Research Clinical Trials: A Pamphlet for Patients and Families

Why is research being done?

WHAT IS BEING STUDIED?

How will participating affect me?

What's the cost?

Is this safe?

When can I stop?

This pamphlet will explain what a research clinical trial is and help you make an informed decision about whether participating in one is right for you and your family member.

OPSEI

BC CHILDREN'S HOSPITAL
An agency of the Provincial Health Services Authority

What are Clinical Trials?

- A clinical trial is the word used by researchers to describe a health-related intervention to scientifically evaluate the effects on participants.
- Clinical trials investigate the effectiveness and safety of specific medical procedures and treatment products before they can be used across Canada.
- Clinical trials may compare a new medical approach to a widely used method, and/or to a placebo (a harmless substance that contains no active ingredients) and/or to no intervention.
- Canadian clinical trials are strictly regulated and must be approved by Health Canada, the hospital or clinic where it takes place, and a Research Ethics Board (REB), which protects the participants of the clinical trial until it is completed.

Children and Clinical Trials

- Adult treatments may have different effects on children.
- Until recently (and still not very often) little testing has been done on drugs and medical procedures performed on children.
- It is important to conduct clinical trials ***on children*** to evaluate if a new proposed method is effective ***for children***.

What is a Trial Protocol?

- Each clinical trial has a written action plan or description of the study, known as the protocol.
- The protocol includes information such as why the trial is being done, how it is conducted, what it entails for the participant, and how safety is ensured.
- It is extremely important to read and understand the trial protocol before deciding whether or not you would like to participate.

What is Informed Consent?

- A very important process in clinical trials is to ensure that all facts are provided before you decide to participate.
- An ***informed consent*** is the voluntary agreement of a person to participate in a clinical trial after understanding the nature of the study, potential risks and benefits, and all other information required to make an informed decision.
- Parental permission is a type of informed consent given by parents or guardians for their child to participate in a clinical trial.
- An ***informed assent*** expresses the willingness of a child, who is old enough to understand but is legally too young to give consent, to participate in a clinical trial.
- Even if assent is obtained from a child, informed consent must still be provided by his or her parents.

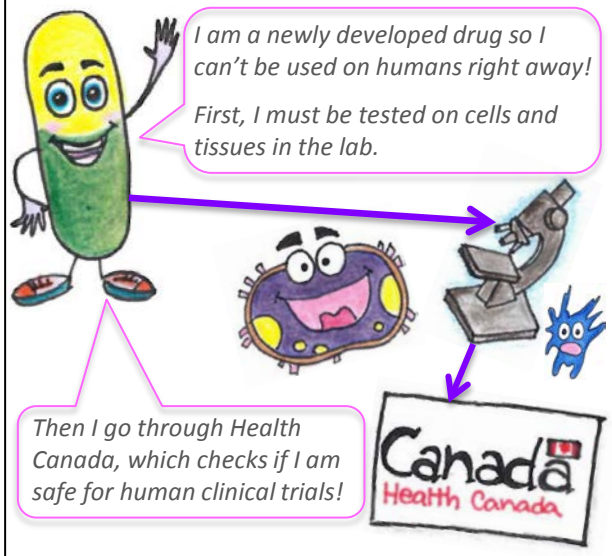
What are Eligibility Criteria?

- Each clinical trial has its own rules used to decide if a person is suitable for the study.
- This set of rules, or eligibility criteria, ensures that people enrolled in a clinical trial share many of the same characteristics (certain age group, sex, medical history, etc.) to produce scientifically accurate results.
- Having a strict set of eligibility criteria will allow researchers to better understand the results of a new treatment.

FAQs & Checklist

- Make sure you **understand the clinical trial** *before* being involved. Don't participate if you don't understand what's going on or have unanswered questions.
- You become a part of the team when you enroll in a study. We are working for the same **goal: to find a cure!**
- **Weigh pros and cons**. Don't participate if it's not helping anybody!
- Our **biggest concern: SAFETY**. Researchers are as concerned with safety as parents.
- If you say yes, **your child's care won't be compromised.**
- **It's okay to say no!** Your treatment won't change and you will still receive the standard treatment if you decide not to participate.
- **THERE ARE NO SILLY QUESTIONS!** → This is about you/your child! If you are uncertain or uncomfortable about anything, please ask!

Clinical Trials involving Drugs



Four Phases of Clinical Trials

Phase 1: I am tested on a small group of people (<100) for the first time to assess my safety.

Phase 2: I am tested on a larger group of people (100 or more) to determine how effective I am.

Phase 3: I am tested on an even larger group of people (1000 or more) to be compared to other treatments.

If clinical trials show promising results, I can be sold in the market!

Phase 4: Much more of my long term risks and benefits are identified.

Potential Benefits and Risks

- Potential benefits and risks vary between different clinical trials and are outlined in the trial protocol specific to the study.

Potential Benefits

- You develop a greater understanding of your condition under close monitoring, care, and support by a research team of doctors and health professionals.
- You can gain access to new treatment which are not yet available to the public.
- New drugs or treatments may be more effective than the standard approach.
- Although most benefits are for finding future cure, you are actively contributing to medical research and are informing the community that these diseases exist!
- Research in kids helps kids.

Potential Risks

- Clinical trials may require more time than non-clinical trial treatments, such as more follow-ups, etc.
- There may be other specific risks which will be discussed with your physician (extra blood work, additional tests, X-ray scans, and confidentiality).
- New drugs or treatments may not always be better or as good as the standard ones.
- You may experience unexpected side effects from the new treatment.

References

- http://www.cancer.ca/en/cancer-information/diagnosis-and-treatment/clinical-trials
- http://www.centerwatch.com/clinical-trials/overview
- https://clinicaltrials.gov
- http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/clinical_trials-essais_cliniques-eng.php
- http://www.nhlbi.nih.gov/studies/clinicaltrials
- https://www.nichd.nih.gov/health/clinicalresearch/Pages/index.aspx
- http://www.phsa.ca/our-research/participate/clinical-trials