OMB Control No.: 0910-0847
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This study is being conducted on behalf of the U.S. Food and Drug Administration.

Attachment A: Initial Training Script

Training Decay for Medical Products: Insulin Pump Usability Study

Informed Consent Form Script

Note: This script is intended to be used at the beginning of the participant's session.

1. Introductory Script

1.1 Introduction and Check Participant In

- Hello, my name is _____ and I am a member of the research team. Also, to be mindful of the COVID-19 pandemic currently happening, I am going to ask that before we get started, we both use the hand sanitizer provided as a precaution given the current circumstances.
- May I please have your first and last name?
- ***Check name on pre-written post-it note & sign off participant's ID on "Participant Check-In Sheet".***
- Thank you, our records show that you are attending your (1st or 2nd) session today and will be receiving ($40 or $75) for your time. Please confirm if this is correct.
- ***If the participant is attending their 1st session and is in cohort 2-4, confirm the 2nd session day and time on the "Participant Check-In Sheet".***
    - Thank you. Can you also please check your schedule and confirm that you are still able to attend the 2nd session on [DAY] and [TIME]?

1.2 Housekeeping

- For housekeeping, restrooms can be found if you exit through the double doors and turn left. The men's restroom is before the elevator and the women's restroom is past the elevator. Would you like to use the restroom at this time?
- We request that you turn off your phone for the purpose of this evaluation. We appreciate if you do not use your phone throughout the session.
- Do you have any questions?

2. Informed Consent Form (ICF) Script

2.1 Before the participant reads the ICF

- I will walk you through the informed consent form.
- First off, we want to thank you for your time and participating in this usability study.
- The purpose of this session is to evaluate an insulin pump to identify whether it can use it safely in a simulated use environment.
- The combined results of all of the participants in this study will be published, but your identity will always remain anonymous.
- If you feel unwell or wish to end the session at any point for any reason, please let me or a member of the research team know. Your token of appreciation will not be affected.
- I will now read-aloud the potential risks to you.
- 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 approved by the San Jose State University's Institutional Review Board.
- To be mindful of the COVID-19 pandemic, the components you are about to use have been touched by individuals other than those outside our study team. However, we are taking every precaution and ensuring we sterilize the items between each individual with a sanitizing wipe, alcohol submersion, UV light sanitization, or other proven methods of disinfection. If you have been in contact with someone who has been diagnosed with COVID-19, fall ill within 14 days of the study session with flu-like symptoms, or are diagnosed with COVID-19, please notify the study team and we may reschedule or cancel your session. In the case that a participant or a study staff is diagnosed with COVID-19, the recruitment lead for the study will suspend testing and notify participants that had already completed sessions of the incident.
- Please read the rest of the informed consent form and let me know if you have any questions. If you agree, please sign at the end.

2.2 After the participant reads the ICF

- Do you have any questions about the informed consent form?
- Here are copies of this form for you to take with you at any time.

Training Decay Usability Study –Training Introduction Script (Insulin Pump)

Note: This script is intended to be used at the beginning of the participant's training session before the training has started.

3. Key Reminders:

- *Make sure that the participant has signed the ICF*
- *Make sure the volume of the TV is at 10*

4. Introduction and Participant Data

- *(If not read by Study Facilitator)* Hello, my name is _____ and I am a member of the research team.
- I am going to start your training video. Some of my colleagues may observe at times.
- For the purpose of the session today, I want you to imagine that you are a caregiver. Later on, you are going to treat a simulated patient named Sam. Sam represents a family member or friend you are caring for. Please care for Sam as you would care for someone in real life.
- Before you treat Sam, you'll have approximately 40 minutes of training that involves watching a video that walks through the basic instructions with some time for hands-on practice after the video.
- Do you have any questions before we begin with training?
- I'm going to step out of the room while you watch the video training. When the video ends, my colleague or I will come back in the room for the hands-on portion of the training.

5. After Video Script

- (*If Trainer is not the Study Facilitator)* Hello, my name is _____ and I am going to cover the hands-on portion of your training today.
- For this half of the training, you will be following a slideshow which will play the video you just saw, but broken out into smaller video clips so that you can follow along more easily. Here are the components you will need to follow along (*place all needed components on table in front of participant).*
- Please feel free to go at your own pace. I'll be with you during this portion of the training and can answer any questions you have as well as help you pause or replay videos if you would like. There will also be some time to ask questions towards the end of this training session
- Just for the purpose of this training, please do not remove the adhesive strips marked "do not remove" on this training set.
- Throughout this training session, the pump may beep several times; if it does, please ignore the beeping as this is a safety function of the insulin pump.
- Do you have any questions before we start?