The G1 Continuous Glucose Monitoring and Human Behavioral Study

Manual of Operations and Procedures (MOP)

ClinicalTrials.gov identifier NCT06472297

WEB LINKS

Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html)

Implementation of NCCIH Policies for Clinical Studies
(http://nccih.nih.gov/grants/policies)

NIH Policy for Data and Safety Monitoring
(http://grants.nih.gov/grants/ guide/notice-files/not98-084.html)

Guidelines for Writing Informed Consent Documents
(http://ohsr.od.nih.gov/info/sheet6.html)

Clear and to the Point: Guidelines for Using Plain Language at NIH
(http://oma.od.nih.gov/ma/customer/customerserviceplan/attachment2.htm)

Open Science Framework
https://osf.io

Dexcom G6 Pro System
https://provider.dexcom.com/products/dexcom-g6-pro/training-resources

A1CNow Self-Check Tutorial Video
https://youtu.be/uO-iMHchlKI?si=LHO2viVWm5ZKJqBm)

1. INTRODUCTION

The goal of this project is to create a new digital health communication intervention that combines wearable CGM feedback technology alongside daily educational video clips aimed at personalized behavioral modifications in diet, physical activity, and glucose self-monitoring to increase glucose control and possibly prevent T2 Diabetes (T2D) over time among people with prediabetes who are underrepresented in their access to such digital health technologies. These video clips, tailored for watching on smartphones, will be altered using video-based artificial intelligence (AI) software for video to text transcoding as well as deep fake video transcoding of characters to multiple languages other than English and Spanish. Original video narrative content will be generated by Latino community health workers known as Promotores de Salud (PdS) who will use the unmasked CGM feedback system]]. We plan to name the resulting CGM feedback plus digital health communication intervention *¡Mi Control!* to counter the belief that prediabetes is uncontrollable by simple behavioral modifications

2. OVERVIEW

In this Phase 0 trial referred to as the G1 Study**,** we will enroll a retained sample of N=20 Spanish -speaking Latino PdS participants meeting positive finger prick screening for prediabetes. This is one of the very few studies to examine CGM use in Latinos with diabetes. Participants will wear CGM for a target of20 days while keeping daily video logs relaying experiences of CGM use and feedback and interpretations of contingencies between changes in variables that changes glucose levels. At post-assessment, video-recorded structured interviews between staff and participants will explore the benefits and barriers to CGM use in daily life during the wear period. We will use video clips from the daily video logs and from the structured interviews to form the basis of the short smartphone educational clips for our ¡Mi Control! intervention. We will then use an AI software tool (Descript) to transcode the captured video clips into text to be edited . After the sample of video clips is reduced to capture production value, a final series will be generated. Aim 1 in Study 1 is to create ten 30-60 second health communication video clips of ¡Mi Control! to be paired with app-based CGM feedback to hasten learning about glucose control within 20 days. We will then use a different AI software to convert all video clips into multiple languages other than English and Spanish while retaining the visual likeness of the original characters in the videos. This will offer a proof of concept that the workload of health communication production can be reduced using this method to increase the capacity for message dissemination in future work.

During the planning phase of the G1 study, Dr. David Black, PI, and the study staff drafted the study protocols to ensure that the MOP accurately described how the study procedures would be performed. Before developing the MOP, the final protocol, Electronic Case Report Form (eCRF), informed consent documents, and administrative forms (e.g., screening and enrollment log, protocol deviation log, etc.) were finalized. The development of the G1 Study and other documents began at the end of September 2023, with recruitment starting on May 29, 2024. Additionally, Adriana Argaiz and Rosalba Cain conducted internal audits of all protocols in both English and Spanish, which were then submitted to the IRB for final approval prior to any trial recruitment efforts. The MOP will be forwarded to the NIH as part of supplemental material for the respective year's annual review and made available to the public on The Open Science Framework (OSF) to meet the advancing guidelines for transparency in trials research. The MOP will be updated throughout the active study period to reflect any minor changes to the study protocols or consent amendments and refine the eCRFs and study procedures accordingly. The MOP version submitted to NIH will represent the final protocols used during the study.

The G1 Study MOP is maintained and can be located in a three-hole binder with the various sections and dividers located at the USC Health Sciences Soto office. Please note that an MOP electronic file is located on a protected share drive for staff to access at any time, and printed manuals are made available upon request. (Staff have more access to digital files across locations than the paper file). All previous versions are archived with the Research Coordinator.

3. MOP CONTENTS AND ORGANIZATION

The MOP details the study procedures and describes the study-specific documents adapted to the G1 Study. includes the following sections:

a. Study Protocol or Synopsis
b. Staff Roster
c. Study Organization and Responsibilities
d. Training Plan
e. Communications Plan
f. Recruitment and Retention Plan
g. Study Design Diagram
h. Screening and Eligibility Criteria and Processes
i. Informed Consent and HIPAA
j. Study Intervention
k. Blinding and Unblinding (Masking or Unmasking)
l. Evaluations and Follow-up
m. Concomitant Medications
n. Safety Reporting
o. Data and Safety Monitoring Responsibilities

p. Study Compliance

q. Data Collection and Study Forms

r. Data Management

s. Quality Control Procedures

t. Study Completion and Closeout Procedures

u. Policies

v. MOP Maintenance

3.1 Study Protocol

The following section describes the study protocols and provides scientific rationale for the G1 Study. The final version of the study protocol with the date of IRB approval and version number are included in the appendix section of the MOP.

3.2 Study Organization and Responsibilities

3.2.1 Continuous Glucose Monitoring Study Roster

The roster below includes the names, roles, and e-mail addresses of study staff members, P50 Center Personnel, USC Department Administration, and Dexcom staff who serve as key contacts for the study.

G1 Project Key Personnel	Role	Address	Email
David Black, PhD	PI - Lead investigator and trialist	KSOM Health Sciences Campus 2001 N. Soto Street, SSB 302D Los Angeles, CA 90033	davidbla@usc.edu
Lourdes Baezconde-G, PhD	Co-I - Community engagement	KSOM Health Sciences Campus 2001 N. Soto Street, SSB 302M Los Angeles, CA 90033	baezcond@usc.edu
Braden Barnett, MD	Co-I Study physician	KSOM Health Sciences Campus 1333 San Pablo Street, BMT-B11 Los Angeles, CA 90033	Braden.Barnett@med.usc.edu
Ralph Weischedel, PhD	Co-I AI Software Design and Application	USC Viterbi – Computer Science 4676 Admiralty Way, Suite 1001 Marina Del Rey, CA 90292	weisched@isi.edu
Marientina Gotsis, MFA	Co-I Cinematic arts and video production	USC School of Cinematic Arts 3470 McClintock Ave, SCI 201U Los Angeles, CA 90089-2211	gotsis@usc.edu

G1 Project Staff	Role	Address	Email
Ruth Flores	Research Coordinator I	KSOM Population and Public Health Sciences Health Behavior Research 1845 N. Soto Street, Bldg SSB Los Angeles, CA 90032	rflores8@usc.edu
My Vu	Biostatistician	University of Southern California 2250 Alcazar Street, CSC 200 Los Angeles, CA 90033	myvu@chla.usc.edu
Nick Arce	Research Assistant	KSOM Population and Public Health Sciences 2001 N. Soto Street, Bldg SSB Los Angeles, CA 90032	nnarce@usc.edu
Devin Hayden	Undergraduate Research Assistant	KSOM Population and Public Health Sciences 2001 N. Soto Street, Bldg SSB Los Angeles, CA 90032	dhayden@usc.edu
Yunlei Liu	Student Worker	KSOM Population and Public Health Sciences 2001 N. Soto Street, Bldg SSB Los Angeles, CA 90032	yunleili@usc.edu
Thalia Bosman	Student Worker	KSOM Population and Public Health Sciences 2001 N. Soto Street, Bldg SSB Los Angeles, CA 90032	tbosman@usc.edu
Milena Amadeus	Phlebotomist	KSOM Population and Public Health Sciences 2001 N. Soto Street, Bldg SSB Los Angeles, CA 90032 1845 N. Soto Street Los Angeles, CA 90032	milenalo@usc.edu
Marisela Miranda	Phlebotomist	KSOM Population and Public Health Sciences 2001 N. Soto Street, Bldg SSB Los Angeles, CA 90032	marisela.miranda@usc.edu

P50 Center Personnel (CHLA)	Role	Address	Email
Michael Goran, PhD	Center Director of Shared Resources	Children's Hospital Los Angeles 4650 Sunset Blvd. Los Angeles, CA 90027	goran@usc.edu
Alaina Vidmar, MD	G6 CGM Assessment	Children's Hospital Los Angeles 4650 Sunset Blvd. Los Angeles, CA 90027	avidmar@chla.usc.edu
Ana Velasquez	Sr. Research Administrative Analyst	Children's Hospital Los Angeles The Saban Research Institute 4650 Sunset Blvd. MS#178 Los Angeles, CA 90027	anavelasquez@chla.usc.edu
Anna Peare	Center Coordinator	Children's Hospital Los Angeles 4650 Sunset Blvd. Los Angeles, CA 90027	apeare@chla.usc.edu
Adriana Argaiz	Recruitment and Translation Services	University of Southern California 2250 Alcazar Street, CSC Los Angeles, CA 90033	adriana.argaiz@med.usc.edu
Rosalba Cain	Recruitment and Screening of Promotore	KSOM Clinical & Translational Sciences Institute (CTSI) USC Health Sciences Campus Los Angeles, CA 90089	rosalba.cain@med.usc.edu
Juan Espinoza, MD	Center Chief Data Officer	Children's Hospital Los Angeles 4650 Sunset Blvd Los Angeles, CA 90027	jespinozasalomon@luriechildrens.org
Claudia Rios, RD	Dietician for NDSR Assessment	Children's Hospital Los Angeles The Saban Research Institute 4650 Sunset Blvd. MS#178 Los Angeles, CA 90027	clrios@chla.usc.edu

USC Department Administration	Role	Address	Email
Jose Morales	Study Post-Award Budget Manager	KSOM Population and Public Health Sciences – USC Health Science Campus 1845 N. Soto Street, SSB Los Angeles, CA 90032	josekarl@usc.edu
Monique Franklin	Human Resources and Staffing	KSOM Population and Public Health Sciences – USC Health Science Campus 2001 N. Soto Street, SSB 300 Los Angeles, CA 90033	Monique.Franklin@med.usc.edu
Rosa Barahona	Senior Project Manager	KSOM Population and Public Health Sciences – USC Health Science Campus 2001 N. Soto Street, SSB 310 Los Angeles, CA 90033	Barahona@usc.edu
Janae' Green	Office Orders and Concur system	KSOM Population and Public Health Sciences – USC Health Science Campus 1845 N. Soto Street, SSB Los Angeles, CA 90032	danieceg@usc.edu
Ryan Wilkerson	Department IT and Equipment Access	KSOM Population and Public Health Sciences – USC Health Science Campus 1845 N. Soto Street Los Angeles, CA 90032	wilkerso@usc.edu
Christina Ayala	DORI Project Manager for Assay Lab	KSOM USC Health Sciences Campus 1975 Zonal Avenue Los Angeles, CA 90033	trujillc@usc.edu
Chanita Hughes, PhD	Coordination of Soto research Activities	KSOM Population Health & Public Health Sciences 1845 N. Soto Street, SSB Los Angeles, CA 90032	hughesha@usc.edu

Dexcom Staff	Role	Address	Email
Ryan Henry	Research Coordinator for G Sensor and Clarity	Dexcom 6340 Sequence Drive San Diego, CA 92121	rhenry@Dexcom.com
Paige Tosello	Purchase orders from Dexcom	Dexcom 6340 Sequence Drive San Diego, CA 92121	paige.tosello@dexcom.com
Christine Wazniak, RDN	Education Specialist	Dexcom 6340 Sequence Drive San Diego, CA 92121	christine.wozniak@dexcom.com

Figure _A_: Continuous Glucose Monitoring Study Roster

Ruth Flores is the Research Coordinator and will be contacted at rflores8@usc.edu regarding special situations and specific study-related questions including:

- Protocol requirements
- Reporting an adverse event (AE)
- Request for study supplies
- Randomizing a participant
- Unblinding a participant (should not be done lightly).

3.2.2 Coordinating Center

The G1 Study day-to-day activities and operations are depicted below as related to the study.

G1 Study Team Members Acronyms Manual of Operations and Procedures **(MOP)** Institutional Review Board **(IRB)** Nutritional Data System for Research **(NDSR)** Children's Hospital Los Angeles **(CHLA)**		
AA – Ariana Argaiz TB - Thalia Bosman CR – Claudia Rios DB – David Black DH – Devin Hayden LBG – Lourdes Baezconde-Garbanati	MA – Milena Amadeus MG – Marientina Gotsis MiG – Michael Goran YL - Yunlei Liu MM – Marisela Miranda MV – My Vu	NA – Nick Arce P50 - P50 Center Staff RC – Rosalba Cain RF – Ruth Flores SV – Sandra Vasquez RW – Ryan Wilkerson

Figure _B_: Study Team Member Acronyms

The responsibilities of the Coordinating Center at the USC Soto Building include individuals who will oversee various study tasks:

- DB is the senior manager with oversight of all study procedures.
- RC, AA, and LGB will assist with community engagement for participant recruitment.
- RF will assist with communicating with study sites, scheduling meetings and training sessions, and responding to and documenting ad hoc communications.
- RF, DB, and DH will assist with developing and maintaining the MOP.
- RF will coordinate daily study activities and procedures.
- DB, RF, NA, MV, and SV will assist with developing the data flow and management procedures, including data entry, error identification, and correction.

- DB, RF, MG, Adverse events monitoring and reporting, processing of adverse events, and health events during the study.
- The IRB will ensure oversight and store accepted protocols through site visits to ensure adherence to the protocol and procedures (RF will oversee audits, oversight, and shadow, and AA and MG will oversee videos).
- P50 CDE protocols are reported and feedback from (P50, MiG and LBG).
- RF, AA, MV, and MG will ensure the validity of English and Spanish transcription, data completeness, irrigating profiles by participant, CGM, and Quality control procedures.
- RF Reports (e.g., enrollment, AEs, participant status, site performance, and quality control overview).
- DB, RF, and P50 are tasked with distributing all changes, updates, and policies of reports and documents to all participating study sites, and the DSMB, as necessary. This includes ensuring that all relevant parties are informed of any modifications or new policies that may affect the study.
- RF, MA, and MM will ensure that proper protocols are adhered to for the A1C finger prick and document results on the appropriate form at the Soto laboratory.
- RW is responsible for ensuring that all computer systems at the Soto Street facility function correctly. This includes regular maintenance, troubleshooting, and addressing any technical issues that may arise during the study.CR from the P50 Center will complete the NDSR assessment after participants have completed all study visits.
- RF, NA, MG, and AA are responsible for video content correction, revisions, and editing.

3.2.3 Study Sites

Dr. David Black, PI, submitted a request for approval of a Clinical Study Site application to Cort Brinkerhoff, Ed.D, at Cort.Brinkerhoff@med.usc.edu. The application for the Clinical Study designation was approved for the on-campus facility located at the Soto Building, room 302D, on September 19, 2024, per Cort Brinkerhoff, Ed.D.

The roles and responsibilities of the investigators and study sites include:

- DB is the senior manager of all research staff and procedures conducted at the study site.
- DB, RF, and SV staff will maintain the MOP study binder at the Soto office.
- RF participation in protocol finalization and preparation of study materials
- DB, RF, and SV compliance with the protocol, MOP, IRB, Federal, and state regulations
- RF, AA, RC, recruitment, screening, and enrollment of participants
- DB, RF, and MV protection of participants' rights - Informed Consent form
- DB, MV, RF, data collection and participant follow-up through study completion
- RF, conduct Semi-Structured Interviews

- DB, RF, and MV, transfer of data to Coordinating Center and resolution of all queries
- DB and RF Compliance with and accountability of administration of study intervention
- MA and MM - Laboratory personnel from the Soto Laboratory conduct an A1C finger prick at the Soto building laboratory
- RF, MA, MM, and SV Retention of specific records (e.g., laboratory or drug distribution records)
- DB, RF, communication of questions, concerns, and observations to the Coordinating Center.
- MG, NA, TB, YL assist with translating video narrative health communication videos

3.2.4 Steering Committees

Steering Committees are not applicable in the G1 Study as this is not a multicenter study.

3.2.5 Other Study Committees

An Executive Committee is not required for the G1 Study.

3.3 Training Plan

All study personnel will have up to two weeks to complete all required training, including the Collaborative Institutional Training Initiative (CITI) certifications.

Continuous Glucose Monitoring Study - Training Plan Employees have up-to 2-weeks to complete all required trainings			
Training Course Name	**Contact Person**	**Training Link**	**Date Completed**
Welcome G1 Study Orientation	Ruth Flores		
Unlicensed Research Application	Tania Guevara		
Social and Behavioral Research - Best Practices for Clinical Research (GCP)		https://about.citiprogram.org/	
Human Research - Social Behavioral Human Subjects (HS)		https://about.citiprogram.org/	
Social Media and Research Recruiting		https://about.citiprogram.org/	
Information Privacy Security HIPAA (IPS-Research)		https://about.citiprogram.org/	
Blood Borne Pathogens		http://trojanlearn.usc.edu	
G1 - Study Protocol	Ruth Flores		
G1 - Manual Base Protocol	Ruth Flores		
Research Electronic Data Capture (REDCap)	Ruth Flores & My Vu	https://redcap.med.usc.edu/	
Descrip Software Video Training (Correct script that the platform generates for recordings)	Ruth Flores & Marientina Gotsis		

Figure _C_: Training Plan

Completed certifications will be verified through their USC IRB profile in the USC iStar system. Training must be completed before observing and participating in any study activities. Study personnel RF will contact TG at Tania.Guevara@med.usc.edu regarding the Keck School of Medicine (KSOM) Unlicensed Research Personnel application process. All requirements must be completed prior to having direct contact with study participants.

Ruth Flores will serve as the Site Coordinator and will periodically update TG regarding the new registration and credentialing of research personnel who are anticipated to have direct participant contact.

3.4 Communications Plan

Ongoing communication with members of the G1 Study study is essential to ensure the study is on track, to discuss status updates and progress, and to address emerging study issues to be resolved with energetic debate.

Audience	Frequency	Preferred Method of deliver	Source	Delivered By	Status Updates	Expected Results
G1 Key Personnel	As needed	Zoom Meeting Email Attachments	Agenda/Status Reports	PI	Management	Review study goals/objectives, development or execution of the G1 research and project development
G1 Staff	Weekly Wed 11:00 a.m.	Zoom Meeting Email Attachments	Agenda/ Status Reports	PI	Completion of all project objectives	Provide status on study activities, timeline, identify and project risks
P50 Center Personnel (CHLA)	Monthly	Zoom Meeting Email Attachments	Agenda/ Status Reports	PI	Progress and status reports	Provide G1 study recruitment updates
USC Department Administration	As needed	Zoom Meeting Email Attachments	Agenda/ Status Reports	PI	Staff & Equipment Processing	Provide action items follow-up, and resolutions
Dexcom Staff	As needed	Zoom Meeting Email Attachments		PI	Equipment Processing	Update on Dexcom equipment for G1 study

Figure _D_: Communication Plan

3.5 Study Intervention

The G1 Study uses. The a test device to prevent or change the natural course of a disease or condition (prediabetes to diabetes). intervention components includesthe CGM system, health communication video clips, and behavioral activities (glucose self-monitoring and self-selected behavioral modifications of diet, physical activity and lifestyle)

Device studies require a detailed description of the device and its intended use. Information on device studies is provided in the Code of Federal Regulations (CFR) Title 21, Parts 800 - 1299, revised as of April 1, 2000 (see http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfrv8_00.html).

Device. The Dexcom G6 Pro Continuous Glucose Monitoring System (Dexcom G6 Pro System) is a real time continuous glucose monitoring device indicates users of age 2 years and older in a home environment while under the supervision of a healthcare professional. Interpretation of the real-time Dexcom G6 Pro System results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 Pro System may also be used as a retrospective glucose recording device indicated for assessing glycemic variability in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. Retrospective interpretation of data recorded by the Dexcom G6 Pro System should be conducted solely by a healthcare professional. The Dexcom G6 Pro System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom G6 Pro System is also intended to interface with digitally connected devices. The Dexcom G6 Pro System can be used alone or in conjunction with these digitally connected medical devices for managing diabetes or assessing glycemic variability

3.6 Recruitment Plan

The initial baseline screening telephone call for the G1 Study initiated on May 24, 2024, and the final screening was conducted on August 30, 2024.
The target population for the G1 Study 1 are 20 individuals who have been working as community health workers in the last six months, diagnosed with prediabetes, and ideally reside in Los Angeles County. At the coordinating P50 recruitment site (SCCLH), staff provide all recruitment material in both English and Spanish.

3.7 Participant Retention

Research participants will be compensated for their efforts at the trial. The total compensation is $500 in the form of gift cards divided into different phases. For participating in the initial visit alone, research participants are compensated with a $100 gift card, for wearing a glucose sensor for 20 continuous days, each participant receives a $200 gift card. For participating in the post visit and the semi structured interview, participants are compensated with a $200 gift card.
RF keeps constant communication with each research participants through emails, text messages and phone calls. RC provides a weekly list of new referrals. The list provided contains participant details such as name, last name, phone number and email address. Once RF obtains a new referral, she sends an initial text message and email to introduce herself. After participant shows

interest in the study, RF schedules a phone call with each potential participant within the following 72 hours. During the screening call, if a participant is deemed eligible for an initial in person visit, RF schedules the visit in the following 7 days and once the screening call ends, she sends a text message to remind each participant of the upcoming initial study visit. Once a participant is enrolled in the study, RF sends daily text messages from days 1 through 20 of sensor wear. Through these messages RF ensures study activities compliance and assesses wellbeing of each research participant.

The PI, research coordinator, and biostatistician will convene weekly to review retention percentages as well as the quality and completeness of captured data. This will entail, at minimum, an overview of participant intake and retention progress, summary reports outlining participant compliance with visits, evaluations, interventions, and a summary evaluating the completeness and quality of key data elements required for characterizing participants. These reports will determine the data captured and process quality to facilitate analyses. The statistician will also update the study's master data file and variable codebook at this exact interval which is stored on REDCap. The codebook and data file will be in a format with sufficient detail to be made publicly and available to support research replication in the field.

3.8 Study Design

Study 1 employs a within-subject design without CGM masking, enabling the measurement of glycemic variability, where participants receive feedback every 5 minutes while wearing the CGM device. This is an observational study where participant glycemic data is observed when CGM feedback is available on their smartphone app. This design captures continuous baseline values on the primary study outcome across 20 consecutive days while recorded video -based narratives are provided by participants each day as well as during the structured interview.

Proposed Accrual Study Timeline

The figure below depicts the proposed timeline for the target enrollment of participants across three independent studies.

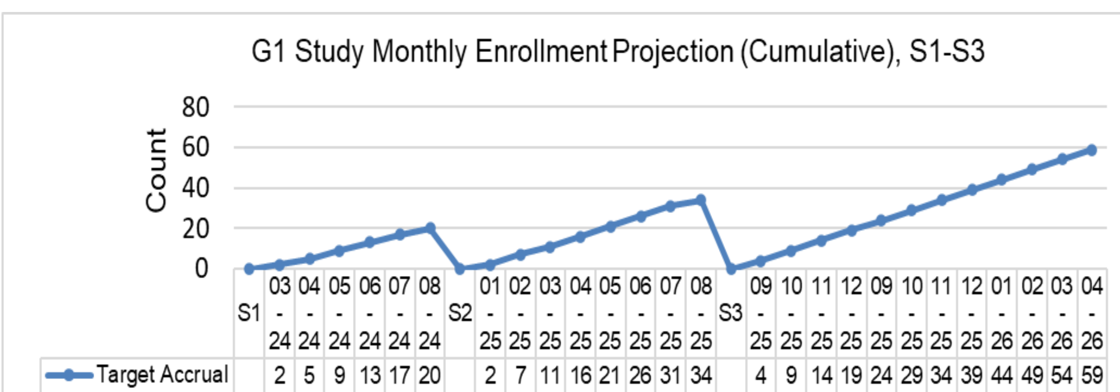


Figure _E_: Proposed Accrual Timeline

Schedule of Assessments

The table below represents the schedule of assessments which details each variable name, applied measure, data capture medium, and the timing of the assessment relative to the study design.

Variable	Measure	Capture	Screen	Baseline Visit	CGM Phase	Post Visit
Eligibility	Age, sex, race/ethnicity, employment, zip, contact info, medical history, CDC prediabetic risk	Phone	x			
A1c%	A1cNow test kit (5.7-6.4%)	Staff		x		
Weight, kg	Digital scale (Tanita WB-3000)	Staff		x		x
Height, cm	Stadiometer (Tanita WB-3000)	Staff		x		x
Dietary log	G6 app daily log upon out-of-range chime	G6 App		x	x	
CGM changed	G6 transmitter replaced	Zoom, Phone			x	
Glucose, mg/dL	Dexcom G6 Pro system	G6 reader		x	x	x
Physical activity	International physical activity questionnaire	RC		x		x
Narrative	Semi-structured interview	Video				x
Satisfaction	CGM satisfaction survey	RC				x
Pattern detection	Ravens' matrices task	Website				x
P50 CDEs	Socio-demo and residential	RC				x
P50 dietary recall	NDSR external date	Phone				x
Daily Videos: Food Intake					X	

Figure _F_: Schedule of Assessments

Study Flow

The G1 Study overview is depicted in a flow diagram illustrating the study's major steps. (see Figure 1 below).

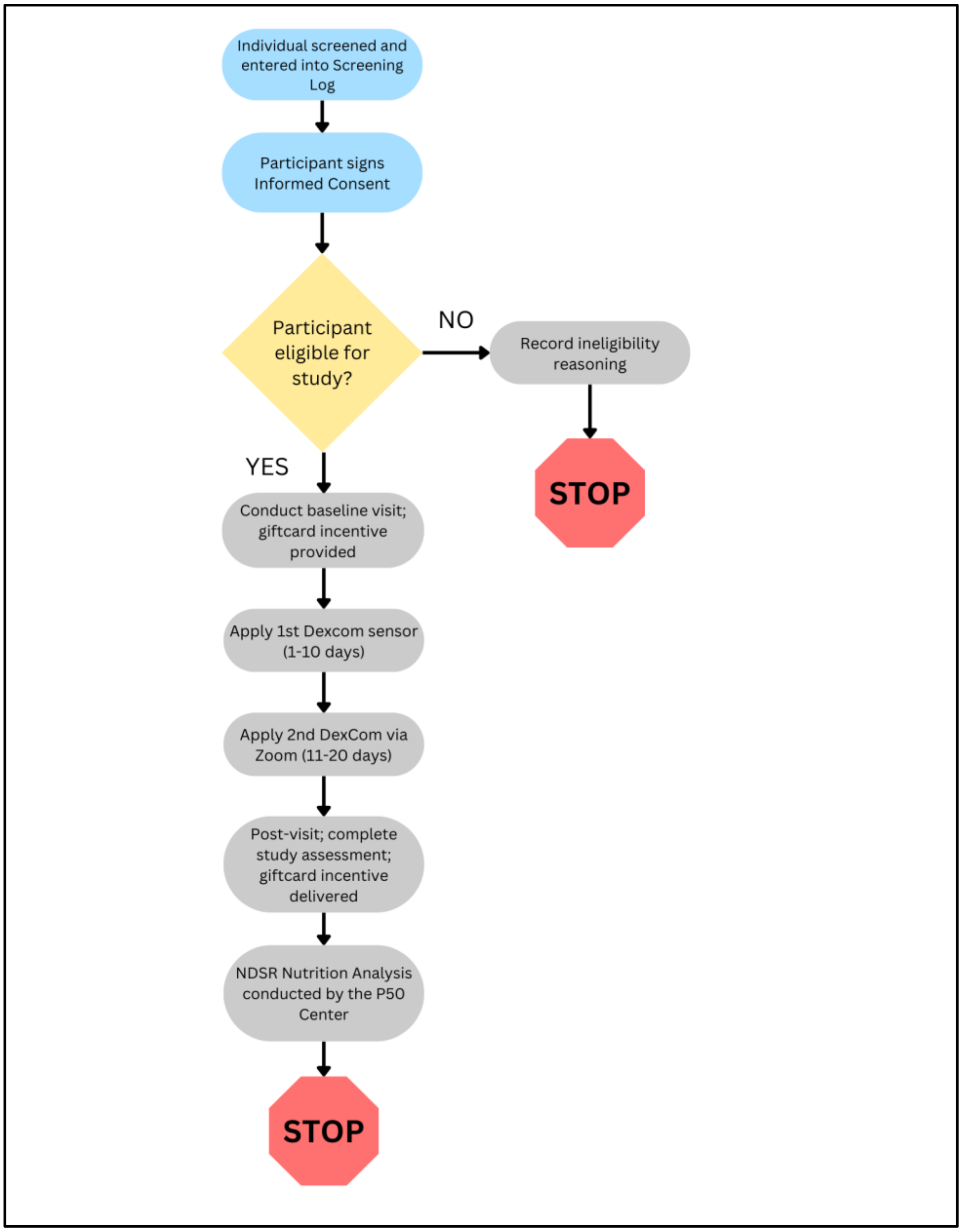


Figure _G_: Continuous Glucose Monitoring Study Flow Diagram

3.9 Screening and Eligibility Criteria

Eligibility inclusion criteria include current or recent PdS, prediabetes risk based on the A1C glucose measure between 5.7% up to 6.4.%, recent prediabetes diagnosis, aged 18 years or older adult in California, self-identified Latino/Hispanic ethnicity, and willing to participate in a study.

The information below describes the instructions on screening procedures for the G1 Study. The information will assist the study team in determining participant eligibility.

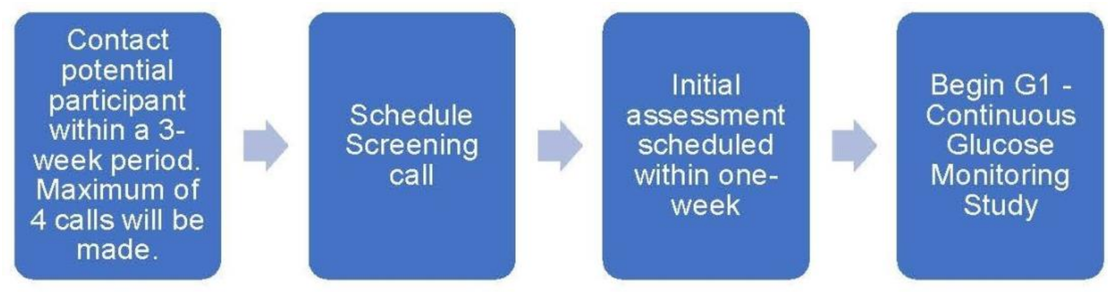


*Figure _H_*

** Important to note that a maximum of four telephone calls will be made to make contact with the potential participant. In addition, telephone messages will be left indicating when and what time the next call will be made in efforts to speak with the potential participant and inquire if they are still interested in participating in the G1 Continuous Glucose Monitoring study.*

Screening by phone

During the pre-screening phase, the P50 staff will make telephone calls to individuals who have been recruited and expressed an interest in the G1 Study. The outreach recruitment is carried out by the P50 team, AA and RC.

The initial baseline screening process is conducted by the G1 study team at the USC Health Sciences Campus, Soto Building. The screening process is facilitated by a computer-assisted verbatim script within the RC system which takes approximately 20 minutes from introduction to competition. Upon scheduling a screening call with the participant, the administrative team will log into their RC account and create a new file in RC for each participant who will be screened.

Once logged into the RC system, the administrative staff will navigate to "My Projects" > "Continuous glucose monitoring in adults - G1 study" > and select the "Record Status Dashboard" tab on the left-hand side of their screen. From there, they will click "Add new record," which will prompt a table named "Data Collection Instrument" to appear. Within this table, the administrative staff member will select the "Screening Call" option, triggering RC to automatically generate a unique RC ID for the participant. The staff member will input the data collected during the screening phone call in real time. Before submitting, the staff member will ensure that all data is entered accurately and complete. An example of the telephone script is provided in Appendix _A_.

3.9.1 Screening Log

A CGM Screening Log documents all participants that are reviewed for study eligibility, and contains the following:

- *Participant identification number*
- *Initial screening date*
- *Eligible for study participation*

- *Date enrolled*
- *Date of initial visit*
- *Reason for ineligibility, if applicable*

A sample Screening Log is included in Appendix_B_.

Note: This information is usually part of the reporting requirements for data and safety monitoring.

An example of the Screening log used in the G1-Study is shown in Appendix _B_.

3.9.2 Eligibility Criteria

The G1 study staff will collect information from all participants to produce descriptive variables (i.e., age, sex, race, race/ethnicity, zip code) as well as assess medical history of chronic disease, current medical diagnosis, and current medications to determine eligibility. Eligibility criteria include current PdS, prediabetes risk, aged 18 years or older adult in California, self-identified Latino/Hispanic ethnicity, and who are willing to participate in the study.

Exclusion criteria are: those individuals who have been diagnosed with diabetes, uncontrolled psychiatric condition making participation potentially a risk, influential medical disorder (i.e., history of seizures, glucose related complications, myocardial infarction or stroke in the past 6 months, abnormal thyroid function) and specific medication use (systemic b-blocker regular use of oral corticosteroids, initiation of a non-insulin drug for glucose control during the past 3 months, regimented use of acetaminophen), pregnancy, current use of a CGM sensor, enrollment in weight loss program or current fasting regimen, and any current obesity treatment medication. In addition, participants who have a telephone device that is incompatible with the Dexcom application. Lastly, if the participants are travelling in the next two months, they would not be eligible for the study.

3.10 Informed Consent

An example of the informed consent is provided in Appendix _D_1_.

During screening call the study staff will assent the participant using Info Assent form, this form can be found in Appendix_D_2_. After the participants during screening procedure, the study staff will explain that during the initial visit, they wil be given an official consent document called the Informed Consent Form. The project staff will send the participant the Informed Consent Form (ICF) in their preferred language via email at least two days before their scheduled visit. Conduct the informed consent process in the privacy of the Soto 302D office with the door closed. Have a hard copy of the ICF ready and accessible during the process. Before the participant starts to read the ICF the study staff will explain to the participant that if they decide to participate they will complete two in person study visits, wear a CGM sensor for 20 continuous days, complete different surveys, record daily videos, and be provided with up to $500 compensation in gift cards in total if they complete each phase of the study.

The study staff will allow the participant to take as much time as necessary and encourage them to ask any follow-up questions. The study staff will give the option to the participant if the ICF should be read by the study staff or if they prefer reading the ICF on their own. Once all questions have been addressed, summarize by asking the participant, "Do you understand that you are volunteering for a research study and that you can withdraw at any time?" If the participant consents, the study staff will have the participant sign the paper copy of the ICF and electronically sign the version in RC, which will be delivered to their email. At the moment that the participant is reading the ICF, the study staff will email the Phlebotomy staff to alert them that the participant will be directed to the lab after signing the ICF. If the participant does not consent, the study staff will record the reason in the participant chart.

Inform the participant that the final step for eligibility is a finger prick to measure capillary blood glucose levels, which will be performed at the laboratory on the first floor of the Soto building. Additionally, inquire if they require a bathroom break before proceeding.

The study staff will collect the signed ICF and place it into a red folder which will be filed in a locked cabinet in office 302D located at the Soto building.

Arrival and Introduction

The study staff will send the participant an email and a text message containing the address, parking instructions, a reminder to write down the participant's email login with the correct password (so they can successfully have access to the Recap survey link sent to their email account) on a piece of paper, and a map, both on two days before the visit, the day before, and the morning of their scheduled visit. Additionally, they will provide a cell phone contact number in case of arriving late or rescheduling purposes. Within 24 hours of the visit, the participants will be contacted by phone to confirm their attendance.

The research staff will request a daily parking pass for each participant a week before their arrival. The research staff will submit a request to be a requisitioner for Internal Service Delivery (ISD) through USC's PPHS Portal. After the approval, the research staff will receive an ISD number, which will be used for each parking spot pass request. Through the Workday portal, the staff will go into the ISD section and will submit the ISD number previously provided and will input the number of passes they will need for that designated day. After the request is approved, it will provide virtual parking passes on the Off-Street Dashboard website. The baseline interview will be conducted at the USC Soto building. Participants should wait in the designated parking area upon arrival. Upon their arrival, the participants will be warmly greeted and thanked for coming. The study staff will introduce themselves, present their USC ID, and specify their role in the "USC Glucose Study." They will verify the participant's name and ensure they are able to stay for the entire 2.5-hour visit. Additionally, participants will be provided their license plate number, and the study staff will create a parking pass registration for the participants vehicle. The registration will be created in the “Off Street” dashboard website. In the registration the participant study ID will be entered. Before the participant is escorted to the Soto 302D office, the study staff will make sure that the participant has at least 2 hours available to complete their visit.

3.10.1 HIPAA Authorization

The HIPAA authorization is not applicable for the Continuing Glucose Monitoring study.

3.11 Randomization

Randomization is not applicable for the Continuing Glucose Monitoring study.

3.12 Blinding and Unblinding (Masking and Unmasking)

Blinding and Unblinding is not applicable for the Continuing Glucose Monitoring study.

3.13 Study Measurements and Procedures

Measures

Prediabetes status. The assessment of prediabetes risk will be conducted using the CDC prediabetes risk measure (https://www.cdc.gov/prediabetes/risktest/index.html) during the initial screening by the study staff, who has access to the target population. Respondents scoring 5 or higher on this measure are deemed to exhibit probable risk of prediabetes and are subsequently invited to attend the study baseline interview at Soto. Exception: If a participant expressed during the screening call that they have been diagnosed with pre-diabetes by their physician, they are eligible for initial visit. During the initial visit, finger prick A1c scores will be reviewed and confirmed, by utilizing the A1cNow Self-test kit (https://www.totaldiabetessupply.com/products/a1c-now-4-test-kit). Non-fasting A1c levels will be measured via finger prick blood spot. Individuals with resulting scores falling within the range of 5.7 to 6.4% will be deemed eligible for enrollment in the study, as this level is diagnostic of prediabetes. [see Davidson et al (2021). Screening for prediabetes and type 2 diabetes. JAMA; Dall et al (2014). Detecting type 2 diabetes and prediabetes among asymptomatic adults in the United States, Population Health Metrics; Tentolouris et al (2013).

Screening for HbA1c-defined prediabetes and diabetes in an at-risk Greek population, Diabetes Research and Clinical Practice.]

Glycemic variability. The primary outcome measure for the project is glycemic variability, which will be assessed using CGM automated data capture and the Dexcom Clarity cloud. We will utilize the Dexcom G6 Pro system (https://provider.dexcom.com/products/dexcom-g6-pro/training-resources) to capture glycemic variability over 14-20 complete wear days, with data recorded automatically every five minutes and timestamped. Participants will change the transmitter once on day 10, as the sensor has a wear time of 10 days. Data will be transferred to the Clarity cloud using an external Dexcom reader. Subsequently, the Clarity file will be exported and sent to the statistician for processing in RC software, where all variables for the complete ambulatory glucose profile (AGP) panel for glycemic variability will be calculated.

Our main outcome analyses will focus on key variables related to hyperglycemia (high glucose outside the healthy range). Additionally, CGM data will allow us to generate important covariates, such as the % time worn by each participant per week and the number of times a participant changed the CGM sensor.

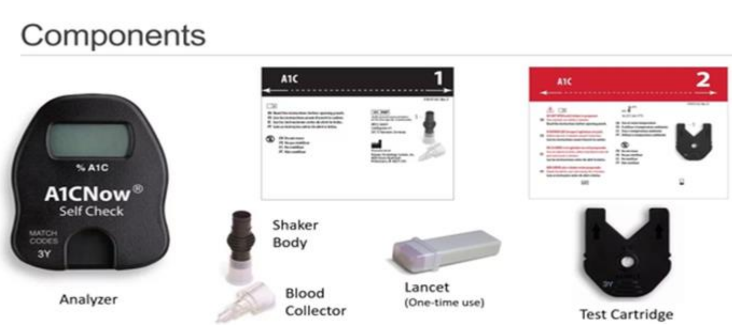
Demographics and eligibility. We will collect information from all participants to produce descriptive variables (i.e., age, sex, race, race/ethnicity, zip code) as well as assess medical history of chronic disease, current medical diagnosis, and current medications to determine eligibility. Eligibility criteria include current PdS, prediabetes risk, aged 18 years or older adult in California, self-identified Latino/Hispanic ethnicity, and willing to participate in a study. Exclusion criteria are: ever diagnosed with diabetes, uncontrolled psychiatric condition making participation potentially a risk, influential medical disorder (i.e., history of seizures, glucose related complications, myocardial infarction or stroke in the past 6 months, abnormal thyroid function) and specific medication use (systemic b-blocker regular use of oral corticosteroids, initiation of a non-insulin drug for glucose control during the past 3 months, regimented use of acetaminophen), pregnancy, current use of a CGM sensor, enrollment in weight loss program or current fasting regimen, and any current obesity treatment medication.

Body composition. Weight and height will be observed in duplicate and charted by the study staff using an electronic Tanita WB-3000 scale, and stadiometer Tanita WB-3000. Staff will capture the information in a physical body measurement form, in addition to entering the data into the RC body measurement form which will automatically calculate participants BMI to prevent calculation errors. An example of a Body Measurement form is provided in Appendix _E_. Below is the procedure for performing and capturing weight and height for participants who are eligible for the study. Weight and height will be captured and recorded for each participant without fasting, and without shoes.

Height and weight. For this procedure, the research staff will have in hand a hard copy of the Body Measurement form abstracted from the RC secure system web-based application. The procedure will take place in workstation 302-10 in front of the 302D office. The research staff will ask the participant to remove their shoes and any heavy clothing such as jackets, phones, and wallets. While the participant is removing his/her accessories, the study staff will sanitize the scale with an alcohol wipe found next to the scale. The study staff will ask the participant to stand as straight as possible on top of the Tanita WB-3000 scale and record their height in centimeters and weight in kilograms on the participant chart using the stadiometer. Document the height and weight on a hard copy of the RC Body Measures Form. Study staff will once again sanitize the scale with an alcohol wipe found next to the scale. Then, request participants to put their shoes back on, redirect the participant back to the office and have the participant take a seat in the chair designated within the office. Inform them that there are three remaining activities including completing a survey on the computer, placement of the glucose monitors as well as the daily video activity.

Finger prick protocol. The finger prick protocol can only be conducted after the ICF is signed by the participant. The finger pricking procedure will take place at the Phlebotomy Laboratory area of the Soto Building located on the first floor. Before directing the participant to the lab, the study staff will explain that the finger pricking protocol will take place downstairs at the phlebotomy lab. If the participant does not understand the procedure the staff will explain that a phlebotomist will prick the superficial skin layer of his/her finger with a 28mm lancet to obtain a small drop of blood and put the drop of blood in a special glucose analyzer to obtain their A1c levels. After answering the participant's questions regarding the finger pricking procedure, the study staff will take the participant to the Phlebotomy Lab area and will also take the hard copy of the "Body Measurements" form from RC. As soon as the study staff and participants arrive at the lab, the study staff will hand the Phlebotomy lab staff the hard copy of the Body Measurements Form. The phlebotomist will capture the A1c levels given by the analyzer and document on the Body Measurement form. The finger prick is a method to capture a droplet of blood on the tip of the finger to measure glucose levels to determine study eligibility.

The instructions for the use of A1cNow Test Kit can be found in Appendix_C_.



Computer-based survey: the self-administered surveys delivered through each study visits are beverages survey, behavior survey, CGM satisfaction survey.

An example of a Body Measurement form is provided in Appendix _E_

Below is the procedure for performing and capturing weight and height for participants who are eligible for study.

- Weight and height will be captured and recorded for each participant without fasting, and without shoes.

For this procedure, the research staff will have in hand a hard copy of the Body Measurement form of the RC platform. The procedure will take in workstation 302-10 in front of the 302D office. The research staff will ask the participant to remove their shoes and any heavy clothing such as jackets, phones, and wallets. While the participant is removing his/her accessories, the study staff will sanitize the scale with an alcohol wipe found next to the scale. Nicely ask the participant to stand as straight as possible on top of the Tanita WB-3000 scale and record their height in centimeters and weight in kilograms on the participant chart using the stadiometer. Document the height and weight on a hard copy of the RC Body Measures Form. Then, request participants to put their shoes back on, redirect the participant back to the office and have the participant take a seat in the chair designated within the office. Inform them that the remaining activities include completing a survey on the computer and the placement of the glucose monitor.

3.13.1 Timeline of Study Assessments

A useful study tool that outlines the G1 schedule of variables, measurement, and timeline are exhibited relative to the study design. An example of a Timeline of Study Assessments is provided in Appendix _F_

3.13.2 Scope/Schema

In this section of the MOP, each visit should be explained in detail enough so that a new or substitute team member can perform the visit. Step-by-step instructions should be provided for all study procedures. This may include defining the purpose of the assessment, the time of data collection, or the processes for handling unscheduled visits.

Baseline visit

<u>Arrival and introduction</u>

The study staff will send the participant an email and a text message containing the address, parking instructions, a reminder to write down the participant's email account with the correct password (so they can successfully get access to the Recap survey link sent to their email account) on a piece of paper, and a map, both on the 7th day and the day before their scheduled visit. Additionally, they will provide a cell phone contact number in case of transportation issues on the day of the visit or for rescheduling purposes. Within 48 hours of the visit, the participant will be contacted by phone to confirm their attendance.

The research staff will request a daily pass for each participant a week before their arrival. The research staff will submit a request to be a requisitioner for Internal Service Delivery (ISD) through USC's PPHS Portal. After the approval, the research staff will receive an ISD number, which will be used for each parking spot pass request. Through the Workday portal, the staff will go into the ISD section and will submit the ISD number previously provided and will input the number of passes they will need for that designated day. After the request is approved the Transportation Office will provide manual exchange tickets that will need to be date-stamped and distributed to each participant upon arrival. These passes will be valid for any unmarked space within the Soto lot.

The baseline interview will be conducted at the USC Soto building. Participants should wait in the designated parking area upon arrival. Upon their arrival, the participants will be warmly greeted and thanked for coming. The study staff will introduce themselves, present their USC ID, and specify their role in the "USC Glucose Study." They will verify the participant's name and ensure they are able to stay for the entire 2.5-hour visit. Additionally, participants will be provided with the designated parking pass which the study staff will indicate to the participant to place the ticket on top of the participant's car dashboard. Before the participant is escorted to the Soto 302D office, the study staff will make sure that the participant has at least 2 hours available to complete their visit.

Informed consent and signatures

Send the participant the Informed Consent Form (ICF) in their preferred language via email 2 days before their scheduled visit. Conduct the informed consent process in the privacy of the Soto 302D office with the door closed. Have a hard copy of the ICF ready and accessible during the process. Before the participant starts to read the ICF the study staff will explain to the participant that if they decide to participate they will complete 2 in person study visits, wear a CGM sensor for 20 continuous days, complete different surveys, record daily videos, obtain a $500 compensation in total if they complete the each phase of the study and complete a recorded interview on their last study visit.

Allow the participant to take as much time as necessary and encourage them to ask any follow-up questions. The study staff will give the option to the participant if the ICF should be read by the study staff or if they prefer reading the ICF on their own. Once all questions have been addressed, summarize by asking the participant, "Do you understand that you are volunteering for a research study and that you can withdraw at any time?" If the participant consents, have them sign the paper copy of the ICF and electronically sign the version in RC, which will be delivered to their email. While the participant is reading the ICF, the study staff will email the Phlebotomy staff to alert them that the participant will be directed to the lab after signing the ICF. If the participant does not consent, record the reason in the chart.

Inform the participant that the final step for eligibility is a finger prick to measure capillary blood glucose levels, which will be performed on the first floor of the Soto building. Additionally, inquire if they require a bathroom break before proceeding.

Finger prick protocol

The finger prick protocol can only be conducted after the ICF is signed by the participant. The finger pricking procedure has been explained in the previous section.

Height and weight

For this procedure, the research staff will have in hand a hard copy of the Body Measurement form of the RC platform. The procedure will be taken in workstation 302-10 in front of the 302D office. The research staff will ask the participant to remove their shoes and any heavy clothing such as jackets, phones, and wallets. While the participant is removing his/her accessories, the study staff will sanitize the scale with an alcohol wipe found next to the scale. Nicely ask the participant to stand as straight as possible on top of the Tanita WB-3000 scale and record their height in centimeters and weight in kilograms on the participant chart using the stadiometer. Document the height and weight on a hard copy of the RC Body Measures Form. Then, request participants to put their shoes back on, redirect the participant back to the office and have the participant take a seat in the chair designated within the office. Inform them that the remaining activities include completing a survey on the computer and the placement of the glucose monitor.

[When the baseline visit is over: log into the RC "Continuous Glucose Monitoring in Adults - G1" study. Navigate to the "Record Status Dashboard" tab on the left-hand side of the screen, where a list of all screened participants will be displayed in the center of the page. Verify the correct ID for the participant, click on "Body Measures" within that participant's record. Input the data such as A1c level, weight, and height from the hard copy of RC forms into the corresponding fields in RC.]

Computer-based survey

Have the participants sit in the 302D office to complete the survey. The research staff will send a RC invitation to the participant by email beforehand, at least 1 hour before the baseline visits take place. Prepare the computer and tell the participant to log into the email they initially gave during their screening call. After the participant has access to their email, ask the participant to find the email called “Informed Consent.” Make sure the participant has the correct email in place, explain to the participant that the first link will prompt out the electronic Informed consent, explain that we need to capture their electronic signature as well. Another important document they will sign before starting the Baseline Visit surveys, is the Image Release form. The study staff will explain that we are kindly asking them to give us consent to be able to use their daily videos and video recorded interviews to be able to create educational videos about their CGM experience. The study staff will then tell the participant that after they have given their consent, 4 surveys will prompt out and usually takes about 30-45 minutes to complete, and it will ask questions related to physical activity, current medication, vitamin use and various behaviors. After the participant has agreed to continue with the survey's procedures, the study staff will ask the participant to login into their email in the PI's office computer. The study staff will ask the participant if they want the surveys to be read to them by the staff or if they desire to complete the surveys on their own. The study staff will remain in the room to make sure all questions regarding the surveys are answered to the participant. At the survey's completion, verify that RC shows that all baseline forms were completed by the participant.

To send the participants a RC invitation/link to the survey forms of RC, the study staff will login into RC and choose the "Continuous glucose monitoring in adults - G1 study." Click on the "Survey Distribution Tools" tab on the left-hand side of the RC page. Once they have clicked on the Survey Distribution tab, they will click on the "Participants List" tab shown on the upper center of the page. DO NOT click on "Public Survey Link." Choose the survey form they want to send to the participant (i.e. demographics baseline). After selecting the survey form, they will click on the "Compose Survey Invitations" tab shown under the selected survey form. Fill in the date and time the email should be sent to the participant, from which study staff's email will the RC system send the survey to the participant, a message written within the email to the participant. On the right-hand side of the page, a list of all the participants' emails will appear. After the study staff verifies the correct email associated with the participant, they will then select the participant's email address. Once they have reviewed and confirmed that each section is filled in with the correct information, the study staff will proceed to email the invitation/link to each participant.

<u>CGM application</u>

The staff will guide participants to download the Dexcom G6 app and the Dexcom – Clarity app onto their personal smartphone. The staff will help in creating a username for their Dexcom app and completing the login process. The Dexcom G6 app will request the participant to create a Dexcom username and password. When creating the Dexcom account, the staff will make sure that the participant is only using the initials of their name (e.i. RF). After the participant logs into their account, the study will ask the participant to turn on their smartphone's Bluetooth, this step is needed for the sensor to be able to link with their smartphones.

The study staff will assist participants in applying the G6-Pro sensor to the back of their arm. This procedure will occur in room 302D with the door closed. Before beginning, the research staff will explain the main steps using the G6 instructions and address any participant questions. Participants should be comfortably seated. After the participant is seated, the study staff will show a Dexcom sensor application video beforehand, this way the participant will have a visual example of what the procedure will be like. The video that will be shown to the participant can be accessed by following the link below: https://youtu.be/eHKFDyrd-Ls?si=91yNAG8RcfP2Fwcl

After seeing the video, the study staff will answer questions asked by the participant regarding the sensor application. The study staff will then gather the Dexcom G6 Pro kit, which includes the applicator, transmitter, and receiver. The study staff will guide the participant to open their Dexcom G6 PRO box and explain each supply found within the box: 1 sheet with the sensor transmitter code, 1 sheet with a visual representation of each step of the sensor application, 2 alcohol wipes, 1 applicator containing the sensor and the Dexcom transmitter. The explanation that will be given by the participant will be demonstrated by the study staff using an old Dexcom G6 PRO Kit. The explanation given is the following: or applying the sensor, begin by using an alcohol wipe to clean a 3-inch diameter area around the intended placement spot. Position the applicator firmly against the skin on the underside of the back of the arm. After placing the adhesive on the skin, the study staff will guide the participant to fold to the side and break off the trigger safety guard; then press the release trigger. Instruct the participant to apply pressure with their finger to the sensor against the skin for 10 seconds. Afterward, use circular motions to firmly rub the adhesive tape around the transmitter-sensor patch, ensuring a secure hold. After the sensor has been applied, the study staff will guide the participant to grab the transmitter and place it in the transmitter slot found in the sensor adhesive. The staff will hold a mirror in front of the participant, that way the participant has a clear view of the sensor and transmitter. A visual description of this procedure is shown on the next page.

After the participant has applied their sensor, the participant will login into the newly created Dexcom account logs, and the study staff will ask the participant to turn on their smartphone's Bluetooth, this step is needed for the sensor to be able to link with their smartphones. After creating their account, the app will prompt for the transmitter Serial Number, located on the “Start Here” page found in the Dexcom box and on the two stickers in the Dexcom Kit box. Enter this number and affix the provided sticker onto the participant's chart for record-keeping purposes. After entering the transmitter serial number, the user will click on the “Save” icon found in the upper right corner of their screen. The smartphone will then prompt a question to confirm the Transmitter Code, after the study staff has verified that the participant entered the correct Transmitter code, the user will be guided to click “Confirm”. The G6 App will take about 5 minutes to recognize it. After the smartphone has recognized the sensor, a new question will appear on the screen, asking the user if they want to pair the transmitter to the smartphone, the study staff will then guide the participant to click on “Pair New”. Once the App has linked with the sensor, the app will show a sign saying that the sensor will warm up for 3 hours and that no glucose data will be shown until the sensor has completely warmed up. After the pairing has been successful, the study staff will ask the participant to go to the “settings” Icon found in the upper right corner of the G6 App, and they will click on the “Alerts” section. After the alerts page prompts out, the study staff will turn off the “Low” alerts and will click on the “High” tab to place 140mg as the level of high glucose alerts. Explain to the participant that the G6 App cannot be closed, that way all collected data is not lost. The study staff will make the remark that the participant's smartphone's Bluetooth always must be on. After completely setting up the G6 App, the study staff will then ask the participant to open the Dexcom Clarity app and the app will ask the participant to login with their Dexcom username and password. After login into the Dexcom Clarity app, the study staff will guide the participant to go into the “profile” section of their app, after touching that section the app will prompt a page where it will show a section called “Manage Data Sharing,” the study staff will ask the participant to select that section and the app will then ask the participant to “Share your CGM data with your clinic” and the participant will be guided to touch the “Continue” tab. After selecting the “continue” tab, the app will ask the user to “Enter clinic code.” The clinic code that will be used for the G1-study is: g1studyusc. After entering the G1-study clinic code, the participants' CGM data will appear on the Clarity platform after the sensor has warmed up.

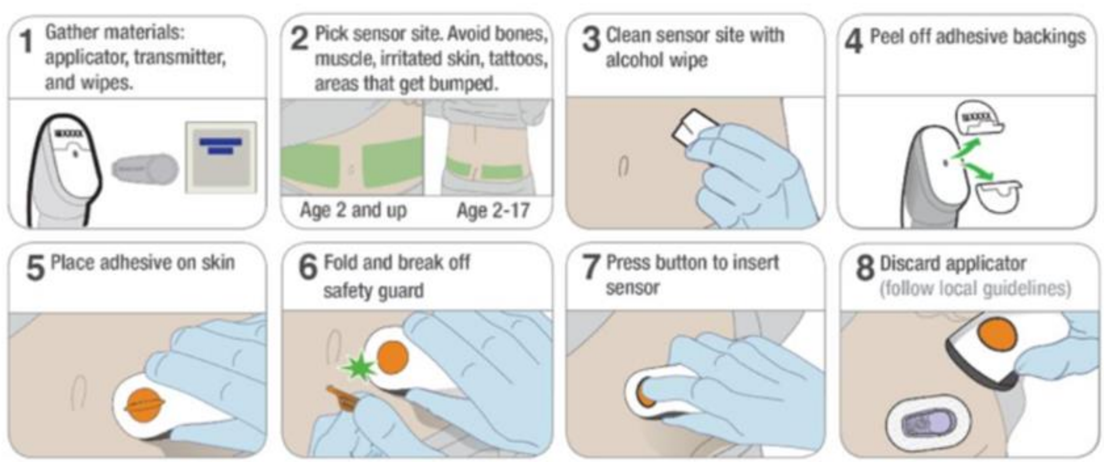
After the study staff has made sure that the participant has linked their smartphone to the CGM sensor, the staff will then link the applied sensor to the G6 PRO receiver. To do so, the staff will grab the G6 PRO reader and click the “On/off” button. After the receiver has turned on, the receiver will ask the user to enter the 4-digit sensor code. The study staff will enter the 4-digit code found in the adhesive backings of the applied sensor applicator. Once the study staff has entered the code. The receiver will take about 5 minutes to link the sensor to the receiver.

The study staff will then congratulate the participant for successfully applying the sensor and pairing the sensor to their smartphone. After words of encouragement have been given, the staff will then explain to the participant that they will complete daily videos in which they will answer questions that the study staff will send through a text message every day, within those videos they will sincerely share their experience with the Dexcom sensor. The study staff will explain that on the days they obtain “high glucose” alerts, they will create a video describing in what situation the participant was in when the alarm was received; they will describe what foods they ingested before obtaining the alarm as well.

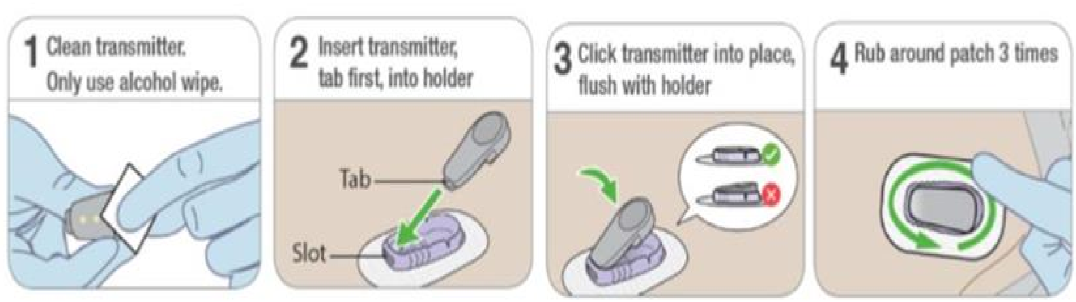
The final step of this procedure involves explaining to participants the signs and symptoms they should report to the research staff regarding the sensor. These include swelling, redness, bruising or bleeding. Participants must notify the research staff if the transmitter falls off or if any errors occur within the app. The study staff will make the remark that the participant cannot remove the sensor unless it is instructed by the study staff. Additionally, participants should be reminded that the transmitter-sensor is effective for 10 consecutive days. Provide each participant with a yellow folder to store the used transmitters. Remind the participant they are to bring their transmitters with them on their return visit.

Before the participant puts his/her smartphone away, the study staff will ask the participant if they already have a Zoom App and Zoom account and explain that this app is needed for the sensor replacement video call. If the participant does not have a Zoom account, the study staff will help and guide the participant to download the Zoom app and with the creation of a Zoom account.

Instructions for G6-Pro placement and transmitter attachment



For additional information related to inserting the sensor, please see the Dexcom G6 Pro CGM System User Guide



1. After the sensor is inserted and the transmitter has been snapped into the sensor pod, open the G6 app and follow prompts to create a username and password. Log in to the app and follow the set-up

wizard. Refer to the unblinded CGM patient handout that is included in your box.

a. The study staff will keep the adhesive backings of the applicator because this adhesive contains the 4-digit code that will be entered into the receiver/reader.

**Special instruction:
Turn off low alerts of 70 for prediabetes.
Set up high alert at 140 for prediabetes
Then be sure to turn off all alerts after you have started up - go to settings on G6 app home page and turn always sound to off.

2. In your box you will find an invitation to share your data. Follow the instructions on how to accept the invitation.

   a. Download the Dexcom Clarity App into the participant's smartphone

   b. Enter the G1-Study clinic code: G1Study. By doing so the system will automatically populate the participant's glucose data into the Clarity system.

3. In 10 days, your G6 Pro sensor session will end. The app will let you know when it has finished. Peel off the entire sensor with a transmitter (like peeling off a Band-Aid) and place in the zip-lock bag and then place in the envelope provided.

4. Return transmitter to research team.

5. Be sure to keep your phone within 20 feet to retain transmission and do not swipe close the app at any time as this will stop transmission of CGM data.

An example of the Dexcom Training Checklist is provided in the Appendix_G_.

G6 Reader

The reader, also known as a receiver, is the device from the Dexcom G6 Pro kit that helps the user verify that the session has started. The reader will not show any real time CGM data. The manufacturers describe this device as a compatible data extraction tool, this will help the research staff to upload patient data to Dexcom Clarity. In a blinded study scenario, the reader will be the only device receiving the data from the Dexcom transmitter. After the application of the Dexcom sensor-transmitter, the study staff will turn on the reader and the reader will ask for the serial number associated with the transmitter. The serial number is on the box, one of the inserts and the bottom of the transmitter. When you turn on the Reader and select “Download Data”, the first thing it asks for is the transmitter serial number.

Each G6Pro box has an insert that comes with 2 stickers which are the serial number. One sticker will be placed into the patient chart. If you are doing it electronically. We will keep a study record of the serial number of the transmitters by participant ID as shown below.

Study ID	Transmitter_1	Transmitter_ 2
001	xxxx	xxxx

Daily videos recording

An email will be sent automatically one day after the participant signs the ICF. The email will contain a RC link in which the participant will be able to upload their daily videos.

After the application of the sensor, the study staff will reiterate to the participant that as mentioned during the ICF process, the participant will create daily videos using their smartphones. The study staff will explain that the participant will create a video after obtaining a “high glucose” alert, in which they will describe what foods they ingested before receiving the alarm and they will describe in what situation they were in in the moment that they obtain the alert. The study staff will explain in addition, the participant will receive a daily text with 2 questions that the participant will answer on a video at the end of the day at approximately 6:00 p.m. The study staff will clarify that the purpose of the daily videos is to record their entire experience with the Dexcom sensor throughout the CGM wear phase. The study staff will explain that every day at 6pm they will also receive an email containing a link with instructions on how to record themselves, and a section link where they will upload their daily videos.

Video Upload Practice

An email will be sent automatically after the participant signs the ICF. The email will contain a RC link in which the participant will be able to upload a practice video during the visit.

After providing a clear explanation, the study staff and the participant will create a practice video in which the staff will explain to the participant the importance of the lighting for the video, and that the participant’s face should be clearly seen. The staff will inform the participant to make their videos in silent places, to eliminate other noises on their video’s audio.

The study staff will kindly ask the participant to check their email to ensure that they have received an email titled “Video Upload.” If the participant cannot locate the email, the study staff will help locate the email either in the participant’s email inbox or in the spam folder. If the study staff is unable to locate the email, the study staff will check the email address that the participant provided during their screening call. After checking the correct email address, the study staff will immediately contact the study’s statistician, so that the participant can receive the video upload link.

Compensation

The study staff will provide $100 gift card compensation to all participants attending the baseline interview and complete the protocols. Since this is the last procedure, the participant will be involved with for this visit, the study staff will provide an envelope to the participant. The envelope will be labeled with the name of the study, the research coordinator’s name and contact number. In the envelope the participant will locate two Ziploc baggies, 1 for each worn sensor. Each baggie will be labeled as “sensor 1” and “sensor 2;” the baggie will also contain one of the stickers designated for each sensor (these stickers will be found within the Dexcom G6 Pro kit box). The study staff will explain to the participant that the bag labeled “Sensor 1” is for them to put in the sensor that has been recently applied on the 10th day and the bag labeled “Sensor 2” is designated for the 2nd sensor they will apply on their own once they have completed the 20 days (about 3 weeks) of the CGM phase.

Data entry

The study staff will ensure to transfer the baseline data collected from the participant's chart into the RC system on the same day as the baseline visit. This will ensure that the main data capture system remains up to date.

CGM Wear Phase

The CGM wear phase will span 20 consecutive days. Throughout this period, we will gather data from the participants on a weekly basis. The sensor will be replaced once on day 10. Each morning, participants will receive text prompts to log dietary behaviors that triggered high out-of-range alarms; these logs will be recorded directly in the app by the participant. During the Zoom-supported sensor replacement call, the staff will replace the sensor and inquire about any adverse events or serious adverse events related to the sensor. Additionally, study staff will conduct Zoom sessions with participants on the 10th day of wearing transmitters during the CGM phase.

Dietary logs

The research staff will send one text per day to each participant, reminding them to report on their daily videos what foods they ingested right before they obtained a “high glucose alert” from the Dexcom G6 app. These reminder texts will be sent at 6pm every day of CGM wear. They will prompt participants to document the type of food consumed on a short video captured by their smartphones. These videos will be made after the participant has received a “high glucose” alert on their Dexcom G6 app and at the end of the day so they can answer questions that will be send out through a text message by the study staff daily. Within their daily text messages, the study staff will text daily questions which will vary throughout the 20 days of the CGM phase. The study staff will provide a video prompt to the participant's email. The video prompt that will be sent will be the following:

“Hi Mrs X,

Thank you for your participation in the G1 Study! As you wear the Dexcom G6 CGM sensor for the next 20 days, we would like to understand your experiences and journey with the device. To do so, we would like you to record a video of yourself answering a few questions using your mobile device’s front camera. We will send out the questions at 1pm everyday via email. This handout is to guide you through recording yourself on the front camera of a mobile device. We will also include how to upload the videos at the end of the handout.

Recording Tips

Posture

It may be helpful to be seated while you are recording yourself. Sitting will allow you to have your back straight to properly project your voice and ensure your body does not fidget or move around too much. In the frame, include your head, neck, and part of your shoulders. Extend your arm in front of you to hold the mobile device. Hold the mobile device far enough away to include these but close enough to ensure the focus is still on your face. The recording should be vertical.

Framing

Frame yourself so your eyes are roughly ⅓ of the way down your screen but above the middle of your screen. This framing will ensure your head, neck, and part of your shoulders are in the frame. See the example below.

Lighting/background

Avoid filming in places where the background is brighter than you are (i.e., with a light source or a window behind). Instead, have a light source (from a lamp, for instance) pointed at you or sit by a window. Lighting in front of you will ensure you are visible in the video.

Audio

Record the video in a quiet place with little to no outside noise. Ensure as best as possible that your voice is the only noise captured. You can test how your voice sounds with a test recording. Make sure your voice is audible in the test recording. Most microphones on mobile phones can pick up voice very well. If your audio does not sound clear, you can use headphones to capture the audio.

Practice

To make it easier to remember the question, we advise writing it down or having the question open in front of you. Additionally, jotting down a few notes for points you would like to cover before the recording can help organize your thoughts. If it is easier to read from your notes, feel free to do so (just make sure you look at the camera occasionally)! It may also help to do more than one take, but typically the one of the first two takes is the best.

Video capture

You will receive an email at [insert time that was set up on REDcap] in which you will find a link called “Video upload” to upload the video. After you click on the link a page will pop up in which you will type in today’s date and under the date section you will find a section with green letters that reads “Upload file,” click on that green section and a box that reads “Choose file” will appear. After clicking “choose file” the page will let you choose the App in which you have your videos saved, select the app in which you have stored your video [ex. Gallery app]. Then you will select the video you created on this day and after selecting the video, click on the “Upload File” blue box. The uploading process may take 1 to 5 minutes.

Daily Videos Capture

With the help of the study’s statistician, we will develop a link on the REDcap platform, this link will be set up to be sent through an email to the participants daily at the same time every day. The steps in which the participant will take to upload the video will be sent on the same Uploading Video Email in which the study staff will explain how the participants will record themselves on their videos.

G6 sensor replacement

The research staff will send a text message to the participant to remind them the date and time they scheduled the sensor replacement 48h before the sensor replacement. The research staff will conduct a Zoom phone call with each participant on day 10 to assist with sensor replacement. The replacement Zoom will be scheduled during the baseline visit. Additionally, participants will be asked about any adverse events related to the CGM sensor as listed on the RC survey form, including inputting AE and SAE. Three days before the scheduled call, the research staff will send each participant a G6-Pro application video tutorial. On the 10th day of wearing the CGM, the research staff will meet with participants via Zoom to guide them through the process of changing the G6-Pro sensor. During this meeting, the research staff will provide a step-by-step explanation of the sensor replacement procedure, allowing participants to ask any questions they may have and receive support from the research team. Participants will be reminded not to discard the used transmitter-sensor; instead, they will be instructed to place it in the envelope provided by the research staff during the baseline visit.

Before the zoom call takes place, the study staff will login into their RC account and select the G1-Study project to be able to access the participants' charts of the G1-Study. After the website takes the staff to the study page, the staff will select the tab called “Record Status Dashboard” found on the left hand of their screen. The platform will then show the list of each participant and with each form/survey involved in each phase of the study. For this activity, the study staff will choose the only survey found on the “CGM Phase” column. The study staff will have this survey open throughout the zoom call and will complete the form after the participant has successfully removed the old sensor and replaced the new G6 PRO sensor. An example of the Sensor Replacement Telephone script is provided in the Appendix _H_.

Compensation

For the CGM phase, each participant will receive $200 compensation, which will be given as gift cards. The first $100 gift card is assigned to the first 7-10 days of successful wear, and $100 is applied to the second 7-10 days of wear after replacement. Both gift cards are given to the participant at their post visit.

Post-Visit

The Post visit will take place on days 21-30, 1 to 10 days after the sensor placement date. The procedures that will take place are measuring the participants height and weight, the participant will fill out a physical activity, beverage intake, residential history, and P50 questionnaire; they will participate in a narrative semi-structured in-depth interview, fill out a CGM satisfaction survey, and self-report habit index.

The day before the visit, the study staff will send the participant an email and a text message containing the address, parking instructions, instructions to bring a piece of paper with their email address and correct password written in it, and a Google map directions link. Additionally, they will provide a study staff's cell phone contact number in case of transportation issues on the day of the visit or for rescheduling purposes. Within 48 hours of the visit, the participants will be contacted by phone to confirm their attendance.

Participant Arrival

The morning in which the Post visit takes place, the study staff will text to remind them at what time they have scheduled their visit for that day, remind the participant to bring the two worn sensors, a piece of paper with the participant's email username and correct password, specify to the participant that they can park at any unreserved parking spot at the Soto parking lot, and a google map link of the USC-Soto Campus.

The post visit will be conducted at the USC Soto building. Participants should wait in the lobby area upon arrival. Upon their arrival, the participants will be warmly greeted and thanked for coming. The study staff will again introduce themselves, present their USC ID, and remind the participant their role in the "USC Glucose Study." The study staff will verify the participants' names and ensure they are able to stay for the entire 2-hour visit. The participant will be escorted to the Soto 302D office.

Upon arrival at the 302D office, the study staff will explain to the participants the dynamics involved within the Post Visit (video recorded interview, Ravens Assessment, capture of body measurements and redcap surveys) and will make a remark that the visit will take up to 2-hours of their time. The study staff will reassure the participant is willing to go along with the Post Visit procedures.

Semi-structured in-depth interview. The interview will take place in the PI's office. The interviewer will explain to the participants that the main purpose of the interview is to capture a narrative of their personal experience with the CGM transmitter, about how their experience with the CGM sensor changed their normal behavior towards their daily diets and physical activity. The interviewer will make the remark that we are not expecting specific answers, and that we want them to give us unmasked feedback from their experience within the study. The way the interviews will be structured is described on pages 14 and 15. The research staff will use the Zoom app to record the interviews. The interviews will be recorded on the Zoom-Outlook cloud. Before the study staff starts recording the interview on the Zoom meeting, the study staff will make sure the participant fits perfectly in the camera frame, the only thing that can be shown in the background is the green screen behind the participant, the office's door must be completely shut, and all smartphones should be placed on "mute." The interview will last approximately 30 minutes.

An example of the Post-Visit Interview questions is provided in the Appendix _I_.

Anthropometric measures. The research staff will take height and weight measurements from each participant after they have completed each RC survey and have taken the Ravens task. These measurements will be taken at workstation 302-10 located in front of the PI's office where the scale/stadiometer will be placed. The measurements collected will be captured on a hard copy RC Body Measurements form.

Raven's Matrices Task

The study staff will create a Raven's Assessment for the participant and will utilize the following instructions:

The following steps apply to creating a single examinee/individual and administering the assessment one-on-one in person. These steps were created for the G1 study.

The study staff will add new participants to Q-Global:

-Select "New Examinee."

Fill in the following text boxes:

-First name: First Initial of first name

-Last name: First Initial of last name

-ID: REDCap ID

-Email

-Gender

-Birthdate

-Save

The study staff will assign Raven’s 2 assessment to the new participant/examinee:
- Click on the checkbox associated with the participant
-Select “Assign Assessment.”
-Click on “Assign New Assessment.”
-Type “Raven” in the text box
-Select “Raven’s 2 Digital LONG form
-Click on Delivery Option “In Person (On-Screen)” (left of screen)
-Click on “Save and Launch Later” (right of screen

Before the participant arrives for their visit, the study staff will login to the G1-study Q-Global account and on the “Examinee” page, they will search for the participant’s previously created assessment. To choose the correct assessment, the study staff will check the Examinee’s initials and study ID shown in the Examinee’s list. After clicking the correct examinee, the page will show a “Launch Assessment” tab, which the study staff will click once the participant is ready to start the Raven’s Assessment. The study staff will explain to the participant that the ravens Assessment is a non-verbal multiple-choice assessment that helps exercise abstract reasoning. It contains 24 multiple choice questions that are listed in order of increasing difficulty. This is a pattern recognition task. The instructions that the study staff will follow to administer the Raven’s Assessment are shown below:

1. Open Q-Global
2. Select the individual by clicking on the name or anywhere in the row
3. Select the assessment name, or click anywhere in the row
4. You are now ready to “Launch Assessment”. Before initiating the assessment, provide the participant with the following instructions:

Assessment Instructions:

1. Before launching the assessment, the study staff will read the following script to the participant:

“You will now begin the pattern exercise. First, you will see three animated samples that demonstrate how to select options to complete the pattern. Next, you will have three practice attempts to do it yourself. Once you complete the three practice samples, I will instruct you to begin the task.

The task is to select the image that best completes the pattern.

When the sound icon appears between animation and practice samples, wait for the arrow and proceed to the next screen.

You will have 20 minutes to complete 24 questions.

Upon completion, you will be prompted to close the window.”

2. Launch Assessment when ready to begin.

If there are wrong answers and/or questions during the sample questions (i.e., A, B, C), provide the participant with the following assistance:

Sample A:

Study staff will say, “The blue square (point to response option 4) goes here (point to question mark) because these are both blue (point across bottom row of stimulus area) and because these are both squares (point down the right column of stimulus area).”

Sample B:

Next, the study staff will say, “The little red circle (point to response option 2) should come next in order (point across stimulus from left to right, then point to question mark).”

Sample C:

Finally, the study staff will say, “This piece (point to response option 3) finishes the picture (point to question mark).”

3. Once the participant has completed the third sample question and before clicking the forward arrow, say the following:

“Now you know what to do. There are more pictures with missing pieces. Click the piece that finishes the picture. When the arrow turns blue, click it to see the next picture.”

Begin 20-minute Timer.

If the participant is not finished within 20 minutes, kindly ask the participant to close the window. (Do not click forward through the arrows)

Once the window is closed, the Raven’s Assessment is complete.

Computer-based surveys. The study staff will have the participants seated in the 302D office to complete the survey. The research staff will turn off the ring light and microphone, then accommodate the monitor, keyboard, and mouse in front of the participant, so the surveys can be completed in a comfortable position. The research staff will send a RC invitation to the participant by email beforehand, 1 day before the baseline visits occur. The study staff will kindly ask the participant to log into the email they initially gave during their screening call. After the participant has access to their email, ask the participant to find the email called “Post Visit” Make sure the participant has the correct email in place. After the participant has access to the Redcap surveys, select the participant’s preferred language on the Redcap platform.

The surveys the participant will complete are a physical activity survey, beverage intake survey, P50 CDC form, and residential history.

CGM Satisfaction Survey. The last survey that will prompt out is a satisfaction survey. The survey's purpose is to obtain a specific review from each participant about their entire study participation. The survey form will be captured on the RC platform.

Dietary Interview Request Form. After completing all the post visit activities, the study staff will fill out the NDSR Interview Request Form provided by the SCCLH team, which is the following:
https://forms.office.com/pages/responsepage.aspx?id=HVNizmW2rkqhdQq1FBwZ2ryFXCgLS5hMj4r325rFPwlUNkw1OE9VQzRRTEJJTjk3ME1MVjRDSkk0VyQlQCN0PWcu

P50 NDSR Dietary Call

The P50 staff will conduct a separate NDSR telephone-based interview with the participant following the completion of the post-visit. This interview will involve dietary recording prompts based on standardized protocols developed by the USDA for use in National Surveys of food intake. Claudia Rios will hold a separate interview to conduct this 45-minute assessment, utilizing 2-dimensional food models to guide portion size estimates.

Compensation. Before the study staff initiates the compensation procedure, the staff will ask the participant to return the two worn sensors. The study staff will ensure that both sensors are provided inside of each designated Ziploc baggie. The participants who participate in the entire post-visit procedures will receive two $100.00 gift cards as compensation for the completion of the Post Visit. Besides obtaining the Post Visit compensation, the participant will receive another $100.00 in gift cards for replacing the first sensor, and an additional $200 in gift cards to compensate the participant for their sensor wear for 20 continuous days. In total the participant will receive $500 in a form of gift cards to complete their entire study compensation. Throughout the study, the research staff will obtain gift cards from vendors already affiliated to USC.

G1-Continuous Glucose Monitoring Gift Card Log

To track efficient detailed records of each purchased and delivered gift card, the research staff will create a gift card log on an excel spreadsheet. When issuing a gift card to a participant, the study staff will kindly ask the participant to sign the gift card log including details on the gift card number, name of gift-card vendor, date, time, and the participant's ID that the gift card was issued to. An example of the Gift Card Log is provided in the Appendix _J_.

3.13.3 Final Study/Early Discontinuation Evaluations.

Participants should be actively followed through all study visits until the final visilt is important to note that if a study participant is discontinued from treatment, he/she should still be followed to the end of the study.

Evaluations for the final study/early discontinuation visit should be described in this section.

The Post visit will take place on days 21-30, 1 to 10 days after the second sensor has been removed. The procedures that will take place are measuring the participants height and weight, the participant will fill out a physical activity, beverage intake, residential history, and P50 questionnaire; they will participate in a narrative semi-structured in-depth interview, and complete the CGM satisfaction survey, and self-report habit index.

The day before the visit, the study staff will send the participant an email and a text message containing the address, parking instructions, instructions to bring a piece of paper with their email address and correct password written in it, and a Google map directions link. Additionally, they will provide a study staff's cell phone contact number in case of transportation issues on the day of the visit or for rescheduling purposes. Within 48 hours of the visit, the participants will be contacted by phone to confirm their attendance.

P50 dietary recall. The P50 staff will conduct a separate phone-based interview with the participant following the completion of the post-visit. This interview will involve dietary recording prompts based on standardized protocols developed by the USDA for use in National Surveys of food intake. Claudia Rios will hold a separate interview to conduct this 45-minute assessment, utilizing 2-dimensional food models to guide portion size estimates.

3.14 Concomitant Medication

Concomitant medication is not applicable with the Continuing Glucose Monitoring study.

3.15 Safety Reporting Guidelines

This section of the MOP details the definitions of and procedures for reporting AEs.

The Guidelines provide:

- *Definitions of AEs, serious AEs, and unanticipated problems*
- *Responsibilities of investigators*
- *Description of terms used in reporting.*

This section should delineate the AEs, as related to the study, serious AEs, and safety reporting procedures.

There is a potential for study participants to experience unexpected side effects. These side effects will be closely monitored by the study staff during any interaction involving the Continuous Glucose Monitoring (CGM) device or research protocol. The research coordinator will be readily available by phone in the event of a study-related participant emergency. If participant adverse events occur, the study physician will review adverse events (AEs) within two workdays and serious adverse events (SAEs) within two workdays, as well as treatment retention rates and reasons for active withdrawal. Safety information for this study will be reported to the study physician in an unblinded manner because the physician will not prepare nor analyze study data for analysis. All relevant information for each SAE, including event details and outcomes, concomitant medications, the subject's medical history, current conditions, and pertinent glucose data, will be reported to both the study physician and the Institutional Review Board (IRB) within two workdays. Subsequently, this information will undergo thorough review by the physician to determine its potential relevance to the study protocols. The physician will provide feedback about protocol alterations based on any relevant information generated from the comprehensive review of the adverse events.

There is a potential for study participants to experience unexpected side effects. These side effects will be closely monitored by the study staff during any interaction involving the CGM device or research protocol. The research coordinator will be readily available by phone in the event of a study-related participant emergency. If participant adverse events occur, the study physician will review adverse events (AEs) within four workdays and serious adverse events (SAEs) within two workdays, as well as treatment retention rates and reasons for active withdrawal. Safety information for this study will be reported to the study physician in an unblinded manner because the physician will not prepare nor analyze study data for analysis.

Reporting processes

All relevant information for each SAE, including event details and outcomes, concomitant medications, the subject's medical history, current conditions, and pertinent glucose data, will be reported to both the study physician and the Institutional Review Board (IRB) within two workdays. Subsequently, this information will undergo thorough review by the physician to determine its potential relevance to the study protocols. The physician will provide feedback about protocol alterations based on any relevant information generated from the comprehensive review of the adverse events.

3.16 Study Compliance

Protocol deviations include, but are not limited to the following:

- *Randomization of an ineligible participant*
- *Failure to obtain Informed Consent*
- *Enrollment of a participant into another study*
- *Failure to keep IRB approval up to date*
- *Wrong treatment administered to participant*

- *Outcome measurement not performed*

This section should describe what constitutes protocol deviations and the process for reporting such deviations to appropriate parties, including the study chair and site investigator, the Coordinating Center, NCCIH, and the DSMB or safety officer, within 24 hours of occurrence if possible, or as soon as they are discovered. Investigators need to follow their IRB requirements for reporting protocol deviations to the Board. In addition, if monitors discover any of these deviations during a site visit, they should list any such occurrence in their monitoring report. The Coordinating Center (for the study) and the study coordinator (for the site) should maintain a log of all protocol deviations and should report them routinely to the DSMB or safety officer. While there may be rational clinical reasons for an occasional deviation, a site with continuous problems is at risk for losing its funding. A log for recording protocol deviations should also be included in this section.

To track compliance from each participant of the study, the research coordinator will keep an up-to-date participant activity log. In this log, the coordinator will capture all phases completed an non completed from all participants that passed the prescreening phase. Each participant will be added in the Activity Log, as soon as they have prescreen passed and they have scheduled an initial visit. This log will be shared with the study's PI on a weekly basis. An example of the Participant Activity Log can be found in Appendix_K_.

3.17 Data Collection and Study Forms

This section describes the study's data collection and data management procedures and should include copies of all forms. Alternatively, they could be maintained in a separate binder.

Data Collection

The data collector plays a crucial role in this study by establishing rapport with participants and ensuring the confidentiality of their information, as outlined in the informed consent form.

The team will collect data using various methods, including computer-assisted telephone screening by the SCLLH recruiter, in-person interviews at the Soto lab by study staff, observational charting by study staff, A1c testing by study staff, CGM Clarity cloud database capture by study PI, and self-administered surveys through both computer and text-based formats. To integrate all this data into a unified dataset, we will utilize the REDCap (RC) system. The RC project, entitled the G1 Study "CGM Monitoring in Adults," acts as the central repository for our data. Study staff members are granted data entry rights to input information into the RC project, which has been designed by biostatistician My Vu. My Vu has exclusive rights to recode data post-capture to prevent errors in data files. Additionally, the P50 center common data elements (CDEs) have been incorporated into the RC system to support center-level data collection for the P50 center.

Once the participant returns the 2 sensors worn during the CGM phase, the coordinator will retrieve glucose data from each transmitter attached to the worn sensors. To obtain glucose data from the worn sensors, participants will return all sensors during their post-visit. The study staff will ensure that the glucose data is retrieved from the sensors within 20 days of the sensor being removed from the participant's arm.To collect the data, the study staff will look up the correct transmitter code, which can be found in the participant's RC records. For Sensor 1, the code will be obtained from the Baseline Visit's Body Measurement form. For Sensor 2, the code will be obtained from the Sensor Replacement Call form.

Once the study staff has retrieved the correct sensor-transmitter code, they will turn on the reader device and select the "Upload Data" option. The reader will then prompt the staff to enter the sensor-transmitter code. After entering the code, it may take up to 2 minutes for the reader to upload the data from the sensor.

After the glucose data is uploaded to the reader, the study staff will connect the reader to the office computer using the reader's USB cable and log in to the Clarity Cloud website used for the G1-Study. After accessing the G1-Study clinic's account, a list of enrolled participants will appear. The study staff will search for the participant's ID, ensuring that the ID from the sensors matches the ID in the Clarity list. After selecting the correct participant, the study staff will click on the "Upload Data" option, and the data will begin transferring from the reader to Clarity Cloud.

To verify that the glucose data was successfully uploaded to Clarity, the study staff will check the participant's record on Clarity. If the data was uploaded correctly, a new session will appear in the participant's Clarity record.

Monitoring data quality

On a monthly basis, the PI, research coordinator, and biostatistician will convene to review the quality and completeness of data. This will entail, at minimum, an overview of participant intake and retention progress; summary reports outlining participant compliance with visits, evaluations, and interventions; and a summary evaluating the completeness and quality of key data elements required for characterizing participants. These reports will serve to judge data capture and processing quality to facilitate analyses. The statistician will also update the study's master data file and variable codebook at this same interval. The codebook and data file will be in a format that has sufficient detail to be made publicly available to support research replication in the field. The P50 staff will have access rights limited to CDE items and will review data quality separately.

We are committed to protecting the confidentiality of our participants and their sensitive data. All project and data files will be stored securely in locked office files on USC secure servers and labeled with numeric codes when not being used for the study. Communication about the study will be conducted exclusively through our secure USC email system. A master list containing names and IDs will be kept in a separate, secure location for tracking purposes and data-sharing agreements. Access to this master list, which links names and code numbers, will be restricted to senior project staff only. The entire staff will closely monitor all assessment and treatment procedures. Since this study involves a low-risk non-clinical population and uses a within-subject case series methodology, there is no need to establish a Data and Safety Monitoring Board (DSMB) committee. We will implement an interval data and safety monitoring process instead.

3.17.1 Source Documentation

A source document is any document on which study data are initially recorded. These data are then transcribed to a paper CRF or electronic CRF (eCRF) to document study-specific data elements.

The study staff will maintain hard copies of signed Informed Consent Forms (ICF), USC-Image Release Form and Body Measurement forms completed at each Baseline and Post Visit. Every survey and study form will also be available as an electronic Case Report Form (eCRF) within the REDCap platform. The source documents that will be captured throughout the study will be the following:

<u>Informed Consent Form</u>: Two hard copies of the ICF will be available for each participant, one will be given to the participant to take home and the other will be. After the participant signs the ICF, the study staff will write down exact date and time of consent. Upon giving physical signed consent, the study staff will guide the participant to find the link to the electronic ICF in a previously sent email. Once the participant leaves the Soto Building, the study staff will place the signed ICF inside of a red folder titled with the participant's study ID.

<u>Image Release Form</u>: A physical Image Release form will be administered after the participant has agreed and consented to take part in the study. A physical and electronic copy of this form will be signed by each participant. Once the participant leaves the Soto Building, the study staff will place the signed Image Release Form inside of the red folder titled with the participant's study ID. An example of this form can be found in Appendix_L_.

<u>Body Measurement Form:</u> This form will be physically completed during baseline and post visits. It contains specific parameters such as weight, height, A1c levels, current medication intake, and date of when data was collected. During the baseline visit, both physical and electronic CRFs will capture weight and height data. The phlebotomy lab will record A1c glucose levels on the hard copy of the Body Measurement Form, after which study staff will transfer this data to the eCRF.

Self-Administered surveys: Different measurements will be collected throughout the study. Before the collection of various measurements, each participant had carefully read the ICF and gave voluntary written and electronic consent. These measurements will be presented as self-administered surveys will be completed using the office's computer. The study statistician has created a system in REDcap that allows study staff to email participants a unique link, which prompts various surveys upon clicking. The surveys that will be administered during the baseline visit will be the Physical Activity survey, Demographics Survey, Beverage survey, and a Behavior survey. During the Post Visit the surveys that will be administered are the Physical Activity survey, Behaviors survey, Beverages survey, CGM satisfaction survey, and a Residential History Questionnaire. The data collected from these surveys will be efficiently captured in the electronic data capture system previously mentioned.

Gift Card Log: The study staff will have a hard copy of a Gift Card Log that will detail specific information of each purchased gift card such as: name of vendor, sequential card number, amount, participant ID, participant's signature, date and time in which the gift card was given. All gift card logs will be kept inside of a yellow manila folder titled: G1-Study Gift Card Log. This folder will be put in a locked cabinet of the Research Coordinator. A sample of what the log will look like is found in Appendix_J_.

Screening Log: The SCCLH team will provide a weekly list of interested potential participants, including their email addresses and phone numbers. Study staff will create an Excel sheet with a unique screening ID for each participant. The Excel log will contain the participant's name, phone number, dates of four contact attempts, the date of screening, and the outcome of the screening call. This screening log will be accessible only to the Principal Investigator (PI) and the study coordinator. It will be securely stored in USC's OneDrive files. A sample of what the log will look like is found in Appendix_B_.

Participant Activity Log: Once participants have passed the initial screening call and a baseline visit has been scheduled by the study coordinator, they will be added to the Participant Activity Log. This log will include the participant's study ID, which will also correspond with the REDCap study ID. The coordinator will use the activity log to record the date of the initial visit, whether the participant was enrolled in the study, the date of the Sensor Replacement Zoom Call, the date of the Post Visit, any Adverse Events presented by the participant, and the date of the event. A sample of this log can be found in the Appendix. Like the screening log, this log will only be accessible to the PI and the study coordinator and will be stored in USC's secured OneDrive files. Upon completion of the study, the coordinator will print a copy of the completed log and store it in a manila folder labeled "G1-Study Participant Logs. A sample of what the log will look like is found in Appendix_L_.

3.17.2 Participant Binder

All essential study documents are stored and filed by the study staff in a red participant folder containing the participant study ID, and stored in a locked cabinet in the PI's office Soto building 302D. The folder contains the following documents:

- Body Measurement Form (e.g., height, weight, A1C results, transmitters, etc.)
- Signed Informed consent form (ICF)
- Signed Image Release form
- Two-transmitters labeled "1" and "2"
- Hard copies of surveys for the participants that cannot access their electronic surveys.

3.17.3 Study Forms

Data must be collected consistently across participants and sites so that any variability is limited to participants' individual responses to the intervention. Study CRFs provide the vehicle for consistent data collection. In this section of the MOP, please provide:

- *Study forms and their collection schedule*
- *Description of each study form and questionnaire*
- *Format for forms production and distribution along with contact person*
- *Forms maintenance*.

Throughout different phases of the G1-study the team will collect different forms using various methods. To integrate this various data into a unified dataset, the REDCap (RC) system will be utilized. The RC project, titled "The G1 Study: CGM Monitoring in Adults," serves as the central data repository. Study staff members have data entry rights to input information into the RC project, which has been designed by a biostatistician.

The study staff will maintain hard copies of signed Informed Consent Forms (ICF), USC-Image Release Form and Body Measurement forms completed at each Baseline and Post Visit. Every survey and study form will also be available as an electronic Case Report Form (eCRF) within the REDCap platform.

Screening phase

During the screening procedure the study staff will fill out the ***Screening form*** through the electronic data capture system used in this study. This form collects demographic, anthropometric, and information from all participants to produce descriptive variables (i.e., age, sex, race, race/ethnicity, zip code) as well as assess medical history of chronic disease, current medical diagnosis, and current medications to determine eligibility. A sample log is presented in…

Baseline Visit

Different forms will be collected throughout this visit. Before the collection of various measurements, each participant will carefully read the ICF and give voluntary written and electronic consent. These forms will be presented as self-administered surveys and will be completed using the office's computer. The study statistician has created a system in REDcap that allows study staff to email participants a unique link, which prompts various surveys upon clicking. The forms administered during this initial visit are the following:

1. Informed Consent Form: Two hard copies of the ICF will be available for each participant, one will be given to the participant to take home and the other will be signed by the participant and by the staff that oversees the consent process. The ICF gives detailed information regarding all the study's activities, the purpose of the study, benefits from participating, potential risks upon participation, duration of their participation in the study and total compensation for their participation. After the participant signs the ICF, the study staff will write down exact date and time of consent. Upon giving physical signed consent, the study staff will guide the participant to find the link to the electronic ICF in a previously sent email. This email will contain a link that will initially prompt out electronic ICF. The study staff will ensure that each participant gives electronic consent as well. Once the participant leaves the Soto Building, the study staff will place the signed ICF inside of a red folder titled with the participant's study ID.
2. USC-Image Release Form: Throughout the study, each participant will be asked to volunteer and contribute to the creation of video content. Participants will be asked to submit daily videos describing their food intake, glucose levels, and behaviors during the glucose sensor wear phase. During the final visit, each participant will participate in a video-recorded interview. For this purpose, an Image Release form will be administered after the participant has agreed and consented to take part in the study. This form establishes an agreement between the participant and the study team, outlining that any video content shared by the participant will be reviewed by the G1-study team and may be used in the future for educational purposes. A physical and electronic copy of this form will be signed by each participant. Once the participant leaves the Soto Building, the study staff will place the signed form inside of a red folder titled with the participant's study ID.
3. Body Measurement Form: This form will be physically completed during baseline and post visits. It contains specific parameters such as weight, height, A1c levels, current medication intake, and more. During the baseline visit, both physical and electronic CRFs will capture weight and height data. The phlebotomy lab will record A1c glucose levels on the hard copy of the Body Measurement Form, after which study staff will transfer this data to the eCRF.
4. Demographic Survey: Study team will collect information from all participants to produce descriptive variables (i.e., age, sex, race,

race/ethnicity, zip code) as well as assess medical history of chronic disease, current medical diagnosis, and current medications to determine eligibility. Eligibility criteria include current PdS, prediabetes risk, aged 18 years or older adult in California, self-identified Latino/Hispanic ethnicity, and willing to participate in a study. This measurement will be presented as self-administered surveys will be completed using the office's computer. The study statistician has created a system in REDcap that allows study staff to email participants a unique link, which prompts various surveys upon clicking. A sample of this form can be found in Appendix_M_.

5. Beverage Survey: This assessment will be presented as a self-administered survey completed using the office computer. The survey will inquire about the participant's intake of various beverages over the past seven days. Participants will respond using a multiple-choice format, selecting answers that range from 0 days to 7 days for each specific beverage. The survey data will be recorded in the previously mentioned electronic data capture system. A sample of this form can be found in Appendix_N_.
6. Behaviors Survey: This assessment will be presented as a self-administered survey completed using the office computer. The survey will inquire about the participant's various behaviors over the past seven days. The different behaviors listed in the survey are meditation activities, pain relieve intake, vitamin C intake, prescribed medication intake, alcoholic drinks intake, use of cigarettes or vape and yoga activities. Participants will respond using a multiple-choice format, selecting answers that range from 0 days to 7 days for each specific behavior. The survey data will be recorded in the previously mentioned electronic data capture system. A sample of this form can be found in Appendix_O_.
7. Physical Activity Survey: The International Physical Activity Questionnaire (IPAQ) is a self-reported tool designed to assess physical activity levels in adults aged 18-65 years. IPAQ collects information on the frequency, duration, and intensity of physical activities across four domains: work-related activities, transportation-related activities, domestic and household chores, and leisure-time activities, including recreational and sports activities. Participants recall their physical activity behaviors over the past 7 days, reporting the time spent in various activities at different intensity levels: vigorous-intensity activities, moderate-intensity activities, and walking. Total physical activity levels are calculated by summing the duration and frequency of activities across all domains. This assessment will be presented as a self-administered survey completed using the office computer. The survey data will be recorded in the previously mentioned electronic data capture system. A sample of this form can be found in Appendix_P_.

CGM Phase

The sensor wear phase can last up to 20 continuous days. During this phase various forms can be collected. The forms pertaining to this phase are the following:

1. G6 Replacement Call: The research staff will conduct a Zoom phone call with each participant on day 10 to assist with sensor replacement. Before the zoom call takes place, the study staff will login into their RC account and select the G1-Study project to be able to access the participants charts of the G1-Study. Once the study staff has access to the specific participant chart; the study staff will then click on the form labelled "G6 Replacement Call" in the REDcap project. This form collects information regarding date and time in which the Zoom call takes place, if the sensor was removed and replaced by the second sensor. If the sensor was not replaced, the study staff will type the reason in the comment section that prompts out after selecting that the participant did not replace the G6 sensor. The form also collects the transmitter code of the second sensor and contains a section to specify where the participant stored the glucose sensor kit prior to the sensor replacement. A comment section is added at the end of the form in which the study staff will be able to add any other related information or data collected throughout the Zoom call with the participant. A sample of this form can be found in Appendix_Q_.
2. Adverse Event form: This form will be used in case of any untoward unexpected event is reported by the participants. The events that will be captured in this form are signs or symptoms that the participants report throughout the study, CGM errors that participants present throughout the CGM wear phase including glucose sensor detachment. In cases where a participant reports any symptoms or any CGM related issue, the research staff will reach out to the participant via phone call. During this call, the study staff will ask for details about the errors shown in the Dexcom Apps. The study staff will fill out an Adverse Event/CGM Error form in the RC platform. In this form, the study staff will specify the date and time when the CGM error started and when the error or issue was resolved. This form includes a comment section in which the study staff will type a detailed explanation of the symptoms or issues that the participants express throughout the phone call. Once the issue has been resolved, the study staff will reach out to the PI within 24 hours to report that an AE/CGM error form was completed for a participant and describe the case to the PI. A sample of the form can be found in Appendix_R_.

Post Visit

Different forms will be collected throughout the last visit. These forms will be presented as self-administered surveys and will be completed using the office's computer. The forms administered during this initial visit are the following:

1. Body Measurement Form: This form will be physically completed during baseline and post visits. It contains specific parameters such as weight, height and current medication intake. During the baseline visit, both physical

and electronic CRFs will capture weight and height data. After the participant leaves the Soto building, the study staff will transfer this data to the eCRF.

2. Physical Activity Survey: This assessment will be presented as a self-administered survey completed using the office computer. Details of what this survey entails can be found in page 54.
3. Beverage Survey: This assessment will be presented as a self-administered survey completed using the office computer. Details of what this survey entails can be found in page 54.
4. Behaviors Study: This assessment will be presented as a self-administered survey completed using the office computer. Details of what this survey entails can be found in page 54.
5. Residential History Survey: This assessment will be presented as a self-administered survey completed using the office computer. This survey collects data regarding residential status of each participant. Questions regarding current and previous home address will be found in the survey. A sample of this survey can be found in Appendix_S_.
6. P50 CDC questionnaire: This assessment will be presented as a self-administered survey completed using the office computer. The survey data will be recorded in the previously mentioned electronic data capture system. This survey is a national health survey. It will cover a wide range of health topics, including doctor visits, medical conditions, health insurance, and physical activity. This questionnaire has three parts: a core component, optional modules, and state-added questions. The core component includes questions on demographic characteristics and current health behaviors. A sample of this form can be found in Appendix_T_.
7. CGM Satisfaction Survey: A post-survey will record the number of times a Dexcom app was viewed. The survey consists of multiple-choice questions to quantify % answers correct out of 20 questions that make direct reference to the CGM .app to verify if it was understood. Additionally, it asks for qualitative feedback on the videos and if there are any recommendations for further improvement. This assessment will be presented as a self-administered survey completed using the office computer. The survey data will be recorded in the previously mentioned electronic data capture system. A sample of this form can be found in Appendix_U_.

3.17.4 General Instructions for Completing Forms

According to ICH Good Clinical Practice (GCP) guidelines, all data recorded on study forms must be verifiable in the source documents maintained by the study site(s). Instructions for completing CRFs ensure quality and consistency in data collection. In this section of the MOP, please provide a set of instructions for completing CRFs. Some useful and frequently used examples are listed below:

Sample instructions:

When completing paper study forms, PRINT IN CAPITAL LETTERS using black ink. Note, participants must not be identified by name on any study document submitted with the forms (e.g., ECG tracing, lab reports). Replace the participant's name with the participant initials and ID number.

- ***Header:*** *Complete the header information on EVERY page, including pages for which no study data are recorded.*
- ***Participant ID:*** *The participant ID must be recorded on EVERY page, including pages for which no study data are recorded.*
- ***Time:*** *Use a 24-hour clock (e.g., 14:00 to indicate 2 p.m.) unless otherwise specified.*
- ***Dates:*** *All dates must be verifiable by source documents. Historical dates are sometimes not known (e.g., date of first symptom); therefore, conventions for missing days and/or months should be described (e.g., UNK or 99).*
- ***Abbreviations:*** *Use of abbreviations not specifically noted in the instructions for completing the forms can be problematic and should be held to a minimum.*
- ***Correcting errors:*** *If an error has been made on the study forms, place a <u>single</u> line through the erroneous entry and record the date and your initials. Indicate the correct response.*
- ***Skipping items:*** *Do not skip any items. Some items may carry "Unknown" or "Not Applicable" response choices which should be selected when necessary.*
- ***Incomplete data:*** *Data may not be available to complete the form for various reasons. Circle the item for which information is not available and indicate the reason near the appropriate field:*

- *If an evaluation was <u>not done</u>, write ND and provide a reason.*
- *If the information is <u>not available</u>, but the evaluation was done, write <u>NAV</u>.*
- ***Note: Only in rare circumstances, as in the case of lost documentation,*** *should NAV be recorded on the form. Every effort should be made to obtain the information requested.*
- *If an evaluation is <u>not applicable</u>, write <u>NA</u>.*
- ***Incomplete or Illegible forms:*** *Incomplete forms that do not have adequate explanation (as described above) compromise the integrity of the entire study. Errors, such as incomplete or illegible forms, are problems that require time and energy to resolve.*

In this section of the MOP, a set of guidelines for incomplete or illegible forms must be included. For example:

- *If an entire page of the form cannot be completed (e.g., no parts have any responses), and it is unlikely that it will be completed, draw a diagonal line* *through the form and write NOT DONE, NOT AVAILABLE, or NOT APPLICABLE, as appropriate.*

- *The header information must be completed even though no data are recorded on the form. If a form can only be partially completed at the time of monitoring, but will be completed when the information becomes available, follow the direction of the clinical monitor.*
- *Do not leave forms incomplete or unused without explanation.*

During the screening call, the study team logged into the RC system. The administrative staff navigated to "My Projects" > "Continuous Glucose Monitoring in Adults - G1 Study" and selected the "Record Status Dashboard" tab on the left-hand side. From there, they clicked on "Add New Record," prompting a table labeled "Data Collection Instrument" to appear. Within this table, the administrative staff selected the "Screening Call" option, triggering the generation of a unique RC ID for the participant. The staff member then input the data collected during the screening call in real time, ensuring all entries were accurate and complete before submission.

During the baseline visit, three source documents were collected by the study staff: two completed by each participant and one by G1 staff. Before the participant's arrival, the study staff printed two hard copies of the IRB-approved ICF form, one copy of the USC-Image Release form, and one copy of the Body Measurement form from the RC platform. After participants agreed to participate, the study staff guided them to sign sections of the ICF and Image Release form designated for participants. Once signed, the study staff reviewed the forms to ensure accuracy and then signed the "Collected by" section.

For data collection on the Body Measurement form, study staff prepared hard copies and using a black or clue inked pen would correctly enter the participant ID, date, and time of data collection. A1c levels were obtained by G1-study trained phlebotomists. Before providing the Body Measurement form to the phlebotomy staff, the RC system was used to input the participant ID, date, and time. Following A1c collection, participants returned to the office, where height and weight were measured using the Tanita-3000 scale and stadiometer. The study staff recorded these measurements on the Body Measurement form. Participants were then asked about any prescribed medications, which were documented with correct dosages. The study staff also collected a sticker containing the sensor code from each Dexcom G6-Pro kit.

During the post-visit, the Body Measurement form was completed, except for A1c levels and glucose sensor codes, which were marked as "Not Applicable."

3.18 Data Flow

It is the site's responsibility to ensure that all forms are complete, intact, and transmitted to the data manager in a single site study or to the Coordinating Center, as appropriate. More recently, in some studies, data are directly entered into an eCRF.

This section of the MOP describes the:

- *Disposition of study forms or data entry into the computer system*
- *Schedule for completion and transmission of forms*
- *List of forms for which copies are to be maintained at the site and forms to be submitted for data entry*
- *Data flow, data entry, and data correction procedures.*

Data is collected in REDCap and Dexcom Clarity. All variables in REDCap are marked as "required" where user will not be able to save the page if required fields are incomplete to minimize missing data. Most variables in REDCap are configured as checkboxes or radio buttons to avoid data entry errors.

The forms that will always be physically available at the study site are hard copies of signed Informed Consent Forms (ICF), USC-Image Release Form and Body Measurement forms completed at each Baseline and Post Visit. Every survey and study form will also be available as an electronic Case Report Form (eCRF) within the REDCap platform.

Data Flow:

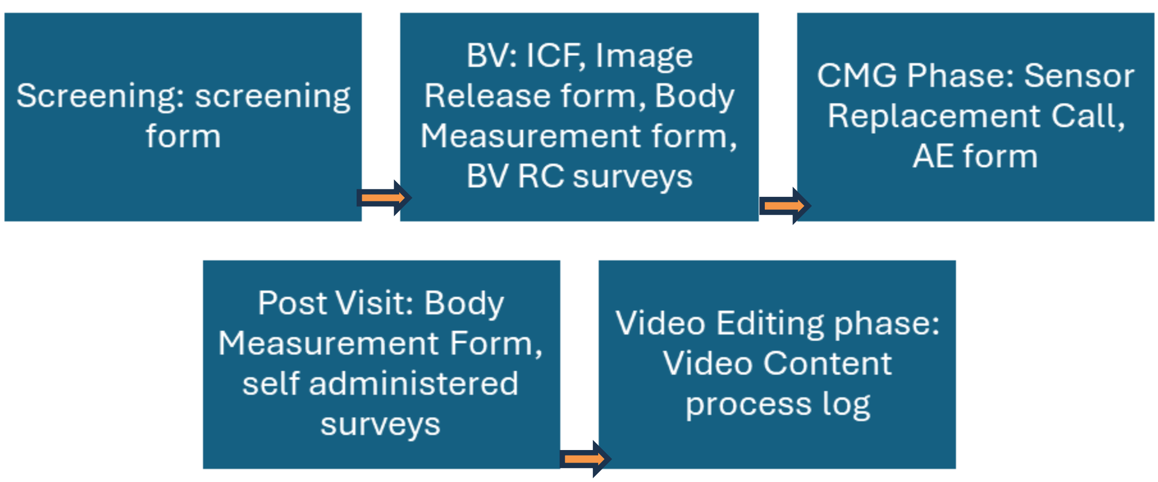


Figure _I_ G1 Study Data Flow

3.19 Administrative Forms

Administrative forms provide documentation of study processes and assist with study operations. They may include the following, as relevant:

- ***Telephone Contact Log****—serves as a record of all conversations regarding the study and study participants.*
- ***Screening Log****—is a record of all individuals screened for participation in the study. It should be arranged chronologically and be kept up to date at all times.*
- ***Participant Identification Code List****—is a record of the participant's name, medical record number, randomization number, and study entry and exit dates. Due to the confidential nature of this information, it should be maintained in a secure location, apart from other forms and data files at the study site. The information contained in the list must be maintained by the site for a period stipulated by NCCIH, the site institution, or other relevant body.*
- ***Protocol Deviation Log****—is used to document deviations from the protocol as they are identified by participants.*
- ***Study Drug Accountability Record****—should be maintained in the Pharmacy by the research pharmacist and must not be shared with other members of the study team.*
- ***Record of Destruction of Clinical Product****—is a log used to document the destruction of any unused study drug. The date and time of incineration as well as how many vials/pills were incinerated must be recorded. This record should be attached to the Study Drug Accountability Record.*
- ***CRF Transmittal Sheet****—serves as a cover page for each packet of CRFs submitted for data entry. It provides an inventory of the forms that are included in each mailing.*
- ***Signature Log****—contains the signature of all members of the site study team. It is the responsibility of the PI and/or clinical research coordinator to:*
  - *Designate individuals authorized to perform outcome measurements, make form entries and changes, and*
  - *Note the date when any study team member is removed from the team for any reason.*
- ***Site Visit Log****—records individuals visiting the site. The most common reasons for visits are site initiation, monitoring, training, and closeout.*

The administrative forms will be completed by the coordinator of the study and will be shared with the study's PI. The administrative forms that are used throughout the study are the following:

Prescreening Log: The SCCLH team will provide a weekly list of interested potential participants, including their email addresses and phone numbers. Study staff will create an Excel sheet with a unique screening ID for each participant. The Excel log will contain the participant's name, phone number, dates of four contact attempts, the date of screening, and the outcome of the screening call. This screening log will be accessible only to the Principal Investigator (PI) and the study coordinator. It will be securely stored in USC's OneDrive files.

Participant Activity Log: Once participants have passed the initial screening call and a baseline visit has been scheduled by the study coordinator, they will be added to the Participant Activity Log. This log will include the participant's study ID, which will also correspond with the REDCap study ID. The coordinator will use the activity log to record the date of the initial visit, whether the participant was enrolled in the study, the date of the Sensor Replacement Zoom Call, the date of the Post Visit, any Adverse Events presented by the participant, and the date of the event. A sample of this log can be found in the Appendix. Like the screening log, this log will only be accessible to the PI and the study coordinator and will be stored in USC's secured OneDrive files. Upon completion of the study, the coordinator will print a copy of the completed log and store it in a manila folder labeled "G1-Study Participant Logs.

Gift Card Log: The study staff will have a hard copy of a Gift Card Log that will detail specific information of each purchased gift card such as: name of vendor, sequential card number, amount, participant ID, participant's signature, date and time in which the gift card was given. All gift card logs will be kept inside of a yellow manila folder titled: G1-Study Gift Card Log. This folder will be put in a locked cabinet of the Research Coordinator. A sample of what the log will look like is found in Appendix…

Video Content Editing Progress: All of video content collected from all the participants will be edited using the Descript platform. The coordinator has created an editing progress log in which details how many transcript files have been obtained from the Descript app after video content upload, what transcript files have been reviewed and corrected by the coordinator. This logs also captures specific problems found in the transcript files such as audio quality and grammar errors. This log will be share with the study PI and G1-study cinematic arts staff through a USC secured One Drive file. A sample of what the log will look like is found in Appendix_V_.

3.20 Retention of Study Documentation

The length of time all study files are to be maintained is specified in this section. NIH policy requires that studies conducted under a grant retain participant forms for **3 years**, while studies conducted under contract must retain participant forms for **7 years**. Individual IRBs, institutions, states, and countries may have different requirements for record retention. Investigators should adhere to the most rigorous requirements and should retain forms and all other study documents for the longest applicable period.

3.21 Data Management

This section should describe the computer system and data management approach that will be used to support the study and details on how data are to be collected, entered (e.g., if eCRFs are used), edited, and corrected. For studies that involve a large number of sites and/or participants, the investigators may wish to consider a computerized approach for data collection.

Whether using a computerized approach or manual procedures, investigators should consider utilizing systems or procedures that encompass the following functions:

- ***Data Tracking****—to provide the status of enrollment, number of forms completed at the sites and number of forms transmitted to a Coordinating Center or lead site, as appropriate*
- ***Data Entry****—that is easy to use and minimizes errors, such as facsimiles of the forms*
- ***Data Editing****—that identifies out-of-range and missing entries, errors in dates and logical inconsistencies (e.g., first treatment date precedes protocol start date or protocol specifies an examination before randomization, but the examination form is missing)*
- ***Updating****—to correct data and maintain an audit trail of all data changes*
- ***Reporting****—to describe and account for accrual, forms entered and completed, etc.*
- ***Statistical Analysis****—mechanism to transmit data to statistical analysis packages (e.g., SAS).*

Investigators should involve staff or colleagues with data management experience to assist with the determination of the data flow, transfer of data from sites in a multicenter study, error identification and resolution, development of useful reports, and deriving a frozen, analytic database from edited or "clean" records. These areas should be discussed in this section.

A Users Guide may need to be developed as a separate document to aid the study staff with data management tasks.

Investigators should be aware that computerized systems used in studies that will be submitted to the FDA must be documented and validated. Guidance for electronic systems is found on the FDA Web site, Title 21 Code of Federal Regulations (21 CFR Part 11) Electronic Records; Electronic Signatures http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm.

Data is collected in REDCap and Dexcom Clarity. All variables in REDCap are marked as "required" where user will not be able to save the page if required fields are incomplete in order to minimize missing data. Most variables in REDCap are configured as checkboxes or radio buttons to avoid data entry errors. However, for free text fields such as heights, weights, dates, etc., there are built-in validation checks (i.e., appropriate ranges) where possible. These are 'soft limits' in which out-of-range values are identified and the data enterer is alerted to correct the values immediately.

A series of additional data checks will also be conducted external to REDCap. Every week, all data will be downloaded from REDCap using the REDCap API. R scripts will be run by study statistician to tabulate missing data and to perform cross-form consistency checks. If inconsistencies or queries are noted, the statistician will inform the study staff to make necessary corrections. Errors will be fixed directly in REDCap.

3.21.1 External Data

External data refers to data sent to or collected at a study organizational component other than a clinical site (e.g., central laboratory, imaging facility, etc.) This section of the MOP should describe how this information will be collected, labeled, handled, shipped, tracked and reconciled, so that study data are not lost. As stated in the HIPAA guidelines, personal identifiers such as name, geographic location, social security number, and 15 other specific individual identifiers should not be used. Therefore, it is important to specify how participant materials will be coded (e.g., by participant identification number) during transmission.

External Data is not applicable for the Continuing Glucose Monitoring study.

3.22 Quality Control Procedures

Data integrity and study credibility depend on factors such as ensuring adherence to the protocol, obtaining complete followup information on all participants enrolled, and using quality control measures to establish and maintain high standards for data quality. A quality control plan should be developed before the study starts and adhered to through completion. It may include standard operating procedures (SOPs), data and forms checks, onsite monitoring, numerous reports, and problem correction procedures. This section should detail the various aspects of the plan and describe any training and certification procedures.

<u>Data Integrity Procedure</u>: As mentioned in previous section on a weekly basis, the PI, research coordinator, and biostatistician will convene to review the quality and completeness of data. This will entail, at minimum, an overview of participant intake and retention progress; summary reports

outlining participant compliance with visits, evaluations, and interventions; and a summary evaluating the completeness and quality of key data elements required for characterizing participants. These reports will serve to judge data capture and processing quality to facilitate analyses. The statistician will also update the study's master data file and variable codebook at this same interval. The codebook and data file will be in a format that has sufficient detail to be made publicly available to support research replication in the field. The P50 staff will have access rights limited to CDE items and will review data quality separately.

Personnel Training: Staff training is important to quality control. Once a new staff has been integrated to the G1-Study, prior to delegation of study related activities the new staff will complete trainings that have been listed in page 15 of this manual. On a Monthly basis the coordinator will review the iStar system to review that the G1-study staff has up-to-date trainings.

3.22.1 Standard Operating Procedures

One aspect of site quality control is a set of SOPs. They describe a site's generic procedures that may have been developed to assist with standardization across studies. SOPs may include laboratory and pharmacy procedures, and storage of study documents. As relevant, SOPs should be developed by a site to ensure quality studies and study staff should be trained on them. The SOPs should be in a central location and made easily available to staff for reference.

SOPs that relate to conduct of clinical trials should be listed in this section of the MOP. Note: printed SOPs should not be inserted in the MOP, as printed versions of SOPs should be limited in order to maintain version control. The location of each SOP (i.e., electronic file name) can be included in this section.

Details of each study visit activities such as consent process, self-administered baseline visit surveys, glucose sensor application, Dexcom applications Bluetooth pairing and compensation procedure can be found in the file *G1. Study Manual.* The research coordinator and phlebotomist created a protocol for finger pricking protocol called *A1cNow Protocol.* For the Ravens assessment delivery, the G1-study staff created a file with detailed instructions that guides the research staff to deliver this assessment. The protocol of Ravens assessment can be found in the G1_*Q-Global_Ravens* file.

3.22.2 Data and Form Checks

Data and form checks depend upon the complexity of the study. Data quality control checks may identify potential data anomalies such as:

- *Missing data or forms*

- *Out-of-range or erroneous data*
- *Inconsistent and illogical over-time dates*
- *Fields on a "completed form" are actually not completed; or no reason for missing data is provided.*

If the study is using electronic data forms, provide a summary of data and form checks that will be implemented for data quality control.

CGM data will be checked periodically throughout the week by study statistician and study staff via Dexcom Clarity to ensure participants' CGM data is being transmitted. If there are any gaps in the data, study staff will contact participants to obtain information on reasons for missing data and resolve any issues within the next day (connectivity, sensor error and failure, etc.). At the post visit, study staff will collect participants' transmitters. Data from transmitters will then be uploaded into Clarity using readers to ensure CGM data completeness.

3.22.3 Double Data Entry

In recent years, there have been several articles written on the value of double data entry. While conventional wisdom used to insist upon double data entry, it may be of questionable value, especially if the data entry system provides edits as data are entered. Double data entry is still recommended for cases in which data entry staff enters data "heads down" or with no edits flagged as the data are entered.

As mentioned in previous section CGM data will be checked periodically throughout the week by study statistician and study staff via Dexcom Clarity to ensure participants' CGM data is being transmitted. If there are any errors in the data, study staff will contact participants to obtain information on reasons for missing data and resolve any issues within the next day (connectivity, sensor error and failure, etc.). At the post visit, study staff will collect participants' transmitters. Data from transmitters will then be uploaded into Clarity using readers to ensure CGM data completeness.

3.22.4 Site Monitoring

In multisite studies, a Coordinating Center may conduct periodic site monitoring visits during the study.

The purposes of monitoring visits are to:

- *Ensure the rights and safety of participants*
- *Confirm that the study is conducted in accordance with GCP guidelines*
- *Ensure maintenance of required documents*
- *Verify adherence to the protocol*

- *Monitor the quality of data collected*
- *Ensure accurate reporting and documentation of all AEs and unanticipated problems.*

During monitoring visits, the data recorded on CRFs are reviewed and verified against source documents to ensure:

- *Informed consent has been obtained and documented in accordance with IRB/FDA regulations*
- *The information recorded on the forms is complete and accurate*
- *There are no omissions in the reports of specific data elements*
- *Missing examinations are indicated on the forms*
- *Participant disposition when exiting the study is accurately recorded.*

Site investigators must ensure that the monitor has access to all study documents, including informed consent forms, intervention accountability records, and source documents.

Once the site visit is complete, a site monitoring report is drafted to provide feedback regarding any problems or issues that may have been uncovered during the visit. The report should state the problems uncovered during the visit and describe recommendations to correct them. A timeline should be agreed upon and included in the report to ensure that followup of the issues is completed and implemented into the study's procedures.

In this section of the MOP, please describe the monitoring plan, including a planned monitoring timeline.

Not applicale for G1-Study, is not a multi-site study.

3.23 Reports

Once a study begins, routine reports prepared by the Coordinating Center or study statistician are an important quality control tool. Monthly reports may describe target and actual enrollment by site and in aggregate, individuals screened with reasons for screen failure, and participant disposition (enrolled; active, completed, and discontinued treatment; and lost to followup). Monthly reports can also list or summarize AEs and SAEs. Administrative reports can list the forms completed, entered, and missing and/or erroneous data and forms. DSMB/independent monitor(s) and NCCIH will specify the type and frequency of reports they wish to receive. Other reporting requirements (e.g., to local IRBs and other regulatory bodies) should also be described.

In this section of the MOP, please discuss the types and frequency of the reports that will be prepared, and the members of the study team who are responsible for their completion.

On a weekly basis, the PI, research coordinator, and biostatistician will convene to review the quality and completeness of data. This will entail, at minimum, an overview of participant intake and retention progress; summary reports outlining participant compliance with visits, evaluations, and interventions; and a summary evaluating the completeness and quality of key data elements required for characterizing participants. These reports will serve to judge data capture and processing quality to facilitate analyses.

The participants will reach out to the research coordinator to report any Adverse Event or CGM error. The research coordinator will then report every Adverse Event or CGM error to the PI in the first 24 hours after a participant has reported any untoward event. The PI and research coordinator will meet on a weekly basis to review Adverse Events reported throughout the week and what prevention plan will be implemented to ensure the well-being of all the G1-study participants. All CGM related events will be reported during this meeting.

Any issue related with the glucose sensor equipment will be reported to the Dexcom contact to ensure accurate glucose data collection from participants. No glucose, personal or identifiable data from participants will be shared with Dexcom personnel. Any updates or changes in the sensor system will be shared by the Dexcom personnel to the study's PI.

Annually during the study, the PI, Center PI, and study physicians will prepare a summary report of its findings regarding safety and quality based on data received to that point in the study. This report will include a summary of all safety findings and an assessment of protocol compliance and data quality. Any recommendations to improve participant safety, protocol adherence, or data quality will be made in the annual report. A copy of the annual report will be sent to the local IRBs along with the annual renewal. The PI will maintain all IRB continuing reviews and keep documents up to date with IRB.

3.24 Data and Safety Monitoring Activities

We commit to safeguard the confidentiality of participants and their protected data. Project and data files, when not in transit for study purposes, must be stored exclusively in locked office files, on USC secure servers, and/or identified by numeric codes. Communication regarding the study should be conducted solely through our secured USC email system. A master list containing names and IDs will be maintained in a separate, secure location as required for tracking purposes and data sharing agreements. Access to this master list, which links names and code numbers, will be restricted to senior project staff only. The entire staff will closely monitor all assessment and treatment procedures. Given that this lower-risk study involving a non-clinical population utilizes a within-subject case series methodology, there is no need *to establish a Data and Safety Monitoring Board (DSMB) committee. We will apply an interval data and safety monitoring process in this respect.*

Safety monitoring activities by the DSMB or independent monitor(s) include: reviewing the protocol with emphasis on data integrity and participant safety issues, monitoring AEs, protecting the confidentiality of the data, and making recommendations to NCCIH and the PI regarding the study and its progress. This section of the MOP should present a data and safety monitoring plan and name the members of the monitoring body.

To assist in preparing a monitoring plan, generic monitoring plans for studies requiring a DSMB or independent monitor(s) are available on the NCCIH Web site. The generic plans describe the monitoring procedures required by NCCIH.

The study statistician will conduct series of periodical data checks to REDCap system. Every week, all data will be downloaded from REDCap using the REDCap API. RC scripts will be run by study statistician to tabulate missing data and to perform cross-form consistency checks. If inconsistencies or queries are noted, the statistician will inform the study staff to make necessary corrections. Errors will be fixed directly in REDCap.

The study statistician and the coordinator will meet on a weekly basis to review all forms collected from each participant. This review will ensure that each study form has accurate data and that there is no missing information on each completed form. Additionally, the statistician and coordinator will log into the Clarity platform to check that glucose data is being collected from all active participants. If any errors are shown on glucose data, the coordinator will reach out to participant to ask what errors are preventing data collection and the coordinator with the help of the PI will guide each participant to solve CGM errors that block glucose data collection.

3.25 Study Completion and Closeout Procedures

Study closeout activities are performed to confirm that the site investigator's study obligations have been met and post-study obligations are understood. This section of the MOP should briefly outline the study completion and closeout procedures. Details should be included in the subsequent sections. Examples of closeout activities include, but are not limited to, the following:

- *Verification that study procedures have been completed, data have been collected, and study intervention(s) and supplies are returned to the responsible party or prepared for destruction*
- *Comparison of the investigator's correspondence and study files against the Coordinating Center's records for completeness*
- *Assurance that all data queries have been completed*

- *Assurance that correspondence and study files are accessible for external audits*
- *Reminder to investigators of their ongoing responsibility to maintain study records and to report any relevant study information to NCCIH*
- *Assurance that the investigator will notify the IRB of the study's completion and store a copy of the notification*
- *Preparation of a report summarizing the study's conduct*
- *Participant notification of the study completion*

Before determining that the study has been completed, the PI, statistician and research coordinator will confirm that appropriate source documentation is present for all subjects. To do so the research coordinator will review each participant file to ensure that all CRFs have been completed, collected, and the proper legible copies are present in study files.

The G1-study statistician will confirm that all electronic CRFs have been completed and submitted to the REDcap platform. The statistician will confirm as well that all data is entered into the database and will ensure that all AEs, UPs, and SAEs have been captured, followed, and resolved per protocol, and reported to the appropriate parties.

The PI, statistician and research coordinator will meet to confirm that all data was collected appropriately and that there is no missing data before the study closeout.

3.25.1 Participant Notification

The PI and study staff or Coordinating Center should develop a letter to notify participants that the study is completed, ask whether they would like to be informed of the results, and thank them for their participation.

In this section of the MOP, please describe a plan for notifying participants about completion of the study

Upon completion of the study, the study staff will reach out to participants through an email. In the email, the study staff will notify the participants that the study has been completed. Participants will be notified that the results of the study are found in clinicaltrial.gov website. The study staff will thank each participant for their participation and will share link to clinical trials website.

3.25.2 Site Procedures

The study leadership may also wish to provide certificates of appreciation to sites that met or exceeded their recruitment goals, provided high quality data, and ensured adequate participant retention.

After the completion of the study, the PI will reach out to the CHLA staff through an email, within this email, the PI will congratulate the CHLA team for their community engagement efforts throughout the G1-study. The PI will share that the desired population was enrolled and completed all of the study activities. The PI will ask for any advice from the CHLA for the possible continuation of the study.

3.26 Policies

The MOP also contains the study's policies, such as confidentiality and publication policies.

Please provide these policies in this section of the MOP.

3.26.1 Confidentiality Procedures

It is the responsibility of the study leadership to outline and enforce participant and study data confidentiality policies. Study staff should be instructed in their responsibilities regarding data safeguards and cautioned against the release of data to any unauthorized individuals, unless such a release is approved by the study leadership and NCCIH and is not in violation of applicable Federal and state laws.

This section of the MOP will discuss the safeguards that have been put in place by the Steering Committee to ensure participant confidentiality and data security.

The following is a list of study participant confidentiality safeguards:

- ***Data flow procedures:** Data identifying participants should not be transmitted from study sites to the Coordinating Center.*
- ***Electronic files:** Data identifying participants that are stored electronically should be maintained in an encrypted form or in a separate file.*
- ***Forms:** Forms or pages containing personal identifying information should be separated from other pages of the data forms.*
- ***Data listings:** Participant name, name code, hospital chart, record number, Social Security Number, or other unique identifiers should not be included in any published data listing.*
- ***Data distribution:** Data listings that contain participant name, name code, or other identifiers easily associated with a specific participant should not be distributed.*
- ***Data disposal:** Computer listings that contain participant-identifying information should be disposed of in an appropriate manner.*
- ***Access:** Participant records should not be accessible to persons outside the study without the express written consent of the participant.*
- ***Storage:** Study forms and related documents retained both during and after study completion should be stored in a secure location. If computers*

are used to store and/or analyze clinical data, the Coordinating Center or the investigator should address the following elements of computer security to ensure that the data remain confidential:

- ***Passwords:*** *Passwords provide limitations on general access to computer systems and to the functions that individuals can use. Passwords should be changed on a regular basis.*
- ***User training:*** *Study staff with access to clinical computer systems should be trained in their use and in related security measures. Training should include explanations of how to access the system and a discussion of the need for, and importance of, system security.*
- ***System testing:*** *Prior to the use of a new computer system, and subsequent to any modifications, the system should be tested to verify that it performs as expected. Testing should verify that the password-activated access system performs as intended.*
- ***System backups:*** *Backup copies of electronic data should be made at specified intervals. Backups should be stored in file cabinets or secure areas with limited access. Storage areas should have controlled temperature and humidity so that the backup tapes are not damaged.*

The G1-study team is committed to protect the confidentiality of each participant and their sensitive data. All data files are stored securely in locked cabinet inside of a locked and secured office in the USC-Health Sciences Soto research building in a restricted area, where only G1-study staff has access to enter the area. Communication about any study activity will be conducted exclusively through our secure USC email system. A master list containing names and IDs will be kept in a separate, secure file for tracking purposes and data-sharing agreements. Access to this master list, which links names and code numbers, will be restricted to project staff only. The entire staff will closely monitor all assessment and treatment procedures. Since this study involves a low-risk non-clinical population and uses a within-subject case series methodology, there is no need to establish a Data and Safety Monitoring Board (DSMB) committee. We will implement an interval data and safety monitoring process instead.

3.27 MOP Maintenance

The Manual of Operations and Procedures (MOP) will be maintained and updated throughout the Continuing Glucose Study (CGS).

The MOP content will be reviewed and updated with changes, edits, or modifications, including the version number, date, and page numbers. The MOP will be distributed to the entire team by an appointed staff member on a continuous basis to ensure that the operating policies and procedures are described accurately. A printed copy will be available at the USC Health Sciences Soto building for review as well

If any procedures have been changed or modified, the MOP should be updated—and the appropriately modified pages distributed, with instructions, for replacement in the MOP. A MOP template for changes is included in Appendix_W_.

4. REFERENCES

References are embedded directly within the text to improve readability.

APPENDIX A: RECRUITMENT TELEPHONE SCRIPT

Date of the recruitment call: _______________

Actions required prior to the interview:

Recruiter will open REDCap (RC), a secure web-based application to create a participant ID number and capture Continuous Glucose Monitoring (CGM) research study data.

Background information - to be gathered before the interview:

Name of the person(s) interviewed:
Contact telephone number:
Participant ID number:

Introduction:

Hello, [Participant's Name]. This is [Staff Name] calling from the University of Southern California Keck School of Medicine. I hope you are doing well today.

The reason for my call today is to see if you might be interested in participating in a research study. Our study focuses on wearing a continuous glucose monitor to better understand blood sugar levels.

This study is designed to evaluate the levels of glucose (sugar) in your body.

Purpose:

This study's purpose is to understand whether the use of a continuous glucose monitoring system is acceptable to users, understand your experience with the glucose feedback, and to capture your explanation of your personal experience.

Eligibility:

If you meet our inclusion criteria based on this interview, you will be scheduled for a study visit.

At the study visit, the research staff will perform one more procedure before being chosen as a participant, that procedure is finger pricking to obtain your A1c results.

Consent Forms:

If you meet study eligibility, you will be asked to sign a consent form if you want to participate. This provides the full details of the study and your participation.

Confidentiality:

Some of these questions are personal questions, however, anything we discuss is confidential and will only be shared with research staff associated with this study.

Study Visit Procedures:

Once you sign the informed consent, a finger prick will be performed on your hand without fasting to determine your level of A1c, a measure of glucose in your body.

Research staff will ask you to complete a series of surveys during the first study visit, asking about your background, your medical history, medications you are taking, eating behavior, physical activity, personality, subjective measures of well-being, and satisfaction with the intervention.

Subsequently, with your consent, a small glucose sensor will be placed in your arm to monitor your blood sugar levels.

You will complete a second study visit about 2 weeks later, during that visit you will be asked if you are willing to participate in a video-recorded interview and you will out a satisfaction survey form

Duration of your participation in this study:

You will be provided with two Dexcom sensors free of charge to use for up to 20 consecutive days. On the 10^{th} you will change the first CGM sensor at home with the help of the study staff through a zoom call.

After completing the CGM, the research staff will schedule your last post visit a week later after completing the CGM phase.

Compensation:

For your participation in this project, you will receive up to a total of $500 in the form of gift cards, depending on how many sections of the study you complete.

If you only complete the first study visit and are not eligible, you will be given a $100 gift card for your participation in the first visit.

Survey:

If you are eligible, are you still interested in participating in the study? If so, I need to ask you a few questions to determine your eligibility. We ask that you please answer each question honestly so as not to alter the results of this eligibility section.

[Recruiter will read RC items verbatim and input responses in RC in real time]

APPENDIX B: SAMPLE SCREEN LOG

Study:

Site:

Investigator:

Screening Number	Name	Email adress	Phone number	Preferred language	Contact attempt 1	Contact attempt 2	Contact attempt 3	Screening Date	Eligible
G1xxx	Glucose study	gstudy@xxx.com	xxx-xxx-xxxx	☐ English ☐ Spanish	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy	mm/dd/yyyy	☐ Yes ☐ No

APPENDIX C: FINGER PRICK INSTRUCTIONS

Finger prick process

1. One of the phlebotomists designated for this study will have the participants wash and dry their hands with Chlorhexidine soap then sit down.
2. Place the A1cNow kit on the table.
3. Put on sterile surgical gloves before opening the A1cNow kit
4. Open the A1cNow kit, separate the analyzer, the lancet, blood collector, shaker body, and test cartridge on the table next to the participant.
5. Open the pouch labeled with the number 1.
6. Ask the participant to choose middle or ring finger on the hand they prefer the test
7. Gently massage the palm of the hand and rub toward the selected finger for 30 seconds
8. Remove the cap from the lancet and depress the lancet to the side of the finger
9. Remove the lancet and massage toward the fingertip once again
10. Clean the puncture site with a 70% isopropyl alcohol swab.
11. Dry the area with a gauze before puncturing the skin with the lancet.
12. Produce a large droplet of blood by finger pricking with the lancet and collect that blood with the collection tube by gently touching the tip of the blood collector to the blood drop to fill it. Tilt the blood collector at a low angle for easy collection
13. The Phlebotomy lab staff will then take the shaker body (of the blood collecting device) and will fully insert the blood collecting device into the shaker doing a pushing and twist movement.
14. The Phlebotomy lab staff will apply a sterile cotton to finger prick.
15. Ensure there is no gap between the blood collector and the shaker body. Vigorously shake it for 5 seconds (about 6 to 8 times) then place the shaker with the blood collector piece on the table standing upright.
16. After placing the body shaker that contains the participant's blood sample on a table, the cartridge will be collected from the pouch labeled with the number 2
17. Confirm that the code found in the lower left corner of the cartridge matches the code of the analyzer, which is also found in its lower left corner.
18. Insert the cartridge into the analyzer by clicking it into place.
19. Place the analyzer on the table and do not move it around.
20. A Wait (WAIT) sign will appear on the analyzer to perform a self-check

21. After the analyzer is completed with the self-check, the analyzer will give a Sample signal (SMPL) to place the blood sample from the shaker into the device (cartridge)
22. The Phlebotomy lab staff will remove the base of the shaker body and push the open end of the shaker into the analyzer in avertical position (a section within the cartridge once it is connected to the analyzer). To apply the sample a simple depression of the shaker into the analyzer will be made.
23. After the blood sample is applied, remove the shaker, and the analyzer will give a running signal (RUN)
24. Leave the analyzer on the table and a 5-minute timer will start on the analyzer
25. After 5 minutes have passed, the analyzer will give the A1c results.
26. Place the lancet and any soiled waste in the biohazardous red waste medical containers.
27. Write down the A1c result on the Body Measurement hard copy form.
28. The analyzer will show how many tests are left on the analyzer. [make sure to throw away analyzers that have no tests left]
29. The Phlebotomy lab staff will place the cotton balls and surgical gloves used in the biohazardous red waste bag.
30. Explain that side effects from finger pricking need to be reported to the RC.
a. Painful redness around the whole tip of the finger not resolved in 48 hours.
b. Swelling of the entire finger.

APPENDIX D_1_: INFORMED CONSENT FORM

University of Southern California
David Black, Ph.D. SSB 302D 2001 N Soto Street
Los Angeles, CA 90033

California Experimental Subject's Bill of Rights

Study Title: Continuous glucose monitoring and behavior (The G1 Study)

Principal Investigator: David Black, Ph.D., M.P.H.

Experimental Subject's Bill of Rights

Study ID: UP-23-01001 Valid From: 4/4/2024

You have been asked to participate as a subject in a behavior experiment. Before you decide whether you want to participate in the study, you have a right to the following information:

California Law Requires That You Must Be Informed About:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: ____________________ Time: ________________

Signature: ____
(Research Participant)

Page **1** of **7**
Version dated 04-04-24

University of Southern California
David Black, Ph.D. SSB 302D 2001 N Soto Street
Los Angeles, CA 90033

Informed Consent for Research

Study Title: Continuous glucose monitoring and behavior (The G1 Study)

Principal Investigator: David Black, Ph.D., M.P.H.

Department: Population and Public Health Sciences

24-Hour Telephone Number: 323-442-8223

Study ID: UP-23-01001 Valid From: 4/4/2024

Introduction

I invite you to take part in a research study about glucose (sugar) levels in your body and your behavior. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask us questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

Key Information

The following is a short summary of this study to help you decide whether you want to participate. More detailed information is listed later in this form.

1. Being in this research study is voluntary–it is your choice. There are no financial costs to you from participating in this study and you will be compensated.

2. You are being asked to take part in this study because you are a community health care worker or community resident. The purpose of this study is to gain information about the effect of glucose monitoring on behavior. A glucose sensor is a small device worn on the arm or abdomen. Your participation in this study will last no more than about four weeks. You will be asked to complete surveys at the start and end of the study, wear a small sensor on your arm for up to 20 days, and then complete an exit interview about your experience that will be recorded and used for the development of a future health intervention.

3. There are possible risks from participating in this study. The most common are:

   - Feeling uncomfortable answering some types of questions by survey or interview.
   - Mild discomfort (pain), bruising or skin irritation at the glucose sensor site.
   - Mild discomfort (pain) from a finger prick to obtain a blood spot.

More information about study risks can be found under "Risk and Discomfort" section.

4. The possible benefits to you for taking part in this study may include:

   -Learning about sugar in your body and changes related to what you eat or drink.
   -Learning about how to control sugar levels in your body.

5. If you decide not to participate in this research, you have the choice not to participate. Not participating will not impact your employment or any standing relationships with the study team or affiliated study sites.

Purpose

The purpose of this study is to find if a glucose (sugar) monitoring feedback system is acceptable to sensor users, to understand the subjective experience of sensor users, and to capture video-based narratives about use of the app system. We hope to learn about the usefulness of the sensor in people who do not have diabetes, and to create future educational video clips from your interview feedback. You are invited as a possible participant because you are an adult Latino with a risk for pre-diabetes. About 50 participants will complete this study. This research is being funded by the National Institutes of Health.

Procedures

If you decide to take part in this study, this is what will happen: you will complete a screening then informed consent process and signature of acknowledgement of informed consent; you will complete two study visits before and after wearing the sensor on your upper arm for up to 20 days; you will log select dietary behavior in your app for this period to keep track of what you were doing that affected sugar levels in your body. The sensor is paired with your smartphone, so you can view your changing sugar levels. Your ability to view feedback from the app will depend on the phase of the study you are in. There may be times you cannot view your app data and this is called masking in research.

In-person study activities will be conducted at the USC Health Sciences Campus in East Los Angeles. You will receive notification of the exact location when scheduling your visit. If you volunteer for this study, we will request that you participate in the following activities:

- Interviews/surveys: There will be two study interview visits in person, one at baseline and another about four weeks later. During these visits, you will meet with a member of our study staff to complete surveys and respond to questions. During the visits, activities can include: body measures (weight and height) in a private area, surveys asking about your background, history of medical conditions, current medications, dietary behavior, physical activity, and satisfaction with the sensor. At the end of the study, you will agree to a video-recorded interview so we can use some of your video to make future intervention clips. We will use computer software to translate these video clips in different languages to potentially help diverse people.

- Glucose monitoring: You will be required to wear a small sensor known as the Dexcom G sensor on your arm to monitor glucose. Our study team will establish a Dexcom account on your behalf to collect data on your sugar levels. You will be provided with two free sensors to use for a total of 20 days and will receive personal training on how to use the sensor and app. The Dexcom app will be installed on your personal smartphone. You will have to remove and reapply the sensor once, and possibly multiple times if there is an error with the device.

- Finger prick: During the baseline interview, you will undergo a non-fasting finger prick to screen your A1c level, a measure of glucose. A drop of blood will be collected by a qualified staff member. This is not a clinical diagnostic test in this study and so clinical recommendations will not be offered. However, if your test indicates diabetes, we will suggest to you to seek out medical care and we will provide information for free clinics near our site if you lack insurance.

Study ID: UP-23-01001 Valid From: 4/4/2024

- Phone contacts and video capture: A member of our research staff will contact you by phone or text message up to once per day to provide information about your recording of videos using your phone. You will be asked to generate brief selfie-style videos once or more a day pertaining to your experiences using the glucose sensor and app. We will select certain footage from your video to be used in future health education videos. You will not provide your name or other identifying content and we will make sure to delete this from the video content if you do.

- Dietary recall: Your name and phone number will be shared with CHLA/USC office to conduct these dietary recall interviews. After completing your interviews, bilingually trained CHLA staff will contact you by phone to ask questions about what you eat. The call runs 30-45 minutes. The dietary survey will be administered and analyzed by trained bilingual staff from CHLA. Data will be indefinitely stored at the SCCLH based at CHLA and may be shared with other organizations, including USC, UCSF, and NIMHD.

Any results about glucose done in research study are for research purposes only and have no clear meaning for health care clinical intervention. Because of this, you will not receive test results other than results for A1c that indicated levels suggesting diabetes.

Risk and Discomforts

Possible risks and discomforts you could experience during this study include:

- Interviews/ Surveys: You may feel uncomfortable answering some of the questions. You have the option to skip or discontinue answering questions at any time. In all recorded videos of you, we will ensure to remove any identifying information you may mention, such as your name or date of birth. We will also remind you not to disclose this information in your videos.

- Research blood spots: Having a blood spot taken from the tip of your finger may cause pain, at the site of the needle prick. We will be sure to sanitize the area before and after the prick.

Breach of Confidentiality

There is a small risk that people who are not connected with this study will learn your identity or your personal information. We use secure data systems to prevent this.

Risk of sharing data

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data. In either case, we cannot reduce the risk to zero.

Benefits

There are no direct benefits to you from taking part in this study. However, your participation in this study may help us learn how to create a glucose control intervention for other people that will be made for free to the public to increase behavioral health.

Benefits of sharing data

You will not receive any direct benefit from sharing your glucose data, yet sharing your data may contribute to research that could help others in the future. Sharing clips from your video recording during the study and at study exit interview will potentially lead to new behavior interventions that can help a diversity of people people better manage their sugar levels.

Privacy/Confidentiality

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will never use your name.

The USC Institutional Review Board (IRB) and Human Subject's Protections Program (HSPP) may review your study records. Organizations that may also inspect and copy your information include the National Institutes of Health and Dexcom. We will not be collecting information from your medical records in this study. We only use the data that you provide to us directly during your participation in the study protocols.

Future use of data

Sharing data: A central data repository system has been created by the Southern California Center for Latino Health (SCCLH) to study health disparities. The data repository is located at CHLA, and your dietary recall data will be stored there. Your dietary data may be used in this research or other research and shared with other organizations (e.g., researcher conducting this study, the study sponsor, or other researchers at CHLA,USC, UCSF, and NIMHD for future research projects that are unrelated to the purpose of this study and will be stored indefinitely. You have the right to decline your data being stored with the SCCLH.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The certificate cannot be used to stop a sponsoring U.S. federal or state government agency from checking records or evaluating programs. The certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Alternatives

An alternative would be to not participate in this study.

Study ID: UP-23-01001 Valid From: 4/4/2024

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Payments/Compensation

Payments for research participation are considered taxable income and participants may be required to pay taxes on this income. If participants are paid six hundred or more in total within a calendar year for participation in one or more research studies, the University will report this as income to the IRS and participants may receive an Internal Revenue Service (IRS) Form 1099. This does not include any payments you receive to pay you back for expenses like parking.

For this study, you will receive compensation in the form of gift cards. The total compensation amount is $500 US dollars for completing study protocols, distributed across different study milestones. We will also provide reimbursement for required travel to the study site and for parking at the study site. The allocation schedule is outlined as follows:

-$100 will be paid upon the completion of the baseline assessment visit, which includes informed consent, baseline assessment, blood draw, and the application of the glucose sensor.
-$100 will be paid on day 7-10, after the participant has worn the glucose sensor and recorded their dietary log for 7 days.
-Another $100 will be paid on day 14-20, once the participant has finished wearing the sensor and has returned the sensors to the study team.
-Finally, a payment of $200 will be made upon completion of the final study exit interview.

Injury

USC does not provide any monetary compensation for injury. If you are injured as a direct result of research procedures, you will receive medical treatment; however, you or your insurance will be responsible for the cost.

New Information

We will tell you about any new information that may affect your health, welfare, or willingness to stay in the research. Our study physician might review your data in the case of clinical glucose values to determine whether to suggest you consult your own doctor.

Voluntary Participation

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your records. If you agree, this data will be handled the same as the research data. No new information or samples will be collected about you without your permission.

If withdrawal must be gradual for safety reasons, the study investigator will tell you. The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

Participant Termination

You may be removed from this study without your consent for any of the following reasons: you do not follow the study investigator's instructions, at the discretion of the study doctor or the

University of Southern California
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investigator David Black, your condition gets worse, or the sponsor closes the study. If this happens, the study doctor or investigator will discuss other options with you.

Contact Information

If you have questions, concerns, complaints, or think the research has hurt you, talk to the principal investigator (David Black, Ph.D., davidbla@usc.edu).

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at hrpp@usc.edu.

Study ID: UP-23-01001 Valid From: 4/4/2024

Statement of Consent

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant **(and Time*)**	Signature	Date Signed

Person Obtaining Consent

I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)

APPENDIX D_2_: INFO ASSESSMENT DOCUMENT

Information Sheet and Verbal Assent to Screen

Instructions for Investigators

University of Southern California

University of Southern California Information Sheet

Phone introduction to study

My name is [staff], and I am a staff member at the University of Southern California affiliated with the Center for Latino Health. I hold a role as [name your job title and employer].

I am conducting a research study on the experience of using continuous glucose monitoring. The name of this research study is the "G1 Study. I am seeking your participation in this study.

Your participation is completely voluntary, and I will address your questions or concerns at any point before or during the study.

You may be eligible to participate in this study if you meet the following criteria:

1. You are over 18 years old.
2. Worked as a Promotores de Salud in the last 6 ~~months~~months.

If you decide to participate in this study, you will be asked to do the following activities:

1. Complete a ~~15 minute~~15-minute phone screen to determine initial eligibility
2. Make 2 on-site visits to our USC Health Sciences location
3. Wear a glucose monitor on your arm for up to 20 days
4. Complete two computer based surveys for 30-45 minutes
5. Complete daily logs on your phone, each taking less than 5 minutes
6. Participate in a 1:1 video recorded interview for 45-60 minutes

You will be compensated up to $500 for full participation in the study: $100 after the baseline visit; $100 for wearing the first sensor; $100 for replacing the sensor; and $200 for completing the post interview. Compensation will be made in gift cards to major chain grocery stores.

I will publish the results in scientific journals. Participants will not be identified in the results. I will take reasonable measures to protect the security of all your personal information. All data will be de-identified prior to any publication or presentations.

Verbal assent to screen for initial eligibility

We will be collecting demographic, body composition, and metabolic health history form you during a phone screen if you provide assent. This information is being collected so that we can track those who are interested in scheduling a visit for the final determination of eligibility and those who do not want to be contacted again for this study. Your taking part in this phone call is voluntary. If you do not agree to continue participating in this phone call, this will not affect and work or care you receive from USC.

Do you agree to continue participating in this phone call to be screened for study participation?

~~I will send a~~ An informed consent form will be sent to you by email, which provides more information about this study ~~can be sent to you~~. Would you like to receive a copy of this document?

If you screen eligible and want to participate in the study further, please read the entire consent form carefully and do not hesitate to contact us for any information. When would be a good time to contact you in the future after you have reviewed the consent form?

If you have any questions about this study, please contact me: [davidbla@usc.edu and 323-442-8223]. If you have any questions about your rights as a research participant, please contact the University of Southern California Institutional Review Board at (323) 442-0114 or email hrpp@usc.edu.

APPENDIX E: BODY MEASUREMENT FORM

Continuous glucose monitoring in adults - G1 study
Page 1

Body measures

Subject ID ________

Were height and weight recorded?
- ◯ No
- ◯ Yes

Why were height or weight **NOT** recorded? ________

Select date of body measurement ________

Insert subject height (in cm): ________ (cm)

Insert subject weight (in kg): ________ (kg)

BMI: [auto-generated] ________

Insert A1c% from digital test ________

(skip at post visit)

Is the patient currently taking any of the following medications?
- ☐ Metformin
- ☐ Insulin
- ☐ Liraglutide
- ☐ Semaglutide
- ☐ Phentermine
- ☐ Topiramate
- ☐ Vyvanse
- ☐ Contrave
- ☐ Ritalin
- ☐ Methylphenidate
- ☐ Other
- ☐ None

Specify names of any other medications currently taken? ________

Sensor ID Code: ________

(skip at post visit)

Is the participant eligible for enrollment?
- ◯ Yes
- ◯ No

Please describe why the participant was not eligible for enrollment: ________

03-09-2024 10:49am projectredcap.org REDCap

APPENDIX F: TIMELINE OF ASSESSMENTS

Variable	Measure	Capture	Screen	Baseline visit	CGM phase	Post visit
Eligibility	Age, sex, race/ethnicity, employment, zip, contact info, medical history, CDC prediabetic risk	Phone	x			
A1c%	A1cNow test kit (5.7-6.4%)	Staff		x		
Weight, kg	Digital scale (Tanita WB-3000)	Staff		x		x
Height, cm	Stadiometer (Tanita WB-3000)	Staff		x		x
Dietary log	G6 app daily log upon out of range chime	G6 App		x	x	
CGM changed	G6 transmitter replaced	Zoom, Phone			x	
Glucose, mg/dL	Dexcom G6 Pro system	G6 reader		x	x	x
Physical activity	International physical activity questionnaire	RC		x		x
Narrative	Semi-structured interview	Video				x
Satisfaction	CGM satisfaction survey	RC				x
Pattern detection	Ravens' matrices task	Website				x
P50 CDEs	Socio-demo and residential	RC				x
P50 dietary recall	NDSR external date	Phone				x
Daily Videos: Food Intake					x	

APPENDIX G: DEXCOM TRAINING CHECKLIST

1. Introduce CGM and review patient expectations
   - o What is professional CGM, purpose of 10-day session and the importance of a follow-up visit for interpretation.
2. Insert sensor and attach transmitter
   - o Follow instructions on Blinded or Unblinded handout to insert the sensor and attach the transmitter.
3. Check status
   - o Check status using Dexcom G6-Pro Reader.
4. Record Transmitter SN
   - o Use Patient Tracking Form (or your office form) to record the transmitter SN. Found on Start Here guide in box.
5. Train patient using appropriate handout located in Dexcom G6 Pro box
   - o Choose one method below - based on HCP recommendation:
     - Blinded Mode* (Use Blinded CGM Patient Handout)
     - Unblinded Mode* (Use Unblinded CGM Patient Handout)
6. Download and interpret clarity data
   - o Choose one of the following options to access data:
7. Access data via reader (Blinded or Unblinded mode)
   - With transmitter in 20 feet range, choose Download Data on reader, enter recorded transmitter serial number, and follow steps on reader. Note: Transmitter must be uploaded within 30 days of session start.

In Dexcom Clarity:

- Add or select patient from Patient List
- Upload data under patient
- Print/Save report.

8. Access data via Dexcom clarity app (Unblinded mode only)
   - o For unblinded patients already sharing data with Dexcom Clarity via Dexcom G6 app:
   - Click on Patient Name in Dexcom Clarity and see Sharing is ON.
   - Confirm desired amount of data captured (accessing data via reader will allow full data capture).

APPENDIX H: SENSOR REPLACEMENT TELEPHONE SCRIPT

“Hello Mr./Mrs.____________,

Thank you for joining me on this call. How are you doing today?

I am so glad to hear that. As we discussed during your Baseline Visit, we scheduled this call for 2 main reasons.

One reason is that the sensor that you applied during the BV expires on this day, therefore, you must remove it and replace it with a new Dexcom sensor on this day.

I am also going to guide you through the entire procedure of your sensor replacement.

I want to remind you that your participation in this study is completely voluntary. Would you still like to continue with your participation in this phase of the study?

[After the participant agrees to continue with their participation]

Excellent! Before we start with the entire process, I want to show you a short video that will help you gain more knowledge about the Dexcom sensor application.

[The study staff will share the video by sharing their screen on the Zoom platform. The video shown will be the following: https://www.youtube.com/watch?v=dWWKa3Fjd9Y from minute 1:44 until minute 3:17]

Now that we have watched the video, do you have any questions regarding the sensor application?

[Study staff will address every question that the participant has at that moment]

Excellent Mr./Mrs._______ We will now start the process of removing and replacing your sensor. I will show you the supplies you will need for these activities.

[Study staff will show on screen the following: manila envelope, labeled Ziploc baggies found within the envelope; Dexcom G6 PRO box containing the applicator with the sensor, the 2 alcohol pads, and the transmitter]

Do you have this equipment on hand?

[If not, give time to the participant to gather every equipment needed for the procedures. Make the participant show on their screen all their equipment]

We will now start by removing your sensor. Localize your sensor, pick one of the corners of the sensor’s adhesive, and start gently peeling off the adhesive as if you are peeling off a band-aid.

[After the participant removes the sensor, tell the participant to show you on screen the removed sensor]

Great job on removing your sensor Mr./Mrs.______, now please grab one of the Ziploc baggies found within the envelope labeled -Sensor 1- and place the worn sensor in the Ziploc baggie, then place the Ziploc baggie inside the manila envelope.

Now, it is time for you to apply your new sensor. Please open your Dexcom G6 PRO box, and the first thing you will find is a sheet with the label of the sensor transmitter code. Please place that sheet on the table and have it ready at the end so you can pair your new sensor with your smartphone.

The second thing you will find in your box is a sheet of paper with the visual representation of each step of the G6 PRO sensor application. You can place it on the table so you can use it as a visual guide for this procedure.

You will now find the alcohol pads, the applicator and the transmitter device. Please grab the applicator and take it out of its container. Ok Mr./Mrs._________, show me what area you are choosing to place the new transmitter. Remember, you will not place the sensor on the same arm that was used for the last sensor. You will place the sensor on the base of the back of your arm. To locate this spot, try to draw an imaginary line from your elbow up to your shoulder; you will aim to place the sensor right in the middle section of the imaginary line. Raise your arm and show me where you will place the sensor.

[the staff will make sure that the participant is aiming in the right area of the back of the arm]

Excellent! Now, please open one of the alcohol pads and clean the area where this sensor will be placed. Use circular motions starting from the center of the area.

[The staff will show the circular motions to the participant]

Now that you have cleaned the area, pick up the applicator and peel off the adhesive backing. Do this carefully and try not to touch the adhesive.

Amazing. Now place the adhesive on top of the area you chose for the sensor application. Once you have successfully placed the applicator onto your skin, fold the safeguard to the side and break it off.

[Staff will ask the participant if the safeguard came off]

Now that you have removed the safeguard, push the orange button on the applicator.

[The applicator will make a sound]

Remove the applicator. As you can see, the adhesive with the sensor has been applied to your skin. Now, pick up the transmitter and slide it into the sensor slot. These instructions are under the section entitled “Transmitter Insertion”. You may refer to these visual aids if you’d like.

After sliding the transmitter, push it onto the sensor from the circular end. The transmitter will make a clicking noise.

[Ask the participant if they have inserted the transmitter, if so, ask if the transmitter made a clicking noise]

Now that you have successfully inserted the transmitter, rub the sides of the adhesive with circular motions. Rub it at least 4 times.

Great job Mr./Mrs.___________, you have successfully applied your new sensor. Let’s now start to pair your new sensor with your smartphone. Unlock your smartphone and go into the Dexcom G6 App. Within your App, touch the settings icon found in the upper right-side corner of your screen

[Show on screen to the participant the settings icon of the app].

Now touch the fifth tab called “Transmitter”. You will see a section called “Pair New” on your screen.

[Show once again to the participant on screen the Pair New section]

Select that tab and hit the “continue” tab. The app will give you the option to either enter the Transmitter Code manually or scan the QR code. I’d like you to choose the QR code option. The app will open the camera so you can capture the QR code found on the sheet I mentioned at the beginning containing the sensor’s code.

[Show on screen once again the sheet with the QR code].

After you scan the code, the app will automatically pair your new sensor with your smartphone. The sensor will take up to 2 hours to warm up. After the 2 hours have passed, the G6 app will show you your glucose levels graph.

Amazing job, Mr./Mrs._________. You successfully replaced and paired your new Dexcom G6 PRO sensor. We will now finish this zoom call with a short survey. Are you okay if we complete this now or do you need to take a 3-minute break?

[Once the participant has accepted to go on with the survey, the staff will go into the RC page that was set up from the beginning of the zoom meeting and will enter the correct data into the RC platform. Within this survey the study staff will schedule the date and time of the Post Visit. After finishing the survey, the staff will answer the participant’s questions and will thank them for their participation]

Thank you so much for participating in this phase of the study. Remember that if you have any problems with your sensor or the Dexcom app, feel free to contact me so I can help you solve the problem.

Before we go, I want to kindly remind you to continue making the daily videoclips so we can capture your entire experience with the glucose sensor."

APPENDIX I: POST-VISIT INTERVIEW QUESTIONS

1. How would you describe your experience with the CGM to someone else?
2. Can you please list the top 3 things you liked about the CGM?
3. What did you not like about it?
4. How did wearing the CGM feel?
5. When would you look at your device typically?
6. If I wanted to check my historic glucose readings, where would I look? How would I interpret this?
7. If I wanted to check my current glucose readings, where would I look? How would I interpret this?
8. In your opinion, are these different readings easy to understand?
9. When did you notice you were having high alarms? What do you believe could have caused this and why?
10. Were there any changes to your eating habits after wearing the CGM?
11. Were there any changes to your exercise habits after wearing the CGM?
12. What is something you would improve about the CGM experience?
13. What are three of your favorite apps on your phone you use in the past 3 months?
14. What do you like about app X? Is there something you don't like about it?
15. Is there something you learned about this experience
16. Would you recommend this to someone else? Why?
17. Were you able to create a general rule about how glucose is related to diet?

APPENDIX J: G1- Continuing Glucose Monitoring Gift Card Log

Batch # _______

Vendor	Card Seq Number	Amount	Date	Participant ID	Participant's Initial	Participant's Signature	Time Given	Baseline Visit	Post-Visit
Amazon		$100.00							
Target		$100.00							
Walmart		$100.00							

APPENDIX K: PARTICIPANT ACTIVITY LOG

Participant ID	Screening Date	Baseline visit date	Enrolled	If not, why?	Date of sensor replacement	Post visit date	Adverse event	Date of AE	Completed
G1xxx	Mm/dd/yyyy	Mm/dd/yyyy	☐ Yes ☐ No	Reason	Mm/dd/yyyy	Mm/dd/yyyy	☐ Yes ☐ No	Mm/dd/yyyy	☐ Yes ☐ No

APPENDIX L: IMAGE RELEASE FORMS

USC University of Southern California

IMAGE RELEASE FORM

I hereby irrevocably consent to and authorize the use by the University of Southern California a California non-profit corporation ("USC"), of any and all photographs, video, voice recordings, or other media taken of me including derivative works thereof (collectively, the "Images"), and any reproduction of them in any form in any media whatsoever, whether now known or hereafter created, throughout the world in perpetuity.

I also consent to the use of my name or likeness, or an assigned fictitious name, in connection with the exhibition, distribution, merchandising, advertising, exploiting and/or publicizing of Images or USC.

I hereby release and discharge USC, its trustees, officers, employees, licensees, and affiliates from any and all claims, actions, suits or demands of any kind or nature whatsoever, in connection with the use of Images and the reproduction thereof as aforesaid. I understand and agree that USC will be the exclusive owner of all rights including, but not limited to, all copyrights, in and to the Images in whole or part, throughout the universe, in perpetuity, in any medium now known or hereafter developed, and to license others to so use them in any manner USC may determine in its sole discretion, without any obligation to me.

I hereby waive any right that I may have to inspect and/or approve the use of the Images or any reproductions thereof, by USC.

Date: ______________________

Signature: ______________________

Print Name: ______________________

Address: ______________________

____
City State Zip Code

____
Phone Number Email Address

____
If above named is a minor child, a parent/guardian must sign

Parent/Guardian Name: ______________________

Parent/Guardian Signature: ______________________

APPENDIX M: DEMOGRAPHICS SURVEY

Page 1

Demographics

Please complete the survey below.

Thank you!

Demographic Questionnaire

What is the highest level of education you have completed?

- ◯ 8th grade or less
- ◯ Some high school
- ◯ High school diploma/G.E.D.
- ◯ Trade/vocational school
- ◯ Some college
- ◯ 2-year college - Associate's degree
- ◯ 4-year college - Bachelor's degree
- ◯ Master's degree
- ◯ Doctoral/Professional degree
- ◯ Not sure

What is your current marital status?

- ◯ Single
- ◯ Married
- ◯ Divorced
- ◯ Separated
- ◯ Widowed
- ◯ Domestic Partnership
- ◯ Other

Please specify your marital status:

____

What is your current employment status?

- ◯ Employed
- ◯ Self-employed
- ◯ Unemployed
- ◯ A homemaker
- ◯ A student
- ◯ Retired
- ◯ Unable to work due to disability

What type of housing do you currently reside in?

- ◯ House
- ◯ Apartment
- ◯ Mobile home
- ◯ Hotel
- ◯ Shared housing with another family
- ◯ Car

11/11/2024 7:49am projectredcap.org REDCap

APPENDIX N: BEVERAGE SURVEY

Page 1

Beverage Survey

Please answer the items below as accurately as possible to calibrate the glucose sensor.

In the last 7 days, how many days did you drink the following drinks (don't include beverages with artificial sugars):

		Never	1 day	2 days	3 days	4 days	5 days	6 days	7 days
1)	Water	○	○	○	○	○	○	○	○
2)	Fruit juice	○	○	○	○	○	○	○	○
3)	Milk	○	○	○	○	○	○	○	○
4)	Diet Soda	○	○	○	○	○	○	○	○
5)	Regular Soda	○	○	○	○	○	○	○	○
6)	Black coffee / tea	○	○	○	○	○	○	○	○
7)	Sweetened coffee / tea	○	○	○	○	○	○	○	○
8)	Wine/ beer	○	○	○	○	○	○	○	○
9)	Energy / sports drinks	○	○	○	○	○	○	○	○

11/11/2024 7:49am projectredcap.org REDCap

APPENDIX O: BEHAVIORS SURVEY

Behaviors Survey

Page 1

Please answer the items below as accurately as possible to calibrate the glucose sensor.

In the last 7 days, on how many days did you:

		Never	1 day	2 days	3 days	4 days	5 days	6 days	7 days
1)	Take Tylenol or aspirin	○	○	○	○	○	○	○	○
2)	Take vitamin C (includes multi-vitamins)	○	○	○	○	○	○	○	○
3)	Take medicine prescribed by your doctor	○	○	○	○	○	○	○	○
4)	Drink one or more servings of alcohol	○	○	○	○	○	○	○	○
5)	Smoke cigs, e-cigs, or vape	○	○	○	○	○	○	○	○
6)	Do meditation (such as mindfulness, breathwork, mantra)	○	○	○	○	○	○	○	○
7)	Do yoga (such as Hatha, hot yoga, Tai Chi)	○	○	○	○	○	○	○	○

11/11/2024 7:49am projectredcap.org REDCap

APPENDIX P: PHYSICAL ACTIVITY IPAQ

Physical activity IPAQ

Please complete the survey below.

Thank you!

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the vigorous activities that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling? ________________ (days per week)

2. How much time did you usually spend doing vigorous physical activities on one of those days?

Example, if you spent 2.5 hours per day, input 2 as hours per day and 30 as minutes per day. If you spent 1 hour, input 1 hour and 0 minute.

{vighour} hours per day
{vigmin} minutes per day

Think about all the moderate activities that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking. ________________ (days per week)

4. How much time did you usually spend doing moderate physical activities on one of those days?

Example, if you spent 2.5 hours per day, input 2 as hours per day and 30 as minutes per day. If you spent 1 hour, input 1 hour or 0 minute.

{modhour} hours per day
{modmin} minutes per day

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APPENDIX Q: SENSOR REPLACEMENT CALL SURVEY

Did the call take place with the participant?	◯ Yes ◯ No
Insert the date that the sensor was replaced:	______________________
Sensor ID code of the replacement sensor?	______________________
Is the Dexcom Glucose kit complete with all its components?	◯ Yes ◯ No
How many days have you worn your CGM since we put it on?	______________________
Have you experienced any problems with your glucose monitoring system (sensor or app)?	◯ Yes ◯ No
Insert notes for sensor problems, smartphone app problems, and adverse events.	___________________________
Was the sensor successfully replaced? [Have the participant show you their smartphone screen to verify working order]	◯ Yes ◯ No
En que lugar almaceno su segundo sensor?	___________________________
Insert any additional notes related to this phone interview that impact the participant or data capture.	___________________________
Other notes:	___________________________
Upcoming visit date:	______________________

APPENDIX R: ADVERSE EVENTS OR ERRORS DOCUMENT

Continuous glucose monitoring in adults - G1 study
Page 1

Adverse Events (or Errors)

Subject ID	______________________
Was this adverse event (or error) CGM related?	○ Yes ○ No
Start Date of the event:	______________________
Stop Date of the event:	______________________
Description of the event:	___________________________
Outcome of the event:	☐ Data quality was affected ☐ Participant's well-being ☐ Other
Please describe the outcome(s): (ex: cgm data is not accurate)	___________________________

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APPENDIX S: RESIDENTIAL HISTORY QUESTIONNAIRE

Page 1

Residential History Questionnaire P4

Please complete the survey below.

Thank you!

Project 4 G1 Study

Do you live at more than one home?[Vive en mas de una casa?]

◯ Yes [S&iacute]
◯ No [No]
◯ Prefer not to answer [Prefiero no contestar]

Average number of days spent per week at home #1[Promedio de d&iacuteas a la semana pasados en casa #1]

◯ 1 day [1 d&iacutea]
◯ 2 days [2 d&iacuteas]
◯ 3 days [3 d&iacuteas]
◯ 4 days [4 d&iacuteas]
◯ 5 days [5 d&iacuteas]
◯ 6 days [6 d&iacuteas]
◯ 7 days [7 d&iacuteas]
◯ Prefer not to answer [Prefiero no contestar]

Average number of days spent per week at home #2[Promedio de d&iacuteas a la semana pasados en casa #2]

◯ 1 day [1 d&iacutea]
◯ 2 days [2 d&iacuteas]
◯ 3 days [3 d&iacuteas]
◯ 4 days [4 d&iacuteas]
◯ 5 days [5 d&iacuteas]
◯ 6 days [6 d&iacuteas]
◯ 7 days [7 d&iacuteas]
◯ Prefer not to answer [prefiero no contestar]

What is your CURRENT HOME address?[Cual es su direccion actual?]

Street address:[Direcci&oacuten:]

____

Town/City:[Pueblo/Ciudad:]

____

Zip Code (if known):[C&oacutedigo Postal (si lo sabe):]

____

11/11/2024 7:50am projectredcap.org REDCap

APPENDIX T: P50 CDE SURVEY

P50 CDE v 1.5

Please complete the survey below.

Thank you!

Version 1.5

Are you of Hispanic, Latino, Latina, or Spanish origin?
((Adapted from PhenX - ethnicity protocol [PX010502]/LOINC: 94158-3))

◯ No, NOT of Hispanic, Latino, Latina, or Spanish origin
◯ Yes, of Hispanic, Latino, Latina, or Spanish origin
◯ Prefer not to answer

If you selected, Yes, of Hispanic, Latino, or Spanish origin,

What part of Latin America, or Spain, are you from?

(Check all that apply)
((Adapted from: https://worldpopulationreview.com/country-rankings/hispanic-countries))

☐ Argentina
☐ Bolivia
☐ Chile
☐ Colombia
☐ Costa Rica
☐ Cuba
☐ Dominican Republic
☐ Ecuador
☐ El Salvador
☐ Equatorial Guinea
☐ Guatemala
☐ Honduras
☐ Mexico
☐ Nicaragua
☐ Panama
☐ Paraguay
☐ Peru
☐ Puerto Rico
☐ Spain
☐ Uruguay
☐ Venezuela
☐ Other
☐ Prefer not to answer

If other, please specify.

____

11/11/2024 7:50am projectredcap.org REDCap

APPENDIX U: SATISFACTION SURVEY

CGM Satisfaction Survey

Please complete the survey below.

Thank you!

The following are statements about your experience with the glucose device you wore. Report how much you agree or disagree with the statement shown.
The glucose monitoring system...

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Helped me manage my weight.	○	○	○	○	○
Made me think more often about my weight.	○	○	○	○	○
Made me worry more than usual.	○	○	○	○	○
Made me feel more frustrated than usual.	○	○	○	○	○
Made me feel more down and depressed.	○	○	○	○	○
Took too much time.	○	○	○	○	○
Was too much of a hassle to use.	○	○	○	○	○
Caused too much skin irritation or bruising.	○	○	○	○	○
Was too painful to use.	○	○	○	○	○
Gave me useful information.	○	○	○	○	○
Helped me identify how food affects blood sugar.	○	○	○	○	○

APPENDIX V: VIDEO EDITING PROGRESSION LOG

Participant ID	Video download	DV Spanish Transcript	DV English Transcript	Interview Spanish Transcript	Interview English Transcript
Gxxxx	Completed	Completed	Completed	Completed	Completed

APPENDIX U (APP. W): SAMPLE MOP MODIFICATION LOG (REPLACE WITH WHAT IS BEING USED)

MOP MODIFICATION LOG					
Section #	Version #	Date Modified	Page #	Text Location	Brief Modification Summary

APPENDIX ?: SAMPLE PROTOCOL DEVIATION LOG (REPLACE WITH WHAT IS CURRENTLY BEING USED) NO DEVIATION LOG FOR G1

Protocol Name:____

Protocol Deviation Code:	Participant Initials	Participant ID#	Date Deviation Occurred: mm/dd/yyyy	Date Protocol Deviation Form Completed: mm/dd/yyyy	Contact Person (if applicable)

SAMPLE PROTOCOL DEVIATION CODES

Consent Form:

1. Missing or not obtained
2. Not signed and dated by participant
3. Does not contain all required signatures
4. Outdated, current IRB-approved version not used
5. Not protocol-specific
6. Does not include updates or information required by the IRB

Randomization:

7. Ineligible participant enrolled and/or randomized
8. Participant randomized prior to determining whether eligible for study
9. Occurs outside protocol window

IRB:

10. Not reporting a serious complication within 24 hours;
11. Approvals not kept up to date
12. Enrollment and/or treatment occurs prior to IRB approval or during period when on “on hold”
13. Reportable serious adverse events not reported to IRB

Participant

14. Receives wrong treatment
15. Visits occur outside expected follow-up window
16. Entered into another study

Study Data and/or Forms

17. Missing data and/or forms
18. Missing radiology and/or operative reports
19. Forms or data not sent from clinical site to coordinating center