JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 13, No. 4, April 2017 "Happy Trials to You"

Clinical Research Ethics Question of the Month: Intermittent Capacity to Consent

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The following situation has been presented:

> As a member of an institutional review board, you are reviewing a cardiology study in a geriatric population. Your IRB will approve the study even though it will create a moderate level of risk for participants. The investigator wants to enroll **residents** in a nursing home, part of the intended treatment population for the drug. Certain residents **in** the nursing home meet the study's eligibility criteria in all respects. The only catch is that some of them have intermittent cognitive capacities. In other words, at some times, they are competent to give informed consent, but, at other times, they are not. You have no other information to make your decision and no clever way to dodge it.

Results

Eighty-two percent of 219 respondents say that nursing home residents with intermittent cognitive capacity have the right to participate in the study.

However, only forty percent of respondents would approve enrolling nursing home residents with intermittent cognitive capacity in the study. Thirty-six percent would not give this approval. Twenty-four percent have a different answer. The most common different answer is that a legally authorized representative (LAR), family member, or witness should (co)sign the consent form or be present. Some respondents would consider the study's level of risk. Some respondents would want to know that continuing consent during the study would be handled appropriately.

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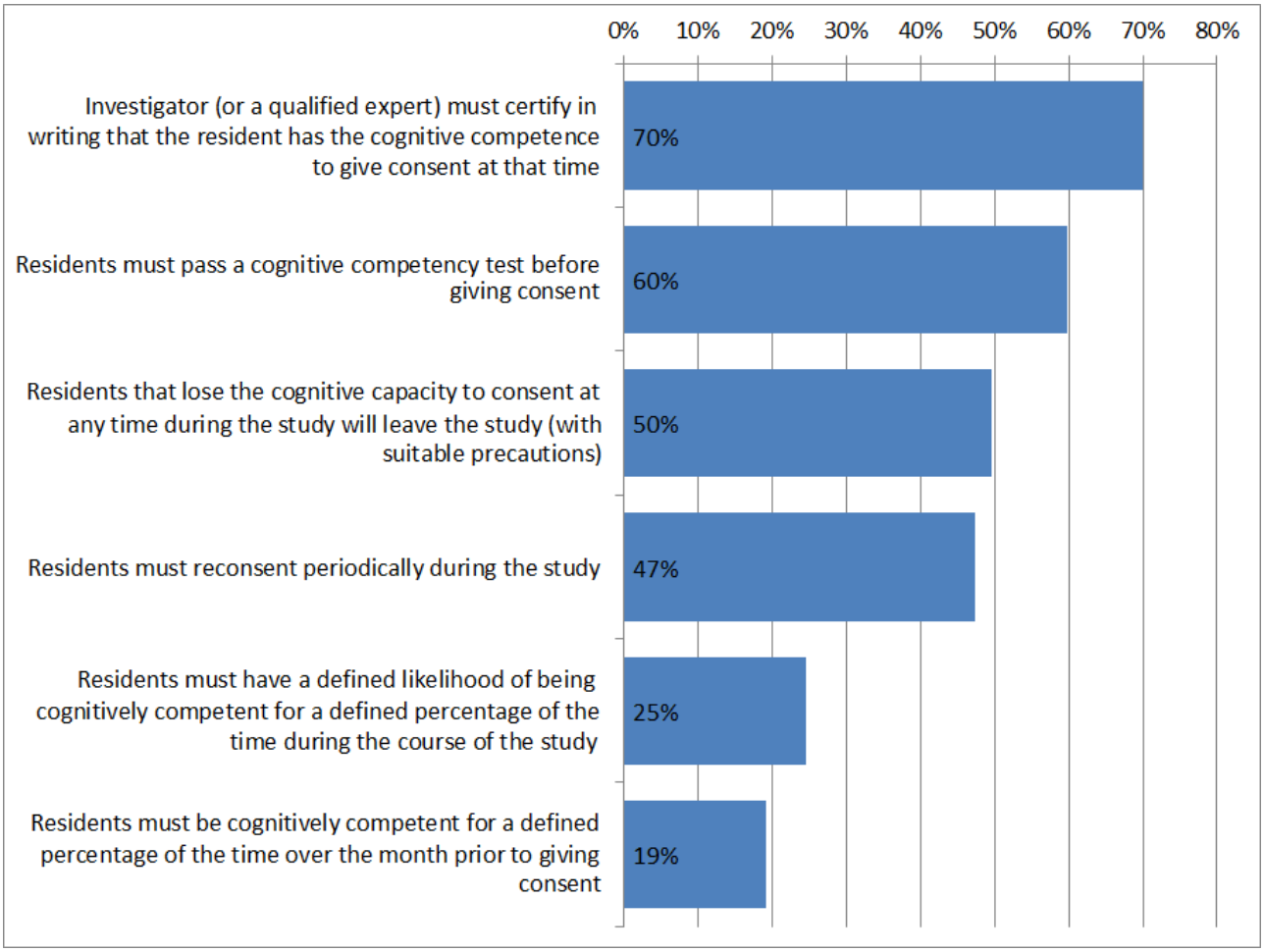
Seventy-six percent of respondents would place additional requirements on the study. Of these respondents, 70% would require the investigator or a qualified expert to certify in writing that the resident has the cognitive capacity to give consent at the time. Sixty percent would require the resident to pass a cognitive capacity test before giving consent. Fifty percent would terminate participation if the resident loses the capacity to consent at any time during the study. Forty-seven percent would require periodic reconsent during the study.



Nineteen percent of respondents say residents must have been cognitively competent for a defined percentage of the time over the month *prior* to giving consent. Of these respondents, 30% say residents must have been cognitively competent 100% of the time, 50% say they must have been cognitively competent 80% of the time, 13% say they must have been competent 50% of the time, and 0% say they must have been cognitively competent 20% of the time

Twenty-five percent of respondents say residents must have the likelihood of being cognitively competent for a defined percentage of the time *during* the course of the study. Of these respondents, 31% say residents must have the likelihood of being cognitively competent 100% of the time during the course of the study, 50% say the likelihood must be 80% of the time, 13% say it must be 50% of the time, and 2% say it must be 20% of them time.

Discussion

Eighty-two percent of respondents say that nursing home residents with intermittent cognitive capacity have the right to participate in the study. However, only 64% would approve their participation.

A significant number of respondents see LARs as the solution to this dilemma. FDA draft guidance recommends the use of an LAR when the cognitive capacity of a (potential) participant *fluctuates*, i.e. can vary over time. However, the guidance does not explicitly address the situation when a participant is *fully* competent to give consent *part* of the time. It is not clear what role an LAR would play when a nursing home resident is fully competent to give consent. Note that most or all people are not fully competent to give consent 100% of the time, e.g., when they are very tired and facing a 30-page consent form written at a grade-14 reading level.

FDA's "Guidance – Informed Consent Information Sheet" (2014 draft) states:

> Impaired consent capacity may involve partial impairment, impairment that fluctuates over time, or complete impairment… Enrollment of subjects with partial impairment may require modifications to the consent form and process to enable those subjects to consent on their own behalf. When a subject's consent capacity is sufficiently impaired that the subject is unable to provide legally effective informed consent, the subject may not be enrolled unless the subject's legally authorized representative consents on the subject's behalf. (21 CFR 50.3(l) and 50.20.)

According to this draft guidance, an LAR should get involved when "a subject's consent capacity is sufficiently impaired that the subject is unable to provide legally effective informed consent." Clearly, this is not the case when a nursing home resident is fully competent to give consent. The draft guidance offers another option: "Enrollment of subjects with partial impairment may require modifications to the consent form and *process* to enable those subjects to consent on their own behalf." One possible change to the consent process would be to wait until the nursing home resident is fully competent to give consent. The consent form could be written to be very understandable, to ensure that the resident's cognitive capacity is not overtaxed. The person obtaining consent could take similar precautions during the consent discussion.

Study participants must also have the ability to *withdraw* consent. Eighty-one percent of respondents say that enrollees must be competent to withdraw consent 80-100% of the time. If a nursing home resident enrolls in a study and something occurs that could justify withdrawal, a lack of cognition would interfere with his or her ability to withdraw. This problem could be addressed in various ways: For example, an LAR could act on the resident's behalf at that time. Or, the protocol could require frequent reconsents. If the study allows, study treatments and procedures could be deferred until the resident regains the capacity to reconsent.

Next Month's Question:

You are the Commissioner of the FDA. A friend has informed you of the following situation: Over 1,000 people with severe, refractive emphysema have banded together to test a drug that is approved for asthma but not emphysema. Some of them are currently taking the drug off-label and believe it is helpful. The manufacturer of the drug has refused to conduct a study or permit any other company to conduct a study. One of the patients, a statistician, will analyze self-reported data in this open-label "study." Participants "drew straws" to determine which of them would ask their physicians for a prescription. The group plans to publish the results of the study. While the FDA has no authority over the practice of medicine, it does have authority over clinical studies that create generalizable knowledge…

Read the full question and give us *your* answer at:
https://www.surveymonkey.com/r/26ZPZ8K.

Please send your ethical conundrums to ngoldfarb@firstclinical.com.

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