Study Title: Randomized Study of Daytime vs. Delayed Eating: Effect on Weight and Metabolism
PI: Kelly C. Allison
Document title: informed consent form (final version before study procedures were completed)
Date of document: Aug 16, 2016

UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT COMBINED INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Randomized study of daytime vs. delayed eating: Effect on weight and metabolism
Principal Investigator:	Kelly C. Allison, Ph.D. 3535 Market St., Suite 3027, Philadelphia, PA 19104 215-898-2823
Emergency Contact:	Psychiatric Emergency Evaluation Center (24-hrs) 215-662-2121

Why am I being asked to volunteer?

You are being invited to participate in a research study because you live or work within a 5 mile radius of the Hospital of the University of Pennsylvania and you are willing to follow study instructions on the timing of your meals and snacks throughout the day. Your participation in the study will help us to determine the effect that timing of eating may have on weight and metabolism. Your participation is voluntary which means you can choose whether or not you want to participate. Your choice to participate or not to participate will not result in any loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The study involves an interview and questionnaires, record-keeping of your eating and sleeping patterns, sleep studies, and a series of blood draws, all of which this form will describe in more detail. Our research team will talk to you about the research study, and we will give you this consent form to read. You may also decide to discuss it with your family, friends, or treatment team. You may find some of the medical language difficult to understand, so if you have any questions, let us know. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to test the effect of two different eating schedules (daytime or delayed) on your body composition and your metabolism. This is a feasibility study that will provide data for a larger study.

How long will I be in the study? How many other people will be in the study?

Your participation in the study will take place over a period of approximately 5 months. There will be 30 participants in this study, with the overall study lasting two years.

What am I being asked to do?

The study consists of 4 phases – screening & baseline assessment, eating condition 1, wash-out period, and eating condition 2. Before and after each phase you will complete a 28-hour inpatient assessment at the Clinical and Translational Research Center (CTRC) of the Hospital of the University of Pennsylvania to study the impact of your eating on body weight and fat content, metabolism, and certain markers of metabolism in your blood.

Screening

In order to participate in this study you must undergo a complete physical examination and tests of your blood and urine. These tests will determine if you have any conditions that would prevent you from participating in the study, including diabetes or any serious uncontrolled medical condition that may interfere with your participation in the study. Other conditions that would prevent you from taking part are pregnancy or nursing, a sleep disorder, the use of certain medications, or night-shift work. All participants will be given a urine drug screening. A urine pregnancy test will be given to women at this screening visit.

You will also complete several surveys of a psychological nature and participate in a clinical interview. Your sleep and exercise schedules are important and will be reviewed during your visit to see if they match with the study requirements. During the 10 days of the screening assessment, you will keep a log in which you will record all food and beverages that you consume. You will also use these logs to record when you sleep and when you exercise. Your activity will be measured by a small electronic wrist activity recorder, called an Actigraph (about the size of a wrist watch), during this time. This recorder, similar to a pedometer, records all activity in your arm, and is very useful in determining if and when you get up at night. We will explain how to keep this information during the baseline visit. You will return the activity recorder and log to Dr. Allison for analysis at the end of the 10-days. You are expected to return all study materials, including the Actigraph, log, and questionnaires.

Assessments

Following successful completion of the screening period, you will complete the first of four assessment visits. This visit will include 28 hours (overnight) spent at the CTRC, where your meals and snacks will be provided.

You will arrive at the CTRC at the Hospital of the University of Pennsylvania at 7 AM. Starting at 8 AM, your blood will be drawn every four hours. A thin needle (an introducer) will be inserted into a vein in your forearm, much like an IV line. Very small blood samples, 10mL (2 teaspoonfuls), will be collected every four hours from 8:00 AM on Day 1 through 4:00 AM on Day 2, and the introducer will be removed when you wake on Day 2. From this blood we will measure hormones related to metabolism, sleep, and stress. You will be provided meals and snacks during this time, and you are free to watch television or participate in other sedentary pastimes while you are there.

At 8 AM on the second morning, your metabolic rate will be measured. You will be asked to fast for 10 hours overnight (you will not be able to eat or drink anything except water for 10 hours starting at 10 PM the night before). Then we will measure your resting metabolic rate for 45 minutes. During the measurements, you will lay on your back in bed with a plastic hood/canopy over your head and neck. You will lay still and breathe normally while the air you inhale and exhale is collected in the canopy/hood and analyzed using a machine that is connected to the canopy/hood.

You will be discharged from the hospital, and research staff will escort you to the Presbyterian CTRC where your body composition will be measured using dual energy X-ray absorptiometry (DEXA). During this test, X-ray pictures of your body will measure how much fat and muscle are present. You will lie flat on a table and a machine will take pictures of different areas of the body. This test will last about 30 minutes. –This will conclude the assessment visit. On the last day of the study, you will be given an additional 10-minute survey regarding your reflections on the study as a whole.

Eating Conditions & Assessments

Upon completion of the baseline assessment, you will be randomly assigned to start with one of two eating conditions: 1) Daytime or 2) Delayed, and then you will switch and eat on the other schedule for the final part of the study. If you are assigned to the Daytime eating condition first, you will be asked to consume all of your meals and snacks each day between 8 AM and 7 PM. If you are assigned to the Delayed eating condition first, you will be asked to consume all of your meals and snacks between 12 noon and 11 PM each day. You will eat on this schedule for 2 months.

During the two-month eating condition periods, all of your meals and snacks will be provided by the research kitchen and will be delivered to you by a member of the research staff every 3 days. You will be provided a personalized menu and asked to track each food item you consume. You will also be asked to record any beverages you consume on this menu (beverages will not be provided). If occasionally you do not eat the meals provided, you will be asked to use your smart phone or electronic device to send a picture of your food to the study team before you eat it, and again if any food is not eaten when you have finished your meal. You will be asked to wear an Actigraph for the duration of the study, and study staff will deliver new devices and collect used devices one time per week. You will be sent and asked to respond to daily queries by text message or email regarding your eating, sleeping, and exercise. At the end of two-months, you will complete the second overnight assessment visit (as described above).

For two weeks following this second assessment, you will be asked to eat as you normally would. During this “wash-out” period you will eat what and when you like. You will then complete the third overnight assessment visit before starting the second eating condition (Delayed for those initially assigned to the Daytime schedule; Daytime for those initially assigned to the Delayed schedule). You will be asked to eat on this new schedule for 2 months. You will then complete the fourth and final overnight assessment. After this final assessment visit, your participation in the study will be complete.

STUDY TIMELINE (After baseline assessment is completed successfully):

	1. Baseline assessment	2. First 2-mo eating condition	3. Post-condition assessment	4. 2-wk wash-out	5. Pre-eating condition 2 assessment	6. 2-mo eating condition	7. Post-condition (final) assessment
Procedure							
Keep food, sleep-wake, and activity logs		X	X	X	X	X	
Wear Actigraph	X	X	X	X	X	X	X
Undergo 28 – hour assessment at CTRC & CWED (blood draws, metabolic testing, DEXA)	X		X		X		X
Eat meals and snacks provided by study	X	X	X		X	X	X

What are the possible risks or discomforts?

- During this study you will be asked questions of a personal nature, such as your weight, age, eating habits, and mood. You may experience some discomfort when answering these questions.

- You may not like all of the foods that we give you which may cause some discomfort. Additionally, the eating schedule may be difficult to manage at times, and this may cause you some inconvenience.

- You will experience the inconvenience of wearing the wrist activity recorder and keeping records of your eating behaviors, sleep, and activity throughout the study.

- For the blood draws, you will experience discomfort on initial insertion of the thin needle (introducer) into a vein on your arm. Bruising may develop at the site of the needle insertion. Dizziness or fainting is a remote possibility. Local clots may form, and infections may occur, but these are rare. The amount of blood drawn will not significantly reduce your blood volume, although there may be a small decrease in your red blood cell concentration (hematocrit). The total volume of blood drawn will be less than 50 teaspoonfuls and this loss is readily restored. Occasionally, mild discomfort may occur from the catheter in the vein. If this happens, we will either change its position or remove it entirely, asking your permission before reinserting it. There may be some bruising when the catheter is removed. You will be asked to apply pressure to the site of the catheter for 10 minutes after its removal. There may be a small scar at the site of the catheter which will disappear over the course of several months.

- This research involves exposure to radiation from the DEXA scans. Therefore you will receive a radiation dose. This radiation dose is not necessary for your

medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very unlikely that you will see any effects from the radiation dose.

- The study involves restraining you from eating for a period of at least 10 hours (overnight) while in the hospital, which may be uncomfortable.

What are the possible benefits of the study?

You may not get any benefit from being in this research study. You may increase your knowledge of your eating and sleeping behaviors. Your participation may contribute important data for understanding how eating at certain times of day affects weight management and how the body processes and stores food.

What other choices do I have if I do not participate?

The only alternative is not to participate.

Will I be paid for being in this study?

You will receive $300 for each of the 4 CTRC assessments you complete, with a $300 bonus at study completion ($1500 total).

Checks for assessment visits will be mailed to you about 4 to 6 weeks after you complete each visit.

You will also be provided all meals and snacks for a total of 4 months (estimated value of $1000).

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must report this as income to the federal government for tax purposes.

Will I have to pay for anything?

All interviews and tests that are part of this protocol will be provided at no cost to you.

What happens if I am injured or hurt during the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator, Kelly Allison, Ph.D. (215-898-2823) or Emergency contact (215-662-2121). You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise offered

from the University of Pennsylvania. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end in two years, after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician or the study Sponsor without your consent because:

- You have not followed study instructions.
- The Sponsor or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What information about me may be collected, used or shared with others?

The following personal health information will be collected, used for research and may be disclosed (shared with others) during your involvement with this research study:

- Name
- Address
- Telephone number
- Electronic mail address
- Medical record number
- Social security number (for payment)
- Personal and family medical history
- Allergies
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate, and temperature
- Blood tests
- Urine tests
- Weight
- Height
- Waist circumference
- Questionnaires

Why is my personal health information being used?

Your personal contact information is important for the University of Pennsylvania Health System and Perelman School of Medicine research team to contact you during the study. Your health information and results of tests and procedures are being collected as a part of this research study and for the advancement of medicine and clinical care.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research study

- The Principal Investigator and the Investigator's study team (other University staff associated with the study).
- The University of Pennsylvania Institutional Review Boards (the committees responsible for overseeing research on human participants) and the University of Pennsylvania Office of Regulatory Affairs (the office which monitors research studies).
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive my information?

Your information may be disclosed to the Office of Human Research Protections and the funding sponsor, the National Institutes of Health.

The Principal investigator or study staff will inform you if there are any additions to the list above during your active participation in the study. Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the Perelman School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization.
- The University of Pennsylvania's Institutional Review Board grants permission.
- As permitted by law.

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your personal health information at any time. You do this by sending written notice to the Principal Investigator of the study at the address listed on the first page of this document. Even if you withdraw your permission, the Principal Investigator may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information, you will not be able to remain in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study. Do not sign this document if you do not want to allow the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator, Dr. Allison. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____		
Name of Subject (Please Print)	Signature of Subject	Date	Time
_____	_____		
Name of Person Obtaining Consent (Please Print)	Signature	Date	Time