POPS-project: RCT ____/ ____/ 2023

Preventive effect of Perinatal Oral Probiotic Supplementation (POPS) on Neonatal Jaundice: RCT

Consent Form

Participant detail

Name	**HKID No.**	**Study Code No. (**For staff only)

I declare that I consent voluntarily to take part in the aforesaid research study:

1. I confirm that I fully understand and voluntarily join the study.
2. I fully understand and agree that I will be assigned to either **Study group #1 (Probiotic group)** or **Study group #2 (Placebo group)** randomly (by computer-generated lottery method like flipping a coin) and take one sachet of the provided supplement (probiotic or placebo) daily from 36th weeks of gestation until one week postpartum. Stool and hair sample from me will be collected just immediately before initiation of the intervention at 36 weeks of gestation and after 3 weeks of intervention (post-intervention sample). During delivery, cord blood and placental samples will be collected. After giving birth in the Prince of Wales Hospital, within the second and on the seventh day of life, my baby will be measured for bilirubin level by touching my baby's skin on the chest using the Jaundice meter. Both 3 ml of breast milk and freshly soiled diapers will also be collected within the second and on the seventh day of birth parallel to bilirubin measurement. Additionally, I agreed that my baby's hair sample will be collected on the 7th day of birth. All the samples and the transcutaneous bilirubin measurement will be made by the research staff at the Prince of Wales Hospital.
2. I agree to transfer ownership of the collected stool, hair, cord blood, placenta and breast milk samples, and bilirubin measurement records of mine and my baby to the POPS-project research team so it can be processed, frozen and stored, analysed, interpreted, translated, and published as research output.
3. I agree that the collected samples will be used for laboratory studies, molecular, clinical prediction, and other non-clinical and clinical studies.
4. I agree to allow the research staff to review my hospital medical records as well as my baby's during the study period for this pregnancy to evaluate the suitability of my samples and for outcome measurements.
5. I agree to answer and complete the questionnaires related to my medical history and family genetic history as well as dietary intake. I also agree to provide my own and my baby's stool samples as above.
6. I agree to all research personnel to contact me in the future regarding my baby's and my health.
7. I understand my participation in the study will not affect my usual medical care and clinical management.
8. I understand that the procedures in the research study will not involve any known additional risk to my health.
9. I understand and agree that I and my baby will not be paid for participation in this study. This research output one day may lead to products. However, I and my baby will not receive money from the commercialization of any such products.
10. I understand and agree that the study and personal data will be kept for three years after the completion of the study and then destroyed.
11. All the information provided by me is correct and will be kept confidential. I authorize the access to, the use of, and the retention of the study information by the investigators, study group, study institutions and their representatives, The Joint CUHK-NTEC Cluster and other regulatory authorities/IRB/ in the manner described in this informed consent process.
    I acknowledge that I understand the contents of this consent form.
    If you have any questions, please contact investigators, Department of Obstetrics and Gynaecology, CUHK or The Joint CUHK-NTEC Clinical Research Ethics Committee during office hours.

Participant	Research Assistant	Witness
Signature	Signature	Signature
Name	Name	Name
Date	Date	Date

It confirms the voluntary participant signed above totally understand the study to be participated, and the authenticity of the consent.