Clinical Investigation Plan (CIP)

Obi Medical Robot: Evaluating Effectiveness Related to Usability.

Obi Manufacturer: DESĪN LLC

7018 A C Skinner Pkwy Ste 270, Jacksonville, Florida, 32256

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Review and Sign-Off The document is effective following the final date of approval.		
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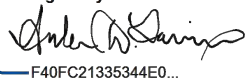
Dr. Andrea D.Fairman, PhD, MOT, OTR/L, ATP, DRP, CDI Principal Investigator The Driving Doctor: ADRS	Signed by:  F40FC21335344E0...	4/11/2025
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A. Clinical Investigation Plan

This CIP was composed with guidance from ISO14155:2020, Annex A.

A.1. General

A.1.1. Introduction

First commercialized in 2016, the Obi medical robot represents an innovative approach to self-feeding restoration, enabling patients with upper extremity mobility (UE) limitations to feed themselves. Obi is a Class I, 510K Exempt medical device (product Code ILC) by FDA classification and is an inherently "low risk" device. To date, over 3,000 devices have been sold across 20 countries without an adverse event. Minor enhancements and features have recently been developed to support increased usability with Obi: The Generation3 (Obi3) project (ECR#172). This project has recently completed successful Design Verification activities, including successful verification of risk control measures, and has been approved for the Design Validation stage in a design review (IFD-DES-080, DESIGN REVIEW, OBI3 VERIFICATION). Prior to commercialization, it is both an FDA regulatory requirement and ISO13485 QMS obligation to validate whether the enhanced design continues to fulfill its intended use and meet the user needs of key stakeholders (as defined in IFD-DES-025 R5.6.0). In addition to these primary objectives, other aspects of usability and stakeholder experience will be explored as secondary objectives.

A.1.2. Identification of the Clinical Investigation Plan

Revision	Summary of Changes
1.0.0	Initial release.

Associated Study Documentation
ICF - Provider
ICF- Patient (Adult)
IAF -Patient (Child)
Survey - Patient (Adult)
Survey - Patient (Child)
Survey - Caregiver
Survey - Provider
Semi Structured Interview - Patient (Adult)
Semi Structured Interview - Patient (Child)
Semi Structured Interview - Caregiver
Semi Structured Interview - Provider
Recruitment Flyer, Obi
CRF, Protocol Deviation
PI CV, Dr. Fairman

A.1.3. Sponsor

Organization Name	Independent Feeding Device LLC, DBA DESĪN LLC.
Address	7018 A C Skinner Pkwy Ste 270, Jacksonville, Florida, 32256
FDA Registration#	3012103590
Website	www.meetobi.com/
Phone	1-844-435-7624
Emails	info@meetobi.com, service@meetobi.com

A.1.4. Principal Investigator; Coordinating Investigators and Site(s)

Name	Address	Email/Phone #
Principal Investigator (PI): Andrea D. Fairman, Ph.D., MOT, OTR/L, ATP, DRP, CDI	The Driving Doctor: ADRS P.O. Box 978 716 Black Hut Road Glendale, RI 02826	the.driving.doctor.adrs@gmail.com (401) 474-9418 / (724) 664-4588
Research Assistant: Ryan Osal, OTD, OTR/L, MS, CHC, CEAS	Ryan will work remotely as an employee of the PI's company. He presently resides in Pittsburgh, Pennsylvania	ryanosal@bu.edu (401) 548-5584
Research Coordinator: Heather Keeton, ATP DESĪN, LLC	Employed by DESĪN LLC, located at 7018 A C Skinner Pkwy Ste 270, Jacksonville, Florida, 32256	hkeeton@desincorp.com (937) 203-0686
Study Site & Sponsor Jon Dekar President & CEO DESĪN, LLC	See A.1.3.	jdekar@desincorp.com (248) 766-2085

Team Member	Qualifications
Jon Dekar Sponsor	Jon has led the research and development of Obi since 2010.Jon is a mechanical engineer with over fourteen years of experience in medical product design and development. He has an intimate knowledge of the FDA and EU regulatory environment, including applicable harmonized standards and quality practices. He has proven proficiency with project management, operations management, medical device systems engineering, quality engineering, mechanical design, human factors and usability design, design of experiments and process design. Jon is an expert on how the device is constructed, how it works, how it's produced and how it's used in the field.
Dr. Andrea Fairman Principal Investigator	Dr. Andrea Fairman is highly qualified to serve as the Principal Investigator (PI) for this study evaluating the impact of the Obi adaptive feeding device on independent self-feeding in people with functional deficits. Her expertise spans assistive technology, rehabilitation science, and pediatric occupational therapy, making her well-suited to lead this research study. Dr. Fairman holds a Ph.D. in Rehabilitation Science from the University of Pittsburgh, with a primary focus on assistive technology, evidence-based practice, and psychosocial aspects of disability. She has served as PI and Co-Investigator on numerous research projects funded by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), the Craig H. Neilsen Foundation, and other agencies. She has utilized the International Classification of Functioning, Disability, and Health (ICF) framework in prior research and has published studies on assistive technologies and their impact on functional independence. Her prior research demonstrates experience in designing and analyzing psychosocial impact assessments. Dr. Fairman also has an extensive record of peer-reviewed publications in leading journals related to assistive technology, disability, and rehabilitation. She has successfully secured research funding for studies on technology-based interventions, demonstrating her ability to manage grant-funded research projects. In summary, given her expertise in assistive technology, pediatric rehabilitation, and psychosocial impact measurement, Dr. Fairman is well-equipped to lead this study, ensuring rigorous methodology, meaningful outcomes, and contributions to the field of assistive technology. *(see curriculum vitae for additional information)*
Heather Keeton Co-Investigator/ Research Coordinator	Heather is a RESNA-certified Assistive Technology Professional (ATP) with over 5 years' experience with Obi user candidate screenings, trial assessments and customer service. She also carries a *CITI* training certification to ensure that research meets federal standards and protects the privacy of research participants. This experience uniquely positions her to effectively enroll patients and assess whether user needs are met. She is an expert on how Obi is used in the field.
Dr. Ryan Osal Co-Investigator/ Research Assistant	Ryan Osal is an occupational therapist with his clinical doctoral degree (OTD) and a PhD student in Rehabilitation Science at the University of Pittsburgh. Ryan's concentration is in health informatics with some experience conducting usability testing of assistive technologies. He currently supports research in the Health and Rehabilitation Informatics (HARI) Lab and the Healthy Home Lab, where he evaluates smart home and mobile health tools with clinicians and older adults. As a licensed occupational therapist with clinical and academic experience, Ryan brings a strong background in user-centered design interdisciplinary collaboration. *(see curriculum vitae for additional information)*

A.1.5. Overall Synopsis of Clinical Investigation

Protocol Synopsis	
Study Title	Obi Medical Robot: Evaluating Effectiveness Related to Usability
Protocol ID- Version	IFD-DES-081
Study Device	IFD-500-031, Obi3, US
Study Objective	• PRIMARY: Validate whether the production equivalent Obi3 device design conforms to the stakeholder needs (providers, caregivers, patients) and intended use as defined within IFD-DES-025 R5.6.0 • SECONDARY: o Determine patient usability in accordance with the Matching Person & Technology (MPT) Assistive technology Framework and assessment (adult and pediatric versions). o Determine caregiver usability in accordance with questions from the MPT and System Usability Scale (SUS) o Determine provider perspectives in accordance with the SUS measure. o Obtain provider feedback regarding the efficacy, efficiency, and satisfaction of the Obi clinical assessment forms and the associated process facilitated by DESĪN LLC's SOP220. o Obtain other qualitative feedback regarding perceived strengths and weaknesses of the Obi design.
Study Design	This is a mixed-methods usability study gathering both quantitative and qualitative data. • Participants will complete a one-week trial of Obi 3. • Data will be collected via non-standardized usability surveys, MPT & SUS rating scales, and semi-structured interviews. • Triadic recruitment providers, caregivers and patients will be encouraged to provide richer usability data. However, if only one or two members of the triad wish to participate, they will still be encouraged to enroll in the study
Study Population	Provider (OTs, SLPs, ATPs): 20 Caregivers of adult and pediatric patients: 20 Patients (adults and children): 20
Estimated # of Sites	Single Site: DESĪN LLC will serve as the site and data will be gathered remotely and electronically using Qualtrics. Participants may reside anywhere in the United States. A description of the Qualtrics software and its capabilities, including data security features, is included later in this proposal.

Enrollment and Subject Participation Duration	Staggered enrollment will occur over a 1- 3 month period. Participation in the study is approximately one week in duration including the trial of Obi Gen 3 and completion of the surveys. A follow-up semi-structured interview is optional and will not be conducted with all the participants. Follow-up interviews may be conducted with participants from any of the stakeholder groups whose responses require clarification or warrant further inquiry.
Primary Effectiveness Endpoint	Assessment of user needs fulfillment after ~ one (1) week trial of Obi Gen3 using the following for each of the three (3) stakeholder groups as participants in the clinical investigation: **I.) Providers** will complete - Survey specifically tailored to gather descriptive demographic data and inquire about their use experiences including whether their needs are fulfilled with the usability of Obi Gen3. **II.) Caregivers** will complete - Survey specifically tailored to gather descriptive demographic data about the caregivers' use experiences and inquire about whether their needs are fulfilled with the Obi Gen3. **III.) Patients** will complete: 1) Survey specifically tailored to gather descriptive demographic data about the patients' use experiences and inquire about whether their needs are fulfilled with Obi Gen3.
Primary Safety Endpoint	Monitoring and recording of any adverse events through company's existing SOP120; None are anticipated due to the Class I device's low risk profile and the device's history of 0 adverse events.
Additional Endpoints	I.) Providers: a. System Usability Scale (SUS) retained in its standardized format b. Obi Medical Device Needs Assessment (MDNA) Form, and the overall service delivery process per SOP220. c. Optional - Semi-Structured Interview II.) Caregivers: a. System Usability Scale (SUS) retained in its standardized format b. Modified Matching Person and Technology (MPT) assessment. The standardization of this tool is no longer retained given the changes made, but will still provide valuable data regarding the caregivers'

	impressions of Obi Gen 3 following the one week trial period. c. Optional - Semi-Structured Interview III.) Patients a. Modified Matching Person and Technology (MPT) assessment. The standardization of this tool is no longer retained given the changes made, but will still provide valuable data regarding the patients' impressions of Obi Gen3 following the one week trial period. b. Descriptive data regarding the patient-participants will be gathered from their completed MDNA Form. c. Optional - Semi-Structured Interview
Inclusion Criteria	- Providers with relevant expertise to recommend and evaluate patients' ability to use Obi - Caregivers directly assisting users with Obi - Adults or children (≥5 years) needing assistive feeding technology to self feed
Exclusion Criteria	- Inability to provide informed consent/assent - Cognitive impairments that may prevent the ability to understand or respond to the survey questions - Non-English speakers (English-only materials) - Residents of California who are new Obi users
Study Procedure	1) Pre-screening by clinical staff per SOP220 to identify potential subjects who would likely meet the criteria for participation in the study. 2) Recruitment Flier is provided electronically and/or hard copy is mailed out with trial Obi Gen3 Medical Robot with triadic recruitment strategy (Provider, Caregiver, Patient) 3) Screening: In-office assessment performed by provider to determine eligibility for home/community trial per Standard Operating Procedures (SOP220) that would be completed regardless of whether participating in the study. While this is not specific to the study procedure, it has been included here to help clarify the process. 4) Informed consent will be obtained for all stakeholders interested in participating (Provider, Caregiver, Patient) electronically using Qualtrics 5) ~ One (1) week home/community trial of Obi Gen 3 with a minimum of a five (5) meal requirement for use by Caregivers and

	Patients. Providers must recommend and assess at least one (1) patient for Obi Gen 3 in their practice setting. 6) Following the ~ one (1) week trial, Qualtrics will send an electronic web-based link. 7) Participants who complete the surveys will receive a $25 electronic gift card 8) Optional: Follow-up interviews completed by telephone, if warranted, within one (1) month of survey completion.
Schedule of Events	1) Pre-Screening 2)Recruitment, electronic and paper flyers 3) Screening (In-office assessment) 4) Informed Consent 5) ~One Week Obi Gen3 trial 6) Survey completion 7) Provide $25 remuneration 8) Optional follow-up interviews

A.2. Identification and description of the Investigational Device

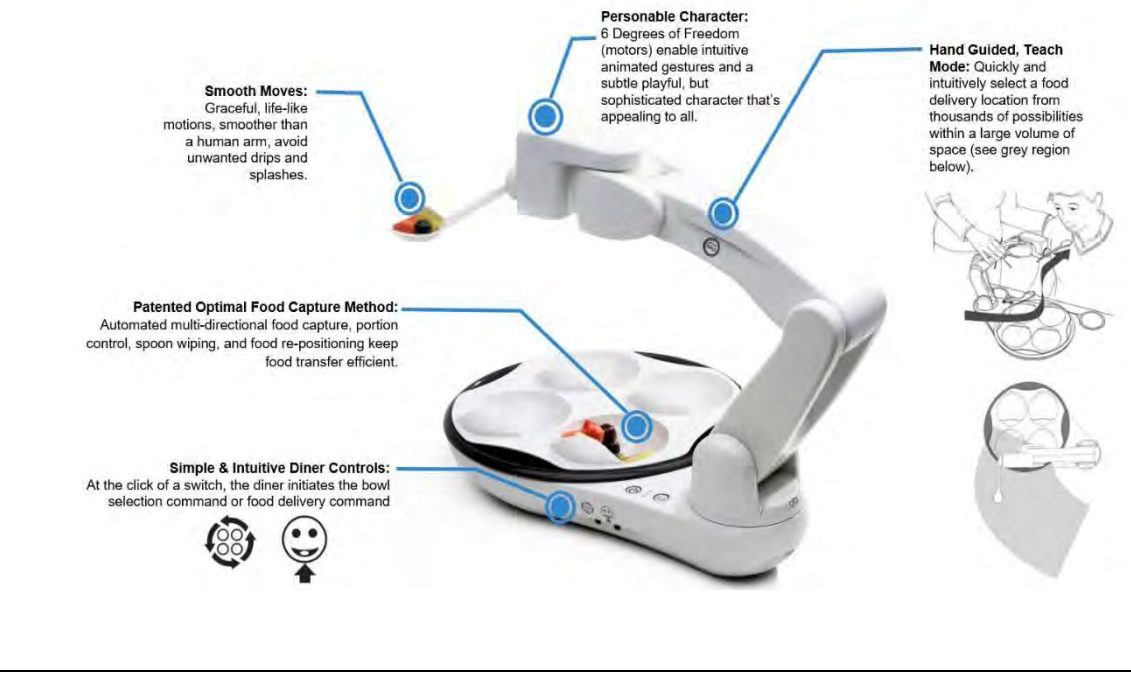
a) Summary Description of Investigational Device

Obi is a reusable robotic utensil intended to compensate for the function of a human arm during mealtime activities to restore a person's functional eating (self-feeding) status. Obi alleviates/ameliorates the disability caused by medical diseases/conditions that completely or severely impair the upper extremities/limbs. Obi provides a cross-cultural, broad user demographic with the ability to make decisions on what and when to eat through an easy-to-learn and use user interface.

The user interface accommodates mobility on most body areas through connections compatible with many different types of off-the-shelf Accessibility Switches. Further, the arm can adjust within a large volume of space, thus accommodating individual ergonomic needs pertaining to the chosen food delivery position. Through Obi's Teach Mode, the food delivery point is taught easily, and the device will perpetually store this position, thus eliminating the need for re-currant setup and minimizing caregiver involvement.

By fulfilling its intended use, Obi has the potential to improve quality of life and alleviate/ameliorate or prevent medical issues known to be associated with lack of self-feeding, including, but not limited to, gastroesophageal reflux disease (GERD), aspiration, aspiration pneumonia, malnutrition, dehydration, and psychological and/or social health impairment.

Obi, a Robotic Medical Device for Self-Feeding.



FDA Device Classification: Obi is an FDA-compliant Class I, 510k exempt medical device. It is categorized under the Physical Medicine panel under product code ILC: Utensil / Eating, Daily Activity Assist Device, Eating. The device listing number is as follows:

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D253086		510(k) exempt	ILC	UTENSIL, EATING	Manufacturer Complaint File Establishment

For more information, including justification for device classification, please refer to IFD-DES-001, US Regulatory Plan.

About Obi3 (Gen3):

Obi Gen1 was released in the summer of 2016, and Gen2 was released in the summer of of 2019. GEN2 focused strongly on design for manufacturability, quality, and reliability-related improvements (see ECR#077). In response to feedback from the marketplace, GEN3 focuses less on internal structural changes and more on minor but significant usability improvements.

Perhaps most notably, some patients have experienced dissatisfaction with limited spoon sizes and the spoon detaching from the device too easily. For example, some patients living with Cerebral Palsy, Spastic Quadriplegia, that are otherwise strong candidates for the device, may struggle to keep the spoon attached to the arm during use. Additionally, pain points are communicated related to the inability to differentiate between the actions of the two provided black pressure switches and a lackluster packaging experience that does not harmonize with the device's quality or aesthetics.

The following table lists the significant changes in scope with Obi3:

Improvement	Description
Utensils (see IFU for photos)	Four (4) new utensils were designed. Changes include a wider variety of spoon-bowl shapes (a smaller spoon, a larger spoon, a spork, and a classic spoon). The resin material was also changed to a more durable food contact resin with better dishwasher properties. The attachment cup geometry was also modified for proper mating with the revised Utensil Adapter
Utensil Adapter	A new attachment point was installed on the end of the Obi arm to correct the spoon's tendency to separate inappropriately under a specific direction of applied force.
Software Features	New features include: Patient Power On: When the AC Adapter is connected, the patient can activate a pressure switch for 1.5 seconds to power on the device. Reward Mode: Using a special code combination, the device will move through special motions for approximately 1 minute to encourage or reward favorable self-feeding behavior. In Bowl Collision Backup: In response to an in-bowl collision with large hard food particles, the device now slightly backs away following the food collision and re-scoops.
Instructions For Use	Language Modifications to the Indications for Use, Absolute Contraindications and Relative Contraindications sections. Additional imagery in the Food Preparation section. New sections pertaining to the revised Obi3 features: new utensils, patient power on, and reward mode. Further specification of Cleaning and Disinfection Instructions.
Quick Start Guide	Revised imagery related to the Food Preparation Section to promote better understanding of food preparation needs for optimal food capture efficiency.
Color change to the provided accessibility switches	Color Change to the 2 provided pressure switches. Now offering 1 in black and 1 in white to promote improved differentiation.
QR Code Label	A QR code is now applied to the Base to promote convenient access to support materials such as an electronic IFU, Quick Start Guide or other instructional videos.
Packing Box	The packing box imagery was updated with a high resolution digital print and a QR code print for easy access to support materials.

b) Details concerning the manufacturer of the investigational device

DESĪN LLC was founded in response to a personal family health tragedy in which the founder witnessed his grandfather lose the ability to eat independently due to a degenerative neuromuscular disease.

DESĪN LLC's facility and its operations are certified to the consensus standard for medical device quality management systems (QMS), ISO13485:2016 by Eagle Registrations Inc., an accredited member of the ANSI National Accreditation Board (ANAB) (Cert#6026). The scope of DESĪN LLC's quality system includes the design, manufacturing, distribution, and servicing of general medical devices, including robotic feeding devices. The company also has a US Safety Listing for Obi with an OSHA Nationally Recognized Test Lab (NRTL), SGS North America, Inc. (Listing Report File No. F2P22725A-05S).

c) Name/Number and Model/type, including software version and accessories

Devices under test with this study will occur with Obi3 production candidate devices utilizing production-intended materials and processes.

Name	Obi3, US
Model#	IFD-500-031

Obi3 will ship to participants with the following content:

Component	Quantity
Obi3 Device	1
Pressure Switches	2
Utensils (2 copies of each)	8
Plate	1
Placemat	1
AC Adapter	1
Instructions for Use	1
Quick Start Guide	1

The following is an image of what will arrive with each device inside the box:

The following is a list of the significant Obi3 production candidate components that will be assembled to Obi's in this study (see included specification sheets):

Name	Part#	Rev
Obi Control Board Software Rev	IFD-700-003	7.2.0
Utensil Adapter, Obi3	IFD-400-110	1.0.0
Small Spoon	IFD-400-102	1.1.1
Classic Spoon	IFD-400-100	1.1.1
Spork	IFD-400-108	1.1.1
Large Spoon	IFD-400-101	1.1.1
Obi Instructions for Use	IFD-600-003	5.1.0
Quick Start Guide	IFD-600-002	2.0.0

The following is an image of the aforementioned Obi3 spoons and spork:

d) Description as to how traceability shall be achieved during and after the clinical investigation (lot/batch/serial numbers)

A quantity of 10 Obi3 production candidate devices will be assembled leveraging DESĪN LLC's production and process controls. Each device constructed will include a documented device history record (See IFD-801-012, Obi Travel Router (DHR)). These DHRs will consist of the Obi serial number, lot number, and component traceability information (rev, serial#, lot#) for all critical components, including the Obi3-specific components listed above. Each record will also include the date of manufacture, the person responsible for building and completing each subassembly, and the inspector's name, which is the quality check for each sub-assembly.

Each device will also include the following labeling affixed to the underside of the devices:

e) Intended Use

Per IFD-600-003: "Obi is a reusable robotic utensil intended to compensate for the function of a human arm during mealtime activities to restore a person's functional eating status[1]. Obi alleviates/ameliorates the disability caused by medical diseases/conditions that completely or severely impair the upper extremities."

[1]

f) Indications for Use/Intended Purpose

Per IFD-600-003: “Obi is indicated for people 5 years and older (or younger, with approval of a qualified healthcare professional) living with congenital or acquired neurological, neuromuscular, or musculoskeletal impairment of the upper extremities affecting the ability to independently perform and participate in mealtime activities for daily living. Obi users may have the following medical diseases/conditions:

- Amputees
- Amyotrophic Lateral Sclerosis (ALS)
- Arthrogryposis Multiplex Congenital (AMC)
- Cerebral Palsy
- Congenital Limb Differences
- Developmental Disabilities
- Essential Tremor
- Multiple Sclerosis
- Muscular Dystrophy
- Parkinson’s Disease
- Spinal Cord Injury
- Other conditions impairing motor control of the upper extremities.

In addition, patients must have the cognitive ability to understand cause and effect (i.e., active a switch to perform a function).”

Absolute Contraindications:

Per IFD-600-003: “Obi has no known absolute contraindications as there are no conditions under which the device must not be used because the risk of use outweighs any possible benefit. However, several conditions may carry risk and therefore, caution should be considered via a benefit/risk assessment with a qualified healthcare professional (see “Precautions”).”

Relative Contraindications/Precautions

Per IFD-600-003: “A patient should NOT use Obi if any of the following conditions are present and of a severity that results in an unacceptable compromise to the benefit/risk ratio provided by the device. Where appropriate, special attention should be given to whether the following attributes pose an unacceptable risk to unsafe feeding or eating.

A. Cognitive/behavioral impairment: Inability to understand or correctly use the device and/or at risk for combative/self-injurious behavior during meals.
B. Deviations from pre-existing dietary restrictions: No changes to food preparation should be made to use Obi that would directly contradict any current recommended food or liquid textures/consistencies prescribed by a healthcare professional.
C. Dysphagia: Significant oral motor, breath, or swallowing impairment that could pose an elevated risk of choking/aspiration (unless found appropriate by a treating healthcare

professional who has reviewed and discussed the benefit/risk assessment with the patient and /or caregiver). Any specific recommendations by the provider must be strictly followed.

D. Excessive movement: Uncontrollable/forceful movements that prevent the device's correct and/or safe use.
E. Insufficient head control: Insufficient head control to position the Obi utensil reliably near the mouth. Or insufficient head and oral motor control to reliably remove content from the utensil.
F. Insufficient movement: Unable to operate any compatible accessibility switches: Pressure Switch, Toggle Switch, Pillow Switch, Sip and Puff, etc.
G. Reclined positions: Patients that cannot be positioned sufficiently upright for food/liquid consumption or maintain a sufficiently upright position throughout a meal (unless found to be appropriate by a treating healthcare professional).
H. Open mouth sores: Any significant cuts, ulcerations, or oral bleeding.
I. Open skin sores: Any open wound on an area of the body used to activate Accessibility Switch(es) or to contact Obi."

Side Effects:

Per IFD-600-003: "Obi has no known side effects."

g) Description of the investigational device, including any materials that will be in contact with tissues or body fluids.

The utensils listed in section A.2.c will contact saliva and food. However, under normal or foreseeable misuse, there should be no intentional contact with other body fluids. No medicinal substances, human or animal tissues, derivatives, or other biologically active substances will be used.

h) Summary of the necessary training and experience needed to use the investigational device based on risk assessment.

The Obi Risk Management File does not identify any necessary training or experience as a risk control measure in order to use the device safely (see References section for a partial list of the ISO14971:2019 Risk Management File documentation).

i) Description of specific medical or surgical procedures involved in the use of the investigational device.

There are no medical or surgical procedures involved in the use of the investigational device.

j) Reference to IB & IFU

An Investigators Brochure was deemed unnecessary for this study due to its single site, the simplicity of the study, and its non-invasive nature.

See A.2.b for IFU.

A.3. Justification for the design of the clinical investigation

a) an evaluation of the results of the relevant pre-clinical testing/assessment and prior clinical investigations, if applicable, carried out to justify the use of the investigational device in human subjects

An independent consultant of DESĪN LLC, Dr. Betsy B. Burgos previously conducted a study on Obi titled: *The Use of Obi Robot for Self-Feeding with Individuals with Upper Extremity Limitations (pending publication with Assistive Technology Outcomes and Benefits Journal)*.

The study consisted of the clinical observations and analysis of the author/independent examiner after assessing the performance data of individuals who used Obi for self-feeding. From the Abstract: "This descriptive study examined the functional performance of self-feeding in 19 individuals with upper extremity limitations using Obi, a robotic self-feeding device. Participants ranged in age from 8 to 60 years and were observed across various environments, including homes, simulated-home setups, clinics, and schools. Participants ' performance with Obi was evaluated using observational methods and secondary data analysis. Results indicated that all participants successfully used Obi to feed themselves independently by activating switches connected to the device, with a 100% success rate in delivering food to their mouths by the final trial session. Different types of switches, customized according to the participants' needs, allowed for personalized feeding experiences and increased their social interactions with family and friends.

With Obi3's scope changes, this study will ensure the device can continue to be operated in accordance with its intended use, continue to meet user needs, and confirm a favorable benefit/risk ratio.

b) An evaluation of clinical data that are relevant to the proposed clinical investigation.

A clinical evaluation has been conducted and documented within IFD-DES-021, Clinical Evaluation Plan (CEP) & Report (CER) pertaining to the Gen2 device in 2024. This document includes the results of a systematic literature review pertaining to powered feeding devices. The conclusion reads as follows:

"Based on the successful review of all data included in this CER, it can be concluded that Obi is well documented in relation to safety and performance and suitable for use per its intended use. Consequently, there has not been identified any outstanding risks that will justify the enrollment of patients in a clinical study and as such, a clinical study is not necessary to demonstrate conformity with the requirements. A small number of non-safety related complaints and no product recalls related to the subject device were identified, and with an accumulated performance-related complaint ratio of 2% worldwide, this CER concludes that using Obi, which is a clas s I low risk medical device, is safe, compliant with state of the art, and that the risk level is acceptable when weighed against the benefits to the patient or even in comparison with the use of the similar devices. The overall benefit vs. risk ratio for Obi remains favorable. Based on

assessment of all available data in respect of Obi, it is considered that the subject device fully complies with the relevant GSPR in Annex I of the EU 2017/745 MDR."

c) a description of the clinical development stage (see Annex I), if appropriate.

This study should be considered predominantly a post-market, non-interventional, observational study (Design Validation).

Obi Gen 3 is a production equivalent Class I medical device intended to assist individuals with upper extremity motor impairments in self-feeding. This usability study is situated in the design validation stage of the product lifecycle, consistent with requirements outlined in ISO 13485 and FDA Quality System Regulation (QSR 21 CFR Part 820.30(f)) for medical device design controls.

This investigation aims to validate that the design of Obi-Gen 3 meets the intended use and user needs as formally documented before broader commercialization. This study is not intended to evaluate safety or efficacy from a regulatory or therapeutic standpoint, as the device does not deliver treatment but facilitates an activity of daily living. Instead, it focuses on:

- Confirming that usability goals (e.g., efficiency, ease of use, satisfaction) are met,
- Gathering qualitative feedback from key user stakeholders (providers, caregivers, patients) and
- Informing whether the design is ready for commercialization and on design enhancements, user support documentation, and deployment strategies.

This stage follows prior internal design and engineering iterations, including formative evaluations, and represents the first structured, multi-stakeholder usability assessment conducted with production equivalent units in real-world use.

A.4. Benefits and Risks of the Investigational Device and Clinical Investigation

Note: There is no "clinical procedure" applicable to the use of Obi.

a) Anticipated Clinical Benefits

a. Device: Patients are anticipated to restore their ability to independently perform self-feeding. Obi has the potential to improve quality of life and psychosocial health. Moreover, Obi may improve the caregiver-patient relationship, have a therapeutic impact, and have labor-saving/economic value.

b. Clinical Investigation - Usability Study

- Provider
- Caregiver
- Patient

b) Anticipated Adverse Device Effects

Device: There are no anticipated adverse device effects. The company has a history of no adverse events in 9 years and has sold over 3,000 devices. This is documented in the IFD-DES-021, Clinical Evaluation Plan & Report, which is current through 2024.

The results of this design validation study will inform an updated Risk Management Report regarding the device's overall benefit-risk analysis, including the identification of any unforeseen potential use errors that require further risk assessment.

c) Risks associated with participation in the clinical investigation

Physical risk: There is minimal physical risk in participating in the study. Obi is a Class I device with a history as a safe and reliable medical device if used according to its Instructions for Use (IFU). Since 2016, the device has never received notice of an adverse event. It carries a medical safety certification and listing compliant with the latest applicable medical device safety standards [e.g., IEC60601-1:2012, IEC60601-1-2:2020, IEC60601-1-6:2015, IEC60601-1-11:2015, etc.]. Obi is also designed, manufactured, and serviced within a certified medical device quality management system in accordance with ISO13485:2016.

The scope of user interface changes for Obi3 are minor adjustments, and do not represent a major conceptual departure whereby legacy post-market data may no longer be relevant. Modifications and new features undergoing development within Obi3 were evaluated with a safety risk assessment per SOP170, Safety Risk Management Procedures and ISO14971 a user interface formative evaluation (per IEC62366:2020) per IFD-DES-064 Formative Evaluation Plan, Obi3 (for results, see IFD-DES-070 Formative Evaluation Report, Obi3). These activities did not result in the identification of any new hazards, or potential use errors associated with the scope of Gen3 changes (see IFD-DES-018, Product Hazards Analysis Table). However, updates to the Product Hazards Analysis were made to correct for previous oversights or unintentional errors. Summative evaluation was not performed as the user interface as it pertains to safety is considered unchanged (see IFD-DES-072, Summative Evaluation Plan).

Fatigue or Frustration: Participants may experience mild fatigue, confusion, or frustration during initial use of the device, particularly during the learning phase. These effects are expected to be temporary and self-limiting. Participants will receive onboarding materials and optional technical support to reduce this risk.

Psychosocial Discomfort: Some participants may feel discouraged or self-conscious if they encounter difficulties using the device. The study includes an option to discontinue at any time and will collect feedback in a supportive, non-judgmental manner.

Data Privacy and Confidentiality: As the study collects identifiable information (e.g., stakeholder role, experience, and feedback), there is a theoretical risk of a breach of confidentiality or unauthorized data access. To mitigate this risk, all data will be collected via the

HIPAA-compliant Qualtrics platform, stored on secure servers, and accessed only by authorized study personnel.

d) Possible interactions with concomitant medical treatments as considered under the risk analysis.

ISO14971 related risk assessment has not identified any possible interactions with concomitant medical treatments (see IFD-DES-018, Product Hazards Analysis)

e) Steps that will be taken to control or mitigate risk.

Risks identified within the Obi Risk Management File have previously been mitigated as far as possible without compromising the benefit-risk ratio (see IFD-DES-022, Risk Management Report). Additionally, Clinical Evaluation has shown a favorable benefit-risk ratio (see IFD-DES-021, Clinical Evaluation Plan & Report). Obi carries an active medical device safety certification to the current version of IEC60601-1 and applicable, related collateral standards. As previously mentioned, a risk assessment per SOP170 and ISO14971 was performed on the features of Obi3, and no new hazards associated with Obi3 were identified.

While risks of the device have been sufficiently controlled, additional steps are taken to ensure the patient is appropriately qualified for use with Obi before taking it home:

In addition to inclusion criteria, the pre-screen step of SOP220 conducted by on-staff providers prior to study/trial enrollment, will help to ensure only qualified candidates are being approved for use with the device and enrollment in the study. Additionally, the office assessment, conducted by the patient's primary provider, most often an occupational therapist), will determine whether that patient's benefit outweighs the risks of using the device. Only those Office Assessments where a favorable benefit-risk ratio is established will proceed to a home use 7-day trial.

f) Rationale for benefit-risk ratio.

See IFD-DES-022 or IFD-DES-021 for further rationale of the benefit-risk ratio.

A.5. Objectives and hypotheses of the clinical investigation

a) The purpose of the clinical investigation, claims for clinical performance, effectiveness or safety of the investigational device that are to be verified

This clinical investigation's purpose is to validate that the production equivalent Obi3 (including its labeling and packaging) conforms to its intended use and formally documented user needs, as required by medical device regulations and standards. The overall usability and user experience of the Obi3 Medical Robotic Feeding Device will also be evaluated among key stakeholder groups, including providers, caregivers, and patients.

This investigation does not seek to establish therapeutic or diagnostic effectiveness, as the device is not intended to treat or manage a clinical condition. Rather, it is intended to support independent self-

feeding for individuals with upper extremity impairments—a key activity of daily living that contributes to personal dignity, autonomy, and quality of life.

The claims for clinical performance and effectiveness to be verified in this study include:

- The device can be safely and effectively operated by the intended users (patients and caregivers) in a home, school, or community setting.
- The device is recommended and integrated into practice by clinical professionals who support individuals with feeding-related disabilities.
- The design features, controls, and user interface support efficient, effective, and satisfactory use.
- The device enables users to independently complete a minimum of five meals during a one-week trial period without undue burden on caregivers or providers.

This clinical investigation also aims to verify that supporting materials (e.g., Quick Start Guide, Instructions for Use, and MDNA form) are usable and that the overall user experience aligns with expectations for performance, ease of use, and satisfaction. These claims will be evaluated through mixed-methods data collection, including surveys and semi-structured interviews. No safety claims are being assessed in this study. Obi Gen 3 is a Class I medical device with minimal risk and has undergone benefit-risk analysis and mitigation per ISO 14971. However, participants will be monitored for device-related issues or unanticipated problems during the trial.

b) Objectives, primary and secondary, are described as 'superiority,' 'non-inferiority,' or 'equivalence,' if applicable.

PRIMARY: Validate whether the production equivalent enhanced Obi3 device design conforms to the formally defined user needs and intended use (per IFD-DES-054-1, Obi Validation Plan, Gen3)

SECONDARY:

- Determine patient usability in accordance with the Matching Person & Technology Assistive Technology Framework.
- Determine caregiver usability in accordance with questions from the Caregiver Burden Index.
- Determine provider perspectives following the SUS as a standardized outcome measure.
- Obtain provider feedback regarding the efficacy, efficiency, and satisfaction of the Obi clinical assessment forms and the associated process.
- Obtain other qualitative feedback regarding the perceived strengths and weaknesses of the Obi design.

c) Scientific justification and clinical relevance for effect sizes, non-inferiority margins, or equivalence limits, where applicable.

This clinical investigation is a formative design validation study intended to assess the usability and user experience of the Obi Gen 3 Medical Robotic Feeding Device. As such, the study is not designed to test predefined effect sizes, non-inferiority margins, or equivalence limits because it does not involve comparing clinical performance outcomes between devices or interventions.

d) Primary and secondary hypotheses, if applicable.

This is not a hypothesis-driven study. This investigation aims to generate qualitative and quantitative data to determine whether the device fulfills its intended use and meets the functional and experiential needs of its users, including patients, caregivers, and providers. These data will guide product refinement, workflow integration, and stakeholder support strategies. Consequently, the scientific and clinical value lies not in statistical thresholds of performance superiority or equivalence but in identifying usability facilitators and barriers. Validated assessment tools used in the study (e.g., Matching Person & Technology Framework, System Usability Scale) provide benchmarks and interpretation guidelines (e.g., SUS score of ≥68 as average usability), which will be used for contextualizing findings. These interpretive thresholds will help determine whether observed results meet clinically meaningful usability standards and support progression to broader deployment. While formal hypotheses regarding effect size or non-inferiority do not apply to the design and objectives of this study, the clinical relevance is embedded in stakeholder feedback, validated usability scores, and evidence that the device enables functional independence as intended.

e) Risks and anticipated adverse device effects that are to be assessed.

The Obi Gen 3 Medical Robotic Feeding Device is classified as a Class I medical device under FDA and MDR regulations, indicating minimal risk to users. As such, no significant adverse device effects are anticipated in the context of this usability study.

See section A4 for identified risks.

A.6. Design of Clinical Investigation

A.6.1. General

a) Description of the design type of clinical investigation to be performed (e.g., randomized, blinded or open-label, parallel groups or crossover, multicentre, international), the control group (e.g., comparative claim and reversible treatment of a chronic state), and the comparator with rationale and justification for the choice. Absence of control(s) shall be justified.

This clinical investigation is designed as a non-randomized, open-label, single-group, single-site validation study. The study will employ a mixed-methods approach, incorporating quantitative and qualitative data to evaluate the usability, acceptability, and real-world applicability of the Obi Gen 3 Medical Robotic Feeding Device.

The study will not include a control or comparator group, as it is not intended to assess therapeutic or clinical effectiveness but rather to validate whether the device design fulfills user needs and intended use criteria. The absence of a control group is justified given the purpose and scope of the investigation, which aligns with medical device design validation under ISO 13485 and FDA QSR 21 CFR 820.30(f), rather than comparative clinical evaluation.

Participants—providers, caregivers, and patients—will be exposed to a single-arm intervention: a one-week home, school, or community trial of the equivalent Obi-Gen 3 device. During this time, stakeholders will interact with the device in naturalistic settings to assess its usability, functional integration, and perceived value.

The open-label nature of the study is appropriate given that:

- The device is visibly distinct and cannot be blinded.
- The study seeks stakeholder feedback, including ease of use, satisfaction, and observed barriers or facilitators to use—all requiring unblinded interactions.

No comparative claims or hypotheses are being tested, and no standard-of-care or alternate devices are being evaluated concurrently. The rationale for this approach is that the Obi Gen 3 is a Class I assistive device, aiming to validate its design performance and real-world usability, not to demonstrate superiority or non-inferiority to other feeding systems.

b) Description of the measures to be taken to minimize or avoid bias, such as randomization, concealment of allocation, blinding/masking, and management of potential confounding factors.

This clinical investigation is a non-randomized, non-comparative usability study designed to evaluate whether the Obi Gen 3 Medical Robotic Feeding Device conforms to its intended use and meets documented user needs. The purpose of the study is not to assess therapeutic effectiveness or to compare outcomes across intervention groups but to validate device usability and stakeholder satisfaction across real-world settings.

Given the nature and objectives of the study, randomization, blinding, and allocation concealment are not applicable. However, several measures will be taken to minimize or avoid bias and manage potential confounding factors:

1. Standardized Protocols and Training
All participants (providers, caregivers, and patients) will engage with the device under a standardized study protocol, including consistent onboarding materials, instructional documents, and usage expectations (e.g., a minimum of five meals during the trial period). These materials were developed based on prior formative feedback and are provided in uniform formats to reduce variability in participant experience.

2. Structured Data Collection Tools

Usability feedback will be collected using validated instruments (e.g., System Usability Scale, Matching Person & Technology framework) and semi-structured interview guides. These tools ensure consistency in gathering information, reduce interviewer bias and facilitate comparisons across stakeholder groups.

3. Triangulation of Stakeholder Perspectives

The study design allows for triangulation of findings by including data from three distinct stakeholder groups (providers, caregivers, and patients). This multi-perspective approach reduces the risk of single-source bias and provides a broader understanding of device usability in real-world contexts.

4. Post-Use Feedback After Trial Exposure

Participants provide their usability ratings and feedback only after completing the one-week trial. This approach helps minimize expectation bias and ensures responses reflect the user experience with the device.

5. Blinding of Data Analysts (if applicable)

The Principal Investigator will conduct the data analysis but will not be involved directly in participant recruitment or data collection, reducing the potential for confirmation bias during the interpretation of results.

Collectively, these measures are designed to support the credibility, reproducibility, and transparency of findings from this usability-focused clinical investigation.

c) Primary and secondary endpoints, with rationale for their selection and measurement. If applicable, composite endpoints, with rationale for their selection and measurement.

Primary Endpoint

The primary endpoint of this clinical investigation is to determine whether the production equivalent Obi Gen 3 device fulfills its intended use and formally defined user needs across three key stakeholder groups: patients, caregivers, and providers. This endpoint reflects the device's design validation objective under FDA and ISO guidelines for Class I medical devices.

To assess this endpoint, the study uses a mixed-methods approach that includes:

- Usability survey responses gathered post-trial via Qualtrics,
- Qualitative interview data to capture real-world experiences and
- Evidence of independent feeding success (i.e., completion of a minimum of five meals during the one-week trial period for patient participants).

Rationale: This endpoint aligns with ISO 13485 and FDA QSR requirements for verifying that a device conforms to documented design inputs and intended use in its target environment. Given that the device facilitates daily living activities rather than delivers clinical treatment, usability, and stakeholder satisfaction are the most relevant performance indicators.

Secondary Endpoints

Secondary endpoints are designed to provide a multi-dimensional understanding of the user experience and support future design refinement and stakeholder-specific training materials.

These include:

1. **Patient Usability** will be measured using an adapted version of the Matching Person & Technology (MPT) Framework and adult and pediatric versions. The study focuses on compatibility between the user and device, perceived benefits, and likelihood of long-term adoption.

2. **Caregiver Usability** will be measured using the System Usability Scale (SUS) and the Matching Person & Technology (MPT) Framework, an adult version adapted for the context of this study. Additionally, a few selective questions from the Caregiver Burden index will help to describe this stakeholder group to understand better the impact of Obi-Gen 3 use on time demands, emotional strain, and caregiving workload.

3. **Provider perspectives and Workflow Integration** will be measured using the System Usability Scale (SUS) and open-ended feedback. The study will assess ease of device recommendation, assessment form clarity, and integration into the service delivery process.

4. **Effectiveness of Training and Support Materials** will be assessed via post-trial feedback on the Quick Start Guide, Instructions for Use, and clinical assessment documentation (Obi MDNA©).

   Rationale: These endpoints reflect stakeholder-specific criteria for acceptability, feasibility, and usability and were selected based on established frameworks in the assistive technology literature.

d) Methods and timing for assessing, recording, and analyzing variables.

This clinical investigation employs a mixed-methods approach to assess the usability and user experience of the Obi Gen 3 Medical Robotic Feeding Device. Both quantitative and qualitative variables will be assessed at multiple timepoints using standardized and non-standardized tools. Data will be recorded electronically and analyzed using descriptive and thematic methods.

Key variables to be assessed include:

- **Usability metrics** (efficiency, effectiveness, satisfaction)
- **Stakeholder-specific experience and acceptance** (patients, caregivers, providers)
- **Functional outcomes** related to self-feeding independence
- **Psychosocial impact** (confidence, autonomy, perceived burden)
- **Feedback on supporting materials** (ease of use of training guides, forms)

As previously described, these variables will be measured using quantitative surveys and rating scales, including the System Usability Scale (SUS) and Matching Person & Technology (MPT) Framework. Qualitative data will be gathered through open-ended questions, which are included in the surveys, and semi-structured interviews conducted by phone, when applicable.

Timing of Assessments

- **Baseline**: Screening and in-office assessment by providers; completion of the Obi MDNA© form to gather demographics and baseline functional feeding status.
- **During trial**: One-week trial of Obi-Gen 3 in home, community, or school settings. Caregivers and patients use the device with at least five meals; providers recommend or assess at least one user in their practice.
- **Post-trial (~ one week to one month)**: Qualtrics survey links will be sent to all participants (providers, caregivers, patients) to gather information post-trial. Optional telephone interviews may be completed within one month of survey completion for additional qualitative feedback.

Data Recording

- All survey and rating scale responses will be collected electronically via Qualtrics, a HIPAA-compliant data management platform.
- Qualitative interview notes or transcripts will be recorded and stored securely using encrypted formats, with identifiers removed before analysis.

Data Analysis: All analyses will be used to determine whether the design of Obi Gen 3 meets the intended use and user needs and to guide product refinement and support resources.

- Quantitative data will be analyzed using descriptive statistics (e.g., means, standard deviations, medians) to assess trends in usability scores across stakeholder groups.
- As a validated instrument, responses to the SUS will be interpreted using established scoring thresholds to determine whether usability targets were met.
- Qualitative data will be analyzed using a structured thematic coding approach to identify key usability themes, barriers, and suggested improvements.

e) Equipment to be used for assessing the clinical investigation variables and arrangements for monitoring maintenance and calibration.

The primary “equipment” under investigation is the Obi Gen 3 unit, which will be used by patients and caregivers in home, school, or community environments and recommended or assessed by providers in clinical settings. Each Obi Gen 3 unit used in the investigation is a production equivalent model that has

undergone quality assurance testing prior to distribution. DESĪN LLC, the device sponsor, is responsible for:

- Verifying proper function of all device components (arm, base, controls) before shipment
- Maintaining a device log to track serial numbers, shipment history, and user assignment
- Providing pre-use visual inspection guidance and basic maintenance instructions to participants.

Because Obi Gen 3 is a non-implantable, non-therapeutic, electromechanical device with no internal measurement sensors requiring calibration, no additional calibration procedures are required during the investigation. In the rare event of a device malfunction or performance concern, participants will be instructed to notify the study coordinator immediately, and the sponsor will either replace the device or conduct further investigation as appropriate.

In addition to the device, the following tools will be used for assessing clinical investigation variables:

- Obi Gen 3 Assessment Forms (D-FRM-021, Obi MDNA) (developed by the sponsor for clinical assessment and workflow documentation)
- Data Collection Tools including:
    - **Qualtrics** – a secure, HIPAA-compliant online platform used to distribute and collect all electronic surveys, rating scales, and interview responses
    - **System Usability Scale (SUS)**
    - **Matching Person & Technology Framework** – adapted
    - **Caregiver Burden Index** – selected items relevant to feeding support

All electronic data collection tools (i.e., Qualtrics) are maintained by the vendor and subject to routine system monitoring, encryption, and security updates per HIPAA and institutional data security policies.

f) Any procedures for the replacement of subjects (generally, not applicable to randomized clinical investigations).

This usability study includes patients, caregivers, and providers as stakeholders and does not involve treatment allocation or randomization.

As such, formal subject replacement procedures are not applicable. Participants may withdraw from the study at any time without penalty, and no individual will be replaced on a one-to-one basis; however, if attrition occurs early in the study (e.g. before completion of the minimum trial period or primary usability data are collected), the sponsor and study team may continue recruitment to maintain a robust and diverse sample that reflects the target user population.

All data from participants who withdraw will be handled according to data management protocols, and partial data may be included in the analysis when appropriate and ethically permissible. Efforts will be

made to ensure adequate enrollment within each stakeholder group (providers, caregivers, and patients) to meet the target sample size and fulfill the study's objectives.

g) Investigation sites: number, location, and, if appropriate, differences in investigation site environment.

This clinical investigation will be conducted through a single-site sponsor model coordinated by DESĪN LLC, the developer and manufacturer of the Obi Gen 3 Medical Robotic Feeding Device. DESĪN LLC is headquartered in the United States and will serve as the central coordinating site for all study activities.

While DESĪN LLC is the designated study site, data collection will be conducted remotely and electronically using a HIPAA-compliant data platform (Qualtrics), enabling participation from individuals located throughout the United States. This distributed recruitment and data collection approach supports broader geographic and demographic diversity among participants and reflects the real-world settings in which the device is intended to be used.

Participants—including providers, caregivers, and patients—will engage with the study in naturalistic environments, such as:

- Home settings (for patients and caregivers),
- Community settings, including schools or assisted living environments,
- Clinical settings, where providers may evaluate or support patients using the device.

The diversity of these environments is intentional and aligns with the purpose of the usability study, which is to evaluate device performance in the context of everyday use. The study will capture data on how different settings and conditions may impact user experience, device integration, and support needs. No formal in-person clinical site visits or on-site research infrastructure is required for participation, and all stakeholders will be provided with study materials, the Obi Gen 3 device, and access to electronic surveys and interviews in a manner consistent with remote, human-centered usability testing.

h) Definition of completion of the clinical investigation (see 8.1).

The clinical investigation will be considered complete when all enrolled participants have concluded their involvement in the study, including:

- Completion of the required ~1-week home/community trial of the Obi Gen 3 device;
- Submission of all relevant post-trial surveys via the Qualtrics platform;
- Completion of any scheduled follow-up interviews (if applicable), which may occur up to 1 month following survey completion;

- All protocol-specified data collection activities have been finalized, verified, and locked for analysis.

The end of the investigation will also include:

- Confirmation that no additional participants remain under observation;
- Documentation of any protocol deviations, adverse events, or device-related issues;
- Completion of final data monitoring activities and closure of the Qualtrics data collection system;
- Submission of a final study report following applicable IRB and sponsor requirements.

A.6.2. Investigational Devices and comparators

a) Description of the exposure to the investigational device(s) or comparator(s), if used.

This clinical investigation involves exposure to a single investigational device, the Obi Gen 3 Medical Robotic Feeding Device, which is a production equivalent version of a Class I FDA-registered medical device intended to assist individuals with upper extremity impairments in self-feeding. Participants in the study—including patients, caregivers, and providers—will be exposed to the device during a short-term, observational usability trial, which occurs under real-world use conditions (home, school, community, or clinical environments). No comparator device is being used.

All exposure to the device is consistent with its intended purpose and involves no modification to existing standards of care or risk to participants. The exposure is limited in duration and is conducted in naturalistic settings to allow the device to be evaluated under realistic use conditions.

Patient and Caregiver Exposure: Patients and caregivers will use the Obi Gen 3 device for a period of approximately one week. During the trial, users are expected to operate the device for a minimum of five meals, though additional use is encouraged to gather meaningful feedback. Participants will use the device independently or with caregiver assistance, following a brief orientation via a Quick Start Guide (QSG) and Instructions for Use (IFU) provided with the device. Device use is non-invasive and involves no physical contact beyond standard utensil-based feeding.

Provider Exposure: Providers (e.g. occupational therapists, speech-language pathologists, assistive technology professionals) will interact with the Obi Gen 3 device in the context of:

- Assessing its fit for at least one patient in their caseload,
- Recommending its use as part of routine practice (if applicable),
- and Providing feedback based on observation or guided use in their clinical setting.

The Providers will not operate the device for feeding themselves but will assess functionality, usability, and alignment with therapeutic goals.

b) List of any other medical device or medication to be used during the clinical investigation if not already specified in the instructions for use.

Not Applicable - No additional medical devices or medications are intended for use in this clinical investigation beyond what is already specified in the Instructions for Use (IFU) for the Obi Gen 3 Medical Robotic Feeding Device.

c) Number of investigational devices to be used, together with a justification.

This usability study will use ten (10) production-equivalent Obi-Gen 3 devices. The study sponsor, DESĪN LLC, is providing these devices, which represent final design units intended for validation prior to broader commercialization.

The selected number is justified based on the following factors:

- The study will enroll approximately 55–60 participants across three key stakeholder groups: providers, caregivers, and patients.
- The study design includes a 1-week device trial per patient-caregiver dyad, during which each device will be rotated and re-used among participants.
- Cleaning and infection control protocols will be implemented between uses to ensure participant safety and device integrity.
- This number allows for redundancy and replacement should a device require maintenance or become damaged during the study.
- The Obi Gen 3's limited-risk profile (FDA and MDR Class I classification) supports the re-use of devices across participants, provided proper decontamination procedures are followed.
- It also ensures sufficient device availability for logistics coordination, shipping, training support, and concurrent participation at different study locations.

This approach balances scientific rigor, operational feasibility, and resource efficiency while supporting timely and representative data collection for design validation purposes.

A.6.3. Subjects

a) Inclusion Criteria for Subject Selection

Participants will be recruited from three key stakeholder groups—providers, caregivers, and patients—who represent the intended users of the Obi Gen 3 Medical Robotic Feeding Device. Inclusion criteria are as follows:

- **Providers** - Licensed healthcare professionals with direct experience in recommending, assessing, or implementing assistive technology, rehabilitation interventions, or feeding-related supports. This may include, but is not limited to, occupational therapists (OTs), speech-language pathologists (SLPs), assistive technology professionals (ATPs), and other qualified providers actively engaged in supporting individuals with self-feeding challenges.

- **Caregivers** - Individuals who provide regular, hands-on support to a person who may benefit from using the Obi Gen 3 device. This includes family members, personal care aides, educational support staff, or other support personnel who assist with or supervise feeding activities in the home, school, or community setting.

- **Patients**: Adults or children aged 5 years or older who require assistive technology to support independent or supported self-feeding due to upper extremity motor impairments or related

functional limitations. Individuals must have the cognitive and physical ability to participate in the one-week usability trial, either independently or with the assistance of a caregiver.

All participants must be able to understand and comply with study instructions and provide consent or assent (when applicable) either by themselves or through a legally authorized representative.

b) Exclusion Criteria for Subject Selection

Participants will be excluded from the study if they meet any of the following conditions:

- Individuals who cannot provide informed consent or assent, either due to legal status, cognitive limitations, or other conditions that impair decisional capacity.
- Individuals with severe cognitive impairments that would preclude meaningful participation in the study's usability tasks, including the ability to interact with the device or provide relevant feedback.
- Non-English-speaking individuals, as all study materials—including consent documents, surveys, and instructions—are available only in English at this time, and interpreter services are not being utilized in this investigation.
- California residents who are new to using Obi. The state of California requires a one-month trial, so the one-week timeline will not be feasible for California residents.

c) Criteria and procedures for subject withdrawal or lost to follow-up

i) when and how to withdraw a subject from the clinical investigation or stop the use of the investigational device,

Subjects may be withdrawn from the clinical investigation at any time due to voluntary withdrawal, investigator decision, or other unforeseen circumstances. Regardless of cause, all early terminations must be documented clearly in the Case Report Form (CRF) (attached to this protocol), including the specific reason for withdrawal. The following outlines the criteria and procedures for subject withdrawal:

Early Termination – General Considerations: All early exits from the study will be promptly recorded, and the rationale for withdrawal should be documented in the CRF to ensure traceability, transparency, and compliance with study oversight requirements.

Failure During Initial Use - While inclusion/exclusion criteria with pre-screening and in-office assessment that is part of the standard operating procedure will optimize appropriate participant selection, they may not be 100% predictive of device compatibility. In some instances, a subject may meet pre-screening criteria but be unable to use the Obi Gen 3 device safely or effectively during initial use. These cases will be identified early—typically on the first day of the trial—and such individuals will be withdrawn from the study. These withdrawals must be clearly documented in the CRF and the reason and relevant observational notes.

Voluntary Withdrawal of Consent - Subjects (or their legal representatives) have the right to withdraw consent and discontinue participation in the study at any time and for any reason, without penalty or loss of benefits. If informed consent is withdrawn, no additional data will be collected from the subject beyond the point of withdrawal. All data previously collected up to the point of withdrawal may be retained and used for analysis unless the subject explicitly requests full data removal, as outlined in the consent form.

Investigator-Initiated Withdrawal - If, at any time during the investigation, the Principal Investigator determines that continued participation poses an unforeseen risk to the subject's well-being or safety—or for other clinical, behavioral, or protocol-related reasons—the subject may be withdrawn from the study. The justification for investigator-initiated withdrawal must be documented in the CRF, and the subject (or caregiver) must be informed of the decision following ethical and regulatory standards.

Subject Death - In the rare and unforeseen event of a participant's death during the study period, the site investigator or their designated representative must notify the IRB and DESĪN LLC within 24 hours of becoming aware of the event. Death will be recorded as a reason for early study termination in the subject's CRF. While Obi Gen 3 is a Class I device with minimal risk, this reporting protocol ensures compliance with good clinical practice and transparency.

ii.) documentation of efforts to be made to trace subjects that are lost to follow-up and possible reasons

This study involves minimal risk and a short duration of participation for most subjects (approximately one week), with optional follow-up within one month for those whose survey responses warrant an optional semi-structured interview conducted by telephone. Despite this, the research team recognizes the importance of accounting for all enrolled subjects and will make reasonable efforts to trace those lost to follow-up. If a participant fails to complete the post-trial survey within one week following the designated trial period, the following steps will be taken:

- **Reminder Emails/Text Messages:** The HIPAA-compliant Qualtrics platform will send an initial automated reminder email and/or text message.
- **Follow-Up Contact:** If no response is received within 3–5 business days, study personnel will make up to two additional attempts to reach the participant by email, text, or phone. (if contact information is available).
- **Documentation:** All follow-up attempts will be documented, including date, time, method of contact, and any responses received.
- **Optional Withdrawal Confirmation:** If a participant expresses that they no longer wish to continue, this will be documented, and their status will be updated as voluntarily withdrawn.
- **Data Retention:** Any partial data collected before loss to follow-up will be retained and analyzed per IRB approval and applicable data use procedures.

Possible Reasons for Loss to Follow-Up May Include:

- Changes in caregiver or patient availability

- Loss of interest or perceived burden of participation
- Technology-related challenges (e.g., issues with email, survey links)
- Medical changes or competing life demands
- Unreachable contact information (e.g., email address no longer active)

Given the minimal-risk nature of the study, no intensive or intrusive tracking methods (e.g., home visits) will be used. Participants will be informed during the consent process that follow-up is optional and that they may discontinue participation at any time without consequence.

iii.) whether and how subjects are to be replaced.

Given the nature of this usability study and the relatively small, targeted sample size, subjects who withdraw voluntarily or are lost to follow-up during the study period will not be replaced. However, if a subject withdraws before completing any meaningful portion of the data collection (e.g., before starting the Obi Gen 3 trial period or before completing in-office assessments), the study team may recruit an additional participant to maintain representation across stakeholder groups (providers, caregivers, and patients). Replacement will occur only as needed to ensure data completeness or demographic diversity aligned with the study's exploratory objectives.

d) Point of enrollment.

Participants are considered enrolled in the study after providing informed consent (or assent, where applicable) and after completing an initial in-office clinical assessment by a qualified provider (typically an occupational therapist) as outlined in SOP220. This point marks the subject's formal inclusion in the study and the beginning of data collection activities using the HIPAA-compliant Qualtrics platform.

e) Point of randomization, if applicable. Randomization does not apply to this investigation.

f) Total expected duration of the clinical investigation.

The total expected duration of this clinical investigation is approximately three (3) months, spanning from April 2025 through June 2025. This time frame includes:

- Pre-screening, recruitment, and enrollment of participants across all stakeholder groups (providers, caregivers, and patients),
- Completion of a one-week home/community trial of the Obi Gen 3 device by up to 60 participants,
- Post-trial survey and interview data collection,
- Final data analysis and reporting of usability outcomes.

The duration also accommodates staggered enrollment and rolling recruitment, which will occur on a first-come, first-served basis until target sample sizes are reached. The study timeline may be adjusted slightly based on participant availability and operational needs but is not expected to exceed the nine-month window.

g) Expected duration of each subject's participation.

Each subject's participation in the clinical investigation will vary based on their role (provider, caregiver, or patient) and level of engagement. The core duration of participation for all enrolled stakeholders is approximately one week, corresponding to the required trial period of the Obi Gen 3 Medical Robotic Feeding Device in a home, school, or community setting.

- **Patients and Caregivers:** Participants are expected to use the device for at least five meals over a one-week period. During this time, they will use the device in real-life contexts and later complete post-trial surveys and optional follow-up interviews.

- **Providers:** Participating providers are expected to conduct an initial in-office assessment to determine patient suitability for the Obi Gen 3, recommend at least one patient for trial use, and provide feedback based on their clinical observation. Their involvement also includes completing a usability survey post-trial and, if applicable, participating in a brief follow-up interview.

Follow-up through telephone-based semi-structured interviews may be conducted within one month to further clarify or expand responses to open-ended questions. These interviews will be scheduled within one month of the trial's completion.

h) Number of subjects required to be included in the clinical investigation, and where needed, anticipated distribution of enrolment among the participating investigation sites.

A total of 60 participants will be recruited using flyers and word-of-mouth strategies

Stakeholder Group	Target Sample Size
Providers [Occupational Therapists (OTs), Assistive Technology Professionals (ATPs), Speech Language Pathologists (SLPs), and other relevant providers)	20 in various practice settings
Caregivers (family members, aides, support personnel)	20 (5 for adults,15 for children)
Patients (adults and children using Obi Gen 3)	20 (5 adults, 15 children)

i) Estimated time needed to select this number (i.e. enrolment period).

The estimated time required to enroll the whole sample for this usability study is 4–5 weeks, given the study's targeted outreach strategy, electronic recruitment methods, and existing professional and caregiver networks available to DESĪN LLC and the investigative team. Recruitment materials, including flyers and direct outreach, will be distributed electronically and through participating service providers to expedite enrollment.

j) Relationship of investigation population to target population.

The study population has been carefully selected to reflect the intended users and stakeholders of the Obi Gen 3 Medical Robotic Feeding Device. The target population includes:

- Patients (adults and children ages five (5) years and older) with upper extremity impairments who require assistance with self-feeding,
- Caregivers (family members or aides) who assist with feeding tasks and
- Providers (e.g., occupational therapists, speech-language pathologists, assistive technology professionals) who assess, recommend, or support use of assistive technologies like Obi.

These participants represent the user base for whom the device is designed, ensuring that usability feedback is directly relevant to real-world performance and future product deployment.

k) Information on vulnerable, pregnant, and breastfeeding population, if applicable.

The study includes children (ages five (5) years and older) who are considered a vulnerable population under federal human subjects research regulations. As such, the study will follow all applicable safeguards:

- Assent will be obtained from pediatric participants when developmentally appropriate.
- Parental or guardian permission will be required prior to participation.
- Study procedures are non-invasive and pose minimal risk.

The study does not intentionally include pregnant or breastfeeding individuals as a target subgroup. However, if an eligible participant (e.g., caregiver or provider) happens to be pregnant or breastfeeding, they will not be excluded unless participation presents a specific risk, which is not anticipated in this minimal-risk usability study.

A.6.4 Procedures

a) Description of all the clinical investigation-related procedures that subjects undergo during the clinical investigation, including any deviation from standard clinical practice.

Recruitment: Recruitment will occur via Electronic Flyers (attached) and Word of Mouth. Individuals will undergo rolling recruitment. Recruitment will also occur via DESĪN LLC's standard outreach and lead qualification per its internal prospecting activities.

Triadic Recruitment: Providers, caregivers, and patients will be recruited together when possible, to enhance data richness.

Pre-Screening: Interested Individuals recruited will then be pre-screened for inclusion criteria by DESĪN LLC's staff (OTR/L or OTA) as part of standard operating procedure SOP220, Trial Assessment Procedures, Pre-Screening topics.

In-Office Assessment: Also part of SOP220, for screened subjects, their provider is sent a device for an in-office device assessment. During this time, the assesses whether the patient can use the device safely and effectively. This assessment is documented on DESĪN LLC's D-FRM-021, Obi Medical Device Needs Assessment (MDNA). This form will also be filled out through Qualtrics.

Enrollment: The patients who pass pre-screening criteria per SOP220, and/or their legal authorized representative (LAR), would then be presented with the Informed Consent Form (ICF). At this time the Providers and Caregivers will also be invited to enroll in the study. Those patients who and/or their LAR sign both the ICF and study agreement, are considered enrolled in the study (Subject). Patients and/or their legal representative will be allowed ample time for review, consideration, and decision to participate in the study. A copy of the ICF should be provided to the subject and/or their LAR. After signing the ICF, the subject is assigned a sequential study number. These numbers are used for subject identification. The data platform, Qualtrics (HIPAA compliant) will be used to electronically enroll subjects.

Obi Trial: The screened subjects who pass the In-Office Assessment will take Obi home for a 7-day in home trial period in accordance with DESĪN LLC's SOP220. Those subjects that complete the trial will then undergo a follow up office assessment with their provider. The providers will complete the secondary component of the MDNA form during the follow-up assessment.

Data Collection & Endpoints: Following the ~one week trial, subjects will be provided electronic links via Qualtrics to complete.

b) Description of those activities performed by sponsor representatives (excluding monitoring)

Sponsor representatives involved in this clinical investigation will engage in select study activities that support study implementation and participant engagement, while maintaining a clear separation from regulatory monitoring functions. Heather Keeton, an employee of DESĪN LLC (the study sponsor), will serve as a designated sponsor representative. In this role, she will perform the following non-monitoring responsibilities in direct support of the Principal Investigator, Dr. Andrea Fairman:

- **Assisting with Participant Communication:** Ms. Keeton will support recruitment and communication with potential and enrolled participants (providers, caregivers, and patients) throughout the study.

- **Obtaining Informed Consent:** Under the direction and oversight of the Principal Investigator, Ms. Keeton will assist in obtaining informed consent and assent (as applicable) from all stakeholder groups using the approved Qualtrics-based electronic consent platform. All consent procedures will follow the IRB-approved protocol and adhere to ethical and regulatory guidelines outlined in 21 CFR Part 50 and institutional policies.

- **Providing Study Materials and Logistics Support:** Ms. Keeton may coordinate the delivery of study-related materials (e.g., recruitment flyers, instructions for use, Quick Start Guides, and study devices) and assist in providing technical support or clarification regarding study procedures or documentation tools.

- **Direct Contact with Participants**: Ms. Keeton may have direct interaction with participants to provide instructions, answer procedural questions, and confirm receipt of study equipment and materials. However, she will not be directly involved in clinical assessments, data analysis, or independent study monitoring.

To minimize potential bias and ensure ethical oversight, Ms. Keeton's involvement will be limited to logistics and communication tasks necessary for study implementation. All clinical decisions, eligibility determinations, and data analyses will remain under the control of the Principal Investigator and designated study personnel. These activities have been disclosed in the IRB submission and are being conducted in compliance with applicable ethical and regulatory standards.

c) Any known or foreseeable factors that can compromise the outcome of the clinical investigation or the interpretation of results.

Several foreseeable factors may influence the outcome of this usability-focused clinical investigation or impact the interpretation of results. These factors are typical of real-world, mixed-methods usability research and have been considered in the study design to minimize potential compromise to data integrity and outcome interpretation:

1. **Variability in User Experience and Abilities**
   The study population includes individuals with diverse diagnoses, functional abilities, and prior exposure to assistive technologies. This heterogeneity may introduce variability in how participants interact with the Obi Gen 3 device, potentially influencing usability ratings. While this reflects real-world conditions, it may also limit the generalizability of results.

2. **Short Trial Duration**
   The initial one-week trial period, while appropriate for assessing first impressions and short-term usability, may not fully capture longer-term use patterns, adaptation curves, or sustained satisfaction.

3. **Subjective Nature of Usability Metrics**
   The surveys used in the study rely on self-report or stakeholder perceptions. These are inherently subjective and may be influenced by participant expectations, mood, or environmental factors during the trial period.

4. **Potential for Response Bias**
   Given that participants know they are using a novel assistive device provided by a sponsor, there

is a risk of social desirability bias, especially among caregivers and providers who may want to provide favorable feedback. This risk will be mitigated through anonymized survey responses and neutral interview techniques.

5. **Technological and Environmental Variability**
   Because the trial takes place in participants' home, school, or community settings, external variables (e.g., table height, feeding environment, caregiver supervision) may affect device use and outcomes. These contextual factors may be difficult to control or fully account for in analysis.

6. **Small Sample Sizes in Subgroups**
   While the overall target sample size (N=60) is adequate for a usability study, subgroup sizes (e.g., pediatric patients or specific provider types) may be too small to detect nuanced differences or trends. This could limit the ability to draw robust comparisons across user types.

7. **Missing or Incomplete Data**
   As with any study involving remote data collection, there is a risk of incomplete surveys, missed interviews, or dropouts. The study team has implemented follow-up reminders and contact protocols to maximize retention and response rates.

d) The Methods for addressing these factors in the clinical investigation

Despite these foreseeable factors, the mixed-methods approach, inclusion of validated usability tools, and efforts to mitigate bias strengthen the reliability of the study and support meaningful conclusions about the Obi Gen 3 device's real-world usability and design readiness. This usability study has been designed to address potential sources of bias, variability, risk, and data quality concerns through a combination of structured procedures, validated instruments, and robust data collection practices. The following methods have been implemented to ensure scientific rigor, participant protection, and the validity of study findings:

- **Standardized Training and Materials**
  All participants—including providers, caregivers, and patients—will receive consistent onboarding materials (e.g., Quick Start Guide, Instructions for Use) to ensure a common understanding of device setup and use. This minimizes variability in use procedures across stakeholder groups and supports equitable engagement with the device.

- **Use of Validated Frameworks**
  The study utilizes established and validated tools, including the System Usability Scale (SUS), Matching Person & Technology (MPT) Framework to assess usability across diverse participants. These tools allow for meaningful interpretation of findings and reduce subjective bias.

- **Mitigation of Risks**
  Identified study risks—such as user fatigue, frustration, and data privacy concerns—are managed through:
  - Brief participation windows (e.g., 1-week trial with a minimum of 5 meal uses),
  - Technical support availability,
  - Secure data collection via the HIPAA-compliant Qualtrics platform,
  - Clear data management protocols for de-identification and limited access

- **Minimization of Confounding Variables**
  Participants are pre-screened using a standardized process (SOP220) to ensure that only individuals meeting inclusion criteria are enrolled. Demographic and baseline data, including functional feeding status and assistive technology experience, are collected to allow subgroup analyses and account for potential confounders in interpretation.

- **Triangulation of Data (Mixed Methods)**
  A mixed-methods design integrates both quantitative data (e.g., rating scales) and qualitative data (e.g., semi-structured interviews), allowing for comprehensive understanding and internal validation of usability findings across stakeholder perspectives.

- **Consistent Scheduling and Follow-Up**
  Data collection occurs at fixed time points following the trial period (e.g., immediately post-trial and optional 1-month follow-up), which supports consistent comparison across users. All interviews are conducted using a semi-structured guide to reduce interviewer variability.

- **Independent Oversight and Conflict of Interest Management**
  To preserve data integrity and transparency, a conflict of interest management plan is in place for the Principal Investigator. This includes institutional oversight and disclosure of funding and sponsor relationships in study materials and reporting.

e) The follow up period during the clinical investigation shall permit the demonstration of clinical performance, effectiveness or safety over a period of time sufficient to represent a realistic test of the investigational device and allow any risks associated with adverse device effects to be identified and assessed.

The ~one week follow-up period for this clinical investigation has been designed to allow for a realistic and contextually appropriate assessment of the Obi Gen 3 Medical Robotic Feeding Device efficacy as it relates to usability in typical use environments (e.g., home, community, or clinical settings). While the device is not intended for therapeutic intervention and poses minimal risk as a Class I medical device, the selected timeframe is sufficient to evaluate its usability, clinical performance, and user experience across diverse stakeholder groups.

The primary follow-up period consists of a ~one-week trial, during which participants (patients and caregivers) are expected to use the device across a minimum of five meal sessions. This time frame reflects common practice in assistive technology evaluation, enabling users to become familiar with the device and providing adequate exposure to assess:

- Effectiveness in supporting independent self-feeding,
- User satisfaction and ease of use,
- Integration into existing routines or caregiving workflows, and
- Identification of any usability challenges or design limitations.

f) Address what specific medical care is appropriate to be provided for the subjects after the clinical investigation has been completed, if applicable.

Specific medical care is not thought to be necessary given the device's safety history of 0 adverse events, and Class I nature.

g) Address recommended follow-up for the subjects after the clinical investigation has been completed.

When warranted, investigators may reach out within a month after the survey is completed for further clarification or expansion of open-ended survey question responses. Risks such as user fatigue, frustration, or device misuse are most likely to emerge within this timeframe. The structured follow-up, including post-trial surveys via Qualtrics and optional phone interviews, will ensure timely identification and documentation of any unexpected adverse device effects, even though none are anticipated.

h) Address the final disposition or potential future use of samples obtained from subjects, if applicable.

Devices used in during the study will be returned to DESĪN LLC, visually inspected, functionally evaluated, cleaned, disinfected and otherwise reconditioned as needed in accordance with DESĪN LLC's SOP120. These devices will then be approved to enter the company's trial device fleet. These devices will be used with new prospective customers.

A.6.5 Monitoring Plan

General outline of the monitoring plan to be followed, including access to source data and the extent of source data verification planned.

There is no official monitoring plan developed. However, to ensure adequate monitoring of the study, the principal investigator and/or study team shall cooperate with DESĪN LLC. This includes, but is not limited to, allowing the assessment of facilities utilized for this study, providing access to subject report forms, and subject medical records reasonably requested.

A.7. Statistical Design and Analysis

With reference to A.5 and A.6, the description of and justification for statistical design and analysis of the clinical investigation shall cover the following.

a) Analysis population (e.g. intention-to-treat, per-protocol, as-treated) and procedures that take into account all the data.

This clinical investigation is a non-randomized, non-comparative, mixed-methods usability study intended to evaluate whether the production equivalent Obi Gen 3 robotic feeding device meets the documented user needs and intended use across stakeholder groups. As such, the primary focus of the statistical design is on descriptive and qualitative analysis rather than hypothesis testing or inferential statistics.

All participants who complete informed consent and the survey be included in the analysis population. Given the non-interventional nature of the study, the analysis will follow an as-treated approach, with all available data from each stakeholder group included in the final analysis.Participants who after consent but before completing any trial procedures will be excluded from the analysis population. Missing data will be documented but not imputed, as the primary intent is to assess observed usability and feedback trends.

b) Descriptive statistics of baseline data, treatments, safety data and where applicable, primary and secondary endpoints.

Descriptive statistics will be used to summarize:

- Baseline demographic and clinical characteristics, including age, gender, diagnosis, and prior experience with assistive technology.
- Trial participation metrics, including duration of use and number of meals completed.
- Survey and rating scale responses, including usability ratings (e.g., System Usability Scale [SUS], Caregiver Burden Index, Matching Person & Technology assessments).

For numeric responses, means, standard deviations, medians, and ranges will be reported. For categorical data, frequencies and percentages will be presented.

Semi-structured interviews and open-ended survey responses will be analyzed using content analysis to identify recurring themes related to usability, satisfaction, and device integration into daily routines. Data will be coded independently by at least two trained reviewers, and discrepancies will be resolved through discussion to ensure thematic reliability.

c) Analytical procedures including measures of precision such as confidence intervals, if applicable.

Given the study's exploratory, design-validation focus, no formal hypothesis testing or inferential statistics are planned. However, where appropriate, confidence intervals (e.g., 95%) may be used to describe the precision of mean usability scores or other key quantitative measures. These measures will help contextualize findings and inform decision-making for potential design improvements or user support strategies.

The primary outcome—validation of the device's usability and fulfillment of user needs—will be assessed based on aggregated stakeholder ratings and thematic saturation in qualitative responses. Results will be stratified by stakeholder groups (patients, caregivers, providers) to support subgroup comparisons where appropriate.

d) The significance level and the power of primary endpoint(s) and the overall statistical testing strategy, if applicable.

If a hypothesis is tested, a significance level alpha 0,05 (two-sided) and 0,025 (one-sided) and powers between 0,8 and 1 minus alpha need no justification. Depending on the characteristics of the investigational medical device or the clinical investigation, higher or lower levels of significance can be used. Examples of justifications include but are not limited to: product standards, scientific reasons or discussion with regulatory authorities.

e) Sample size calculation and justification taking into account:

1) all relevant clinical data on outcome variable and effect size, if applicable;

Sample size will be determined and justified using guidance issued by the FDA for human factors validation testing (FDA], 2016). The following are excerpts from *Appendix B, Considerations for Determining Sample Sizes for Human Factors Validation Testing:*

"If the device has more than one distinct population of users, then the validation testing should include at least 15 participants from each user population. The FDA views user populations as distinct when their characteristics would likely affect their interactions with the device or when the tasks performed on the device would be different. For example, some devices will have users in different age categories (pediatric, adolescent, adult, or geriatric) or users in different professional categories (e.g., health care provider, lay user); other devices will have users with different roles (e.g., installers, healthcare providers with unique specialties, or maintenance personnel)."

"Since the parameters needed to determine sample size cannot be estimated easily or cannot be estimated at all prior to testing, a sample of 15 people to detect most of the problems in a user interface constitutes a practical minimum number of participants for human factors validation testing. This sample size theoretically provides the best possibility of detecting user interface design flaws while limiting the amount of resources required."

"Thus, although a 15-participant minimum is suggested, a larger sample size might be beneficial if a thorough analysis of the product, or previous knowledge about the product and/or similar systems, indicates a need."

2) **assumptions of expected outcomes across treatment groups, if applicable;**

   not applicable

3) **adjustments due to any pre-planned interim analyses, if applicable;**

   not applicable

4) **detectable effect size and non-inferiority margin, which shall be smaller than the detectable effect size and justified with reference to the effect of the comparator, if applicable;**

   not applicable

5) **randomization allocation ratio (e.g. 1:1, 1:2), if applicable;**

   not applicable

6) **expected drop-out rate, such as withdrawal, lost to follow-up, death (unless death is an endpoint).**

Given the short duration and minimal risk nature of this usability study, the expected drop-out rate is anticipated to be low (less than 10%). Participants will be engaged for a one-week home or community-based trial of the Obi Gen 3 device,. The limited time commitment, non-invasive nature of participation, and flexibility of remote data collection (via Qualtrics and telephone interviews) are expected to support high retention.

Potential reasons for early withdrawal or loss to follow-up may include:

- Lack of interest or time to complete the trial period or follow-up activities
- Health-related issues or changes in caregiving responsibilities
- Technological issues or accessibility barriers (e.g., inability to access electronic surveys)
- In rare cases, discomfort or dissatisfaction with the device

Because the study does not involve treatment, diagnostic procedures, or invasive interventions, death is not anticipated and is not an endpoint. Any withdrawal or loss to follow-up will be documented with reason, when available. Data collected prior to withdrawal will be included in the analysis, consistent with an as-treated approach.

f) The rationale for the number of procedures to be performed by a single user as part of the learning curve and how these data are to be analysed, if applicable.

Given that this investigation evaluates the usability of a robotic feeding device designed for individuals with upper extremity impairments, caregivers, and providers, it is important to account for the initial learning period associated with device setup, operation, and integration into daily routines. The one-week trial period with a minimum expectation of five completed meals per patient/caregiver dyad is designed to reflect a realistic and sufficient exposure to allow users to become familiar with the device and overcome early learning curve effects.

This threshold was selected based on preliminary feedback from internal evaluations and stakeholder consultations, which indicated that users typically require **3–5 sessions,** to feel comfortable with basic functions (e.g., powering on, positioning the spoon, switching food compartments). For providers, the requirement to recommend and assess at least one patient supports evaluation of the device within their existing workflow, allowing observation of setup, training, and follow-up in a practical setting.

Although this study does not include formal repeated-measures testing or time-stamped use logs, reported experience over multiple uses (i.e., across several meals and settings) will provide insight into how effectively users can learn to operate the device independently. This data will inform training recommendations and design refinements to support intuitive, low-burden use in real-world environments.

g) Pass/fail criteria to be applied to the results of the clinical investigation.

As a design validation study, the primary objective of this clinical investigation is to determine whether the Obi Gen 3 production equivalent device meets its formally documented user needs and intended use across three key stakeholder groups: patients, caregivers, and providers. The pass/fail criteria are based on usability outcomes aligned with ISO 13485 and FDA design validation requirements. The following criteria must be met for the device to be considered as having “passed” the clinical investigation:

Primary Endpoints: Acceptance criteria is based on safety and quality risk (see IFD-DES-054-1, Design Validation Plan, and IFD-DES-054-2, Design Validation Protocol). Note: Design Validation planning involves more than just human subject testing. This CIP covers only the human subject portion.

Intended Use: For all subjects that complete the 1-week trial, the following must be met:

- ICF performance qualifier for Functional Eating must drop at least one severity level (ex. “severe” to “moderate”) for 85% of patients.
- No Serious Adverse Device Effects (SADE), Serious Health Threat, or Unanticipated Serious Adverse Device Effect (USADE).

User Needs: For all subjects that complete the 1-week trial, 50% of respondents must be in favor that the requirement has been fulfilled (see IFD-DES-051-1 Validation Plan)

If the investigation meets or exceeds these thresholds across all stakeholder groups, the design will be deemed to have passed and is considered validated. If one or more criteria are not met, the results will be analyzed to determine if design modifications, additional training resources, or workflow adjustments are necessary prior to commercialization.

h) The provision for an interim analysis, criteria for the termination of the clinical investigation on statistical grounds, where applicable.

This clinical investigation is designed as a non-randomized, non-comparative, mixed-methods usability study with a modest sample size and descriptive analytic approach. As such, no formal interim analysis is planned, and no statistical stopping rules are defined.

Given the exploratory nature of the study and its focus on collecting usability and user experience data from stakeholder groups (providers, caregivers, and patients), data will be monitored periodically for completeness, diversity of responses, and thematic saturation in qualitative data. These periodic reviews will serve quality assurance purposes and support ongoing project planning, but they will not serve as formal interim analyses for statistical decision-making. The study is not powered to detect statistical differences, and there is no intention to perform comparative analyses or draw inferential conclusions. Therefore, termination of the clinical investigation on statistical grounds is not applicable. However, the study may be terminated early for administrative, logistical, or ethical reasons, at the discretion of the Sponsor.

i) Management of bias and, when randomization, matching, or blinding are applied, plan for assessment of success thereof.

This clinical investigation is a non-randomized, mixed-methods usability study conducted to evaluate whether the Obi Gen 3 production equivalent device meets documented user needs and intended use. The design reflects a real-world, observational approach that prioritizes ecological validity over experimental control. Randomization, matching, and blinding are not applicable to the design or objectives of this study, no formal assessment of the success of these methods is planned. Instead, the focus remains on implementing procedural safeguards and objective analytic approaches to support the integrity of findings. However, several strategies will be employed to minimize potential sources of bias and enhance the credibility of findings:

Selection Bias - To reduce selection bias, recruitment efforts will include a triadic strategy involving providers, caregivers, and patients. Participants will be enrolled from diverse clinical and caregiving contexts, and purposeful sampling will be used to ensure representation across age, diagnosis, and experience levels. Pre-screening will follow standardized procedures (SOP220), and inclusion/exclusion criteria will be consistently applied.

Performance and Observer Bias - While participants and researchers are not blinded due to the nature of the usability intervention, standardized instructions, materials, and procedures (e.g., Quick Start Guide, assessment forms) will be used across all participants to reduce variability. providers conducting in-

office assessments will follow a pre-established protocol, and all qualitative interviews will be conducted using a semi-structured guide to minimize interviewer influence.

Response Bias - To mitigate social desirability or expectancy effects in surveys and interviews, participants will be informed that there are no right or wrong answers and that their honest feedback—positive or negative—is valued. Electronic data collection using Qualtrics ensures investigator bias cannot be introduced in the data collection of the survey responses, particularly from caregivers and patients.

j) Management of potential confounding factors (e.g. adjustment, stratification, or stratified randomization).

As this is a non-randomized, observational usability study, no randomization or formal control group is used. However, several measures will be implemented to identify, minimize, and account for potential confounding factors that could influence the usability and user experience outcomes. To manage variability in perspectives and experience, participants will be stratified into three predefined stakeholder groups:

- providers (e.g., OTs, SLPs, ATPs)
- Caregivers (e.g., parents, aides, support personnel)
- Patients (adults and children using Obi Gen 3)

Data will be analyzed separately within these strata to prevent confounding across roles and to allow tailored interpretation of usability from each unique perspective.

k) Description of procedures for multiplicity control and adjustment of error probabilities, if applicable.

This study is not designed to test multiple formal hypotheses or to evaluate statistical significance across treatment arms or outcomes. Therefore, no multiplicity adjustments or formal procedures for controlling Type I or Type II error rates are planned. The focus of the analysis is on descriptive statistics and qualitative feedback to characterize usability outcomes across stakeholder groups (patients, caregivers, providers). Where confidence intervals are calculated (e.g., for mean usability scores), they are intended to describe measurement precision, not to support inferential claims.Given this context, error probability control methods such as Bonferroni correction, false discovery rate (FDR) adjustments, or family-wise error rate control are not applicable to the design or analysis of this investigation.

l) The specification of subgroups for analysis, if applicable, or if response to treatment is expected to be different in these groups.

Although this study is not powered to detect statistically significant differences between groups, subgroup analysis will be conducted to explore potential differences in usability perceptions and experiences across key stakeholder groups and user characteristics. The following subgroups will be descriptively analyzed:

- **Stakeholder Type**:
    - **providers** (e.g., OTs, SLPs, ATPs)
    - **Caregivers** (adult and pediatric support persons)
    - **Patients** (adult and pediatric device users)
- **Age Group of Patient Participants**:
    - Pediatric (ages 5–17)
    - Adult (ages 18 and older)
- **Experience with Assistive Technology**:
    - Participants with prior experience using earlier versions of Obi
    - Participants with no prior experience using Obi

These subgroups are specified to assess whether perceptions of usability, burden, satisfaction, or integration into routine practice differ based on clinical role, age, or familiarity with similar devices. It is anticipated that these factors may influence how users interact with Obi Gen 3 and interpret its usability. While no treatment effects are being tested, identifying subgroup-specific trends may inform future design enhancements, training material development, or targeted implementation strategies.

m) Management, justification, and documentation of missing, unused or spurious data, including drop-outs.

Given the usability-focused, non-interventional design of this clinical investigation, the approach to managing missing, unused, or spurious data will prioritize transparency, traceability, and context-based interpretation rather than imputation or statistical correction.

Missing Data - All efforts will be made to minimize missing data by:

- Using structured and user-friendly electronic data collection tools (Qualtrics),
- Providing reminders for survey completion, and

- Offering support to participants during the trial period.

When data are missing, the specific nature and reason for the missing information (e.g., participant withdrawal, technical issues, non-response) will be recorded in the study database. Missing data will not be imputed, as the primary goal is descriptive analysis rather than inferential statistical modeling. Analyses will be conducted using available data only, and the extent of missingness will be reported for each data element.

Unused or Incomplete Data - Incomplete survey responses or interviews that do not meet minimal content thresholds (e.g., <50% of questions answered) may be excluded from individual item-level analysis but will be retained in the dataset for auditability. The rationale for excluding such data will be documented in the data analysis plan and in the final study report.

Spurious or Implausible Data - Any values that are clearly spurious (e.g., internal inconsistencies, out-of-range responses) will be flagged during data quality checks. If these data cannot be resolved through source verification (e.g., interview notes, metadata review), they will be excluded from analysis and annotated accordingly in the dataset with justification.

Participant Drop-outs - Participants who withdraw from the study after enrollment will be asked, if willing, to provide a brief reason for withdrawal. Drop-outs will be tracked, and their status will be clearly documented in the final dataset. Data collected prior to withdrawal will be included in the analysis unless the participant requests removal of their data per the informed consent agreement. The rate and pattern of drop-outs or early discontinuation will be described in the final study report to assess potential biases or operational challenges affecting the usability evaluation.

n) **Exploratory analysis and sensitivity analysis (e.g. to explore robustness of results of primary and secondary analysis with respect to different methods used for handling missing data), if applicable.**

   Not applicable. This study is concerned with qualitative insights and limited scope of variables.

o) **Procedures for reporting any deviation(s) from the original statistical analysis plan.**

Any deviation from the original statistical analysis plan (SAP), whether related to the analysis population, analytical methods, handling of missing data, or presentation of results, will be documented in the protocol deviation log and addressed in the final clinical investigation report.

If deviations are necessary during the course of data analysis—such as the inclusion of alternative summary measures, subgroup analyses not originally specified, or adjustments to account for unforeseen data collection challenges—these will be:

- Clearly documented with a justification for the change,

- Dated and signed by the responsible investigator or data analyst,
- Reviewed by the principal investigator and, if applicable, the sponsor, and
- Reported transparently in the final report, along with the impact of the deviation on the interpretation of the study outcomes.

All such deviations will be made prior to unblinding or final data lock to ensure analytical integrity and avoid bias in interpretation. Because this is an exploratory usability study using descriptive and qualitative methods, formal pre-specification of statistical hypotheses is limited; however, the principles of transparency, traceability, and justification will be upheld for any post hoc analytical decisions.

p) For multicentre clinical investigations, a strategy for handling the potential imbalance of the numbers of subjects across investigation sites.

Not applicable. This study involves a single site.

q) A strategy for pooling data, if applicable.

Not applicable based on the study design.

A.8. Data Management

a) Methods (e.g. CRF) for data entry and collection.

All data unrelated to normal company processes (see SOP220) will be collected and managed through Qualtrics. Data on these assessment forms will be monitored/queried by the principal investigator. Information and questionnaires completed by the subject or the investigator and collected by study site and related study conduct will be considered source documents. Other records that may be considered source documents are hospital records, progress notes, lab results, clinic charts, test results, autopsy results (if any), any note related to AEs. A print-out of the eCRF cannot be used as a source document. The investigators and/or their designee are responsible for ensuring the accuracy, completeness, and timeliness of data entry. Data from these assessment forms will be used in analysis of study results. Data collection, entry and appropriate reporting is the responsibility of the supervision of the principal investigator. All participant information will be aggregated and de-identified.

b) Procedures used for CRF tracking, data review, database cleaning, and issuing and resolving data queries. Specifically, timely, and reliable processes for recording data and rectifying errors and omissions, medical coding uniformity, and reconciliation, if applicable, are necessary to ensure delivery of a quality database and the achievement of the clinical investigation objectives through the implementation of the planned analysis.

All changes made to the data will be tracked, recording the current value, previous value, reason for change, date timestamp of data change and identification of the person who changed the data.

c) Procedures for verification, validation, and securing of electronic clinical data systems, if applicable.

All electronic clinical data for this study will be collected and managed using Qualtrics, a HIPAA-compliant, cloud-based data collection platform. Qualtrics has been selected based on its capabilities to support secure electronic survey distribution, structured data input, and real-time monitoring of study responses across multiple stakeholder groups. The following procedures ensure verification, validation, and data security:

- All electronic surveys and forms (e.g., System Usability Scale, Caregiver Burden Index, Matching Person & Technology assessments) will be programmed and reviewed by the Principal Investigator (PI) personnel with experience in Qualtrics configuration and human subjects research.

- Internal testing procedures will be conducted prior to study launch to verify that skip logic, branching, scoring algorithms, and response piping function correctly across all instruments.

- A validation checklist will be completed to confirm alignment with the approved study protocol and data collection requirements. This includes verifying data field accuracy, response ranges, and user interface usability for all participant types.

Qualtrics is certified under HITRUST, ISO 27001, and FedRAMP, and is hosted on secure, encrypted servers that comply with the U.S. Health Insurance Portability and Accountability Act (HIPAA) and GDPR standards. Data are encrypted both in transit (TLS 1.2 or higher) and at rest, ensuring the protection of sensitive information submitted by participants. Access to the Qualtrics data dashboard is restricted to authorized research personnel only, with role-based permissions and two-factor authentication (2FA) enforced. Audit logs are automatically generated and maintained by the platform to track all system-level and user-level interactions with the data.

d) Procedures to maintain and protect subject privacy.

All subject data will be de-identified or coded using unique participant identifiers at the time of collection. No personally identifiable information (PII) will be linked to study data in the analysis datasets. Only authorized study personnel will have access to the master list that links identifiers to participant names, and this list will be stored in a secure, password-protected location accessible only to the Principal Investigator and designated research staff. All electronic data, including surveys and interview responses, will be collected using Qualtrics, a HIPAA-compliant, encrypted web-based platform. Data transmission will occur over secure (HTTPS) channels, and data will be stored on secure servers with access restricted by user roles and passwords.

For remote interviews, participants will be informed in advance about the nature of the questions and their right to withhold any information they are not comfortable sharing. No audio recordings will be

made without explicit permission, and any identifiable audio content will be transcribed, de-identified, and deleted upon completion of transcription and verification.

All research team members will complete training in human subjects protections and data confidentiality. Physical materials (e.g., consent forms mailed or printed) will be stored in locked cabinets in secure, access-controlled facilities when not in use. Results will be reported only in aggregate or in a manner that prevents re-identification of individual participants.These measures ensure that participants' privacy is protected throughout their involvement in the study, and that data are handled according to the highest ethical and regulatory standards. Upon study completion, all data will be exported and stored on encrypted, access-controlled institutional servers for long-term archiving in accordance with IRB and sponsor requirements.

e) Methods for database locking at the start of the analysis and storage upon completion of the clinical investigation.

All study data will be collected and managed using Qualtrics, a secure, HIPAA-compliant electronic data capture system. Prior to initiating formal data analysis, the following steps will be taken to ensure the integrity and completeness of the dataset:

1. Data Review and Cleaning
   The study team will conduct a final review of all entered data to identify and resolve any discrepancies, missing fields, or formatting issues. This process will include:
   - Verification of subject identifiers and completeness of required fields
   - Validation of data ranges and consistency across entries
   - Review of open-text responses for completeness and clarity
2. Finalization of Dataset
   Once data cleaning is complete, a final dataset will be generated. A member of the study team not involved in the data entry process will independently verify the dataset against source entries to confirm its accuracy and completeness.
3. Database Lock
   After verification, the database will be considered locked. This status will be documented in a Database Lock Memorandum signed by the principal investigator or designee. Once locked:
   - No additional data entries or modifications will be permitted
   - Only read-only access will be maintained for auditing and analysis purposes

4. Archiving and Version Control
   The locked dataset will be archived and version-controlled, with backup copies stored securely in accordance with DESIN's electronic data management procedures (SOP110, Records, SOP200, Computer Security, and SOP210, Privacy). This version will be used for all statistical and qualitative analyses included in final reports and regulatory submissions.

These procedures ensure the reproducibility and transparency of study findings and align with good clinical practice (GCP) and ISO 14155:2020 guidelines for clinical investigations of medical devices.

f) Procedures for data retention.

The principal investigator will maintain all essential study documents and source documents which support the data collected on the study subjects according to local regulations at the end of the study. The investigator is responsible for making sure these essential documents are not accidentally damaged or destroyed.

At the end of study, routine close-out activities will be conducted to make sure records/data are completed and accurate, remaining study materials are returned to DESĪN LLC, device accountability is accurate and complete. The principal investigator is also in charge of notifying in writing and providing appropriate reports to their IRB about the study completion.

DESĪN LLC is the owner of the data and may also store copies of the data separately in its HIPAA compliant data systems following completion of the study per its SOP200 Privacy, and SOP210, Computer Security procedures. This includes procedures and processes for 21CFR11 Electronic Records compliance, including system validation.

g) Specified retention period.

Per DESĪN LLC's SOP110, Records (no less than 6 years).

h) Other aspects of clinical quality assurance, as appropriate.

None**.**

A.9. Amendments to the CIP

Description of the procedures to amend the CIP.

If a revision to the CIP is deemed necessary by the principal investigator, it shall be reviewed and approved by DESĪN LLC per the document control procedures (SOP020).

A.10. Deviations from the CIP

a) Statement specifying that the investigator is not allowed to deviate from the CIP, except as specified in 5.6.4 c).

A protocol deviation happens when the investigator (intentionally/unintentionally) did not conduct the study according to the protocol and/or study agreement. Examples include late follow-up

visits, missed visits, required assessment not completed, non-adherence to Inclusion/Exclusion criteria, etc. Such events shall be reported to DESĪN LLC and will be reviewed/assessed. The investigator is not allowed to deviate from study protocol except under emergency circumstances where necessary, to protect the life or physical well-being of a subject. These emergency deviations should be reported to the IRB and DESĪN LLC in writing as soon as possible, but no later than 5 days after the emergency occurs. There will be unforeseen circumstances that are beyond the investigator's control (e.g., subject does not attend follow-up visit despite multiple reminders). Investigators are still required to report these as deviations. All deviations should be recorded on appropriate protocol deviation CRF and submitted electronically to DESĪN LLC.

b) Procedures for recording, reporting, and analyzing CIP deviations.

All deviations from the approved Clinical Investigation Plan (CIP), including protocol-specified procedures, eligibility criteria, or data collection processes, will be documented, reviewed, and analyzed in accordance with ISO 14155:2020 guidelines and DESĪN LLC Standard Operating Procedures (SOPs) for document and change control (SOP010, and SOP020). Any deviation from the CIP identified during the course of the study will be promptly recorded by the study team. Each deviation will be logged in a CIP Deviation Log, which includes:

- A description of the deviation
- The date of occurrence
- The individual responsible
- The stakeholder(s) involved (provider, caregiver, or patient)
- The reason for the deviation (if known)
- Actions taken to address or mitigate the deviation

Minor deviations (e.g., missed data fields, slight delays in follow-up) will be documented but do not require immediate reporting unless they impact data integrity or participant safety. Deviations that impact participant safety, rights, or data integrity will be reported to the sponsor, and, if necessary, to the IRB in accordance with applicable regulations and timelines. Serious or repeated deviations will be escalated for sponsor review and potential corrective action.

All deviations will be reviewed at the conclusion of the study and analyzed for:

- Frequency and patterns (e.g., recurring issues at a particular stage of the study)
- Impact on data quality, usability findings, or participant experience
- Root causes, including potential improvements to study tools or instructions

Findings from deviation analysis may inform updates to SOPs, user instructions, Qualtrics forms, or future clinical protocols. A summary of deviations and their resolution will be included in the Final Clinical Investigation Report.

c) Notification requirements and time frames.

All required notifications will be submitted in accordance with applicable regulatory, ethical, and institutional guidelines, including those specified in ISO 14155:2020, the U.S. FDA regulations for Class I medical devices, and the policies of the reviewing Institutional Review Board (IRB). DESĪN LLC also has standard procedures for reporting to meet regulatory requirements, per SOP120 (5.2).

The Clinical Investigation Plan (CIP), informed consent materials, recruitment documents, and all supporting documents will be submitted to the IRB for initial review and approval prior to initiating any clinical investigation activities. No participant recruitment, enrollment, or data collection will begin until formal written approval is received.

Any substantial modifications to the protocol, such as changes to the study design, recruitment strategy, informed consent documents, or study instruments, will be submitted to the IRB for approval prior to implementation, unless changes are required to eliminate immediate hazards to subjects. Non-substantive or administrative amendments (e.g., typographical corrections) will be reported as per IRB guidance.

Although this study involves a minimal-risk Class I device, any unanticipated adverse device effects (UADEs) or unanticipated problems involving risks to participants or others will be reported to the IRB and sponsor within 10 business days of becoming aware of the issue, or in accordance with IRB-specific reporting timelines. Serious events will be reported immediately when necessary to protect participant safety.

If required by the IRB, a continuing review submission will be provided at least 30 days prior to study expiration, including enrollment status, summary of adverse events (if any), and protocol deviations.

Interim reports and updates may also be provided to stakeholders or sponsors as needed during the course of the investigation. A final report or closure notification will be submitted to the IRB and sponsor upon completion or early termination of the study. This will include a summary of the study conduct, data collected, participant outcomes, and any relevant findings or deviations.

d) Corrective and preventive actions and principal investigator disqualification criteria.

DESIN LLCs maintains SOP080, CAPA Procedures. CAPAs are triggered based upon a risk assessment. If there is a suspected issue with the CIP surpassing the calculated risk threshold, corrective and preventive action procedures will be triggered per DESIN LLCs quality system procedure SOP080, CAPA Procedures.

For final analysis, subjects who have major protocol deviations will not be included in the statistical analysis of the “per-protocol” population.

A.11. Device Accountability

a) Description of the procedures for the accountability of investigational devices as specified in 7.9;

This study will use production equivalent/production candidate devices, which have been constructed in accordance with DESĪN LLC's Quality Management System production controls. Accordingly, each unit of Obi will be labeled as a "study device" identified by a model number, lot number and date. A device accountability log will be maintained in accordance with the company's SOP220, Trial Assessment Procedure. This procedure includes processes for documenting dates of receipt, use, return of the device, the device lot number, and the subject number for whom the device was shared with. This process will be maintained until the conclusion of the study.

b) Procedures and particular materials and instructions for the safe return of investigational devices, including those that are potentially hazardous.

In the event of suspected or confirmed device deficiency, or adverse event, the device must be returned to DESĪN LLC for investigation in accordance with its SOP120, Return and Service Procedures.

Complaints will be logged per D-FRM-005, Complaint Form per SOP120. Coordinating with the subject for returning the device will be conducted by DESĪN LLC.

A.12. Statements of Compliance

a) Statement specifying that the clinical investigation shall be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki

This clinical investigation shall be conducted in full accordance with the ethical principles outlined in the Declaration of Helsinki, including its most current amendments, which guide the protection of the rights, safety, and well-being of human participants involved in medical research.

b) Statement specifying compliance with this document and any regional or national regulations, as appropriate.

This clinical investigation will be conducted in full compliance with the principles and requirements set forth in the ISO 14155:2020 – Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice. This includes adherence to the requirements for protection of human subjects, scientific integrity, and accountability throughout all phases of the investigation. In addition, the study will comply with all applicable regional and national regulations, including:

- U.S. Food and Drug Administration (FDA) regulations relevant to clinical investigations of medical devices under 21 CFR Part 812 (Investigational Device Exemptions), specifically under the

abbreviated IDE provisions for Non-Significant Risk (NSR) studies;

- 21 CFR Part 50 (Protection of Human Subjects) and 21 CFR Part 56 (Institutional Review Boards);
- Health Insurance Portability and Accountability Act (HIPAA) privacy and data protection requirements for the collection and storage of personal health information;
- Any additional guidance or requirements as set forth by the reviewing Institutional Review Board (IRB).

c) Statement specifying that the clinical investigation shall not begin until the required approval/favourable opinion from the EC and regulatory authorities have been obtained, if applicable

The clinical investigation will not commence until all required approvals and favorable opinions have been obtained from the appropriate oversight bodies. Specifically, the study will not begin enrolling participants or initiating study procedures until approval has been granted by an Institutional Review Board (IRB) as required by 21 CFR Part 56 and ISO 14155.

If applicable, any additional regulatory approvals required by national or local authorities will also be obtained prior to initiating the investigation. Documentation of these approvals will be retained by the Sponsor and Principal Investigator and made available for audit or inspection upon request.

This protocol, informed consent forms, recruitment materials, and data collection tools will all undergo IRB review to ensure compliance with ethical principles, protection of human subjects, and regulatory requirements. Only upon receipt of a written IRB approval or favorable opinion will participant recruitment and study activities begin.

d) Statement specifying that any additional requirements imposed by the EC or regulatory authority shall be followed, if appropriate.

This clinical investigation will be conducted in accordance with the approved Clinical Investigation Plan, applicable U.S. federal regulations, and the principles outlined in ISO 14155:2020 for the ethical conduct of medical device investigations. The Sponsor and Principal Investigator acknowledge that any additional requirements imposed by the reviewing Institutional Review Board (IRB), or relevant regulatory authority will be followed, if appropriate. This includes, but is not limited to, additional safety monitoring, consent language modifications, reporting obligations, or oversight procedures deemed necessary to protect the rights, safety, and well-being of participants. All amendments, protocol deviations, or other substantive changes will be submitted for review and approval in accordance with the policies of the IRB and applicable

regulatory bodies. The investigation team is committed to maintaining full compliance with all ethical and regulatory expectations throughout the duration of the study.

e) Statement specifying the type of insurance that shall be provided for subjects, if appropriate.

Dr. Fairman maintains professional liability insurance the policy is included as an uploaded document with this proposed CIP.

DESIN LLC maintains commercial general liability insurance, product liability insurance and an umbrella policy (please see provided certificate).

f) Statement addressing the financing of the clinical investigation including a description of the agreement between the sponsor and investigation sites and where applicable with the investigators if not addressed in a separate agreement.

This clinical investigation is financially supported by DESĪN LLC, the sponsor and manufacturer of the Obi Gen 3 Medical Robotic Feeding Device. DESĪN LLC is responsible for funding all aspects of the study, including investigator compensation, participant reimbursement, device provisioning, software licensing (e.g., for Qualtrics), and any administrative or data management expenses incurred during the conduct of the investigation.

The agreement between the sponsor and the primary investigation site—DESĪN LLC itself—outlines responsibilities for study oversight, subject recruitment, data collection, device training and support, and regulatory compliance. Because the investigation is conducted through a single-site model with remote participation across the U.S., no additional clinical sites are financially engaged beyond DESĪN LLC.

The sponsor has also entered into a formal agreement with the Principal Investigator (Dr. Andrea Fairman) to lead and manage the study in accordance with Good Clinical Practice (GCP), ISO 14155:2020, and all applicable institutional and regulatory requirements. Dr. Fairman is compensated for her role in the design, implementation, coordination, and oversight of the investigation. This financial relationship is fully disclosed and managed under an institutional Conflict of Interest (COI) Management Plan.

There are no financial arrangements in place that would incentivize outcomes or participant enrollment. The financing supports scientific and operational execution only and does not influence data interpretation or reporting. All deliverables and reporting obligations have been outlined in the sponsor-investigator agreement, including provisions for confidentiality, intellectual property, and publication rights.

A.13. Informed Consent Process

a) Description of the general process for obtaining informed consent and incentives

Informed consent will be obtained from all participants—providers, caregivers, and patients—prior to enrollment and before any study-related procedures are initiated. The consent process will be conducted electronically via the HIPAA-compliant Qualtrics platform, allowing participants to review the consent materials at their own pace and submit their consent securely.

Participants will receive a detailed explanation of the study purpose, procedures, risks, benefits, voluntary nature of participation, confidentiality safeguards, and contact information for the study team and IRB. The electronic consent form will be tailored to each stakeholder group, with language appropriate to the participant's role (provider, caregiver, or patient). Participants will have the opportunity to ask questions before agreeing to participate. For pediatric participants (ages 5–17), informed consent will be obtained from a parent or legal guardian, and age-appropriate assent will be obtained from the child when developmentally appropriate.

Incentives for participation will be provided in the form of a modest $25 electronic gift card, as IRB-approved compensation for time and effort.

b) Description of the informed consent process in circumstances where the subject is unable to give it; in case of emergency treatment.

This study is not designed to include individuals who are unable to provide informed consent, and no emergency treatment or urgent clinical interventions are part of the study protocol. Participants must have the cognitive and communicative ability to understand the study information or have a legally authorized representative (LAR) who can consent on their behalf.

In cases where a subject is unable to consent due to age or disability:

- A legally authorized representative (such as a parent, guardian, or healthcare proxy) will provide informed consent.
- If appropriate, assent from the participant will also be obtained in accordance with ethical guidelines and IRB requirements.

No situations requiring waiver of consent or emergency enrollment are anticipated. All participants will be fully informed and will consent voluntarily before any data is collected or device use occurs.

A.14. Adverse events, adverse device effects, and device deficiencies

a) Definitions of adverse events and adverse device effects.

An Adverse event (AE) is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including any abnormal laboratory finding) in subjects, users, or other persons, whether or not related to the medical device.

A serious adverse event is any AE that:

- Led to death,
- Led to serious deterioration in the health of the subject that either resulted in:
- A life-threatening illness or injury; or
- A permanent impairment of a body structure or a body function; or
- In-patient or prolonged hospitalization; or
- Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or body function; or
- Led to fetal distress, fetal death or congenital abnormality or birth defect.

All adverse events that do not meet any of the above criteria for seriousness should be regarded as non-serious adverse events.

Note: Medical conditions that exist at study enrollment are not considered AEs, unless the condition worsens after enrollment.

b) Definition of device deficiencies.

A device deficiency is the inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. This includes malfunctions, user error and inadequate labelling. Alleged device deficiencies will be treated and handled as a complaint per SOP120.

c) Definitions of serious adverse events including serious health threat and serious adverse device effects and, where appropriate, unanticipated serious adverse device effects.

Serious Adverse Device Effect (SADE)

A **serious adverse device effect** is an ADE that can be **attributed—wholly or in part—to the use of the investigational device** or any procedure involved in the clinical investigation. This includes any event that meets the criteria for a serious adverse event and is reasonably related to the device, including:

- Device malfunction or failure,
- Device misuse stemming from unclear instructions or design-related issues,
- Unexpected physiological or psychological responses due to interaction with the device.

Serious Health Threat

A serious health threat refers to any situation in which the investigational device or study-related activity poses an immediate and significant risk to the health, safety, or welfare of a participant or others. This includes events requiring urgent action or modification of study procedures to mitigate risk.

Unanticipated Serious Adverse Device Effect (USADE)

An unanticipated serious adverse device effect is a SADE that was not previously identified in nature, severity, or frequency in the risk analysis or device documentation provided in the clinical investigation plan. USADEs must be reported promptly and may trigger changes to the risk management strategy, informed consent documentation, or continuation of the study.

Although Obi3 is a Class I device with minimal risk, the study team will monitor for any such events and report them in compliance with its SOP120, its associated D-FRM-005, Complaint Form and in accordance with ISO 14155, 21CFR812, and IRB requirements.

d) List of non-reportable adverse events, if applicable, including rationale.

Given that Obi Gen 3 is a Class I, non-invasive, robotic feeding aid, there are no anticipated adverse events inherently associated with the device under intended use. Minor discomforts such as mild user frustration or meal spillage due to unfamiliarity with controls are not considered adverse events if they resolve quickly and do not require intervention.

Rationale: These types of issues are consistent with expected variability during first-time use of assistive technology, especially in a non-clinical trial setting, and do not pose harm or risk to the participant. Such experiences will be captured in usability feedback but do not require AE reporting.

e) Time period in which the principal investigator shall report all adverse events and device deficiencies to the sponsor and, where appropriate, to ECs and the regulatory authority.

The principal investigator (PI) is responsible for reporting all adverse events (AEs), serious adverse events (SAEs), and device deficiencies to the sponsor within 24–48 hours of becoming aware of the event.

f) Details of the process for reporting adverse events (date of the adverse event, treatment, resolution, assessment of both the seriousness and the relationship to the investigational device and the related procedure).

All device deficiencies, whether or not they result in an adverse event, must be documented and reported to DESIN LLC within 48 hours of discovery. Reporting should include:

- Description of the deficiency or malfunction
- Date of occurrence
- Whether or not the deficiency led to device unavailability, user risk, or disruption of the study
- Any corrective actions taken or recommended
- Whether the deficiency was identified before or during use

The need to capture AEs is not dependent upon whether the clinical event is associated with the use of the study device or study procedure.

Complaints regarding the device, including notice of an adverse event, or adverse device effect will be processed in accordance with DESĪN LLC's SOP120, Return and Service Procedures, which include processes and timing for adverse event handling, documentation and reporting to regulatory authorities.

DESIN LLCs Service Manger will be provided a copy of the study device serial numbers in order to flag complaints resulting from the study. Any complaints, including notification of adverse events, resulting from study devices will be promptly sent to Heather Keeton & PI Dr. Fairman.

For the purposes of this study, all AEs/SAEs/SADEs/USADE, or Serious Health Threats (events) must be collected from enrollment (ICF signature) through study completion. The principal investigator is ultimately responsible for reporting such events to the IRB.

Events should be recorded in standard medical terminology rather than the subject's own words.

- Note the duration by entering the date of onset and date of resolution.
- Note the worse intensity of the event as mild/moderate or severe.
- Note the frequency of the event as a single episode, intermittent, or continuous.
- Note the actions taken as none, medication, procedure, or other.
- Note the relationship to study procedure or device as not-related, unlikely, possibly related, probably-related, or causal relationship.

g) Details of the process for reporting device deficiencies.

Device deficiencies, including handling of adverse events, and adverse device effects (including timeframes for reporting), will be processed in accordance with the company's complaint handling procedure, SOP120, including D-FRM-005, Complaint Form. Device deficiencies will be recorded using the Complaint form and reviewed by the quality and engineering teams for tracking and analysis.

Corrective/Preventive Action will occur in accordance with SOP080, CAPA procedures, and any advisory notices or recalls will be executed per SOP070, Non-Conformance procedures.

h) List of foreseeable adverse events and anticipated adverse device effects, together with their likely incidence, mitigation, or treatment.

There are no anticipated serious adverse events (SAEs) based on the device's classification and prior real-world use. The following are foreseeable but rare adverse device effects during use of the Obi Gen 3:

- Frustration or anxiety related to unfamiliar technology or difficulty in control coordination
- Meal spillage or choking risk due to poor positioning or inadequate supervision in certain user

These events are considered low risk, especially when users are screened appropriately and receive training. Mitigation strategies include:

- Device orientation and training prior to use
- Provider oversight during setup and monitoring
- Encouragement of caregiver presence during early use

i) Emergency contact details for reporting serious adverse events and serious adverse device effects.

See sponsor contact information, A.1.3.

j) Information regarding the DMC, if established.

Given the minimal risk nature of this study and the non-interventional design, a formal Data Monitoring Committee (DMC) has not been established. All safety oversight will be managed internally by the Principal Investigator in collaboration with the sponsor. Any unexpected safety issues or emerging risks will trigger an ad hoc safety review, and the IRB will be informed accordingly.

A.15. Vulnerable Population (if applicable)

a) Description of the vulnerable population to be included in the clinical investigation.

This clinical investigation includes participation by children aged 5 years and older who require assistive technology for self-feeding. Children are considered a vulnerable population under federal and international research guidelines due to their limited legal capacity to provide informed consent and their potential dependence on caregivers and authority figures. Additionally, the study may include adults with disabilities, another potentially vulnerable group, particularly if cognitive or communication challenges are present.

b) Description of the screening process to identify and protect the vulnerable population.

Pre-screening will be conducted by qualified clinical staff in accordance with SOP220, which includes assessment of developmental, cognitive, and physical ability to participate meaningfully in the usability trial. Only individuals who demonstrate the ability to interact with the Obi Gen 3 device with or without assistance and are capable of participating in basic study activities (e.g., completing feeding tasks, expressing feedback with support) will be included. For all participants, providers will verify that participation is voluntary and appropriate given the individual's medical, cognitive, and psychosocial context. Caregivers and/or legal guardians will be involved in the initial screening and enrollment decision.

c) Description of the specific informed consent process.

The informed consent process for this study will be conducted in compliance with applicable ethical guidelines, including ISO 14155, the Declaration of Helsinki, and U.S. federal regulations (21 CFR Part 50 and 45 CFR 46). The process is designed to ensure that all prospective participants—including patients, caregivers, and providers—are fully informed about the purpose, procedures, risks, benefits, and voluntary nature of the study prior to participation. All eligible participants will receive an IRB-approved informed consent form (ICF) appropriate to their role in the study (e.g., provider, caregiver, or patient). The consent process will occur electronically using the Qualtrics platform, which is configured to ensure secure delivery and storage of consent records in a HIPAA-compliant environment. Participants will be

provided with sufficient time to read the consent form, ask questions, and make an informed decision. For pediatric participants, age-appropriate assent will also be obtained, along with consent from a parent or legal guardian.

The process includes:

- Electronic delivery of consent forms via email link (Qualtrics)
- Participant review and acknowledgment of understanding
- Entry of electronic signature and date
- Secure, time-stamped storage of signed consent documents

Informed consent must be completed before any study-related activities occur. The study team will monitor incoming consents to confirm eligibility and document participant enrollment accordingly. No coercion or undue influence will be used, and participants may withdraw at any time without penalty. Any updates to the consent process, form content, or electronic platform will be submitted for IRB review and approval prior to implementation.

d) Description of the EC's specific responsibility.

For this study, no EC has been formed. We are seeking guidance from the IRB for any ethical considerations or concerns.

e) Description of what medical care, if any, will be provided for subjects after the clinical investigation has been completed.

Not applicable, no medical care will be provided

A.16. Suspension or premature termination of the Clinical Investigation

a) Criteria and arrangements for suspension or premature termination of the whole clinical investigation or of the clinical investigation in one or more investigation sites.

DESĪN LLC reserves the right to suspend or terminate enrollment or other study activities at a site/institution at any time, upon giving written notice. This may be based on the following reasons (but is not limited to):

- The site/institution has not complied with the protocol, study agreement, requirements of the IRB or repeated failure to complete study assessments.
- Failure to report safety, device deficiencies/malfunctions within 2 business days of awareness.
- Repeated protocol violation

- The site's principal investigator leaves the institution, and not adequate replacement is available.

DESĪN LLC will notify the relevant site/institution and/or their IRB within 5 business days in the instance of site/institution suspension. A suspended site/institution may not enroll or offer Obi without sufficient evidence/proofs to DESĪN LLC that preventive and corrective actions have been implemented to resolve the root-causes of the problem identified. DESĪN LLC must approve the enrollment or suspension lift in writing. Approval of IRB may be required, where applicable.

b) Criteria for access to and breaking the blinding/masking code in the case of suspension or premature termination of the clinical investigation, if the clinical investigation involves a blinding/masking technique.

Not applicable. Blinding is not part of the study design.

c) Requirements for subject follow-up and continued care.

In the instance of a study termination, any reportable safety concerns should be reported and recorded by the sites/institutions through the end of the subjects' participation in the study.

A.17. Publication Policy

a) Statement that the clinical investigation will be registered in a publicly accessible database (see 5.4).

In accordance with ISO 14155:2020 Section 5.4 and ethical principles for transparency in clinical research, this clinical investigation will be registered in a publicly accessible database prior to the enrollment of the first participant. Registration will include key protocol details such as the study title, objectives, design, inclusion/exclusion criteria, and primary endpoints. The registry platform selected will meet international standards for public accessibility and transparency.

b) Statement indicating that the results of the clinical investigation will be made publicly available.

Furthermore, the results of this clinical investigation will be made publicly available following study completion and data analysis. Study findings will be disseminated in one or more of the following formats:

- Submission to a peer-reviewed scientific journal,
- Presentation at a scientific or professional conference,
- Summary of findings posted to the same publicly accessible trial registry.

Any publication or presentation will include proper acknowledgment of DESĪN LLC as the sponsor, and disclosure of any financial relationships or conflicts of interest, including that of the Principal Investigator.

This publication policy aligns with ethical guidelines and regulatory expectations for openness in clinical research and reinforces the commitment of the sponsor and investigators to contribute to the scientific community and broader assistive technology field.

c) Statement indicating the conditions and timeframes under which the results of the clinical investigation will be offered for publication including the role of the sponsor and criteria for authorship.

Any participating investigator wishing to publish data from this study (poster, abstracts, articles, etc.) must first seek review from DESĪN LLC. Where applicable, study drafts (poster, abstracts, articles, etc.) should be submitted to DESĪN LLC prior to submission to publication.

A.18. Bibliography

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Appendix A: DESĪN LLC's Document References

DOC#	TITLE	REV	ECO
SOP220	TRIAL ASSESSMENT PROCEDURE	1.1.0	167-6
SOP210	COMPUTER SECURITY PROCEDURES	1.0.0	157
SOP200	PRIVACY PROCEDURES	1.0.0	157
SOP170	SAFETY RISK MANAGEMENT PROCEDURE	2.0.0	122
SOP120	RETURN AND SERVICE PROCEDURE	3.0.1	138
SOP110	RECORDS	2.2.0	157
SOP080	CAPA PROCEDURES	1.2.0	152
SOP070	NON-CONFORMANCE PROCEDURES	1.2.0	122
SOP020	DOCUMENT CONTROL PROCEDURE	1.2.0	122
SOP010	DESIGN CONTROLS	1.2.0	122
NA	SGS SAFETY CERTIFICATION (SAFETY & EMC)	NA	NA
NA	CONSULTING AGREEMENT, DESIN LLC & ADAPTIVE DRIVING SOLUTIONS	NA	NA
NA	CERTIFICATE OF INSURANCE, DESIN LLC	NA	NA
IFD-DES-080	DESIGN REVIEW, OBI3 VERIFICATION	1.0.0	172-16
IFD-DES-070	FORMATIVE EVALUATION REPORT, OBI3	1.0.0	172-8
IFD-DES-064	FORMATIVE EVALUATION PLAN, OBI3	1.0.0	172-6
IFD-DES-054-1	DESIGN VALIDATION PLAN, OBI3	1.1.0	172-18
IFD-DES-053-2B-R2	DESIGN VERIFICATION RESULTS, OBI3 (TRIAL 2)	1.0.0	172-18
IFD-DES-053-2B-R1	DESIGN VERIFICATION RESULTS, OBI3	1.0.0	172-16
IFD-DES-053-2A-R1	DESIGN VERIFICATION RESULTS, OBI3	1.0.0	172-16
IFD-DES-025	MARKETING REQUIREMENTS	5.6.0	172-18
IFD-DES-022	SAFETY RISK MANAGEMENT REPORT	2.1.0	122
IFD-DES-021	OBI CLINICAL EVALUATION PLAN & REPORT	3.0.0	167-5
IFD-DES-018	PRODUCT HAZARDS ANALYSIS	5.1.0	172-5
IFD-DES-003	OBI SAFETY RISK MANAGEMENT PLAN	3.0.0	172-3
IFD-DES-001	OBI US REGULATORY PLAN	2.1.2	167-1
IFD-801-012	OBI TRAVEL ROUTER	5.4.1	167-4
IFD-700-003	OBI CONTROL BOARD SOFTWARE, RELEASE NOTES	7.1.0	172-17
IFD-600-003	INSTRUCTIONS FOR USE	5.1.0	172-18
IFD-600-002	QUICK START GUIDE	2.0.0	172-14
IFD-400-110	UTENSIL ADAPTER, OBI3	1.0.0	172-10
IFD-400-108	SPORK, OBI3	1.1.1	172-11
IFD-400-102	SMALL SPOON, OBI3	1.1.1	172-11
IFD-400-101	LARGE SPOON, OBI3	1.1.1	172-11
IFD-400-100	CLASSIC SPOON, OBI3	1.1.1	172-11
D-FRM-005	COMPLAINT FORM	2.0.0	138
Cert#6026	ISO13485 CERTIFICATE	NA	NA

Appendix B: Other Supporting Documentation

Research Study Required Documentation
PI Insurance Certificate
CITI Cert, 62378273 (Andrea Fairman)
CITI Cert, 50766681 (Andrea Fairman)
CITI Cert, 33760261 (Andrea Fairman)
CITI Cert, 50766679 (Andrea Fairman)
CITI Cert, 27227298 (Andrea Fairman)
CITI Cert, 47659142 (Andrea Fairman)
CITI Cert, 62122050 (Andrea Fairman)
CITI Cert, 68267401 (Heather Keeton)
CITI Cert, 68267399 (Heather Keeton)
CITI Cert, 68267400 (Heather Keeton)
CITI Cert, 64948276 (Ryan Osal)
CITI Cert, 66280848 (Ryan Osal)