Key Questions to Ask Before Participating in a Clinical Trial

1. What is the main purpose of this study?
2. Does the study involve a placebo or a treatment that is already on the market?
3. How will the treatment be given to me?
4. How long is the study going to last and what will I be asked to do as a participant?
5. What has been learned about the study treatment and are any study results published?
6. Do I have to pay for any part of the study? Will my insurance cover these costs?
7. Is there any reimbursement for travel costs?
8. Will I be able to see my own doctor?
9. If the treatment works for me, can I keep using it after the study?
10. Can anyone find out whether I'm participating in the clinical trial?
11. Will I receive any follow-up care after the study has ended?
12. What will happen to my medical care if I stop participating in the study?
13. Does the physician/investigator have any financial or special interest in the clinical study?
14. What are the credentials and research experience of the physician and study staff?

Resources

General

The International Conference on Harmonization - www.ich.org

Search Clinical Trials - Public service that compiles clinical trial listings, study results, and news from multiple sources www.searchclinicaltrials.org

International Clinical Trials Registry Platform - Web site that enables users to search a central database of clinical trials, including some conducted in Canada www.who.int/trialsearch

CenterWatch - Listings of clinical trials and therapies in research (including those in Canada) - www.centerwatch.com

World Health Organization - www.who.int

Canadians for Health Research - Voluntary, nonprofit national organization providing information about Canadian health research - www.chrcrm.org/main

Health Canada Publications
http://www.hc-sc.gc.ca/dhp-mps/pubs/index-eng.php

Current Controlled Trials - Electronic links to over 50 registers of controlled trials, including clinical trials in Canada www.controlled-trials.com

Government

Minister of Health - 613-957-0200

Canada International Clinical Trials Registry from Health Canada - www.hc-sc.gc.ca; 613-957-2991

Clinical Research Initiative (CRI) - National health agency taking measures to set and create a network for mapping and monitoring clinical trials in Canada; (613) 941-0057 http://www.cihr-irsc.gc.ca/e/22113.html

Disease specific

Canadian HIV Trials Network
www.hivnet.ubc.ca/e/home/

International Network for Cancer Treatment and Research
www.inctr.org

Current Controlled Trials - Canadian HIV trials network
www.controlled-trials.com

MS International Federation
www.msif.org

Parkinson Society Quebec - www.infoparkinson.org

Alzheimer Society - www.alzheimer.ca/

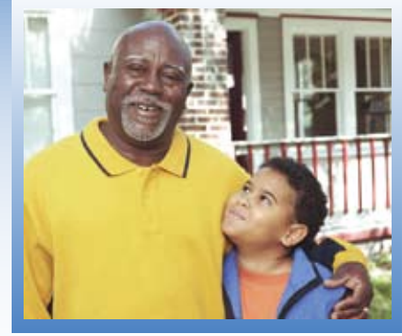
EDUCATION before PARTICIPATION

Helping you make an informed decision about clinical research participation.

CISCRP is an independent non-profit organization founded for the purpose of educating the public, patients, media, and policy makers in order to promote greater understanding and awareness of clinical research participation and the role it plays in public health.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

1-877 MED HERO • www.MEDHERO.org



How Volunteers are Protected

- Health Canada supports 'Good Clinical Practice', an international quality standard that is provided by the International Conference on Harmonization (ICH). This international organization creates clinical trial standards and protocol, which governments can then adopt as regulations for clinical trials involving human subjects.
- Health Canada has committed to increasing awareness and transparency of clinical trials to enable Canadians to make informed healthcare decisions.
- Health Canada is also participating in international initiatives aimed at promoting registration of clinical trials.
- The World Health Organization is working on a global approach to clinical trial registration, and both Health Canada and CIHR are represented in this process.
- Health Canada recently posted the Department's 2003-2004 Summary Report of Compliance Inspections of clinical trials on its website.

CISCRP is not involved in recruiting patients for clinical trials nor is it involved in conducting clinical trials.

About Clinical Trials

What are clinical trials?

- A research study involving human volunteers to answer specific health questions.
- Carefully conducted clinical trials are the safest and fastest way to find treatment that work in peopleand new ways to improve health.
- Clinical trials are conducted according to a plan called a protocol.
- A protocol describes what types of patients may enter the study; schedules of tests and procedures, drugs, dosages, and length of study, as well as outcomes that will be measured.
- Each person participating in the study must agree to follow the protocol.

Why are clinical trials conducted?

- To see if a new drug or device is safe and effective for people to use.
- To compare existing treatments to determine which is better.
- To study different ways to use standard (approved) treatments, so they will be more effective, easier to use, and/or decrease side effects.
- To learn how to best use the treatment in a different population, such as children, in whom the treatment was not previously tested.

What are some of the possible benefits of my participation?

- Gain access to potentially new research treatments.
- Receive expert medical care for the condition being studied, since investigators are often specialists in the disease area being studied.
- Help others by contributing to medical research and treatment advances.

What are some of the possible risks of my participation?

- There may be unpleasant, serious, or even life-threatening side effects resulting from the treatment.
- The treatment may not be effective.
- Participation in the trial may be demanding and time consuming.

For answers to additional questions, visit our Web site at www.MEDHERO.org or call 1-877 MED HERO.

CISCRP – helping you to make an informed choice.