IRB Approval:	8/6/2018
IRB Accepted:	8/6/2018
IRB Expiration:	8/5/2019

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

0116-17
Committee #

Name of Study Volunteer

Ecological Momentary Assessment and Passive Sensing of Weight-Related Behaviors and Experiences During Weight Loss Treatment: Study 2

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 70-years old, you have overweight or obesity, you have at least one medical condition that is a risk factor for cardiovascular disease (e.g., hypertension, high cholesterol, prediabetes/Type 2 diabetes), and you have no medical conditions that indicate that you should not participate in the study. The purpose of this study conducted by Graham Thomas, PhD and his colleagues at The Miriam Hospital, is to assess weight-related experiences and behaviors that occur during a 24-week behavioral weight loss and maintenance program.

We expect to enroll a total of 40 of subjects into this study, all of whom will be enrolled through The Miriam Hospital. The study is sponsored by The Miriam Hospital.

2. Explanation of Procedures:

If you take part in this study, you will first be asked to attend an orientation and baseline assessment visit at the Weight Control and Diabetes Research Center (WCDRC) in downtown Providence, RI where you will learn about the study and have the opportunity to ask questions. If you decide to enroll by completing this form, we will ask you to complete a variety of questionnaires about your physical activity, eating behaviors, weight history, and demographics. We will also meet with you

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individually to discuss the requirements for the study and to ensure that the program is a good fit for your needs.

If you complete the steps described above you will be scheduled for your initial treatment visit approximately two weeks after your orientation. During this week's time, we will ask you to wear a motion sensor (similar to a wrist-watch) on your dominant wrist for one week. This device will measure level of physical activity as well as the timing, duration, and rate of eating. To be eligible to start treatment, you must have at least 10 hours of wear time on each of 5 weekdays and 1 weekend day. To achieve these goals, we ask that you wear the wrist-watch each day of the week during waking hours and charge the device during the nighttime hours on a charging stand that we will provide. During these two weeks, you will also be scheduled to speak with our study staff over the phone on 4 separate days (two weekdays and two weekend days) to recount the type and amount of all food and drink consumed over the previous days. These calls will be scheduled at your convenience.

If you are able to meet the requirements above, you will begin a 12-session weekly weight loss program at the WCDRC. Sessions will last 30 minutes and will focus on topics such as changing your diet, keeping track of your health behaviors, and coping with difficult emotional and social influences. We will encourage you to lose weight at a rate of 1 to 2 pounds per week and to achieve a 7 to 10% weight loss during the course of the study. To do this, we will recommend that you record your food intake and exercise every day. Your weight will be recorded at the WCDRC each week and you will be taught skills for interpreting weight change over time. Additionally, data will be downloaded from your wrist-worn device by a research assistant. We will teach you how to limit your dietary intake based on your body's needs and how to increase your physical activity slowly over the course of the study.

After 12 weeks, you will enter the maintenance phase of the study. During this time, you are expected to continue the weight control practices learned in the initial 12 weeks of the program to either maintain or continue losing weight. You will meet with your weight loss councilor once per month at the WCDRC to be weighed, download data from your wrist-worn device, and discuss progress towards your goals. Additionally, you will be scheduled for an appointment at the WCDRC once per month solely for the purposes of obtaining your weight and downloading data from your device. You will be paid $20 for attending these visits. At your orientation, we will provide you with detail for how to care for your wrist-worn device.

Throughout the duration of the study, you will be asked to wear the wrist-worn sensor every day. Every other week (biweekly), you will be asked to complete short surveys about your eating behavior on your personal smartphone. There will be approximately 4 short surveys per day and each one should take approximately 30-60 seconds. If you do not have a smartphone, you will be lent a device for the duration of the study. At your orientation, we will provide you with more instruction for answering the questions on your smartphone (or study smartphone).

During the two weeks between your orientation and initial treatment session, you will be asked to have 4 separate phone calls over a period of 4 days with WCDRC personnel to recount all foods and drinks consumed over the previous 24-hours. This will be repeated at weeks 5, 11, 17, and 23 of the study. We will schedule these calls at your convenience. At your orientation, we explain in more detail how to prepare for these calls.

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There are no costs for participating in this study.

Contact Information:
Please call Graham Thomas, PhD at (401) 793-8154 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 program 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.

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
Other behavioral weight loss programs are available from healthcare providers and companies.

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. 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 Graham Thomas, PhD at (401) 793-8154.

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;
- Weight loss councilors 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.

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Study Volunteer Initials

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 8/5/2019.
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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