Société Alzheimer Society

Checklist for Participating in Clinical Research

Clinical research uses human volunteers to study the effects of an exposure (for example, a drug or behavior) on a health outcome (for example, blood pressure, symptom relief or improved quality of life). The knowledge we gain through clinical research helps improve the ways we can prevent, diagnose and treat disease.

There are two main types of clinical studies you might be interested in being involved with:

- **Clinical trials:** these studies examine the effects of an experimental intervention, delivered as part of the trial. Interventions can include new drugs, devices or ways to receive health-care, as well as things like changes in behaviour, such as diet and exercise programs. People in the trial may be assigned to receive the intervention, or not, to compare health outcomes between the people in each group.
- **Observational studies:** participating in these studies involves interviews and/or tests. The key difference with clinical trials is that participants in observational studies are not assigned to receive an experimental intervention as part of the study.

There are potential risks and benefits to participating in any kind of research. It is important that you understand both before participating in a research study. The following questions are meant to help you make the best decision, for you and your family, about participating in research. We suggest that you use this sheet to take notes of the details of each clinical research study that interests you. Many of these questions will require a detailed conversation with someone working on the study.

Name of study: _____

Lead/Principal investigator: _____

Study coordinator

Name: _____

Telephone number: _____

Email address: _____

Address: _____

Date:

STUDY OBJECTIVES:

What is the purpose of the study?

Why is this study important?

ELIGIBILITY:

Who can participate in the study?

Who is excluded from the study (for example, people on certain medications or with certain existing health conditions)?

STUDY DESIGN:

What type of study is it?

☐ Clinical trial (I might receive an experimental intervention, like a new drug, device, way to receive health-care, or diet or exercise program)

☐ Observational study (I might have to undergo some extra interviews and/or tests, but I will not be given an experimental intervention)

CLINICAL TRIALS ONLY: Details of intervention(s) being studied

- What intervention(s) could I get while I am in the study, including in the comparison group?
  - Experimental:
  - Comparison:
- How has the experimental intervention(s) been tested in humans before, even for other medical conditions?
- How will it be decided whether I receive the experimental or comparison intervention?
- Will I be told if I am receiving the experimental or comparison intervention(s)?
- Will the study team know if I am receiving the experimental or comparison intervention(s)?
- If I benefit from the intervention(s), will I be able to continue to access them after the study ends?
- Was the trial reviewed and approved by Health Canada?

IF I CHOOSE TO PARTICIPATE:

Ongoing care during the study

May I continue to take my regular medication? (If no, this should first be discussed with your family and regular health-care provider)

Who will be responsible for my care during the study? (For example, my family doctor)

Will I be informed of any test results, including any abnormal results?

Will my regular doctor be informed of any test results, including abnormal results?

Who should I contact if there is a sudden change in my health while I am in the study?

Time commitment

How long will the study last?

How long will my involvement in the study last?

Is there any reason the study would be stopped early?

How often will I need to visit the hospital or study site?

How long will these visits last?

What sort of procedures, tests and assessments will I need to undergo and what do they involve (for example, answering questions about my health and life history, giving blood samples, being put under anaesthesia)?

- Survey:
- Laboratory:
- Imaging:
- Cognitive:
- Other:

Will I need to stay in hospital overnight?

Will I need someone to come with me for the study visits, like a friend or family member?

Financial commitment

Are there any costs associated with participating in the study?

Will the costs be reimbursed?

Is there any other compensation for participating in the study?

Leaving the study

What happens if I decide to leave the study early?

What happens if my memory or my overall health gets worse while I am in the study?

After the study is complete

What sort of long-term follow-up is available as part of the study?

When will the study results be published?

How will I learn about the results of the study?

RISKS AND BENEFITS:

What are the known risks?

What are the known benefits?

How will my safety be protected?

How will my privacy be protected?

STUDY DETAILS:

Who is funding the study?

Was the research study reviewed by a Research Ethics Board?