VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Milk To Go
Version Date:	09/30/2025
PI:	Kathryn Sunthankar, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The Milk To Go study is a multi-center study conducted in collaboration with Willow Innovations Incorporated to determine if wearable breast pumps help physician parents returning to work after the birth of a child (or children) achieve lactation goals. Participants in this study may benefit as they would receive a complimentary Willow 2.0 or Willow 360 breast pumps (both FDA approved) for their use throughout and after the study. There are no additional risks outside of usual risks associated with breast pumping including discomfort and irritation. The time commitment is minimal and flexible as it is through surveys completed on their own time – one intake survey (15-20 minutes), monthly surveys (2 minutes each) and an exit survey (15-20 minutes). There are no limitations or restrictions on breast pumping, utilization of other pumps or nursing. These pumps only serve as an aid to help lactating persons reach their lactation goals. The participant may be asked to participate in future sub-studies that are optional.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are a physician trainee at Vanderbilt University Medical Center who has indicated they are currently pregnant or recently pregnant. As a physician trainee, you are provided a smart phone which is an inclusion criterion for participation in this study to use the Willow App.

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You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. There is no connection to your medical record and this study.

Side effects and risks that you can expect if you take part in this study:
Pumping milk, in general, has some risks associated with the activity regardless of the device used. The American College of Obstetrics and Gynecology reports that common risks (≥10%), include:
Engorgement, sometimes leading to infection
Nipple injury
Breast pain
Perceived or actual low milk supply
Infant lack of interest in breastmilk (early weaning)
Physical incompatibility with wearing the devices

There are no severe or life-threatening risks associated with utilization of a Willow pump.

For best results, it is important to research all of the available options to support lactating parents. If you are struggling with any of these symptoms, consult with your lactation consultant (IBCLC), a Willow lactation specialist (provided online at no additional cost to any owner or a Willow pump), or manufacturer help guides available through this study. Wearable devices are an effective way to sustain lactation when traditional resources may not be accessible or available. Best production results may be using traditional pumps, consult your primary care provider or a lactation consultant to ensure best results.

Participants can withdraw from the study if any of the above risks occur and inform the study leads if you encounter one of these health conditions.

Risks that are not known:
Willow 2.0 and Willow 360 devices were FDA approved in September 2019, therefore most risks are known. However there may be risks that we do not know about at this time. Additionally, there may be pregnancy risks that are not known yet. For this reason, you must tell the study contact right away if you get pregnant during the study.

Good effects that might result from this study:

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The benefits to science and humankind that might result from this study: confirmation that wearable pumps help lactating persons reach their lactation goals.

Additionally, wearable breast pumps increase the flexibility of the parent to choose when and where they can pump milk at work or outside of work. These devices are quieter than normal pumps and do not need to be tethered to a power outlet. They also fit discreetly under clothing.

Pumping milk at work in general provides the following direct benefits, supporting breastfeeding goals, health benefits for both parent and baby, comfort and relief from engorgement from milk, provides natural and free nutrition from baby, provides parent with fulfillment for being able to work and provide nutrition to infant.

Indirect benefits include short- and long-term health benefits for both parent and baby by allowing the parents to provide milk for a longer duration than if they had switched to formula and stopped pumping.

Procedures to be followed:

- One intake survey (15-20 minutes)
- Monthly surveys (2 minutes)/ month participating in study (up to 24 months)
- One exit survey (15-20 minutes)
- Utilization of Willow App to pump (required to use pumps); the devices will automatically log the number of minutes and sessions each day.

Payments for your time spent taking part in this study or expenses:
There is no direct financial payment for participation in this study. However, participants will receive either a Willow 2.0 or Willow 360 breast pump, valued at $350 and $500 respectively. These pumps are for the participant to keep indefinitely.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or Willow Innovations Inc. to pay for the costs of any additional care. There are no plans for Vanderbilt or Willow Innovations Inc. to give you money for the injury.

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Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Katie Sunthankar at katie.sunthankar@vumc.org.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
There may be pregnancy risks that are not known yet. Therefore if you become pregnant, you will be taken out of the study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor.

Confidentiality:
The researchers will keep your identity confidential, as required by law. The researchers may publish the results of the study. If they do, they will only discuss aggregate results. Your name will not be used in any publication or presentation about the study.

Your study information will be labeled with your research ID number. The study team will keep a separate list that matches your name to the research ID number. All of this information will be stored on a secure, password-protected RedCap server. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn't have it.

If you sign this form, the research team will collect, use and share your survey responses (which include health information) as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from three survey types and data from the Willow App regarding duration and frequency of breast pumping. Others at VUMC might need to look at your research records. They include the Institutional Review Board or other committees and offices that review and monitor research studies.

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It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

Privacy:
Any data and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors (including Willow Innovations Inc.), other sites in the study (Indiana University School of Medicine, Providence Health, Kansas University Medical Center, Children's Mercy Medical Center and University of Michigan), and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Study Results:
You will be notified of study results if you select this option in the final survey. You will be told about any study results that directly affect your medical care.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form, and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

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Can we keep your contact information for future studies? ☐ Yes ☐ No
Can we keep your data for future research studies? ☐ Yes ☐ No

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____