RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Engaging men from blue-collar industries in weight loss: Tailoring recruitment and treatment approaches
Sponsor(s): National Institute of Diabetes and Digestive and Kidney Diseases

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 test whether a new, tailored behavioral weight control intervention focused on changing eating and activity is acceptable to participants as compared to a standard behavioral program. Both programs will be delivered during 16 group sessions delivered online.

If you agree to participate in this study, your participation may last up to 6 months and you will be asked to complete 3 study visits.

During these visits, you will be asked to fill out an online survey and will have your height, weight, and waist measured. You will also be asked about your health and physical activity. You may also be asked to take part in a short interview.

This study includes little risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam For a detailed list of risks you should know about, please see the "*What are the risks and discomforts of participating in this*

study?" section of this consent form.

You may benefit from the information you learn through group sessions or lesson materials about healthy eating and physical activity However, because individuals respond differently to programs like this, no one can know in advance if it will be helpful for you.

If you decide not to participate in this study, there is other care available to you, such as joining a commercial, medical, or community-based weight loss program. The study doctor will discuss these choices with you. You do not have to be in this study to be treated for weight loss.

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 a man whose weight places them in an overweight category and you work in an industry such as construction, transportation, or manufacturing.

How many participants will take part in this study?
Approximately 60 participants are expected to take part in this study at Rush University Medical Center.

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

Everyone who chooses to participate in this study will be asked to complete 3 assessments and 16 online program sessions. You may be asked to participate in an interview.

Three assessment visits will be scheduled before the program starts, approximately 3 months later, and 3 months after that. For each assessment visit, you will come to Rush University Medical Center for an appointment. At the appointment, your weight, height, and waist circumference will be measured similar to how it is measured at your doctor's office. A member of the study staff will ask you questions about your physical activity and about any health concerns you may have experienced in the past three months. You will be asked to complete online questionnaires either before your visit or during your visit using a study supplied tablet or computer. The questionnaires will ask about your health, diet, physical activity, and other habits. This visit will take less than 60 minutes.

After you complete the baseline visit, you will be randomly assigned (meaning by chance, like the flip of a coin) to receive either a tailored program or a standard program that focuses on helping you to change your eating and physical activity. Both programs include 16 online group sessions. These sessions will be held each week for 3 months, twice a month for 1 month, and 1 time a month for two months. These sessions will all be conducted online using the Zoom conferencing website. You will be emailed a link to join these meetings. The sessions will last up to 60 minutes and will include learning about topics related to weight loss, diet, and activity. During the program, you will be encouraged to track your progress toward weight loss goals by recording your weight, eating

habits, and activity. This will require additional time outside of the group sessions. You will also be given access to video or printed information related to the group sessions. The group sessions will be audio recorded to allow study team members to review the material covered during the group sessions.

You may be asked to participate in an interview. During the interview, you will meet with a member of the study team (either in person, over the telephone, or over Zoom) who will ask you questions about your experiences in the program. This may take up to 30 minutes to complete. This session will be audio recorded.

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

What are the risks and discomforts of participating in this study?
Side effects, risks, and/or discomforts from participation in this study may include:

- Risks of Increasing Physical Activity: Risks involved with increasing your physical activity include, but are not limited to, injuries to the muscles, ligaments, tendons and joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will follow guidelines and safety recommendations for physical activity set forth by the American College of Sports Medicine. The study will provide you with information and recommendations for safely increasing your physical activity and will make modifications to your program if you experience any of the above problems.
- Risk of Breach of Confidentiality: Because you will be asked to attend group meetings, research staff cannot guarantee confidentiality of your identity, or information discussed during group sessions. However, although there is a slight risk that your confidentiality will be breached, all study volunteers are strongly encouraged to maintain strict confidentiality.

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.

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. Melissa Crane, her 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. Crane and her 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:

- Demographic and occupation information: this will help us understand who is taking part in the study.
- Weight, waist circumference, and height: These measures will help us understand whether the weight loss program has an effect on your body.
- Eating, activity, and weight control strategies data: These measures will help to see whether the program helps you to change your behaviors in these areas.
- Audio recordings of the interviews and group sessions. These recordings will be stored securely and will be transcribed. No identifiable information will be included any reports of the interviews.

Dr. Crane and her 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:

- The study Sponsor, NIDDK, and its representatives;

- 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. Crane 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. 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. Audio recordings of interviews and treatment sessions will be kept for up to 2 years after the completion of the study to allow for additional analysis. These recordings will be destroyed/deleted after that time.

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. Crane at melissa_m_crane@rush.edu or 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. Following the completion of the study, all identifying information (e.g., names) will be removed from the dataset and all remaining information will be linked by identification numbers alone

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#): NCT05386238.

What are the costs to participate in this study?

All costs for the required study will be paid for by the sponsor.

Will you be paid for your participation in this study?

You will be paid via cash or Amazon gift card for each completed study visit for a total of up to $125. If you do not finish this study, you will be paid for the study visits you have completed. You will be paid after each completed visit immediately, if in person, or within one week via email if not in person. You will be paid the following:

- $25 for completing the baseline visit
- $25 for completing the 3-month visit
- $50 for completing the 6-month visit
- $25 for completing the interview (optional)

Who can you contact for more information about this study?

Questions are encouraged. If you have further questions about this study, you may call Melissa Crane, PhD at 312-563-0269 or email her at melissa_m_crane@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. Crane in writing at the address on the first page. Dr. Crane 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