

## RIGHTS AND RESPONSIBILITIES CHARTER OF A RESEARCH PARTICIPANT

### RIGHTS OF RESEARCH PARTICIPANTS

As a participant in a research study, you have the right:

1. To an informed discussion, with the researcher explaining the research question the study is trying to answer, how you would be involved, how long shall the study last, and your role in the study. This discussion shall be conducted in the language you understand, without any pressure and allow you sufficient time to decide whether you wish to participate in the study.
2. To be told about the reasonably foreseeable risks and possible benefits of participating in the study.
3. To be informed whether there are any costs associated and whether you will be compensated for participating in the study.
4. To privacy and confidentiality.
5. To be informed as to who will have access to information collected about you, and how your confidentiality will be protected.
6. To understand what part of the research is experimental and what is the standard of care.
7. To be told whom to contact with questions about the research, about research-related injury, about your rights as a research subject, how to voice a complaint to express concerns, violation of your rights and/or grievance and seek redressal.
8. To withdraw from the study or refuse to participate at any time without penalty or loss of benefits (leaving the study will not affect your medical care, student status, work status, etc.).
9. To be informed about the other non-research treatment choices you have and maintain continuity of care
10. To be informed regarding treatment details should you have a research-related injury, and who will pay for the same.

### RESPONSIBILITIES OF RESEARCH PARTICIPANTS

As a participant in a research study, you are expected to have the following responsibilities:

1. Read the consent form and other documents. Ask questions if you do not understand something about the study, or your rights and responsibilities as a research participant, weigh the risks and benefits when deciding whether to participate in the study or need more information.
2. Follow the directions for proper use, dosing and storage of self-administered study medications, providing biological samples, and preparing for tests, procedures or examinations.
3. Follow directions for abstaining from non study related medications, or other contraindicated medications or procedures.
4. Show up at scheduled appointments on time, and inform the staff within a reasonable time if you need to reschedule an appointment.
5. Provide truthful answers to questions asked during screening/enrolment and during the study.
6. Report any discomfort, pain and other problems and symptoms you experience during the study.
7. Not to take any medications without the knowledge of research doctor and research study team.
8. To disclose to doctors and research study team if you are currently part of any other Clinical Trial or have participated in any other Clinical Trial in the last one year.
9. Provide complete and accurate information about your health including your previous medical history, and all the medications that you are presently taking including alternative treatments like Ayurveda, Homoeopathy, Unani or herbal medications, all records of previous investigations and treatment and of allergic reactions, especially sensitivity to any drug.
10. If you decide to withdraw from the study, inform the doctor or staff and follow the procedures for withdrawal.