Official Title:	Time Restricted Eating for Weight Loss Maintenance (TWIST): A Single-Site, Pilot Feasibility and Acceptability Randomized Clinical Trial in Adults With Recent Weight Loss
NCT Number:	NCT05742165
Study Number:	22-01453
Document Type:	Informed Consent Form
Date of the Document:	• September 19, 2024

NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	**T**ime-restricted eating for **W**e**I**ght lo**S**s main**T**enance (TWIST): a single-site, pilot feasibility and acceptability randomized clinical trial in adults with recent weight loss
Principal Investigator:	Mary Ann Sevick, ScD Institute for Excellence in Health Equity Department of Population Health NYU Grossman School of Medicine 180 Madison Avenue New York, NY 10016 646-501-3427
Emergency Contact:	Holly Lofton, MD 212-263-3166

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

Even though some people can lose weight quickly, they usually can't keep it off for a long time. This might happen because their bodies start feeling hungrier after they lose weight. There are ways to try to lose weight and keep it off, but a new idea that hasn't been tested yet is to only eat during certain times of the day, which is called “time-restricted eating or TRE." The purpose of the study is to compare 2 different TRE programs where you will restrict your eating window (e.g., the time between your first and last meal) for weight management. In Program 1, you will restrict your eating window to 6 hours per day and in Program 2 you will restrict your eating window to 10 hours per day. We’re asking you to take part in the study because you have been diagnosed with overweight or obesity.

3. How long will I be in the study? How many other people will be in the study?

This study will last 5 months or less. About 50 people will be in the study.

4. What will I be asked to do in the study?

We will further determine if you are eligible for the study. We screened you over the telephone but now we will **measurement** you by having you:

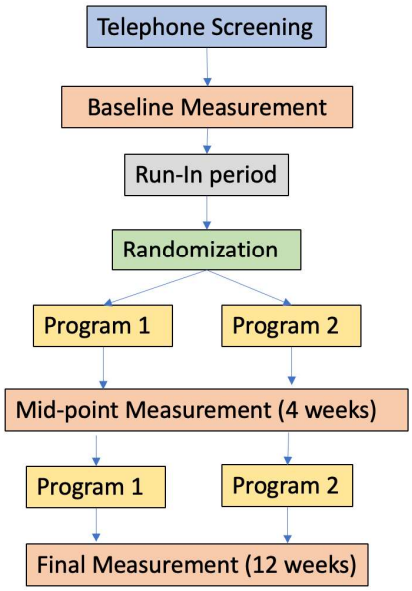
1. Record your food into a smartphone app called myCircadianClock or mCC app (details listed below), which measures your eating patterns, such as the timing of your food and beverages.

2. Determine your willingness to record your diet in a mCC application.
3. Measure your body composition, like how much body fat and muscle mass you have.
4. Measure your physical activity and eating patterns with a TWO activity monitors
5. Provide you with a body weight scale where you will measure your weight daily (the scale will be used during the duration of the study but will be collected at week 12 of the measurement visit)

During the next 4-weeks, called the **run-in** period, you will wear the activity monitors, log your meals into the mCC and log your weight daily. After the run-in period, if you appear to be eligible, you will be **Randomized** (like the flip of a coin) to one of two 12-week diet Programs (Program 1 or Program 2). Neither you nor the study investigators will know in advance which group you will be assigned to. You will have an equal chance (1 in 2) of being assigned to each group. Regardless of which group you are assigned to; you will be asked to reduce your eating window. In other words, you will be asked to eat your 1st meal and last meal in a given period of time. Measurement appointments will be repeated at 4 weeks (midpoint) and 12 weeks (final).

The purpose of these measurement appointments is to collect data that will tell us how the two programs compare for weight management. The **Measurement** visit will be completed at 180 Madison Ave, New York, NY, 10016. The **Randomization** and **Programs** will occur using WebEx™ (a free videoconference program similar to Zoom) which you can join from any location. We will help you install WebEx™ onto your preferred device (mobile phone, laptop or home computer) and show you how to use it. Each of these steps is shown in Figure 1 below, followed by details concerning what occurs during Screening, Measurement, and the 2 Programs.

Figure 1: Flow Diagram



If you enroll, you will continue to receive routine care from your treating physician throughout the study. The proposed intervention does not replace medical care.

The myCircadianClock application

As part of this study, you will use the app myCircadianClock (mCC) to log some data and you may receive information and survey through the app. The mCC app uses encrypted methods to transmit data between the app and the database.

- **Activities.**
  - The myCircadianClock (mCC app) mCC app serves as an electronic food, activity, and sleep diary to track 24-hour behaviors.
  - The mCC app may ask you to enter data about your lifestyle (e.g., body weight, exercise). **However, you are only asked to enter data about what you are eating and drink.**
    - For diet information, mCC will prompt you to take pictures of every food and beverage 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.
  - The app sends occasional reminders to complete study activities.
  - Educational material may be sent through the app.
  - If you fail to log any food data for more than 1 day, we will follow up with you as necessary.
  - 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.

- **Sensor and health data**
  - This study can gather sensor data from your phone if you allow it to upon installation.
  - The mCC app may use the built-in accelerometer in certain phones to passively keep track of physical activity (passive because this happens automatically and you do not need to enter any information). The app interprets accelerometer data as steps taken, or as different intensity levels of activity. The app can also detect when you use the phone to get an independent estimate of your rest or sleep period. You can also sync the app to Apple Health Kit or Google Fit to capture activity, heart rate, and body temperature data.
  - For these activity measures to be accurate, you should carry the smartphone on your person as much as possible (e.g., in your pocket, or clipped to your waist). For instance, if the phone is left on a desk or in your car when you go for a walk, it will not be able to detect your walking.
  - 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.
  - <u>The use of the mCC 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.</u>
  -
- **Data Gathering**
  - 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, the mCC app analyzes your data to provide personalized insights into how your daily 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 a few days 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, mCC 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: photos or names of food/beverages you take and a timestamp of entries.
        - You are not required to log activity/exercise, sleep, and health entries into the app, but if you wish you do so you may.
        - You can allow or deny to turn on the geographic location data from entries in the app.
    - We take several steps to protect your privacy and the privacy of your app data.
    - 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.
    - Your encrypted data will be sent to a secure database where it will be stored with a unique identifier. The identifier does not contain any personal information. You will also receive your encrypted data back from the server for visualization on your phone.
    - App-generated data is associated only with a random participant code, and this code is used in all future analyses separating it from any personally identifiable information.
    - 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.
    - These steps ensure that researchers analyzing the coded study data will not be able to connect it to any individual user.
- **Utilizing Data**
    - Study investigators and researchers in this section refer to the research team who is conducting this study and the research team at the Salk Institute who oversee the use of the app.
    - Study investigators will analyze coded (no personal identifiers) app data from everyone who agrees to participate in the myCircadianClock study. From the analyses methods and the result, 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.
    - Your coded data will be used for research and may be shared with other researchers.
    - 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).
  - Some questions may make you uncomfortable. Any information you provide is completely up to you. You can decline to answer survey questions or participate in the app's tasks. If a survey question makes you feel uncomfortable, you are free to leave questions blank.
  - 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 Wi-Fi capability and must connect to internet in order to transmit data to our servers.

- **Study Tasks**
  - The mCC gives you the choice to allow the mCC app to access your location in order to determine the local time. You can allow or deny these features when you first install the mCC app, and are able to change these settings at any time.
  - mCC has the option to add some information that requires a brief task away from the smartphone, such as: blood glucose, total cholesterol. However, for this study you will not be required to enter this data. Entering this data is optional.
  - The mCC app may provide personalized feedback in the form of graphs and text to display your progress, and provide insights into your health behaviors.
  - The app may summarize 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.
  - For the passive sensing of your physical activity in some phone models to be accurate, it is important to carry your smartphone on your person (e.g., in your pocket, or clipped to your waist). Carrying your phone will also help you log food, beverage, water and activity data as soon as these events occur.
  - 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.

Study Procedures

Baseline measurement (length = 1 hr, 30 minutes) at 180 Madison Ave, New York, NY 10016.

- We will ask you to complete questionnaires that ask about your medical history, personal habits, and characteristics such as your race, ethnicity, and gender (sex). We will collect and review your questionnaires for completeness.
- We will obtain signed informed consent from you.
- We will measure your height and weight.
- We will measure your body composition (bioelectrical impedance analysis, BIA) by stepping on a scale that measures how much muscle and body fat you have.
  - If you have an implantable device then you will skip the BIA measurement.

- We will help you download an application called myCircadianClock (mCC) onto your mobile phone and train you in how to use it to record your meals. You will be asked to log everything you eat and drink for the next 10 days.
    - We will provide a loaner phone to you if you do not have a smartphone. We will have you sign the Device Loan Agreement. Phones will be returned at the 12-week measurement visit.
- We will provide you with an activity monitor (Actigraph GT9X). This device is worn on your non-dominant wrist and tracks your sleep and physical activity. You will be instructed to wear the activity monitor at all times over a 10-day period. You will return the activity monitor in the pre-paid postage box.
- We will provide you with eating pattern monitor (Actigraph GT9X). This device is worn on your dominant wrist and measures the timing of your eating. You will be instructed to remove the device each night and charge while you sleep. You will wear the eating pattern monitor while you are awake. You will do this for 10-days and return the activity monitor in a pre-paid postage box.
- We will provide you with a Renpho scale for you to measure your body weight at home for 4 weeks.
    - You will weigh yourself daily, in the morning, in-minimal clothing and after using the restroom.
    - You will use the Renpho scale during the course of the study at return it at the last measurement visit (Week 12).
- If you are eligible for the study, you will be randomized to Program 1 or Program 2.
- We will provide you a ClinCard, like a debit card with a preloaded amount of $25.00. If you are eligible for the study you will have the same ClinCard throughout.

Program Activities:

- Program 1: You will be asked to restrict your eating window to 6 hours per day and fast for 18 hours. In the first month, you will attend 4 weekly one-hour WebEx group sessions. In months 2 and 3, you will attend bi-monthly (twice a month) one-hour WebEx group sessions. The session topics will be on body weight management.
- Program 2: You will be asked to restrict your eating window to 10 hours per day and fast for 14 hours. In the first month, you will attend 4 weekly one-hour WebEx group sessions. In months 2 and 3, you will attend bi-monthly one-hour WebEx group sessions. The session topics will be on body weight management.

Measurements at 4 and 12 weeks (length = 30 minutes, each) at 180 Madison Ave, New York, NY 10016.

- We will call you to schedule your 4- and 12-week measurement appointments.
- We ask you to complete questionnaires, measure your height, weight and BIA.
- We will provide you with two activity monitors (ActiGraph GT9X) to measure your activity and eating patterns. You will do this for 10-days and return both activity monitors in a pre-paid postage box.
- We will load an additional $25.00 onto your ClinCard after each measurement visit.

Interview of Program Experience (Subgroup)– Webex appointments (length = 1 hour)

- We may ask you to be interviewed based on your participation in the study. Not everyone will be interviewed.
- If you are interviewed, we will ask you questions about your experience with the Program you were assigned. For example, "*describe a typical day while following your program*," or "*describe your motivation to continue using the Program for managing your body weight*."
- We will call you to schedule this remote interview done using Webex videoconferencing

- The interview will be audio and video recorded because we will later transcribe what you to see if there are common themes among all participants' related to their experience. We will ask that you not verbalize your name or any other identifying information to better protect your confidentiality. You will also be required to sign a separate informed consent for this.

5. What are the possible risks or discomforts?

Fasting: Fasting for extended periods of time (>8-12 hrs) could cause hunger, dizziness, headache, stomach discomfort, irritability, or fainting. If you experience these symptoms, we instruct you to eat a small meal including foods that are common in your diet.

Privacy and Confidentiality: There's a small risk people not connected with this study will learn your identity or personal information. We will follow all institutional requirements to keep your study information safe. The mCC app is secured and data encrypted and **does not** collect or transfer: a) your health information or personal identifiers; b) mobile phone numbers, serial numbers or any other information that can be used to identify you; c) GPS tracking or information on your location.

Unforeseeable Risks: While we will do everything we can to protect your safety and privacy, it is possible that the research may involve risks that are currently unforeseeable.

Time: We estimate the total time for all measurement appointments to be roughly 3 hours (4 hours if you are interviewed), and we will do everything we can to minimize the time needed to perform the measurements. There is the possibility of some measurements running longer than normal. Program 1 & 2 participants will attend WebEx group sessions lasting a total of 8 hours during the 12 week period.

Physical activity/eating monitor: There is a very small risk some people who wear the physical activity/eating monitor may experience redness, itchiness and swelling.

6. Can I be in the study if I am pregnant or breastfeeding?

If you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you become pregnant, you will be required to withdraw from the study.

7. What if new information becomes available?

During the course of this study we may find out more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

Potential benefits from this study include better management of your body weight. It's also possible you will not benefit directly from taking part in the study. Your participation in this study will provide information that may help others with difficulty maintaining a lower body weight.

9. What other choices do I have if I do not participate?

Standard of care therapy for weight management a comprehensive lifestyle intervention program designed for weight loss (lifestyle therapy) that includes a healthy meal plan, physical activity, and behavioral intervention, You may choose to not participate in this research study. You may discuss alternatives with your physician. You may seek dietary counseling from other healthcare professionals.

10. Will I be paid for being in this study?

You will be paid $75.00. If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for $25.00 for each completed visit.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, ClinCard, or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

You must let us know immediately if/when the total research payments presently equal or are likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please tell the PI on page 1. However, you are required to report to the IRS all payments made to you by NYU Langone for your participation in any research for this calendar year, even payments under $600.00.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

11. Will I have to pay for anything?

There will be no charge to you for your participation in this study. Your health insurance will not be billed for any study activities, tests, or procedures. The cost of all procedures and tests will be covered by funds received from the sponsor. The sponsor will pay for all study supplies, including blood glucose sensors, activity monitors, and mobile phones (if you need one).

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

12. If I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the emergency contact as soon as possible. The emergency contact's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU Grossman School of Medicine or NYULMC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

If you withdraw, no more information will be collected from you. When you indicate you wish to withdraw, the investigator will ask if the information already collected from you can still be used.

14. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: The National Institutes of Health (NIH)
- Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. Electronic Medical Record and Release of Study-Related Information

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?
The 21st Century Cures Act allows patients increased access to their EMR. However, the law allows for exceptions to your immediate access to certain research information when needed for the research study.

As a research participant in this study, some research-related information will be placed in your EMR and will be available to you immediately and some research-related information will not be available to you until the end of the study.

The research-related information that will be available to you immediately are as follows:

- ***Results in the medical record that will be immediately accessible:*** *height*

For these results, you will have access to the research-related information placed in your EMR before the researchers have had the opportunity to review the information.

In this study, some research-related information in your EMR will not be available to you until the end of the study. This information will not be accessible in your EMR immediately in order to protect the integrity of the research trial results or (you can list other reasons here).

- ***Results in the medical record that will not be immediately accessible:*** *weight, BMI*

Considering this a weight management study, we will withhold these results until the end.

The researchers will provide you access to this research-related information in your EMR when the study is over.

If you would prefer not to have access to research-related information, you may state this preference to the researchers and you will not be given access.

In this study, some research-related information will never **be m**ade available to you in your EMR. This information will not be accessible in your EMR because the information is specific to this research and is not part of your medical history and clinical care.

- ***Results that will not be placed in the medical record:*** *Body composition, questionnaire data, activity monitor data, and mCC data.*

17. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of doctors, nurses, scientists, people from the community.

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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

19. Research with Applications, Software & Novel Technology

This study will use a mobile application to gather information for the researchers as part of this study. This mobile application is provided by Dr. Satchidananda Panda's lab at the Salk Institute for Biological Studies called MyCircadianClock application. The privacy policy is detailed in section 4, under the MyCircadianClock section in this document. All data collected through the MyCircadianClock mobile application is encrypted data meaning there are no personal identifiers to identify you and a random code is generated. If you do not want this data collection to continue by the vendor after the study ends, you will need to uninstall/delete the use the MyCircadianClock app. The research team can help explain how to do this.

We will ask you to share information with us about your health and how active you are by using a product or device made by a company or organization. Products or devices are things like fitness trackers, mobile apps that can be used on a smartphone or tablet, websites and web apps, or types of computer software.

This mobile app is provided by Dr. Satchidananda Panda's lab at the Salk Institute for Biological Studies called MyCircadianClock application. This application can collect information from your mobile phone that

would identify your geographic location when data is collected. To help protect your privacy, the research team can help to deactivate the location services if you wish.

This Dr. Satchidananda Panda's lab at the Salk Institute for Biological Studies called MyCircadianClock application will use the data function on your phone, and, depending on much data you use for other things, you may have data charges.

If you do not already have the product or device, we may give one to you to use for the study. If we give you a product or device to use, you must agree to the company's rules before you can use it, just as if you bought the product or service for yourself. The researchers of the study do not control these rules. We will help you understand these rules in the "Terms of Service" or the "End User License Agreement" that come with the product or device. Please read these rules carefully. These rules may ask you to agree to certain things, like not to sue the company if something goes wrong with the product or device. These rules may also allow the company to get, keep, or give others a copy of your information that comes from the product or device. Although this study will protect the copy of your information that you give us, we cannot protect or control what the company does with the copy that goes to them. If you do not agree to the company's rules, you do not have to take the product or device. You can say no and still be in other parts of the study.

Interest in future studies

If you are interested in being contacted about future studies, please check the box below:

☐ Checking this box indicates I agree to be contacted about future studies.

_____
Subject Initials

_____	_____	_____
Name of Subject (Print)	Signature of Subject	Date

_____	_____	_____
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date