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

2096-18
Committee #

Name of Study Volunteer

Intervention approaches for improving long-term weight loss success

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 between the ages of 18 and 60 and you meet all of the other eligibility criteria for this study. The purpose of this study is to examine two approaches for improving long-term weight loss success. We expect to enroll approximately 65 individuals. The study is sponsored by a National Institutes of Health grant awarded to Dr. Jessica Unick.

2. Explanation of Procedures: If you decide that you are interested in taking part in this study, the next step is that you will complete a baseline assessment. As part of this assessment, we will measure your height and weight and you will be asked to complete a series of questionnaires, have a brief interview with study staff, wear an armband for 10 days, and answer surveys on your smartphone for 10 days. After completing each of these steps and if it is determined that you are eligible for the study, you will be asked to complete a 12-week weight loss program in which you will attend weekly, group-based meetings. Following this, you will receive one of two interventions aimed at improving long-term weight loss outcomes: cooking/dietary instruction classes or yoga (described in further detail below). Following the 12-week weight loss program, you will be randomly assigned "randomized into one of these study groups. 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 being in either of the two groups. Further, you will be asked to complete

assessments at baseline, 12 weeks, 24 weeks, and 1 year which will be used to evaluate these programs. The assessment visits and weight loss programs are described in detail below.

Assessment visits: Assessment visits will take approximately 1 hour to complete and will be completed at baseline, 12 weeks, 24 weeks, and 1 year. At each visit, you will be asked to complete multiple questionnaires and your height and weight will be measured. In addition, at the baseline, 12-week and 24-week assessments, you will be equipped with a physical activity monitor to wear, and you will be provided with instructions for the 10-day monitoring period.

10-day monitoring period: At baseline, 12, and 24 weeks you will be asked to wear a physical activity monitor (armband, which is worn on your upper arm) for 10 days. In addition, during this same 10-day period, you will also receive 5 text messages per day, delivered randomly to your smartphone between the hours of 8:00am and 10:00pm. When you receive these text messages, you will be asked to respond to a 3-5 minute survey. These surveys ask you about your mood, daily events, eating, and exercise behaviors. If you respond to less than 80% of these text messages at baseline or do not wear the armband as specified, you will not be eligible to participate in the weight loss program. Similar procedures for wearing the armband and answering surveys via your smartphone will also occur at 12 and 24 weeks. Please note, as part of this research study, you will receive about 5 text messages to your smartphone daily for a total of 4 weeks. In addition, the study will use your smartphone's Internet connection to transmit questions to you and receive your answers. The study is designed to use as little data as possible, but you are responsible for any costs associated with using your smartphone for study purposes.

12-week weight loss program: Everyone will attend weekly group meetings for the first 3 months which will last approximately 60 minutes. These weekly meetings will be held on the same night every week and the group will have approximately 15-20 members that will also be changing their diet and exercising in order to lose weight. If you are in this group, you will be placed on a diet that encourages you to decrease the amount of total calories and fat that you eat. You will be given a calorie goal ranging from 1200-1800 kcal/day with a goal of producing approximately a 1-2 pound weight loss per week. Also, you will be instructed to exercise 5 days per week with the duration on each day increasing to 200 min/week of aerobic exercise. You will record your food intake and your exercise in a diary, and this information will be provided to the investigators weekly.

Skills classes to maintain weight loss long-term: Following the completion of the 12-week weight loss program, you will be randomized to group-based cooking/dietary instruction classes or yoga classes. Both groups will meet twice per week for 12 weeks. The cooking/dietary instruction classes will focus on teaching you basic principles to healthy eating and will include weekly cooking demonstrations and taste testing. Participants who are randomized to the yoga group will practice approximately 55 minutes of group-based yoga, twice per week at our center. The type of yoga that we use is called Iyengar yoga which incorporates breathing, postures and mediation practices and utilizes 'props' (e.g., straps, blocks), to help maintain proper alignment and to reduce the risk of injury.

Compensation: You will not be compensated for completing the baseline assessment procedures. However, you will be compensated for the 12-week, 24-week, and 1 year assessment procedures. At the 12 and 24-week assessment time points, you will receive $0.50 for each text message survey that you respond to, and a $25 completion bonus if you respond to >80% of all text messages and wear the physical activity monitor as specified. In addition, you will be compensated $25 for completing the 12-week and 24-week in-person assessment visits (which includes questionnaire measures) and $50 for the 1-year in-person assessment visit, which also includes

questionnaires. In summary, you can earn up to a possible $75 at the 12-week assessment period, an additional $75 at the 24-week assessment period, and $50 at the 1-year assessment period. All payments will be in the form of cash.

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. An example of these 'research only' services includes the behavioral weight loss program, cooking and yoga classes that you will receive. 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 services you receive through your primary care provider or other healthcare professional outside of the Weight Control and Diabetes Research Center during the course of this study**.** 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:

Please call Dr. Jessica Unick at 401-793-8966 if you have any questions about these procedures for the study.

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. You may also experience mild skin irritation from wearing the armband, although this is not typical.

4. Benefits

All participants in this study will receive information about weight loss, healthy eating, 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.

5. Alternative Therapies

A variety of weight control programs are available from physicians, health clinics, and commercial programs.

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. In addition, the sponsor may choose to end the study at any time, for reasons unrelated to health care. Finally, if you were to become pregnant while enrolled in this study, you will no longer be able to participate.

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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.

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: NIH
- 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;

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- 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.

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

Permission to contact

_____ (initials) **YES**, I give permission to be contacted in the future for research studies.

_____ (initials) **NO**, I do not give permission to be contacted in the future for research studies.

Note: Your name and contact information will be stored separately from your personal health information (e.g. weight, questionnaire data, etc.).

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.

SIGNATURE

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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 does not have an 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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