Clinical Research Center
Faculty of Medicine Chulalongkorn University
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Frequently Asked Questions

Here are some frequently asked questions about volunteering to participate in a clinical trial.

What is a clinical trial?

A clinical trial is a research study to answer specific health questions. A lot of research is done to see if a new drug or device is safe and effective for people to use. Some studies compare existing treatments to determine which one is preferable. Other clinical trials are aimed at studying different ways to use already available treatments so they can be more effective, easier to use, or to decrease side effects. Sometimes studies are done to learn how to best use a treatment in a particular population, such as children, for whom the treatment has not been previously tested.

By following a plan called a protocol, clinical trials are conducted to collect data regarding the safety and efficacy of drugs, devices, or preventive measures in humans. The protocol describes the study background, types of patients for whom the study is designed, schedules of tests and procedures, drugs or interventions uses, dosages, and length of the study as well as the measured outcomes. Each person participating in a study must be comfortable with the protocol and sign an Informed Consent form (a form on which a participant agrees and certifies his/her willingness to participate in the trial) before deciding to participate. It is precisely because the protocol is the leading guideline for a study and must be followed by investigators, nurses, patients, data managers and any others involved.

Clinical trials at ChulaCRC are carried out in compliance with International Conference on Harmonization (ICH) / WHO Good Clinical Practice Standards. These standards provide a unified standard for the European Union (EU), Japan, and the United States as well as for Australia, Canada, the Nordic countries and the World Health Organization (WHO). In most of these countries, the law dictates that these guidelines are to be strictly followed; while in Thailand, the Ministry of Public Health urges adherence to these guidelines. By adhering to these guidelines, data gathering is standardized and results may be applied across countries as the ethics and science behind the data are sound.

Phases of Clinical Research

Pre-Clinical studies aim to determine whether a drug behaves the same way in humans as in previous tests done with test tubes and animals indicated. A small dosage, below the amount expected to be used to have an effect, is given to a small group of subjects to identify if the drug acts in the particular part of the body that it was designed for and in the way that was anticipated. For example, a drug designed to lower cholesterol would be tested to see if it acts in blood vessels, the heart, etc., and to see if that interaction meets expectations. This can further avoid unnecessary testing in cases where a drug is inactive beyond prediction.

Phase I trials assess the safety of a drug or a device. This phase will include only a small number of healthy volunteers, usually less than 100 subjects. This phase is designed to evaluate what effect the drug or device has in humans and how it interacts with the human body, including absorption, metabolization, and excretion. This phase also looks at drug side effects occurring at different dose levels.

Phase II trials assess the effectiveness of a drug or a device and may include hundreds of participants who have a particular disease. Phase II trials are preferably conducted as randomized studies in which one group of patients receives the experimental drug and the other control group receives a standard treatment or placebo (a harmless substance given to a subject instead of medicine, without telling them it is not real). These studies are often blinded, that is to say neither the patients nor the researchers know who have received the experimental drug. This process allows regulatory and drug registration authorities access to the comparative information on the relative safety and effectiveness of the investigational drug. It is mandatory that the regulatory and drug registration authorities give approval for the drug or device prior to investigators moving the research on to phase III studies.

Phase III trials are largely randomized and blinded studies. They may involve hundreds to thousands of subjects. These studies may last from several weeks to several years in order to provide the pharmaceutical company and the regulatory and drug registration authorities with important information on the long term safety and effectiveness of the investigational drug. These studies also evaluate the benefits and possible adverse reactions to the drug. Approximately 70% to 90% of drugs entering phase III studies successfully complete this phase of testing. The pharmaceutical or device company can request the regulatory and drug registration authorities approval for marketing after completion of the phase III studies.

Phase IV trials are conducted after a drug or device has been approved for sale. These post-marketing studies are put through in an effort to clearly delineate additional information on the drug's risks, benefits, and optimal use. This phase is an operational surveillance after the medicine is made available to doctors who start prescribing it. The effects are monitored in often thousands of patients to help identify any unforeseen side effects or impact on a patient's quality of life.

How important are clinical trials?

Have you ever wondered how a physician determines which medication to prescribe to treat a specific medical condition?

Every year pharmaceutical companies and research centers develop new medications to save lives, extend lifespans, or improve the quality of life. Before these medications can become available, they first must be tested by clinical studies that strictly follow Food and Drug Administration (FDA) rules. The FDA looks closely at the results of these clinical trials and then determines how safe and effective the drugs are for the public. All prescription medications must go through a series of clinical trials prior to obtaining FDA approval. Good clinical trials must indicate the safety and effectiveness of medication. The FDA also approves the indications of the drug, i.e. for what medical condition a particular drug might be prescribed. Without these controlled studies, a physician would not know which medications are safe and effective enough to treat a patient medical condition.

What are the costs?

For a volunteer, there is no cost to participate in a clinical trial. Generally, a clinical trial is subsidized by the government, or private industry including pharmaceutical and biotech companies, medical institutions, foundations and the like.

Should I participate?

Volunteers in clinical trials play an important and necessary role in the development of new treatments to save human lives and extend lifespans. By participating in a clinical trial, you may not only receive treatment for your own medical condition, but also help find a cure to prevent the disease from affecting future generations. All over the world, millions of people participate in clinical trials. The reasons why they opt to participate are:

- They have a medical condition that is unable to be controlled by available medicine.
- They want additional medical care such as physical exams, diagnostic and lab tests or medical equipment provided to qualified participants at no cost.
- They want to learn more about their medical condition.
- They may discover undiagnosed medical problems.
- They may help discover a new medical treatment for themselves, relatives or others.
- They may receive medication or education to treat their medical condition at no cost.

Not everyone, however, can join clinical studies. This depends on the inclusion and exclusion criteria for the study. Participants must also be willing and able to follow the trial protocol as well as scheduled clinic visits.

Would you like to benefit from participating in a clinical trial or help discover new treatments that could improve the lives of others? If you have answered, then please call us at 02 256 4000 ext. 3547, 02 251 6704 or fax 02 251 6706.

What are the risks and benefits?

Ethical and legal codes governing medical practice also apply to every stage of clinical trials. Every process in clinical trials carefully follows the controlled protocols or plans, outlining what researchers will do in the study. Most clinical research provides built-in safeguards to protect the participants. Even so, participants must understand and evaluate the potential risks and benefits of a study prior to participation.

The participants may risk:

- Experiencing unpleasant, serious or even life-threatening side effects derived from investigational treatment
- Additional time required and frequent travel for research visits
- Being dismayed at the ineffective experimental treatment

The participants may benefit by:

- Gaining access to new research treatments before its general availability
- Obtaining additional information on a specific disease
- Playing an active role in their own disease management
- Helping others by contributing to medical research

What is informed consent?

Informed consent is the participant's agreement to be engaged in a study after being fully notified of what the study would involve. Informed consent begins with a discussion between the research staff and the prospective participant. Based on this discussion, participants are asked to sign in writing a consent form that includes vital information about the study. The form should comprise explanations of the following:

- The purpose of the study
- The procedures involved
- The risks and benefits of participating in the study
- The length of the study
- The level of participant's confidentiality
- The outcome after the possible harm incurred from study by participants
- That participation is voluntary
- That participants are free to withdraw from the study at any time

Before signing, the participant is encouraged to bring the consent form back home to discuss with family and friends. If the participant decides to participate, they will be given a copy of the signed consent form so that they can review it at any time. The participant should not hesitate to ask the researchers any questions before, during, and after the study.

Who participates?

All clinical trials have specific guidelines about who can participate. Each trial is set up with a specific list of inclusion and exclusion criteria which participants must meet prior to enrollment. These criteria are based on such factors as age, gender, type and stage of a disease, previous treatment history, and other medical conditions. Inclusion and exclusion criteria are not employed for rejecting people, but rather identifying appropriate participants and keeping them safe. Participants with a specific group of inclusion and exclusion criteria ensure that the researchers will be able to answer the questions planned to study.

What are the types of studies?

- Treatment studies test investigational drugs and devices, new combinations of drugs, or new approaches to surgery or radiation therapy.
- Prevention studies look for better ways to protect people from getting a disease or to prevent the disease returning. These trials may include medicines, vaccines, vitamins and minerals, or lifestyle changes.
- Diagnostic studies are conducted to find better tests or procedures for diagnosing a particular disease or condition.
- Quality of life studies explore ways to improve the comfort and the quality of life of individuals with a chronic illness.