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## **Respecting Vulnerability: Informed Consent in Persons with Alzheimer's Disease**

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### **Abstract**

Researchers and Institutional Review Boards struggle with the problem of how to protect vulnerable populations, such as persons with Alzheimer's disease, when participating in research. It is essential to balance this protection with the need to assure that these vulnerable individuals have opportunities to participate in research. There has been little written in the nursing and medical literature about ethical concerns to consider in obtaining informed consent for research with persons with Alzheimer's disease. This paper presents background information on obtaining informed consent in persons with Alzheimer's and provides practical guidelines for implementation of protocols to help ensure both autonomy and protection of vulnerable populations in the informed consent process.

**Keywords:** informed consent, vulnerable populations, Alzheimer's disease

## **Respecting Vulnerability: Informed Consent in Persons with Alzheimer's Disease**

### **Introduction**

There are approximately 5.3 million Americans with Alzheimer's disease; this number has more than doubled since 1980 and is expected to increase to somewhere between 11 and 16 million by 2050.<sup>1</sup> With the rapidly increasing world-wide prevalence of Alzheimer's disease, there is increased recognition of the need to include people with dementia in research studies.<sup>2</sup> Although it is clear that informed consent is a necessary prerequisite to research participation, it is less clear how to proceed when potential research participants may lack the capacity to provide this informed consent.<sup>2</sup> It is important not to assume that all individuals with a diagnosis of Alzheimer's disease are incompetent and unable to participate in decision-making for informed consent.<sup>1</sup> In view of the prevalence of Alzheimer's disease and the vulnerability of these individuals, the ethics of obtaining informed consent for persons with Alzheimer's is a critical issue for researchers to consider. This paper focuses on approaches to obtaining informed consent that would facilitate carrying out research in this vulnerable population.

## Background

Individuals with dementia present a specific challenge to researchers. Despite many years of regulatory controls to protect the vulnerable, the definition of this term remains unclear.<sup>3,4</sup> Current definitions range from the comprehensive expression of humanity, in which respect for the balance between the endeavor for immortality and the finite nature of human suffering is stressed, to a more circumscribed definition that focuses on the potential of exploitation and the ability of individuals to give informed consent.<sup>5,6</sup> As Hurst<sup>3</sup> suggests, this lack of clarity in definition presents serious problems, in that without a clear definition, one cannot know who should receive protection for vulnerability and what form this protection should take.

Some researchers have begun to address this issue. Studies suggest that it is important to focus not only on cognitive aspects of participation of persons with dementia in research, but also emotional and social dimensions.<sup>7</sup> One study focused on determining how individuals with dementia could be included in research by abiding by their responses to either agree or object to participation.<sup>2</sup> Informed consent was obtained from responsible parties for each of the 185 people with middle to late stage dementia who were recruited for this study. Responsible party was defined as the legal guardian, the agent named in a personal directive, or the family member in closest contact with the person with dementia. However, despite the informed consent, if the individual with cognitive impairment did not provide credible assent, they were not included in the study. Detailed and practical guidelines for inclusion of this vulnerable population in research were outlined with suggestions for further discourse recommended.

Other studies have focused on approaches for helping persons with dementia to understand information in the informed consent. Dewing<sup>8</sup> reported on a method that focuses on consent as a process that runs through the whole of a research project, not just the beginning. This method relies on the skill of the researcher to

engage with persons with dementia and to continually reflect on the questions: “Is this person consenting?”, “Does this person have informed appreciation of their consent?”, and “Is any lack of objection genuine?” In order to proceed with research, the researcher should assure that the first question is answered affirmatively. Depending on the effects of dementia on the participant, it may be difficult to affirmatively answer the latter questions, but they should lead the researcher to reflect critically and continually on the participative process.

In order for researchers to identify effective approaches for obtaining informed consent in persons with dementia, it is important to challenge the dominant rational approach to ethical decision-making in this population.<sup>9</sup> If health care professionals view the rational understanding of autonomy as being the capacity to exercise freedom of choice, they may feel justified in resorting to a proxy for making decisions on behalf of the person with dementia. McCormack<sup>9</sup> argues that this approach reinforces the mind-body dualism that dominates health and social care discourse. While in many cases, proxy decision-making may be appropriate, evolving research suggests that it is important to look at social and emotional aspects of the situation and to hear the voice of the person with dementia through a ‘narrative identity’ that can be developed and used to underpin informed consent decisions.<sup>9,10</sup> This narrative identity in the informed consent process acknowledges not only cognition, but also feelings, individual actions in relation to one another, and the relationship between persons interacting in the research.<sup>9</sup> Paying attention to an individual’s narrative identity provides a way of respecting the autonomy of the individual with dementia in a way that is consistent with their overall life plan.<sup>9</sup>

### **Guidelines for obtaining informed consent in persons with dementia**

Despite increasing awareness of the need to include persons with Alzheimer’s disease and other dementias in research, researchers may encounter barriers in the need to satisfy the demands of research ethics committees.<sup>7</sup> Ethics committees have a large amount of control in the exclusion and inclusion of research participants and older persons with dementia may be excluded from being involved in research as active participants if ethics committees believe it is too difficult to ensure informed consent or assent.<sup>7</sup> Perhaps researchers have accepted too readily the traditional approach to informed consent that relies on cognitive ability and too slow to explore viable alternative methods.<sup>7</sup>

The authors experienced this dilemma in the process of submitting a research proposal to a university Institutional Review Board (IRB) for approval of a study to carry out research related to ethical concerns in persons living with Alzheimer’s. The research protocol called for persons with early-stage Alzheimer’s to sign an informed consent in order to be interviewed for the study. The IRB initially denied approval of the study due to the need to protect this vulnerable population who might not understand what they were consenting to do. The IRB recommended use of assessment instruments such as the Mini

Mental State Examination (MMSE) and the MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR) to assure competency to consent to participation in the study. The authors, however, had already decided that use of these assessment tools was not likely to yield sufficient capacity-to-consent information and could create unnecessary stress for prospective participants.<sup>11</sup> As a result of this decision by the IRB, the authors reviewed the literature to identify approaches to obtaining informed consent that would facilitate carrying out research in this vulnerable population.

Two documents were identified that provide valuable guidelines for obtaining informed consent in persons with Alzheimer's: "Informed consent in people with Alzheimer's disease,"<sup>11</sup> prepared by Catherine Cole for the American Nurses Association (ANA) Center of Ethics and "Research consent for cognitively impaired adults: Recommendations for Institutional Review Boards and investigators,"<sup>12</sup> a consensus statement by the Alzheimer's Association.

The "Research consent for cognitively impaired adults: Recommendations for Institutional Review Boards and investigators"<sup>12</sup> document provides specific suggestions that can guide researchers and IRBs in operationalizing the informed consent process for persons with cognitive impairment. The "Informed consent in people with Alzheimer's disease" document outlines important considerations for nurses planning to carry out research involving persons with Alzheimer's.<sup>11</sup> It notes that although "competency is ultimately a legal question, the realities of clinical practice cause nurses and other health professionals to make competency judgments on a daily basis. In particular, professionals continually face the question of whether a person with Alzheimer's disease is competent to refuse or consent to nursing intervention and research."<sup>11p1</sup> The document also notes that researchers face the ethical dilemma of determining when the person with Alzheimer's disease is still competent to participate in the informed consent process. Thus, if incompetence is assumed and the wishes of a cognitively impaired older adult are not given due respect, the risk is that researchers will infringe on individual autonomy.

As a result of consulting these two documents and related literature, the authors revised the protocol for their proposed study, integrating theoretical perspectives from the work of Dewing<sup>8</sup> and McCormack.<sup>9</sup> The revised protocol stated that in order for persons with Alzheimer's to participate in the study, the researchers would affirm that the participant: understands the nature of the research and his/her participation; appreciates the consequences of his/her participation; shows the ability to consider alternatives, including the option not to participate in the study; and shows the ability to make a reasoned choice. Due to the judgment of minimal risk for participants in the study and the effort to provide as much individual autonomy as possible, specific revisions in the research protocol were designed to enhance the informed consent process and improve understanding of the consent materials. The following points were addressed:

1. The co-investigators or Graduate Research Assistants who have received training in the interview process will personally obtain the informed consent, collect the signed documents, and give a copy of each consent document to the participant.
2. The prospective participant will be asked to read the informed consent and then asked whether he or she has questions about what has been read. The researchers will answer all questions and follow up by repeating important information from the informed consent document and asking the prospective participant several questions to assure understanding, e.g. "Do you understand that you do not need to participate?" The researchers will allow extra time for casual interactions with the prospective participant to avoid rushing the process and to compensate for slowed processing time.
3. Persons who verbally assent and whose responses indicate that they understand the informed consent materials will be asked to sign the informed consent. If the person dissents, no further requests to participate will be made.
4. If the person agrees to participate and there is any doubt as to the person's understanding of what the participation involves, an adult family member will be asked to also sign the informed consent.
5. During the interview process, the researchers will provide frequent opportunities for the participant to ask questions related to the process and will observe the participant for any unusual stress that might signify confusion about what participating in the study involves.

With the revised protocol, the authors received approval from the university IRB to conduct the study. The study has been completed and the authors believe that the informed consent guidelines were effective in assuring opportunities for personal autonomy, as well as protection of this vulnerable population. Participants were able to give voice to their narrative identity, articulating their experiences of living with Alzheimer's and expressing appreciation for the opportunity to "tell their story." Their stories contained poignant insights to help health care professionals understand ethical concerns of persons living with Alzheimer's.<sup>10</sup>

## Conclusions

With the number of elderly people projected to increase across the globe, issues related to the vulnerability of the elderly and especially those with dementia will also increase. To assume that individuals with dementia are not able to participate in research not only denies them the chance to make a contribution to research, but also deprives future generations of any benefits gained from the research.<sup>13,14</sup> Research suggests that while personal expression may be compromised in individuals with dementia, they can relate important information about the quality of life they are experiencing.<sup>10,15</sup> As Slaughter, Cole, Jennings,

and Reimer emphatically state, "It is morally unacceptable *not* to do research with vulnerable populations."<sup>2p28</sup>

The dilemma of how to incorporate these vulnerable individuals into research, yet protect them, remains a serious subject of debate. In an effort to protect vulnerable populations in research, international regulations have been developed and are under constant revision. Public outcry, ethical debate, and legislation abound whenever abuse of vulnerable populations is suspected and/or confirmed. Romanchuk<sup>4</sup> acknowledges that controversy exists over which populations and individuals are considered truly vulnerable, but emphasizes that despite this debate, researchers must strive to translate the ethical concepts and regulatory guidelines into practical application.

It is interesting that in the study described above, persons with early-stage Alzheimer's who participated in the study were carrying out daily activities, such as driving, that required considerable judgment. Yet, it is easy to assume that a diagnosis of Alzheimer's precludes rational decision making. It is critical that researchers protect vulnerable populations such as persons with cognitive impairment. It is also critical, however, not to assume that a diagnosis of Alzheimer's means that a person no longer has the capacity to provide an informed consent to participate in research. Both researchers and IRBs need to continue to educate themselves on optimal approaches to obtaining informed consent for all persons who are members of vulnerable populations and to critically question and actively discover methods of including the voices of persons with dementia in research.

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