PATIENT INFORMATION SHEET

1. **TITLE OF STUDY: IMPACT OF PERINEAL BODY LENGTH AND THE EXTENT OF PERINEAL INJURY DURING LABOUR AMONG WOMEN UNDERGOING VAGINAL DELIVERY AT HOSPITAL TUANKU JA'AFAR, SEREMBAN, MALAYSIA**
2. **NAME OF INVESTIGATOR : DR.SABEETHA A/P SEGARAN**
   INSTITUITION: HOSPITAL TUANKU JA'AFAR, SAREMBAN
3. **NAME OF SPONSOR: NO EXTERNAL SPONSOR**

4. INTRODUCTION:

It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you would like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to determine whether the length of the perineal body is associated with the extent of perineal injury among women who have a vaginal delivery.

The perineal body is the area of tissue between the vaginal opening and the anus. During vaginal childbirth, this area stretches to allow the baby to be delivered. The study will investigate whether differences in the length of this area are associated with the degree of perineal injury sustained during vaginal delivery.

The study will also examine the occurrence of obstetric anal sphincter injury (OASI), which refers to third- and fourth-degree perineal tears involving the anal sphincter complex. The study will be conducted for duration of 12 months (19/10/2026 till 30/10/2027). The expected number of participants is 1600 women.

6. Why have I been invited to participate?

You are being invited because you are an adult woman who has been admitted to the labour room and may fulfil the eligibility criteria for this study.

Participation is voluntary. Your decision whether or not to participate will not affect the medical care you receive.

7. What are the potential risk and side effect of being in this study?

This study involves minimal additional risk.

The perineal body measurement will be performed before vaginal examination that is part of your clinical care. You will not experience any discomfort during the procedure as it will not be invasive.

No medication, procedure or intervention will be given as part of the study to alter your labour or delivery.

8. What are the benefits of being in the study?

You may not receive any direct personal benefit from participating in this study.

However, the information obtained may improve understanding of the relationship between perineal body length and perineal trauma during vaginal delivery and may contribute to future research and improvements in obstetric care.

9. Who is funding this study?

This study does not receive any external funding

10. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study, qualified monitors and auditors, and governmental or regulatory authorities may inspect the study data, where appropriate and necessary.

11. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about this study, please contact the study doctor, Dr.Sabeetha Segaran at telephone number: 06-7684000.

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407/8205/8888.

INFORMED CONSENT FORM

Title of Study: IMPACT OF PERINEAL BODY LENGTH AND THE EXTENT OF PERINEAL INJURY DURING LABOUR AMONG WOMEN UNDERGOING VAGINAL DELIVERY AT HOSPITAL TUANKU JA' AFAR, SEREMBAN, MALAYSIA

By signing below, I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at any time feel free to withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study currently. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study. *(*delete which is not applicable)*

Subject: **Impartial witness:**

Signature: I/C number: Signature: I/C number:

Name: Date: Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date: