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Cognitively-impaired human research subjects need better protection

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(Garrison, NY) Practices for protecting human research subjects with Alzheimer's disease and other conditions that make them incapable of giving informed consent are widely variable and in need of more concrete ethical and legal guidance, according to a study in IRB: Ethics & Human Research.

The findings are significant for several reasons. First of all, the authors write, many countries have made research on dementia a national health priority and launched clinical trials that involve people who are, or are likely to become, cognitively impaired. These trials increasingly involve invasive interventions which may pose more than minimal risk. And yet throughout the world, regulations and guidelines provide little direction to ethics review committees about how best to protect these people – and about who can make decisions on their behalf.

The new study, part of a larger Canadian research program called Substitute Consent for Research in Elderly Subjects (SCORES), involved telephone interviews with 46 research ethics board chairs in Canada, assessing their attitudes toward enrolling in clinical trials older adults without decision-making capacity and asking what safeguards they would require. Twenty respondents said they had reviewed research protocols involving such persons during the past year and all allowed them to participate in research under certain conditions, such as minimal risks or consent from a substitute decision-maker.

More than half of the ethics board chairs said that they required

additional protections for this population, such as assessing decisional capacity. "Yet the fact that some REBs [research ethics boards] did not require these additional safeguards is cause for concern," wrote the researchers. Four allowed older adults without decision-making capacity to participate in minimal risk studies that could benefit them personally, even when there was no one legally authorized to provide substitute consent. The authors raised concerns about this practice, though they acknowledged that the legal requirement regarding substitute consent for research is unclear in the provinces where those REBs are located.

Given the variability in research protections for older adults with cognitive impairment, the researchers "recommend that policy-makers and stakeholders consider developing appropriate protective measures for this population."

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