INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**YMCA of the Blue Water Area / "The YMCA Healthy Lifestyle Program for Prediabetes"**
Protocol Number:	**IIS-2024-173**
Principal Investigator: (Study Doctor)	**Sushma Reddy, MD**
Telephone:	**810-987-6400 ext 117** **810-987-6400 (24 Hours)**
Address:	**Young Men's Christian Association of the Blue Water Area** **1525 3rd Street** **Port Huron, MI 48060**

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form.

KEY INFORMATION

You are invited to take part in a research study called the Y-HELP study. This research study is investigating whether a healthy lifestyle program at the YMCA (Young Men's Christian Association) using a real time continuous glucose monitor (CGM) with results that you can see in real time (as opposed to wearing a CGM that doesn't show you the results)can improve glucose levels, dietary habits and

physical activity in individuals with prediabetes. This study is sponsored by the YMCA of the Blue Water Area

A continuous glucose monitor (CGM) can tell you how your body responds to food, physical activity and daily life. The CGM, also called a sensor, is worn on the arm and measures glucose levels continuously through a slim sensor wire. The health coach will help insert the sensor using an automatic applicator. You may feel a pinch or pressure while the sensor is being inserted, although many find it to be painless.

You will have weekly sessions with a health coach for the first 3 months followed by 3 monthly sessions. The health coach will do simple fitness activities and give you tips on healthy eating and coping with stress.

You will receive a Y Family Membership at no cost and will be able to participate in a Y class of your choice.

You will be asked questions about your physical activity, diet and health throughout the study. Measurements of your body (weight, waist size and body fat) will be taken every 4 weeks.

The duration of the study is 26 weeks. There are two kinds of CGMs that are used in the study. One is the Stelo, which allows you to see your glucose levels in real time on your phone. The other is the Dexcom G7 (G7), which does not allow you to see your glucose levels in real time. While, the study doctors will be able to see your glucose levels, these results from the Dexcom G7 will not be shared with you during the course of the study. Both the Stelo and the G7 are worn on the back of your arm.

You will wear a G7 at the beginning of the study. Subsequently, you will be randomly assigned by chance (like the flip of a coin) to wear the Stelo CGM continuously for 24 weeks or to wear the G7 for 10 days at 6 weeks, 12 weeks and 24 weeks. If you are assigned to the group wearing the G7 at 6, 12 and 24 weeks, your glucose data is blinded and you will not be able to see it in real time during the study. You will, however, receive all of your glucose data at the end of the

study. Please consult your primary care physician (PCP) if you have any questions or concerns related to that data following participation in the study.

All personal information is confidential and securely stored. Also, if the information collected is used for publication, no identifying information (names, addresses etc.) will be attached to it.

The Y-HELP study is the first time a CGM is being used in a healthy lifestyle program at the Y to prevent diabetes. It is expected that 84 individuals will be enrolled in the study. This study has the potential to improve your physical activity, encourage healthy eating habits and decrease glucose levels. In addition, by participating in the Y-HELP study, you are helping to develop a fun and engaging healthy lifestyle program at the Y that is intended to help people feel better, be more physically active, make healthier food choices and ultimately prevent type 2 diabetes. The results from the Y-HELP study can help establish statewide and nationwide diabetes prevention programs, thus having a major impact on the prevention of type 2 diabetes.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have prediabetes.

Individuals with prediabetes are at risk for developing diabetes and heart problems. We know that adopting a healthy lifestyle can reduce the risk of developing diabetes by 58%. Yet, the number of individuals with diabetes continues to grow. In 2021, 38.1 million adults aged 18 years or older (14.7% of all US adults) had diabetes with a higher occurrence of 29.2% among those aged 65 years or older. An estimated 97.6 million adults had prediabetes in 2021.

Continuous glucose monitors (CGM) track glucose levels continuously and help individuals know how their bodies respond to physical activity and different foods. It was found that when individuals used CGM, they were more likely to modify their physical activity and eating habits.

We would like to develop a healthy lifestyle program using CGM that is fun and

engaging while helping individuals feel better, be more physically active and encouraging healthy eating habits, which may prevent the development of type 2 diabetes.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately 26 weeks and will include approximately 18 study visits to the Y (study center).

Screening:

Before any study-related tests and interventions are performed, you will be asked to read and sign this consent document. The following screening tests will be obtained to determine if you qualify to take part in this study:

- Prediabetes risk assessment: this is a short list of questions that gives you a score. Anyone with a score of 5 or higher is at greater risk for diabetes
- A1c test: this is a blood test that measures the average amount of glucose in your body over the last 3 months
- Fasting glucose test results
- Enrollment form: medical history and personal information

This study will use competitive enrollment. This means that when a target number of subjects begins the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of subjects has already begun the study.

If you qualify to take part in this study and proceed with study enrollment, the following will happen:

Baseline Assessment:

You will be assigned a study specific number. All information, questionnaires and assessments are de-identified and collected under your study specific number rather than your name.

The health coach/study staff will obtain the following:

- Weight, body mass index, waist circumference and body fat percentage will be measured using the Tanita scale

You will be asked to wear a continuous glucose monitor (CGM) for 10 days for baseline measurements. A CGM tracks your glucose levels continuously day and night. It is a small discreet device that you wear on your arm. It measures glucose levels in the space just under your skin through a slim sensor wire. A patch holds the CGM monitor in place so it can measure glucose readings throughout the day and night. You will be wearing the G7 sensor for 10 days and will be able to go about your usual activity while wearing the monitor. This is to ensure you do not have any skin irritation or discomfort with the sensor. The health coach will insert the sensor using an automatic applicator. You may feel a pinch or pressure while the sensor is being inserted, although many find it to be painless. You will not be able to see your glucose data while wearing the G7. You will be given a G7 receiver that will store the glucose data. A receiver is a small device that looks like a phone. You may remove the sensor at day 11 or return to the Y to have it removed.

You will be asked to fill out the following questionnaires after you have worn the G7 sensor for 10 days. This will be done on an iPad/smart device and the study staff will be available to assist as needed. The questionnaires are:

- Nutritional assessment using Picture Your Plate (PYP), a brief dietary assessment questionnaire developed to assess how well an individual's eating habits line up with current evidence-based recommendations.
- Physical activity assessment using International Physical Activity Questionnaire (IPAQ), a 7-question self-reported measure of physical activity
- Self-perceived health and wellness assessment
- Prediabetes empowerment scale: how confident and capable you feel about managing prediabetes

Study Treatment:

If you have no skin irritation or discomfort from the CGM, you will be randomly assigned by chance (like the flip of a coin) to wear the Stelo CGM continuously for 24 weeks or to wear the G7 at 6 weeks, 12 weeks and 24 weeks.

You will be able to see your glucose data in real time if you are assigned to the group wearing the Stelo CGM. If you are assigned to the group wearing the G7 at 6, 12 and 24 weeks, your glucose data is blinded and you will not be able to see it. However, the glucose data will be given to you at the end of the study. You have a 50% chance of being assigned to the group wearing the Stelo CGM.

This is an open-label study. This means you, the study doctor, study staff and the sponsor will know whether you are wearing the Stelo CGM or the Dexcom G7. The Stelo is worn for 24 weeks and the G7 is worn for 10 days (at 6, 12, and 24 weeks). You will be able to take the CGM off at the end of the wear period. This is like taking a bandaid off. You will be asked to return the used G7 to the Y.

You will have the following study visits and undergo the following interventions and assessments:

- Group sessions with a health coach weekly for the first 12 weeks followed by 3 monthly sessions. These sessions will include physical fitness activities and educational information on nutrition, motivation, coping, stress management and glucose levels. The first session will be 120 min. All subsequent sessions will last 60 minutes
- Weight, BMI, waist circumference and body fat percentage will be measured every 4 weeks using a simple weight like scale
- Personalized recommendation for a Y class
- Family Y Membership for 24 weeks. You will receive a 12 week Membership at the time of enrollment. This Family Membership will be renewed for an additional 12 weeks at the time of the 12 week visit
- Final class at 24 weeks

The following assessments will be performed at 12 and 24 weeks:

- Nutritional assessment using Picture Your Plate (PYP), a brief dietary assessment questionnaire developed to assess how well an individual's eating habits line up with current evidence-based recommendations.
- Physical activity assessment using International Physical Activity Questionnaire (IPAQ), a 7-question self-reported measure of physical activity
- Self-perceived health and wellness assessment
- Prediabetes empowerment scale: how confident and capable you feel about managing prediabetes
- Study specific questions: about your experiences with the program and with Stelo
- Functional fitness assessment

<u>After Study Treatment</u>:

Your complimentary Y Family Membership will last for the full 24 weeks of the study and not after the study is over. The CGM device will not be provided after the study is completed.

EXPECTATIONS

If you participate in this study, you will be expected to:

- Wear a CGM
- Attend weekly group sessions with the health coach for 12 weeks followed by 3 monthly sessions. The first session is 120 min and subsequent sessions are 60 min
- Have an A1c blood test. The study staff will do this by poking your finger at the beginning of the study, at 12 weeks and at the end of the study (24 weeks)
- Enroll and attend a Y class of your choice
- Fill out all questionnaires at the beginning of the study, at 12 weeks and at the end of the study (24 weeks)

- Do a fitness assessment with the health coach at the beginning of the study, at 12 weeks and at the end of the study (24 weeks)
- Have your weight, BMI, waist circumference and body fat percentage measured every 4 weeks
- Optional: a one hour phone interview about your experiences during the study

ARE THERE RISKS INVOLVED IF I AM IN THIS STUDY?

This study is being performed as part of a healthy lifestyle program at the YMCA of the Blue Water Area. You will be asked to wear a continuous glucose monitor (CGM) that measures glucose levels continuously in the interstitial fluid. The CGM devices are FDA approved for use in individuals with diabetes. Risks associated with CGM insertion and use are bleeding/skin irritation at the site of insertion and pain.

We will poke your finger to obtain an A1c blood test. This will be done at the time of screening and at 12 and 24 weeks. Possible side effects from finger stick blood test include faintness, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

The weekly group sessions with the health coach involve physical fitness activities, which are individualized to your preferences. These may cause muscle aches, muscle cramps or rarely muscle injury

If you are on a medication that lowers glucose levels (as prescribed by your treating physician, as this study does not provide any medications), it is possible you will experience symptoms of low glucose such as blurred vision, feeling weak, lightheaded, shaky or dizzy. You should inform the study staff if you notice any of these symptoms

The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

There may be other risks that are unknown.

WILL BEING IN THIS STUDY HELP ME?

Potential benefits of being in the study include helping you learn about healthy nutrition, physical fitness and prediabetes. You will receive a Family Membership for 24 weeks and a Y Class of your choice at no cost to you. This study provides an opportunity to improve your eating habits, physical fitness, physical activity and glucose levels.

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

There will be no charge to you for your participation in this study. The continuous glucose monitor (CGM), A1c blood test, study visits with the health coach, Y class and Y Family Membership will be provided at no charge to you or your insurance company.

A personal smartphone/smart device is required for the study. The study does not pay for the smartphone/smart device or any charges such as Wi-Fi associated with use of the device

WHO IS PAYING FOR THIS STUDY?

This study is being conducted by the YMCA of the Blue Water Area(Y). The Y has received a grant from Dexcom to help pay for the expenses associated with the study.

WILL I RECEIVE PAYMENT?

You will be paid up to a total of $100 if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $75 for completing weekly visits and all questionnaires during the first 12 weeks
- $25 for completing the monthly visits and all final questionnaires

You will be paid in installments at 12 weeks and 24 weeks.

If you do not complete the study, for any reason, you will be paid for the portion of study visits you complete.

If you decide to participate in a voluntary one hour optional phone interview about your experience during the study, you will receive $30 for your time.

If you have any questions regarding your compensation for participation, please contact the study staff.

DO I HAVE TO BE IN THIS STUDY?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you and you will not lose any benefits. Your ability to participate in activities at the Y will not be affected whether or not you decide to be in the study. If you want to stop being in the study, tell Sheila Volker, Dr Reddy or the study staff. If you leave the study, Dr Reddy and the YMCA staff will still be able to use your information that they have already collected.

Enrollment of Employees/Family Member

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You/your family member may withdraw from the study at any time and for any reason, and neither your/your family member's decision to participate in the study, nor any decision on your/their part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical research center. You/your

family member may refuse to participate or you/your family member may withdraw from the study at any time without penalty or anyone blaming you.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for prediabetes. Your options may include:

- Obtaining a Y Membership
- Enrolling in a Y Class
- Obtaining a CGM over the counter or through your personal doctor
- Increasing your physical activity, eating healthy foods and losing weight
- Seeing your primary care provider to consider taking a medication such as metformin to better manage your blood glucose levels

Please talk to the study doctor or study staff about your options before you decide whether or not you wish to take part in this study. We also encourage you to discuss any data that you receive regarding the CGM if you have questions or concerns and before you make any decisions about your health.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your identity and protected health information will be protected according to HIPPA regulations, as required by law and as per the privacy practices of YMCA of the Blue Water Area. Be aware that your CGM data, A1c, medical history, fitness assessments, consent form and all questionnaires will be shared as needed with the study staff to analyze data and report outcomes. Information about the data collected in this study may be published in reports or journals or presented at scientific meetings; however, you will never be identified in these reports.

Records of your participation in this study will be held confidential, except when sharing the information is required by law or as described in this informed consent. The Study Doctor, the sponsor or persons working on behalf of the sponsor, and, under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name.

This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff you think you have been injured, they will help you get the care you need.

If it is determined you are injured as a result of using the CGM or from interventions done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;

- The Study Doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Study Doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00083644.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒**YES** (If yes, please complete the information below)

❒**NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions, and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the

Consent Discussion

_____ _____

Signature of the Person Conducting the Date

Consent Discussion

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (if applicable)

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of YMCA of the Blue Water Area
- Representatives of Dexcom
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- A data safety monitoring board which oversees this study

Your health data will be used to conduct and oversee the research, including for instance:

- To see if CGM improve physical activity, nutritional habits and glucose levels

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ (IF APPLICABLE)

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date