

# Clinical Trials at PMH



UHN

## What You Need To Know...



## A Guide for Patients, Their Families and Friends in the PMH Cancer Program

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**Created:** 08/2007

**Form:** D-5450 (07/2010))



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**Princess Margaret Hospital (PMH)** is a research hospital. Patients at PMH may be asked if they would like to be involved in a clinical trial during their time at the hospital. The staff at PMH has created this brochure in order to provide patients, their families and friends with some basic information about clinical trials.

Participating in a clinical trial is always voluntary.

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## What is a Clinical Trial?

A **clinical trial** is a type of research study that is done to help learn about new ways to prevent, diagnose or treat a disease. This type of research involves human beings who choose to participate. There are different types of clinical trials. Some types of clinical trials that occur at PMH include:

- **Prevention Trials:** The goal of these studies is to prevent a disease or condition.
- **Diagnostic Trials:** The goal of these studies is to better detect an existing disease or condition. Diagnostic studies may also look at detecting a risk of developing a disease or condition.
- **Treatment Trials:** The goal of these studies is to find better ways to treat a disease or condition.
- **Quality of Life Trials:** The goal of these studies is to see how patients are feeling.

## Why Clinical Trials are done

### To improve medicine

Clinical Trials are one of the last stages of cancer research. Before a clinical trial is started, a lot of promising research has already occurred. Research that shows promise must first be tested in a clinical trial before it can be used in everyday medicine, or as the **standard of care**.



### To provide patients with an other option

For patients, clinical trials offer one more choice in their medical care.

Sometimes, patients who participate in clinical trials will have access to treatments and procedures that otherwise would not be available. However, it is important to understand what is involved in a clinical trial before deciding to participate.

# How a Clinical Trial is Started

## Designing the clinical trial

Once it has been decided that a clinical trial is needed, a team of researchers will write a protocol.

The **protocol** is like a recipe for the research team. It tells them why, when and how different parts of the study are to be done.

## Approving the Clinical Trial

All clinical trials must be approved by a Research Ethics Board before any patient is approached about the study.

A **Research Ethics Board** is a group of individuals with different professional backgrounds that review all clinical trials to make sure that patients' rights are protected.



Health Canada also has to approve certain clinical trials, such as any clinical trial that is using an investigational product.

An **Investigational Product** is a medication, agent or device that is not yet on the market.

Only approved clinical trials can be carried out at this hospital. Approved clinical trials may or may not be beneficial to the clinical trial patients and approval does not guarantee that there are no risks involved with the clinical trial.

## How a Clinical Trial is Run

At this hospital, a doctor leads a clinical trial. There is always one main doctor that is responsible for the trial. This person is called the **Principal Investigator**. There are also other doctors and researchers that work with the Principle Investigator and they are called the **Co-Investigators**.

**Clinical Research Coordinators** work with the doctors and the researchers to help organize and run the study and to help care for the clinical trial patients.



Clinical Trials are made up of different stages. The main stages for most clinical trials are:

- The Informed Consent Process
- Screening Stage
- Active Stage
- Withdrawal Stage
- Follow-up Stage

## The Informed Consent Process

The **informed consent process** involves the sharing of information about the clinical trial between the patient and clinical research team. This process starts from the moment that a patient is first approached about participating in a clinical trial, and continues throughout the study.



Patients are given information from many sources. The doctor and research staff will talk to the patient about the trial, and will answer any questions that they might have.

Also, a document called the **Informed Consent Form** will be given to the patient. This form provides a lot of information, and if the patient decides to participate in the study they will be asked to sign this form. Patients will be provided with a copy of the informed consent form for their records.

During the study, any new information about the clinical trial will be shared with the clinical trial patient.

## Screening Stage

Not all clinical trials are right for everyone. The study protocol outlines what characteristics a patient must have to be involved in a clinical trial.

The **screening stage** is the process involved to determining if the patient is eligible to be involved in the clinical trial. This process may involve extra tests or procedures.



## Active Stage

If a patient is found to be eligible for a clinical trial during the screening stage they can begin the active stage of the clinical trial. The **active stage** is when the clinical trial patient receives the treatment, agent, or procedure being tested.

## Withdrawal Stage

The withdrawal stage is when the final information is collected about the patients experience during the active phase. This stage starts when the active stage is stopped.

## Follow-up Stage

Some clinical trials will have a follow-up phase.

**Follow-up** is when the research team will continue to check a patient's medical progress after they have finished the active and withdrawal phase of a clinical trial. Follow-up allows doctors and scientists to see the long-term outcome of the clinical trial.



# Frequently Asked Questions

## What Would My Responsibilities Be?

### Extra Tests, Procedures and Time

Clinical Trials may involve extra tests, procedures and visits to the hospital. The informed consent form will explain what additional tests, procedures and visits should be expected. The additional tests, procedures and visits will often have to occur at specific times throughout the study.

### Communication

It is very important for clinical trial patients to communicate with their research team. The research team will collect a lot of information each time a clinical trial patient is in for a visit. It is also important that the clinical trial patient continues to communicate with the research team between study visits.

Some of the information that the research team will want to know include:

- **Medical History**
- **Changes in medications.** The research team will ask for the name, the dose, what the medication is for and when the change happened. It is important for the study team to know everything that a clinical trial patient is taking, even if it is not a prescription medication.
- **Changes in health** (positive and negative). The research team will ask when the changes started and stopped and how the clinical trial patient is managing.
- **Continued Study Involvement.** If the clinical trial patient decides that they want to stop being involved in the clinical trial, they need to notify the research team.



## What are the Research Team's Responsibilities?

All medical professionals involved in clinical research, and all clinical research staff must follow certain professional guidelines called the Guidelines for Good Clinical Practice. These guidelines help protect the rights, safety and well being of clinical trial patients.

The research team has certain responsibilities to clinical trial patients.

These responsibilities include:

- **Informing the Clinical Trial Patient:** Clinical trial patients have the right to receive information that may change their decision to be involved in a clinical trial.
- **Freedom of Choice for the Patient:** The research team has a responsibility to make sure that a patient's choice to be involved in a clinical trial is voluntary and that they do not feel pressured to participate.
- **Respect for the Patient:** The research team has a responsibility to respect the privacy, confidentiality and the decisions of the clinical trial patient.
- **Be Qualified:** The research team has a responsibility to be qualified to run the clinical trial and to care for the clinical trial patients.

## What is a placebo?



A **placebo** is sometimes referred to as a ‘sugar pill’. It is a product that has been created to look like a type of medication or agent but that does not contain the ingredient that is responsible for the effect of the medication or agent.

## Are placebos used in all studies?

No. Placebos are **not** used in all clinical trials.

There are only certain types of clinical trials that are allowed to use a placebo:

- When there is no proven treatment available for a group of patients. In this case, taking a placebo is similar to receiving the standard treatment.
- When a condition being treated is not severe and the use of a placebo will not cause increased harm to the patient.

## Why are placebos used in clinical trials?

Placebos allow researchers to see if a medication or agent is actually working, or if the trial results are just by chance.

## What if there is an emergency and a doctor needs to know what medication I am on?

If ever there was an emergency, the research team is able to find out whether the clinical trial patient was taking the placebo or the study medication.



## **What do they mean by ‘randomized’?**

Randomization assigns patients into a treatment group by chance. The research team is not involved in deciding what type of treatment the patient is going to receive during the clinical trial.



## **Do all clinical trials use Randomization?**

No. Not all clinical trials are randomized. Clinical trials that have more than one treatment group may use randomization to decide which treatment a patient will receive.

## **Why is randomization used in clinical trials?**

Randomization is used in clinical trials to make sure that all patients are treated equally. Randomization ensures that all patients have the same chance of being on any of the treatment groups in the study.

## **What about Side Effects?**

### **How will I know what side effects could happen?**

The Informed Consent Form will list the side effects, or adverse events, that may happen while on the clinical trial and what the chance is of experiencing the events listed. Patients are given this information before they decide to get involved in the clinical trial and they are also informed if there is a change to this information.

### **Are these the only side effects that I could have?**

No. Unexpected side effects can happen during the clinical trial. The Informed Consent Form will list the adverse events that are known, but that does not mean that other adverse events could not happen.

### **What happens if I have a side effect?**

If a clinical trial patient experiences a side effect while on a clinical trial, they will receive the necessary medical attention needed.

**What if I don't want to be in the study, is my Doctor going to be upset?**

No. Doctors and research teams want to make sure that patients are told about clinical trials, because it is a treatment option, but they are very understanding of a patient's right to decide. Even if a patient chooses to be involved in a clinical trial, they can always change their mind and this decision will not negatively affect their medical care at the hospital. This is one of the rights of a research patient.

## I Want to Know More About Clinical Trials...

There are many resources available to learn about oncology clinical trials.

This list is only a few of the available sources:

- **Your Doctor**
- **Ontario Cancer Trials Website:** This website includes a database of cancer clinical trials in Ontario that patients, their families and friends can search. There is also general information about clinical trials on this website. The website is <http://ontariocancertrials.ca>
- **Canadian Cancer Society:** The Canadian Cancer Society can provide patients, their families and friends with information about cancer and cancer research. The society has a website at [www.cancer.ca](http://www.cancer.ca). They can also be reached at 1-888-939-3333.
- **National Institutes of Health:** This website includes a database of clinical trials that are running for many diseases and conditions. This database includes clinical trials that are running across North America and parts of Europe. The website is [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- **Health Canada:** The Health Canada website has information about different drugs and health products. This includes information about how clinical trials are regulated in Canada. The website is [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca).
- **PMH Patient and Family Library:** The main PMH Patient and Family Library is located on the main floor of PMH in the Atrium. The staff and volunteers at the library are more than happy to help



patients, their families and friends find information about any topic.

There are computers in most clinics and in-patient areas at PMH for patients, their families and friends to use. These computer areas are called Patient and Family Resource Centres.

## **How Do I Get Involved in a Clinical Trial at PMH?**

The best way to get involved in a clinical trial at Princess Margaret Hospital is to talk to your doctor.

You can also contact the Clinical Trials Support Unit for a list of available trials at PMH, however it is up to you and your doctor to decide what trial is best for you.

You can reach the Clinical Trials Support Unit by e-mail at **ClinicalTrials-PMH@uhn.on.ca** or by phone at 416-946-4501 extension 3835.

