

OMB Control No.: 0910-0847
Expiration Date: 12/31/2022

Training Decay Usability Study – Initial Training 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.

1. Key Reminders:

- *Make sure the section regarding potential risks has been read out loud to the participant.*
- *Make sure that the participant has signed the ICF.*

2. Introduction and Participant Data

- Hello, my name is _____. I am the moderator, and I’ll be walking you through this session, and _____ may observe at times.
- First off, we want to thank you for your time and participation in this usability study.
- Before we get started, do you have any questions about the informed consent form?
- The purpose of this session is to evaluate an insulin pump to identify whether it can be used safely in a simulated use environment.
- The combined results of all 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 know.
- For purpose of this evaluation, we request that you turn off your phone. We appreciate your not using your phone throughout the session.
- For 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 whom you are caring for. Please care for him/her as you would care for someone in real life.
- Before you treat Sam, you’ll attend a training that includes 20 minutes of walking through the instructions and approximately 10 minutes of hands-on use.
- Do you have any questions before we begin?