Participate in Clinical Trial Programs

INSTITUT JANTUNG NEGARA
National Heart Institute

Please read this leaflet carefully. If you have any additional questions, please feel free to ask us.

1. What is a clinical trial and why is it conducted?
A clinical trial is an investigation of the effectiveness and safety of a new drug or new treatment or new medical device on a group of patients. Clinical trials are an extremely vital process in advancing medical care and treatments.

2. Who sponsor a clinical trial?
An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. In most cases they work together with public & private hospitals and universities.

3. Who conducts a clinical trial?
Clinical trial will be conducted by a research team lead by a doctor known as Investigator, the team may consist of study coordinator and others depending on the requirements of the clinical trial.

4. Who makes sure my right are protected?
An Institut Jantung Negara Research Ethics Committee (IJNREC) will review and approve the clinical trial before it can be implemented to ensure your rights and safety are protected and given the utmost priority.

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

All of the records and data from your participation will be kept confidential. The results of your participation in this clinical trial may be used for publication or for scientific purposes, but neither your name nor your identity will be disclosed unless you give separate specific consent to this, or unless required by law. The research records for this clinical trial may be reviewed by some agencies.

5. Are you eligible to participate?
Anybody can participate in the clinical trial. Each clinical trial defines who is eligible to take part in the clinical trial. If you are eligible, your doctor will approach and explain further on the clinical trial schedule.

Eligibility. The factors that allow someone to participate in a clinical trial are called inclusion criteria, and the factors that disqualify someone from participating are called exclusion criteria. They are based on characteristics such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

6. What is "Informed Consent"?
A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by mean of a written, signed and dated informed consent form.
Your participation is strictly voluntary. Refusal to participate will not involve any penalty, loss of benefits, or reduction in the quality of medical care.

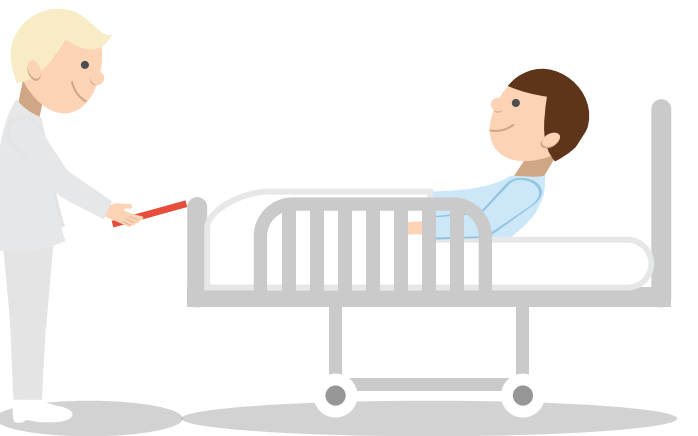
7. How can I participate in a clinical trial?
Talk to your doctor to see if you would benefit from participating in a clinical trial. Your doctor can find out what clinical trials relevant to your medical condition that are going on.

8. What are the risks and benefit?
There are both benefits and risks associated with clinical trials. By participating in a clinical trial, you may benefit by:

- Gaining access to new treatments that are not yet available to the public
- Obtaining expert medical care at a leading health care facility
- Playing an active role in your own health care
- Helping others by contributing to medical research

Risks:

- There may be unpleasant, serious side effects from treatment
- Treatment may not be effective for some individuals
- The clinical trial may require a lot of time for traveling to the clinical trial site, receiving treatments, or hospital stays



9. How long do clinical trials last?
The length of a clinical trial varies, depending on what is being studied. Participants are told prior to participate in the clinical trial.

10. What will happen if I withdraw from the clinical trial?
Participant have rights to withdraw from clinical trial at any time without compromise their standard of care or legal rights.

Contact Us

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Change your bad habits and live a healthier and happier life with your family.
Love Your Heart. Lead A Healthy Lifestyle.

Do Not Smoke

Exercise Regularly

Healthy Diet

Medical Check Up Minimum Once A Year

For more information, please contact:
Clinical Research Department

Internationally Accredited Heart Centre

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