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Informed Consent and Assent Decisions by Persons with Dementia and their Legally Designated Representatives

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Goal. To evaluate the appropriateness of the permission for research on cognitively impaired elders in which their care giver (CG) gives the permission. This approach may not be in the best interests of either the person with dementia (PWD) or the CG, and may overlook crucial dimensions of the consent process and of respect for the cognitively impaired. The proposed research directly questions the time-honored, but probably inadequate approach, and promises to offer useful insight into ways of improving this consent process.

The purpose of this study is to evaluate, in vulnerable potential research subjects with dementia and their caregivers: (1) level of understanding of what research participation involves and (2) willingness or reluctance to participate and (3) reason for wanting to participate or not participate. The study proposes to ask persons with early and mid-stage dementia (PWD) and their designated legal representative caregivers (CG) to evaluate a series of proposed study scenarios used as exemplar study protocols and consent forms (controlled trial of a new drug; memory improvement study; behavioral management of symptoms study). This study will provide insights into the meaning of research participation for PWD and CG, dyads who eventually would be involved in real "proxy" decision-making situations.

The PWD will undergo brief mental status testing to determine level of cognitive impairment. PWD with MMSE 16-24/30 will be eligible. PWD and CG participants will be asked to read the same exemplar protocols (in separate rooms) and then answer a series of questions posed by the investigators to determine their level of understanding of the protocol and the elements of informed consent, their sense of the decision they would make, and the rationale for their choice.

Scientific & ethical justification. One of the most vexing questions facing PWD and their CG following diagnosis is whether or not to participate in the smorgasbord of studies investigating dementia etiology and treatment. Many of these studies offer little of no direct benefit to PWD, yet have great potential benefit to future sufferers of the disease. Currently PWD participate in many studies where their legal representatives, frequently their CG, make the participation decision on their behalf because the PWD is considered to have diminished capacity to understand both the research study and the informed consent process. Yet few studies have been reported where investigators attempted to get at what PWD and CG understand about studies, what decision-making strategies they use to decide on participation versus non-participation and why they make the choices they do. This is particularly important because PWD have insights into their declining memory and problem-solving abilities early in the disease process and may be cut out of decision-making earlier than is necessary or involved to inappropriate extents depending on CG knowledge and understanding of their wishes.

Differences may be found in the responses of PWD and CG in relation to willingness to have the PWD participate in research. This has important implications for our understanding of how the risk of developing cognitive impairment needs to be assessed by PWD as they age, so that methods of protecting decision-making capacity around research participation are both available to PWD and honored by legally designated representatives. The study uses exemplar protocols that do not expose the participants to the risks inherent in committing to be part of a 'real' study, yet allow an important discourse about cognitive vulnerability and 'proxy' consent, essential if the scientific community is to embrace notions of personhood enshrined in the Belmont principles.

Objections or barriers. Most recent published studies involving PWDs report informed consent by the legally designated representative rather than by the PWD, even for studies involving high functioning PWDs with minimal impairment. In the author's experience, IRBs err on the side of caution in considering whether a PWD is capable of meaningful informed consent and make a determination that all participants be consented using a 'proxy' mechanism. Practically this translates into many PWDs never being asked their opinion about the research and their participation in it. Indeed the PWD may not even be present at the time of informed consent. While in many situations this may be highly appropriate because the PWD is moderately to severely impaired, for PWDs who are minimally impaired it may be an issue in several important respects: (1) The extent to which the PWDs are aware of their medical diagnosis is sometimes unclear. (2) The PWDs may never have discussed their wishes regarding research participation with their CG. (3) The PWD may have different responses to participation in the proposed study than their CG. From the extensive research literature on CG coping strategies it is clear that protection of the dignity and personhood of the PWD is important to CGs and may impact the PWD's needs for self-expression. (4) Over the course of a study, particularly longitudinal studies, the cognitive ability of the PWD may decline significantly such that their level of capacity to consent and assent diminishes.

In this study, the IRB may: (a) Be conflicted about what type of informed consent is appropriate for participation

of PWD in this study. (b) Find it an issue that PWDs are being asked about their ability to make decisions. This may be seen as too threatening or potentially emotionally upsetting for PWDs since they are dealing with a degenerative, incurable illness that impacts memory and judgment and the proposed research focuses on this area of cognitive vulnerability. (c) Question the use of exemplar protocols instead of asking PWDs enrolled in current protocols about their informed consent experience. (d) Be concerned about the method of recruitment. One could readily find PWDs and CGs who are already enrolled in studies and recruit that way. To find PWDs with early dementia advertisements in clinics, via the Alzheimer's Association, by public advertisement and by 'snowball sampling' will be necessary.

Suggested Empirical Approaches:

1. What is the decision-making capacity of PWDs, relevant to deciding whether to participate in research, in various stages of the disease process?
2. What is the level of understanding of PWDs, at different levels of cognitive impairment, of the elements of informed consent in various protocols?
3. What differences, if any, exist in the PWDs' understanding and involvement in the consent process, and in their willingness to become a participant in different types of research, compared to that of the CG?