Informed Consent Form for Caregivers and Patients Participating in the Usability Study of the Obi Assistive Technology Device

TITLE:	Obi Medical Robot: Evaluating Effectiveness Related to Usability
PROTOCOL NO.:	None WCG IRB Protocol #20251472
SPONSOR:	DESIN LLC
INVESTIGATOR:	Andrea Fairman, PhD PO Box 978 Glendale, Rhode Island 02826 United States
SUB-INVESTIGATOR:	Heather Keeton, ATP
STUDY-RELATED PHONE NUMBER(S):	(937) 203-0686 (24 hours) hkeeton@desincorp.com

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Why is this research being done?

You are being asked to participate in a research study evaluating the Obi adaptive eating device. The goal is to understand how well Obi Gen 3 supports independent self-feeding among children and adults with upper extremity disabilities. We are also gathering feedback from caregivers and users about how easy the device is to use and how it fits into daily routines.

Why have I been asked to take part in this research study?

You are being asked to participate because you are either:

- A caregiver who helps someone with self-feeding or
- A person who will be using the Obi-Gen 3 device during a home or community trial.
- In this consent form, "you" refers to the participant. If you are a Parent/legal guardian/legally authorized representative, please remember that "you" refers to the study participant.

What will I be asked to do if I participate in this study?

If you agree to participate, you will be asked to:

- Try the Obi device at home or in your community for about one week (at least five meals), including Reward Mode (aka "Celebrate Mode" or "Party Mode" and the power-on feature
- Answer short surveys about how the device worked for you
- Optional: Participate in a brief follow-up phone call to share additional feedback
- Participation in this study will last about 3 months

Are there any risks to me?

There are no known physical risks associated with participation. There is the risk of a loss of confidentiality of your research-related information.

You may choose not to answer any questions that make you uncomfortable.

Are there any benefits to me?

While you may not directly benefit, your participation will help improve the Obi device and support other users in the future.

Will I be paid for my participation?

Yes, you will receive a $25 electronic gift card for participating in the study.

Do I have to take part in this study?

No. Participation is completely voluntary. You may stop at any time, and it won't affect the care or services you receive.

What about confidentiality?

Your private information and your research records will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

Your information will be kept private. Responses will be de-identified and reported in aggregate form, and may be used for future research or distributed to another investigator for future research without your consent. We won't use your name in any reports; your responses will be combined with others for analysis. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Who can I contact if I have questions?

For questions about the study or your rights as a research participant, please contact:

Heather Keeton, Study Coordinator & Sub-Investigator
Email: hkeeton@designcorp.com
Phone: (937) 203-0686 (24 hours)

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Consent Statement

Assent instructions for Adult Patient Participants unable to consent:

- All participants unable to consent are required to assent.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

Assent instructions for Children:

- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- If assent is obtained, have the child sign an assent form, unless the investigator determines that the child is not capable of signing.

By signing below, you agree that:

- You have read (or had read to you) the above information
- Your questions have been answered
- You agree to participate in this study

You will receive a copy of this signed consent form.

Participant Name (Type): _____

Signature of Caregiver or Adult Patient Participant able to Consent: _____ **Date:** _____

Signature of Parent/Legal Guardian /Legally Authorized Representative: _____ **Date:** _____

Authority of Signing Person: _____

Relationship of Legally Authorized Representative to the Participant: _____

I have explained the study to the participant and the participant's parent/guardian/legally authorized representative, and the participant has orally agreed (if able) and the participant's parent/guardian/legally authorized representative has agreed to the participant's participation in the study.

Researcher Name (Type): _____

Signature: _____ **Date:** _____