CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: **Evaluation of a Remotely-Delivered Intervention for Persons Who Regain Weight after Bariatric Surgery**

Sponsor(s): **National institute of Diabetes and Digestive and Kidney Disease (NIDDK)**

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent (permission) form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Temple University will not change or be affected.

The purpose of this study is to learn more about the effectiveness of a behavioral remotely-delivered weight control program designed to minimize weight regain after bariatric surgery. Specifically, this study will evaluate how successful this program is in helping patients maintain or lose weight after bariatric surgery.

If you agree to participate in this study, your participation may last up to 12 months and you will be asked to complete 4 study visits (baseline, 3 months, 6 months, 12 months). During these visits, you will be asked to complete questionnaires, complete physical measurements (i.e., weight, blood pressure), and undergo a blood draw. You will also be asked to complete one of two treatments, which are both delivered remotely (via Internet and/or telephone), which will be 6 months in duration. For a detailed description of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are risks to you for participating in this study. In this study, potential risks associated with undergoing lifestyle interventions that include diet and exercise modification include injury from

exercise, inadequate nutrition from caloric restriction, hypoglycemia (especially if you have diabetes), and hypotension (especially if you are using medications that lower your blood pressure). If enrolled in the study, you will be encouraged to follow guidance from study personnel and your physician to help prevent these risks.

There are other options available to you if you decide not to participate in this study. You may choose another form of treatment or care for weight regain without being in a study such as:

- Seeking weight loss help from your doctor
- Joining a community-based weight loss group

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you underwent bariatric surgery 6 to 48 months ago and report a weight regain of at least 5% of your lowest weight since surgery.

How many participants will take part in this study?

About 200 participants are expected to take part in this study. This is a multi-site study and 100 participants are expected to enroll at Temple University.

What are the activities you will be doing if you participate in this study?

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

Screening and Randomization

At the beginning of the study, you will be interviewed to determine if you are eligible to participate in the study. It is up to the research team to make a final decision about whether it is advisable for you to participate in the study. This judgment will be based on all of the information available to the team.

If you are eligible for the study you understand that you will be randomly assigned to one of two conditions. Being randomly assigned means that you will have an equal chance of being assigned to either the Intervention condition or the Control condition. To determine which condition you are in, a random procedure (similar to drawing a number from a hat or flipping a coin) will be conducted.

Treatment Conditions

Intervention. If you are assigned the intervention condition, you will complete a 6-month intervention delivered online and through phone coach calls where you will be asked to follow a plan to maintain or lose weight by altering your eating habits, your physical activity, and the way you think about your eating and weight. You will receive a Wi-Fi scale to complete regular weight measurements.

Control. If you are assigned to the control condition, you will complete 6-months of phone coach calls where you will review dietary and behavioral instruction that you received as part of your bariatric surgery process. You will receive a Wi-Fi scale to complete regular weight measurements.

Assessments

Study assessments will be completed at baseline (i.e., at study enrollment, prior to starting treatment), mid-treatment (i.e., 3 months after study enrollment), post-treatment (i.e., 6 months after study enrollment), and follow up (i.e., 12 months after study enrollment. Each assessment includes:

- Weight measurement
- Blood pressure measurement
- Blood draw to evaluate blood glucose, HbA1c, cholesterol, and triglycerides (after a 12 hour fast)
    - Blood will be drawn from a vein in your arm at each assessment visit
    - 5-10 mL of blood will be drawn at each assessment (4 visits), i.e., 20-40 mL total (or, approximately 1.5-3 tablespoons)
- The completion of the online surveys
- Wearing a muti-sensor monitor on your wrist for 7 days to measure physical activity

At the baseline, mid-treatment, post-treatment, and follow up assessments, you will also be asked to:

- Complete 7 brief surveys daily on your smartphone that will measure your in-the-moment eating behavior and internal states (e.g., cravings, hunger, emotions)

What do you need to know regarding the collection of biospecimens?

Biospecimens are materials that come from your body that may include blood, tissue, urine, bone marrow, saliva, cells, etc. In this study, we will collect blood.

Most biospecimens contain DNA. We will not use biospecimens collected as a part of this study for whole genome sequencing, which involves mapping (identifying the location of genes and the distance between them) of all of your DNA.

Will your information be used for research in the future?

Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about participating in future research?

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

Will you receive your individual results from the study?

Generally, activities performed for research purposes are not meant to provide clinical information. We may learn things about you from this study which could be important to your health or treatment. However, we will not share these results with you.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. No negative consequences will be result should you decide to withdraw from the research study.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Temple University will not withhold (keep back) or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Sarwer, his study team, and other Temple personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information (the personal information we collect about you) that identifies you for the study described in this document.

During the study, Dr. Sarwer and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Temple may use or disclose for this research includes:

- Weights (pre-bariatric surgery and any time points after surgery
- Height
- Any surgical complications
- History of treatment with the surgery team (e.g., surgeon, dietitian, psychologist)
- Lab data
- Medical conditions

Dr. Sarwer and his study team may share your health information and the results of your study-related procedures and tests with people outside of Temple who assist with the conduct and review of this study. The people who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- The study Sponsor, NIDDK, and its representatives, including the Data Safety Monitoring Board
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Sarwer is not required to release study information to you that is not part of your medical record. Temple is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. A small portion of phone coach calls will be recorded to help ensure the treatment is delivered correctly. After records are reviewed by Dr. Sarwer, they will be deleted.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Sarwer at 3223 N Broad Street Philadelphia, PA 19140. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety (the entire time) of this research study. It will expire when the study is completed or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All identifiable information will be removed for analyses and none will be directly linked to your data (i.e., you will receive a unique study identifier).

The Temple Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.***

If you tell us about actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly

adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

All costs for the required study visits, examinations, and laboratory procedures will be paid by the study Sponsor, NIDDK.

Will you be paid for your participation in this study?

You will be paid for completing each assessment, including $50 at baseline, $50 at mid-treatment, $75 at post-treatment, and $75 at 6-month follow-up, with an additional up to $31.50 for baseline, mid-treatment, post-treatment, and follow up smartphone prompts (i.e., $0.75 for completing each smartphone-based survey within 45 minutes of prompts). If you do not finish this study, you will be paid for the study visits you have completed. You will be paid within approximately 30 days.

You will also be paid for travel expenses incurred while traveling to and parking at Temple. Travel reimbursement is set up in the following structure: $10 reimbursement for an hour of time and $20 reimbursement for two hours of time spent at Temple.

Federal tax law requires to you to report this payment as income to the Internal Revenue Service. You may be asked to tell us your social security number. If payments are more than $599.00, we will report them to the Internal Revenue Service and send you a Form 1099-MISC. If you do not give us your social security number, you may take part in this research if you agree to not be paid.

Payments will be made to you using ClinCard, a secure, reloadable MasterCard debit card supported by Greenphire. We will mail you the card. You will be given one card for the entire time of your participation. You will also get a pamphlet about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts MasterCard.

Greenphire is a company working with Temple University to manage and process payments. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. They will not receive any information about your health status or the study in which you are participating.

This information will not be associated with the information or data you provide for this research. It will be stored separately from your data, it will not be linked in any way, and your identifying information will be destroyed within 1 year of study completion.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Temple University will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Sarwer at telephone number (215) 707-8632.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Temple University has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can I talk to about this research?

If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team at:

3223 N. Broad Street, Suite 175
Philadelphia, PA 19140
(215) 707-8632
dsarwer@temple.edu

Federal law provides additional protections of your personal information. These are described in an attached document titled “Authorization to use and disclose your protected health information.

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (215) 707-3390 or e-mail them at: irb@temple.edu for any of the following:

- 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 subject.
- You want to get information or provide input about this research.

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	