**SDM TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST GRADUATION CENTRE AND PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE, TERDAL-587315, KARNATAKA.**

**PATIENT INFORMATION SHEET**

**1. Study Title:**

**“A CLINICAL COMPARATIVE STUDY TO EVALUATE THE EFFECT OF *MUSTA CHURNA* AND *SHATAVARI CHURNA* IN THE MANAGEMENT OF *STANYA KSHAYA* W.S.R TO LACTATION FAILURE ”**

**2. Invitation:**

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve, please take time to read the following information carefully and discuss it with parent(s) / guardian(s) if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**3. What is the purpose of study?**

The purpose of the study is to evaluate the therapeutic effect of *MUSTA CHURNA* OVER *SHATAVARI CHURNA* in the management of *STANYA KSHAYA* W.S.R TO LACTATION FAILURE.

**4. Why have I been chosen?**

Being a patient of *STANYA KSHAYA* you are considered as an ideal candidate for the study.

**5. Do I have to take part?**

It is up to you to decide whether to take part or not. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form later. If you agree to take part, you are still free to withdraw at any time even without giving any reason. This will not affect the standard of care you receive.

**6. What will happen to me if I take part?**

If you agree to take part in this study, you will be subjected to *MUSTA CHURNA* OR *SHATAVARI CHURNA*, prior to which you have to undergo general physical examination and Investigations which includes routine blood tests under necessary conditions.

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

You have to adhere to the instructions given to you by your Investigating physician regarding the treatment as advised and reporting for assessment on the prescribed day. During the course of the trial, you can safely continue with your regular medication (for which you need to intimate your investigating physician) and the only word of caution is that you should follow and obey the instructions of your investigator very religiously while continuing with the trial treatment.

**8. What is the drug or procedure that is being tested?**

The patient selected in the clinical trial will be given the following Ayurvedic Treatment:

Name of the Treatment: *Shamana aushadhi*.

Name of the Medicine: GROUP (A): *MUSTA CHURNA*.

GROUP (B): *SHATAVARI CHURNA.*

Dose: 6g (3g BD).

Route of Administration: Oral.

Time of Administration: *Pragbhakt*a (Before food) (Starting from 5th day after the delivery)

Duration of treatment: 30 days

**9. What are the expected side effects / risks of the treatment?**

Though the side effects are not very common, an Investigating physician will take a brief history and reveal the facts about the benefits and side effects of the treatment, yet individual specific side effects may appear at any time during the course of the clinical trial which you have to report immediately to your investigating physician.

**10. What are the possible benefits of taking part**?

This treatment is expected to relief from the signs and symptoms of the disease. It is not guaranteed that you will definitely get cured of your ailment and feel rejuvenated after completing the course of the trial drugs, but your participation will help us in generating sufficient data to validate the effect and safety of *MUSTA* *CHURNA* AND *SHATAVARI CHURNA* in the management of *STANYA KSHAYA* W.S.R TO LACTATION FAILURE .

**11. What if new information becomes available?**

If during the course of the clinical trial, some new information becomes available about the Ayurvedic treatment being studied, you will be informed about that by your investigating physician after which you are free to decide whether you want to continue in the study or not. If you decide to withdraw, this will not adversely affect your routine care in the hospital. If you decide to continue in the study, you will be asked to sign a fresh consent form. On the other hand upon receiving new information, your investigating physician might consider it to be in your best interests to withdraw you from the study. Your investigating physician will explain the reasons for dropping you from the study and arrange for your routine care to continue.

**12. What happens when the research study stops?**

You will be given appropriate advice for future line of treatment.

**13. What if something goes wrong?**

If you experience any adverse effects, you should inform the researcher immediately. You can call

Dr. Sreelekha Sethi to her mobile no- 8249438906 or meet the study doctor directly.

**14. Will my taking part in this study be kept confidential?**

Yes, all your information will be kept confidential. But, any of your medical records may be inspected by the concerned authority for the purpose of analyzing the results. They may also be looked at by members of Institutional Ethics Committee and by Regulatory authorities / Court to check that the study is being carried out correctly. Your name, however, will not be made public and any sensitive matter regarding your state of health will be kept confidential.

**15. What will happen to the results of the research study?**

The results of the clinical trial will be published in leading medical journals so that other doctors and researchers can benefit from the results. You can ask your investigating physician for a copy of the publication.

**16. How to withdraw from the study?**

Subjects will be free to withdraw from the study at any stage without assigning any reason, without penalty or loss of benefits to which he/she would otherwise been titled.

**17. Compensation of subjects for disability or death in the duration of study?**

Not applicable.

**18. Contact for further information:**

If desirous of any relevant information at any stage of the clinical trial, you may feel free to ask your investigating physician for that information.

Dr. Sreelekha Sethi, mobile no- 8249438906

You would be given a copy of the information sheet and a signed consent form.