# Patient-Participant Narratives of the Decision to Join Non-Therapeutic Intraoperative Neurophysiology Research: A Qualitative Analysis



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# Background

- Non-therapeutic intraoperative neurophysiology studies involve basic neuroscience research conducted during a neurosurgical procedure, such as the implantation of a deep brain stimulator (DBS) device for Parkinson's disease (PD).
- Such research includes electrical recording or stimulation, unrelated to the patient's clinical care, for the purpose of advancing knowledge of the human brain.<sup>1</sup>
- Since this research is non-therapeutic, these studies do not offer any added clinical benefit but may subject already vulnerable patients to further risk.
- This evolving field of research raises novel ethical concerns related to informed consent, acceptable risk, and overlap of clinical and research components of neurosurgical care.<sup>1,2</sup>
- Most ethical and qualitative research about this field has focused on perspectives of researchers and physicians with little focus on the patient experience of nontherapeutic research during DBS surgery.

# Objective

Explore patient-participant narratives surrounding their decision to join non-therapeutic intraoperative neurophysiology research.

#### Methods

- As part of an ongoing qualitative study funded by the BRAIN Initiative, semi-structured interviews were conducted with 12 patients (P1-P12) who had participated in non-therapeutic research during their surgical implantation of a deep brain stimulator for Parkinson's disease, dystonia, or essential tremor.
- The interviews were transcribed and coded using a codebook emphasizing risk, patient engagement, and motivations to participate.
- A focused thematic analysis of the narratives involving the decision to participate in the intraoperative research was completed.

<sup>1</sup>Joncarmen V. Mergenthaler, et al. (2021) A Qualitative Analysis of Ethical Perspectives on Recruitment and Consent for Human Intracranial Electrophysiology Studies, *AJOB Neuroscience*, 12:1, 57-67, DOI: 10.1080/21507740.2020.1866098

<sup>2</sup>Winston Chiong, et al. (2018) Neurosurgical Patients as Human Research Subjects: Ethical Considerations in Intracranial Neurophysiology Research, *Neurosurgery*, 83:29-37, DOI:10.1093/neuros/nyx361

#### Results

An analysis of patient responses when asked about their decision to join indicated the following themes:

## Immediacy of decision

"[My surgeon] did say, he goes, 'You can take a minute to think about it.'
And I was like, 'I don't have to. Just put me in the study.'" (P5)

"It was just something they asked if I'd be willing to do and I said, 'Sure, what the hell?'" (P3)

"I merely asked if it would help someone else. They said it would, and I said, 'Okay.'" (P2)

## Impact of personal experience

"I've always liked helping people.

Also I've lost several very dear
friends to Parkinson's. And so
anything that I can do to help make
people feel better and continue to
live, it's better." (P8)

"I wanted to help the doctors involved, because they made such a large difference in my life." (P4)

"I'm not sure of the correct count, but half the people I was dealing with [in my local Parkinson's Association] over the years passed away...And so, I guess I'm doing it in their memory." (P1)

#### Desire to help improve care

"I feel, as myself, as being like a donor, when my body goes on. If anything, a part of my body can help save somebody else, that's great. So my thing is with Parkinson's, is anything that I can do to maybe further along, it might not benefit me but it might benefit somebody down the road or from there." (P9)

"I believe in teaching hospitals... So I wanted to make sure that I would be able to, while I was getting relief from my essential tremor, that it could then help others." (P5)

"I decided to join it so that hopefully I can help somebody else in the same situation or similar circumstances... to benefit the research and keep things moving in up and up." (P12).

Analysis of quotes addressing decision making throughout the interviews yielded the following additional themes:

#### Trust

"The basic thing is, if I didn't trust him then I wouldn't have agreed to have the surgery done at all. So, I'm trusting him with that and if this is a way that can help anybody." (P3)

#### Unique position

I thought, "Well, they can't have too many people that they are asking this stuff of, I'll be glad to help." (P11)

#### Comparative risk

"You're already going through all this risk and preparation and stress and they're going in your brain anyway. As long as you're there, if you can accomplish something helpful, that was the thinking." (P3)

## Conclusion

- The decision to participate in non-therapeutic research during DBS implantation was immediate for several patientparticipants, suggesting some patients have reason to feel comfortable joining intraoperative research without hesitation.
- When all interviewees were asked about their decision, their responses revealed that personal experience and the desire to improve care were primary motivations; additional factors, such as trust, their unique position as neurosurgical patients, and the minimal risk compared to the DBS surgery provided further context to patients' reasoning and/or lack of concern.
- These personal and contextual factors are not all traditionally emphasized in the process of informed consent yet seem to play an important role in patients' decision-making.
- Therefore, patient-participant narratives provide valuable insight towards patient-centered informed consent practices and should be incorporated when determining acceptable risk of future non-therapeutic research as the field evolves.
- This qualitative analysis is limited by the selection of patients who consented to both DBS placement and intraoperative research; further studies should explore the perspectives of those who decline to participate.