- PROTOCOL TITLE: Lactation at Work: A Wearable Breast Pump (Willow) Device Study

INSTRUCTIONS[i]:

- *Use HRP-503 - TEMPLATE PROTOCOL to prepare a document with the information from following sections.*
- *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as "NA". For example, research involving a retrospective chart review may have many sections with "NA." For subsections, like 1.x or 8.x, you can delete it if it's not applicable.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*
- *For submission of a protocol specific to a participating Site as part of a Multi-Site Study, use HRP-508 - TEMPLATE - SITE SUPPLEMENT.*

PROTOCOL TITLE:

- *Include the full protocol title.*
  - Lactation at Work: A Wearable Breast Pump (Willow) Device Study

PRINCIPAL INVESTIGATOR:

- /Michigan- assuming each group would have their own
-
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- Jennifer Keeton, EdD, KUMC Wellness HR Director

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VERSION NUMBER/DATE:

11/26/2024

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

Table of Contents

1.0 Study Summary

Protocol Information	Description
Study Title	Lactation at Work: A Wearable Breast Pump (Willow) Device Study
Study Design	
Primary Objective	Does the wearable willow pump help working mothers reach their pumping goal
Secondary Objective(s)	Does the wearable willow pump help mothers achieve a minimum of 6 months pumping Does the wearable willow pump help mothers achieve a 2+ year goal
Research Intervention(s)/ Investigational Agent(s)	Andrea McMillin, Kelly Laurent, Jennifer Keeton
IND/IDE #	Medical school employee population 4000/50% female, unknow percentage of women of childbearing age that plan to get pregnant during study window. Expectation would be 60 women over next three years.
Study Population	Unknown
Sample Size	Unknown
Study Duration for individual participants	Self-determined goals, recommendation is to pump a min of 6 months up to two years.
Study Specific Abbreviations/ Definitions	

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives.

- This is a post-market study to provide breast pumps to employees at an academic medical center as an additional layer of support in reaching lactation goals. Workers that do not have flexible break times and/or reliable close and secure pumping space face barriers to reaching their lactation goals. Wearable pumps provide users autonomy and flexibility regarding their pumping schedules. These devices are not covered as a "free" breast pump through most insurance companies and, while discounted, are often still at a higher price point for most new parents. By providing these for free to users, we expect to see the institutions' metrics regarding duration of pumping and satisfaction with meeting goals will be higher than national metrics. In partnership with Willow, our institution will provide free pumps to individuals as part of a study including participant consent.

2.2 State the hypotheses to be tested.

3.0 Among employees, medical residents and fellows; and early career physicians at the Institution during the study window of 3 years, who have delivered a baby, does access to a wearable Willow pump improve lactation experience and meeting goals regarding duration of pumping/providing milk?

4.0 Background

4.1 Describe the relevant prior experience and gaps in current knowledge.

MPH capstone based on this research focused on medical residents, 2 years as chair of university lactation committees, 5+ years in lactation research and education.

4.2 Describe any relevant preliminary data. Current model of a recycling program has successfully supported 70 individuals at this institution. This model would be expanding to other individuals at the institution and

providing new pumps to users. National data does not look at wearables or the impact of pumping at work specifically only breastfeeding in general, this study would fill a gap in that knowledge regarding supporting work.

4.3 *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge*

The AAP, HP2030 and WHO lactation recommendations are based on decades of research regarding health outcomes for both the lactating parent and infant.[1,2,3] Research shows that for the infant, the short-term benefits of lactation (described as 3 to 6 months of exclusively consuming human milk) include building important immunities against common illness in the first year of life and reducing the risk of ear infections, stomach flu, Respiratory Syncytial Virus (RSV), Crohn's disease, eczema, diarrhea and childhood cancers.[6,7,2,8,9] Short-term benefits for the lactating parent include quicker recovery from giving birth, increased bonding with the infant, and lower risk of postpartum depression. [8,9,12,13] Long-term lactation, described as exclusively consuming human milk for six to 24+ months, provides lifetime health benefits for the infant including lower risk of asthma, diabetes, Sudden Infant Death Syndrome (SIDS), as well as, providing important nutrition (protein, calcium, vitamin a) and enhancing brain development. [6, 8, 9,10,12,14]

This evidence has also shown that infants who exclusively consume human milk for six months had higher IQs (intelligence quotient) compared to those who consumed human milk for less than six months. Lactation can also provide emotional support for infants as a soothing tool and physical comfort during teething.[8,9] Long-term health benefits for the lactating parent include decreased risk for cancers (breast, ovary, endometrial, thyroid), type 2 diabetes, osteoporosis, cardiovascular disease, high blood pressure, and high cholesterol.[6,8,9,10,11] Successful long-term lactation for working parents includes pumping 2-3x per day to maintain milk production and creating a supply for the infant to consume when away from the providing parent.[8]

Even with this research and education during pre- and post-natal visits with the healthcare team, it can be difficult to balance lactation, returning to work, and creating a pumping schedule. A recent study showed that Hispanic (48.4%), Black (35%), Native American (37.3%), White (52.3%) or Asian (71%) mothers stop lactation by six months.[9] With more

women in the workplace than ever before, returning to work after a birth is extremely common and employers must work to create welcoming environments for new parents.

Healthy People 2030 has set the goal that 42.4% of infants in the United States are provided human milk exclusively for the first six months, but as of 2020 only 25.4% of infants have reached this milestone.[2] The Center for Disease Control (CDC) data reported from the National Immunization Survey reports that nationally 58.2% of infants receive "any milk" through 6 months of life and in Kansas, this rate is 61.6%.[15] While many parents set a goal of six months, there is a wide range of individual goals that new mothers may set based on circumstances. One of the questions asked in this study is intent vs. actual pumping goal since this is another area that has not been explored. According to the CDC, 60% of mothers do not reach their lactation goal.[17] In a 2012 study conducted by the San Diego Breastfeeding Center, researchers discovered that 85% of the parents in their cohort intended to pump for 3 or more months but only 32.4% met their intended goal.[18] These data reinforce the fact that providing human milk exclusively while returning to work is a monumental task that requires resources, commitment, and support.

In general for physicians new publications show this doesn't change much as residents leave training and enter practice. While they may have more autonomy and higher salary, they face the same challenges of time and access to private space without the protection of training program requirements or supervisor support. "individuals, institutions, and professional organizations."

In 1938, the U.S. Labor Department created the Fair Labor Standards Act (FLSA), which was amended in 2010 to expand protections to nursing mothers and, again, in 2022, with additional protections and clarifications regarding lactation break time and space requirements.[19] The 2022 FLSA revisions, named the Providing Urgent Maternal Protections (PUMP) Act, was revised to include more employees, who are also lactating parents at work, with protections for pump break times and harassment/mistreatment.[20] Even with these protections in place, the top three reasons that people stop pumping at work are a lack of space, a lack of support from co-workers, and a lack of flexible work schedules.[16] Educating supervisors and co-workers on what a lactating parent needs can make a difference in how long a parent chooses to pump milk.

Residents/Fellows and Physicians

This training cohort consists of women of "peak" reproductive age, as defined by the American College of Obstetrics and Gynecologists (ACOG).[21] ACOG states that in the U.S., "peak" reproductive age for women begins in late teens up to age 30 when fertility rates begin to decline.[21] By age 45, natural pregnancy is unlikely and associated with higher risks for most women.[21] While residents face the same barriers as other working mothers (e.g., inadequate space, support, and time), there are unique challenges for this group. Residents have training limitations to length of allowed parental leave outlined by their specialty boards (most boards only allow 6-8 weeks).[5,22] Longer leave may result in the following situations: (1) a delay in receiving board certification; (2) a delay in graduation, having to extend training; and (3) an impact on their career options post-training.[5,22] Since these residents are considered trainees, they are also beholden to their training program schedule, supervising faculty expectations, and team structure in the healthcare setting.

A thorough literature review shows most information focuses on exclusively consuming human milk specifically, with little to no inclusion of the value and importance of pumping at work to support lactation. Without regular human milk removal or pumping, the parent's milk supply will slowly drop in production with both parent and infant feeling frustrated. Research that focused on pumping milk in residency is limited, with most publications dated 2018 or later and tied to specific training programs. Examples include *Pregnancy and Motherhood During Surgical Training; Availability of Lactation Accommodation Information for Urology Residency Programs* by Sandozi A, Lee J, Shpeen BH, et al (2022), or more broadly on policy, *Crafting an Evidence-Based, Accreditation Council of Graduate Medical Education-Compliant Lactation Policy for Residents and Fellows by* Johnson HM, Walsh DS. *(2020)*.[25,26,27] In 2018, Rangel, Smink, et al studied the implications of female residents who have children during surgical training and the future workforce challenges.[5] Sandozi A, Lee J, Shpeen BH et al evaluated if Urology residency programs that provided lactation resources for trainees on their websites as part of female resident recruitment (the majority did not).[27] Johnson HM, Walsh DS. focused on development of a lactation policy template, compliant with the ACGME requirements.[25]

At the same time, the Accreditation Council for Graduate Medical Education (ACGME) updated its Common Program Requirements to include required lactation support.[31] This

expanded coverage from multiple entities only confirms the argument that supporting parents returning from leave is important to the workforce and the employer, including training programs. Infants who consume human milk have lower incidents of illness resulting in lower absenteeism among parents; also, parents who feel supported at work have higher satisfaction and retention rates.[19] Residents do not have clearly defined and protected time for pumping breaks; they rely on a faculty supervisor to approve breaks based on a clinical/operating schedule. Residents who work on a clinical team are expected to work an average of 60 hours per week, this may be exceeded in surgical specialties. The new language in the PUMP Act specifies that the employer must provide "reasonable break time" for pumping with the expectation on the employee and their supervisor to determine what that means.[20] This places the burden on the resident to communicate and justify their needs with their supervising faculty (which can change based on clinical experience).

Mothers/parents who are unable to create a reasonable pumping schedule to support their milk production and health may experience lower milk production, early infant weaning and may stop pumping altogether due to work barriers. Inability to regularly pump based on infant need and parent preference can lead to mastitis[33] (described as inflammation and infection of the breast/chest tissue due to a blockage in the milk ducts) and early lactation cessation. Emotionally and mentally, the lactating parent may have feelings of failure, inadequacy, dissatisfaction and depression. [4,5,22,23,24]

2025 literature update review

There really aren't any interventions out there that are at the scale that we are attempting for wearable pumps. the larger systematic reviews focus on layered support including policy, training, FAQs and space, so it's important that we call out our rooms and website as well here. data suggests that best outcomes are from workplace interventions to support with co-worker/leadership support in addition to self-efficacy.

https://pubmed.ncbi.nlm.nih.gov/39049792/

Sheffield V, Tomlinson S, McCaffery H, McCormick AD. One Pump at a Time: A Wearable Lactation Pump Pilot for Graduate Medical Education Trainees. *Breastfeed Med*. 2024;19(11):885-888. doi:10.1089/bfm.2024.0134

At the University of Michigan, which created a similar program modeled after the KU program, resident physician users reported that wearable pumps were beneficial to meeting goals and reduced barriers on meeting educational and clinical care responsibilities.

OUR DATA --https://meridian.allenpress.com/jgme/article/13/3/422/466354/A-GME-Wearable-Breast-Pump-Program-An-Innovative

The popularity of the program was apparent from the first call for users, within three years the office owned 17 pumps and had also added mini fridges as well that residents could borrow to place in their office or work rooms. In those first three years the GME office was able to support over 30 residents and as of this writing in early 2025 we have supported 67 residents. In addition to pumps and fridges, the GME program has expanded to include, lactation education materials, a welcome gift that is a book for mom and child written from the perspective of a physician mom describing their job "doctor mom superhero" and portable milk chillers.

The program has also expanded to support medical residents and other employees at the university of Kansas that don't have a reliable pumping space close to their workstation. Programs similar to this have begun to pop up in other institutions, notably John's Hopkins as well as a multi-site intervention design developing between KUMC, Vanderbilt and University of Michigan.

Based on feedback from users over half of our resident users intended to pump 7+ months 75% (31/41) and 56% (23/41) achieved pumping greater than 7 months. Residents reported that 31% were able to pump for 10+ months and 75% stated that they met or exceeded their pumping goal.

> *"Results:* Of the 542 respondents analyzed, 321 (59%) had used a wearable pump in the workplace and 221 (41%) had only used a traditional electric breast pump. Those who had used a wearable pump reported statistically significant shorter lactation breaks ($p < 0.00001$) and were more likely to be able to provide breast milk to their infants for

their entire intended duration ($p = 0.005$) compared to the traditional pump group. The ability to pump as often as needed while at work ($p = 0.16$) and the frequency of lactation breaks throughout the day ($p = 0.223$) were not significantly different when comparing the two groups."

Workplace Lactation Support

Institutional interventions to support lactation are more successful when they not only support the individual through creating spaces but also have clear policies that support both the individual and the team in understanding the needs and rights of the breastfeeding individual. Most common forms of support included designated spaces, support from co-workers and supervisors, flexible scheduling for breaks. Also included BF education and counselling at the workplace, written policies.

Providing pumps and giving parents flexibility to work at home and pump were the two least common interventions.

Many institutions place the burden on the parent to figure it out (no or unclear policies, no centralized location for lactation/parent resources)

5.0 Study Endpoints

5.1 *Individual Participant Endpoint-* cessation of lactation (2 year goal)

5.2 *Describe any primary or secondary safety endpoints.-*

- Need to ask if Willow wants to have an endpoint for study
- If individual decides to pump before end of the 2-year goal

6.0 Study Intervention/Investigational Agent

6.1 *Description: Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

Individuals will be given a free Willow device to keep at enrollment with the agreement that in exchange for usage of the device they complete an intake and outtake survey, as well as monthly.

surveys, to measure goals, experience, and final metrics. The product will be covered under the company device warranty for one year. They will also consent to Willow and the institutions utilizing their mobile app data via their device serial number Willow will sign the standard research agreement with the understanding that the results from the study are the property of the institution. Data can be pulled by serial number, no identifiers attached. (email, phone, username)

Surveys will be delivered to individuals based on their serial number assignments monthly via redcap for the duration of their pumping experience, devices do not need to be returned to the institution or Willow.

This is a post-market research project targeting employees at the institution that have recently given birth and plan to provide human milk for some duration after birth.

This study will be held over the duration of (3 years??)

PI will share results with Willow at agreed upon intervals to provide good faith study data. Final results will be shared in de-identified reports with the intent to present at national academic conference in conjunction with two other medical schools that are also delivering this intervention and submission for publication in academic medical journals

6.1 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- Devices stored in GME or shipped directly to individuals from Willow. No special handling needed for devices, individuals responsible for cleaning and maintenance, devices covered under warranty for first year.

6.2 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- N/A

7.0 Procedures Involved

7.1 Describe and explain the study design.

- Willow pumps provided directly before birth of child. Obtaining the pumps prior to childbirth allows individuals to have devices at home and practice with them before returning to work.

7.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

- Monthly check in with individuals via survey to assess how their lactation experiences is going, what changes from their initial plan have been made and their satisfaction with device and ability to feed child with human milk to their goals and expectations.

7.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*
- *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*
  - Describe:
    - Providing Willows early to allow for practice
    - Single user per device per FDA regulations
    - Access to Willow and Lactation experts for support
    - ATTACHED AT END - The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)

7.4 what data will be collected during the study and how that data will be obtained.

- INTAKE SURVEY – EXPECTATION AND GOALS FOR LACTATION JOURNEY, DEMOGRAPHICS, KNOWLEDGE
- MONTLY SURVEY – CHANGES TO PLAN, CURRENT VOLUME, FREQUENCY, SATISFACTION
- OUTTAKE SURVEY – final experience input, expectations vs reality, total length of time pumping and providing milk

7.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

- None

7.6 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

- N/A

8.0 Data and Specimen Banking

8.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

- N/A

8.2 List the data to be stored or associated with each specimen. N/A

8.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. N/A

9.0 Sharing of Results with Subjects

9.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental

findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared. N/A

10.0 Study Timelines

10.1 Describe:

- *The duration of an individual subject's participation in the study.* Determined by individual, during intake survey they will provide their expected duration, and will notify the team when they have finished pumping
- The monthly survey will ask users to identify if they are complete with pumping, they will then be directed to the outtake survey- branching logic to outtake survey and ask them to contact PI/administrator to remove from monthly survey queue.

- *The duration anticipated to enroll all study subjects*- min six months.
- *The estimated date for the investigators to complete this study (complete primary analyses).* 2-3 years

11.0 Inclusion and Exclusion Criteria

11.1 Describe how individuals will be screened for eligibility.- Participants will self-identify and notify investigators when they are going to start pumping. Some parents are proactive and plan out ahead of time their lactation needs, some pivot from original plan after returning to work and request support after initiation, intervention will accommodate both and surveys will begin at pumping initiation. *Describe the criteria that define who will be included or excluded in your final study sample.* University employees and residents

11.2 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the below populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent*- NO

- *Individuals who are not yet adults (infants, children, teenagers)* - NO
- *Pregnant women*- yes
- *Prisoners*- NO

12.0 Vulnerable Populations

12.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.*- device is specifically for new moms so they will no be pregnant when using the device.
- *If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the HRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.*
- *If the research involves cognitively impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.*

13.0 Local Number of Subjects

13.1 20-40 per year

13.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete

the research procedures (i.e., numbers of subjects excluding screen failures.)

14.0 Recruitment Methods

14.1 Describe when, where, and how potential subjects will be recruited. If applicable, describe procedures for oral or written communication with the prospective subject or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility.

- (FOR GME) Through notification at regular 6 month intervals
- Send out a mass email about the program to university
- Include in HR/well-being events/activity fairs
- Include in information on website with the page that links to leave information – where do we have bright
- on the university well-being intranet site and dedicated lactation support resource pages
- Periodic Lunch and Learn sessions
- Newsletters and Calendars

14.2 Describe the source of subjects. – Academic Medical Center University employees

14.3 Describe the methods that will be used to identify potential subjects. If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility.- none, they will find us. For GME we have sent out regular email reminders to the female identifying residents to remind them of the resource. Can include in FMLA and pregnancy leave paperwork info

14.4 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for

broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

- Link in policy and procedure pages regarding lactation resources.
- Word of mouth
- lactation resource page
- application
- Customary internal communication platforms such as university calendar and e-newsletters
- Fliers distributed in lactation rooms

14.5 Describe the amount and timing of any payments to subjects. No payments but they get to use and keep the free device. Will be given device upon their request, if possible before they deliver to be able to practice at home. They keep device at end of study.

15.0 Withdrawal of Subjects-

A subject can really withdraw at any time for any reason by themselves or by the study team for a couple of ranges (termination of employment, ???) .**Employees no longer employed with the institution will have emails deactivated and removed from study as part of HR process.**

15.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent. None?

15.2 Describe any procedures for orderly termination. None unless program termination is advised by HR, legal counsel or other designated university official. Communication will be through the same mechanisms as recruitment and participants will keep the devic

15.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection. None?

16.0 Risks to Subjects

16.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.- *Minimal (?) potential* risk to participants' milk supply due to device mechanism. Education on how to best to use the device and to explore other options that can help them achieve their goals (standard pump or hospital grade pump) will be offered.

16.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. None other than known inherent risks of pumping breast milk such as infection, blocked duct, etc.

16.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. NONE

16.4 If applicable, describe risks to others who are not subjects. NONE

17.0 Potential Benefits to Subjects

17.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits. Substantial benefit to participants is anticipated in helping them have more autonomy and success with pumping at work so they can pump longer and experience improved work-life integration. Numerous health benefits for both participant and infant. The longer they are able to provide milk. Participants gain access to the equipment without having to pay out of pocket for an expensive device.

17.2 Indicate if there is no direct benefit. Do not include benefits to society or others.

18.0 Data Management and Confidentiality

18.1 Describe the data analysis plan, including any statistical procedures or power analysis.

18.2 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Data stored on institutional secure shared drives or in survey tool. Survey tool is designated for research purposes at the academic medical center.

18.3 Describe any procedures that will be used for quality control of collected data. Deidentified data tied to the serial number so it can be matched back to device analytics.

18.4 Describe how data or specimens will be handled study-wide: Investigators will have access to the data for analysis and aggregate reporting purposes. Data stored on secure internal network drives. Investigators are responsible for receipt and any transfer of the data through secure network tools.

18.5

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have access to the data or specimens?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How data or specimens will be transported?*

19.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects. Participation is fully voluntary and there will be no undue influence to

pump if a participant is unhappy or unable to use the devices, individuals will need to let us know when they are done so Investigatorscan send them the final survey and remove them from the monthly send. Our survey will ask questions about what made them stop pumping and there is an open text box for those that would like to provide any detail about their experience.

19.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.* Individuals will be surveyed monthly on basic data but will be asked to assess if they are satisfied with the device, and utilization, Investigatorswill ask users to let us know when the cease pumping so Investigatorscan send the outtake survey (probably link it to the monthly survey) and then Investigatorswill end monthly survey

- *What data are reviewed, including safety data, untoward events, and efficacy data.* unknown
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).* n/a

- *The frequency of data collection, including when safety data collection starts*. Quarterly review of aggregate data, negative response to key questions** will trigger an alert to investigators
- *Who will review the data.* Project Investigators
- *The frequency or periodicity of review of cumulative data*. n/a investigators will review data once a final survey has been completed and overall data quarterly including any anonymous comments, if there are concerns about safety in the comments, investigators will ask individuals to notify us immediately so Investigators can reassess.

- *The statistical tests for analyzing the safety data to determine whether harm is occurring.* n/a
- *Any conditions that trigger an immediate suspension of the research.* n/a

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 *Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.* Participants will be deidentified in the survey using their infant DOB as their identifier, wondering how we can tie it back to their serial number to match data from the study??) to protect anonymity, individual data for the post survey will be reviewed to ensure there are not any serious triggers in the final comments that would indicate concerns with the program but the data reviewed cumulatively and as deidentified

20.2 *Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures. Project information, objectives, goals, and protections will be provided on intranet page;* surveys will be completed via RedCap. Individuals that reach out to participate will be provided information on pumping with the Willows and the informed consent form at the beginning.

20.3 *Indicate how the research team is permitted to access any sources of information about the subjects.* Biographic data will be collected through the RedCap survey. And only collected at planned intervals (quarterly) to assess midpoint measurements as deidentified combined and/or aggregate data.

21.0 Compensation for Research-Related Injury

21.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury. None.

21.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury. Attached

22.0 Economic Burden to Subjects

22.1 Describe any costs that subjects may be responsible for because of participation in the research. Responsible for purchasing any extra parts or accessories for their devices.

23.0 Consent Process

23.1 Indicate whether you will you be obtaining consent, and if so describe:

- *Where will the consent process take place.* At time of device handover
- *Any waiting period available between informing the prospective subject and obtaining the consent.* none
- *Any process to ensure ongoing consent.* Consent statement at beginning of all surveys
- *Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, describe:*
    - *The role of the individuals listed in the application as being involved in the consent process.*
    - *The time that will be devoted to the consent discussion.*
    - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
    - *Steps that will be taken to ensure the subject's understanding.*

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.* Unknown, anticipate employees and residents are fluent in English; support provided on

case-by-case basis with support from university resources (eg., Human Resources)

- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception) **N>A**

- *Review the HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to ensure you have provided sufficient information for the IRB to make these determinations.*
- *If the research involves a waiver of the consent process for planned emergency research, please review the HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research to ensure you have provided sufficient information for the IRB to make these determinations.*

Subjects who are not yet adults (infants, children, teenagers) **N>A**

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
    - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "children."*
    - *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for*

consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in HRP-013 - SOP - LARs, Children, and Guardians.

- *Describe whether parental permission will be obtained from:*
  - *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
  - *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
- *When assent of children is obtained describe whether and how it will be documented.*

Cognitively Impaired Adults **N/A**

- *Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require cognitively impaired adults to sign assent documents.*

Adults Unable to Consent **N/A**

- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
    - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "legally authorized representative."*
    - *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in HRP-013 - SOP - LARs, Children, and Guardians.*
- *Describe the process for assent of the subjects. Indicate whether:*
    - *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
    - *If assent will not be obtained from some or all subjects, an explanation of why not.*
    - *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

Humanitarian Use Device (HUD) **N/A**

- *For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.*

24.0 Process to Document Consent in Writing

24.1 Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing.

24.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. Minimal risk

24.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information. You may use HRP-502 - TEMPLATE CONSENT DOCUMENT to create the consent document or script.)

25.0 Setting

25.1 Describe the sites or locations where your research team will conduct the research. Individuals will use devices in normal life and complete surveys based on their experience.

- *Identify where your research team will identify and recruit potential subjects*. Investigators will promote the research project for those that may be interested but will not approach users to recruit directly.

- *Identify where research procedures will be performed*. **N/A**
- *Describe the composition and involvement of any community advisory board.* **N/A**

- *For research conducted outside of the organization and its affiliates describe:*
    - *Site-specific regulations or customs affecting the research for research outside the organization.* **N/A**
    - *Local scientific and ethical review structure outside the organization.* **N/A**

26.0 Resources Available

26.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?* Approximately % of 2000 female employees of reproductive age,
- *Describe the time that you will devote to conducting and completing the research.* Monthly check ins and approx. 2 months to refine and finish the survey (10% time) then the same at wrap up time for data
- *Describe your facilities.* n/a
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequence of the human research.* **N/A**
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions*. PhD, EdD and MPH as well as physician and lactation consultant included in the design process and will be included in the final data review and paper

27.0 Multi-Site Research

27.1 Study-Wide Number of Subjects

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

27.2 Study-Wide Recruitment Methods

- *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.*
- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*
- *If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See HRP-830 - WORKSHEET - Communication and Responsibilities. All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
- *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.*
    - *All local site investigators conduct the study in accordance with applicable federal regulations and local laws.*

- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

27.3 Describe the method for communicating to engaged participating sites (see HRP-830 - WORKSHEET - Communication and Responsibilities):

- *Problems (inclusive of reportable events).*
- *Interim results.*
- *The closure of a study.*

27.4 If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See HRP-830 - WORKSHEET - Communication and Responsibilities.)

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Data	Willow	KUMC
Serial Number	Via app (User profile)	Via RedCap (project participation (email address)
Time & Frequency	Via app	Self-reported via RedCap Survey
Volume		Self-reported via RedCap Survey (deaggregate)
Satisfaction/Goals		Self-reported via RedCap Survey (deaggrate)

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