Online Ethics Center
FOR ENGINEERING AND SCIENCE

The Ethics Of Research With Subjects Who Have Dementia (Bibliography)

Year

2000

Description

An annotated bibliography of resources on the ethics of research with dementia patients.

Body

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Annotated Bibliography

High, D. M., Whitehouse, P. J., Post, S. G., Berg, L.

"Guidelines for Addressing Ethical and Legal Issues in Alzheimer Disease Research: A Position Paper." *Alzheimer Disease and Associated Disorders* (1994) 8 (Suppl. 4): 66-74. This article summarizes a survey of Alzheimer's Disease research centers as interpreted in a consensus conference convened with support from the National Institute of Aging. It discusses six basic recommendations:

1. Recruitment, selection, and enrollment of persons with AD in research should be inclusive and equitably distributed with regard to ethnicity and gender.

2. Each research protocol should specify the means for determining a subject's capacity to consent and recognize that a diagnosis of AD and cognitive test results are relevant to, but not determinative of, incapacity for informed consent.
3. Researchers should follow practices of seeking informed consent from each prospective competent subject and seeking consent from family surrogates together with assent from each incompetent subject. A presumption in favor of family members to serve as surrogates for AD research subjects should be observed.
4. Understanding communicative difficulties encountered by persons with AD is essential to conducting sound AD research. Researchers should make every effort to engage AD subjects and their families in dialogue.
5. Research Centers, IRB's, and individual researchers should ensure that no evident or substantial conflict of interest will be likely in circumstances when a patient, receiving clinical care, is also recruited to participate in clinical trials or other research protocols.
6. In all research, investigators should strive to minimize the risks and potential harms to participants and maximize benefits. Research that involves potential risks but no direct benefits to the subject may be justified if the anticipated knowledge sought is deemed of vital importance for alleviating the disease in the future.

Because no consensus currently exists regarding acceptable degrees of risk for persons who are cognitively impaired, further national studies should be undertaken.

Cahill, M., Wichman, A.

"Research Involving Persons with Cognitive Impairments: Results of a Survey of Alzheimer Disease Research Centers in the United States." *Alzheimer Disease and Associated Disorders* (2000) 14(1): 20-27. These authors asked directors of 29 U.S. Alzheimer Disease research centers the funded by the National Institute on Aging to provide policies or guidelines used in their research with cognitively impaired subjects. Twenty-four centers responded, five of which had authored their own policies, seven of which used guidelines issued by the Department of Health and Human Services for Protection of Research Risks, and twelve (50%) of which had no policy or guidelines. The authors argue that the lack of policies reflects a lack of seriousness about the rights of subjects.

Of the five research centers that had their own written policies, all provided guidance on the selection of a surrogate decision maker. In each policy, a court-appointed guardian, if one exists, holds decisional authority. Next is a person indicated by the subject's durable power of attorney for health care, if such a document exists. Next, these centers use the next-of-kin hierarchy as set forth in their state's statute for health care decisions.

Four of these five centers indicate that a subject's dissent or unwillingness to participate in research must be honored. These centers allow carefully justified research with greater levels of risk when it holds potential benefit for the subject. If research does not hold potential benfits to subjects, it can still be conducted by surrogate consent as long as various protections are in place. This is in contrast to the Alzheimer's Association statement, which indicates a need for prior consent from the subject while competent, including the possibility of a research advance directive, for research that is not likely to benefit the subject and that goes beyond minimal risk.

From Research Ethics Module Supporting Pages

Notes

Caroline Whitbeck introduced methods and modules for discussing numerous issues in responsible conduct of research at a Sigma Xi Forum in 2000. Partial funding for the development of this material came from an NIH grant. Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional societyâ€™s code that is referred to in an item. If you have suggestions for updates, please contact the OEC.

Contributor(s)

Caroline Whitbeck

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Resource Type

Bibliography

Parent Collection

Scenarios for Ethics Modules in the Responsible Conduct of Research

Topics

Human Subjects Research

Discipline(s)

Life and Environmental Sciences