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REQUEST FOR YOUR PARTICIPATION IN RESEARCH

TITLE OF THE STUDY

Insulin Pump Usability Study

FUNDING SOURCE

This project is externally funded through the U.S. Food and Drug Administration (FDA), BBA Number EETWP26.

NAME OF THE RESEARCHERS (STUDY PERSONNEL)

- Shannon Clark, PE (Co-Primary Investigator): CEO and Human Factors Engineer at UserWise, Inc.
- Dan Nathan-Roberts, Ph.D. (Co-Primary Investigator): Assistant Professor in the Industrial and Systems Engineering Department at San Jose State University.
- Lana Sneath (Researcher and Research Manager): Human Factors Engineer at UserWise, Inc.
- Kelli Sum (Research Assistant and Laboratory Manager): Graduate student in Human Factors and Ergonomics at San Jose State University.
- Reggie Moore (Researcher): Human Factors Engineer at UserWise, Inc.
- Alyssa Kristedja (Researcher): Human Factors Engineer at UserWise, Inc.

PURPOSE

The purpose of this usability evaluation is to help test the product design and obtain user opinions. Keep in mind we are evaluating the product; we are not evaluating you or your abilities.

Before you decide whether to participate in this research, it is important for you to understand why the research is being done and what it will involve. The risks are that you may handle a device with a needle and distilled water and may experience negative emotions, such as frustration and annoyance. Participants will receive a token of appreciation up to $115. Documentation stating your identity will be kept secure and will not be made publicly available. If the research results are published, your identity will remain secure to the extent permitted by law. The decision to participate in this research study is up to you. Your participation is completely voluntary. Ask a member of the research team about anything that is not clear. If you would like more information, read more details below and decide whether or not you want to participate in this research study.

Not all aspects of the study are being disclosed up front but will be provided after the study, during a debriefing.

PROCEDURES

The study session will take place in room 494, Engineering Building, One Washington Square, San Jose, CA 95192-0085. A researcher will be with you in the study room and will be moderating the study session. Additional researcher(s) may either sit in the room next to the study room to observe via a one-way mirror or may observe real-time via video. The audio-visual system in the rooms will provide audio to the study room. You will be able to communicate with the researcher at any time. All sessions will be recorded. Only the researchers will have access to recordings, which will be stored on a password-secured hard drive or on a password-protected server (i.e., Google Drive).

This research study is looking at the usability (ease of use) and safety of an insulin pump and its associated accessories (the **Study Devices**). The Study Devices have been approved or cleared by the FDA for use and sale.

You will be given a brief description and training of general use of the device and training on safe use of the device before using each one and then will perform tasks and answer questions related to the tasks, such as how easy or difficult it was for you to perform each task. A member of the research team will be present to watch you as you perform each task. By signing this form, you give your permission to be photographed and audiovisual recorded for the purpose indicated in this form. The media will be de-identified by permanently blurring or obscuring any participant identifying features from the shoulders up in any publicized files prior to release. If you do not wish to be photographed, recorded, or video recorded, you may not participate in this research study. A member of the research team will collect the Study Device and all study-related material before you leave the research facility. This will be the end of your study session.

When you arrive at the study session, you will be greeted by a member(s) of the research team. You will not inject or deliver any medication to yourself or anyone else as part of this study.

At the end of your participation in the study, the Study Devices and study-related materials will not be available to you and will have to be returned to the research team. The Study Devices include components that contain a real needle. Water will be used in place of the active medication; however, you will not take any medicine or be asked to inject yourself or anyone else with a needle, during this study. Instead, you will simulate the injection into an injection pad that will be strapped to a manikin. During the product evaluation session, you will be asked to perform some tasks with the Study Devices, working on your own as needed.

The first study session is estimated to last approximately 90 minutes. You may be invited to participate in a second study session, estimated to last approximately 60 minutes. Eligibility to participate in the second study session will be disclosed upfront and will not be dependent on your performance. The total expected duration of your participation is estimated to be up to approximately 2 hours and 30 minutes if you participate in both study sessions, with a break in between that may vary from one hour to one week. You will be asked to perform physical and cognitive tasks, during the study sessions.

At the end of the study, you will fill out a post-study questionnaire to collect further subjective feedback and demographic information. An example of the post-study questionnaire is provided with the Institutional Review Board (**IRB**, a company that monitors the study and ensures participants' safety) Application.

It is important that you follow the research team's instructions throughout the study. If you have questions or want further information, contact a member of the research team.

POTENTIAL RISKS

Your participation in this study is voluntary. You can refuse to participate in the entire study or any part of the study at any point. You have the right to skip any questions you do not wish to answer.

Study personnel will stop the test session if, at any time, they believe that there is an immediate risk of harm to you. During this research study, you may be handling a product that contains distilled water or decontaminated water, using ultraviolet light. In the case that the device has a needle in it, it will contain a sterile needle. Please keep in mind that some of the components available for use, during the session, contain needles, so be very careful when handling the equipment and let the study personnel know, at any point, if you feel unsafe.

There is a small risk that you may get a needle-stick injury if you are not careful when handling the components containing needles, during the study. If these risks occur, the study personnel will stop the testing and seek first aid for any injury. If necessary, a paramedic will be called. Additionally, you might become fatigued by the end of the visit or may experience negative emotions, such as frustration and annoyance. If you have any concerns or experience distress, during the study, please tell a member of the research team, immediately. This study has been reviewed by the San Jose State University's Institutional Review Board.

POTENTIAL BENEFITS

There are no direct benefits to you from your taking part in this research.

This research is not designed to diagnose, treat, or prevent any disease. You have the option of whether to take part in the research.

COMPENSATION

You have been invited to participate in either one or two study sessions. Participants will receive a token of appreciation for participating in the full study. Your eligibility for a second session will be disclosed upfront and will not be dependent on your performance:

- $75 for completing one session (lasting approximately 90 minutes)
- $40 for completing a second session if you are invited at a specific later date (lasting approximately 60 minutes)

If you are an SJSU student, you may opt for course credit that approximately matches the length of the session(s) instead of receiving the payment amount.

You will not receive a token of appreciation for travel-related costs to participate in this study.

Payment will be made within fifteen (15) business days of your participation in the study session(s).

You will not have to pay anything to participate in this study.

CONFIDENTIALITY

Any information you acquire related to this usability evaluation session is confidential. By signing this form, you agree that you will not discuss this evaluation with anyone. Also, as we are trying to get individual opinions, please do not relate your experience or opinions to other potential participants.

Documentation stating your identity will be kept secure to the extent permitted by law, and if results are published, your identity will remain secure as well.

If you volunteer to take part in this study, information about you will be collected and analyzed; this will include information about you, such as your age, ability to read and understand English, occupation, education level, and whether you have experience using insulin pumps. Anonymized information from this study will be submitted to the FDA, third parties working with the FDA, such as monitors and auditors, representatives of regulatory health authorities (such as the FDA), and the SJSU IRB. Your identity will remain confidential if any study results are published. You will not own any of the information collected or produced for the purpose of this study.

Your name will not be used in any reports from this study. All data will be kept confidential to the fullest extent permitted by law. Any personally identifiable data that is captured will be stored and analyzed, using an identifier randomly assigned to each participant before the trials. All of your study data will be kept in a secure location. Computer-based files will be available only to authorized research members, using access privileges and passwords. Your personal information will not be given out unless required by law.

By signing this form, you authorize us to use one or more of your deidentified images or pictures captured in video and photographs of your participation in study activities for more general purposes, such as illustrating technical presentation slides and technical articles.

PARTICIPANT RIGHTS

Your participation in the evaluation is completely voluntary. You may decide to stop your participation at any time. If you decide not to participate, there are no adverse consequences to you, and you will not lose any benefits to which you would otherwise be entitled.

If you decide to participate, you will be asked to sign and date this Participant Agreement, and you will receive a signed and dated copy for your records. You are free to withdraw (stop your

participation) at any time, without giving a reason and without penalty or loss. Tell a member of the research team if you want to stop participating in the study.

If you withdraw from the study, the data collected up to the time of your withdrawal will continue to be used.

You will be informed of important new information or any changes in the study or devices that may affect your decision to continue participation in the study. You will have an opportunity to discuss the new information with a member of the research team before deciding to continue or not.

Your participation in the study may end at any time with or without your permission, due to any of the following reasons:

- You decide to withdraw
- Your research team decides you should be withdrawn for any reason
- You do not follow the instructions for participation
- A regulatory health authority, such as the FDA or the IRB, has stopped the study

QUESTIONS OR PROBLEMS

You can ask questions about this consent form or the study before you decide to start the study, at any time during the study, or after completion of the study.

- For further information about the study, please contact Shannon Clark (UserWise@userwiseconsulting.com or 650-701-7746) or Dr. Dan Nathan-Roberts (dan.nathan-roberts@sjsu.edu or 408-924-7501)
- Complaints about the research may be presented to the Industrial and Systems Engineering Department Chair, Yasser Dessouky (yasser.dessouky@sjsu.edu or 408-924-4133)
- For questions about participants' rights or if you feel you have been harmed in any way by your participation in this study, please contact Dr. Pamela Stacks, Associate Vice President of the Office of Research, San Jose State University, at 408-924-2479.

In case of emergency, dial 911 or go to the closest emergency room or hospital.

SIGNATURES

I have read this information and consent form in a language that I understand, and its contents were explained to me. I voluntarily agree to be in this research study for the purpose listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Participant Signature

_____	_____	_____
Participant's Name (printed)	Participant's Signature	Date

Researcher Statement

I certify that the participant has been given adequate time to learn about the study and ask questions. It is my opinion that the participant understands his/her rights and the purpose, risks, benefits, and procedures of the research and has voluntarily agreed to participate.

_____	_____	_____
Name of Person Obtaining Informed Consent	Signature	Date