

## *Participation in Research*

### **BACKGROUND**

Scientists around the world are working to find the causes, better treatments and, ultimately, a cure for Alzheimer's and related diseases. Researchers are also trying to better understand the psychological and social effects of the disease on people with the disease and their families. Many people with Alzheimer's disease are participating in this research. They and their families take comfort and find hope in being able to help increase our understanding of the disease and its effects.



## THE ISSUES

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### *For people with Alzheimer's disease:*

*Ability to make informed decisions:* As cognitive abilities such as memory, language, reasoning and judgment decline, people with Alzheimer's disease become less able to understand the consequences of their involvement in research. This affects their ability to continue to make informed decisions. There is concern that people with the disease not be subjected to undue risk or exploitation.

### *For family members and caregivers:*

*Conflicting needs:* The participation of people with Alzheimer's disease in research often places demands on families. There is also a potential for conflict between the wishes of the person with the disease and the wishes of family members.

*Substitute decision-making:* When a person is unable to understand the consequences of participation in research, the decision to participate in research, in some provinces, rests with the person named as substitute decision-maker (usually a family member). If the person with Alzheimer's disease does not have previously-stated wishes regarding participation in research, it may be difficult for the substitute decision-maker to weigh the risks and benefits of research participation for that person.

### *For researchers:*

*Ensuring informed decision-making:* Researchers should ensure that research participants, including those with cognitive problems, fully understand and appreciate the consequences of their participation throughout the course of the study. When a person is no longer able to make informed decisions, the researcher should ensure that the substitute decision-maker makes choices that respect that person's wishes.

*Keeping care and research separate:* The dividing line between the provision of care for the person with Alzheimer's disease and the health-care

professional's commitment to research is sometimes unclear. There may also be a potential for conflict of interest when researchers in drug trials accept funding from the pharmaceutical industry.

*Using placebos in drug trials:* To determine if a new drug is safe and effective for use, research studies will compare a group of people taking the experimental drug with a group taking a placebo (a pill that may look like the new drug but has no medical effect). This means a person participating in a drug study could receive a placebo and not have access to existing medications.

The availability of medications to treat Alzheimer's disease symptoms has triggered a debate about the appropriateness of continuing to use placebos in studies of new drugs for Alzheimer's disease.

The use of placebos in drug trials is the subject of a current national initiative. The guidelines that emerge from this initiative will likely influence future drug research in Canada.

## THE PRINCIPLES THAT GUIDE RESEARCH ON ALZHEIMER'S DISEASE IN CANADA

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*The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* governs research conducted by universities and university-affiliated hospitals involving human subjects in Canada. This policy statement was created by the three federal government research organizations that fund research involving human subjects in Canada. It sets out standards and procedures for conducting safe and ethical research and describes the consent process. Each study must be reviewed and approved, in advance, by an ethics review board or committee. This body is also responsible for monitoring the research process to ensure that it follows the *Tri-Council Policy Statement's* requirements.

These requirements include obtaining and maintaining informed consent for all research.

At present, *research involving human subjects in Canada conducted outside a university or university-affiliated hospital is not necessarily governed by the Tri-Council Policy Statement* and may be reviewed according to different standards. An example of this would be research on a new drug sponsored by a drug manufacturer and conducted in the private offices of family doctors. Such studies must meet certain ethical standards and undergo review. However, they do not necessarily meet all of the standards described in the *Tri-Council Policy Statement*.

When considering participation in research, it is appropriate to ask:

- Who is the sponsor of the study?
- Who conducted the ethical review of the study?
- Was the ethical review conducted according to the *Tri-Council Policy Statement*?

## PREFERRED CHOICE

There are certain principles that should be followed when people with Alzheimer's disease participate in research:

### *Respect for the person's wishes*

The wishes of the person with Alzheimer's disease should be the guide when considering participation in research. The assessment of the person's ability to provide informed consent should focus on the individual's ability to understand the nature of the research, appreciate the consequences of participation in the study and understand alternative choices. The person's ability to make an informed decision will be affected by the progression of the disease. From time to time, throughout the assessment, the person's agreement to participate must be re-confirmed.

## SOME FACTORS TO CONSIDER

### *Role of the substitute decision-maker*

When the person with Alzheimer's disease becomes unable to provide informed consent, consent must be requested or sought from a substitute decision-maker. The substitute decision-maker may be appointed by the person or by the courts. Laws about substitute decision-making and participation in research vary from province to province.

The wishes of the person with Alzheimer's disease and those of the substitute decision-maker may differ. The research team has an obligation to determine, to the best of its abilities, that the decision about participation in research has been guided by the wishes of the person with the disease. When that cannot be determined, the decision should be made with the person's best interests in mind.

### *Balancing the risks and benefits*

Balancing the risks and benefits of Alzheimer research is difficult for all concerned. Levels of risk vary among studies. Also, everyone has their own perception of risk. Because of the frequent involvement of family caregivers in Alzheimer research, analysis of the risks and benefits should consider the effects of the research on not only the participant but also the family members.



Local ethics boards or committees have the task of evaluating the risks and benefits of studies and take this into account when deciding if a study can be approved. Information about risks and benefits is then passed on to the person and/or the substitute decision-maker through the informed consent process.

Throughout the course of the research, everyone involved should continue to evaluate the balance between the risks and benefits and re-confirm the commitment of individuals and families to continue participation in the research.

### *Separating medical care from research*

The dividing line between the health-care professional's management of a person's health care and the commitment to research must be clearly understood by everyone. Provision of the best medical care is the priority and must not conflict with participation in research.

### *Equitable participation*

All people with Alzheimer's disease, no matter where they may be in the disease process, should have the opportunity to participate in research. However, for safety reasons and for the scientific soundness of the study, each study will have its own objectives and specific criteria defining who can and cannot participate in the study. People have the right to decide to participate or not participate in a study. They also have the right to withdraw from a study, at any time, without the decision having a negative effect on their health care.

### *Ongoing communication*

It is essential that the research team maintain an ongoing dialogue with the person with Alzheimer's disease, family members and health-care professionals throughout the research process. The type and frequency of communication will vary, depending on the research study. Everyone involved should be given a summary of the outcome of the study when it is completed.

### *IN CLOSING...*

Advancing our knowledge of Alzheimer's disease and developing effective treatments requires an open dialogue among everyone involved in research to ensure that the interest of the person with Alzheimer's disease remains a priority at all times.

#### *RESOURCES:*

Contact your local Alzheimer Society for province-specific information on:

- Substitute decision-making for health care

*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Medical Research Council of Canada et al., October, 1999.

Also available at:

[www.nserc.ca/programs/ethics/english/policy.htm](http://www.nserc.ca/programs/ethics/english/policy.htm)

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# Alzheimer Society

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