Research Participant Consent Form

1. Project name: The impact of daily mother-infant skin-to-skin contact in postpartum women on sleep quality ,maternal confidence ,and mother-infant bonding

2. Research basic information Medical record number:_____

1. Project number:
   IRB case number / application number:
2. Testing institution: Renai Hospital, Dali, Taichung
3. Unit where the executor belongs: Department of Obstetrics and Gynecology
4. Commissioning unit / manufacturer : None
5. Host: Chen Rongdi Service unit: Yuanlin Christian Hospital
   Job Title: Head Nurse electricity talk: 0980-407312
   Co-host: Wang Wenzhong Service unit: Taichung Dali Renai Hospital
   Job Title: Director of Obstetrics and Gynecology electricity talk:_____
   Emergency contact number for study participants: 0 980-407312
6. Study Participant Name: Study Participant Study Number:
   gender: Date of birth:
   Correspondence address:
   Contact number:

3. Introduction:

Hello, we would like to invite you to participate in a study on daily skin-to-skin contact between mother and baby in postpartum women. This study will be conducted at Dali Renai Hospital in Taichung. By regulation, you must be informed of the purpose of the research and possible risks. Before you agree to participate in this study, the contents of this subject consent form will be explained to you. Please read this subject consent form thoroughly again and ask any questions clearly.

4. Research purpose:

Understand the impact of daily skin-to-skin contact between mother and baby in postpartum women on sleep quality ,maternal confidence ,and mother-infant bonding.

5. Inclusion/exclusion conditions:

1. You are eligible to participate in this trial if you meet the following inclusion/exclusion conditions

1. Inclusion criteria

(1) Primiparous women who give birth vaginally

(2) Full-term delivery 3 and 7 weeks or more

(3) The pregnancy and delivery process are low-risk cases

(4) Can listen, listen, read and write Chinese
(5) Agree to participate in this study
(6) No mental condition
(7) The newborn’s vital signs are stable after birth
(8) The body appearance is normal after birth and there are no other complications.
(9) Can be discharged from hospital together with mother
2. Exclusion conditions
(1) Transfer of newborn to sick nursery after birth
(2) Mother takes sleeping pills
(3) Maternal women under 18 years old

6. Description of test methods and procedures:
The estimated number of participants in this study is 108 , who will be randomly assigned to the experimental group and the control group. The study participation period lasts for one month from the first day to the thirtieth day after delivery. The relevant measures in the experiment are postpartum skin-to-skin contact measures between mother and baby. Please complete the consent form. The method of proceeding will be explained later. This research department will conduct invasive behaviors, but if during the course of the postpartum research, the research intervention plan cannot be continued due to personal factors, we may terminate the research project participation at any time.

7. Expected risks, side effects, incidence rates and treatment methods:
1. Physiological aspects: Physiological discomforts such as postpartum uterine contraction discomfort, vaginal wound discomfort, etc., affect the skin-to-skin contact between mother and baby.
Treatment: Take painkillers as directed by your doctor.
2. Psychological aspect: Insufficient experience in postpartum childcare causes stress.
Processing method: Contact the study leader.
3. Social aspect: Family members do not understand the implementation purpose and have insufficient support, which affects the skin-to-skin contact between mother and baby.
Treatment method: The researcher will assist in explaining.

8. Other possible treatment methods and instructions: None

9. The taboos and restrictions of this test, please ensure your full cooperation:
When making skin-to-skin contact between mother and baby, the mother’s mental

state should be awake and stable, pay attention to warmth when interacting with the baby, and pay attention to whether the baby's respiratory tract is blocked.

10. Expected test results:

According to foreign studies, skin-to-skin contact between mother and baby immediately after delivery can stabilize the newborn's body temperature, heart rate, respiration, blood oxygen concentration, actively suck breast milk, improve immunity, reduce pain perception, and increase parent-child interaction. For mothers, it can promote postpartum uterine contractions, reduce postpartum hemorrhage, increase breastfeeding rates, reduce postpartum perineal wound pain, stabilize postpartum emotions, improve parent-child relationships, and many other benefits; continuous mother-infant skin-to-skin contact can help parent-child interactions become more coordinated and harmonious. Newborns respond better to the outside world; their maternal anxiety is reduced and postpartum depression is less likely to occur, so participating in this study in the future may be beneficial to both you and your newborn.

11. Handling of emergency situations:

If you are participating in this study and an emergency occurs and mother-infant skin-to-skin contact cannot be performed, the host Chen Rongdi's 24-hour emergency contact number is 09 80-407-312 .

12. Subsidies, cost burdens and damage compensation:

1. Subsidy: None.
2. Cost burden: No fees are required.
3. Damage compensation:

(1) If an adverse reaction occurs in accordance with the research plan established by this study and causes damage, the hospital and the trial host shall be responsible for compensation according to law. However, no compensation will be provided for expected adverse reactions recorded in the consent form of participants in this study.
(2) If adverse reactions or damage occur as a result of the research plan formulated in this study, our hospital is willing to provide professional medical care and medical consultation. You do not have to pay for necessary medical treatment to treat adverse reactions or injuries.
(3) Except for the compensation and medical care in the first two items, this study does not provide other forms of compensation. If you are unwilling to accept such risks , please do not participate in the trial/research.
(4) You will not lose any legal rights by signing this consent form.

13. Protect privacy and confidentiality:

1. There will be a research code representing your identity. This code will not display your name, ID number, or address.
2. The research host will keep the results and diagnosis of your interview confidential and carefully maintain your privacy. If the research results are published, your identity will remain confidential.

3. Please also understand that by signing the consent form, you agree that your interview records can be directly reviewed by monitors, auditors, research ethics committees and competent authorities to ensure that the research process and data comply with relevant laws and regulations. The above persons also promise not to breach the confidentiality of your identity.
4. Please understand that for safety reasons, the research team may inform or contact your attending physician in other departments to let them know about the trial you are participating in and the treatment status of the disease, so as to avoid harm caused by drug interactions.
5. Since the experimental drugs are being tested in the United States and the European Union at the same time, the test results will be published in accordance with the drug management regulations of the United States or the European Union. clinical trial information websites: clinicaltrials.gov (US) , clinicaltrialsregister.eu (EU) , but your personal information remains It will be kept confidential and only a summary of the trial results will be available on the site. You can search the site at any time. (Please delete this paragraph if it does not apply)

14. Withdrawal and suspension of the trial:
Research participants or consent signers have the right to request to terminate participation in the trial at any time without any reason. This will not derogate from your legitimate medical rights and legal rights. The trial host or sponsor may also suspend the trial if necessary. For your safety, you must withdraw from the trial/study when:
(Please list exit conditions)
When there is important new information in the execution of the trial/research (referring to your rights and interests or affecting your willingness to continue to participate), you will be notified and further explained. Please reconsider whether to continue to participate. You can make your decision freely and will not cause any problems. Any unpleasantness or impact on the physician's future medical care for you.
When you withdraw from this trial/study or the moderator determines that you are not suitable to continue participating in this trial/study, the data obtained before withdrawal will be retained and will not be removed. After exiting, you can choose how to handle the specimens you previously provided, and decide whether to agree to the trial host (or sponsor) to continue to collect your information.
1. Regarding the specimens I provided previously
□I agree to continue to authorize this trial/study to be used for research related to the disease in this trial. If the use exceeds the scope of the original written consent, you need to obtain my consent again.
□I do not agree to continue to authorize the use of this test/research, but in order to ensure the accuracy of the completed inspection, I agree that

the test/research related specimens can be re-confirmed by the laboratory and then destroyed.

☐ If you do not agree to continue to authorize the use of this test/research, please destroy my previous specimens related to this test/research from the date of withdrawal.

2. After withdrawing, let the trial host (or sponsor) continue to collect my information, such as obtaining subsequent medical procedures and laboratory test results through my medical records. While data collection continues, your privacy and the confidentiality of your personal data will still be maintained.

☐Agree to collection.

☐I do not agree to the continued collection or review of my data by this trial/research, except for records that can be searched through public databases.

15. Rights of research participants:

1. For the collection, processing and use of your personal data, the research institution/trial host will handle it in accordance with the research participant consent form, relevant regulations on human research and the relevant provisions of the Personal Data Protection Act. You may exercise the following rights by contacting the trial institution/trial host in writing in accordance with the provisions of the Personal Data Protection Law :

(1) Inquire or request access to your personal information;
(2) Request a photocopy of your personal information;
(3) Request to supplement or correct your personal information;
(4) Request to stop collecting, processing or using your personal information;
(5) Request to delete your personal information.

2. During the research process, any significant findings that may affect your willingness to continue receiving research will be provided to you in a timely manner. If you have any questions or problems during the research process, please contact the moderator.

3. If you have any questions about your rights as a research participant or suspect that you have been harmed by participating in a research, you can contact the research participant rights protection unit of our hospital for consultation. The phone number is: (04) 24819900 ext. 11160

4. We respect your decision whether to participate in this study. You will not receive any differential medical or non-medical treatment due to not signing the consent form, and your personal wishes are respected .

16. Test results and ownership of rights and interests:

If the results of this pilot project produce academic literature publication, substantial benefits, or derive other rights and interests, we also agree to donate it to the hospital free of charge.

17. Preservation and reuse of personal information, specimens and specimen derivatives:

(If destroyed directly, please indicate: **After the end of this research, any**

remaining specimens will be destroyed and will not be saved).
All new research plans must be reviewed and approved by the Human Research Ethics Committee of Dali Renai Hospital. If the Human Research Ethics Committee determines that the new research exceeds the scope of your consent, we will require us to obtain your consent again.
Do you agree to provide the remaining specimens for future ○ ○ ○ ○ research purposes, and authorize the Human Research Ethics Committee of Dali Renai Hospital to consider whether it is necessary to obtain your consent again:
☐ 1. I do not agree to save my remaining specimens. Please destroy them after the test.
Subject's signature:_____ date:__year month day
☐ 2. Agree to save my remaining specimens in a non-delinked manner. If the use exceeds the scope of the original consent, you need to obtain my consent again before using my specimens for new research.
☐I agree that the remaining specimens after the completion of this research will be deposited in the human biological database of Renai Hospital, Dali , for use in other subsequent research approved by the Human Research Ethics Committee of the hospital. (Please also sign the Human Biobank Participant Consent Form)
Subject's signature:_____ date:__year month day
☐I agree that the remaining specimens after the completion of this research will be deposited in the organization bank of Renai Medical Foundation Dali Renai Hospital for use in other subsequent research approved by the Human Research Ethics Committee of our hospital. (Please also sign the remaining specimen consent form)
Subject's signature:_____ date:__year month day
3. Genetic testing results (if this plan does not involve genetic testing, please delete this item)
Please choose one of the following contents to fill in according to the test situation.
Example 1: If there is any new information from the genetic test results, do I need to provide information to inform you:
☐Need to inform ☐No need to inform
Example 2: Genetic test results will not inform individual patients of their test results.

18. Statement:
1. The content of this trial and the consent form have been_____ _(Please fill in the name of the person who obtained the consent form) Complete oral notification and explanation. The research participant/legal representative has fully understood and agreed. This consent form is in duplicate. A copy of the consent form for collection of human specimens for research has been handed over to the researcher. participants.
2. If you participate in this study as a prisoner, it will not have any impact on your parole. [When your research includes research participants who are prisoners, please add Note 2., if this study has nothing to do with prisoners,

please delete Note 2.]

A. Subject:_____(Print name)

_____(sign) date: Year moon day

B. The person who obtained the consent:_____(Print name)

_____(sign) date: Year moon day

C.Co - host :_____(Print name)

_____(sign) date: Year moon day

D. Research Moderator:_____(Print name)

_____(sign) date: Year moon day

When the subject of the case meets item (1) of [Instructions for Signing the Consent Form], this field must be signed

E. Legal representative/person with consent/guardian/assistant:_____

(Print name)

_____(sign)

date: year month day

Relationship to study participant:_____

When the subject of the case meets item (2) of [Instructions for Signing the Consent Form], this field must be signed

F.Witnesses:_____(Print name)

_____(Signature) Date: year month day