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Inconsistent Approaches to Research Involving Cognitively Impaired Adults: Why the Broad View of Substituted Judgment is Our Best Guide

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This case study highlights some of the most challenging ethical issues in biomedical research: when and how can we justifiably use cognitively impaired adults to benefit other people? Forty years after the issuance of federal regulation 45 CFR 46, practice in this area remains unsettled. The Common Rule lacks specificity; guidance from the Office for Human Research Protections (OHRP) defers the matter largely to the states; and most states fail to explicitly address the topic, despite many thoughtful reports (American College of Physicians 1989), including from two Presidential Commissions (National Bioethics Advisory Commission 1998; Presidential Commission for the Study of Bioethical Issues 2015), recommendations (National Institutes of Health 2009), and commentaries (Berg 1996; Glass and Speyer-Ofenberg 1996; Yarborough 2002).

As a result, institutional review board (IRB) practices, and thus research opportunities, can be wildly discordant. For example, in jurisdictions lacking state statutes that authorize surrogates to make research decisions for incapacitated adults, an IRB may prohibit all such non-therapeutic research, reasoning that the absence of a law authorizing surrogate consent for research means that that state does not want this research to occur. In that same state, another IRB may

decide the exact opposite, reasoning instead that if the state had wanted to prohibit such research, it would have done so explicitly.

Discordance does not end at the question of whether we can legally conduct non-therapeutic research with impaired adults. Among those IRBs that determine such research is legal, we find divergence on what research is permitted. Some may prohibit all non-therapeutic research. Others may permit non-therapeutic research but restrict all research to health conditions relevant to adults with impaired decision making, like the research addressed in this case study. It might also be within the discretion of an IRB to restrict surrogate consent to, for example, surrogates able to employ the substituted judgment standard of consent, similar again to this case study.

In light of this confusing landscape, the Presidential Commission for the Study of Bioethical Issues has called for clear legal standards regarding surrogate consent (Presidential Commission for the Study of Bioethical Issues 2015). In their absence, we can never have consistent answers to substantive questions such as who is qualified to give consent and whether consent should be restricted to research related to the health and well-being of cognitively impaired adults.

The most critical step toward greater consistency is making settled policy for clinical decision making settled policy for research as well: require the substituted judgment legal standard of surrogate decision making for research with cognitively impaired adults. This is the approach reflected in this case study: the protocol instructs the surrogate decision maker who has durable power of

attorney (DPA) to consider the subject's "preferences and values".

Two major implications would flow from this. First, research candidates without suitable surrogates could not participate in any non-therapeutic research, because nobody would be qualified to make substituted judgments on their behalf. Second, surrogates would have to be given appropriate guidance on how they exercise their discretion in making decisions for research candidates, regardless of the level of risk and potential for therapeutic benefit.

The literature is significantly divided on this guidance point. One school of thought severely restricts surrogates' discretion. It argues that substituted judgments that do not come close to matching actual prior decisions or previously expressed sentiments are invalid (Berg 1996; Beauchamp and Childress 1994). The problem with this approach is that it assumes that there is a prior research candidate decision or considered view about research participation that surrogates can accurately approximate, an assumption likely borne out in reality much less frequently than we would care to admit (Yarborough 2005). Following this school of thought, then, we would have to exclude surrogates who lacked information about the research candidates that closely approximates prior participation views. This would drastically restrict research.

An alternative approach more in line with the protocol in this case study grants substantially more discretion to surrogates by stressing *characteristic* rather than *accurate* decisions. Just because there is no prior research decision that a surrogate can accurately match, it does not follow that surrogates cannot make respectful decisions for candidates. According to this approach, surrogates

construct, rather than match, decisions by using not just their prior knowledge of the values and preferences of research candidates, like the protocol in question does, but also their familiarity with the life narratives of candidates. This "constructed judgment" implementation method of substituted judgments better assures a respectful denouement of research candidates' lives during their time of dependency on others (Yarborough 2005).

Concern for respect leads directly to the question posed in this case study about evaluating the c*apac*ity of research candidates to appoint an agent with DPA if they do not have one. If we truly want to treat research candidates with the full measure of respect they are due, then this should be done. If we assume that people's life narratives often contain sufficient information to responsibly guide surrogate decisions, then it behooves us to work with individuals to identify their most appropriate surrogates. Determining whether or not a research candidate has the capacity to identify such a person extends this added demonstration of respect.

This more expansive interpretation of respectful treatment diverges from the Belmont Report, which restricts respectful treatment of people with diminished capacity to protection from harm (U.S. Department of Health and Human Services 1979). Hence, IRBs and investigators might be reluctant to move in this direction. This could prove unfortunate; adults with impaired decision making deserve more from us than simple protection. They deserve recognition for the individual people they are and the lives they are continuing to lead.

Making good faith efforts to consider what role research participation should play in those lives affords them that recognition.

It is disheartening that after decades of deliberation we have yet to reach consensus that surrogate research decision making for cognitively impaired adults should more closely parallel clinical decision making. This would guarantee that IRBs would defer to the substituted judgment standard of informed consent. Further consensus about how that standard is best implemented could yield important benefits. Agreement around the constructed judgment or some similar implementation method would mean that surrogate familiarity with the life narratives of research candidates is the most salient ethical consideration in research, not the degree of risk or the nature of the health condition being studied. Requiring investigators to seek out the most qualified surrogates would maximize the chances that respectful research decisions are made. This, in turn, likely would result in surrogate decisions that would permit more and varied research with this population of research candidates. Such judgments would be implicit in research candidates' life narratives, reflected by the fact that so many are motivated throughout their lives by the welfare and needs of others and not just themselves. There is no reason that diminished decisional capacity must rob people of their ability to continue such a legacy.

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