HD CLINICAL TRIAL RESEARCH

QUESTIONS AND ANSWERS ABOUT CLINICAL RESEARCH IN CANADA

WHAT IS THE DIFFERENCE BETWEEN A CLINICAL TRIAL AND BENCH RESEARCH?

Clinical Research involves research using human volunteers with the intention to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies.

Bench Research refers to a scientist or physician scientist who works in a laboratory setting and who generally does not see patients.

Research into Huntington disease is vital to the development of effective treatments for this debilitating disease. The Huntington Society of Canada is aware of the importance of research and has as part of its mission to “further research to slow and prevent Huntington disease”. We do this through the funding and support of key individuals who are doing work in the HD field, as well as working jointly with other groups, such as the Huntington Disease Society of America, Huntington Study Group and CHDI.

BEFORE YOU CONSIDER PARTICIPATING IN RESEARCH THERE ARE A NUMBER OF THINGS FOR YOU TO THINK ABOUT:

Why do I want to participate in research?

What types of research will be conducted?

How do I contact those who are doing research?

How do they take care of my best interests and minimize risk to my family and me?

Once I start participating how long do I have to continue?

LET’S LOOK AT THESE QUESTIONS ONE AT A TIME.

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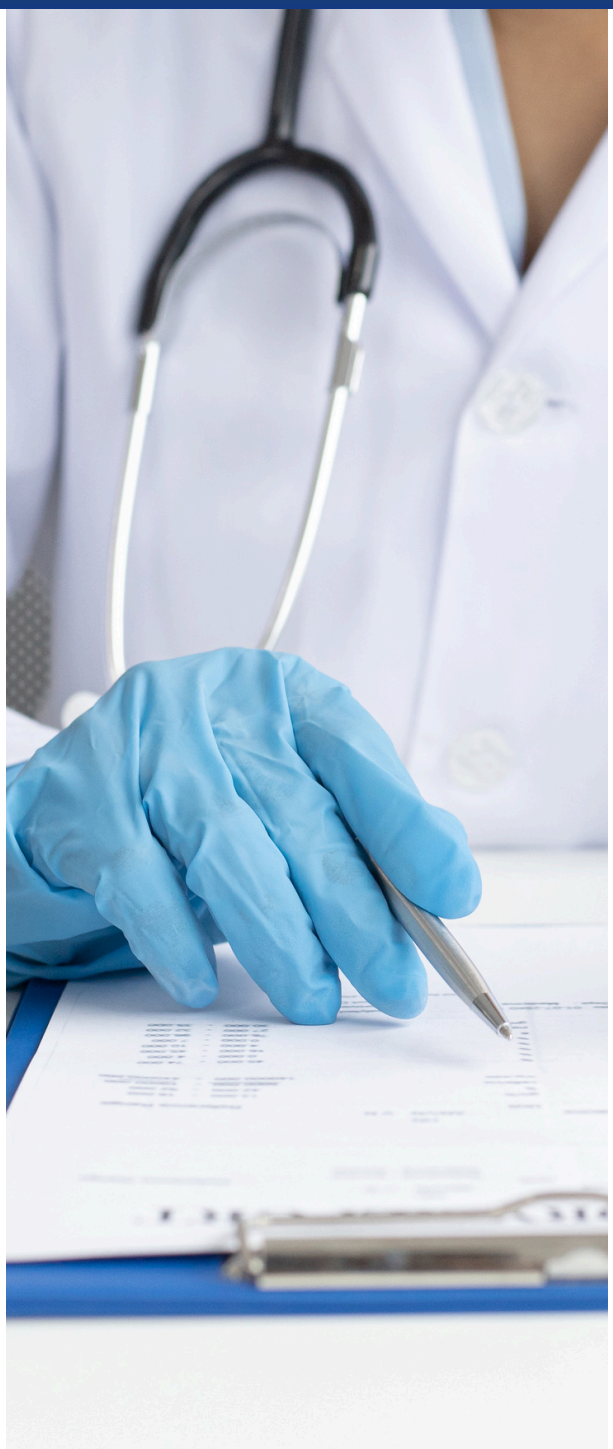
CHOOSING TO PARTICIPATE

At the 2006 HSC Conference, we conducted a survey to ask people about their views of research and why they did, and did not participate. The results of this survey showed that for those who participate the main reason they do so is that it is important that they be a part of finding a meaningful treatment. As well, they have an interest in research and knowing more about HD. For those choosing not to participate, the main reason cited was that they were afraid and did not know much about the research process and how they could contribute.

For each person who participates in research it is an important personal decision, but one that should be based on accurate information. This freedom of choice is built into how researchers conduct their work, and you should never be pressured to participate, and always feel free to ask questions.



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TYPES OF RESEARCH

Research is generally divided into two categories: basic and applied research. Basic research is when a researcher has a particular idea or interest that he/she will investigate without a particular application in mind. This type of research can be very valuable to improving knowledge about diseases or chemical responses, for example.

Applied research is when a researcher has a particular application for the information that will be learned from the investigation. Clinical research or trials are a common form of research in Huntington disease. In these studies, volunteers are involved in assisting investigators to verify clinical process, medications, procedure, etc.

Many different types of people can participate in research: those with HD, those at-risk, and families. This will depend on the type of research that is being conducted at any given time, by each researcher. Essentially, not every person is appropriate for every research study. There are often specific criteria that you will need to meet: age, gender, risk status, etc. Just because you may not be a candidate for one study, it does not mean that you will not be appropriate for other studies. Because research can happen in many different ways, interviews, analysis of blood and other specimens, taking a new drug or trying a new method of treatment, each research study will be different.

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WHO IS DOING HD RESEARCH IN CANADA?

There are many researchers who are doing investigations in Canada, which may or may not be appropriate for you. If you are interested in participating in clinical research, talk with the Huntington Society of Canada or a local Resource Centre Director, or member of your care team (genetics, neurology, psychiatry, social work) to see if there is a way that you can participate.

WHAT IS HSC'S ROLE IN CLINICAL RESEARCH?

HSC plays a key role in bridging the relationship between researchers and individuals by educating Canadians on the importance of the clinical trial process; how they can get involved; and why their participation is so crucial. The urgency lies in not only educating as many people as possible, including efforts in rural and culturally diverse communities but also ensuring clinicians have sustainable mechanisms in place to support the process.

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PROTECTING RESEARCH PARTICIPANTS

Historically, research has not always been stringently regulated resulting in many people being hurt or participating without their knowledge. This is no longer the case. Before any research can be conducted it must meet specific guidelines that ensure that individuals who participate in the research studies have all the information about the study, the risks and benefits to them, and have provided their consent.

In order for any researcher to get approval to do research, they must adhere to ethical standards that are set out internationally. In Canada, the federal government sets the minimum standard in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

IN THIS STATEMENT IT OUTLINES THE PRINCIPLES THAT RESEARCHERS MUST BUILD INTO THE RESEARCH APPLICATION:

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harm and benefits
- Minimizing harm
- Maximizing benefit

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QUESTIONS AND ANSWERS ABOUT CLINICAL RESEARCH IN CANADA

PROTECTING RESEARCH PARTICIPANTS (CONTINUED)

Essentially, these principles when put into practice will mean that the research that you are participating in will treat you with respect, keep you aware of all important information so that you can decide if you want to join, keep all information about you private and confidential, it will be fair and include a variety of people (gender, ethnicity, etc. where appropriate), the risks that you will be exposed to will be minimized, and that there will be the most benefit possible. While there still may be some risk, you will be informed of this and will be able to make your personal decision with the information that the researchers provide to you. To ensure that this happens and is followed, each investigator must include approval from an “Office of Research Ethics”, with the institution that they are connected with, e.g.: university, hospital, etc. Those that are funding the research also require that the research be followed ethically.

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