**CONSENT TO PARTICIPATE IN A
RESEARCH STUDY AT CHILDREN'S MERCY HOSPITAL**

Lactation at Work: A Wearable Breast Pump (Willow) Device Study
Protocol ID: STUDY00003776

SUMMARY (Details of this information are in the sections below)

We are asking you to be in this research study. Being in a research study is completely voluntary, and your choice will not affect your regular medical care.

This research study is being done to determine if wearable breast pumps, like the Willow, help parents returning to work/school after the birth of a child (or children) achieve lactation (breastfeeding) goals. In addition, the study will help other institutions determine if a wearable breast pump program could work for their employees and students.

The following things are part of this study:

- completing an intake survey (~30 min),
- a monthly survey during period of pumping (~10 min,
- an outtake survey at the conclusion of pumping(~30 min),
- and use a Willow wearable breast pump device for pumping needs at work.

Total expected study duration is one year, or however long you continue to pump up to 18 months.

The biggest risks from being in this study are potential discomfort associated with pumping milk and loss of confidentiality. There may be direct benefit to being in this study. Receiving a Willow wearable breast pump may help to feel more in control of your pumping schedule and make it easier to continue breastfeeding while at work or school. Instead of being in this study, you can continue to get regular medical care.

WHO IS DOING THIS STUDY?

A study team led by Thomas Ayres, Ph.D. is doing this study. Other health care professionals may help them.

One Willow is working with Children's Mercy Hospital to do this research study. Funding for this study comes from the One Willow Company. The study team will not receive any personal payment because of your decision.

We are asking you to be a part of this research study. Please read the information below and ask questions about anything that you do not understand before you make a choice.

WHY IS THIS STUDY BEING DONE?

The goal of this study is to determine if wearable breast pumps, like the Willow, help parents returning to work/school after the birth of a child (or children) achieve lactation (breastfeeding) goals. In addition, the study will help other institutions determine if a wearable breast pump program could work for their employees and students.

Most institutions only offer basic support for breastfeeding, such as break time and a private space. But these options don't always work well for everyone. Some parents struggle to find time or a convenient place to pump.

The Willow pump is different from traditional pumps. It's small, quiet, and can be worn under clothing. It doesn't need to be plugged in, so it gives parents more freedom to pump when and where they need to.

The Willow Go and Willow 360 pumps are approved by the FDA and already use by lactating adult females. We are studying them because they offer a new and flexible way to support breastfeeding. We hope this study shows that wearable breast pumps can be a helpful and lasting option for parents. If it works well, other institutions might want to offer similar support programs for breastfeeding parents.

WHO CAN BE IN THIS STUDY?

We are asking you to be a part of this research study because you are a current resident or fellow at Children's Mercy Kansas City, are pregnant, plan to feed your child breast milk, and plan to pump.

The study will run for two years and up to 25 adults, ages 18 through 40, will be asked to be in this study at Children's Mercy Hospital per year.

WHAT WILL HAPPEN TO ME IN THIS STUDY?

If you decide to be in this study, the following things will happen:

We will ask you to fill out three types of surveys:

- An intake survey completed once. This survey will take about 30 minutes to complete.
- A monthly survey completed each month you are actively pumping. This survey will take about 10 minutes to complete.
- An outtake survey at the completion of your pumping journey. This survey will take about 30 minutes to complete.

The information collected will include the following:

- demographics, previous lactation experiences, lactation goals, pumping frequency and volume, burnout, engagement, and reflections about pumping journey that can identify you.
- We will collect your infants date of birth to schedule to the monthly surveys. No other information about your child will be collected.
- Only the research team at CMKC will have access to your identifiable data.

The survey(s) may contain questions that address sensitive topics. You do not have to answer all the questions if you do not want to.

You will receive one Willow Go wearable breast pump and a Ceres chill breast milk storage container.

Information collected for this study will be de-identified and shared with One Willow in the form of a White Paper, a non-peer reviewed scientific paper studying whether Willow wearable breast pumps help mothers in healthcare reach their lactation goals.

Future Research:

- Your information , even if de-identified, will not be used for future research.

- Optional Future Research Contact:
    - You will be asked whether we may contact you in the future about taking part in future research studies related to lactation (breastfeeding). Your decision will not affect your ability to be in this research study and will not affect your routine care. You will be able to mark your choice at the end of this form.

WHAT ARE THE RISKS OF THE STUDY?

There are certain risks in this study. These risks may include:

Pumping milk, in general, has some risks associated with the activity regardless of device used. The American College of Obsterics and Gynecology reports that common risks include:

- **Engorgement**: When breasts become overly full of milk, which can feel painful and may lead to infection if not relieved.
- **Nipple injury**: Soreness, cracking, or bleeding of the nipple from frequent or improper pumping.
- **Breast pain**: General discomfort or aching in the breast area during or after pumping.
- **Low milk supply**: : Feeling like you're not making enough milk, even if you are, or actually producing less milk than needed.
- **Baby not wanting breastmilk**: Sometimes babies lose interest in breastmilk, which may lead to stopping breastfeeding earlier than planned.
- **Pump fit issues**: The wearable pump may not fit comfortably for everyone, depending on body shape or size

To get the best results from pumping, it's important to learn about all the options available to support breastfeeding.. If you have any of these symptoms talk to a lactation consultant (IBCLC) or one of the Willow lactation specialists. You will also have access to help guides from the pump manufacturer during the study.

Wearable breast feeding devices (pumps) can be a helpful way to keep breastfeeding going, especially when traditional options (like private pumping rooms or break time) are not available. Some people may get better results with regular, plug-in pumps. If you're unsure what works best for you, talk to your primary care provider or a lactation consultant.

- If you think you may have become pregnant while being in this study, please tell the study investigator or other study personnel.

- There is a slight risk of loss of confidentiality. Your confidentiality will be protected to the greatest extent possible.

  By providing your email and/or phone number, the study team may communicate with you regarding setting up appointments, sending copies of permission/assent forms, and any other non-clinical study related communication. If you are enrolled in the My Children's Mercy Portal, the study team may also communicate with you via the portal. Information shared through the portal may be saved as part of your permanent medical record.

  The Children's Mercy Hospital standard is to send emails securely by encryption. If you reasonably request unencrypted email communication or respond without the use of encryption, please understand that unencrypted electronic communications, such as unencrypted email, may be intercepted or accessed by unauthorized people. Unencrypted information stored or viewed on your personal devices, like cell phones or computers, may be accessed or viewed by unauthorized people, especially if you share your device with other people. You acknowledge that you have been informed of the risk of unencrypted email.

  We also offer the option of receiving study information and updates via SMS text message. Text messages are sent directly to the personal phone number that is provided. Text messages are sent from study-related Children's Mercy Hospital phone numbers. There is a potential risk of loss of confidentiality when using text messaging, as it is hosted by a third party. Please be aware that these communications can be intercepted in transmission or misdirected. You acknowledge that you have been informed and understand that we cannot guarantee text messages will be confidential.

You can choose to stop being in the study at any time. If you have any of these problems or changes in the way you feel, you should tell the investigator or other study personnel as soon as possible.

There may be risks we don't know about right now. We will tell you about any new information that might change your decision to stay in the study.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

There may be direct benefit to you from being in this study. Receiving a Willow wearable breast pump may help to feel more in control of your pumping schedule and make it easier to continue breastfeeding while at work or school.

Breastfeeding has many health benefits for both the parent and the baby. These benefits increase the longer a parent can provide milk. By using a wearable pump, participants may be able to pump for a longer period of time.

WHAT ABOUT EXTRA COSTS?

The research procedures described in this consent (see "What Will Happen to Me in This Study") will not be billed to you or your medical plan. Basic expenses such as transportation and the personal time it will take to come to study visits will be your responsibility. You or your medical plan will be responsible for any other care you receive from Children's Mercy and this care will be billed in the ordinary manner.

WHAT ABOUT CONFIDENTIALITY?

You have rights regarding the privacy and confidentiality of your health information. When health information includes identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers) that link it directly to an individual, it is called protected health information (PHI). Federal laws require that PHI be kept secure and private. In certain situations, federal law also requires that you approve how your PHI is used or disclosed. A research study is one of those situations.

By signing this consent form, you are permitting the following people to have access to your medical record and use your PHI for the research purposes described in this form. You are also permitting your PHI to be shared with everyone listed below:

- The research team, which includes persons involved in this study at Children's Mercy Hospital;
- The One Willow and the people or groups hired to help perform this study;
- The Institutional Review Board at Children's Mercy Hospital;
- Other researchers, hospitals, and institutions that are part of this study and their Institutional Review Boards;
- People from organizations that provide independent accreditation and oversight of hospitals and research;
- Government/regulatory agencies (both US and international), such as the Office for Human Research Protections, the Food and Drug Administration, and National Institutes of Health offices whose job it is to protect human subjects and oversee the conduct of research.

The research record is separate from your medical record. Information about you that is obtained during this study will be recorded in a research record and may also be recorded in your medical record. A research record will be created and kept in the Center for Wellbeing research office. The research record may include documents that have your name, assigned study ID number, home street address, telephone number, dates of service, medical device number, and email address. All research records will be maintained in a confidential manner.

Portions of that research medical record will be sent to One Willow. This information sent to One Willow will include your assigned study ID number and medical device number.

By signing this consent form, you are allowing your health information to be recorded in the research record. You are also permitting your research record and medical record to be shared with everyone listed above.

Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. We will share your health information only when we must, will only share the information that is needed, and will ask anyone who receives it from us to protect your privacy. However, once your information is shared outside of CMH, we cannot promise that it will remain private.

You may choose not to sign this consent form and not be in the study. You may cancel your permission to use and share your PHI at any time by contacting the study personnel listed on this form. You may also contact Children's Mercy Hospital Health Information Management (HIM) in writing. If you cancel your permission, you may no longer participate in this study. Your PHI that has already been collected for the study may still be used; however, no new information will be collected except information related to adverse events or other safety issues.

If you do not cancel your permission, your PHI may continue to be recorded until the entire study is finished. This may take years. Any study information recorded in your medical record will be kept forever. Unless stated elsewhere in this form, you may not have access to your research record or research test results.

Results of this study may be made public. If made public, you will not be identified in any publications or presentations.

WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?

Instead of being in this study, you may choose not to be in the study.

WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?

You will receive a Willow wearable breast pump and Ceres chill breast milk storage container. Because Willow pumps ceres chill containers are designed for one person to use only, you will be able to keep the pump and the ceres chill. This is required by the FDA for safety and hygiene reasons.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. You do not have to be in this study to receive medical care. If you choose not to be in this study or withdraw from this study, there will be no penalty or loss of benefits to which you are otherwise entitled.

We will inform you of any new information that we find out during this study. This information may affect your decision to stay in the study. If you choose to withdraw from (quit) the study or if you are asked by your personal doctor to withdraw from the study, you must tell the study team as soon as possible.

If you withdraw from the study early for any reason, the information that already has been collected will be kept in the research study and included in the data analysis.

Withdrawal will not have consequences. If you withdraw before the 6 months, you will be able to keep your pump and ceres chill.

Thomas Ayres, Ph.D. One Willow, the Institutional Review Board or the FDA may stop the study at any time. The investigator(s), your doctor, or One Willow may remove you from the study at any time without your permission.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Thomas Ayres Ph.D. is in charge of this research study. You may call Thomas at 918-232-4404 with questions at any time during the study. You may also call Kim Vipond, the study coordinator, at 816-234-3122 with any questions you may have.

You should call Dr. Ayres if you believe that you are sicker or have suffered injury of any kind as a result of being in this research study.

You may also call Children's Mercy Hospital' Pediatric Institutional Review Board (IRB) at (816) 731-7474 with questions or complaints about this study. The IRB is a committee of physicians, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

CONSENT OF SUBJECT

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. I consent to be in this research study. A copy of this signed form will be given to me.

Optional Future Research Contact:

Please read each sentence below and think carefully about your choice. After reading each sentence, circle "Yes" or "No" and initial each item.

Someone from this Center for Wellbeing research team may contact me in the future to ask about me participating in future research studies.

Yes No _____ Initials

I agree that a member of this Center for Wellbeing research team may share my email address with the sponsor. Someone representing the sponsor may contact me in the future about other studies I may qualify.

Yes No _____ Initials

_____ _____
Signature of Adult Date

STUDY PERSONNEL

I have explained the purposes, procedures, and risks involved in this study in detail to:

_____
Print name(s) of Subject

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Print Name of Person Obtaining Consent _____