Indiana University Informed Consent Statement for Research

Lactation at Work: A Wearable Breast Pump (Willow) Device Study
Protocol #28045

You are being asked to participate in a research study. This consent form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

Why is This Study Being Done?

We are doing this study to determine if wearable breast pumps help parents returning to work or school after the birth of a child (or children) achieve lactation goals. In addition, the study will help other institutions determine if a wearable breast pump program could work for their employes and students.

We are asking you if you want to be in this study because you are a resident or fellow at Indiana University School of Medicine who has recently given birth or plans to provide breast milk during the study period.

The study is being conducted by Zeina Nabhan, MD from the Indiana University School of Medicine. The study is not sponsored; however, the wearable breast pumps are provided by One Willow.

What Will Happen During the Study?

- **Willow Pump & Mobile App**
  You will receive a Willow wearable breast pump before your parental leave to practice at home. You'll use the Willow mobile app to track pump use. The app will collect usage data, including frequency, duration, and amount pumped, and send it to the research team using only your pump's serial number (not your name). This data sharing and app usage will be explained during consent, and the privacy policy and terms of use will be provided for your review.

- **Surveys**
  - **Intake Survey (start):** About 10–15 minutes; asks about your background, lactation goals, and experience.
  - **Monthly Surveys (while pumping):** 5–10 minutes each; covers current lactation practices, milk volume, device satisfaction, and goal updates.
  - **Final Survey (at end):** 10–15 minutes; asks about overall experience, whether your goals were met, and other methods used.

Time in the Study
Your participation will start when you begin using your Willow pump and end when you stop pumping. For most people, this will be between 6 months and 2 years. The total time to complete the surveys will be about 1–2 hours spread out over your time in the study.

Results
The information collected in this study is for research purposes only. You will not receive individual results from your surveys or the app data. We will share overall study results in reports and publications, but your name will not be used.

What Are the Risks of Taking Part in the Study?

Participation in this study involves minimal risk. The potential risks are those ordinarily associated with expressing human milk using a breast pump. These may include breast or nipple discomfort, reduced milk supply, or, rarely, infection such as mastitis. Participants may also experience frustration or stress if pumping does not meet their expectations or if workplace conditions remain challenging.

You may also feel uncomfortable answering some of the questions on the surveys, especially if they relate to personal experiences or challenges with lactation. You may skip any question you do not wish to answer.

Although steps will be taken to protect your privacy, there is a potential risk of loss of confidentiality. Survey responses and pump usage data will be collected and stored securely, and identifying information will be removed from research reports. However, no system can guarantee absolute confidentiality.

The study team will provide device education and information on lactation support resources to help minimize risks.

What Are the Benefits of Taking Part in the Study?

It is not known whether participants will directly benefit from participation in this study. Possible benefits may include increased flexibility and autonomy in pumping schedules, the ability to pump discreetly in more settings, and access to a wearable pump that may otherwise be cost-prohibitive. Findings from this study may help determine whether providing wearable pumps to medical trainees improves lactation outcomes and workplace experiences. The information gained may benefit future lactating employees or students at this and other institutions.

Will I be Paid for Participating?

There is no payment for this study. You will be able to keep the Willow device at the end of the study.

Will it Cost Me Anything to Participate?

There is no cost to you for receiving and using the Willow breast pump provided by the study. You may choose to purchase optional, commercially available, accessories for the pump (for example, parts in different sizes or styles) to improve comfort or fit. If you choose to buy these accessories, you will be responsible for the cost, and the study will not reimburse you.

There will be no medical visits or billable services associated with this study.

How Will My Information be Used?

The following individuals and organizations may receive or use your identifiable information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- State and Federal government agencies as permitted by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- The following research sponsors: One Willow

Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information in this way, we will remove information that could identify you, such as your name and contact information, before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing.

How Will My Information be Protected?

We will do our best to keep your personal information private, but we cannot promise complete confidentiality. We won't share any information that we think could be used to identify you in publications about this study. However, your personal information may be shared outside the research study as described above and/or if required by law.

Who Should I Call with Questions or Problems?

For questions about the study, contact the researcher, Zeina Nabhan, MD by email: znabhan@iu.edu or

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

What if I Do Not Want to Participate or Change my Mind?

After reviewing this form and having your questions answered, you may decide to participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your relationship or employment with Indiana University.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw. If you decide to withdraw, please let a member of the research team know.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

Agreement to be Contacted by Text and/or Email

We would like to communicate with you about this study by email. We might email you to send you the study related surveys.

Emails are not secure methods of communication. The information sent email, which may include sensitive or personal information, such as protected health information, could be accessed or read by someone other than you. If you would like us to communicate with you via email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____ I authorize the researchers to send me emails related to this research study

Email address for this communication: _____

You can still participate in this study even if you do not want us to contact you by text or email.

Participant's Consent

I agree to participate in this research study.

Participant's Printed Name:_____

Participant's Signature:_____**Date:**_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent: _____**Date:**_____