RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: REBOOT: Response to Behavioral Obesity Treatment
Sponsor(s): National Institutes of Health (NIH)

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 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 Rush University Medical Center will not change or be affected.

The purpose of this study is to find out why some people lose more weight in behavioral obesity treatment programs than others. Behavioral obesity treatment programs are generally effective, with most people losing between 15 and 25 lbs. within 6 months. However, not everyone benefits equally. In this study, we will measure a wide variety of factors that are thought to influence how much weight people lose in a behavioral weight loss program that has been well-studied and is already known to be effective.

If you agree to participate in this study, your participation may last up to 7 months. You will be asked to complete a screening interview, either online or on the telephone with a researcher. The screening should take about 10 minutes. Your height, weight, and the distance around your waist will be measured. We will also ask you questions about your household, including your educational history and your current financial situation. There are also questions about your medical history, substance use, and previous stressful life experiences.

If you are eligible, the next step would be to complete a set of surveys, which would likely take between 45-60 minutes. You will have the option to complete some of these surveys at home on the computer. In addition to the surveys, you will be asked to complete some brief cognitive tasks on a computer. These tasks measure your processing speed, short-term memory, and impulse control. We would then assist you in downloading a free smartphone app that allows you to complete brief surveys several times per day. For the first week of the study, you will receive five notifications to complete a brief survey on your phone. Each survey should take less than four minutes. You will receive $1 for each survey that you complete within 1 hour of the notification. You will also be asked to wear a small device called an accelerometer, which tracks your physical activity. The device is about the size of a watch, and is worn around the waist under your clothing. You will need to wear the device every day for the next seven days, from the time you wake up until the time you go to sleep. Before going to sleep, you will have to take the device off of your waist and wear it on your wrist using a wrist strap.

All participants who enroll in this study will receive the same 6-month behavioral weight loss program. It is a group-based program, and about 16-18 people are expected to attend the sessions. The program includes 16 sessions, each lasting about an hour. We will provide you with the schedule of sessions. All sessions take place here in the Department of Preventive Medicine. Throughout the weight loss program, we encourage you to track what you eat in a free diet monitoring app/program called Lose It!. The researchers need to check your diet records, so you can either share your login information for Lose It!, or use a shared Lose It! account that we create for you. In months 1, 3, and 6 of the weight loss program, you will return to complete research assessment visits that include height and weight measurements, completing surveys, wearing the accelerometer (physical activity tracker) for 7 days, and completing surveys on your smartphone for 7 days. Altogether, the study involves about 6 hours for attending assessment visits and completing mobile surveys on your smartphone, and about 16 hours for the weight loss program.

STUDY ACTIVITY	**MONTH**						
	0	**1**	**2**	**3**	**4**	**5**	**6**
In-person research visit at Rush (90 mins)	X	X		X			X
Smartphone surveys (7 days)	X	X		X			X
Wear activity tracker (7 days)	X	X		X			X
Weight loss program sessions (16 total)		X	X	X	X	X	X

In this study, there is a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.

You may benefit from taking part in this study. Based on prior research using this weight loss program, we believe most people will have some degree of success losing weight. However, because individuals respond differently to the program, no one can know in advance if it will be helpful for you.

There are other options available to you if you decide not to participate in this study. You may choose another method of weight loss, including other behavioral programs, weight loss medications, or weight loss surgery. You should discuss these other options with your study doctor.

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 are interested in losing weight.

How many participants will take part in this study?
Approximately 230 participants are expected to take part in this study at Rush University Medical Center.

Will your information or biospecimens 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 or biospecimens are 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

What are the risks and discomforts of participating in this study?
One risk of being in this study is loss of confidentiality. It is possible that people other than the investigators will obtain your medical information, but precautions will be taken to prevent this from happening. Also, other participants who attend the group-based weight loss program may share information about their interactions with you outside of the group. The research team will ask all group members to respect each other's privacy, but cannot guarantee they will do so. The weight loss program itself is safe and does not involve any risks. However, when people become more physically active, there is a risk that they can injure themselves. In very rare circumstances, people can have a heart attack or stroke when they begin exercising. There may be other risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

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.

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. Rush University Medical Center and its affiliates ("Rush") will not withhold 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. Appelhans, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Appelhans 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. The health information that Rush may use or disclose for this research includes:

- Your height and weight measurements
- Your medical history, including any major health problems that can lead to weight gain, interfere with weight loss, or make it unsafe for you to exercise and lose weight

Dr. Appelhans and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons 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:

- To the Researchers, including members of the research team at University of Washington and Pennsylvania State University;
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB);

- MetricWire, the company that owns and maintains the platform for collecting the mobile phone surveys you will complete;
- Your email address (but not your health information) may be shared with CT Payer for the purpose of sending you electronic gift cards.

While you participate in the study you will have access to your medical record, but Dr. Appelhans is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Your identity will not be revealed on any report, publication, or at scientific meetings.

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. Appelhans at 1700 W. Van Buren St, Suite 470, Chicago, IL 60612. 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 of this research study. It will expire upon completion of the study 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. Your identity will be separated from your medical information. All of the information you provide will be coded with a numeric identifier to protect your identity.

The Rush 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. This research study can be found by searching for the following Clinical Trial Registry Number (NCT#): NCT05326477.

What are the costs to participate in this study?
All costs for the required study visits, examinations, and weight loss program will be paid by the National Institutes of Health.

You or your insurance will be responsible for paying for the cost of any routine medical care that you would receive whether you participate in this study or not.

Will you be paid for your participation in this study?
You can earn up to $340 if you complete all of the assessments and mobile surveys in this study on time. There are 4 in-person research assessment visits in this study, and you will receive $50 for completing each of them. You will also be asked to complete mobile surveys on your smartphone for 7 days following each of the in-person assessments. There are about 5 brief mobile surveys per day, and you will receive $1 for each mobile survey that you complete within 30 minutes of the notification.

You will receive payment in the form of a reloadable prepaid Visa debit card issued by a company called CT payer. At the end of assessment, we will add to your debit card the amount you have earned for completing both the in-person assessment and the mobile surveys on time (ranging from $50 to $85 total). Payments will be loaded onto the same physical debit card each time you complete a research visit, so you must keep the same card through the whole study, even if it reaches a balance of $0.00 (don't throw it away). If you do not finish this study, you will only be paid for the study activities you have completed. You will be paid within approximately 3-7 days after completing each assessment. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to pay you and for tax reporting purposes to the United States Internal Revenue Service (IRS).

You will not be paid for attending the weight loss program. To offset travel costs for weight loss program sessions, you will receive either a voucher to park in the Triangle Office Building visitor parking lot, or up to $8 reimbursement for public transportation.

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, Rush University Medical Center 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. Appelhans at telephone number 312-942-8260.

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.

Rush University Medical Center 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 you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Michelle Li at 312-942-8260 or email her at EatingLab@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Appelhans in writing at the address on the first page. Dr. Appelhans may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

_____	_____	_____
Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

_____	_____
Signature of Individual Obtaining Consent	Date of Signature