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Indian Society for Clinical Research
ISCR
Enhancing patient outcomes through clinical research

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Clinical Trials

A Guide for Participants

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What is a clinical trial?

1 Before a new medicine is approved for use in a wider population, it must undergo extensive testing and be approved by relevant regulatory agencies. Clinical trials are carefully designed and monitored research studies to test investigational study drugs, devices or procedures to find out if they are safe and effective before they can be approved for marketing and use for general public. The investigational product may be new and not tested on human beings before, or may be an existing medicine on the market that is going to be used in a new way.

Why should I take part in a clinical trial?

2 People take part in clinical trials for a number of reasons. If you are a patient with a health condition, you may wish to receive new investigational drugs that are intended to treat your health condition before these drugs become widely available. This may be because your health condition is not responding to standard medical treatment. Your participation will also help advance understanding of the disease and how to treat it. Everyone who takes part in a clinical trial is playing an important role in understanding a disease and making new medicines available.

Who is eligible to take part in a clinical trial?

3 Each clinical trial uses specific criteria to determine if volunteers are eligible to participate. These criteria include specific factors, such as age, type of disease, medical history and current health. Depending on the study, participants may be healthy individuals or those with the particular illness being studied. Well-defined inclusion and exclusion criteria are put in place for every clinical trial to ensure that only eligible participants are chosen for the study.

Does a person have to have an illness to take part in a trial?

4 Those who take part in a trial can be healthy volunteers or patients with an existing illness, depending on the phase and requirements of the study. A Phase I trial is performed on healthy volunteers (with the exception of studies on cancer medicines) and is designed to determine the best dose of the study drug and to check for any potential side effects. These trials usually involve a small numbers of participants. In Phase I trials, volunteers generally stay in a specially designed, hospital-like clinical unit during the entire duration of the study so that they can be monitored around the clock to confirm their safety. Phase II-IV studies are performed on patients who are suffering from the existing illness under investigation. In Phase II-IV studies, the patient is expected to periodically visit the hospital or clinic where the study is taking place. The frequency of these visits depends on the drug and disease being studied and study protocol, and the patient is closely monitored by the doctor in charge of the study as well as his/her study staff.

How can a patient take part in a clinical trial?

5 If the study doctor feels that a patient may qualify to take part in a study, the doctor invites him/her to take part in the study and takes him/her through the informed consent process. This consists of the doctor providing written information about the study to the patient in the language he/she is most comfortable with and explaining the risks and benefits of taking part in the study to the patient. The patient is informed that taking part in a trial is purely voluntary and

he/she can choose not to take part in a trial. Once a patient voluntarily decides to take part in a clinical trial, he/she has to go through a detailed assessment to see if he/she qualifies for the study.

What kind of information should a participant ask before deciding to take part in a clinical trial?

6 A potential study participant has the right to know and should ask the study doctors any questions he/she has related to the conduct of the trial and its potential impact on him/her before volunteering to take part. Some of these questions are:

1. Has the study drug been tested on humans before? If so, to what extent? What was the outcome?
2. What is the purpose of this study?
3. What are the likely benefits?
4. What are the known and possible risks?
5. Will any invasive procedures be carried out?
6. What is the study drug type and how often will it have to be taken?
7. How long will the study and each study visit last?
8. How often will I need to come to the hospital or clinic to take part?
9. What happens in case I become ill or develop any side effects?
10. What other treatment options do I have if I choose not to take part in the trial? If I enroll in the trial, do I have an option to stop taking part in the trial at any time? What happens to my treatment if I decide not to continue?

What is the 'Informed Consent Process'?

7 Informed consent refers to the process by which a potential clinical trial participant is informed by the doctor conducting the clinical trial of all the details of the study prior to his/her participation in a study. This includes treatment details and possible risks and benefits. This consent process must be done in a language that the patient is most comfortable with. The "Informed Consent Form" which contains all details about the study is used to aid the discussion. This document is written at a level that can be understood by a lay person and is approved by the Ethics Committee overseeing the study. The Informed Consent Form must be signed by the patient and the doctor prior to the subject's participation in a study, and a copy of the signed form must be handed over to the patient to keep. If the patient is unable to read/write, the study doctor provides all the information verbally and an impartial witness needs to be present during the entire informed consent discussion and must sign the Informed Consent Form indicating that all necessary information was provided to the patient. The informed consent process is required to be recorded on video under new guidelines in India.

How are a patient's rights protected?

8 Patient safety is of utmost importance in any clinical trial. Clinical study protocols are developed to ensure that risks to study participants are minimized. These protocols are carefully reviewed by an Institutional Review Board or Ethics Committee as well as country regulatory authority before a clinical trial can start.

Can a patient stop taking part in a trial midway?

9 Yes, a patient has the right to refuse to be part of a clinical trial at any point in time once he/she is enrolled and can leave at any time and for any reason. By doing so, the participant does not lose his/her right to receive the current standard of care.

Are people paid for participating in a clinical trial?

10 The payment for a clinical trial is based on the nature of the study a patient takes part in. In a Phase I study, a volunteer is compensated for the time spent at the clinical unit. The compensation varies by study and depends on the duration and type of study. In Phase II-IV studies, participants are reimbursed for expenses incurred in participating in a trial. This may include transportation costs, as well as boarding and accommodation costs in case a patient has to travel out of his/her place of residence to take part in a study. Participants in all phases of a clinical trial receive free medical consultation and medical care. Indian Good Clinical Practices Guidelines clearly state that payments should not be so large or the medical services so extensive so as to act as an inducement for a patient to take part in a study against their better judgement. All payments, reimbursement and medical services are approved by the local Ethics Committee.

The goal of clinical research is to bring superior and life-saving medicines and new devices and medical technologies to patients in need. Safety of the study participants is the most critical component of clinical trials, and that is why there are laws, regulations and processes in place to protect trial volunteers at every step. Nations around the world establish and enforce rules for the ethical conduct of clinical research which ensures that patient safety is made a priority.

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