TRUST, PATIENT ADVOCATES, AND RECONSENT: IMPROVING CONSENT IN INTRAOPERATIVE BRAIN RESEARCH

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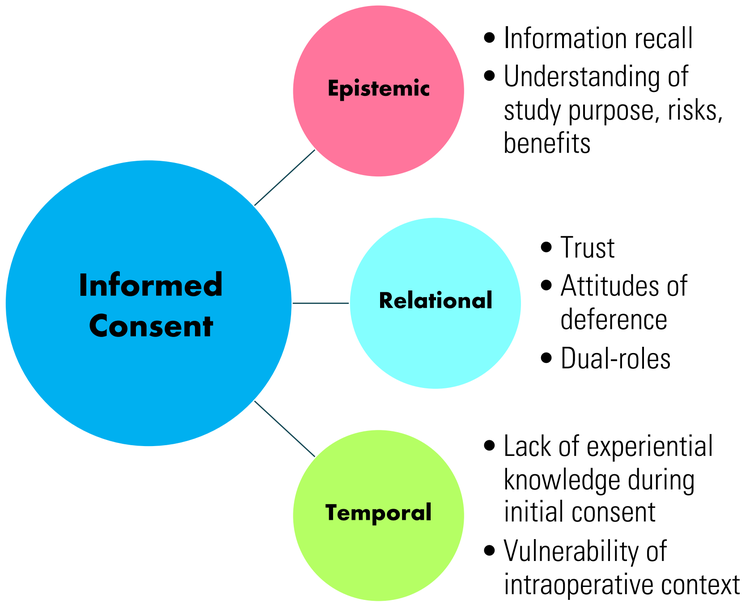
Several features of basic brain research suggest the need for innovative informed consent procedures.

- Its surgical context, which might occlude proper appreciation of research-related risks.
- Its non-therapeutic intent, which offers no immediate clinical benefit to participants.
- The diagnoses of those potential participants, which include neurodegenerative diseases and potential impacts on cognition.
- The dual roles of those involved: surgeon-researchers and patient-participants.

Previous proposals to improve informed consent in this context focus on information recall, suggesting teach-backs or in-depth one-on-one conversations.[1-4,6]

These suggestions privilege the *pre-surgical epistemic* components of informed consent. However, informed consent also has relational and temporal components. Relational components have to do with the interpersonal relationships between patient-participants and their research-care team. Temporal considerations have to do with the typical emphasis on initial consent, which occurs when patients are neither maximally informed nor maximally vulnerable.



Two Problems

Epistemic:

Many consent practices do not fully consider the potential for ***context to change what matters*** for informed choice and for ***experiential knowledge*** to change perspectives on participation.

Methods like teach-back are promising only to the extent that what is being taught back enables informed choice in this context.

Relational:

Many practices do not fully consider the effects of trust between patient-participants and surgeon-researchers, and the possibility that ***trust may both enable and threaten consent***.

Methods like preventing clinician-researchers from consent may miss opportunities for patients to build trust and have honest consent conversations.

Epistemic considerations

Studies involving the narratives of participants of intraoperative brain research have found low information recall regarding study risks, benefits, and details.[5,6]

Many participants reported that they did not know any study details beyond that it might help others, but also, crucially, that they did not need to know.

Instead, when asked about the study purpose, many participants offered answers that centered why they found the study to be valuable, including longer-term hopes for translation and the importance of furthering knowledge about the brain.

> 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 it was, somebody's getting something out of it.[5]

> I just know regardless, it's going to benefit somebody down the road. For me personally, I don't think I need to know [how].[5]

Relational considerations: the many roles of trust[5]

Trust in physician and research team	I felt confident in the doctor and his capabilities.
	Well, I figured if they were good enough to be working in that department they should be good enough to talk to me and ask me some questions and put me through some tasks.
Trust regarding mitigation of risks	If there was a risk, they would have stopped it or they would've done something like that. I mean, they wouldn't just keep asking me questions if there were risks.
	I don't think there's any risk or harm. I just, I just fully trust.
Trust in beneficiality	I just know regardless, it's going to benefit somebody down the road.
Trust regarding study goals	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 okay.

Temporal considerations: undergoing awake brain surgery-research

Patient-participants expressed mixed experiences of participation: some seemed to derive value from the opportunity to contribute to research; others presented more negative responses, noting pain during the research, fatigue, and that they had considered 'giving up' mid-research; still other responses were mostly neutral.

> Because no matter how you look at it, it is a traumatic experience… people need to know that before you get into this. To me, did I go in there blindly? Some of it was blindly, yeah. Did I read up on it? Yeah, I did. I learned the mechanical way about how the surgeon was going to go. What about the emotional part? Not so much.[5]

Suggested improvements to informed consent:

Third-party patient advocate during initial consent

Others have suggested a hybrid approach with both the clinician-researcher and another research team member present.[3] This would both maximize patient understanding and provide space to mitigate the influence of the clinician.

Our findings highlight the significance of the trust patient-participants place in their clinician-researchers. However, they also point to the risk of overly deferential attitudes and mixed experiences of participation.

Researchers are not uninvolved: they have interests in the study, including patient enrollment and study completion, but may not have pre-existing trusting relationships.

We advocate hybrid consent, but propose that the additional party be an unaffiliated patient advocate.

Verbal, intraoperative reconsent

If patients are awake before research initiation, and they have then acquired experiential knowledge of what this surgery is like, then they should be approached to reconsent. They are arguably more informed than pre-surgical consent, and views about participation may have changed.

We propose requiring verbal intraoperative reconsent. However, narratives point to the complexity of the intraoperative context and how difficult it may be to provide meaningful opportunities to reconsider participation.[5,6]

This need not be a lengthy process, as additional operating time extends risks, but may need to be a formal opportunity. Thinking about the importance of reconsent supports additional motivations for the hybrid initial consent – trust may be a minimal condition for reconsent during awake brain surgery meaningful and voluntary.

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