Rights and Responsibilities of Research Participant
INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD

RIGHTS OF PARTICIPANTS IN A RESEARCH

A] What should you know about trial regulation?

1. Every research/ trial is undertaken only after due approval from competent government authorities and a local Institutional Ethics Committee made up of scientists, doctors, advocates and community members.
    a. These committees ensure that trial participants are exposed to the minimum possible risks and that the risks associated with the trial are reasonable in relation to the expected benefits.
    b. All participants need to be informed about the Institutional Ethics Committee details and are free to approach it for any grievance related to research/ clinical trial
2. To further ensure the safety of participants, a Data Safety Monitoring Board (DSMB) is commonly used.
    a. The DSMB is an impartial group that monitors the progress of clinical trials.
    b. They are not involved in the conduct of the trial but ensure patient safety by analysing the safety and effectiveness of the experimental treatment periodically during ongoing trial.
    c. They can terminate a trial if expected risk-benefit ratio is not being achieved.

B] What should you know about trial before consenting to participate in research?

1. Rights of Participants of research/ clinical trials are protected under law when participating in clinical trials.
2. The informed consent process is one of the key aspects of protecting research participants and decision to volunteer for a study is individual and free from undue influences. Before consenting to participate in clinical trial, potential participants are expected to
    a. Understand all the possible benefits and risks involved
    b. Understand duration and overall conduct of the study including follow up plan
    c. Understand what will be expected of you as a participant
3. The participant has the right to know everything that is going to happen in a study.
    a. He can ask any question and express all concerns about participation in the study
4. The potential participant has the right to refuse to take part in research without affecting his right to get due medical treatment [without prejudice or loss of future treatment].
    a. Participant is also free to withdraw from the study at any time without giving any reason and without having any effect on future treatment
5. During the research/ trial, the privacy of participants and the confidentiality of their data are maintained.
6. If new benefits, risks or side effects are discovered during a study, you will be informed about the same by investigator

RESPONSIBILITIES OF PARTICIPANTS IN A RESEARCH

- To adhere to taking the trial medication according to the prescribed dosages and schedule
- To undergo periodic investigations/ follow up as prescribed in trial protocol on schedule
- To immediately report any observation/untoward event (possible side effect) during the trial