NATIONAL CANCER GRID
COLLABORATION FOR CANCER CARE

CLINICAL TRIAL AWARENESS

"We Believe That Awareness Helps to Decide Better"

What is Clinical Research?

Clinical Research is a process to understand or search new safe and effective ways to improve the health by detecting, diagnosing, treating and preventing the disease that one might be suffering from.

I do not understand the jargons in document given to me.

Understanding the given document, also called “Informed Consent Document” is very essential for making decision regarding the participation in the trial. You can always ask your research doctors to explain the terms and answer your questions related to the trial. Your doctor will explain in detail regarding the trial including the aspects of the clinical trial like details, purpose, duration, procedures required, risks and potential benefits, emergency contacts, etc.

Does clinical research mean that doctors/ hospitals are experimenting on me?

Absolutely not. Clinical research is purely based on prior lab and animal studies as well as other preexisting scientific facts. It does allow research on human participant but that too is done ethically under the country laws and regulations. All the institutions/hospitals are obligated to take Institutional Ethics Committee's approval which ensures that the trial is ethically and scientifically sound or not.

How will it help me?

It may or may not help you but these new medicine in research will eventually become the new standard of care that will be offered to future patients. As whatever treatment is available these days has come out as a result of the research conducted over the years. In order to improve the outcomes of your disease, we do need to continue clinical research.

What is expected of me, if I participate in clinical research?

You are expected to follow study requirements for example, taking the study medication as directed, showing up for appointments, informing your research doctor or research staff about health problems, completing surveys or diaries (if any), weighing risks and benefits carefully before giving consent, informing the research staff regarding any changes in the contact information or if you wish to discontinue in the trial.

How do clinical trials ensure the protection of the participant's safety?

Clinical Trials are conducted in compliance to National/ International Regulations as well as Good Clinical Practice Guidelines. These guidelines are in place to safeguard the rights and welfare of the trial participants along with morals of science.

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Myths Vs. Truth

MYTHS	TRUTHS
 **I will be given treatment without my knowledge.**	It is actually reverse; the patients are invited to participate in the clinical trials and given a document to read and understand about the trial which is called Informed Consent Document. Your rights, safety and wellbeing are protected as there are stringent guidelines which make sure that the participants are treated with respect and dignity.
 **There is no way out, once you enter in clinical trial.**	Even after signing an informed consent form, participants are always free to leave the trial at any time point after informing the research team, without providing any reason.
 **My data privacy will not be maintained.**	Out of all the principles of clinical research, protecting and maintain the privacy of the trial participants is the utmost responsibility of the trial staff. Participants are made aware what all information is needed for trial and also that they can refuse anytime if they do not wish to share their data for further research purpose.
 **There will be frequent hospital visits.**	As every trial is different in nature, the visits and schedules vary too. Some trials need tests, procedures, clinic visits, and scans on weekly and monthly basis but many at times it does not require any more than the standard treatment requirements. Additional visits and procedures are done to closely monitor the participant safety only.
 **I have to bear the cost of the treatment if I get harmed.**	Usually, the cost of the trial treatment is borne by the sponsor. There are set of provisions for compensation if any trial participant is harmed during the trial.

Biotechnology Industry Research Assistance Council (BIRAC) is a Government of India enterprise which has taken an initiative to accelerate and support clinical trials.

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