Study Title: The Stimulation To Induce Mothers (STIM) Study: A Parallel Group Randomized Controlled Trial

NCT Number: NCT05079841
Unique Protocol Id: 2000031338
Date: May 21, 2025

Study Consent Form

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE YALE-NEW HAVEN HOSPITAL

CORNELL UNIVERSITY
WEILL CORNELL MEDICINE
ALEXANDRA COHEN HOSPITAL FOR WOMEN AND NEWBORNS

Study Title: The Stimulation Therapy to Induce Mothers (STIM) Study
Nipple stimulation with an electronic breast pump for labor induction: A multi-center parallel- group randomized controlled trial

Principal Investigator (the person who is responsible for this research):

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Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to evaluate the use of nipple stimulation with the aid of an electronic breast pump for induction of labor. A secondary purpose of this research study is to understand the differences in biomarker levels among women undergoing induction of labor by nipple stimulation compared with those receiving intravenous oxytocin infusion (sub-study).
- Study procedures include: You will be interviewed, and your medical record will be reviewed, for a basic history. The information collected is outlined in detail below. You will receive a standard manual cervical exam prior to induction of labor by your maternity care provider, followed by random assignment to either nipple stimulation with the aid of an electronic breast pump or immediate standard exogenous oxytocin infusion without nipple stimulation. If assigned to nipple stimulation, you will receive a brief tutorial from a labor nurse or research staff. Participants in this group will be asked to keep a brief “diary” of their experience during labor. Participants in both groups will be assessed for pain during childbirth, and all participants will be

asked to fill out several questionnaires, once during their postpartum hospital stay, once at 2 weeks postpartum, once at 4-12 weeks postpartum, and once at 6 months postpartum via telephone, text message, and/or email.

- No additional healthcare visits are required.
- There are potentially some risks from participating in this study. There have been a few reports of fetal distress with electric breast pump use to induce uterine contractions, in one reported case requiring an urgent cesarean section delivery. It is important to recognize that uterine contractions and the labor process can naturally cause fetal distress, and the small prior studies that have compared breast pump use with oxytocin use during labor have not shown breast pump use to be more dangerous. You also may have some mild nipple or breast discomfort or soreness. You will have the option to discontinue breast pump use at any time if this occurs, or for any other reason.
- The study may have no benefits to you. However, we hypothesize that breast pump use will improve your labor induction process, increase your sense of control during labor, and improve your readiness for, or success with, breastfeeding. It may benefit other women by ultimately allowing a more individualized approach to induction of labor that prioritizes each woman's preferences and values for the childbirth process.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

  Biomarkers of milk production initiation after labor induction by nipple stimulation or intravenous oxytocin labor: STIM Sub-Study:

  - The purpose of this research study is to understand the differences in milk biomarkers and milk composition (such as milk sodium, macronutrients and milk RNA expression) among women undergoing induction of labor by breast stimulation compared with those receiving intravenous oxytocin infusion.
  - The procedures will include: an interview and review of your medical record for relevant information and milk/colostrum sample collection during your hospitalization time.
  - The risks of this study are minimal. The amount of colostrum collected for the study are small (less than a teaspoon up to twice in 24 hours). You will be able to choose how much milk to contribute to the study, to make sure you have enough milk for your baby. Samples collection can be skipped if you do not feel ready for collection at the time set for sample collection.
  - The sub-study may have no benefits to you. It may benefit other women by improving our understanding of how nipple stimulation therapy works during

labor and how to improve its use for women who need to undergo induction of labor.

- Taking part in this sub-study is your choice. You can choose to take part, or you can choose not to take part in this sub-study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

Why is this study being offered to me?

We are asking you to take part in a research study because **you are over 18 years of age, your gestational age is at least 36 weeks, your gestation is vertex-presenting (the fetal head is down), and you are planned to receive supplemental oxytocin for labor induction**. We are looking for **988** participants to be part of this research study.

We are asking you to take part in this sub-study because you eligible to participate in the Stimulation Therapy to Induce Mothers (STIM) research study.

Who is paying for the study?

This study is being funded in part by the Albert McKern Scholar Award and the National Institutes of Health awarded to the principal investigator.

What is the study about?

The purpose of this research study is to evaluate the use of nipple stimulation therapy with an electronic breast pump for induction of labor. Induction of labor typically involves receiving an intravenous (IV) medication called Pitocin. Pitocin is currently considered the standard of care for induction of labor. Pitocin has the same function as a hormone called oxytocin, which your brain naturally produces at the end of pregnancy to bring on labor and birth, but Pitocin is administered through an IV. Nipple stimulation causes the body to produce more of this oxytocin hormone in the brain which may have more benefits. This study will evaluate whether nipple stimulation during the labor process can improve labor and delivery outcomes, breastfeeding outcomes, and cost. We hope that this will ultimately allow a more individualized approach to induction of labor that prioritizes each woman's preferences and values for the childbirth process.

The purpose of this sub-study is to improve our understanding of how lactation initiation and milk composition is impacted by induction of labor. Induction of labor typically involves receiving an intravenous (IV) medication called Pitocin. Pitocin is currently considered the standard of care for induction of labor. Pitocin has the same function as a hormone called oxytocin, which your brain naturally produces at the end of pregnancy to bring on labor and birth. Breast stimulation causes the body to produce more of this hormone as it has an important role in milk development or production. This study will compare milk biomarkers for lactation initiation, and milk composition of women receiving IV Pitocin versus those using breast stimulation. We hope that this will allow us to better understand

how induction of labor affects lactation initiation, which in the future will help us improve long term breastfeeding outcomes.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

You will be briefly interviewed, and your medical record will be reviewed, for the following information:

- Reason for induction of labor
- Demographic information: age, race, ethnicity, insurance status
- Medical history: first clinic weight, current weight, height, chronic disease history
- Obstetrical history including outcomes of any prior pregnancies
- Social history: marital status, educational level, alcohol use, and tobacco use
- Current pregnancy complications

The process will then begin with a manual exam of your cervix by your healthcare provider (as would be conducted prior to any induction of labor). You will then be randomly assigned to participate in usual induction of labor care or induction using nipple stimulation therapy (50-50 chance, like flipping a coin).

Your treating obstetrician or midwife has decided that you will receive Pitocin for induction of labor as the current standard of care. You are being asked to agree to be randomized to either current standard of care (immediate Pitocin) or to try nipple stimulation therapy for inducing labor. If you are randomized to nipple stimulation for inducing labor, Pitocin (standard of care) will always be available as a back-up if nipple stimulation does not adequately work.

If you decide to participate in the sub-study, milk specimens will be collected by our research team or your nurse in the following schedule:

- Approximately 12 hours after delivery (6-10 drops or 0.3-0.5 ml of milk)
- Approximately 24 hours after delivery (6-10 drops or 0.3-0.5 ml of milk)
- Approximately 48 hours after delivery (0.5-2.5 ml of milk)
- If you are still at the hospital by 72 hours after delivery (6-10 drops or 0.3-0.5 ml of milk)

If you are a participant in the STIM study who was randomized to the nipple stimulation group:

- We will collect 0.5-2.5 ml of milk if you get milk before your delivery.

If you are randomized to nipple stimulation, you will receive a 5-minute tutorial on the use of the breast pump by a labor nurse or research staff. A hospital-grade breast pump (Medela Symphony® Breast Pump), the individual pump kit, and lanolin ointment

will be provided to you. You may choose to use your own personal non-hospital breast pump and pump kit if you prefer. You will also have the option to perform nipple stimulation by hand, but it is preferred that you use a breast pump. We ask that you maintain a "diary" during this process, which will describe the starts and stops in stimulation, the pump suction used, the transitions between breasts, and any additional notes you wish to make. Stimulation with the breast pump will be applied for no more than 30 minutes before alternating to your other breast. This will continue until contractions are adequate for labor progress (occurring at least every 3 minutes). If contractions become too frequent, the stimulation will be decreased, or the stimulation will be stopped. You may request a decrease in pump suction or a pause in stimulation at any time, but this pause should not exceed 30 minutes if the frequency of your contractions becomes less than every 3 minutes. We ask that you perform breast pump stimulation for a minimum of two hours. After at least two hours of breast pump stimulation, if there has been no cervical change or the desired contraction pattern is not achieved, your provider may recommend transition to synthetic oxytocin use (Pitocin). In addition, you may choose to cross over to Pitocin if you desire at any time, even before the recommended two hours of breast pump stimulation.

If you are randomized to exogenous oxytocin, oxytocin infusion will be initiated at the standard rate of 2 mU/min and will not exceed 20 mU/min. This will be done as part of your standard of care. Decisions to change the infusion rate are based on fetal status, contraction pattern, and maternal coping and any such changes will be in keeping with Yale-New Haven Hospital Department of Obstetrics, Gynecology, and Reproductive Sciences policy and will not be affected by your participation in this research.

Regardless of randomization group, your induction will not be considered to have "failed" until at least 12 hours have elapsed since both rupture of membranes and use of synthetic oxytocin.

All participants will be asked to complete several questionnaires. These questionnaires take less than 5 minutes to complete and will ask about your mood, infant feeding, breastfeeding/milk supply, income/employment, and quality of life of you and your infant. The same questionnaires will be repeated at each of the time points described below.

- At time of study consent, all participants will complete questionnaires to establish baseline. Based on your preference, these questionnaires will be administered either in paper form and inputted into the secure online research database by trained study staff or can be completed by you electronically. Should your score on the Edinburgh Postnatal Depression Scale (EPDS) questionnaire suggest an increased risk for depression, we will notify your primary obstetric provider/team and refer you to them for additional care.
- After randomization but before the intervention starts, all participants will be asked to assess their pain using the visual analog scale, and then again 2 hours after the start of the study intervention. These pain assessments will be administered in paper form and inputted into the secure online research database by trained study staff.
- During the hospital postpartum stay prior to discharge, all participants will be asked

to assess the pain experienced during childbirth using the visual analog scale and asked whether they experienced breastmilk let-down during their labor, whether they were able to collect colostrum during labor, and whether they were able to store the colostrum/breastmilk and feed it to their infant postpartum. They will also be asked to complete questionnaires. Based on your preference, these hospital postpartum questionnaires can be administered either in paper form and inputted into the secure online research database by trained study staff or can be completed by you electronically, using a study tablet/laptop or a secure web-based link sent via text or email.

- At two weeks after giving birth, all participants will be asked to complete questionnaires. Based on your preference, these questionnaires will be sent to you via email or text message using a secure web-based questionnaire link. Participants may receive a follow-up phone call, email, or text message if the questionnaires are not completed.
- Between 4 and 12 weeks postpartum, all participants will be asked to complete questionnaires. Should your score on the EPDS questionnaire suggest an increased risk for depression, we will notify your primary obstetric provider/team and refer you to them for additional care. In addition, patients will be asked if they had unanticipated office or hospital visits since their delivery hospitalization discharge. Based on your preference, these questionnaires will be sent to you via email or text message using a secure web- based questionnaire link. Participants may receive a follow-up phone call, email, or text message if the questionnaires are not completed.
- At 6 months postpartum, all participants will be asked to complete questionnaires. Based on your preference, these questionnaires will be sent to you via email or text message using a secure web-based questionnaire link. Participants may receive a follow-up phone call, email, or text message if the questionnaires are not completed.

What are the risks and discomforts of participating?

Oxytocin is naturally produced by the human body and is the most commonly used method of labor induction, which occurs in over a quarter of all pregnancies in the United States. Oxytocin should not be used in cases where labor and vaginal delivery are not considered safe.

Most commonly, oxytocin is well tolerated by the mother and fetus. The **most common** complication is excessive uterine contractions, which is called tachysystole and can cause fetal distress. This occurs in about 5 in 100 labor inductions with exogenous oxytocin administration. You will be monitored for signs of tachysystole during labor induction, and oxytocin infusion will be stopped if these signs develop. There are several **rare but serious** side effects to consider. Low sodium levels in the blood, which in severe cases is associated with headache, nausea, vomiting, abdominal pain, drowsiness, unconsciousness, seizures, and irreversible brain damage. Severe symptoms occur extremely rarely but have been reported. Lastly, low blood pressure can occur as it has been seen with very high doses of oxytocin administration, though it has never been reported as a side effect of the infusion protocol used at Yale-New Haven Hospital.

Endogenous oxytocin use via nipple stimulation has not been as heavily studied as exogenous oxytocin, which is why our study may yield important scientific advancement, but endogenous oxytocin use may also be associated with unknown risks as a result. There may be potential risks or inconveniences such as inadequate uterine contractions which may be consequently associated with prolonged labor. Similarly, like Pitocin, it is possible that nipple stimulation can cause excessive uterine contractions (tachysystole). You will be monitored for signs of tachysystole during labor induction, and nipple stimulation will be stopped if these signs develop. Research to date has shown no increased risk of cesarean section or other negative outcomes with the use of nipple stimulation compared to oxytocin infusion.

You may experience breast discomfort from the use of the breast pump. One study found that 1 in 6 women had nipple discomfort with the breast pump on a high suction setting that resolved with decreasing the suction, and no participants had skin damage or other injury to the nipple. If you experience discomfort during the study, you are able to pause your breast pump use at any time.

For the sub-study, there is a minimal risk in milk collection including temporary discomfort in the breast/nipple for a short time after pumping/expression. We anticipate that the small volume of milk (0.5ml up to twice a day at the first 24 hours and 2.5ml at 48 hours after delivery) collected for the study will not affect infant growth or interfere with the nutritional needs of full term infants.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

The benefits of using a nipple stimulation for labor induction are currently unproven. However, breast stimulation for labor induction may:

- Increase your sense of control or yield other improvements in your childbirth experience
- Decrease your risk of heavy vaginal bleeding (postpartum hemorrhage) after your delivery
- Improve your readiness for, or success with, breastfeeding, which in turn has substantial benefits to mothers and babies

How can the study possibly benefit other people?

This study may help determine if endogenous oxytocin (from your body, released via breast stimulation) outperforms exogenous oxytocin (synthetic) for the purposes of

labor induction. Ultimately, this will allow a more individualized approach to induction of labor that prioritizes each woman's preferences and values for the childbirth process. Further, this study may allow a better understanding of whether the total amount of oxytocin is different between women exposed to intravenous oxytocin compared with those exposed to breast stimulation and whether this concentration correlates with birth outcome.

The benefits to science and other people may include a better understanding of how laboring women's bodies respond to nipple stimulation therapy. This may include:

- A better understanding of whether the milk production biomarkers (such as milk sodium levels and RNA expression) are different between women exposed to intravenous oxytocin compared with those exposed to breast stimulation and whether this concentration correlates with breastfeeding outcome

Are there any costs to participation?

If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). However, there may be additional costs to you such as those costs associated with your hospital stay for labor induction, childbirth, and your postpartum period which will be billed to you and/or your insurance. You will be responsible for any co-payments required by your insurance. If you have no insurance, or your insurance refuses coverage for any part of your care, you will need to pay these costs.

Will I be paid for participation?

You will be paid up to a total of $50 if you complete the questionnaires at all 5 questionnaire time points. This means that you will receive $10 for completing questionnaires at each of the 5 specified study timepoint (baseline, 1-3 days postpartum, 2 weeks postpartum, 4 to 12 weeks postpartum, and 6 months postpartum). You will receive these payments in the form of a pre- paid debit card. We will have to share your name, address, and telephone number with the banking institution issuing the debit card for ePayments at Yale. You may receive a card in the mail with the first payment following completion of the first set of questionnaires. You will need to activate the card over the phone. At Weill Cornell Medicine, you will receive a re-loadable gift card at the time of randomization. Your following payments will be added to your gift card after each survey you complete. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

If you are randomized to nipple stimulation therapy, you will also be gifted a hands-free breast pumping bra and cooler bag to keep. If you are randomized to immediate synthetic oxytocin infusion (control group), you may also be gifted a pack of infant diapers to keep.

What are my choices if I decide not to take part in this study?

Instead of participating in this study, you may elect to proceed with your usual care with your maternity care provider. As you were determined to be eligible for this study, this will likely include exogenous oxytocin use, but ultimately, your healthcare plan will be determined by you and your maternity care provider.

Instead of participating in the sub-study, you may elect to proceed with participating in only the STIM study or you may proceed with your usual care with your maternity care provider.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

We will have your name and phone number only visible to two research staff members. Once we have contacted you by telephone and collected information about your delivery, we will remove your name and other identifiers. We will replace these with a code number. This deidentified information will then be kept in a password-protected database on a password- protected computer. These files will only be accessed by a small group of research staff.
Information will be kept for 7 years.

Biological specimens (milk) will be labeled with your code number and stored for analysis without identifiable private information. Your biospecimens may be stored without identifiable private information and could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. De-identified samples will be sent to Cornell University, Ithaca, for analysis. Your biospecimens (without identifiable private information) may be used for commercial profit, and you will not share in this commercial profit.

We will also give data obtained from your specimens to an NIH-supported data sharing repository for other research studies that may be done in the future. NIH supported scientific data repositories store biologic and individual characteristics like gender, age, medical conditions from people participating in many studies across the country. Repositories share that information with researchers. The research may be about labor, or research could be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We will send this information about you and other people in this study to an NIH-supported Scientific Data Repository. It will be coded and your name and other information that could identify you will be removed. NIH will not identify or make any attempt to identify information as coming from you or any other individual. NIH will share the collected

information with researchers who submit applications to NIH to do research with information from the repository. Special data sharing committees will review those applications and decide whether or not to share the information with the researcher. The researchers who receive your information must promise to keep it confidential and to use it only for the research purpose approved by NIH. Your biospecimens (without identifiable private information) may be used for commercial profit, and you will not share in this commercial profit.

Your consent form documents will be kept in a locked cabinet in our research office, accessible only by research staff.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we will ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to the Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- The entire research record and any medical records held by **Yale-New Haven Health or Weill Cornell Medicine-Alexandra Cohen Hospital for Women and Newborns** created from the start of your pregnancy and up to 3 months after delivery.
- Records about your study visits
- Information obtained during this research regarding:
    - Indication for labor induction (if applicable)
        - 39 weeks of gestation or greater and no other medical indication
        - Premature rupture of membranes
        - Maternal medical indication, such as pre-gestational diabetes, chronic hypertension
        - Pregnancy indication, such as oligohydramnios, cholestasis of pregnancy, gestational diabetes, hypertensive diseases of pregnancy
    - Components of the modified Bishop score: cervical dilation, cervical effacement, and fetal station from digital cervical exam
    - Demographic information: age, race, ethnicity, insurance status

- Medical history: first clinic weight, current weight, height, chronic disease history
- Obstetrical history including outcome(s) of any prior pregnancies.
- Social history: marital status, educational level, alcohol use, and tobacco use
- Current pregnancy complications

How will you use and share my information?

We will use your information to conduct the study described in this consent form. We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) This is done so the FDA can review information about the device (Medela Symphony® Breast Pump) involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor study conduct.

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to **Molly McAdow, MD, PhD** at: Yale School of Medicine, 333 Cedar Street, P.O. Box 208063, New Haven, CT 06520, or by emailing **Moeun Son MD,** MSCI at Weill Cornell Medicine at mos7003@med.cornell.edu.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. If you withdraw from the study, we will clarify with you whether you wish to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which you previously gave consent, may continue. If you completely withdraw from the study, no new health information identifying you will be gathered after the date you withdraw unless we receive your permission to do so. Non-identifying information that has already been collected up until the point of your withdrawal may still be used and given to others to ensure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine/Yale-New Haven Hospital and Weill Cornell Medicine/Alexandra Cohen Hospital for Women and Newborns do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

What if I want to refuse or end participation before the study is over?

Taking part in this study and/or sub-study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. For example, this may occur if you develop serious side effects while participating in the study. Or for the sub-study if your nurse determines that collecting your milk samples is too challenging and/or uncomfortable for you.

What will happen with my data if I stop participating?

If you withdraw from the study, we will clarify with you whether you wish to withdraw from all components of the trial or only from the interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which you previously gave consent, may continue. If you completely withdraw from the study, your milk samples will be destroyed and no new health information identifying you will be gathered after the date you withdraw unless we receive your permission.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at 475-414-5328.

If you have questions about your rights as a research participant, or you have complaints

about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial (NCT05079841) will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study. We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Participant e-mail

Person Obtaining Consent Printed Name		Person Obtaining Consent Signature
Date		

_____(initial) I **agree** to have milk samples collected as described in this consent document

_____(initial) I **opt-out** of having milk samples collected for research purpose