CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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PROJECT #: 2004733
STUDY TITLE: "A short term evaluation of a structured weight loss plan in overweight and obese adults"

INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand. This project is a research study. Research studies include only people who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study. Please take your time to make your decision.

You are being asked to take part in this study because you would like to lose weight. This study is being sponsored by the company Atkins Nutritionals and The University of Missouri. Dr. Elizabeth Parks has consulting relationship with the Atkins Nutritionals Company. In order to participate in this study, it will be necessary to give your written consent.

WHY IS THIS STUDY BEING DONE AND HOW MANY PEOPLE WILL TAKE PART?

The goal of this study is to determine the amount of weight that can be lost over a 4-week period using a meal plan that combines commercial food products that are low in carbohydrate (the Atkins diet) with meals prepared on your own. Our goal is to follow blood pressure for 1 month after people have been through a 4-week weight loss program. The tests performed are not part of standard medical care. About 40 people will be screened and 20 people will complete the study at the University of Missouri.

WHAT IS INVOLVED IN THE STUDY AND HOW LONG WILL I PARTICIPATE?

In general, this research is measuring how short-term weight loss may improve health. You will be screened to find out if you are eligible to participate. As described below, this research includes a screening visit, 5 study visits and 3 food pickup trips over a two-month period.

PROCEDURES

The following paragraphs describe the schedule for the study screening and five study visits.

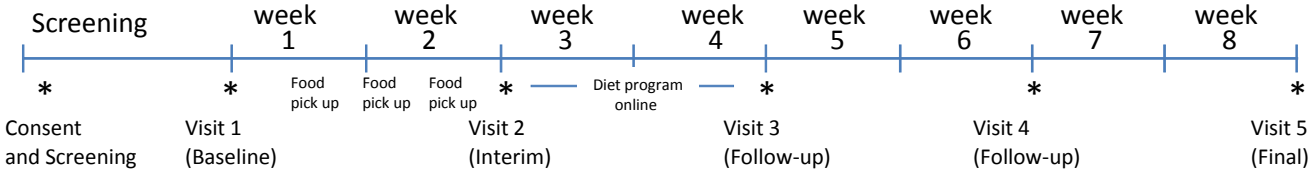
SCREENING VISIT

To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgeries you have had. This visit is located at the Clinical Research Center (CRC). The CRC, located on the 5th floor of the University Hospital, has clinic rooms specially designed for research. You will come to the CRC after fasting overnight for 12 hours (no food or drink, except water). This visit will take 1 hour and you are welcome to bring a family member or close friend to this visit.

Research staff will meet with you at the CRC to review the study procedures, answer questions, sign this consent form and review your medical history. A small amount of blood will be drawn (about 2.7 tablespoons) to check your general health which includes a test for hepatitis. Your height, weight, and blood pressure will be measured and you will be given a chance to learn about a procedure called calorimetry, which we use to measure how many calories your body burns. If you enter the study, this technique will be performed twice, at the beginning and end of the weight loss period. Within a week after this visit, you will receive the results of all screening tests and someone on the study team will go over the results with you. Since this is not a treatment study, these lab tests are not being used for

standard medical care. You will be given a copy of the results which you can share with your primary physician.
If your screening results qualify you to be in the study, and if you are interested in proceeding with the study, you will be scheduled for a second, baseline visit, as shown in the figure below. For this and the other visits, you will come to the CRC at the hospital. Parking will be provided if needed. You will be given a device (Fitbit Flex® device, San Francisco, CA) to wear to track your steps. You may keep this device when the study is over.

Figure 1. Study Timeline, the * denote the times when you will have blood drawn



BASELINE VISIT 1: For 24 hours before you come to the baseline visit, please do not exercise, and for 12 hours before the visit, do not use caffeine, alcohol, and vitamin supplements. First thing after you awaken, you will collect a urine sample at home and bring the urine sample with you when you report to Gwynn Hall. You will come in after fasting overnight for 12 hours - no food or drink, except water after 7 PM. This visit will take about 2½ hours and you will undergo five procedures. The first procedure is you will have blood drawn (about 4 tablespoons); the second procedure is calorimetry (calorie burn). The third procedure is called flow mediated dilation and the fourth is pulse wave velocity. Finally, you will have your body fat measured by a technique called DEXA and then you will be given a snack to eat. You will be asked to fill out some questionnaires to assess your physical activity level and food intake.

If all the baseline procedures are successful, you will begin the low-carbohydrate diet. You will take home the foods you will eat over the next three days. At the end of this period you will come to Gwynn Hall on the University Campus to pick up the next set of meals and keep eating the prepared diet for 2 weeks.

INTERIM VISIT 2: The first thing in the morning of visit 2, you will collect a urine sample at home and bring the urine sample with you when you report to the CRC. Do not use caffeine and vitamin supplements; don't drink alcohol for 24 h. You will come in fasted and have measurements made of your body weight, waist circumference, heart rate, and blood pressure. Blood will be drawn (2 tablespoon) and this visit will take 60 minutes. After these measurements we will supply you with breakfast and you will begin to prepare the diet on your own. We will teach you how to use the Atkins online diet program for recipes to cook on your own and to keep track of your food intake.

FOLLOW-UP VISIT 3: Please do not exercise within 24 hours before you come for the visit 3. For 12 hours before the visit, do not use caffeine, alcohol, or vitamin supplements. The morning of visit 3, after a 12-hour fast, you will collect a first-morning urine sample at home and bring it with you to the CRC. All procedures performed in baseline visit 1 will be repeated and this visit will take about 2½ hours. The total blood draw will be about 4 tablespoons. Following this visit the diet portion of this project is concluded.

FOLLOW-UP VISIT 4: For 12 hours before visit 4, do not use caffeine or vitamin supplements, don't drink alcohol. The morning of visit 4, after a 12-hour fast, you will take a urine sample and bring it with you to the CRC. We will measure your blood pressure and body weight. Blood will be drawn during this visit (2 tablespoon). This visit will take 30 minutes.

FINAL VISIT 5: Please do not exercise within 24 hours before you come for the visit 5. For 12 hours before the visit, do not use caffeine and vitamin supplements, don't drink alcohol. The morning of visit 5,

after a 12-hour fast, you will take a urine sample and bring it with you to the CRC. We will measure your blood pressure and body weight. Blood will be drawn (4 tablespoon) and this visit will take 30 minutes.

WHAT ARE THE PROCEDURES AND RISKS OF BEING IN THIS STUDY?

CALORIMETRY

This test measures how many calories your body uses. This procedure will be performed at visit 1 and visit 2. Calorimetry requires resting quietly on your back for 20-30 minutes under a large, clear, plastic hood. You will breathe room air normally and your breath goes into an analyzer to measure what you breathe out. The test is painless; however, persons who are uncomfortable in confined spaces may find this slightly stressful. You will get a chance to familiarize yourself with this procedure during screening.

URINE COLLECTION

You will be asked to collect a first morning urine sample before visits 1-5. You will be given instructions of how to do this, a special container to collect the urine in, and an ice pack to keep the sample cold while you bring it to the CRC.

MEASUREMENT OF BODY FAT AND MUSCLE BY DEXA

This test will be performed at visit 1 and 3. A DEXA (Dual Energy X-ray Absorptiometry) is a procedure to measure your body composition - how much fat and muscle your body has. It is a type of x-ray machine with a moving arm. This procedure involves lying on a table for 20-30 minutes while the DEXA machine passes over your body. Although you will need to remain very still and quiet, you will feel nothing and should have no discomfort. If you have participated in any other research study involving ionizing radiation exposure in the past 12 months, discuss this with the Investigator to determine if you are eligible to participate in this study. You will be exposed to a small radiation dose which is about 2% of the average radiation dose from all sources (natural background radiation, consumer appliances, radon gas, medical tests, etc.) that a person receives in the United States receives each year. However, radiation effects are cumulative. You should always inform future doctors of your participation in this study. For female participant, a urine pregnancy test will be performed before the scan.

ARTERIAL STIFFNESS AND BLOOD PRESSURE

This test will be performed at visit 1 and 3. A special non-invasive device will be used to assess blood pressure and aortic pulse wave velocity, a marker of arterial stiffness. A blood pressure cuff will be wrapped around your upper arm and upper leg. They will periodically inflate to ~200 mmHg for less than 60 seconds. A pressure sensor (tonometer, the size of a pencil) will be placed over the skin of the neck region to obtain the pressure wave form in the carotid artery. The total time for this procedure is 15 min. The blood pressure cuff will squeeze the arm and leg tightly; however, any discomfort will be alleviated as soon as the pressure in the cuff is released.

RISKS OF BLOOD DRAWING

During screening and at visits 1-5, you will have blood drawn through a needle. Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely. As a result of your participation in this study you will have given blood. If you wish to perform other research after you finish this project, you should let the investigator know that you have donated 9.5 oz (or about 1.2 cup). Your blood volume will be checked during screening to make sure that your volume is in safe limits.

TEST DIETS

The study is designed to measure how well the diet causes you to lose weight over two weeks. Foods: All foods given to you are commercially available and sold in supermarkets. You will be assigned by chance to one of two dietary patterns in which all your food is provided for two weeks. **Diet 1**: The "Grab-and-Go" plan will provide Atkins shakes and bars for breakfast, lunch, and snacks. For dinner you will be given a freshly-prepared meal. **Diet 2**: The "Jump-Start" plan will provide Atkins frozen meals at breakfast, lunch and dinner and these meals will be supplemented with fresh salads and vegetables. The reason for the two diets is to understand how subjects like the diets. The diets have the same calories, are otherwise similar in content, and not expected to differ in their ability to cause weight loss.

Beverages: You will be asked to consume eight, 8-oz glasses of liquids per day. You may also consume coffee or tea without nondairy creamer added. You may add non-caloric sweeteners, and/or a maximum of 2 oz of cream per day to the coffee or tea. Diet soda or non-caloric beverages are allowed.

We anticipate no medical risks from consuming these diets for 2 weeks and no risk of eating the Atkins type of diet for 4 weeks. For the first 2 weeks, you will be consuming only the prescribed foods given to you and no other foods, then, you will be cooking and preparing the Atkins diet at home. Consuming this type of diet may get boring or you may experience a little frustration due to limited food and beverage choices. Support from our staff will be provided to help you comply with the diet. It is advised that if you have a special event coming up in the next month (wedding, vacation travel, etc.) that you not participate in the study at this time. You should not consciously change your physical activity while you are in the study. In other words, if you would like to join a gym or begin exercising more, we ask that you wait until the 4-week diet is over before you do this.

WHAT WILL BE MY RESPONSIBILITIES DURING THE STUDY AND ARE THERE BENEFITS?

While you are part of this study, the researchers will follow you closely to determine whether there are problems. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions, particularly in consuming the diet.
- Let the researchers know if your telephone number or address changes.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem, or purchased over the counter.
- Report to the researchers any injuries or illnesses while you are on the study, even if you do not think they are related.

If you agree to take part in this study, there may not be direct medical benefit to you. It is likely that you will lose weight but this cannot be guaranteed. You will be given a small device to track your steps. You may also expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned will benefit others in the future.

WHAT ARE THE COSTS?

You will not be charged for any procedures that are part of this research study. Parking will be provided but there is no compensation for travel to our facilities or for childcare during this study.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

You will be compensated a total of $250 for completing this study: $25 will be given for baseline visit 1; $75 will be given for consuming the 14-day diet and visit 2, $100 for the participating in the tests in visit 3, and $25 each to return for visits 4 and 5.

WHAT OTHER OPTIONS ARE THERE?

You do not have to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Information produced by this study will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law. It is possible that your medical and/or research record, including identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), federal or state government agencies, MU Health Sciences IRB, or hospital accrediting agencies, in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, the University of Missouri will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

The results of this study may be published in a medical journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

WHAT IF I AM INJURED?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff.

The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care at the University of Missouri. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation in this study at any time after she has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed. You will be informed of any significant new findings discovered during the course of this study that might influence your health, welfare, or willingness to continue participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Health Sciences Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181. You may also contact the Research Participant Advocate (RPA) at (573) 884-1925 or (888) 280-5002 (toll-free). If you prefer email, you can reach the Advocate at somrpa@missouri.edu. You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Dr. Elizabeth Parks at (682) 433-9012. A copy of this consent form will be given to you to keep.

SIGNATURES

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered.

My signature below indicates my willingness to participate in this study.

Subject name (print)	Subject signature	Date	Time
Staff obtaining consent (print)	Staff signature	Date	Time

HS IRB USE ONLY
Approval Date: April 13, 2016
Expiration Date: April 13, 2017