

Participating in Research Studies: Where to Start

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Barely a week goes by without an item on the news or in the newspaper about research findings relevant to individuals with Alzheimer Disease. These findings are often exciting and promise a better understanding of what causes Alzheimer Disease and/or potential treatments (biological or psychosocial). These findings arise from research studies involving cells in a lab, animals or human subjects. Learning more about the research process will help you understand these findings and assist you in deciding whether you want to participate in a research study.

Research studies are a complex process governed by a number of rules and regulations. These determine how studies are planned, funded and carried out. When a researcher or team of researchers want to study some aspect of Alzheimer Disease they have several things to do before they can recruit participants. They usually have to write a grant proposal outlining what is known about the topic at hand, what they want to study, how they want to study it (for instance, which individuals with the disease are eligible for the study and what they will be asked to do) and how they will analyze and publicize their results.

The research group must apply for funding to cover the costs of their study. These costs may be covered by private industry (i.e. a drug company) or non-profit agency (government sponsored organization or non-profit agency such as the Alzheimer Society). The latter will have groups of scientists review the proposal and only approve those that are scientifically sound and are designed in accordance with ethical principles. All research groups must

also outline how they will deal humanely and respectfully with animals or human subjects in their study. To this end they have to send their proposal to a Research Ethics Board - a group of clinicians, lawyers, ethicists and lay people at a hospital, community agency or university who look over the proposal and ensure that it meets certain standards. These are outlined in Canada in the Tri-policy Statement on Ethical Conduct for Research Involving Humans. The ethical principles in this statement include: respect for human dignity; respect for free and informed consent; respect for vulnerable persons; respect for privacy and confidentiality; respect for inclusiveness; balancing harms and benefits; minimizing harm and maximizing benefit.

The principle of informed consent is of particular interest and importance. Participants in any research study have the right to make a free and fully informed decision before they agree to take part. This includes the right to withdraw from the study at any time. It also includes the right to know the risks and benefits involved in participating in the study. All individuals involved in a study will sign a consent form after being informed about the study. It should be written in laymen's terms that are easy to read and understandable. If the person is not able to understand the information or appreciate the potential risks and benefits someone will be asked to sign on their behalf (usually a substitute decision maker but this may differ from province to province).

Participating in a research project may be an exciting, fulfilling and rewarding experience. However, it also involves a commitment to work

collaboratively with the research team. The participant is a research partner who must make the commitment of time, energy and follow the instructions laid out by the researchers. The research team commits to treat the participants with respect and to monitor the results of the study. This includes halting the study or removing a participant if it is discovered that there are harmful outcomes from being in the study. Sometimes individuals feel they must participate in a study because of an obligation to the physician who asks them or because they do not know that they can say no. Being in a study is entirely voluntary and one's normal medical care will not be jeopardized in any way if one chooses to say no. So why would you consider participating in a research project? Usually participants cite the potential benefits to themselves or their families and the opportunity to increase their knowledge about their illness. They also describe the opportunity to advance science and help others with the illness. Being in a research project may provide a sense of purpose at a difficult time in one's life.

What should you consider before entering into a research study? Some have likened it to the process of finding a new family physician. You should learn about the research team including the scientists, clinicians and research assistants and coordinators.

References:

1. www.mcgill.ca/macdonald/research/human/guidelines/ (accessed 2004/04/06)
2. www.library.utoronto.ca/medicine/medUT/researchprinciplesOctober11th.pdf (accessed 2004/04/20)
3. www.cdc.gov/hiv/pubs/brochure/unc3bro.htm (accessed 2004/04/06)
4. www.pre.ethics.gc.ca/english/index.cfm (accessed 2004/04/20)

Here are some of the questions you should ask before agreeing to participate:

1. What are the goals of the research project?
2. What are the risks and benefits to participants?
3. Who has funded the research?
4. What Ethics Review Board has approved the project?
5. How will your privacy be protected during the study?
6. Will you have access to the same treatment after the study has finished?
7. How will the results of the study be publicized and disseminated?