



Perspective

The Ethics of Deep Brain Stimulation for Treatment-Resistant Psychiatric Disorders

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ABSTRACT

Deep brain stimulation has moved beyond movement disorders into an expanding, but still largely investigational, role in treatment-resistant psychiatric illness, most notably obsessive-compulsive disorder and major depression.

This review examines the ethical questions that recur across this literature: the difficulty of securing genuinely informed, uncoerced consent from patients who have exhausted every other treatment option, and the possibility that stimulation alters affect, impulsivity, or narrative identity rather than only the target symptom.

We also examine what the failure of a major sham-controlled depression trial revealed about equipoise and premature translation in this field, and how the narrow humanitarian device exemption pathway used for obsessive-compulsive disorder sits against the weaker evidentiary base for other indications.

Emerging closed-loop, adaptive systems introduce a further layer of concern around continuous physiological data collection and the blurring of agency between patient and device.

We conclude that responsible expansion of psychiatric deep brain stimulation depends on treating uncertainty about mood and identity effects as something to disclose rather than minimize, and on building data-governance and long-term device-stewardship frameworks into trial design now rather than after wider deployment.

Keywords: deep brain stimulation; psychiatric ethics; informed consent; personal identity; neuroethics

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INTRODUCTION

Deep brain stimulation has spent two decades moving

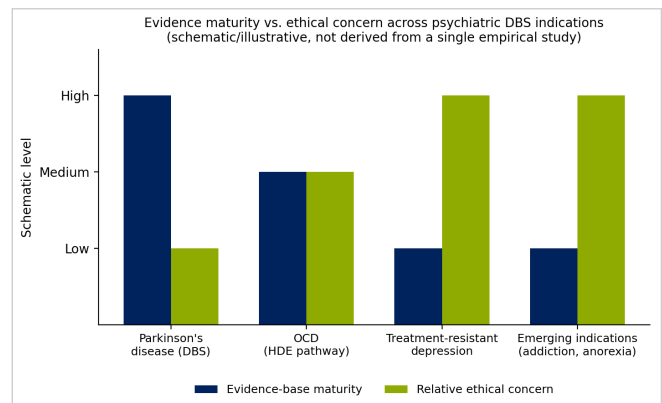
from a treatment for movement disorders into something considerably harder to classify ethically: an investigational intervention for psychiatric conditions

that have already exhausted medication, psychotherapy, and, in many cases, electroconvulsive therapy. The basic technology is unchanged since its use in Parkinson's disease -- electrodes implanted in specific subcortical targets, connected to a pulse generator that delivers continuous electrical stimulation -- but the ethical terrain shifts considerably when the target circuit is implicated in mood, obsession, or motivation rather than tremor [1]. A patient who elects DBS for Parkinson's disease is choosing to treat a symptom that is, in an important sense, separable from who they are. A patient with treatment-resistant depression or obsessive-compulsive disorder is asking to have a circuit implicated in affect and cognition altered directly, and altering that circuit can change more than the target symptom. Commentators writing early in the field's expansion into psychiatry argued that its ethical future would be shaped less by the surgery itself than by how honestly the field disclosed what remained unknown about these downstream effects, a warning that has aged well [2].

Table 1. Ethical concern domains in psychiatric deep brain stimulation, by indication and their representative literature response.

Ethical domain	Nature of the concern	Representative literature/response	Current regulatory status
Informed consent / therapeutic misconception	Treatment-resistant patients may overweight a last-resort trial's benefits	Uncertainty about mood/personality effects should be disclosed as genuinely unknown, not folded into boilerplate risk	No indication-specific consent standard; governed by general research-ethics review
Personal identity and authenticity	Stimulation may alter affect, impulsivity, or self-narrative rather than only symptoms	Distinguishing superficial from narrative-level change; investigators themselves disagree on classification	Not formally regulated; addressed case-by-case in follow-up care
Equipoise and trial design	Open-label enthusiasm has repeatedly outrun controlled-trial results	A large sham-controlled depression trial stopped for futility reshaped standards for target validation	No mandated blinding standard beyond general clinical-trial regulation
Device stewardship and closed-loop data	Long-term responsibility for implanted hardware after a trial ends; continuous neural sensing	Consensus calls for governance of data ownership and device maintenance built in before deployment	OCD approved via humanitarian device exemption; depression remains in investigational

Figure 1. Schematic comparison of evidence-base maturity against the relative intensity of open ethical concern across psychiatric DBS indications (illustrative, not derived from a single empirical study).



Two indications dominate the psychiatric DBS literature. Obsessive-compulsive disorder has an approved (if narrow) regulatory pathway in the United States via a humanitarian device exemption, following open-label and controlled work showing meaningful symptom reduction in a subset of patients with the most severe, treatment-refractory presentations [3,4]. Treatment-resistant depression has no such pathway: promising open-label results targeting the subcallosal cingulate and related circuits [5] were followed by a large industry-sponsored randomized sham-controlled trial that was stopped for futility, a result that reshaped how the field talks about equipoise and premature translation [6]. A separate multisite trial targeting the same general region later reported more encouraging findings using a different implantation and programming protocol, underscoring how much of the apparent effect size in this literature still depends on target selection, patient selection, and stimulation parameters that remain unsettled [7]. This review works through the ethical questions that recur across this literature: what informed consent can actually mean for a study whose primary outcome measure includes changes in the patient's mood and cognition; what it means to describe a stimulation-induced change in affect or personality as a "side effect" rather than as a change in the person; how research ethics committees have handled the gap between a device's approved indication and the population it gets tested in; and what happens to patients, and to the field's evidentiary base, when a trial like the depression pivotal study fails. Table 1 sets out how these ethical concerns vary in intensity across the major indications now under investigation, and Figure 1 presents the same comparison schematically.

INFORMED CONSENT AND THE PROBLEM OF THERAPEUTIC MISCONCEPTION

Every DBS-for-psychiatric-illness trial recruits from a population defined by treatment failure: patients who have not responded to first-, second-, and often third-line therapies, and who are frequently in substantial distress by the time they are approached

about an invasive, investigational brain surgery. That context makes therapeutic misconception -- the tendency for research participants to overestimate the likelihood of personal benefit from a study designed primarily to generate generalizable knowledge -- a persistent concern rather than a hypothetical one [8]. A patient who has tried everything else may reasonably experience a DBS trial as their last realistic option, which is precisely the condition under which voluntary, uncoerced consent becomes hardest to secure even when every procedural requirement of informed consent has been satisfied on paper.

The consent problem compounds because DBS trials are unusually difficult to describe accurately in advance. Unlike a drug trial, where the intervention and its likely side-effect profile can be characterized from prior pharmacological data, early-phase psychiatric DBS trials are frequently exploring both a novel target and a novel indication at once, so investigators cannot fully specify what stimulation at a given site will do to mood, cognition, or personality before the study is under way [9]. Ethicists writing on the failed depression pivotal trial have argued that this uncertainty needs to be disclosed as uncertainty -- named explicitly as unknown rather than folded into a generic risk list -- precisely because patients recruited from a treatment-resistant population are especially likely to discount speculative risks against a concrete hope of relief [10]. The humanitarian device exemption pathway used for OCD raises a related but distinct problem: that pathway was designed for rare conditions where a full randomized efficacy trial is impractical, and applying it to a psychiatric indication where placebo response can be substantial has drawn criticism for allowing a device to reach limited clinical use on a lower evidentiary bar than a psychiatric drug would require [10].

PERSONAL IDENTITY, AUTHENTICITY, AND THE MEANING OF "SIDE EFFECTS"

The most philosophically distinctive ethical issue in this literature is the possibility that stimulation changes something closer to the person than to their symptoms. Case reports and qualitative interviews describe patients experiencing themselves as unfamiliar to themselves after stimulation changes -- more impulsive, more aggressive, or conversely flattened and less like their pre-illness selves -- in ways that are difficult to classify cleanly as either "the treatment working" or "an adverse effect" [11]. In-depth interviews with OCD patients who underwent DBS describe a comparable ambivalence: many reported substantial symptom relief alongside a sense that their sense of agency and self-continuity had shifted in ways the consent process had not prepared them for [12].

Philosophers working on this question have pushed back against treating every reported change as evidence of an identity threat. A careful analysis of what "personality change" actually means in the DBS

literature distinguishes changes that are superficial or transient from changes that plausibly alter a patient's values, commitments, or narrative self-understanding, arguing that conflating the two inflates the ethical stakes of routine stimulation adjustments while under-describing the rarer cases where something more fundamental does appear to shift [1]. Recent survey work with the researchers actually running next-generation DBS trials found considerable disagreement among investigators themselves about how to interpret and report personality- and mood-related changes, including uncertainty about whether such changes should be captured as adverse events, efficacy signals, or a separate category the field has not yet built adequate measurement tools for [13]. That uncertainty among investigators is itself an ethical finding: if researchers cannot agree on how to characterize these changes, patients cannot be adequately informed about them in advance, no matter how thorough the consent document. A recent synthesis of the psychological and neuroethical literature on DBS makes a related point, that mood and cognitive effects have historically been studied with far less rigor than motor outcomes, leaving the field short on the longitudinal psychological data it would need to say with confidence how common genuinely identity-level change actually is [14].

The identity question has also reached down into adolescent populations, as pediatric OCD cases have begun to be considered for DBS in the most severe, refractory presentations. Interviews with adolescent patients and their caregivers found that concerns about authenticity and normalcy featured prominently in how young patients anticipated the treatment, often more prominently than concerns about surgical risk, suggesting that identity-related worries are not a niche philosophical concern but something patients themselves foreground when asked [15].

EQUIPOISE, TRIAL DESIGN, AND THE FALLOUT FROM A FAILED PIVOTAL TRIAL

The 2015 report that the industry-sponsored ventral capsule/ventral striatum trial for treatment-resistant depression had been halted for futility became a reference point the whole field has had to reckon with [6]. A treatment that had looked strikingly effective in open-label pilot work produced no significant separation from sham stimulation in the blinded, randomized phase -- a pattern familiar from other neuromodulation and psychiatric-surgery literatures, where open-label enthusiasm regularly outruns what a controlled trial can confirm. A systematic review of the broader depression-DBS evidence base concluded that, across the studies conducted to that point, the quality of evidence remained low relative to the scale of surgical risk being asked of patients, and that stronger trial designs were needed before the field could responsibly expand access [16]. A more recent review of surgical complications and ethical challenges

across psychiatric neurosurgery indications more broadly reached a similar conclusion, arguing that perioperative risk disclosure in this population has not kept pace with the expanding range of conditions being proposed for surgical treatment [17].

The ethical fallout from a result like this runs in more than one direction. Trial sponsors and investigators owe something to the patients who participated and, in many cases, continued to carry implanted hardware after a program was discontinued -- a device-abandonment problem that recurs whenever an investigational neurotechnology trial ends before a long-term maintenance plan exists [18]. The field has also had to weigh how much a single negative pivotal trial should be read as evidence against the entire approach, given that a different multisite trial using different targeting and programming produced considerably more encouraging results only two years later [7]. Bioethicists have generally converged on the view that a failed trial should prompt more careful attention to patient selection, target validation, and blinding methodology rather than abandonment of the research question altogether, but that conclusion depends on continuing to treat the patients already enrolled as owed ongoing care rather than as a closed chapter in the trial's history [19].

CLOSED-LOOP SYSTEMS AND THE NEXT WAVE OF ETHICAL QUESTIONS

A newer generation of "adaptive" or closed-loop DBS systems, which sense a patient's neural or physiological state and adjust stimulation in real time rather than delivering constant stimulation, is beginning to reach psychiatric applications and brings its own distinctive ethical profile. Continuous physiological sensing generates a stream of intimate data about a patient's neural state that raises privacy and data-governance questions with no clear precedent in earlier, open-loop DBS practice [19]. It also sharpens the personal-identity question discussed above: if a device is adjusting stimulation moment-to-moment in response to detected mood or symptom states, the line between "the patient's own fluctuating affect" and "an algorithmically imposed affective state" becomes harder to draw, and patients participating in adaptive-DBS trials have reported mixed feelings about how much agency they retain over their own emotional experience once a device is making these adjustments autonomously [20].

A multidisciplinary consensus statement on responsible neurotechnology development has argued that closed-loop psychiatric devices need governance frameworks built before, not after, wide deployment -- covering data ownership, algorithmic transparency, and a patient's ability to understand and, where desired, override the device's decisions -- precisely because retrofitting such protections onto an already-marketed device has proven difficult in other domains of implantable technology [18]. Whether that

guidance translates into actual regulatory requirements before closed-loop psychiatric DBS reaches wider clinical use remains, at the time of writing, an open question rather than a settled one.

CONCLUSION

Psychiatric DBS occupies an unusual ethical position: mature enough, after two decades of trials, that its risks and open questions are reasonably well characterized, but not mature enough that any single indication beyond the narrowest OCD population has a settled evidentiary and regulatory footing. The consent problem is real but not intractable, provided trial designs disclose uncertainty about mood and personality effects as genuine unknowns rather than folding them into boilerplate risk language. The personal-identity question is genuine but easy to overstate in either direction -- some reported changes are superficial, some are not, and the field still lacks a shared vocabulary for telling the two apart in real time. The failure of the largest depression pivotal trial was a setback for the field's evidentiary base, not a refutation of the underlying hypothesis, but it does mean that expansion of psychiatric DBS beyond its current narrow footholds should track the strength of controlled evidence rather than the momentum of open-label enthusiasm. Closed-loop systems will likely make several of these questions harder before they make them easier, which argues for building governance structures for data ownership, algorithmic transparency, and long-term device stewardship into trial design now, rather than treating them as problems for later.

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Conflict of Interest

The authors declare no conflicts of interest relevant to this work.

Author Contributions

Rui Antoniou conceived the review, drafted the introduction and conclusion, and coordinated the manuscript. Ines Peeters conducted the literature synthesis on informed consent, trial design, and the failed depression pivotal trial, and critically revised the manuscript. Marco Saez-Bermudez contributed the sections on personal identity, authenticity, and closed-loop systems, and provided final approval of the submitted version. All authors read and approved the final manuscript.

Ethics Statement

As a literature review synthesizing previously published, publicly available research and policy analysis, this article did not involve new data collection from human participants and did not require institutional ethics committee approval.

Data Availability

No new data were generated or analyzed for this review. All sources discussed are cited in the reference list and are publicly available through their respective publishers.

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