Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

- ☐ Rhode Island Hospital
- ☐ Bradley Hospital
- ☒ The Miriam Hospital
- ☒ Newport Hospital
- ☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

0122-17
Committee #

Name of Study Volunteer

Optimization and Evaluation of a Tailored Behavioral eHealth/mHealth Weight Loss Intervention for Cardiac Rehabilitation Patients Using the Multiphase Optimization Strategy

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

You are being asked to take part in a research project because you are currently participating in The Miriam Hospital's Cardiac Rehabilitation (CR). You are between the ages of 21 and 75 with a body mass index (BMI) of 27 kg/m2 or above. You also speak English and have in-home access to an Internet-connected device such as a home personal computer, tablet, or smartphone. You are currently participating in The Miriam Hospital's or Newport Hospital's Phase-II (outpatient) CR. Dr. Wu, the medical director of CR, has declared you medically safe to participate in this program.

The purpose of this study is to evaluate online program and new technology-based tools that may help CR patients lose weight. We expect to enroll 160 subjects into this study. The study is sponsored by the National Heart, Lung, and Blood Institute.

2. Explanation of Procedures

If you take part in this study, you will allow a member of the study staff to go into your medical chart and record a list of the health problems you have (e.g., diabetes, high blood pressure) and the

specific diagnosis that caused you to come to CR (e.g., a heart attack). This information will be kept in a confidential chart.

If you choose to participate in this study, you will be asked to attend a baseline assessment visit at either the WCDRC, CR, over the phone, via mail, or via video conference using Microsoft Teams, GoToMeeting, or Zoom where you will complete questionnaires about your physical activity, eating behaviors, mood, health, and strategies you have used to lose weight as well as a demographic questionnaire. Some of these questionnaires will be on the computer, and some will be a pencil and paper survey. You will complete a very brief assessment of your cognition; this assessment feels like completing a few puzzles and word games. Your height and weight will also be measured or recorded from your CR chart. You will also wear an armband on your upper arm for one week during the majority of your daily activities. This armband will be sized to fit you comfortably. It tracks your physical activity while you are awake. It will not interfere with any devices in your body, particularly devices that affect your heart (e.g., implantable cardioverter defibrillator). All of the information that you provide or that is taken from your medical chart will be kept confidential. Please see Section 9 of this form for additional details on the ways the research staff will maintain your privacy. This first visit will take up to 90 minutes. You will be asked to return to the WCDRC or CR for an assessment visit 3 months into the 6-month treatment program, and again at the end of the 6-month treatment program. Alternatively, you may complete the assessments online via a secure link, by mail, and/or over the phone with one of the research staff members. In that case, you will need to either receive the armband in the mail and send it back to us, or pick it up and drop it off. Again, we will accommodate you based on your preference. At these assessment visits, you will again complete questionnaires and have your weight measured. You will also wear the armband for one week prior to these visits. We will mail the armband to you ahead of time, or you are welcome to meet a member of the research staff to pick it up if that is your preference. You will receive $25 via cash, check or gift card for completing the 3-month visit, and you will receive $50 via cash, check, or gift card for completing the 6-month assessment visit. These two visits will take up to 75 minutes each. Free parking adjacent to the building is available at both sites. All study sites are equipped with automated external defibrillators and CPR-certified staff in the event of an emergency, and CR and the WCDRC are within a 4-minute drive of the The Miriam Hospital and Rhode Island Hospital, respectively.

All the participants will receive a 24-week Internet weight loss program. You will be given access to a study website that contains weekly video lessons. These lessons will provide audio and video training for healthy eating and physical activity and will teach you behavioral strategies for implementing these changes. A new video will be posted each week for the first 12 weeks, and you will be able to watch these videos whenever you choose. Each video is approximately 15-25 minutes in length. In the second half of the study (months 4-6), you will gain access to one video each month that is specifically tailored to patients like you who have heart disease and are trying to lose weight or maintain weight they have already lost. In addition, you will be asked to enter your daily caloric intake, weight, and exercise minutes onto the study website 12 weeks. After 12 weeks, you will only be asked to enter your weight for that week. Each week, you will receive written online feedback on your progress in the program. The physician that referred you to this study will also be mailed periodic reports over the course of the 24-week weight loss program with information about your progress in the program (e.g., number of video lessons viewed, amount of weight loss). You can be mailed a copy of these reports if you request them. This website is tailored specifically to the needs of CR patients, and it is complementary to your CR program, so you will

not receive conflicting advice about what is healthy for you. The website was tailored to meet your needs under the advice of staff from The Miriam Hospital's CR.

If you consent to participate in this study and complete the baseline assessment visit, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of receiving each additional component, and you will be equally likely to not receive each component. Some people in the study will not receive any additional components, while some people will receive 1, 2, 3, or all 4. Some participants will receive no additional components beyond the 24-week weight loss program, and by agreeing to be in the study, you are willing to use however many components you are randomized to receive.

Component 1: Fitbit with a Structured Physical Activity Intervention

Half of the participants in this study (80 people) will receive a commercially-available Fitbit, which is a wrist-worn physical activity monitor. These participants will also receive a 10-minute weekly informational video with exercise tips and advice on meeting recommended weekly physical activity minute goals. The research team will encourage participants to walk to meet their physical activity goal due to walking's safety and accessibility. The research team will monitor these participants' physical activity through the Fitbit system and will send personalized feedback intended to help participants reach their activity goals. For individuals already achieving the weekly recommended physical activity minute goals, we will provide encouragement and advice for sustaining this frequency and intensity of physical activity. All participants in this group need to have an email address; study staff can help participants set one up if they do not have an email address or want one that will be used solely for the purposes of this study. This email address will be linked to a Fitbit account, and this password-protected account will seamlessly send your data (daily step counts, activity minutes, sleep patterns, and heart rate) to our program. This means that you do not have to log into our system to tell us how many steps you took each day. After the study has been completed, participants who were randomized to this component will keep the Fitbit as their own personal device and data will no longer be extracted from the Fitbit.

Component 2: Bite Counter Device for Dietary Restriction

Half of the participants in this study (80 people) will receive a commercially-available wrist-worn device that counts the number of times that food is brought to the mouth during an eating episode. Participants in this group will be instructed to wear the Bite Counter on their dominant wrist during waking hours and press a button on the watch when they start and stop eating. After two weeks of using the Bite Counter in this fashion, we will provide a bite goal for each meal. The bite goal is a number of bites to take per meal that should allow you to eat enough food without going off the reduced-calorie diet that we recommend; the bite goal is tailored to you based on how you tend to eat. When you reach the bite goal, a small alarm will sound from the watch notifying you to stop eating; the Bite Counter tracks the number of bites for you. The device can be customized with different bands of different styles and sizes to meet your needs and to maximize comfort. We will ask participants in this condition to briefly visit our office two weeks into the study, then another 2 weeks later, and then monthly so we can download the data (the number of bites you took each day). This visit will be 5 minutes long and scheduled at your convenience. At this visit, we will wipe your old data off your device and help you if you are running into trouble with the Bite

Counter. Alternatively, we can help participants send us the data using a secure server that does not record your personal information.

Component 3: Virtual Reality for Behavioral Weight Loss Skills Practice

Half of the participants in this study (80 people) will receive exclusive access to an online program that allows participants to practice using behavioral weight loss skills in a virtual reality setting. All participants must have a home personal computer or laptop to complete this program. The program provides 4 interactive scenarios (1 every 2 weeks), and each scenario (once released) is available for the duration of the study. The purpose of each scenario is to allow you to assume the role of the character, Alex, who is navigating her home, work, social, and gym environments as she tries to make healthy choices in service of weight loss. There are no right or wrong answers, but you will be allowed to choose Alex's actions and see the consequences. The purpose of the program is to allow you to practice the skills that will help you successfully lose weight in a non-judgmental setting from the comfort of your own home.

Component 4: Virtual Group Meetings

Half of the participants in this study (80 people) will receive hour-long biweekly via Microsoft Teams,GoToMeeting, or Zoom, which are free software packages you will download on your home computer. You will be asked to participate in at least 6 of these meetings during your participation, but you are encouraged to complete as many as 12. These group appointments are led by an expert and are designed to give you additional weight loss support. The same group topic will occur twice in one week (one daytime meeting and one evening meeting) to accommodate your schedule. The topics are designed and selected to benefit patients with heart disease who are trying to lose weight or maintain a healthy weight loss. We will ask you to please maintain the confidentiality of other members in the group. Since the topics will be presented on a rotating schedule, participants may join at any time and will not experience a repeated topic. You can log into the portal to view which meeting topics you have already attended and to see the schedule of future meetings.

Follow-Up Medical Record Check

Our hope is that this program reduces your risk of having another cardiac event or a worsening of your symptoms. We would like to check your medical record 18 months after you complete our program to see if you have attended cardiac rehabilitation again, if you have been rehospitalized or visited the emergency room, if you have another major medical event (e.g., a heart attack), or if you pass away. By signing this consent form, you are allowing the research staff to check your Lifespan medical record one year after you finish the study to assess for these. If you withdraw from the study, we will automatically not look in your chart.

<u>Future Studies</u>

It is possible that you may qualify to participate in future studies related to weight management or heart health. If you would like to be contacted about future studies that you may qualify for, including phone-based follow-ups to hear how you are doing after the program ends, please indicate your choice below. If you would like to grant us permission to contact you, your contact information will be stored in a secure list under the Principal Investigator's control. Your information will not be distributed to anyone outside of the Weight Control and Diabetes Research

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Center or Lifespan's Cardiac Rehabilitation. You will only be contacted about specific studies that may interest you that we believe you may qualify for.

____ You have my permission to contact me about future studies that I may qualify for.

____ I do not give my permission for you to contact me about future studies that I may qualify for.

_____ _____
Signature of study volunteer Date

You have the right to change your mind at any time regarding being contacted about future studies or follow-ups. If you decide to quit the study please tell the head researcher, Dr. Carly M. Goldstein, PhD, at 401-793-8960 or *carly.goldstein@lifespan.org*.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include access to the online core weight loss program and access to any of the additional components (e.g., the fitness tracker, the virtual meetings). Those services will be paid for by the study and will not be billed to you or your health insurance company.

Other services you will receive during this research study are considered "routine clinical services" that you would have received even if you were not in the research study. Examples are the services involved in your participation in cardiac rehabilitation. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information:

This study's primary investigator is Dr. Carly M. Goldstein, PhD, Research Scientist for The Miriam Hospital and Assistant Professor (Research) at Brown Medical School. You may reach her any time at 401-793-8960 or carly.goldstein@lifespan.org; she is available to answer questions about the research study or to address any concerns. Please do not hesitate to reach out to her prior to signing this form or any time after you consider whether or not to participate. In the event of an emergency, please do not contact Dr. Goldstein; please immediately call 911 or present to the emergency room if it is safe for you to do so. In the event of an emergency that relates to your health or participation in the study, please contact the study staff after you are safe to do so.

3. Discomforts and Risks

The risks of participating in this study are minimal. The programs may not be effective in helping you lose weight. It is possible that you could feel some hunger if you reduce your food intake to try to lose weight, or could be injured from exercise during this program.

There are also some risks associated with exercising after a cardiovascular event. These risks are no greater than the risks you accept when you sign up to attend cardiac rehabilitation. To protect you, a cardiologist (Dr. Wu, the CR's Medical Director) will review your medical record to determine that it is safe for you to participate in this program. The staff you will interact with are CPR-certified and know what to do in the event of a health emergency. You should always adhere to your healthcare provider's recommendations, and in the unlikely event that the study member or a member of the study staff recommends a practice that contradicts the advice of your healthcare provider, please follow your healthcare provider's advice and contact the research team immediately to notify us of this discrepancy.

4. Benefits

All participants in this study will receive information about weight loss, healthy eating, cardiovascular disease self-management, and physical activity. Participation in this program may help you lose weight; however, there is no guarantee that this program will help you lose weight. Participation in this program may help you reduce your risk of a future cardiovascular event (e.g., heart attack); however, there is no guarantee that this program will help you reverse cardiovascular damage or reduce your risk of a future cardiovascular event.

5. Alternative Therapies

Other behavioral weight loss programs are available from healthcare providers and companies. Additionally, you may participate in cardiac rehabilitation without also participating in this research study.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 18-months. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record. We will be looking for indicators of your health like hospitalizations, new diagnoses, lab values like your lipid profile, your blood pressure, death, and new participation in cardiac or pulmonary rehabilitation.

____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

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_____ _____
Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher, Dr. Carly M. Goldstein, PhD, at 401-793-8960 or *carly.goldstein@lifespan.org*.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

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Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor, The National Institutes of Health
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

Clinical Trials:
Additionally, 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.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

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SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on August 16, 2022. DO NOT sign this document after this expiration date

The Researcher is required to provide a copy of this consent to you.

_____ _____ _____
Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

_____ _____
Signature of witness (required if consent is presented orally or at the request of the IRB) Date

_____ _____
Signature of Translator Date

_____ _____ _____
Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

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