IRB Approval:	11/20/2017
IRB Accepted:	11/20/2017
IRB Expiration:	11/19/2018

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

2047-14
Committee #

Name of Study Volunteer

Exercise Study

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 the relationships between how you feel, exercise and eating. We expect to enroll approximately 150 individuals. The study is sponsored by a National Institutes of Health grant awarded to Dr. Jessica Unick.

2. Explanation of Procedures: If you take part in this study, you will be randomized to either a 12-week exercise program or a delayed exercise condition, meaning that you cannot choose which group you are placed in (see below for additional details explaining both conditions). You will also be asked to complete assessment visits before the start of the study, half way through the study, and at the end of the study and you will be compensated for the 6-week and 12-week assessments. The following outlines all study procedures.

Condition 1: Exercise condition:
If you are randomized to the exercise condition, you will be given a weekly exercise goal of 200 min/week of moderate-intensity exercise and be asked to exercise on at least 5 days/week. Most of this exercise will be done on your own, but you will also exercise at our center 2 times/week during the first 4 weeks and once per week during weeks 5-12. During these exercise sessions at our center, we will frequently monitor your exercise intensity, your heart rate, and how you are feeling. The remaining exercise sessions you will do on your own, while wearing an armband which measures

exercise intensity. You will be asked to record the type and amount of exercise you did each day in a diary and downloaded armband data will be used to verify your diary reports. For each week that you achieve the exercise goal of 200 minutes, you will receive $10 in cash at the following weeks exercise visit; thus you will have the opportunity to earn up to $120 in cash across the 12-week period for achieving your weekly exercise goals. Further, as an additional incentive to meet your exercise goal, you will receive a $50 bonus (in the form of a gift card) at the completion of the study if you averaged >180 minutes/week of moderate-intensity exercise (as verified via the armband) across the 12-week period. To assist you in meeting your exercise goals, you will be required to get a gym membership for the 12-week period and you will be reimbursed up to $120 towards start-up and membership fees. The reimbursement schedule is as follows: Week 1: reimbursed for month 1 membership, Week 5: reimbursed for month 2 membership, Week 9: reimbursed for month 3 membership and start-up fees. This total will not exceed $120 and it will be given in cash at the time points specified. You will be required to provide verification of payment in order to be reimbursed.

Condition 2: Delayed exercise condition:
If randomized to the 'delayed exercise' condition, we ask that you make a strong effort not to change your exercise habits over the initial 12-week period. However, after the 12 weeks you will be given two options for increasing your exercise. Option 1: If you choose this option, you will receive one individual session with an exercise physiologist at our center and will be given an exercise prescription that you can do on your own. You will not come to any other visits at our center after that. Option 2: If you choose this option, you will be asked to commit to the same exercise program as described above in the 'exercise' condition. Thus, you will work your way up to 200 minutes/week of exercise over a 12-week period, you will be required to get a gym membership, and you will be asked to exercise at our center 2x/week for the first 4 weeks and once per week during the remaining weeks. You will receive the same compensation outlined above: reimbursed up to $120 in cash for gym fees, up to $120 in cash for meeting weekly exercise goals, and a $50 gift card if you average >180 min/week over the 12-week period. Thus by choosing option #2, you are committing to being in this study for an additional 12 weeks. Further, you will be asked to commit to doing additional assessments at 18 and 24 weeks (see below for more details).

Assessment visits: Compliance to assessment procedures is extremely valuable in helping us to answer our research questions. Assessments will occur at baseline, mid-intervention (week 6) and post-intervention (weeks 11-12) for individuals randomized to both the exercise condition and the delayed exercise condition. For those 'delayed exercise' condition participants choosing Option #2 outlined above, additional assessments will occur mid-way through the exercise intervention (week 18) and at the end of the exercise intervention (weeks 23-24). Given the importance of these assessment measures, you will be compensated for your time for all assessments, except the baseline assessment. See below for a detailed description of all assessment measures at each time point as well as the compensation schedule.

Baseline Assessment: At baseline, you will be asked to come to our center for approximately 1.5 hours. During this time, you will complete a packet of questionnaires and height and weight will be measured. Further, you will do a fitness test on the treadmill which typically lasts no longer than 10 minutes, and we will measure your body composition using a bioelectrical impedance analysis technique which requires electrodes to be placed on your skin and wires are then used to connect the electrodes to the body composition analyzer. Further, you will be given an armband to wear on your upper arm which measures physical activity and asked to where that for a 14-day period. During

that same 14-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 this study. Please note, as part of this research study, these text messages and surveys 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. You will not be compensated for any baseline assessment procedures and non-compliance to these procedures could mean that you are ineligible to participate in this study.

Mid-intervention Assessment: This assessment will occur during week 6. Your weight will be measured and you will be asked to complete several questionnaires. The visit to our center will be approximately 30 minutes. You will be compensated $25 in cash for this visit.

Post-intervention Assessment: This assessment will occur during weeks 11 & 12 and all measures will be identical to the baseline visit and you will also be asked to complete a brief computer task. You will be compensated $25 in cash for attending the 1.5 hour assessment visit at our center and completing all assessment procedures, including the questionnaires. Further, you will be asked to wear the armband and answer questions on your smartphone for a 14-day period. You will receive $0.50 for each text message responded to, and a $30 completion bonus if you respond to >80% of all text messages and wear the physical activity monitor as specified during the post-intervention assessment period. This means that you could earn up to an additional $65 in cash for wearing the armband and answering all of the surveys over the 14-day period at post-intervention.

Weekly Assessment: Throughout the 12-week program and also during weeks 13-24 for those in the delayed exercise condition choosing Option #2 above, you will be asked to complete a very brief (~1 minute) survey on your computer. You will be reminded to complete these surveys at the beginning of each week.

Week 18 and 24 Assessments: Assessments at 18 and 24 weeks are only for those participants randomized to the delayed exercise condition and choosing option #2 outlined above. The Week 18 visit will be identical to the 'mid-intervention' visit outlined above and the Week 24 visit will be identical to the 'post-intervention' visit outlined above. Thus, you would have the opportunity to earn $25 at the 18-week visit and an additional $90 at the 24-week visit, which will be paid in cash upon the completion of all assessment procedures for that time point.

Compensation: To summarize what is written above, participants randomized to the 'exercise' condition will have the potential to be compensated up to $405 ($355 in cash and $50 in gift card) over the 12-week period (up to $120 for gym membership, up to $170 for doing all of the prescribed exercise, and up to $115 for assessment procedures). Participants randomized to the 'delayed exercise' condition choosing option #1 outlined above will have the potential to be compensated up to $115 in cash over the 12-week period ($25 for mid-intervention and up to $90 for post-intervention assessment). Finally participants randomized the 'delayed exercise' condition choosing option #2 outlined above will have the potential to be compensated $520 ($470 in cash and $50 in gift card) over the 24-week period (up $115 for mid- and post-intervention assessments,

up to $120 for gym membership, up to $170 for doing all of the prescribed exercise, and up to $115 for weeks 18 and 24 assessments).

Text messaging

As mentioned above, text messaging is part of this research study. This may include you receiving text messages from research staff and/or you sending text messages to research staff. Lifespan takes your confidentiality seriously and will take steps to protect the information contained in the text messages to the degree permitted by the technology being used. Depending on the nature of the study, some of the following steps may be taken: encrypting the data during transmission, eliminating sensitive health care information from the texts, storing all data gathered on secure servers, providing you with a secure device when the circumstances warrant, and/or remote data deletion in the event of a lost or stolen device.

Specifically, in this study, the only text messages you will receive are those with the study name, instructing you to click on a link to complete the online survey. Once directed to the online survey, which is a secure website, all of the data obtained will be linked to an identification number assigned to you.

However, Lifespan can make no guarantees about the secure transmission of texts you send to us, nor can Lifespan guarantee security after you receive the text message from Lifespan. For example, text messages that display on your phone screen may be seen by someone close by, or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the texts about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen, and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared.

Finally, it is also possible that the mobile phone company that transmits the text messages may keep copies of ALL your texts (those from the study, and your other texts) even after the study is ended. Lifespan has no control over these companies and cannot make any guarantees about their conduct.

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 fitness tests and body composition analyses. 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. It is possible that you may experience some soreness due to exercise participation or it is possible that you could injure yourself while exercising. You may also experience mild skin irritation from wearing the armband, although this is not typical.

4. Benefits

By participating in this study, you will receive information about your fitness level and body composition. Further, you will be given an exercise program and provided with additional accountability and incentives to help you reach these exercise goals. Participation in this exercise program may help you to increase your fitness and improve your health; however, there is no guarantee that this program will produce these health benefits.

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.

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;
- 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.

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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.).

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 11/19/2018.
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 Date

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is presented orally or at the request of the IRB)

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.