Address : Jl. Telegraf I Blok C3 No. 16 Taman Telkomas, Makassar. Email: unhas.dsmfirmenich@gmail.com. Telp: 087754728228

INFORMED CONSENT FORM & RESEARCH QUESTIONNAIRE

Official Title:

Human Milk Oligosaccharides in Breast Milk and Its Relation to Gut Bifidobacterium, vitamin D and Immune Modulation in Infants

NCT Number : (not yet assigned)

Document Dates : 10TH July 2025

Responsible Personnel

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INFORMED CONSENT FORM (*To be completed by the Participant*)

I, the undersigned:

Mother's Name : .....

Age : .....

having heard/read and understood the explanation provided regarding the purpose, benefits, and procedures of this study, hereby consent to participate in this study voluntarily and without coercion. I also agree to provide samples (breast milk, infant blood, and infant stool) as needed.

I understand that my participation is voluntary and without coercion, so I may refuse to participate or withdraw from this study at any time. I have the right to ask questions or request clarification from the researcher if there are any unclear points or if I wish to know more about this study.

I also understand that all costs incurred in connection with this study will be covered by the researchers. I trust that the security and confidentiality of the research data will be ensured, and I hereby consent to all my data generated in this study being presented in both oral and written form.

By signing below, I confirm my voluntary participation in this research study.

Name	Signature	Date
……..	……..	……..

Principal Investigator:

Name : dr. Bahrul Fikri, M.Kes, Sp.A(K), Ph.D

Address : Jl. Telegraf I Blok C3 No. 16 Taman Telkomas

Mobile Number : 087754728228

Address : Jl. Telegraf I Blok C3 No. 16 Taman Telkomas, Makassar. Email: unhas.dsmfirmenich@gmail.com. Telp: 087754728228

RESEARCH QUESTIONNAIRE

Study Title: Human Milk Oligosaccharides in Breast Milk and Their Relation to Gut Bifidobacterium, Vitamin D, and Immune Modulation in Infants.

A. GENERAL INFORMATION (*To Be Completed by the Staff*)

Subject No :

MOTHER'S IDENTITY

1. Mother's Name : _____
2. Date of Birth : ___ / ___ / _____ Age : _____ years
3. Address : _____

   _____
4. Mobile No (WA) : _____
5. National ID Number : _____
6. Mother's Job : _____
7. Education Level : ☐ Elementary School ☐ Junior High School

   ☐ Senior High School ☐ Diploma ☐ Bachelor

   ☐ Master's/Doctorate ☐ Other (please specify)

BABY'S IDENTITY

8. Baby's Name : _____
9. Baby's Gender : ☐ Male ☐ Female
10. Date of Birth : ___ / ___ / _____
11. Current Age : _____ month(s) _____ day(s)

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B. RESEARCH PARTICIPANT SCREENING FORM *(To Be Completed by the Staff)*

(Check (√) if eligible)

1. Are you and your baby in good health right now?
   ☐ Yes ☐ No
2. Was your baby born at full term (37–42 weeks)?
   ☐ Yes ☐ No
3. Was your baby born weighing 2,500–4,000 grams?
   ☐ Yes ☐ No
4. Does your baby have any congenital abnormalities or conditions present at birth?
   ☐ Yes ☐ No
5. Have you been exclusively breastfeeding your baby since birth?
   ☐ Yes ☐ No
6. Are you currently taking antibiotics or other medications that could affect the quality of your breast milk?
   ☐ Yes ☐ No
7. Has your baby ever taken or is currently taking antibiotics (oral or injection)?
   ☐ Yes ☐ No
8. Do you have a breast condition (e.g., infection, abscess, breast tumor)?
   ☐ Yes ☐ No
9. Are you and/or your baby currently participating in another research study or clinical trial?
   ☐ Yes ☐ No
10. Are you willing to participate in this study and sign the informed consent form?
    ☐ Yes ☐ No

C. MATERNAL HEALTH AND NUTRITION HISTORY *(To be completed by the Staff)*

11. Do you have any chronic conditions?
    ☐ No ☐ Yes, specify: _____
12. Are you currently taking any specific medications?
    ☐ No ☐ Yes, specify: _____
13. Do you take vitamin supplements or probiotics during pregnancy or while breastfeeding?
    ☐ No ☐ Yes, specify: _____
14. How often are you exposed to direct sunlight?
    ☐ Every day (>15 minutes) ☐ 3–4 times a week ☐ <3 times a week ☐ Never
15. Do you regularly consume fermented foods or beverages?
    ☐ No ☐ Yes, specify: _____

D. BIRTH AND BREASTFEEDING HISTORY (*To be completed by the Staff)*

16. Delivery method : ☐ Vaginal Delivery ☐ Cesarean section (C-section)
17. Breastfeeding method * : ☐ Direct breastfeeding (DBF) ☐ Expressed breast milk

(both may be checked)

18. When was your baby first breastfed after birth?

☐ <1 hour ☐ 1–6 hours ☐ >6 hours

19. Is your baby given vitamin D supplements?

☐ No ☐ Yes, starting at: _____ days, dose: _____ IU/day

E. BABY'S STOOL OBSERVATION (*To be completed by the Staff)*

20. Average frequency of the infant's bowel movements per day:

☐ <1 time ☐ 1–3 times ☐ >3 times

21. Consistency of the baby's stool:

☐ Soft ☐ Liquid ☐ Firm

F. ALLERGY HISTORY AND RISK FACTORS (*To be completed by the Staff)*

22. Does your baby have any allergies?

☐ No ☐ Yes, please specify: _____ (Examples: runny nose, eczema, asthma, food allergies)

23. Is there a history of allergies in the immediate family (Father/Mother/Siblings)?

☐ No ☐ Yes, please specify: _____ (Examples: runny nose, eczema, asthma, food allergies)

24. How many siblings does your baby have?

☐ _____

25. How many family members live in the same household as your baby?

☐ _____

26. Do you have any pets at home?

☐ No ☐ Yes, please specify: _____

G. GENERAL PHYSICAL EXAMINATION (*To be completed by the Staff)*

MOTHER :

27. Vital Signs : Blood Pressure : _____ / _____ mmHg
    Pulse : ____ beats / minute
    Respiratory : ____ breaths/minute
    Temperature : ____ ^{0}C
28. Anthropometric Status: Wieght : _____ kg Height : _____ cm
    BMI : _____ kg/BB^2

BABY :

29. Vital Signs : Pulse : ____ beats / minute
    Respiratory : ____ breaths/minute
    Temperature : ____ ^{0}C
30. Anthropometric Status: Wieght : _____ kg Height : _____ cm
    BMI : _____ kg/BB^2