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

**Rights of participants in a Research**

Before enrolling oneself in a research/ clinical trial, each participant must go through the following:

1. Participants of research/ clinical trials have rights, and they are protected under law when participating in clinical trials.
2. The informed consent process is one of the key aspects of protecting research participants.
3. The decision to volunteer for a study is individual and free from undue influences; no one can persuade a person to consent to greater than reasonable risk.
    a. Understand all the possible benefits and risks involved with participating in a clinical trial.
    b. Understand how long the study will last, where it will be conducted and the overall plan for the trial.
    c. Understand what will be expected of you as a participant in the clinical trial.
4. 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
5. 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].
6. During the research/ trial, the privacy of participants and the confidentiality of their data are maintained.
7. If new benefits, risks or side effects are discovered during a study, the researchers have to inform the study participants of the same.
    a. Stay informed of all the latest findings during the clinical trial that may affect your commitment to participation.
8. Sponsor has post-trial obligations regarding the appropriate follow-up with study participants
9. Every research/ trial is undertaken after due approval from competent authorities and a local Institutional Ethics Committee made up of scientists, doctors, advocates and community members.
    a. The committee meets to review and monitor a hospital or research institution's clinical trials.
    b. 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.
    c. Any institution that conducts clinical trials is required to have the trials reviewed and approved by its IRB before participants can enrol.
    d. All participants need to be informed about the Institutional Ethics Committee details and are free to approach it any time they feel like in case of any query regarding the participation in a given trial
10. 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 trial in any other way but ensure patient safety by checking for health-related problems called adverse events and by analysing the safety and effectiveness of the experimental treatment before the trial is completed.
    c. They can terminate a trial, if not found to be conducted as per the prevalent rules and regulations

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**Responsibilities of participants in a research**

- Adhere to taking the trial medication according to the prescribed dosages and schedule as poor medication adherence by research participants may have a detrimental effect on a trial
- Immediately reporting any observation/untoward event (possible side effect) during the trial
- Are expected to maintain their own health and avoid unnecessary risks whilst on the trial
- Need to discuss immediately any significant changes in participant's behavioural patterns with the trial team as it may impact trial results