TIME RESTRICTED EATING PILOT – BARIATRICS
NCT04006366
OCTOBER 18, 2016

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA
AUTHORIZATION FORM

Protocol Title:	Psychosocial and Behavioral Aspects of Bariatric Surgery
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Why am I being asked to volunteer?

You are being invited to participate in a research study. You are being asked to volunteer because you meet the requirements for enrollment in this study. You are an adult aged 18-65 years old, and have a body mass index (BMI) and health profile that make you a candidate for bariatric (weight loss) surgery (that is, BMI of at least 40, or at least 35 plus weight-related health problems). Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no 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 research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

This study will look at the relationship between your psychosocial functioning prior to surgery on changes in weight and psychosocial status in the first two years after bariatric surgery. We will use computer tasks, surveys, interviews, urine test, and height/weight measures. We will track how preoperative psychological and social factors are related to changes in weight and these same psychological and social factors following bariatric surgery. The study is being sponsored by the National Institutes of Health (NIH).

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

Your participation in the study will last for 24-42 months (depending on scheduling and how quickly the screening procedures for your surgery are completed). There will be a total of 300 participants enrolled in the study.

What am I being asked to do?

Your decisions about weight loss surgery (whether or not to have it, and which type of surgery you may have) and your eligibility for surgery are in no way related to your participation in this study. This section only discusses your participation in this research study and does not address the surgery itself.

In order to participate in this research study, you will be asked to come to the University of Pennsylvania for several visits. The first visit will be a screening visit to determine whether you are eligible to participate in the study. The four subsequent visits will be assessment visits. What you will do at each of these visits is described below.

Screening Visit

The purpose of this visit is to explain the study to you and see if you meet the requirements to participate in the study. This visit will last approximately 30 minutes. If you agree to participate in this study, we will review your medical record to confirm that you meet the body mass index (BMI) requirements of the study and other medical requirements for the study. You will meet with the study's research coordinator who will confirm that you have the appropriate physical characteristics to participate in the study. The study's nurse practitioner (or physician) will review the results of your medical history and examination, completed as part of medical screening for surgery, to confirm that you are medically eligible for the study. Once you are confirmed to be eligible, you will be provided with a link to complete questionnaires at home prior to your scheduled baseline assessment.

Assessment Visits

You will complete a total of four assessment visits. Each visit will be about 4 hours long and will take place at your Penn Medicine surgery clinic. The first visit will be a baseline assessment. We will attempt to schedule your baseline assessment as close to your surgery date as possible, approximately 2-6 weeks before your surgery. The follow-up assessment visits will occur 6, 12, and 24-36 months after your surgery date. The procedures to be completed at each assessment visit are identical. They are described below.

You will arrive at the Bariatric Surgery Program at the Penn Medicine (your location may vary depending on where you see your surgeon). You will have your weight, height, and waist circumference measured and provide a urine sample (to test for substance use). Before each assessment, you will be provided with a link to questionnaires to complete at home before you come to the Bariatric Surgery Program for the visits.

When you arrive at the Bariatric Surgery Program, you will be asked to complete three computer tasks in a quiet room; these tasks will take approximately 25 minutes. You will also complete a clinical interview with trained research staff to evaluate your psychosocial functioning and eating habits. This interview will take approximately 3 hours. If you have not completed the questionnaires that were provided to you prior to each assessment visit, you will be asked to complete them on the computer at each visit. These surveys will ask you about your eating habits, physical activity, and other areas of psychosocial status.

If your baseline assessment occurs more than 3 months before you have surgery, you may be asked to return to the clinic to complete the computer tasks and the 24 hour food diary.

What are the possible risks or discomforts?

There are no known risks associated with the computer tasks you will be asked to perform during the study. The surveys and interviews you will be asked to complete also present little risk. You could become a little tired in performing these tasks.

Your overall physical health will be monitored by the bariatric surgeon and/or primary care physician. If these or other medical issues come to the attention of research study staff during a study visit, the patient will be encouraged to communicate these findings to his or her physician.

It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you, if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

This study is not intended to provide treatment for any condition. Although you may find the research interesting, you are not expected to get any direct benefit from being in this research study.

The results of this research are expected to increase scientific knowledge about changes in weight, psychopathology, disordered eating, and impulsivity associated with bariatric surgery. This knowledge may contribute to the development of ways to improve the outcomes of weight loss surgery.

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

Your alternative is not to participate in this study.

Will I be paid for being in this study?

To compensate you for your time and effort, you will receive $100 at the first visit (baseline), $50 at the 6 and 12 month visits, and $100 for the 24-36 month visit. If you complete all visits, you will receive a total compensation of $300. If you are asked to return to the clinic because your baseline assessment occurs more than 3 months before your surgery date, you will be provided an additional $25 for the completion of this visit. If you decide to complete the final assessment visit (24-36 months after surgery) in person, you will be provided with a $25 gift card. You may also receive compensation for parking and travel (SEPTA tokens) for study-related assessment visits.

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 Internal Revenue Service for tax purposes.

Will I have to pay for anything?

There will be no cost to you for any visits or procedures required by this study.

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

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

- Dr. Kelly Allison (site Principal Investigator for the study) feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, or the Principal Investigators, have decided to stop the study.

If you decide to participate, you are free to leave the study at any time. 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 during your involvement with this research study:

- Name, address, telephone number, e-mail address, date of birth
- Social Security Number
- Personal and family medical history
- Results from physical examinations, tests or procedures
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, weight, height, and waist measurements
- Results of tests and procedures you will undergo during this research study as described in the informed consent form

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Conduct the research
- Oversee the research
- See if the research was done right

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigators and the study team
- The University of Pennsylvania Bariatric Surgery Program
- Authorized members of the workforce of the University of Pennsylvania Health System and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.)

Who, outside of the School of Medicine, might receive my information?

Results of this study (without the inclusion of identifying information) will be shared with the individuals who are responsible for reviewing the progress and safety of the study. Dr. Dale Bond at the Warren Alpert Medical School of Brown University will review information on study progress. Information could also be shared with the National Institutes of Health (NIH), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The Principal Investigators or study staff will inform you if there are any additions to the list above during your active participation in the trial. This study is also being conducted at Temple University. Authorized members of the study team may also inspect your information. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you

have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

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 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 after ensuring that appropriate privacy safeguards are in place
- As permitted by law

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

Yes. At any time you may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the Principal Investigators for the study at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from this research 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.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Disclosure of money received outside of the study:

Dr. Sarwer, a member of the study team, receives extra money from BARONova and Medtronic (companies that manufacture medical and surgical devices) for consulting work that is not a part of this study. If you would like more information, please ask the researchers or the study coordinator.

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 Investigators, Drs. Kelly Allison and David Sarwer, listed on page one of this form. 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

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