

Risks, Benefits, and Value: Patient-Participant Perspectives on Basic Intracranial Human Research

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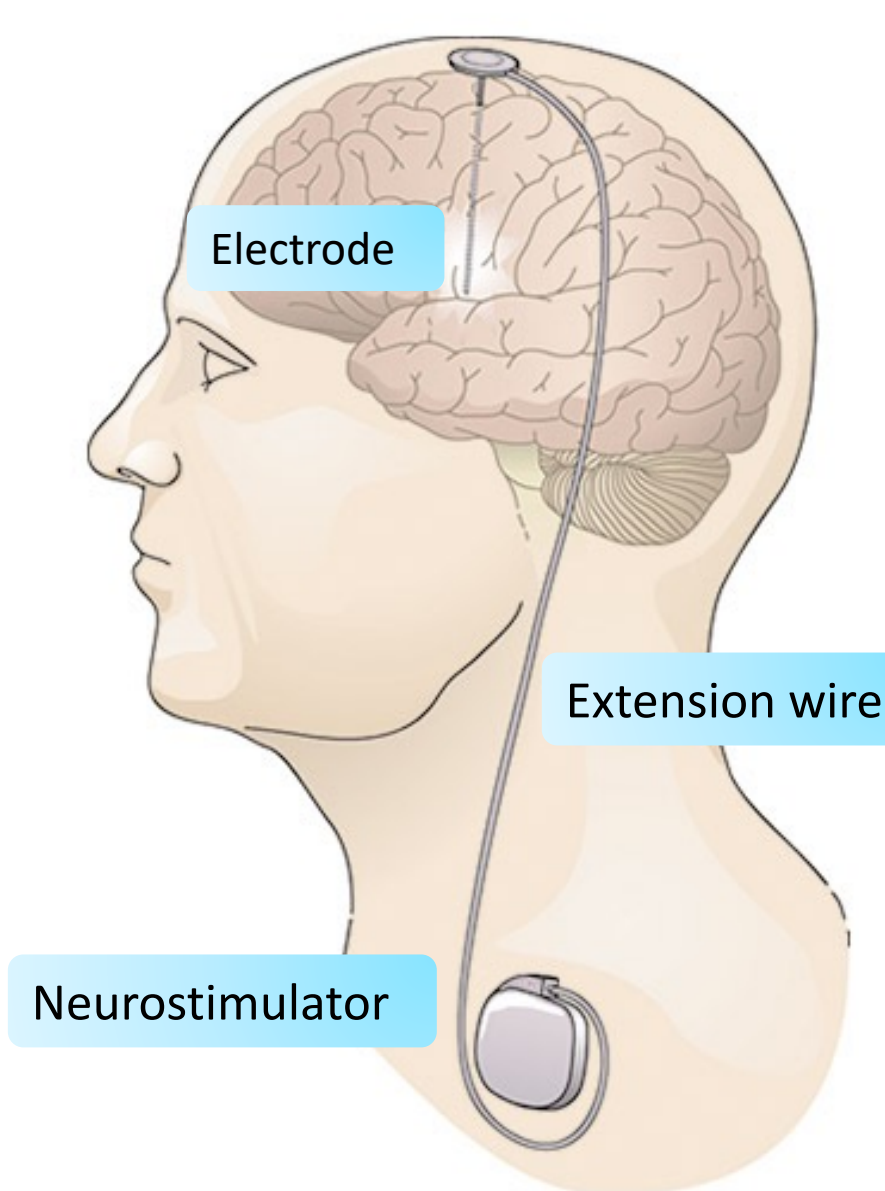
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BACKGROUND

Several neurosurgical interventions require intracranial electrodes for either diagnostic or therapeutic purposes (such as deep brain stimulation for Parkinson’s disease and epilepsy), providing unique opportunities to conduct basic, non-therapeutic intracranial human neuroscience research. This research has advanced our understanding of human brain function across multiple domains, including language, sensorimotor function, and memory. While invasive human research is not unique to neurosurgery, **the lack of therapeutic benefits, the vulnerability of patient populations with neurological or psychiatric diagnoses, the rarity of access to intracranial data, and the common occurrence of clinician-investigators,** necessitate ethical scrutiny.



THE PROBLEM

Despite increasing interest in the ethics of invasive brain research,^{1,2} there is a lack of focus on two areas:

basic intraoperative brain research

patient-participant perspectives

Without patient-participant input, we may be problematically privileging the scientific community’s values with respect to risks, benefits, importance of basic brain research, and optimal informed consent procedures.

OBJECTIVE

To elucidate patient-participants’ perspectives on basic intracranial brain research to better understand their experiences, values, and motivations for enrolling.

METHODS

As part of an ongoing qualitative study, semi-structured interviews were conducted with patient-participants (n=14) across two sites who had participated in non-therapeutic research during their implantation of a deep brain stimulator for Parkinson’s disease, dystonia, or essential tremor. The interviews were conducted by members of the team who do not conduct intracranial research. Interviews were recorded, transcribed, and coded independently by at least two team members, using a codebook developed by all team members. A grounded thematic analysis was completed to develop emerging themes.

RESULTS: Initial Themes

Ease of Decision to Join

Question Prompt: Was the decision to join difficult?

Dr. [X] just asked nicely, “Would you like to be a part of this?” And I went, “Sure. It’s a study and it’ll further knowledge.” That’s what I’m all about...Dr. [X] did say, “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)

I did, of course, trust him. But I didn’t give it a great deal of thought, I just made the decision to participate. (P4)

It was an easy decision for me. I was just like, yea, that’s going to help someone else. Absolutely I’ll go for it. (P12)

Minimal Concerns about Risk

Question Prompt: Did you have any concerns about the study, for example, related to any additional risks?

No, it didn’t occur to me. I personally don’t feel that I had any increased risk in participating. (P4)

I didn’t really think about that...If there was a risk, they would have stopped it or they wouldn’t have done something like that. I mean, they wouldn’t just keep asking me questions if there were risks. (P11)

Maybe just taking on a little bit of extra risk might seem, if something had gone wrong, maybe you’d feel stupid for extending the risk, but it really didn’t seem like taking on that much risk. (P3)

Limited Understanding of Study Goal

Question Prompts: What did you take the benefits of the research study to be? What did you take the purpose of the study to be?

I have no idea. I don’t know what they were doing at all. Maybe they’re mapping the brain, maybe they’re just training somebody how to apply an electrode. I have no idea. I just trust that somebody’s getting something out of it. (P3)

I don’t know the purpose of the study really, like what they’re expecting to find, or what they’re hoping to find, I don’t know how it will affect the surgery...but that’s ok. (P11)

I don’t know what the heck I’ve contributed to it, but I feel good about it, Okay?...There’s not a whole lot of information out there on it, so why not...I liked being a part of something obviously bigger than myself. (P14)

Emergent Complex Themes

Motivations to Help Others

- I think that’s why I did it. You feel good that you’re able to do something that helps someone else down the line. Somebody is benefitting from it...And I’m the benefit of a million people going through tests...somebody has to be the first to do something. (P3)
- Someone had to do all this stuff before me, so anything I can do to help somebody down the road is, I think beneficial. (P9)
- One reason I helped was just that I can’t imagine there’s a ton of people who have the surgery...maybe I’m wrong about that. So that’s one reason I thought, “Well, they can’t have too many people that they are asking this stuff to, I’ll be glad to help.” (P11)
- I think it’s important to help in the advancement of human knowledge and to support other researchers and scientists. (P13)

Importance of Basic Brain Research

- The more we understand about the human body and obviously the brain...if it can be helpful, it’s worthwhile. If we have a better understanding of the brain, how it works, and what it does, then that just moves us one step to providing perhaps new techniques or more success. (P2)
- But it might help down the road. You never know what kind of small detail can be connected. (P5)
- You never know with the way research is, they could find the cure tomorrow or 10 years down the road, or they could never find the cure. But I feel, as myself, as being like a donor...if a part of my body can help save someone else, that’s great...it might not benefit me but it might benefit someone down the road. (P9)

Trust

- 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)
- If I was anywhere where I thought I was at risk, they would say, “okay, we’ve got to get out of this study...and we’ve got to move on.” So I never once hesitated. (P9)
- I don’t think there’s any risk. I just, I just fully trust. (P7)

Impact of Surgical Context

ON COMPARATIVE RISK EVALUATION:

- 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. (P3)
- I would have been more concerned about the surgery then...Any surgery, you get your tooth pulled, potential problems, but no. It just never occurred to me that there would be any concerns at all. (P2)

ON OPPORTUNITY

- It was a good opportunity, since I had my head open anyway, to try and poke around inside of it and see what was going on inside of there. (P13)
- I was very grateful for the people that did anything to help so I can have the surgery, somebody has to practice stuff and learn stuff, so as long as you’re in there you might as well go for it. (P3)

ON EXPERIENCE

- I don’t even feel like I was really in a study...I just felt like that was stuff I would expect to do during a surgery of this type anyway. (P5)

Impact of Illness Experiences

- I’ve lost several very dear friends to Parkinson’s, so anything I can do to help make people feel better and continue to live. (P8)
- Half of the people I was dealing with in my local Parkinson’s Association over the years passed away...I guess I’m doing it in their memory. (P1)

DISCUSSION

These narratives impress upon two areas of ethical importance:

Benefit and Value

There may be under-appreciated sources of benefit and value for patients in intraoperative studies, such as participating in research they find significant, participating in a scientific process they feel has benefitted them, and helping others. While experiences with illness and the need for surgical intervention may be sources of vulnerability, they may also contribute to the value of this research to patients. Further work, which recognizes and responds to these values in ethical assessments of basic intraoperative studies, is needed.

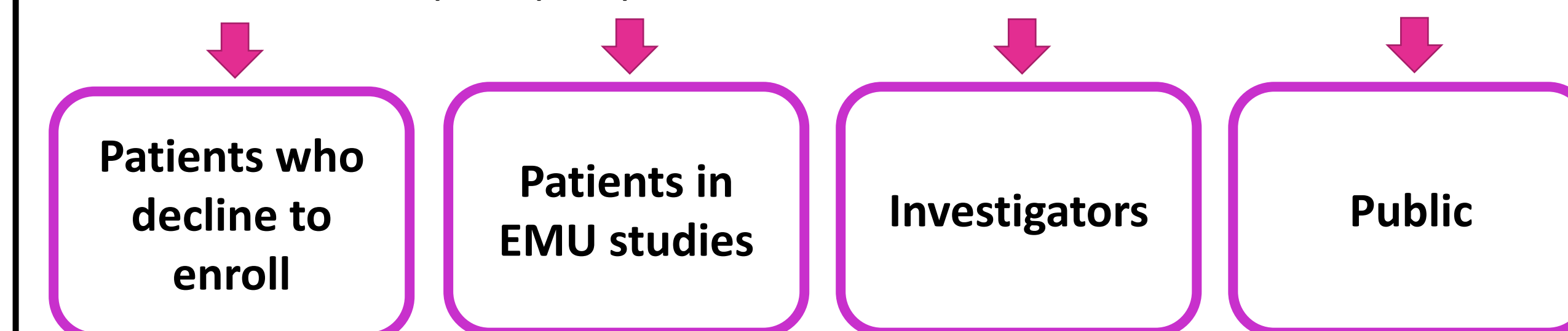
Informed Consent

The ease of the decision to join, minimal concerns with risks, and limited understanding of study goals may raise concerns about informed consent, and prompt particular interventions (e.g. teach back) to increase understanding.³ But, more complex participant narratives suggest that trust, surgical context, experiences with illness, and valuing of basic research play a significant role in contextualizing how patients think about participation. In these studies, attitudes of trust and deference may be more central to consent interactions than traditional features, such as understanding risks and study goals. While the latter features are important, **ideal consent procedures may need to include practices aimed at developing good clinical and study relationships, so that attitudes of trust and deference are morally grounded and not exploited.**

CONCLUSIONS, NEXT STEPS

Our interviews help elucidate the unique position that patient-participants in basic intracranial research occupy. This position may make possible additional sources of value but also necessitates efforts at patient protection. Practices should be responsive to both.

NEXT STEPS: Compare perspectives across studies and stakeholders



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