PATIENT INFORMATION SHEET

Study Title: Conducting Quality Health Assessment of Indian Women

Kindly read the patient information sheet carefully. You are free to clarify any queries regarding the study

1. **What is the background to and purpose of the study?**
   This data is being collected for root cause identification of patient indication from the purview of Alternate Medicine in synergy with mainstream medication.

2. **Do I have to take part?**
   It is up to you whether or not to take part in this study. You may refuse to take part or stop taking part in this study at any time. If you choose to do so, there will be no penalty or loss of benefits that you are already receiving.

3. **What will happen to me if I take part?**
   Taking part in this research study is voluntary. You may refuse to take part or you may withdraw from the study at any time for any reason without penalty and without any effect on your future medical care. The study staffs are required by law, to respect your wishes to not continue participation in this study. Whether or not you choose to take part in this study, you will still receive the standard medical care you already have been receiving

4. **What do I have to do?**

If you agree to take part in this study, you will first sign this patient Information sheet and informed Consent Form before filling the following General Health Assessment Form.There would be no additional test or procedure to be done other than the routine test /procedures required for the treatment you will undergo as part of standard treatment protocol.

5. **What are the possible side effects, risks and discomforts of taking part?**
   This is observation research study and participation involves no risk as only information will be collected during the study period.

6. **What are the possible benefits of taking part?**
   This is a study so the information and results acquired may not be beneficial or any benefit guaranteed. However the information generated may benefit future patients with the same condition for which you require treatment

7. **What if new information becomes available?**
   The study investigator may receive new information about the study procedure. If the investigator believes it may affect your decision to take part in the study, you will be told. If this changes your decision to take part in the study, please talk with the investigator or your physician about your decision. You may contact the study investigator at any time after your participation ends to find out if any new information about this study has become available.

8. **What are the costs of taking part?**
   You will not be paid for taking part in this study. Any other procedure as part of standard treatment would be charged to you as part of routine investigation and treatment
   .

9. **How will my personal data be used?**

By signing this form, you consent to the Study investigator and his or her staff to collect and use personal data about you for the study ("Study Data"). This includes: your date of birth, your sex, your ethnic origin and personal data on your health condition.

The Study Data shared with the any authorized person is protected by the use of a code (the "Code"), which is a number specific to you. The Study investigator is in control of the Code key, which is needed to connect Study Data to you.

An authorized person of the Sponsor, regulatory authorities or other supervisory bodies may review any Study Data held by the Study investigator. The Study investigator will use Study Data to conduct the Study. The Study investigator and sponsor are responsible for their handling of Study Data in accordance with applicable local Data Protection law(s).

If you withdraw your consent, the Study investigator will no longer use Study Data or share it with others. The Sponsor or study doctor may use Study Data that was shared before you withdrew your consent By signing this form, I consent to the use of Study Data as described in this form

10. **Will there be provision for free treatment for research related injury?**

As all the procedure which will be done by a doctor is part of the normal process for the condition which you will undergo treatment, hence there are no risks of disability or death to the subject.

11. **Will compensation be paid to the subjects if disability or death results from such injury?**

Since, all the procedures are part of standard treatment we understand that there is no/minimum scope of research related injury. Therefore there will be no compensation paid or applicable.

12. **Whom should I contact if I need more information or help?**

You have the right to ask questions about this study at any time and are encouraged to do so. If you have any questions about this research study you may contact the study the study staff at:

Investigator's Name: **Daytime telephone number(s):** **24-hour contact number(s):**

13. **If you have questions about your rights as a research subject, you may contact the (IEC Member Secretary Contact Details & Address).**

An Institutional Ethics Committee is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's rights and welfare in mind. IEC has reviewed and approved the research study described in this patient Information sheet and informed Consent Form.

If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IEC at the above mentioned number if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator.

Disclaimer: The study does not aim to provide any treatment advice to the participants