General Protocol Template

(HRP-580 – TEMPLATE - General Protocol)

PROTOCOL TITLE:

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

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REVISION HISTORY

This Revision History table is provided for the benefit of study team version control. If this table will not be useful please delete it.

Revision #	Version Date	Summary of Changes	Consent Change?

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STUDY INFORMATION

1.0 Study Summary*

2.0 Objectives*

2.1 Purpose, specific aims or objectives: *Describe the purpose, specific aims, or objectives. If more than one objective be sure to list separately.*

This is a post-market study to provide breast pumps to residents at a pediatric academic medical center as an additional layer of support in reaching lactation goals. Residents 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.

Among medical residents and fellows during the study window of 3 years (one year providing devices and up to three years collecting data, tracking users through end of pumping experience), who have delivered a baby. Does access to a wearable Willow pump improve lactation experience and meeting goals regarding duration of pumping/providing milk?

2.2 Hypothesis: *State the hypotheses to be tested.*

Using a wearable breast pump will allow working mothers to continue in their professional obligations and reach their pumping goal.

Secondary: Working mothers' burnout will not increase during the use of wearable breast pump.

3.0 Background*

3.1 *Describe the relevant prior experience and gaps in current knowledge.*

The relevant prior experience of the PIs includes expertise in measuring the employee experience, and 3+ years of supporting resident and fellow mothers through GME. We are conducting this study in partnership with multiple academic medical centers that include experts in lactation research and support.

3.2 *Describe any relevant preliminary data.*

Relevant preliminary data is outlined in the following literature study and experience from other institutions using a current model of a recycling program has successfully supported 70 individuals at this institution. This model will be shared with other institutions as well to create mirror projects and expand the data by 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.

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

The AAP, HP2030 and WHO lactation recommendations of six months exclusive breastfeeding up to two years of breastfeeding with table food, 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, gastroenteritis, 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 and Prevention (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 from "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 and up to 80 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.

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

We want this study to initiate a similar program at CMKC. The desire for the program from CMKC residents has been apparent from multiple requests each year and comparisons to the KUMC program. The popularity of the KU 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 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." Colbenson GA, Hoff OC, Olson EM, Ducharme-Smith A. The Impact of Wearable Breast Pumps on Physicians' Breastfeeding Experience and Success. Breastfeed Med. 2022;17(6):537-543. doi:10.1089/bfm.2021.0266

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. 1: Vilar-Compte M, Hernández-Cordero S, Ancira-Moreno M, Burrola-Méndez S, Ferre-Eguiluz I, Omaña I, Pérez Navarro C. Breastfeeding at the workplace: a systematic review of interventions to improve workplace environments to facilitate breastfeeding among working women. Int J Equity Health. 2021 Apr 29;20(1):110. doi: 10.1186/s12939-021-01432-3. PMID: 33926471; PMCID: PMC8082937.

Ortiz Worthington R, Adams DR, Fritz CDL, Tusken M, Volerman A. Supporting Breastfeeding Physicians Across the Educational and Professional Continuum: A Call to Action. Acad Med. 2023 Jan 1;98(1):21-28. doi: 10.1097/ACM.0000000000004898. Epub 2022 Dec 22. PMID: 35921171; PMCID: PMC10423406.

Many institutions place the burden on the parent to figure it out (no or unclear policies, no centralized location for lactation/parent resources) Ashby EL, Donepudi S, Padilla HM. Understanding lactation policies and resources across a university system: survey and document review. BMC Pregnancy Childbirth. 2024 May

15;24(1):367. doi: 10.1186/s12884-024-06541-9. PMID: 38750490; PMCID: PMC11094989.

4.0 Study Endpoints

4.1 *Describe the primary and secondary study endpoints.*

The Individual Participant Endpoint will be at the individuals self-determined endpoint, ideally at the cessation of pumping.

- The study end point will be at the three year anniversary of study start.
- The individuals may also determine to end study participation before they are finished pumping before the 2-year goal.

4.2 *Describe any primary or secondary safety endpoints.*

Individuals may also determine to end study participation based on the recommendation of their primary care physician.

5.0 Study Design*

5.1 **Study Design:** *Describe and explain the study design.*

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. They will also consent to Willow and the institution utilizing their mobile app data via their device serial number. This data includes time of using pump, length of use, frequency, and estimated and recorded volumes of pumped milk. 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. The PIs will not need access to the application data, Willow will share data with the institution at agreed checkpoints. The data will be transmitted via password protected cloud link. Once transmitted the data will be stored on the PIs password protected cloud storage OneDrive.

Data Sharing	Willow to CMKC	CMKC to Willow

Serial Number	Via app (User profile)	Via RedCap (project participation (email address) – CMKC team will record device as they are provided to individuals, log them in redcap with their email address, email address blinded in final data
Time (duration of pumping, total minutes) & Frequency (how freq the devices are turned on for use)	Via app	Self-reported via RedCap Survey **How many times do you use your Willow pump a day?**
Volume (fluid ounces)		Self-reported via RedCap MONTLY Survey (deaggregate) **How many ounces to express with your Willow pump a day?**
Satisfaction/Goals		Self-reported via RedCap MONTLY Survey (deaggregate) **Do you feel like you are meeting your current lactation goals?** **Which devices are you using to accomplish your lactation goals?**

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 students and 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 one year for device distribution and remain open for up to two years or until the last participant indicated completion by completing the endpoint survey.

PI will share results with Willow at agreed upon intervals to provide good faith study data. 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

Drug/Device Handling: 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. (*Products are covered under manufacturer 1 year warranty. All Mom's are asked to contact Willow directly for warranty/troubleshooting and exchange/replacement requests) Please see our site for in depth warranty information https://onewillow.com/pages/faq. Our customer care team number to call is located here with days/times for live help and other avenues of communication to obtain live help. https://onewillow.com/pages/contact*)

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5.2 Table of Events: *The Table of Events is another helpful tool to present the study procedures in a clear and concise manner. A Table of Events not only helps in the facilitation of IRB review, but is also a useful tool for communicating study details to study staff and even research participants.* ***It is highly recommended to include a Table of Events for any study involving more than one visit****.*

The table below is provided as an example and may be modified as appropriate. The Table of Events must capture the procedures that will be accomplished at each study visit/interaction and all contacts with study participants e.g. telephone contacts. This includes any tests that are used for eligibility, stratification, or decisions on study intervention or discontinuation. Allowable windows should be stated for all visits.

	Intake Survey	Monthly Survey	Outtake Survey
Informed Consent	X		
Delivery of Willow	X		
Demographics	X		

	Intake Survey	Monthly Survey	Outtake Survey
Expectation for Lactation Goals	X		
Previous Lactation Experience	X		
Outcome Evaluation		X	X
Changes to Lactation Goals, practices, current volume, frequency, satisfaction, and well-being		X	X
Final experience input, expectations vs reality, total length of time pumping and providing milk		X	X

6.0 Study Interventions*

Description: *Describe the study intervention and/or experimental manipulation that is being evaluated.* The Study design is to distribute willow pumps directly before birth of child for subjects that choose to enroll in the study, pumps will be provided prior to individual going on leave, this allows individuals to have devices at home and practice with them before returning to work.

Research procedures will include subjects to complete the consent and intake survey at initiation of pumping, completing monthly surveys through pumping and then a endpoint survey to collect final experiential data.

Describe:

Individual will be provided Willow Pumps prior to delivery and leave to allow for practice.

Willows are single user devices per FDA regulations

The institution will provide educational materials for users and access to Willow experts for support

Attachments included: consent form, intake, monthly and endpoint surveys.

Data collected during survey

INTAKE SURVEY – expectation and goals for lactation experience, demographics and knowledge of lactation from previous experiences.

MONTHLY SURVEY – changes to lactation practices, current volume, frequency and satisfaction.

OUTTAKE SURVEY – final experience input, expectations vs reality, total length of time pumping and providing milk

No current plans for long-term follow-up

Not a Humanitarian Use Device (HUD)

6.1 Behavioral Intervention: *If this study involves a behavioral intervention, describe the intervention in detail. Be sure to address whether the intervention is experimental or considered to be an accepted standard.*

- **Deception:** *If the study includes any aspect of deception, explain the deceptive aspects as well as the scientific rationale for the deception.*

N/A

6.2 Drugs, Biologics, or Devices: *If this study involves the administration or dispensation of a drug or biologic, or the use of a medical device (including mobile medical apps), within FDA approved labeling or outside of FDA regulation, complete the table below.*

***NOTE,** if the study is:*

- *Evaluating of the safety or effectiveness of a drug, biologic, or medical device,*
- *Using a drug, biologic, or medical device outside of current FDA approved labeling, or*
- *If your study requires an IND, IDE or HDE*

Then this is not the protocol template that should be used. Refer to the CM Clinical Trial Protocol Template which is designed for these types of clinical investigations.

Drug/Biologic/Device Name	Describe how the article is being used under current FDA approved labeling
Willow wearable breast pump	Willows are single user devices per FDA regulations
Mobile app	Not FDA approved; Mobile app is being used under current labeling. Per FDA's policy for Device Software Functions and Mobile Medical Applications. The Willow Mobile app qualifies as

	NOT a Medical device per example 6: Software functions that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness.

- **Drug Handling:** *Describe plans to store, handle, and administer the drugs so that they will be used only on participants and by authorized investigators.*
    - *Reference the established, approved organizational SOP (e.g. Research Pharmacy SOP for the Control of Investigational Drugs) that will be followed. If deviating from approved SOPs, explain why the approved SOPs would not suffice for this study and the rationale for deviating.*
- **Device Handling:** *Describe plans to store, handle, and administer the device(s) used in this study so that they will be used only on participants and by authorized investigators.*
    - *Reference the established, approved organizational SOP (e.g. Research Policy 7.04 Investigational Devices - Control), that you will be following. If deviating from approved SOPs, explain why the approved SOPs would not suffice for this study and the rationale for deviating.*

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. (*Products are covered under manufacturer 1 year warranty. All Mom's are asked to contact Willow directly for warranty/troubleshooting and exchange/replacement requests) Please see our site for in depth warranty information https://onewillow.com/pages/faq. Our customer care team number to call is located here with days/times for live help and other avenues of communication to obtain live help. https://onewillow.com/pages/contact*)

PARTICIPANT MANAGEMENT

7.0 Inclusion and Exclusion Criteria*

7.1 Eligibility Criteria: *Describe the criteria that define who will be included or excluded in the final study sample. If the study design includes multiple groups, be sure to list the criteria for each group.*

Inclusion Criteria

Participant eligibility will be based on employment or enrollment in a CMKC residency or fellowship program. Participant eligibility will be obtained vial self-enrollment, individuals 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.

The specific population of study will be individuals of birthing age that give birth while in a CMKC residency or fellowship program and have determined that they plan to provide human milk and pump at work post-delivery.

7.2 Equitable Selection: *Inclusion/exclusion criteria should be both fair and appropriate to the research question. If the study involves inclusion/exclusion criteria based on demographic characteristics such as sex, race/ethnicity, language, provide rationale for the criteria. For example, if excluding non-English speaking participants, provide rationale for why it is not possible to include non-English speaking participants.*

7.3 Vulnerable Populations: *Check any vulnerable populations that are being targeted for enrollment into the study: (Members of the following populations may not be included as participants in the research unless selected here.)*

☐ Children/Minors (under 7 years of age)
☐ Children/Minors (7-17 years of age)
☒ Neonates (infants less than 30 days old)
☐ Neonates of Uncertain Viability (infants less than 30 days old)
☐ Non-Viable Neonates (infants less than 30 days old)
☐ Wards of the State
☐ Fetuses
☒ Pregnant Women

☐ Adults with impaired decision-making capacity

☒ CM Employees
☒ CM Students/Residents/ Fellows
☐ Economically or Educationally Disadvantaged Persons
☐ Prisoners

- *For each population selected above, describe the additional safeguards designed to protect their rights and welfare. To ensure that sufficient detail is provided, see the "Tips and Tools for Vulnerable Populations" below for more detailed information on the appropriate protections for each specific population.*
- *If the research involves enrolling CM employees or students, indicate how the potential for employees/students to feel coerced or unduly influenced to participate will be minimized. For example, the risk of coercion may be minimized by ensuring that employees will not be recruited or enrolled by their direct supervisor.*

This protocol is specifically designed for individuals to use a device already in the market designed for lactation (post pregnancy). There could be circumstances where a user becomes pregnant while also providing milk for an existing child, which is also a norm in this population. The risk of coercion for residents and fellows will be minimized by ensuring that employees will not be recruited or enrolled by their direct supervisor.

We will collect the baby's Date of Birth making them a secondary participant. No other information about the baby will be collected. The DIB is collected in order to start the monthly lactation emails. Questions during the survey are targeting the mother's experiences with lactation. Mother's will be asked how old their child is in each monthly survey in order to verify the number month survey and month of pumping are lining up correctly.

8.0 Local Number of Participants

8.1 *Indicate the total number of participants or charts to be enrolled locally as well as the accrual goal. If the study includes multiple groups or cohorts, be sure to describe the number of participants required for each*

cohort. If one of the groups includes a chart review, each chart is considered a participant and needs to be reflected in the numbers below.

	Group 1	Group 2 (if applicable)	Totals
Enrollment Goal: *Number of participants to be enrolled = the number of participants to be consented or to be screened for chart reviews.* The current rate of pregnancies in training at CMKC is approximately 20-25 per year, with the expansion of this offering we are anticipating that it will at most double. Willow has not indicated a limit on number of devices they will provide.	25 per year		25 per year

9.0 Identification and Recruitment of Potential Participants*

9.1 Identification of Potential Participants:

How will participants be identified? (Check all that apply)

☐ Chart reviews

☐ By their treating physician who will then provide the study team's contact information to the potential participant/family

☐ By their treating physician who will obtain patient/family permission to share contact information with the study team

☒ Self-refer in response to IRB approved advertisements or websites

☐ Through Cerner or other CM sources (e.g. databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

☐ List of candidates provided through the Data Report Request Form

☐ Registry of individuals interested in research opportunities

☐ Past participant list

☐ Participants will roll-over from another research study: Study #

☒ *Other:* Six month email notifications to potential subject group in Graduate Medical Education

Newsletters and Calendars

9.2 Pre-Screening prior to HIPAA Authorization

Will any of the identification methods checked above involve access to Protected Health Information (PHI) prior to obtaining HIPAA Authorization?

☐ Yes

☒ No

- *If yes, a "Partial Waiver of HIPAA Authorization" is required. Be sure to make this selection in the "HIPAA & Confidentiality" section below and complete* ***Addendum E: Waiver/Alteration of HIPAA Authorization***

9.3 Recruitment of Potential Participants:

- *Describe when, where, and how potential participants will be recruited.*
- *If the study involves the recruitment of participants from Divisions/Departments other than the PI's or Co-Investigators' Division/Department, describe how potential participants will be introduced to the study (e.g. telephone call, email, letter, personal introduction by treating physician). NOTE: It is best practice for the initial contact to be initiated by an individual with a clinical relationship with the potential participant. If this is not possible, and to satisfy HIPAA requirements, the initial contact must be made by a study team member who is an agent of CM.*
- *Upload any recruitment materials, including telephone scripts, in the myIRB application, Recruitment Materials section. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape or transcript. Wording of the advertisement may be submitted prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.*

- *If recruitment strategy involves contacting individuals multiple times, describe how frequently and in what manner individuals will be contacted and the maximum number of attempted contacts for any one individual.*

Subjects will be from CMKC Residents and Fellowships

Subjects will be primarily self-identified for the institution, through Graduate Medical Education there is a more focused approach by filtering notifications to just female identifying residents to remind them of the resource. Word of mouth from current users is also an important aspect to recruit participants as study grows.

Material provided during recruitment and to participants include the following:

Existing Policy and Procedures information

Lactation resource page which includes education resources

Willow product information

Utilization of internal communication platforms such as university calendar and e-newsletters

Fliers distributed in lactation rooms

Users will not be paid for their participation but will be allowed to keep the devices.

Per the Human Subjects Training the reviewers will follow the permissible recruiting regarding preparatory to research for any in person recruiting events targeted towards individuals that disclose they are pregnant or planning for pregnancy.

10.0 Surveys and Psychometric Testing:

- *Describe any surveys or psychometric testing that will be conducted as part of the study. Address whether the instruments used have been previously validated.*

- *List the names of each instrument (survey, questionnaire, test, etc). Upload copies of any surveys, psychometric tests, or other instruments that will be administered for research purposes in the myIRB application, Other Attachments section.*

INTAKE SURVEY – expectation and goals for lactation experience, demographics and knowledge of lactation from previous experiences.

MONTHLY SURVEY – changes to lactation practices, current volume, frequency and satisfaction.

OUTTAKE SURVEY – final experience input, expectations vs reality, total length of time pumping and providing milk

11.0 Additional Study Activities

11.1 *Provide a description of all research activities beyond surveys and psychometric testing that are being performed and when they will be performed, including activities being performed to monitor for safety or minimize risks. Address:*

N/A

11.2 *Blood and Other Specimen Collection:*

N/A

12.0 Follow-up

- *Describe the follow-up schedule, what data will be collected during this period, and how the data will be collected (e.g. telephone, email with link to data entry site, clinical chart review).*

No current plans for long-term follow-up

13.0 Genetic Analysis Information

N/A

14.0 Sharing of Results with Participants

N/A

15.0 Risks to Participants*

15.1 *List the research risks. Research risks are any potential physical, psychological, social, legal, privacy, confidentiality risks or economic harms that may come from participating in the study. This does not include the risk of any procedures conducted as part of standard care.*

- *Where applicable, describe the probability, magnitude, duration, and reversibility of the risks.*
- *Describe the measures taken to minimize these risks as this will be useful for the IRB in making their risk/benefit determination.*
- *If collecting or accessing sensitive data which may pose legal, economic, or reputational harm, describe this risk in detail.*

15.2 *Indicate whether the researchers believe the risks involved in this study are minimal, or if the study poses greater than minimal risk of harm to participants.*

15.3 *If applicable, indicate which activities may have risks to the participants that are currently unforeseeable.*

15.4 *If applicable, indicate which activities may have risks to an embryo or fetus, should the participant be or become pregnant.*

15.5 *If applicable, describe risks to others who are not participants (e.g. pregnant partner of a male participant)*

There is minimal risk to participants other than normally occurring risks when pumping milk. These include low supply, infection, or stressors that can lead to individual's cessation of pumping. The study team will work to provide education on the device and access to lactation education to minimize risk.

16.0 Potential Benefits*

16.1 *Describe the potential of any direct benefits that individuals may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits as this will be useful to the IRB in making their risk/benefit determination.*

There is substantial benefit to participants, we are anticipating that participants will experience more autonomy and success with pumping at work, ability to pump longer, improved work-life integration. There are numerous health benefits for both participant and infant as outlined in the literature study included above which increase over time providing milk. Participants gain access to equipment that is currently at a higher price point compared to the free devices covered by insurance.

16.2 *Describe the potential of any benefits to society/science or others related to the possible knowledge gained.*

There is substantial benefit for society and science. Continued evidence for the benefit for supporting lactation for new mothers in the workplace can support continuing trends towards better and normalized support for others.

17.0 Investigator Assessment of Risk/Benefits Ratio*

17.1 *Please provide an assessment of risk and benefits in the table below. Note, the IRB makes the final determination based upon responses in the two preceding sections.*

Select as applicable:	**Pediatric Risk Category:**	
☒	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
☐	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants. (45 CFR §46.405 and 21 CFR §50.52)
☐	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
☐	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
☒	Not Greater than Minimal Risk	
☐	Greater than Minimal Risk	

18.0 Payment, Reimbursement and Tangible Property provided to participants*

Is payment, reimbursement, or tangible property part of the study?

☒ Yes ☐ No *(If No, delete the following subsections)*

18.1 ***Payment to Participants:*** *If providing payment for participation (e.g. cash equivalent for participation, payment for time off work), select the form of payment:*

☐ Gift card
☐ Prepaid Merchant Gift Card: (Merchant:_____)
☐ e-Gift card
☐ Other: _____

Note: "Prepaid Merchant Gift Card," "e-gift card," and "Other" options require approval by Research Administration. Upon submission in myIRB, ORI staff will initiate the Research Administration approval process.

Payment Schedule: Describe the payment schedule (if the payment schedule is involved, consider using a table to display this information) including:

- *The total amount anticipated*
- *The study time points when payments will be made and the amount of compensation at those time points.*
- *To whom payments will be made (i.e. to participants, to parents/LAR, or will this be based on some criterion such as age of participant).*
- *If total amount of payCCment and/or tangible property for an individual participant may exceed $600, include plans for the collection of Social Security Number (SSN) or Individual Tax Identification Number (ITIN) as required by CM policy.*

18.2 **Reimbursement:** *If providing reimbursement (repayment to research participants and/or their families to cover out-of-pocket expenses they incur), select the form of reimbursement:*

☐ Gift card
☐ Other: _____

18.3 **Tangible Property:** *If providing tangible property or any item of value given for participation (e.g. a toy, a tote bag, a water bottle, an electronic device), describe:*

- *The item(s) to be given.*
- *How and when the item(s) will be distributed*
- *The estimated total maximum value of the item(s). If the total value is $100 or more, provide a plan for tracking the items and value and how you will report this to Research Administration at the end of the year for 1099 purposes.*
- *If the estimated total maximum value of payment and/or tangible property provided to an individual participant may exceed $600, include plans for the collection of Social Security Number (SSN) or Individual Tax Identification Number (ITIN) per CM policy.*

We will provide a Ceres Chill with each willow pump to allow moms the ability to keep milk cold throughout the work day without needing a fridge. The item will be distributed at the beginning of the study with the willow pump. The maximum value of the item is $70.00. Willow INC is providing a Willow GO wearable Pump. The maximum value of this item is $349.99.

19.0 Compensation for Research-Related Injury

N/A

20.0 Economic Burden to Participants

N/A

21.0 Parental Permission and Adult Consent Process*

21.1 Indicate below all methods of Permission/Consent that will be used in this study.

- *If the study includes **multiple study groups**, be sure to indicate which method is being used with each group.*
- *If requesting a **Waiver of Documentation**, a complete **Waiver**, or an **Alteration**, complete the required addendum at the end of this document.*

Written Informed Permission/Consent

☐ **Written informed permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies:

☒ **Written informed consent of adult participants**

Study group(s) to which this method applies: All participants

Informed consent will be obtained at the beginning of the survey process at device handoff, individuals will complete the consent form which will trigger the survey timing.

Non-English-Speaking Subjects

It is unknown if there will be any non-English speakers enrolled in the survey, the institution hires and trains individuals that do not speak English as a primary language, but they are expected to be able to be fluent in English for their training and employment. If a subject is minimally fluent in English, we will work with the Human Resource office to navigate communication barriers.

☐ **Written informed consent of participants turning 18**

This includes the continued access to and use of their PHI by the study team.

Study group(s) to which this method applies:

Waiver of Documentation of Permission/Consent

Permission/Consent form provided but signature will **NOT** be obtained (e.g. verbal consent)

Must complete *Addendum A: Waiver of Documentation of Permission/Consent*

☐ **Waiver of written documentation of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies:

☐ **Waiver of written documentation of consent of adult participants**

Study group(s) to which this method applies:

☐ **Waiver of written documentation of consent of participants turning 18**

Study group(s) to which this method applies:

Waiver or Alteration of Permission/Consent

Parent/LAR permission/adult consent will **NOT** be obtained, or an alteration to an element(s) of consent.
Must complete *Addendum B: Waiver of Permission/Assent/Consent*

☐ **Waiver/Alteration of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: Moms babies date of birth. The consent form will be provided electronically for them to indicate agreement and consent.

☐ **Waiver/Alteration of consent of adult participants**

Study group(s) to which this method applies: Primary participants, moms. The consent form will be provided electronically for them to indicate agreement and consent. All participants

Informed consent will be obtained at the beginning of the survey process at device handoff, individuals will complete the consent form which will trigger the survey timing.

Non-English-Speaking Subjects

It is unknown if there will be any non-English speakers enrolled in the survey, the institution hires and trains individuals that do not speak English as a primary language, but they are expected to be able to be fluent in English for their training and employment. If a subject is minimally fluent in English, we will work with the Human Resource office to navigate communication barriers.

☐ **Waiver/Alteration of consent of participants turning 18**

Study group(s) to which this method applies:

Additional Methods

☐ **Obtaining permission/assent/consent of non-English speaking parents or participants**

Must compete *Addendum C: Non-English Speaking Participants*

Study group(s) to which this method applies:

☐ **Surrogate decision maker consent to be used when adults are not capable of consenting for themselves**

Must complete *Addendum D: Surrogate Decision Maker Consent*

Study group(s) to which this method applies:

21.2 Permission/Consent/Consent at 18 Discussion: *If selected options for "Written" or "Waiver of Documentation" above, describe below how the informed permission/consent discussion will be conducted. Describe:*

- *Where and when the discussion will take place.*
- *Steps that will be taken to minimize the possibility of coercion or undue influence.*
- *Any supplemental materials that will be used to enhance the discussion (e.g. videos, eConsent, educational pamphlets).*
- *Any measures that will be taken to ensure that parent(s)/LAR have adequate time to ask questions and decide if they will permit their child to participate in the study (e.g. providing copy of permission form in advance of visit).*
- *How comprehension of the permission form will be verified (e.g. teach back).*
- *If obtaining permission via telephone, confirm CM research policy will be followed.*
- *Process to ensure ongoing consent during the study.*

21.3 Documentation of Permission/Consent/Consent at 18: *If selected "Written" options above, explain how informed permission will be documented. Describe:*

- *Whether CM Research Policy "10.04 Obtaining Permission/ Assent/ Consent" and "Research Documentation in the Electronic Health Record" will be followed. If not, describe whether and how permission of the parent(s)/LAR will be documented in writing.*
- *Whether e-Consent will be used to document permission (non-FDA regulated studies only).*

21.4 Identification of participants turning 18: *Explain the process for tracking participants to ensure that consent is obtained to continue participation once they turn 18 years of age.*

22.0 Assent of Pediatric Participants

22.1 Select the option(s) that apply to the study:

☐ **Assent of pediatric participants WILL BE SOUGHT following assessment of ability to assent.**

☒ **Obtaining assent of pediatric participants is NOT POSSIBLE due to:**

☒ *The capability of the participants (considering the ages, maturity, physical and/or psychological state) is so limited that they cannot reasonably be consulted.*

☐ *The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research.*

☐ **Obtaining assent of pediatric participants is NOT PRACTICLE given the context of this study** (e.g., minimal risk, no direct contact with participants). **Must complete *Addendum B: Waiver/Alteration of Permission/Assent/Consent***

23.0 HIPAA and Confidentiality

HIPAA regulations apply to this study if the data used or accessed relates to:

- The past, present or future physical or mental health or condition of an individual;
- The provision of health care to an individual; **OR**
- The payment for the provision of health care, **AND**

identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

23.1 HIPAA Authorization

Select all applicable methods of HIPAA Authorization that apply to this study.

☒ Full Written HIPAA Authorization will be obtained (within the p/a/c form or standalone form)

☐ Partial Waiver of HIPAA Authorization (e.g. waiver for recruitment and pre-screening purposes only)
Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

a) *Describe what PHI must be accessed for recruitment/pre-screening purposes prior to obtaining HIPAA Authorization..*

☐ Alteration of HIPAA Authorization (some but not all required elements of an Authorization are present, e.g. signature will not be obtained)
Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

a) *Describe which proposed elements to be altered.*

☐ Waiver of HIPAA Authorization (authorization will NOT be obtained)

☐ If Other, explain:

23.2 Specify the PHI for which accessing ("viewing") or recording ("writing down") is necessary for the purpose of this research:

*To minimize risks, only the minimum necessary identifiable data should be **accessed/viewed** and/or **recorded/written down**.*

PHI	Accessed Only	Recorded
1. Name/Initials	☐	☒
2. All elements of date (except year) directly related to an individual (e.g. date of birth, admission date, discharge date, date of death)	☐	☒
3. Medical record number	☐	☐
4. Account number	☐	☐
5. Health plan identification number	☐	☐
6. Social Security Number	☐	☐
7. Device identifiers and serial number	☐	☒
8. Certificate/License number	☐	☐
9. Telephone number	☐	☐
10. Fax number	☐	☐
11. Email addresses	☐	☒

12. Web addresses (URLs); Internet IP addresses	☐	☐
13. Street address, city, county, precinct, zip code or equivalent geographical codes	☐	☐
14. Full face photographic images and any comparable images (this includes use of video recordings via Teams)	☐	☐
15. Biometric identifiers, including finger and voice print (this includes recorded Teams audio)	☐	☐
16. Vehicle identifiers and serial numbers, including license plate number	☐	☐
17. Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g. **student or employee ID number**)	☐	☒
18. Elements of date, including year, for persons 90 years or older	☐	☐
19. Other:	☐	☐

23.3 *Indicate how the research team will protect the confidentiality of participant data during storage, use, and transmission (e.g. training, authorization of access, password protection, encryption, physical controls, and separation of identifiers and data [master list]). Remember: Sensitive CM data, including research data, must be stored on a file server on the CM network domain – not on a workstation hard drive.*

Data will be stored in redcap until study concludes with monthly data reports delivered via secure email to those included in the DUA. Data from Willow will be provided by serial number for data matching to Redcap data. Redcap is designated for research purposes at the academic medical center. Data will be quantitatively analyzed via SAS by the biostatistical partner, contracted through the institution. Willow will provide

Individual users will be deidentified data and enrolled in the study by serial number for data matching with Willow application data.

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.

23.4 *State whether a Certificate of Confidentiality has been issued for this study. Certificates are automatically issued for NIH funded research per NIH policy. For non-federally funded research involving identifiable, sensitive information, investigators may apply for a Certificate if desired. See the NIH website on Certificates of Confidentiality for more details.*

There has not been issued a Certificate of Confidentiality for this study.

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24.0 Provisions to Protect the Privacy Interests of Participants*

24.1 *Describe the steps that will be taken to protect participant's privacy during recruitment and while obtaining permission/assent/consent. For example, best practice is to obtain permission/assent/consent in a separate area where a private conversation can be had. If this is not possible, be sure to explain what steps will be taken to provide as much privacy as possible.*

Participants will be deidentified in the survey using a assigned study ID. This study ID will allow us to link their survey data and their serial number of the Willow Go pump to match data from the surveys to the data from Willow. 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.

24.2 *Describe what steps you will take to make the participant 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 participant might experience in response to questions, examinations, and procedures.*

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. Participants do not have to answer any questions they do not feel comfortable.

24.3 *Indicate how the research team is permitted to access any sources of information about the participants and how the research team will protect the confidentiality of the data.*

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.

25.0 Withdrawal of Participants*inclusio

25.1 *Describe anticipated circumstances, under which participants will be withdrawn from the research without their consent.*

A subject can withdraw at any time during the study without being required to return the device.

25.2 *Describe procedures that will be followed when participants are withdrawn from the research, including data retention plans or partial withdrawal from procedures with continued data collection.*

If the subject leaves to the institution (institutional email is deactivated) they will be terminated from the study unless they notify the institution of the transition to remain in the study and provide a new email.

DATA MANAGEMENT

26.0 Data Collection*

26.1 *Provide a general description of the **types or categories of data** that will be collected during the study (e.g., lab test results, procedure outcomes, length of stay, questionnaires, surveys).*

We will collect survey data about the participants well-being, experiences with lactation, lactation goals, and history of lactation practices.

We will also collect device data from Willow Inc. that measures timing of pumping, length of pumping, and estimated volume.

*Describe the **source** of the data and how that data will be obtained (e.g. electronic medical record, previous research study, clinical database, surveys/questionnaires).*

We will collect this data via an entry survey, a monthly survey for the duration of pumping, and an exit survey. We will receive the device data from Willow using the device serial numbers to link with participant data.

26.2 Sensitive Data: *If collecting or accessing sensitive data which may pose legal, economic, or reputational harm, please specify here.*

None of the data we are collecting should pose legal, or economic harm. Participants may feel if their lactation goals are not met, that the data could pose reputational harm. Therefore we will ensure data is deidentified immediately when downloaded from RedCap. And stored on password protected computer and cloud storage devices.

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27.0 Adverse Events and Unanticipated Problems*

27.1 Monitoring: *Describe the process for monitoring participants and data to identify adverse events and other unanticipated problems.*

On each monthly survey, we are asking about barriers that they may be experiencing. If the participant responds to this question, their response will be sent as an auto-notification to the site coordinator to review and take action as appropriate to protect and support the participant.

27.2 Reporting: *Confirm Policy 5.11 Reportable Events of the CM Research Program Policies and Procedures will be followed in regards to reporting adverse events and other unanticipated problems to the CM IRB. If deviating from, or expanding upon this policy, explain why the approved policy would not suffice for this study and the rationale for deviating/expanding.*

We will follow policy 5.11 Reportable Events and report adverse events or other unanticipated problems to the CM IRB.

28.0 Statistical Analysis*

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

We plan to examine changes in professional fulfillment and burnout using repeated measures t-test. We also plan to utilize descriptives and qualitative comments to show evidence of whether the Willow device helps the participant reach their lactation goals.

28.2 *Describe how the sample size for the study was determined (e.g. formal sample size calculation, convenience sampling). To minimize the risks associated with a possible breach of confidentiality, appropriate sample size calculations limit the amount of patient data being recorded to the amount necessary to answer the research question.*

For all the planned analyses, having a study sample of 125-150 will be sufficient. This presents the goal for each site to have 20-25 participants over the next two years.

•

29.0 Data and Specimen Management*

29.1 Data Management: *Describe how data will be handled, including:*

- *How the data will be collected and stored. (e.g., REDCap, Excel, paper forms)*
- *How long the data will be stored.*
- *Who will have access to the data.*
- *Who is responsible for receipt or transmission of the data.*
- *Methods for transferring data.*

Data will be stored in redcap until study concludes with monthly data reports delivered via secure email to those included in the DUA. Data from Willow will be provided by serial number for data matching to Redcap data. Redcap is designated for research purposes at the academic medical center. Data will be quantitatively analyzed via SAS by the biostatistical partner, contracted through the institution. Willow will provide

Individual users will be deidentified data and enrolled in the study by serial number for data matching with Willow application data.

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.

29.2 Specimen Management: *Describe how specimens will be handled, including:*

N/A

29.3 Biosafety Information

1. Will this study involve handling, transporting, or shipping any potentially hazardous biological material at/from a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

   ☐ Yes

   ☒ No

2. Will this study involve processing any potentially hazardous biological material at a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

   ☐ Yes

   ☒ No

3. If processing potentially hazardous biological materials, where will this work be conducted?

   ☐ Pediatric Clinical Research Unit (PCRU)

   ☐ Children's Mercy Research Institute Biorepository (CRIB)

   ☐ Children's Mercy Research Institute labs (mySafety ID#:_____)

   ☐ Other location

   If "Other location," identify the location and mySafety ID# of the corresponding IBC protocol:

   Location: _____

   mySafety ID#: _____

4. List the material(s)/agent(s) that will be processed at Children's Mercy: (List)

•

30.0 Storing of Data and/or Banking of Specimens for Future Research

30.1 *If this study involves storing of data or banking of leftover specimens for future research, indicate how the use will be managed:*

☐ Contributing data and/or leftover specimens to an existing CM repository protocol (myIRB#_____)

☐ Contributing data and/or leftover specimens to an existing non-CM repository (Institution/Repository Name: _____)

☒ Not contributing to an existing repository for the management of data/specimens for future research use.

☐ Other:

30.2 *If not contributing to an existing repository, describe:*

- *What data/specimens will be stored.*
- *Where the data/specimens will be stored.*
- *How long they will be stored.*
- *How the data/specimens will be accessed.*
- *Who will have access to the data/specimens.*
- *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 (e.g. CM research only, external researchers), and the data/identifiers to be provided with specimens.*
- *If study population includes minors whose specimens will be retained for long term research, be sure to address plans for when participants turn 18 years of age. The process may include re-contacting and obtaining consent, de-identifying samples when participants turn 18, or requesting to waive the requirement of consent at 18.*

Data will be stored in redcap until study concludes with monthly data reports delivered via secure email to those included in the DUA. Data from Willow will be provided by serial number for data matching to Redcap data. Redcap is designated for research purposes at the academic medical center. Data will be quantitatively analyzed via SAS by the biostatistical partner, contracted through the institution.

31.0 Provisions to Monitor the Data to Ensure the Safety of Participants

This section is required when research involves more than Minimal Risk to participants.

N/A

31.1 *In addition to the Principal Investigator, which individual or group will be responsible for monitoring the data and safety for this study?*

☐ Sponsor or Sponsor Designee (including the Sponsor CRO)
☐ Data and Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC)
☐ Independent Monitor (s)
☐ Internal Committee at CM
☐ Other: _____

31.2 Data Safety Monitoring Plan: *If a DSMB charter or other external monitoring plan is available, upload in the myIRB application, Other Attachments section. If such a charter/plan is not available, describe:*

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee and reporting data monitoring committee findings to the IRB and the sponsor. For NIH funded research, see requirements for Data and Safety Monitoring*
- *What data are reviewed, including safety data, untoward events, and efficacy data.*
- *How the safety information will be collected (e.g. with case report forms, at study visits, by telephone calls with participants).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the data.*
- *The frequency or periodicity of review of cumulative data.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that trigger an immediate suspension of the research.*

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 Investigators can 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.

Individuals will be surveyed monthly on basic data but will be asked to assess if they are satisfied with the device, and utilization,
Investigators will ask users to let us know when the cease pumping so Investigators can send the outtake survey (probably link it to the monthly survey) and then Investigators will end monthly survey
Data reviewed monthly will include number of active users in the study, volume of milk and frequency of pumping.
Quarterly review of satisfaction with Willow devices and utilization of other resources will be reviewed in aggregate. Early cessation in the study will be reviewed for qualitative responses to determine trends in cessation.
Project Investigators will review monthly report and provide to Willow
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.

STUDY MANAGEMENT

32.0 Setting & Locations*

32.1 *Describe the sites or locations where the research will be conducted.*

- *Identify where research procedures will be performed including any non-CM affiliated locations. For any non-CM affiliated locations, upload a letter of support in myIRB which states that the site is aware that research will be conducted on their premises.*
- *Describe the composition and involvement of any community advisory board.*
- *For research conducted outside of CM and its affiliates describe:*
  - *Regulations or customs affecting the research*
  - *The local scientific and ethical review structure*
- *Describe the availability of medical or psychological resources that participants might need as a result of taking part in the study.*

32.2 CMKC - Individuals will use devices in their normal settings of home and work and complete surveys based on their experience.

- Investigators will promote the research project for those that may be interested but will not approach users to recruit directly.

33.0 Multi-Site Research

Choose ALL relationship types that apply:

☒ ***Multi-Site Research:*** *Multiple sites will be engaged in this human research project. Sites will use the **same** protocol to conduct the **same** human research activities (except for minor variations due to local context considerations).*

☐ ***Collaborative Research:*** *Multiple sites will be engaged in this human research project. Sites will **not** be performing the **same** research activities. The Site submission will specify the specific research activities each site will perform.*

> ***REQUIRED**: Enter summary of site-specific activities that differ from the overall protocol:* *Click or tap here to enter text.*

☐ ***Student(s)*:** Student(s) will help with this project and will be engaging their home institution.

☐ **Visiting *Resident(s) /* Visiting *Fellow(s)*:** Visiting Resident(s) / Visiting Fellow(s) will help with this project and will be engaging their home institution.

Is Children's Mercy (CM) acting as the single IRB of Record (sIRB)?

☒ ***No, each site is getting their own IRB approval.***

☐ **Yes, some or all sites will rely on the CM as the sIRB**.

- ***Reliance is required** for non-Exempt **NIH** or other **Federally Funded** research where:*
  - *The institution's employees or agents intervene or interact with human subjects for research purposes;*
  - *The institution's employees or agents obtain individually identifiable private information or identifiable biospecimens about human subjects for research purposes; or*
  - *The institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.*

If CM is sIRB for another site, complete the chart for that site(s) (*Add a new row for each site relying on the CM IRB, delete chart if not acting as sIRB):*

Site Name	Enrollment Goal for Site(s) *Choose One*	Relying on CM IRB?
Insert Site Name	☐ **Site Enrollment Goal:** *Insert #* ☐ **Site will not enroll**	☐ External Site will rely on the CM IRB as the IRB of Record using a reliance agreement. () ☐ **Not Applicable**. Site will **not** interact or intervene with human participants or their identifiable data / identifiable biospecimens. Site is also not a primary NIH or federal grant recipient.

34.0 International Research

N/A

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Addendum A: Waiver of Documentation of Permission/Consent

Regulatory Criteria: *To qualify for a waiver of documentation of parental permission or adult consent, the study must fit into at least one of the three scenarios below. Indicate which scenario(s) applies.*

☐ **The only record linking the participant and the research would be the permission/consent form and the principal risk is potential harm resulting from a breach of confidentiality.** Each parent/LAR or adult participant will be asked whether they want documentation linking the participant with the research, and the parent/LAR's or adult participant's wishes will govern.

OR

☐ **The research presents no more than minimal risk of harm to participants and involves no procedures for which written parental permission or adult consent is normally required outside of the research context.**

OR

☐ **The parent(s)/LAR or adult participants are members of a distinct cultural group or community in which signing forms is not the norm**, the research presents no more than minimal risk of harm to participants and an appropriate alternative mechanism for documenting that informed parental/LAR permission or adult consent was obtained will be provided. Describe the alternative mechanism provided:

Addendum B: Waiver/Alteration of Permission/Assent/Consent

What's the difference between a "waiver" and an "alteration" of parental permission, child assent, or adult consent?

- A "waiver" of parental permission, child assent, or adult consent is when **all 9 required elements of permission/consent are waived.** If the IRB approves a waiver then the study team does not need to obtain the parental permission or adult consent in order to include a participant in the study.

- An "alteration" of parental permission, child assent, or adult consent is when **one or more of the 9 required elements are waived** because they are not relevant to the research activity. If the IRB approves an alteration, then the study team must still obtain parental permission or adult consent in order to include a participant in the study, but certain elements may not be required in the form/discussion.

NOTE: *If requesting a waiver of parental/LAR permission because parental permission is not a reasonable requirement to protect the participants [e.g. research on neglected or abused children], contact irb@cmh.edu to discuss additional regulatory requirements.*

Regulatory Criteria: *To qualify for a waiver or alteration of parental permission or adult consent,* ***ALL*** *of the following must apply. Explain how the study meets each of the regulatory criteria below.*

Criteria	Explain how the study meets the criteria
The research involves no more than minimal risk to the participants	
The research could not practicably be carried out without the requested waiver/alteration (i.e., explain why the study could not be done if permission/assent/consent were required)	
If the research involves using identifiable private information or identifiable	

biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	
The waiver/alteration will not adversely affect the rights and welfare of the participants	
Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation	

Proposed Alteration (if applicable):

Select which required elements of permission are to be omitted.

☐ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

☐ A description of any reasonably foreseeable risks or discomforts to the participant;

☐ A description of any benefits to the participant or to others that may reasonably be expected from the research;

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

☐ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

☐ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant;

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

☐ A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Provide the rationale for omitting the item(s) selected:

Addendum C: Non-English Speaking Participants

There are special considerations that must be made when obtaining permission/assent/consent from participants who prefer to communicate in a language other than English. To ensure that adequate processes are in place to obtain effective permission/assent/consent from these participants address each of the items below.

Indicate which language(s) other than English are understood by prospective participants or representatives.

☐ Spanish
☐ Arabic
☐ Burmese
☐ Somali
☐ Vietnamese
☐ Other:_____

Describe the plan for enrolling non-English speaking participants (e.g. fully translated consent forms, use of Qualified Bilingual Study Staff or interpreters):

If providing fully translated consent forms, explain if the ORI Translation Program for internally and/or federally funded studies will be used, or if translation services will be obtained through the study sponsor or some other service.
NOTE: If using ORI Translation Program services for an industry sponsored study, contact Research Business Operations staff to get this negotiated in the study agreement/contract.

Addendum D: Surrogate Decision Maker Consent

Assessment of Decision-Making Capacity:

- *Describe the process to determine whether an individual is capable of consent. See CM Research Policy 9.10 Incapacity, Temporary or Fluctuating Decision-Making Capacity for more information on the proper procedures for enrolling adults who are not able to consent for themselves.*

Identification of Surrogate Decision Maker

- *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 states of Missouri and/or Kansas, review CM Research Policy 9.10 Incapacity, Temporary or Fluctuating Decision-Making Capacity to be aware of which individuals in the state meet the definition of "legally authorized representative."*
- *For research conducted outside of Missouri and/or Kansas, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel review the protocol.*

Assent of Adult Participant

- *Describe the process for assent of the adult participants who are unable to consent for themselves. Indicate whether:*
    - *Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.*
    - *If assent will not be obtained from some or all participants, an explanation of why not.*
    - *Describe whether assent of the participants 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 or require participants to sign assent documents.*
    - *Describe how participants will be closely monitored.*
    - *Describe whether participants will be withdrawn if they appear to be unduly distressed.*

Addendum E: Waiver/Alteration of HIPAA Authorization

What's the difference between a "waiver" and an "alteration" of HIPAA Authorization?

- A "waiver" of HIPAA Authorization is when **the requirement to obtain authorization is completely waived.** If the IRB approves a waiver then the study team does not need to obtain HIPAA Authorization in order to include a participant in the study.

- An "alteration" of HIPAA Authorization is when **one or more of the required elements of authorization are waived.** If the IRB approves an alteration then the study team must still obtain HIPAA Authorization in order to include a participant in the study, but certain elements may not be required in the form/discussion. The study team should still verify the identity of the participant as part of the process. For an online survey, for example, this could be accomplished by having the participant type in their name.

Regulatory Criteria: *To qualify for a waiver/alteration of HIPAA Authorization,* ***ALL*** *of the following must apply to a study. Explain how the study meets each of the regulatory criteria below.*

Criteria	*Explain how the study meets the criteria*
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: a. Plan to protect PHI from improper use and disclosure: b. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: c. Assurance that PHI will not be reused or disclosed to any other person or entity:	

The research cannot practicably be conducted without the waiver/alteration, i.e. explain why a signature for HIPAA Authorization cannot be obtained.	
The research cannot practicably be conducted without access to and use of the PHI, i.e. explain why access to PHI is needed for this study.	