Hartford HealthCare

Informed Consent for Research

6816

Principal Investigator: Mary Marshall-Crim Hartford Hospital
Lactation Program
(860) 972-1313
Ruth Lucas, UConn School of Nursing
(860) 207-6730

You have been asked to participate in the research study, Promoting Self-Management of Breast and Nipple Pain with Biomarkers and Technology (PROMPT) for Breastfeeding Women study. This research study is expected to last 1 year and will enroll approximately 280 participants of whom approximately 225 will be from Hartford Hospital.

This research is funded by Ruth Lucas, University of Connecticut School of Nursing and the National Institute of Nursing Research. Dr. Ruth Lucas is paying Mary Marshall-Crim and Idelisa Freytes at Hartford HealthCare and Marisa Merlo and Dr. Dana Scott at UConn Health to conduct this research.

KEY INFORMATION FOR Promoting Self-Management of Breast and Nipple Pain with Biomarkers and Technology (PROMPT) for Breastfeeding Women study

We are asking you to choose whether or not to volunteer for a research study about self-management of breast and nipple pain during breastfeeding using text-based interventions and genetic testing. You are being asked to participate because you are planning to breastfeed. This page is to give you key information to help you decide whether to consent to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about how your physical, psychosocial and genetic characteristics may influence nipple and breast pain with breastfeeding and your milk supply. We will hope to understand the reasons and personal characteristics women may stop breastfeeding their newborn. Your participation in this research will last about 24 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The study will provide basic information about breastfeeding, your health after birth, and your infant's growth and ways to play during the first 24 weeks after birth. The study may not benefit your breastfeeding directly but will help us to understand how new mothers maintain their breastfeeding goals.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The study may be a time burden with a new baby at home. You may not be comfortable providing a buccal (cheek cell) and/or blood sample for genetic testing of your pain sensitivity and milk supply or telling us when you stop breastfeeding.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Mary Marshall-Crim, MSN, IBCLC (Principal Investigator, PI) from the Hartford HealthCare Lactation Program and Dr. Ruth Lucas, PhD, RNC from the University of Connecticut School of Nursing. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study their contact information is: Mary Marshall-Crim, (860) 972-1313, mary.marshall-crim@hhchealth.com and Dr. Ruth Lucas, (860) 207-6730, ruth.lucas@uconn.edu and for UConn Health, Dr. Dana Scott, (860-679-4106).

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact representatives from the Hartford HealthCare Human Research Protection Program Integrity between the business hours of 8am and 5pm ET, Monday-Friday at (860) 972-2893.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

The purpose of this research is to evaluate the outcome of a self-management intervention on breast and nipple pain for breastfeeding women. The study will evaluate the influence of your psychosocial, sensory and genetic characteristics on breastfeeding outcomes.

A.2. What procedures are involved with participation in this research study?

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what the activities of the study are. You will be randomized – like flipping a coin -- to one of two groups, either an intervention group or a control (usual care) group. Neither you nor any of the study personnel will have any influence on the group into which you are randomized.

You will be asked to complete questionnaires, a breastfeeding journal, an audio recorded interview at 6 weeks and 6 months, undergo sensory assessments, and provide buccal (cheek cell) and/or blood samples (3 teaspoons) for assessment of select pain sensitivity and your milk supply genes and DNA methylation. The sensory testing will involve the application of different stimuli, such as pressure and vibration, to the surface of your skin on your arm. Pain sensitivity genes are units of your DNA that determine how you feel pain. DNA methylation is a biological process that increases or decreases DNA activity and is one way to identify women at risk for postpartum depressive symptoms.

You will begin the study at the hospital. You will be asked to repeat these assessments again at 6 and 24 weeks at the Women's Ambulatory Health Service (WAHS), Hartford Hospital Outpatient Lactation Clinic, or UConn Health Outpatient Clinic, and be interviewed about participating in the study. Together the assessment and interview will take 75 minutes. At 1, 2, 3, 9, 12, and 18 weeks you will be asked to complete questionnaires via smartphone text into UConn Health's Research Electronic Data Capture (UConn Health REDCap) links, https://health.uconn.edu/clinical-researchcenter/ which will take about 30 mins to complete. After you are discharged home, for the first 6 weeks, you will receive biweekly 5- 7 minutes long video modules related to taking care of yourself and your baby. You will also receive a 5 – 7 minutes long video module about your infant's development and ability to play at 4, 8, 12, 16, 20, and 24 weeks. If you are in the intervention group,

you will be asked to complete a daily breastfeeding journal and watch biweekly two 5 – 7 minutes long video modules on breastfeeding pain self-management. Daily entries will be completed via a smartphone link Monday – Friday for 6 weeks. Journal entries take 2-5 mins to complete and will ask about infant breastfeeding behaviors at each feeding. Please see table below for when the assessments happen.

Week	Day	Measure	Location	Time	Compensation
0	Baseline Assessment	• Consent • Blood sample (3 teaspoons) and/or cheek swab collection • Sensory Testing • Questionnaires	Hospital	60 mins Questionnaires on own time via smartphone link	$25 Card
1	Days 1-5	**Intervention Group ONLY:** Journal: 1 entry/ day Breastfeeding Coaching Texts 2 times/week Breastfeeding Modules 1-3 Maternal/Infant Care Modules 1-2	Personal computer (PC)/ smartphone (SP)	5 mins per entry 5-15 mins/ module	
	Days 1-5	**Control Group ONLY:** Texts 2 times/ week with links to Maternal/Infant Care Modules 1-2	PC/SP	7 mins/ module	
	Day 5	**Both Groups:** Questionnaires	PC/SP	30 mins	$25 Card
2	Days 8-12	**Intervention Group ONLY:** Journal: 1 entry/ day Breastfeeding Coaching Texts 2 times/week Breastfeeding Modules 4-6 Maternal/Infant Care Modules 3-4	PC/SP	5 mins per entry 5-15 mins/ module	
	Days 8-12	**Control Group ONLY:** Texts 2 times/ week with links to Maternal/Infant Care Modules 3-4	PC/SP	7 mins/ module	
	Day 12	**Both Groups:** Questionnaires	PC/SP	30 mins	$ 25 Card
3	Days 15-19	**Intervention Group ONLY:** Journal: 1 entry/ day Breastfeeding Coaching Texts 2 times/ week Breastfeeding Modules 7-9 Maternal/Infant Care Modules 5-6	PC/SP	5 mins per entry 5-15 mins/ module	
	Days 15-19	**Control Group ONLY:** Texts 2 times/ week with links to Maternal/Infant Care Modules 5-6	PC/SP	7 mins/ module	
	Day 19	**Both Groups:** Questionnaires	PC/SP	30 mins	$25 Card
Weeks 4-6	Days 21-40	**Intervention Group ONLY:** Journal: 1 entry/ day Breastfeeding Coaching Texts 2	PC/SP	5 mins per entry	

		times/ week Maternal/Infant Care Modules 7-12		7 mins/ module	
	Days 21-40	**Control Group ONLY:** Texts 2 times/ week with links to Maternal/Infant Care Modules 7-12	PC/SP	7 mins/ module	
Week 4	Day 26	**Both Groups:** Infant development and play modules at 4 weeks	PC/SP	10 mins	
Week 6	Day 40	**Both Groups:** • Blood sample (3 teaspoons) and/or cheek swab collection • Sensory Testing • Questionnaires • Recorded interview about study	Clinic, smartphone	60 mins 15 mins	$50 Card
Week 8	Day 54	**Both Groups:** Infant development and play modules at 8 weeks	PC/SP	10 mins	
Week 9	Day 61	**Both Groups:** Questionnaires	PC/SP	30 mins	$35 Card
Week 12	Day 82	**Both Groups:** Questionnaires Infant development and play modules at 12 weeks	PC/SP	40 mins	$35 Card
Week 16	Day 110	**Both Groups:** Infant development and play modules at 16 weeks	PC/SP	10 mins	
Week 18	Day 122	**Both Groups:** Questionnaires	PC/SP	30 mins	$35 Card
Week 20	Day 138	**Both Groups:** Infant development and play modules at 20 weeks	PC/SP	10 mins	
Week 24	Day 166	**Both Groups:** • Blood sample (3 teaspoons) and/or cheek swab collection • Sensory testing • Questionnaires • Infant development and play modules at 24 weeks • Recorded interview about the study and breastfeeding outcomes	Clinic, Interview, smartphone	60 mins 10 mins 15 mins	$75 + $25 bonus Card Total Card: $355

During the first study visit, Dr. Lucas or a trained research assistant will talk to you at the hospital to complete the consent form, questionnaires, sensory testing, and collect blood and cheek cell samples. At the hospital, Dr. Lucas or a trained research assistant will show you how to complete the questionnaires on your own personal device, either a computer/tablet/smartphone, and by telephone consult with a study team member. If you do not have a smartphone, the research team will provide you with a smartphone. The first study visit in the hospital will take approximately 60 minutes to complete. After the initial visit you will be randomly assigned to either the intervention group or the usual care group.

After discharge home, all journal entries, questionnaires, and video modules will be made available to you through text message and/or a web-based email link to UConn Health REDCap. Completing questionnaires and watching the video modules will take 5-30 minutes depending on the task. You will receive up to 2 reminder

text message or emails per questionnaire at 1, 2, 3, 9, 12, and 18 weeks to complete. If you fail to complete all study data collection points in a timely manner, the study investigator may exclude you from the study.

The study questionnaires ask questions about your breast and nipple pain and how it is affecting your mood, ability to take care of yourself and your baby, level of stress, and breastfeeding experience. Examples of the questions that will be asked include rating your pain "at its worst in the last 24 hours", "at its least in the last 24 hours", and "on average". The sensory testing will involve the application of different stimuli, such as pressure and vibration, to the surface of your skin on your arm. A research team member who is trained to perform the sensory test will remain in the room with you. Sharp and dull sensations will be assessed by applying a nylon filament to the surface of your skin. You will be asked to identify whether the sensation is sharp or dull in response to having the nylon filament against the surface of your skin. A pressure probe will be applied to the surface of your skin to assess pressure sensation, and you will be asked to rate the level of pain in response to the amount of pressure applied. To assess sensation to vibration, a tuning fork will be applied to the surface of your skin and you will be asked to rate the level of pain. The sensory testing will be done at the hospital visit, 6 weeks, and 24 weeks.

At the 6 week and 6 month data collection, you will be asked questions about the study. The interview will be recorded for later analysis. The interview will ask you about the study and what about the study was helpful or difficult. The interview should take 15 minutes. The audio recordings of your interview will be uploaded into a HIPAA compliant system at UConn Storrs called One Drive. The study staff will use Microsoft 365 audio transcription program to convert the audio recordings into text. The audio recordings will be destroyed when the study is closed. Only the study team will have access to the audio recordings and text files.

In order to participate in the study, you must be willing to provide a buccal (cheek) swab and/or blood sample (3 teaspoons) at the hospital visit, 6 weeks, and 24 weeks - a total of 9 teaspoons of blood. You will need to rinse your mouth with an alcohol based oral rinse and rinse with clean water, before rolling the sterile buccal brush firmly on the inside of the cheek (10 times). Trained hospital staff or member of the research team will draw your blood. The cheek swab and blood samples for the study will be used to measure genetic factors and DNA methylation that are thought to influence pain sensitivity, milk supply and emotion. The genes being evaluated in this study do not have any diagnostic or clinical value. Therefore, the results of these tests will not be shared you. All samples will be labeled with a unique study identification number and taken to the laboratory in the School of Nursing in Storrs. Samples will be stored in the School of Nursing until further processing by a laboratory service center at the University of Connecticut and Dr. Erin Young at the University of Kansas Medical Center. Once study analyses of your samples have been complete, your samples will be de-identified, meaning they will not be linked with any of your contact information, and will be maintained in the School of Nursing indefinitely. Other researchers who may want to perform tests on the samples that you've provided must request approval from the PI and the IRB.

A.3. Which of these procedures is experimental?

The entire study is experimental.

A.4. Where will participation take place?

The initial participation will take place at the hospital after you give birth to your infant. The weekly questionnaires, modules, and journaling will be a link on your smartphone that you complete at home. The 6 week and 24 weeks participation will take place at the WAHS or UConn Health Outpatient clinics.

A.5. How long will participation last?

You will be asked to be involved in the study for 24 weeks.

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

This is a minimal-risk study. The risks are:

- You may be inconvenienced by the time needed to complete the questionnaires and watch the videos
- You may be uncomfortable about answering some of the questions.
- You don't have to answer anything that you don't want to.
- Sensory testing may cause minimal discomfort, but you may move away or stop at any time.
- Cheek swab testing may result in slight irritation in your mouth, but you rinse your mouth afterward.
- Blood draws may result irritation, pain, infection, bruising at the site, and fainting. Only experienced hospital or research staff will draw blood and no more than 2 attempts will be made to obtain blood.
- You may feel distressed, or possibly suicidal, call 988. For additional mental health professional or social worker referrals, so, please contact Mary Marshall-Crim, (860) 972-1313, mary.marshall-crim@hhchealth.com and Dr. Ruth Lucas, (860) 207-6730, ruth.lucas@uconn.edu.
- You may be at risk for COVID-19 transmission during face-to-face contact at the hospital and at the follow-up data collection at the WAHS or UConn Health outpatient clinic. The research team will follow best practice for COVID-19 transmission consistent with CDC guidelines, state guidelines, and applicable University and hospital policies.

C. There are possible benefits to you or others to be expected from your participation in this research.

It is possible that you will not directly benefits from participating in this study. However, you will receive educational information about breastfeeding, self, and infant care. Clinicians from the scientific knowledge that may be gained, which may help in their ability to help other women breastfeed without pain.

D. There are alternatives to participation in this study that you should consider.

This is not a treatment study. You may choose not to participate in this study without any penalty to you.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. A member of the research team and Dr. Lucas are willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
the research, research-related treatments, or a research related injury	Mary Marshall-Crim, Lactation Program Ruth Lucas, PhD, RNC, University of Connecticut School of Nursing UConn Health IRB	(860) 972-1313 (860) 207-6730 (860)-679-4849 (860)-679-8729
your rights as a research participant	An IRB Representative	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

F. Your participation in the research is voluntary.

You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Harford HealthCare or at UConn Health Center.

G. You will receive financial compensation for your participation in this research.

There are no costs associated with study participation. You will be paid in monetary cards after each data time point and if you complete all of the data time points, you will receive a study completion bonus. You will receive a $25 card at the hospital. After discharge home, you will receive a $25 card at 1, 2, and 3 weeks, and a $35 card at 9, 12, and 18 weeks. At 6 weeks you will receive a $50 card and $75 card at 24 weeks, and $25 gift card as a completion bonus. You may potentially earn up to $355 if you complete the entire study.

A note about the Internal Revenue Service (IRS): UConn Storrs is required to report payments of $600 or more to the IRS. This means that if you receive $600 or more from UConn Storrs during the calendar year, your compensation will be reported to the IRS and you will receive an IRS 1099 Form.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford HealthCare will protect all the information about you and your part in this study, just as is done for all patients at Hartford HealthCare. Your records will be maintained in accordance with applicable state and federal laws and has a Certificate of Confidentiality from NIH (National Institutes of Health). However, private

identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form.

Potentially identifiable information about you and your baby will consist of names, dates of birth and contact information in order to continue to support you during the study. All personal identifying information will be kept in password-protected files and these files will be deleted at the end of the study. Data is being collected for research purposes only. The data collected as a part of this study will have a unique participant identifier number (PID#) composed of random numbers, not names, and will be stored separately from the consent form in a secured, locked research-designated office at the University of Connecticut School Of Nursing. All electronic data will be stored at the University of Connecticut (UConn) Storrs in their HIPAA compliant systems. Blood and/or cheek cell samples will be labeled with PID numbers and stored in a secured research laboratory at the University of Connecticut until it is processed at stored in a secured research a laboratory service center at UConn Storrs and/or Dr. Young's laboratory at the University of Kansas Medical Center. No information will be used in subsequent publications that will identify you as a subject.

In addition to the research, we intend to do, it is possible that unexpected and/or unrelated information will be discovered that is not the focus of this study. This information will not be disclosed to you, your relative or insurance company.

A Federal law, called the **Genetic Information Nondiscrimination Act (GINA)**, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Mary Marshall-Crim, Dr. Ruth Lucas and the research team will maintain high regard of you and your baby's confidentially as participants in the study. However, if you screen positive for post-partum depression symptoms or members of the study team are concerned for the safety and wellbeing of yourself, we will advise you to contact your provider. If the research team is concerned for the safety and wellbeing of yourself, we will encourage you to seek professional support or refer to regional psychological hotline. In addition, if during the course of this research study, a member of the research team suspects that a minor (under the age of 18) has been abused, neglected, or placed at imminent risk of serious harm, it will be reported directly to the Department of Children and Families (DCF) or a law enforcement agency. We will do our best to protect the confidentiality of the information we gather from you, but we cannot guarantee 100% confidentiality.

You should also know that the Hartford Healthcare (IRB) and/or representatives of UConn Health, may inspect records representatives of UConn Health, may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will receive help in the following way:

If you have medical insurance, Hartford HealthCare will collect fees for medical treatment at Hartford HealthCare from your insurance company. If you are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford HealthCare will cover these expenses.

There is no plan for Hartford HealthCare to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

UConn Health does not provide insurance coverage to compensate subjects if injured during this research. However, compensation may still be available by filing a claim against the State of Connecticut. For a description of this process, contact a representative of UConn Health's Institutional Review Board (IRB) at 860-679-4849 or 860-679-8729. UConn Health does not offer free care. However, treatment for a research related injury may be obtained at UConn Health for the usual fee.

J. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, Promoting Self-Management of Breast and Nipple Pain with Biomarkers and Technology (PROMPT) for Breastfeeding Women study and that you consent to the performance of the procedures listed above. You have also been provided with a copy of the Genetic Information Non-Discrimination Act (GINA) handout. My signature also indicates that I have received a copy of this consent form.

□ I consent to providing genetic samples
□ I do not consent to providing genetic samples

Participant's Signature	Printed Name	Date

Person Obtaining Participant's Signature	Printed Name	Date

Witness signature	Printed Name	*Date*

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

IRB Use Only.

HHC-IRB
IRB NUMBER: E-HHC-2021-0143
IRB APPROVAL DATE: 04/11/2023
IRB EXPIRATION DATE: 04/10/2024