloged moral rationales, feasibility barriers, and shared-responsibility models for continued access, which are particularly salient in low-resource settings.[103] Most conclude that predictable flashpoints at study closeout—misaligned stakeholder incentives, ambiguous data, and unclear payment—are deeply entrenched.

B. *Shifts in Policy*

As a result of these flashpoints, post-trial access disputes persist. The underlying structural features of these disputes cut across time and technologies. In other words, post-trial access controversies are iterative reprises: contested expectations at the research-care boundary; persistent legal

98. *Id.* at 547 n.5, 550–51, 551 n.6.

99. *Id.* at 551–53.

100. 272 F. App'x 582 (9th Cir. 2008).

101. *Id.* at 583–85. Plaintiffs in different but related contexts have also sought to hold manufacturers liable under a products liability framework without success. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 315–20 (2008); Day v. Howmedica Osteonics Corp., 2015 U.S. Dist. LEXIS 189268, at *15–23 (D. Colo. 2015); Millman v. Medtronic, No. 14-CV-1465, 2015 WL 778779, at *1–6 (D.N.J. 2015).

102. *See generally* Esther Chang, *Fitting a Square Peg into a Round Hole: Imposing Informed Consent and Post-Trial Obligations on United States Sponsored Clinical Trials in Developing Countries*, 11 S. CAL. INTERDISC. L.J. 339 (2002) (discussing enforceable post-trial obligations); Saver, *supra* note 78, at 433–36 (discussing Declaration of Helsinki and CIOMS).

103. *See, e.g.*, Christine Grady, *The Challenge of Assuring Continued Post-Trial Access to Beneficial Treatment*, 5 YALE J. HEALTH POL'Y L. & ETHICS 425, 428–32 (2005); Saver, *supra* note 78, at 413–14; William M. Janssen, *A "Duty" to Continue Selling Medicines*, 40 AM. J.L. & MED. 330, 348–66, 379–80 (2014). *See generally* Ariella Kelman, Anna Kang & Brian Crawford, *Continued Access to Investigational Medicinal Products for Clinical Trial Participants—An Industry Approach*, 28 CAMBRIDGE Q. HEALTHC. ETHICS 124 (2019) (exploring this phenomenon).

gaps; ethics guidance ahead of enforceable obligations; and recurrent calls for policy-based, not ad hoc, solutions. As courts have signaled for years,[104] clearer ex ante standards from regulators and sponsors—disclosure, budgeting, eligibility criteria, time limits, and shared roles—are a great venue for progress.

Since the mid-2000s, there has been some progress—a trend toward the maturation of the ecosystem of soft-law guidance and sponsor policies that increasingly require clear, prospectively defined plans.[105] Early calls for shared responsibility and advance planning manifest in the language of leading ethics codes, funder expectations, institutional review practices, and corporate policies.[106]

International ethics instruments have crystallized the norm that post-trial access must be planned prospectively and disclosed.[107] By way of example, the Declaration of Helsinki's 2013 revision specifies that before a study begins, sponsors, researchers, and host country authorities should provide for post-trial access to beneficial interventions and inform participants of these arrangements in consent.[108] And the Council for International Organizations of Medical Science's 2016 International Ethical Guidelines similarly frame "continued access" as a shared obligation to be addressed in protocols and consent forms in ways that attend to feasibility, acknowledge alternatives, and account for local health-system capacity.[109]

Industry sponsors have translated these soft-law expectations into company-level policy. Roche Pharmaceuticals adopted and publicly posted a Global Policy on Continued Access in 2013, operationalizing a prospective-planning mandate, identifying eligibility criteria, and emphasizing reassessment based on safety, efficacy, and local availability of alternatives.[110] The policy

104. *See supra* Section II.A.

105. *See, e.g.*, World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subject*s, 310 J. AM. MED. ASS'N 2191, 2193–94 (2013) (requiring advance provisions for post-trial access and disclosure in consent).

106. *See, e.g.*, COUNCIL FOR INT'L ORGS. OF MED. SCIS., INT'L ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS 22–23 (2016), https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf [https://perma.cc/3U9Z-NANL] (framing "continued access" as a shared, feasibility-sensitive obligation).

107. Kelman et al., *supra* note 103, at 125–26; ROCHE, GLOBAL POLICY ON CONTINUED ACCESS TO INVESTIGATIONAL INTERVENTIONS (2025), https://assets.roche.com/f/176343/x/1b18e080e0/2025-revision-roche_global_policy_on_continued_access_to_investigational_interventions.pdf [https://perma.cc/32XY-GYE4].

108. WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 6 (2024), https://www.wma.net/policies-post/wma-declaration-of-helsinki/ (click "PDF") [https://perma.cc/AB7K-WQRM]; *see* Kelman et al., *supra* note 103, at 129–31.

109. Kelman et al., *supra* note 103, at 129–31; COUNCIL FOR INT'L ORGS. OF MED. SCIS., *supra* note 106, at 22–23.

110. ROCHE, *supra* note 107; *see also* Kelman et al., *supra* note 103, at 125–27 (discussing the Roche plan).

directs early determination of post-trial access needs, embeds scope and duration in protocol planning, and conditions site selection on the ability to continue basic services post-trial—seeking to ensure participants are "not worse off" after study completion.[111]

Funders and oversight bodies are also starting to require post-trial access plans. In neural device research specifically, the National Institute of Health ("NIH") Brain Research Through Advancing Innovative Neurotechnologies ("BRAIN") Initiative's Neuroethics Working Group has articulated two high-level principles—a plan for post-trial needs and informing participants—and noted that some NIH funding opportunities now require long-term care plans (for example, through the "Long-term Care Plan for Patients" section required for some grant applications).[112] Empirical data show parallel shifts in review practice: in an international survey of neural-implant investigators, eighty-eight percent reported including post-trial access plans in IRB submissions, seventy-seven percent included plans in consent agreements (over half were required by IRBs to include such plans), and responsibilities were shared across stakeholders in two thirds of trials.[113] These trends represent a shift toward clearer post-trial access plans and emphasize the stakeholders' recognition of the importance of post-trial access to care.

III. POLICY AND POST-TRIAL ACCESS IN NEURAL IMPLANT DEVICE RESEARCH

Especially when it comes to implanted neural technologies, device-trial experiences accelerated agreement on the need for clearer post-trial access planning and cost-sharing mechanisms. Because explantation and long-term implantation pose nontrivial and sui generis risks, the duty to do no harm requires stronger post-trial obligations and clear plans for access, maintenance, updates, and, when appropriate, removal. In this final Part, we explain why post-trial access to care and maintenance plans for beneficial neural implant devices is particularly important and show that such care is essential for sustaining public trust in neural-device research and fostering responsible innovation in neurotechnology.

111. ROCHE, *supra* note 107.

112. Hendriks et al., *Continuing Trial Responsibilities*, *supra* note 69, at 3144–47; *see also* Dasgupta et al., *supra* note 42, at 10. For an example of a grant application requiring a "Long-term Care Plan for Patients," see *BRAIN Initiative: Clinical Studies to Advance Next-Generation Invasive Devices for Recording and Modulation in the Human Central Nervous System (UH3 Clinical Trial Optional)*, U.S. DEP'T HEALTH & HUM. SERVS. (May 07, 2021), https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-21-024.html [https://perma.cc/AP79-XNCX].

113. *See* Higgins et al., *supra* note 33, at 5 (reporting eighty-eight percent inclusion of PTA plans in IRB protocols; seventy-seven percent in consent; fifty-three percent in IRB-required planning; and sixty-six percent in shared responsibilities).

A. *Unique Vulnerabilities*

Participants in neural implant trials are uniquely vulnerable to the risks imposed by device abandonment or obsolescence. Clinical, psychological, and social factors converge to distinguish their experience from that of participants in most other medical research.

In short, when participants lack access to post-trial care for their investigatory neural devices—particularly beneficial devices—they face unprecedented and unparalleled harm.

1. Severity and Persistence of Underlying Conditions

Most neural implant trial participants suffer from severe, treatment-resistant neurological or psychiatric disorders—such as advanced Parkinson's disease, refractory epilepsy, major depression, or profound paralysis—where conventional therapies have repeatedly failed.[114] For them, neural implants are often a last resort. And the benefits they yield are not merely incremental but transformative; these devices often restore lost functions or enable basic communication and autonomy.[115] If a device is abandoned or becomes obsolete, participants may lose the only effective intervention available to them, with no alternative recourse.[116] Data shows that these participants are also regressing to below-baseline functioning—they could be worse off if the device stops working than they were before they enrolled in the trial.[117]

2. Physical Irreversibility and Invasiveness

Unlike patients who seek other interventions, people who enroll in clinical research trials investigating neural implants undergo a physically invasive procedure. Implantation means neurosurgery for that person, as do adjustment, surgical revision due to migration or gliosis, and removal.[118] Unlike some medications or external devices, implanted neural devices cannot be discontinued without risk. Explantation carries surgical hazards, but leaving a nonfunctional device in place risks infection and hardware failure.[119] This physical embeddedness amplifies the stakes of abandonment as participants may be left with a device that is not only useless but potentially harmful.[120]

114. Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1508–10.

115. *See* Lázaro-Muñoz et al., *Device Maintenance, Abandonment, and Cost*, *supra* note 3, at 1030–31.

116. *See* Okun et al., *supra* note 53, at 1–2.

117. *See* Lázaro-Muñoz et al., *Device Maintenance, Abandonment, and Cost*, *supra* note 3, at 1030–31.

118. Sierra-Mercado et al., *supra* note 49, at 760–61.

119. *Id.* at 760.

120. *Id.* at 760–61.

3. Specialized Support and Dependence

The safe and effective use of neural implants requires ongoing access to highly specialized clinical expertise, device programming, and technical maintenance—resources that are often available only at select research centers or through the device manufacturer.[121] When stakeholders abandon a device or an implanted device becomes obsolete, participants may find themselves unable to obtain necessary follow-up care, repairs, or upgrades, which can increase their medical and psychological vulnerability.[122] Further, these devices can also complicate standard medical care. For example, an implanted device makes routine imaging, like a magnetic resonance imaging (or "MRI") scan, difficult without specialty equipment to manage the device. What is more, the presence of a DBS device can exclude individuals from participating in other clinical trials if additional treatment is needed in the future.[123]

4. Impact on Identity, Agency, and Social Participation

Neural implants can become deeply integrated into a participant's sense of self, agency, and social participation.[124] This effect—where the device becomes a part of someone both literally and figuratively—intensifies when the device restores communication, mobility, or emotional stability.[125] The sudden loss of such a device can result in profound psychological distress, a sense of betrayal, and a loss of dignity or self-worth.[126] One participant described a lingering sense of loss after having a device removed: "It was like taking away that part of myself that made me complete."[127]

5. Inadequate Informed Consent and Unanticipated Risks

The many problems of the informed consent process in neural implant device trials are largely outside the scope of this Article. They have been extensively documented elsewhere.[128] But chief among these is the fact that the rapid pace of technological change and the lack of long-term safety data mean that participants may not be fully informed about the risks of device

121. Higgins et al., *supra* note 33, at 6–8.

122. *Id.*

123. *Id.*

124. Goering et al., *supra* note 42, at 28–29; *see also* Joseph J. Fins, Amanda R. Merner, Megan S. Wright & Gabriel Lázaro-Muñoz, *Identity Theft, Deep Brain Stimulation, and the Primacy of Post-trial Obligations*, HASTINGS CTR. REP., Jan.–Feb. 2024, at 34, 35–36; Arthur L. Caplan, *Joseph J. Fins'* Rights Come to Mind: Brain Injury, Ethics and the Struggle for Consciousness, *in* CEREBRUM 2017: EMERGING IDEAS IN BRAIN SCIENCE (2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6132041/ [https://perma.cc/YB5X-LSBE].

125. Goering et al., *supra* note 42, at 28.

126. Drew, *supra* note 70, at 1155.

127. *Id.*

128. *See, e.g.*, Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1509–10 (collecting sources and addressing the issue).

obsolescence or abandonment at the time of consent.[129] Many participants, motivated by desperation or "treatment search fatigue," may focus on the hope of benefit and underestimate the possibility of losing access to device support in the future.[130]

6. Lack of Alternative Therapies and Social Support

Because neural implant trial participants often have no other viable treatment options, the loss of device care and function can leave them isolated and unsupported, both medically and socially.[131] Adding to this problem, participants often must travel long distances for care and may lack the financial or logistical means to seek alternative solutions—in the unlikely chance they exist at all.[132]

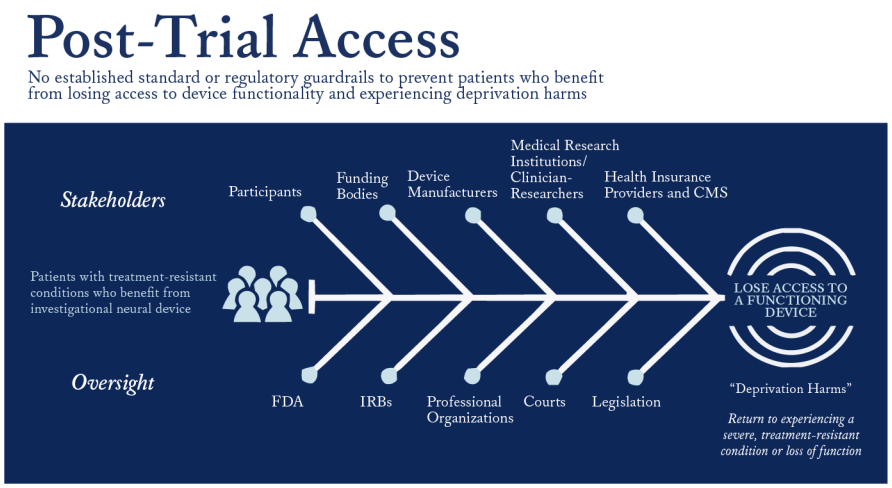
129. *Id.* at 1510.

130. *See* Lauren R. Sankary, Megan Zelinsky, Andre Macahdo, Taylor Rush, Alexandra White & Paul J. Ford, *Exit from Brain Device Research: A Modified Grounded Theory Study of Researcher Obligations and Participant Experiences*, 13 AM. J. BIOETH. NEUROSCI. 215, 218 (2021); Lázaro-Muñoz et al., *Device Maintenance, Abandonment, and Cost*, *supra* note 3, at 1031.

131. Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1508–10.

132. Higgins et al., *supra* note 33, at 2.

Figure 1: Post-Trial Access Landscape for Investigational Neural Devices[133]



The unique vulnerability of these participants arguably imposes heightened ethical (and legal) obligations on stakeholders to mitigate the risks of abandonment and obsolescence. Failure to do so risks not only physical and psychological harm but also a breach of trust and justice, as those who have contributed to scientific progress are left unsupported.[134]

B. *Undermining Public Trust and Responsible Innovation*

The absence of guaranteed post-trial care for individuals implanted with neural devices presents a profound ethical and policy challenge with implications that extend far beyond individual patient welfare.[135] In addition to threatening the well-being of vulnerable participants, this gap problematically

133. Figure adapted from Kara A. Johnson, Nico U.F. Dosenbach, Evan M. Gordon, Cristin G. Welle, Kevin B. Wilkins, Helen M. Bronte-Stewart, Valerie Voon, Takashi Morishita, Yuki Sakai, Amanda R. Merner, Gabriel Lázaro-Muñoz, Theresa Williamson, Andreas Horn, Ro'ee Gilron, Jonathan O'Keee, Aryn H. Gittis, Wolf-Julian Neumann, Simon Little, Nicole R. Provenza, Sameer A. Sheth, Alfonso Fasano, Abbey B. Holt-Becker, Robert S. Raike, Lisa Moore, Yagna J. Pathak, David Greene, Sara Marceglia, Lothar Krinke, Huiling Tan, Hagai Bergman, Monika Pötter-Nerger, Bomin Sun, Laura Y. Cabrera, Cameron C. McIntyre, Noam Harel, Helen S. Mayberg, Andrew D. Krystal, Nader Pouratian, Philip A. Starr, Kelly D. Foote, Michael S. Okun & Joshua K. Wong, *Proceedings of the 11th Annual Deep Brain Stimulation Think Tank: Pushing the Forefront of Neuromodulation with Functional Network Mapping, Biomarkers for Adaptive DBS, Bioethical Dilemmas, AI-Guided Neuromodulation, and Translational Advancements*, at 13 fig. 7, *in* 18 FRONT. HUM. NEUROSCI. art. 1320806 (2024).

134. Sankary et al., *supra* note 130, at 220.

135. *See* Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1510–11.

undermines public trust in the research enterprise and risks stifling responsible innovation in neurotechnology.[136]

The prospect that research participants may be abandoned after contributing to scientific progress—sometimes at great personal risk—raises serious concerns about exploitation and fairness. As commentators and empirical studies have noted, participants and their families often assume that enrollment in a clinical trial entails a commitment to ongoing maintenance, especially when the intervention is as consequential as a brain implant.[137] When these expectations are unmet, it can erode trust not only in individual researchers or institutions, but in the broader research enterprise.[138] Public trust is a foundational prerequisite for the continued recruitment of participants, the legitimacy of research ethics oversight, and the social license for innovation in neurotechnology.[139] As the NIH Neuroethics Working Group has emphasized, "consistent policies, if followed, could improve trust between patients and researchers, and between patients and device companies."[140]

The lack of post-trial maintenance also poses a barrier to responsible innovation in neurotechnology. If participants and the public perceive that neural device research entails unacceptable risks of abandonment or harm, they may be less willing to participate in trials or to support the development and adoption of new technologies. This, in turn, could slow the pace of scientific progress, limit the generalizability of research findings, and exacerbate disparities in access to cutting-edge therapies.[141] Moreover, the absence of clear policies may incentivize patchwork solutions, imposing undue burdens on investigators and institutions and creating inequality among participants.[142] As a matter of policy, establishing robust post-trial maintenance frameworks is essential for ensuring both that the benefits and burdens of research are distributed fairly and that innovation proceeds in an ethically and socially sustainable manner.[143]

136. Goering et al., *supra* note 42, at 28–29.
137. Sankary et al., *supra* note 130, at 220.
138. Higgins et al., *supra* note 33, at 8.
139. *See* Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1510–11.
140. Dasgupta et al., *supra* note 42, at 9.
141. *See* Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1510–11.
142. *See* Dasgupta et al., *supra* note 42, at 9–10.
143. *Id.*

C. *A Glimpse at the Path Forward*

Leading scholars and policy bodies have called for the integration of post-trial care obligations into the design and funding of neural device research.[144] This would include requiring grant applicants to budget for post-trial support, mandating clear disclosure of post-trial care plans in informed consent documents, and developing public-private partnerships or insurance mechanisms to cover ongoing device-related needs.[145] Such measures are not only ethically justified but are also necessary to sustain public trust and foster a culture of responsible innovation.[146] As a related proposal recently published in Science put it,

> If participants in these clinical trials are injured, the costs may be theirs alone to bear. Recognition of this asymmetry, prompted by, for example, a high-profile lawsuit, could provide a compelling disincentive for potential participants, with clear repercussions for human trials.[147]

As neurotechnology advances, enforceable post-trial care policies will be critical to protecting research participants and realizing the promise of neural-device research for all. There are many ways this goal might be achieved, and we summarize them here, although the details of each are beyond the scope of this Article. First, because this participant population is exceptional,[148] courts may come out differently when assessing tort and contract claims raised in connection with brain-implant, post-trial access disputes. Next, there is some interest from industry in pursuing legislative solutions[149] as the courts have urged,[150] and some templates are already in place with "Right to Try" legislation around the country.[151] Finally, there are several creative contractual solutions to consider that might help to appropriately distribute the risks, costs, and benefits amongst stakeholders, which we will explore in later work.

144. Hendriks et al., *Ethical Challenges*, *supra* note 10, at 1510–11; Dasgupta et al., *supra* note 42, at 11–12.

145. Lázaro-Muñoz et al., *Device Maintenance, Abandonment, and Cost*, *supra* note 3, at 1032.

146. Dasgupta et al., *supra* note 42, at 10.

147. Rotenberg et al., *supra* note 50, at 1137.

148. *See supra* Section III.A.

149. Conversations among Professor Gabriel Lázaro-Muñoz and industry participants (on file with author).

150. *See supra* notes 90–92 and accompanying text.

151. *Right to Try*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try [https://perma.cc/2K95-L769 (staff-uploaded archive)].

CONCLUSION

Neural-device research sits at an inflection point. The science is accelerating, trial portfolios are expanding, and early successes are profound. Yet the enterprise's legitimacy depends on more than headline-grabbing breakthroughs. Ensuring post-trial access to beneficial neural devices is the cost of doing responsible science—and the price of the public trust on which the future of neurotechnology rests.

We look forward to answering the practical question of how to implement a duty to provide post-trial care access to those who benefit from investigational neural implant devices in a way that is proportionate, feasible, and predictable, for another day.