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GUEST EDITORIAL

Individualizing Informed Consent: For Whom, and How Far?

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INTRODUCTION

In 2018, the U.S. federal guidelines were updated to require *the reasonable person standard* during informed consent in research settings (Khatiwada et al. 2026). According to the standard, researchers must disclose to participants the risks, benefits, and purpose of the research that an "average person" would want to know before deciding to participate in research (Khatiwada et al. 2026). However, as Khatiwada et al. articulate in their target article, "Reasonable to Whom…," there is a lack of consistency in defining and operationalizing who "the average person" is and what she would want to know (Khatiwada et al. 2026). Moreover, they argue that the reasonable person standard often does not incorporate the informational needs of participants who are members of the minoritized community under study (Khatiwada et al. 2026). For instance, they point to their empirical findings that patients with Autism want to be informed not just about the potential harms and benefits of research participation, but also about the research team's positionality on Autism; whether the research uses pathologizing language; and whether it aims to or could later be used to reduce Autistic traits or eradicate Autism (Khatiwada et al. 2026). According to Khatiwada et al., these matters go beyond what the "average person" would want to know (Khatiwada et al. 2026).

To address these issues, Khatiwada et al. propose what they call an "individualized understanding of the reasonable person standard," whereby consent is tailored to the needs and unique concerns of an "average person" *in the target population* rather than to those of an "average person" in general (Khatiwada et al. 2026). Their proposal to individualize informed consent in research is twofold. First, they recommend individualizing the *content* disclosed during informed consent, including informing participants about how the research might impact their and their community's unique concerns in the long-term, and supplying a positionality statement articulating the relevant views, values, and aims of the research team (Khatiwada et al. 2026). Second, they recommend individualizing the *delivery* of information disclosed. This includes, where possible, conducting consent one-on-one, providing consent materials in advance, and offering extra time to participants who process information more slowly (Khatiwada et al. 2026). Research teams can individualize both the content and delivery of their information disclosure processes by conducting community-based participatory research (Khatiwada et al. 2026). This involves consulting members of the target population with lived experience for their insights, concerns, and general feedback on consent forms, processes, and protocols (Khatiwada et al. 2026).

Like Khatiwada et al. and others, we believe that research teams should treat members of their target populations not merely as subjects but also, when applicable, as "co-creators of research" (Abbasian and Boyd n.d., 3). We also support Khatiwada et al.'s recommendation to individualize the *delivery* of information during informed consent to accommodate participants with distinct emotional and learning needs (Khatiwada et al. 2026). However, drawing from our work on the ethics of consent for translational neural device research, we would like to raise two questions about their proposal to individualize the *content* of information disclosed. First, Khatiwada et al. do not address whether ethical concerns raised by the minoritized communities under study should be disclosed only to those participants or to all participants. Second, it remains to be seen whether individualizing the content of information could place too large of a burden on research teams and participants, or bias participants against research participation.

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INTERPRETING THE INDIVIDUALIZED REASONABLE PERSON STANDARD FOR DISCLOSURE IN RESEARCH CONSENT

Khatiwada et al. do not make explicit whether an individualized informed consent process would require disclosing ethical concerns raised by the minoritized communities under study to minoritized participants alone or to all participants. We believe that all participants should be informed about legitimate and relevant ethical research concerns regardless of whether they belong to the potentially affected communities. For instance, before consenting to participating in an Autism-related research study, both neurotypical and neurodivergent participants should be informed of salient ethical concerns raised by the Autistic community.

Khatiwada et al. may be correct that the average person is unlikely to identify the importance of specific research-related concerns raised by the Autistic community. However, we respond that this does not necessarily reflect an informed, reasoned decision but rather a lack of exposure to the "neurodiversity paradigm," which posits Autism as a "mere-difference" rather than a "bad-difference" "in need of 'fixing'" (Khatiwada et al. 2026). Without understanding this view, one is not equipped to grasp the Autistic community's qualms with research that aims to reduce Autistic traits or "eradicate autism" (Khatiwada et al. 2026). The reasonable person standard is not about what the average person would want to know *prima facie*, but rather what they would need to know to make an informed, rational decision. As DeLuca et al. point out in this issue, "the standard asks not what most people do, but what reasonable prudence requires under the circumstances" (DeLuca et al. 2; *Vaughan*; *The T.J. Hooper*). This includes disclosing information that potential participants do not know they need to know. Thus, a reasonable person would want to be informed of ethical research concerns raised by minoritized communities under study so they do not ignorantly participate in research that they might otherwise find unethical.

That said, as Khatiwada et al. point out, informing participants of these kinds of concerns may not be happening in practice because they often involve potential harms that are "causally distal to the research itself" and "largely experienced by non-participants," and the Health and Human Services (HHS) mandate only requires disclosing potential harms to participants (Khatiwada et al. 2026). Unfortunately, this problem is not remedied by Khatiwada et al.'s suggestion for an individualized reasonable person standard if it does not require disclosing these concerns to all participants. Thus, instead, we raise the possibility that the HHS expand their current guidelines for risk disclosure to include potential downstream harms and potential harms to non-participants. On one hand, this could equip all participants to consider the ethical and societal consequences of participating in research. On the other hand, as we will discuss in the following sections, extra disclosures like this could make informed consent overly burdensome and discourage people from participating in research that is low risk and all-things-considered justified.

DISCLOSING ETHICAL AND DOWNSTREAM SOCIETAL CONSEQUENCES OF RESEARCH AND THE POSITIONALITY OF RESEARCH TEAMS

Should participants be informed of the potential ethical and downstream societal consequences of research? To what extent? These questions are particularly pressing in the context of our own work on the ethics of translational neural device research. While investigating participant informational needs in this setting, we have found that many research teams have financial ties to neural device companies, which raises concerns about commercial influence that research participants might deem important (Parsons 2025). Moreover, even neural device research that is itself free from commercial influence can be adapted later on for commercial use.

We believe that participants are likely to want to be informed about these commercial affiliations because medical and commercial neural device research can differ in both objectives and methodology. Regarding differences in objectives, several neural device companies and industry leaders plan to go beyond the therapeutic aim of treating disorders, illnesses, and disabilities to enhancing or extending human capabilities and achieving direct interaction between AI systems and the human brain (Paradromics n.d; Neuralink n.d; Marsh 2018). As Paradromics CEO Matt Angle stated, "Anyone who's building interfaces with the nervous system is building both the capability to restore capabilities and enhance capabilities" (Lee 2026). Participants might want to know whether knowledge discovered and technology developed during medical research could be used in the future for human enhancement purposes because such goals might raise new unforeseen risks to society or otherwise conflict with their values.

Regarding methodological differences, there is a significant lack of regulatory oversight governing

commercial neural device research relative to medical (Hong 2027). Indeed, some have criticized Neuralink trials for their lack of transparency and scientific rigor, animal rights abuses during earlier pre-human trials, and taking advantage of patients' desperation by recruiting participants on social media (Hurley 2024). Participants would likely want to know whether research will be conducted unethically or irresponsibly or whether it could later contribute to irresponsibly or unethically conducted research.

In light of major neuro tech companies' rapid developments, visions for the future, and lack of traditional oversight, neural device researchers may need to consider and disclose their work's potential ethical and societal consequences (Goering et al. 2021; Stuijvenberg et al. 2026). Currently, however, the HHS only requires research teams to consider and justify the downstream societal risks of research that enhances potential pandemic pathogens or involves biological agents and toxins, and even then does not require disclosing these potential harms to participants during informed consent (Hassel 2020; Parthemore and Regan 2024).

Obligating research teams to disclose their positionality, commercial ties, and potential downstream consequences would raise a host of questions, however. For instance, how should research teams talk to potential participants about these issues during already long consent conversations, without overwhelming or exhausting them (Hallinan et al. 2016)? What are participants then likely to do with this information? On one hand, discussion about commercial influences and troubling future uses might discourage trust and participation. On the other hand, research in behavioral economics indicates that disclosing risks can have a backfire effect of strengthening trust rather than inviting scrutiny, even if scrutiny is warranted (Cain et al. 2005). So long as informed consent conversations accurately reflect potential harms and benefits, we believe that this extra disclosure is unlikely to bias participants toward or against research. Still, the practical details of such disclosures ought to be further studied before they are ethically recommended as part of research consent.

CONCLUDING REMARKS

Khatiwada et al. propose to individualize information disclosure in research (Khatiwada et al. 2026). We add that while research teams should individualize *how* information is disclosed, they should not necessarily individualize the information *itself*, especially information that may or should concern all participants on ethical grounds. Participants have a right to know and weigh the ethical dimensions of their participation in research. For instance, until the tech industry is better regulated, participants in neural device research should be informed of their potential contributions to the agendas and operations of neural device companies. To ensure that the ethical dimensions of research are disclosed to all participants, we have explored whether the HHS should require researchers to disclose potential harms that are downstream and experienced by nonparticipants. While its practical details ought to be worked out before it can be recommended, such a disclosure, or others like it, could help establish a normative standard in both medical and commercial neural device research going forward, and more broadly, encourage ethical deliberation across all stakeholders in research.

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