DUKE UNIVERSITY HEALTH SYSTEM

Subject Name: _____

History #:_____

Consent To Participate In A Research Study
Incentivizing behavior change skills to promote weight loss

INTRODUCTION

You are being asked to take part in this research study because your recent weight measurement was higher than recommended using a measurement called the body mass index (BMI). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Shaw and Voils' and her research team's salaries will be paid by this grant.

Dr. Ryan Shaw, a nursing researcher from the School of Nursing at Duke University Medical Center and Dr. Voils from the University of Wisconsin-Madison, will conduct the study. Dr William Yancy, a general internist, is the study doctor.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. William Yancy will be your study doctor. Your regular health care provider will continue to be your doctor throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test a new weight loss program. This study involves using a diet application ("app") on your smartphone to record what you eat, a cellular scale to weigh yourself at home, and text messages to help you lose weight. You may receive small cash incentives for losing weight or tracking what you eat and drink.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 200 people from Duke primary care clinics or the community will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign this consent form. You will have to do the following to make sure that you are eligible:

- We will check your height, weight, and blood pressure.
- Women of childbearing potential will be administered a urine pregnancy test
- You will be asked questions about general medical history and about your previous weight loss attempts.
- You will be asked about your mobile phone and data plan, past experience with mobile apps, and if you have internet access from a computer.
- The interview will take between 30 to 60 minutes.

- If you qualify to be in the study, you will be randomly assigned (like drawing numbers from a hat) to 1 of 4 groups. All groups will receive between 1 and 4 informational and/or motivational texts per week that could help you lose weight. Each group will receive different messages.
- You will be asked to participate in a group-based weight-loss program that uses a low-carbohydrate diet. Groups will meet once a week for the first 3 weeks and then every 2 weeks within a 24-week period. This is a total of 14 visits. Group meetings can last up to 2 hours, but typically are between 1 and 1 ½ hours. At each group meeting, we will measure your weight and blood pressure, you will answer short surveys, and you will receive group diet counseling by a dietitian or other member of the study team.
- While you are participating, you will weigh yourself regularly and track what you eat.
    - We will give you a cellular scale to keep at home. This scale will use cell towers to send a record of your weight to the manufacturer, BodyTrace. BodyTrace will then send your data to our data system, called Prompt. If the scale is damaged during the study, it will be up to the discretion of the PI to replace the scale.
    - To track what you eat daily, we will ask you to download 2 applications ("apps") onto your smartphone. One is Fitbit, and the other is MyFitnessPal/Calorie Tracker. You will use MyFitnessPal to track your food and drink. MyFitnessPal will send your entries to Fitbit, and Fitbit will send data to our system (Prompt).
        - You will be asked to create an account on two apps: MyFitnessPal and Fitbit. We will use a false email address to create the account. All other registration information for MyFitnessPal and Fitbit (name, date of birth) can also be false information provided by the study team. However, if you prefer, you can provide your actual information.
- You will receive text messages between 1 – 4 times per week with reminders and other study messages.
- Should you change your cell phone number during the study, we ask that you notify us at **919-684-9434.**
- At the end of the study, we will help you delete the MyFitnessPal and Fitbit apps and any health data installed on your phone or transmitted through these devices. We will not do this if you choose to continue using the apps.
- After the study is over, you will have the option of keeping the scale. If you choose to keep it, you can keep using it to weigh yourself. However, we will disconnect it from our system (Prompt) so we will not be able to see those weights.
- At the end of the study, we may ask you to participate in a telephone interview to get your feedback about the study. This interview will be audio recorded and will be stored on a Duke server. Access will be restricted to only members of the study team. We will transcribe the interviews so that we can analyze your responses. The transcriptions will not contain information that can be used to identify you (e.g., your name). We will use a study ID instead of your name.

HOW LONG WILL I BE IN THIS STUDY?

DUKE UNIVERSITY HEALTH SYSTEM

Subject Name: _____

History #:_____

Consent To Participate In A Research Study
Incentivizing behavior change skills to promote weight loss

Your participation in this study will last about 24 weeks. You may choose to stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to our study doctor first.

WHAT ARE THE RISKS OF THE STUDY?

The low carbohydrate diet may cause dehydration (lightheadedness or feeling faint), muscle cramps, headache, bad breath, constipation, or kidney stones. Drinking adequate fluids (at least six 8-ounce glasses of water each day) can prevent these effects. Less frequently, some people may experience diarrhea or increased cholesterol levels. Other side effects associated with weight loss could include hair loss, fatigue, weakness, feeling too cold, and electrolyte abnormalities, or gallstones (signs of gallstones can include pain in your upper right abdomen, nausea and vomiting, fever, or changes in the color of your urine or stool). Also, low blood sugar or low blood pressure (fatigue, lightheadedness, or fainting) may occur during weight loss if you are taking medications for diabetes or high blood pressure.

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a urine pregnancy test will be done, and it must be negative before you can be randomized in this study. If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study doctor immediately.

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. The information we gather will be kept in databases on password-protected computers at Duke. Your data will also be accessible to Dr. Voils, who is at the University of Wisconsin-Madison. The information we collect will be used only for this study. Only study staff approved by the Duke Institutional Review Board (IRB) will be able to see your information. None of your data will ever be sent to third parties except as described in this consent form, with your permission, or as may be required by law.

Information collected by devices (cellular scales) and mobile apps is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have

security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your phone or what information from your phone may be stored outside of Duke. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. Similarly, there are potential security risks with the cellular scale.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

We are not asking you to make any health decisions based on the use of these devices or mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, you may lose weight and experience benefits that occur with weight loss. We hope that in the future the information learned from this study will benefit other people who have difficulty losing weight.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify you at Duke University and the University of Wisconsin-Madison will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, or as outlined in this consent, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration or representatives of the Duke University Health System Institutional Review Board. If any of these groups review your research record, they may also need to review your entire medical record.

In order to keep in touch with you, we will collect phone numbers where you can be reached. This information will be encrypted and stored in a remote secure database.
Many applications on your smartphone and email services you commonly use work with text, email, and cloud-based companies to send and receive information. In order to send you send text messages, we use Twilio, Heroku, and Amazon S3. These companies encrypt your information on their servers, but no system is completely safe. If these companies decide to share these data, it may no longer be covered under the privacy protections. Text messaging does not provide a completely secure and confidential means of communication.

DUKE UNIVERSITY HEALTH SYSTEM

Subject Name: _____

History #:_____

Consent To Participate In A Research Study
Incentivizing behavior change skills to promote weight loss

Information that identifies you and the data from the electronic devices and from your mobile phone may be sent to and permanently kept by BodyTrace, Fitbit, MyFitnessPal, Twilio, and their business associates. Information disclosed to these companies or to outside reviewers for audit purposes may be further disclosed by them and not be covered by the federal privacy regulations.

The study results will be retained in your Duke research record for at least six years after the study is completed. At that time, the research information may be destroyed or information identifying you may be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study. Routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. In addition, if you currently have restriction on the number of text messages or data you may receive, you may incur cell phone charges as a result of being in this study.

WHAT ABOUT COMPENSATION?
Participants who wish to discontinue study procedures will be asked to return at 24 weeks for outcomes assessment. You will have the option of either keeping the scale or receiving $25 for that visit. If you choose to accept the $25, then you will be asked to return the scale at that visit. You will not be paid for attending group weight loss sessions. If you are selected to participate in an interview by telephone at the end of the study, you will receive an additional $25 in compensation.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact the study doctor **Dr. William Yancy** at **(919) 681-2863** during regular business hours and at (919) 970-9012 on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new information about you will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

DUKE UNIVERSITY HEALTH SYSTEM

Subject Name: _____

History #:_____

Consent To Participate In A Research Study
Incentivizing behavior change skills to promote weight loss

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Ryan Shaw in writing and let him know that you are withdrawing from the study. His mailing address is

Duke University School of Nursing
307 Trent Dr., DUMC 3322
Durham, NC 27710

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Ryan Shaw at (919) 684-9434 during regular business hours.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____
Signature of Subject Date and Time

_____ _____
Signature of Person Obtaining Consent Date and Time