INFORMED CONSENT FORM

Name :

Date : ☐☐/☐☐/☐☐☐☐

Time : ☐☐:☐☐

Explanation Form to Subject Candidates

I am dr. Andini Juwan Prabandari with our research team Prof. Dr. Mustofa, M.Kes., Apt, Dr. dr. Diah Rumekti Hadiati, SpOG(K)-KFM, MSc, dan Dr. dr. Setyo Purwono, M.Kes, Sp.PD form Center for Herbal Medicine, Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, Yogyakarta, Indonesia. We will conduct a clinical trial research with the title: "Efficacy of ASIMOMMY® Compared to Domperidone and Placebo in Increasing Breastfeeding: Randomized Single-Blind Controlled Trial in Indonesia".

This study aims to determine the comparison between ASIMOMMY® and domperidone in increasing breast milk production in postpartum mothers. The research team invites you to participate in this study. This study requires about 45 research subjects.

A. Voluntary participation in The Study

You are free to choose to participate in this study without any coercion. If you have decided to participate, you are also free to withdraw/change your mind at any time without being subject to any fines or sanctions. If you are not willing to participate, you will still receive treatment according to the applicable standard procedures.

B. Research procedure

If you are willing to participate in this study, you are asked to sign this consent form in duplicate, one for you to keep, and one for the researcher.

The next procedure is:

1. You will be interviewed by the doctor to ask for: name, age, parity, gestational age at delivery, education, obstetric history, medical history, allergy history, and breastfeeding history in previous deliveries.
2. You will be measured for weight, height, vital signs such as blood pressure, pulse, respiration, and temperature as well as breast nipple condition.
3. You are not taking any medications or breast milk enhancement supplements.
4. You will be given lactation counseling before the start of the study.

5. Your baby will be measured for weight and assessed for suction reflex. Your baby will only consume breast milk.
6. You will be given a research product, which you and the researcher do not know. The rules of use will be on the bottle and will be explained to you during the administration process.
7. You will receive all capsules of the research product on the first day to take for 7 days.
8. You will be given a daily breastfeeding diary card to control your compliance with the study product, monitoring of side effects, frequency and duration of breastfeeding, and food and beverages consumed by you.
9. At the beginning of the study, on day 3 after delivery, you will make your first visit to the health center for baseline weighing of your baby before the start of the intervention.
10. The intervention starts on the 3rd day after delivery until the next 7 days (10th day postpartum) of product administration, and the baby's weight is evaluated on the 7th day of the intervention. Then, the weight gain was assessed, which was obtained from the difference between the baby's weight on day 7 of the intervention and the baby's weight on day 0 (before the intervention).
11. In this study, the drop out criteria included you/your baby was sick so you could not continue the study, your baby drank formula milk while the intervention was still ongoing, you did not drink the study product for 2 consecutive days and there was an allergic reaction to the study product given. You were lost to follow up if you did not come to weigh your baby's weight as scheduled.
12. Baby weight weighing was conducted at Tegalrejo Health Center and Jetis Health Center, at 08.00-10.00 WIB using Onemed OD-231 digital baby scale with accuracy of 0.01 kg. When weighing the baby, do not wear clothes or pampers.

C. Obligations of research subjects

As a research subject, you are obliged to follow the research rules or instructions as written above. If there is anything that is not clear, you can ask the researcher further. During the study, you are not allowed to take other drugs or herbs other than those given by the researcher.

D. Risks and Side Effects and Management

During the study, the researcher provided necessary examinations and treatment in case something untoward happened. The examination and treatment provided by the researcher are anticipatory measures and treatment due to side effects and complications. If allergies,

side effects or complications occur, they will be treated according to complaints and consulted to the relevant specialist appointed by the researcher. The cost of examination and treatment is entirely borne by researchers from Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, Yogyakarta, Indonesia.

E. Benefit

The direct benefit you get is that you get information about the effectiveness of ASIMOMMY® in increasing breast milk production in postpartum mothers.

F. Confidentiality

All information related to the identity of the research subjects will be kept confidential and will only be known by the research team. The results of the research will be published without the identity of the research subjects.

G. Compensation

The mother's involvement in this study will receive transportation costs from the researcher of IDR 200,000.

H. Funding

All research-related costs will be borne by the researcher.

I. Additional Information

You will be given the opportunity to ask any questions you may have about the study. If at any time there are side effects or need further explanation.

You can contact Andini Juwan Prabandari, MD at 082220358710 at the Center for Herbal Medicine, Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, Yogyakarta, Indonesia. You can also ask about research to the Ethics Committee for Medical and Health Research, Faculty of Medicine UGM (Tel. 0274-588688 pswt 17225, +628112666869 or email: mhrec_fmugm@ugm.ac.id).

INFORMED CONSENT FORM

Clinical Trial of ASIMOMMY®

Completed by : Doctor or Midwife Site

Subject ID : ☐/☐☐/☐☐☐

Date Signature: ☐☐/☐☐/☐☐☐☐

Time : ☐☐:☐☐ (using 24 hour format)

Informed Consent Form **(Agreement after explantion) as Research Subject**

I, the undersigned below:

Name : ……..

Age : …….. years

Address : ……..

Has received an explanation as written on the Explanation Sheet to Prospective Subjects previously regarding participation in the Clinical Trial research entitled "**Efficacy of ASIMOMMY® Compared to Domperidone and Placebo in Increasing Breastfeeding: Randomized Single-Blind Controlled Trial in Indonesia**".

I have understood the purpose and procedure of this research and understand that I may terminate my consent to participate at any time.

I understand that if I need an explanation, I can ask dr. Andini Juwan Prabandari. I have been given the opportunity to ask questions and have understood the answers to my questions.

By signing this form, I agree to participate in this research voluntarily without coercion. If there are complications and or side effects that are not due to the doctor's negligence, then I will not make demands.

Researchers who gave *informed consent*: Research subject

…..…… …..……

Independent Witness
(if participant cannot read/write)

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