



**Each year thousands of people volunteer to participate in clinical studies/trials. The benefits of volunteering in a clinical study/trial include:**

- *Become actively involved in your healthcare.*
- *Learn new information about your medical condition or disease.*
- *Gain access to new medications or treatments and receive comprehensive expert medical care during the study/trial, usually at no cost to the patient.*
- *Receive follow-up monitoring to ensure your safety and that the new medication or treatment works as intended.*
- *Help others by contributing to medical and scientific knowledge that will improve medical treatment and patient care.*

## What are my risks?

Clinical studies/trials are designed to minimize risks to their participants while maximizing the potential benefits to the community. While participants' safety is the most important aspect in every clinical study/trial, there are however, some potential risks involved. These are summarized below:

- There may be unpleasant or unwanted side-effects caused by the new drug or treatment being studied.
- The new drug or treatment being studied may not be effective.

## How can I participate in a clinical study/trial?

Talk to your doctor to see if you would benefit from participating in a clinical study/trial. Your doctor can find out what clinical studies/trials relevant to your medical condition are going on or will soon be initiated by contacting Clinical Research Malaysia (CRM) or the Clinical Research Centre (CRC) Units in major public hospitals.

### *Glossary of Clinical Study Terms*

#### **PRINCIPAL INVESTIGATOR OR STUDY PHYSICIAN**

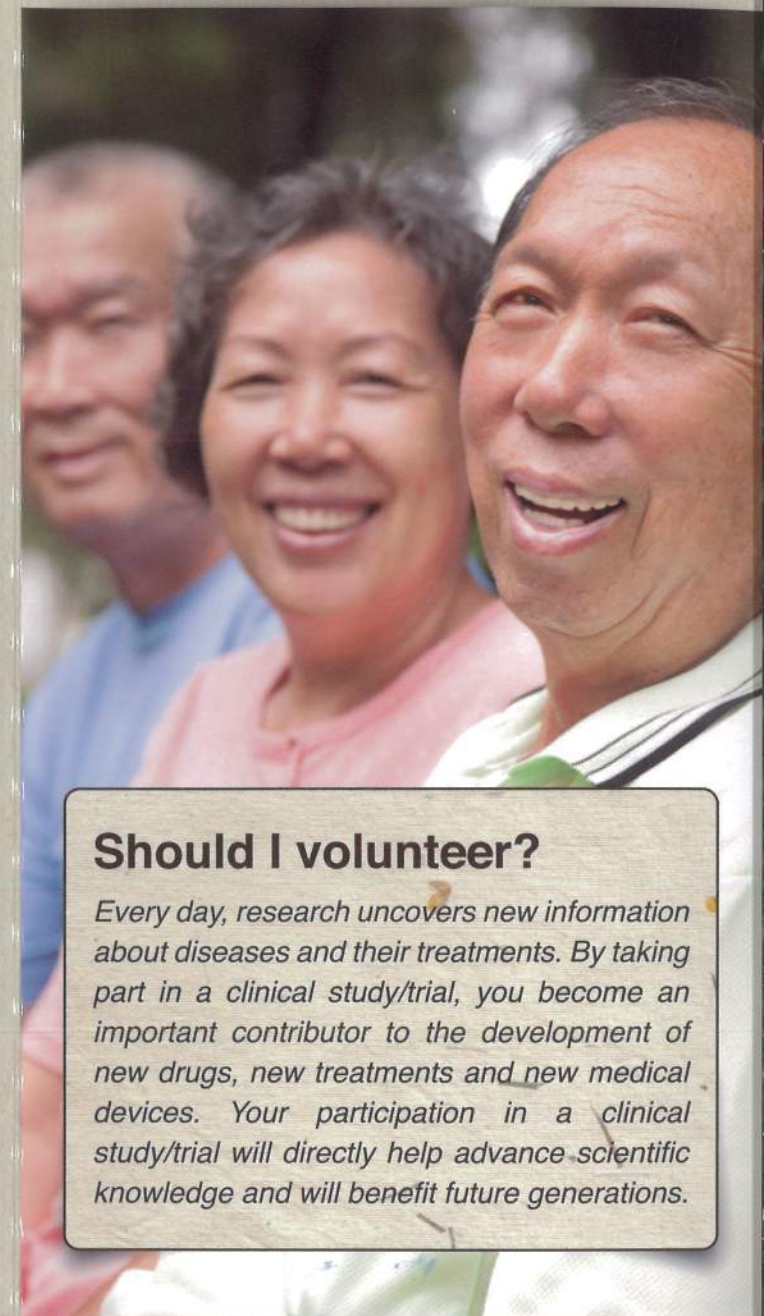
A medical researcher in charge of carrying out a clinical research study/trial.

#### **CLINICAL RESEARCH STUDY/TRIAL**

A process designed to study the effects and/or safety of a new medication, treatment or medical device on a group of patients.

#### **INFORMED CONSENT**

A discussion of procedures, benefits and risks of a clinical study/trial between clinical investigators and persons interested in participating in the study/trial. The clinical investigators must reveal all relevant information pertaining to the study/trial. Persons who decide to volunteer for the clinical study/trial will have to sign an Informed Consent form to indicate they understand and accept what is expected of them and the risks-benefits associated with the clinical study/trial.



## Should I volunteer?

*Every day, research uncovers new information about diseases and their treatments. By taking part in a clinical study/trial, you become an important contributor to the development of new drugs, new treatments and new medical devices. Your participation in a clinical study/trial will directly help advance scientific knowledge and will benefit future generations.*



## What is a clinical study/trial?

A clinical study/trial is an investigation of effectiveness and safety of a new drug or new treatment or new medical device on a group of patients. Clinical studies/trials are an extremely vital process in advancing medical care and treatments.

## Who sponsors a clinical study/trial?

Private companies (generally pharmaceutical, medical device and biotech companies) or government agencies usually sponsor most clinical studies/trials. In most cases they work together with public & private hospitals and universities.

## Who makes sure my rights are protected?

An Ethics Committee (also known as an Institutional Review Board) must carefully review and approve the clinical study/trial before it can be implemented to ensure your rights and safety are protected and given the utmost priority.

An Ethics Committee is composed of a group of scientific and non-scientific experts in various specialities and disciplines. Their role is to ensure that the clinical study/trial has a legitimate medical purpose, is safe for participants and will benefit the community.

## Who conducts a clinical study/trial?

Clinical studies/trials are usually held in hospitals, universities, medical centres or doctor's clinics. The actual implementation of the study/trial will be conducted by a research team that is led by a senior doctor known as the Principal Investigator. The team may also include nurses, social workers, pharmacists, dental officers, dieticians and others, depending on the requirements of the study/trial.

## Who can be in a clinical study/trial?

Each clinical study/trial will have different requirements for participants such as age, sex, medical condition, etc. These requirements are known as the inclusion-exclusion criteria.

The research team will make an evaluation based on the inclusion-exclusion criteria to decide if you are eligible to participate in the study/trial. The team also has to undertake an "*Informed Consent*" process to educate you on the potential risks-benefits of participating in the clinical study/trial.



## What is "Informed Consent"?

Informed Consent is a process that takes place before you enroll into the study/trial. A qualified member of the research team will explain the purpose and objectives of the study/trial, the procedures involved, and the risks-benefits involved. You have the right to ask any questions you may have about the study/trial.

You will be informed about how your personal medical history will be kept confidential and who are authorized to view it. If you decide to take part in the study/trial, you will be asked to sign the Informed Consent form. Please ask questions about any part of the Informed Consent form that you do not understand. Please note that even after you have signed the form, you will always have the right to change your mind and withdraw from the clinical study/trial at any time.

## What can I expect as a study/trial volunteer?

During the study/trial period, the research team will review your medical history, give you instructions on what to do and when-and-how to do it and monitor your health carefully. Some clinical studies/trials may need regular tests and doctor visits. In most cases, this high standard of medical care is paid for by the study/trial sponsor.