**Consent Form (includes HIPAA Authorization)**

**Title of Research Study** ***Time Restricted Eating As a Viable Alternative to Caloric Restriction for Treating Hyperglycemia in a Population with Type 2 (T2DM) diabetes - SEEFOODSTUDY3***

**Investigator Team Contact Information:**

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

| | |
|---|---|
| Investigator Name: Lisa Chow, MD<br>Investigator Departmental Affiliation:<br><br>Department of Medicine- Division of Endocrinology, Diabetes and Metabolism<br><br>Phone Number: 612-625-8934<br><br>Email Address: chow0007@umn.edu | Study Staff: Abdisa Taddese and Brad Yentzer<br><br>Phone Number: 612-624-1469 for study related calls<br><br>Cell Number for text messaging: 612-419-5738<br><br>Email Address: endores@umn.edu |

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

***Supported By: This research is supported by National Institutes of Health (NIH).***

## *Key Information About This Research Study*

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

## What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

## Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are diagnosed with diabetes, are between the ages of 18 and 65, and are overweight.

## What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

## Why is this research being done?

The purpose of the study is to see how restricting your eating window (called time-restricted eating) might affect your eating habits, weight, and blood measures compared to reducing your food intake. Time-restricted eating means that you would have a daily 8 hour eating window during which time you can eat whatever you want. Outside of the eating window, you would only take water and your medications.

## How long will the research last?

We expect that you will be in this research study for about 7 months. Optional research surveys will be emailed to you 1 month and 3 months after your last visit to see if you stay with the program. Whether or not you stay with the intervention after the study is done is entirely up to you.

## What will I need to do to participate?

You will be assigned to one of two groups, Time-restricted eating (TRE) or Caloric Restriction (CR), and will be supervised by a dietician for the first 12 weeks and allowed to manage your intervention yourself for an additional 12 weeks. You will be asked to complete three 1-hour study visits and three brief visits (less than 30 minutes) at the University of Minnesota. The three 1-hour study visits (Visits 1, 2, and 3) will be conducted for study related tasks (ie measuring height, weight, blood draws, surveys). The three

brief visits (less than 30 minutes) will be to either place or remove monitors which track your physical activity and sleep (Actigraph monitor) and sugar levels (continuous glucose monitor: CGM). The Actigraph is a watch that you wear on your wrist and the CGM is a monitor that sticks on your skin with a small, plastic tube, to track your sugar levels. You will wear the Actigraph and CGM for 2 weeks at a time. For the three 1-hour study visits (Visits 1, 2, 3), you will be asked to have blood drawn in a fasting state (at least 8 hours from last reported food intake). In addition, you will receive 9 phone calls administering a 24 dietary recall (3 calls after Visit 1 and 3 calls prior to Visit 2 and to Visit 3) to ask about your dietary intake in the last 24 hours.

At your screening visit, we will ask you to download the "My Circadian Clock" (mCC) app, a free research-based app, onto your smart phone and to monitor your food and beverage intake for the entire study.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

## Is there any way that being in this study could be bad for me?

Time-restricted Eating:

If you are assigned to the time-restricted eating group, you may feel hungry outside of your designated eating window.

Fasting:

While fasting in this study for the purposes of the blood draws, you could feel hunger and lightheadedness. You will be asked to drink water as you feel appropriate to keep yourself hydrated. The fasting period will be 8 hours.

Questionnaires:

The questions asked of you in this study relates to your eating habits, perception of food and hunger, and quality of life. It is highly unlikely that the questions that are asked of you in this study may make you feel uncomfortable. That being said, some of the questions asked may be potentially sensitive in nature and may be embarrassing for some people to answer. You do not have to answer any questions that you do not want to answer.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

## Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. We do not know if restricting the eating window might be different than caloric restriction on influencing sugar levels or weight. Information learned in this study will help us provide dietary advice to future patients with type 2 diabetes.

### What happens if I do not want to be in this research?

If you do not want to be in this research, you may continue to follow the dietary advice provided by your physician.

## *Detailed Information About This Research Study*

The following is more detailed information about this study in addition to the information listed above.

### How many people will be studied?

We expect about 200 people will enroll in this research study with about 56 people finishing the study. We anticipate that drop out may occur for the following reasons: 1) not meeting eligibility criteria, 2) not able to use the mCC app, 3) unable to commit to the study duration (total duration of 7 months).

### What happens if I say *"Yes, I want to be in this research"?*

If you agree to participate in this study, you will be randomly assigned to one of two groups:

Time-restricted eating (TRE) group: You will have 8 hours where foods of your choice can be eaten. You can also eat as frequently as you wish during this 8 hour period. Medications that need to be taken multiple times in a day with food can and should be taken as prescribed, even if this falls outside your eating window. Outside of your 8 hour window (the fasting period), you can only drink water and take your medications (it is ok to take with a small amount of food if prescribed by your provider). You will receive weekly dietary telephone-based counseling for the first 12 weeks of the intervention (Supervised Intervention). You will receive counseling to use the mCC app and will receive weekly text/emails regarding the mCC logging. In addition, you will weigh yourself weekly using the wi-fi scale that we will provide. After the 12 weeks of Supervised intervention, you will move to the Self-Maintained Intervention where you continue with the intervention yourself, without study dietitian input, for 12 weeks. During the Self-Maintained Intervention, you will continue to log your food and beverage intake daily using the mCC app and you will continue to weigh yourself weekly using the wi-fi scale.

Caloric Restriction (CR) group: The study dietician will create a meal plan with you to reduce your caloric intake by 15%. You will receive weekly dietary telephone-based counseling from the dietician for the first 12 weeks of the intervention. You will receive counseling to use the mCC app and will receive weekly text/emails regarding the mCC logging. In addition, you will weigh yourself weekly using the wi-fi scale that we will provide (Supervised Intervention). After the 12 weeks of Supervised intervention, you will move to the Self-Maintained Intervention where you continue with the intervention yourself, without study dietitian input, for 12 weeks. During the Self-Maintained Intervention, you will continue to log your food and beverage intake daily using the mCC app and you will continue to weigh yourself weekly using the wi-fi scale.

All groups will use the myCircadianClock (mCC) app to document their food and drink intake for the entire study.

At Visit 1, 2, and 3, all participants will wear Actigraph sensors to measure their physical activity and sleep. For the sugar measurements, you will wear a CGM sensor on your skin to continuously monitors your glucose for about 10-14 days. The CGM sensor has a tiny plastic tube is inserted into your skin to

monitor your sugar. The CGM is a commercially available product currently used in the clinical setting to manage people with diabetes. We will be following manufacturer's recommendations for application and removal, which will be about 14 days. You will be provided the results from the continuous glucose monitoring if you wish.

Your participation would last about 7 months, and you would have 1 virtual screening visit, 3 in person study visits at the University of Minnesota, 3 brief visits to remove or place the Actigraph and CGM sensors, and 9 phone visits to conduct the 24 hour dietary recall. Of note, you will be asked a screening questionnaire about COVID-19 related exposures or symptoms before any in-person visits (either the day before or the day of the visit). You can expect the following procedures at these visits:

Screening Visit (Virtual):

This visit will last about 1 hour.

- The study staff will discuss this consent form with you.
-After youhave signed the consent form, you will access the online app mCC ("My Circadian Clock"), which you will download onto your smartphone. You will be asked to log the food that you eat for 7 days. You will use your smartphone to collect data about your eating patterns. You will take pictures of your food or drink every time you ingest something. This information will be time stamped and stored.
- You will report your height and weight.

You will receive a call about 10-12 days after your screening visit to let you know if you are eligible to proceed to Visit 1.

Visits 1, 2 and 3 (In Person: at the M Health Clinical Research Unit (CRU)):

These visits will last about 1 hour each. Height, weight, and blood pressure will be measured. Blood will be drawn (about 3 tablespoons) in fasting state (at least 8 hours from last-reported non-water intake) to measure your hemoglobin A1c (HbA1c), blood glucose, hemoglobin (Hgb), insulin, and lipid profile. At your first visit, we will also measure your Creatinine, AST, ALT, and TSH to examine your liver and kidney function. You will be asked survey questions about your appetite and lifestyle. At Visit 2 and 3 you will be asked a few questions about your satisfaction with the study. For all 3 in-person visits, a blood sample will be saved if you give your permission later in the consent form. A pregnancy test will be administered if indicated. As appropriate, the Actigraph and CGM sensor will either be applied or removed at these visits.

You will receive a call a few days after Visit 1 to let you know about your results and whether you are eligible to proceed with the study. If you are eligible, you will be asked to continue to log your food and beverage intakedaily using the mCC app until the end of the study at Visit 3. You will also be asked to weigh yourself weekly using the wi-fi scale until the end of the study (24 times).

Brief visits:

There will be 3 brief visits to the Delaware Clinical Research Unit (DCRU) to remove or place the Actigraph and CGM. Two weeks after Visit 1, we will ask you to come to the DCRU so that we can remove these sensors. **You will be randomized at this time**. In addition, at this visit we will provide you a wi-fi scale. We will help you download a free app that is associated with the wi-fi scale that will record your weight on-line. We will assign a de-identified ID to your app account so that we can document your weekly weight.

Two weeks prior to Visit 2 and Visit 3, wewill ask you to come to the DCRU to receive the Actigraph and have the CGM applied. You will return these sensors when you attend your Visit 2 and Visit 3 at the CRU.

- Actigraph sensor: You will receive a wearable sensor that can measure sleep duration, the

quality of your sleep, your basal metabolic rate (how much energy your body uses when you are at rest), and your activity levels. The sensor looks like a wrist bracelet. You will wear this sensor for up to 14 days and will return it to the study team.
- CGM: A continuous glucose monitor will be placed on the skin. A catheter will be inserted into the skin for this procedure. This will be removed about 14 days later.

Phone Call Visits for 24 hour Dietary Recall (2 week period after Visit 1 and 2 week period prior to Visit 2 and Visit 3):

Each phone call visit will take about 20-30 minutes. You will receive a total of 9 phone calls. Three calls will occur in the 2 week period following Visit 1 and 3 calls in the 2 week period prior to Visit 2 and prior to Visit 3. The study team will ask you general days and times that are convenient for you to receive these calls. The calls themselves are unscheduled.

The study team will call and ask you questions regarding the previous day and what you had to eat and drink. We will ask that you refer to the Food Amounts Booklet (FAB) that the study team will give to you.

Randomization: You will be randomized to either the TRE group or the CR group when you return the sensors after Visit 1. The experimental treatment you get will be chosen by chance, like flipping a coin. You will have an equal chance (50%) of being assigned to either group. Neither you nor the study doctor will choose what experimental treatment you get.

The following table outlines the study visits:

| | **Baseline** | | | | **Intervention** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | **Supervised Intervention (Weeks 1-12)**<br>- app daily logging<br>- weekly weighing using scale<br>- weekly dietician calls<br>- weekly texts to encourage mCC logging | | | **Self-Maintained Intervention (Weeks 12-24)**<br>- app daily logging<br>-weekly weighing using scale<br>- weekly texts to encourage logging | | |
| | **Screen Visit** | **Visit 1** | ***Dietary Recall (3 calls)*** | ***Removal of and CGMsensors***<br>***Randomize*** | ***Placement of and CGMsensors*** | ***Dietary Recall (3 calls)*** | **Visit2** | ***Placement of ondCGM sensors*** | ***Dietary Recall (3 calls)*** | **Visit 3** |
| **Time points** | Day 1 of **Baseline** | Week2 of **Baseline** | Week 2-4 of **Baseline** | Week4 of **Baseline**<br>Week 1 of Intervention | Week 10 of **Intervention** | Week 10-12 of **Intervention** | Week 12 of **Intervention** | Week 22 of **Intervention** | Week 22-24 of **Intervention** | Week 24 of **Intervention** |

An optional survey will be emailed to you via email 1 month and 3 months after the intervention to follow-up on the study. See the optional section at the end of this consent form to let us know if you would like to receive the survey.

## What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Coming to the study visits
- Answering the surveys as best as possible
- Participating in study procedures
- Tracking food intake

## What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

## Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. This is primarily if you do not meet the eligibility criteria for the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

## What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Blood Sample:

Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

Continuous Glucose Monitor (CGM):

The monitor attaches to your skin with adhesive. Upon initial insertion, we will use a small disposable needle to initially attach the monitor to your body. After the initial attachment, the needle will be removed and the monitor will sample your sugar levels through a small plastic catheter. There may be a risk for bleeding or bruising when initially placing the continuous glucose monitor. You will wear this

monitor for about 14 days. Side effects include a rash to the sensor adhesive, or the sensor might not stay securely on your skin. Please tell your study doctor if you have any skin/tape allergies.

Dietary Recall:

There is a risk about breach of confidentiality. Study staff will call participants and ask about dietary intake for the last 24 hours. The actual call will be unannounced but there will be 3 calls within a specified 2 week window. Participant will be aware of the 2-week window. This will occur 2 times during the study.

Documentation of eating events using the my Circadian Clock application:

All documented eating events (time, image) will be stored and sent deidentified as per Salk Institute protocols. By consenting to this study, you are also consenting to use mCC app and also allowing the Salk research team to share data from the mCC app with our team. Of note, upon enrollment in the study, you will be provided a deidentified account number to sign into the mCC app to provide an extra layer of privacy.

**myCircadianClock smartphone application (mCC app).**

The mCC app was created by and managed by Dr. Satchidananda Panda's lab at the Salk Institute for Biological Studies. It is HIPAA compliant and double-encrypted. Consenting to use and using the mCC app is necessary and critical for participation in the study.

**Activities.**

The myCircadianClock app may ask you to: Answer survey questions about your health behaviors, record what you eat or drink.
The app sends occasional reminders to complete study activities.
Educational material may be sent through the app.

**Sensor and health data**

This study can gather sensory data from your phone if you allow it to upon installation.
The app will also use the built in GPS sensor to tag the location only when you log your data. This will help you to track what and where you eat, which may help you adjust your diet. It helps the research to account for any unusual change in your eating or sleeping pattern due to a change in time zone when you travel. Change in time zones or moving to a different latitude within the same time zone can change the local sunrise and sunset time or local day-length, which can affect your circadian clock for a few days.
The use of the myCircadianClock app is not intended to evaluate your health and is not a diagnostic test. If you are concerned about any aspect of your health, you should consult with your physician.

**Weekly weighing**

We will have you weigh yourself at home using a wifi enabled scale. We will set you up on this scale with a deidentified ID. There is a risk for breach of confidentiality and potential anxiety

with using the scale. You can keep the scale at the end of the study if you wish.

**Data Gathering**

Our daily pattern of activity, sleep, and eating changes with season, latitude, work schedule, and travel. Collected data may reveal how daily behaviors affect your quality of life and body weight, and also advance clinical research into circadian rhythms.

Learn more: myCircadianClock helps you keep track of health behaviors such as diet, activity, sleep and taking your medications or supplements.

Data that you share through the app as part of the research study will create an unprecedented large-scale database of daily behaviors and health provided by people just like you.

Studying this real-world data will help researchers understand how daily behaviors influence health in real life, with a resolution never achieved before. (Traditionally, these studies are done by asking people to recall answers to very long questionnaires on paper).

At the same time, myCircadianClock analyzes your data to provide personalized insights into how your daily eating, sleeping and activity patterns relate to your overall health, and can help you maintain a healthy lifestyle. Since the feedback is determined from multiple days of your routine behavior, some of these insights will be accessible in your phone after two weeks of data collection.

To improve data collection, the app may send you a reminder and push notifications. If you do not want to be bothered with these reminders, you can turn this option off.

By combining a personal app and a research study, myCircadianClock will help explore how the smartphone may be used with new kinds of clinical research in the future.

**Privacy**

The following personal health information will be collected from you by the app: email address, country, language, photos of food/beverages you take, activity/exercise, sleep, and health entries, timestamp of entries, and geographic location data from entries.

Your data will be sent to a secure database where it will be separated from your personal identity.

We take several steps to protect your privacy and the privacy of your app data.

App-generated data is associated only with a random study code, and this code is used in all future analyses separating it from any personally identifiable information.

These steps ensure that researchers analyzing the coded study data will not be able to connect it to any individual user.

Whenever app data is transferred to a research study computer, it will be encrypted so that others cannot interpret the data or associate it back to you.

Encrypted app data (stripped of personal identifiers, and associated only with a random code) will be sent to secure data servers used for the myCircadianClock research study.

Study investigators chose Amazon Web Services for this important responsibility because they are a world leader in the secure storage and protection of sensitive data. They have a proven track record of safeguarding and managing potentially sensitive biomedical data in accordance with regulations that govern human research and medical information (e.g., regulations mandated by Institutional Review Boards [IRB] and the Health Information Portability and Accountability Act [HIPAA]).

We will de-identify your data and use secure computers, but we cannot ensure complete

privacy.

One potential loss of privacy would be if someone sees your data from myCircadianClock on your smartphone. For security, myCircadianClock suggests that your smartphone be protected either by a passcode or fingerprint sensor. This ensures that only you can enter and use the app.

**Utilizing Data**

Your coded data will be used for research and may be shared with other researchers.

Study investigators will analyze coded (no personal identifiers) app data from everyone who agrees to participate in the myCircadianClock study, but they will be unable to connect it back to any individual user.

The results of this research may be published in a scientific or medical research journal so that others can learn from this study. Results will never be published in a way that would allow data to be associated with individual users.

After this study is completed, other researchers may request access to the coded study data (already stripped of personal identifiers), so that it can be analyzed in a new way to benefit medical research . Those requesting data must agree to use the data for research responsibly and in accordance with applicable regulations; these data requests will be reviewed by a group of study investigators. Amazon Web Services will have no oversight over future research conducted with coded study data.

Other researchers who are granted access to coded study data will not be able to connect the data back to you.

Study data will never be sold to any third party.

**Issues to Consider**

Your participation in this study will take 5-10 minutes per day on average. Entering information and responding to surveys should take on average 2-3 minutes each day. Occasionally, tasks may take a few minutes longer (e.g., a longer questionnaire).

Participation in this study does not require you to change anything related to your smartphone account or data plan. However, your phone must have data or wifi capability and must connect to internet in order to transmit data to our servers. The app can use either an existing mobile data plan or Wi-Fi connections: you may configure the app to use only Wi-Fi connections if you wish to limit impact on your data usage.

**Safety and Legality**

As with any smartphone app, follow prevailing laws about when and where you use your smartphone. Similarly, follow local and federal regulations about the usage of a smartphone in specific areas.

Additionally, the app should not be used in any capacity to perform or document illegal activity.

The Salk Institute for Biological Stu dies, Dr. Satchidananda Panda and all members of his research team, including collaborators, are not liable for any illegal activity that is performed, captured, or stored by the myCircadianClock app.

Study Survey

Some of the tasks in this study will require you to answer survey questions about various health and lifestyle factors.

myCircadianClock will collect some of its data on your health behaviors through short survey questions, such as: Did you forget to eat breakfast today? When did you wake up this morning? Do you feel sleepy during the day?

For dietary information, myCircadianClock will prompt you to take pictures of every food, beverage, water, medication, and supplement(s) you take.
When picture taking is difficult or socially awkward as in a meeting, if you forgot to take picture or you are repeatedly eating the same item, you can also enter the information textually from a different screen.
In general, more data entered into the app results in more accurate and informative personalized insights.

**Study Tasks**

Although this is not required by the study, you have the option of including health information in the app, including activity (step counts/distance), heart rate, height and weight, you can sync other smartphone apps and sensory devices (such as Apple Health Kit and Google Fit) with myCircadianClock. You also have the choice to allow the myCircadianClock app to access your location in order to determine the local time. You can allow or deny these features when you first install the myCircadianClock app, and are able to change these settings at any time.

All data entered is used solely for tracking purposes, not diagnosis. The Salk Institute for Biological Studies, Dr. Satchidananda Panda and his lab are not responsible for providing medical advice and are not liable for your medical care. You should contact a medical professional for medical advice.
The myCircadianClock app provides personalized feedback in the form of graphs and text to display your progress, and provide insights into your health behaviors.
The app summarizes data about how food, sleep or activity patterns in specific time of the day are associated with your health and wellbeing. These insights may help you understand your health behaviors better, and help you manage your health. Viewing the graphs and text is optional but may be useful or interesting to you.
In your Profile within myCircadianClock, you can set reminders for yourself to complete app activities. In general, more data entered in the app results in more accurate and informative insights.
Meals, activity, and sleep: The smartphone application myCircadianClock (mCC app) will serve as an electronic food, activity, and sleep diary.

On the server side, a sub-study dashboard will be created for this specific project. Clinical coordinators from Dr. Chow's research team will have password-protected access to the study data. In the study summary dashboard, your study code and the date of activation of the app will be shown along with your daily log. If you fail to log any food data for more than 1 day, the dashboard flags you and sends an alert to the coordinator. The coordinators will login to the dashboard at least twice weekly to monitor food intake data, and follow up with you as

necessary.
If you are randomized to the time-restricted eating arm, you will self-select an interval of 8 hours per day within which to consume your food. You can easily track your progress of the daily eating pattern with the time-stamping feature of the app that offers a visual summary.

If you have any difficulty logging data, or have questions about any of the features of the app, you will be able to contact the study coordinator through the feedback feature of the app. The questions will be delivered to a HIPAA compliant email server specifically set up for this study.

Breach of Privacy:

There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

## Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. All activities performed for the research will be paid for by the study.

## What happens to the information collected for the research, including my health information?

***We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.***

***Overview***

## Consent Form (includes HIPAA Authorization)

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

***What health information will be made available?***

Health information about you to be used and shared for the research includes those items checked by the research team below:

D Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

**181** Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

***What about more sensitive health information?***

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

D My drug & alcohol abuse, diagnosis & treatment records ____ (initial)

D My HIV/AIDS testing records ____ (initial)

D My genetic testing records ____ (initial)

**D My** mental health diagnosis/treatment records ___ (initial)

D My sickle cell anemia records ____ (initial)

***Who will access and use my health information?***

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)), individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- National Institutes of Health (NIH);

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

### *Additional sharing of your information for mandatory reporting*

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

### *How will my information be used in publications and presentations?*

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

**What will be done with my data and specimens when this study is over?**

With your permission, we will use and may share deidentified data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data. We will never do genetic testing on these specimens.

***Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?***

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

***Does my permission for making my health information available for use and sharing ever expire?***

No, there is no expiration date.

***May I cancel my permission for making my health information available for use and sharing?***

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

***What happens to my health information after it is shared with others?***

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

***Will I be able to look at my records?***

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

**Certificate of Confidentiality**

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings,

for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

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

## Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The study team will share results that would be clinically meaningful with you(ie lab results, weight trends, sensor data).

## Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent without your permission ahead of time.

## Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

### Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant.

You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

## What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

## Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you for your time and effort. All study tests, procedures, and materials are provided to you free of charge.

Payment Schedule:

| Visit | Payment |
|---|---|
| Screening Visit (virtual) | $15 |
| Visit 1 (in person) | $50 |
| Visit 2 (in person) | $50 |
| Visit 3 (in person | $50 |

If you complete the entire study (screening visit to final visit), your total compensation will be $165. You will also be allowed to keep the wi-fi scale we will provide you that has a value of $90.

If you do not complete all study visits, your compensation will be less than the total amount, based on how many visits you completed.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive a cardholder agreement. Be sure to read all of this information for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name, date of birth, and address. They will use this information as part of the payment process.

## Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

| Yes, I Agree | No, I disagree | |
|---|---|---|
| | | The investigator may email me the optional post-intervention survey at 1 and 3 months, as discussed earlier in this form. This is to see if you continue with the intervention after the study is done. Whether or not you continue with the intervention after the study is done is entirely up to you. |
| | | The investigator may contact me in the future to see whether I am interested in participating in other research studies by Lisa Chow. |
| | | We would like your permission to store your blood. These samples will be stored indefinitely using a unique code without personal identifiers. Dr. Chow will be custodian of these samples. This means that she will manage the use of these samples. Results from testing these future samples will not be given to you. No genetic studies will be performed on these samples. |

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent