Institutional Review Board
3800 Spruce St., First Floor Suite 151
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE: 25-Oct-2018
TO: Kelly C Allison
CC: Mccuen-Wurst, Courtney E

RE:
IRB PROTOCOL#: 823735
PROTOCOL TITLE: Psychopathology, Disordered Eating, and Impulsivity as Predictors of Outcomes of Bariatric Surgery

SPONSOR: NATIONAL INSTITUTES OF HEALTH
REVIEW BOARD: IRB #8

IRB CONTINUING REVIEW: NOTICE OF APPROVAL

Dear Dr. Allison,

The above referenced protocol was reviewed and re-approved by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 on 24-Oct-2018. This study has been determined to be eligible for expedited review category(ies) 5,7.

This approval is for the period 24-Oct-2018 to 23-Oct-2019.

ADDITIONAL ITEMS: Please respond as instructed to each notification listed below:

Please note that the IRB was unable to transition this protocol to the 2018 Common Rule Regulations and therefore the study has been reapproved via expedited mechanism and contains an expiration date. Please see the Common Rule Update Guidance Page of the IRB website (https://irb.upenn.edu/common-rule-update-2018) for more information about how the IRB applies these regulations and whom to contact with any questions you may have regarding the IRBs determination.

The documents included with the application noted below are approved:

-HS-ERA Continuing Review Submission (Confirmation Code: chejjgfb), submitted on 10/08/2018

STUDY SITES: The University of Pennsylvania IRB is serving as the IRB of Record for the study sites listed below per the terms of previously executed reliance agreements. The above referenced IRB approval applies to these sites:
-Temple University

ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes

to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.

- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Psychosocial and Behavioral Aspects of Bariatric Surgery
Principal Investigators:	Kelly Allison, Ph.D. 3535 Market Street, 3rd Floor Philadelphia, PA 19104 215-898-2823 David Sarwer, Ph.D. Temple University 3223 N. Broad Street, Suite 175 Philadelphia, PA 19140 215-707-8632
Emergency Contact:	Psychiatric Resident on Call : 215-662-2121

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 24-30 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 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 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. 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 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

IRB Informed Consent Version: October 18, 2016

IRB Approval From: 10/24/2018 to 10/23/2019

Predictors of Outcomes of Bariatric Surgery Study

Consent for Audiorecording

I, (name) _____, authorize the staff of the Predictors of Outcomes of Bariatric Surgery Study to audiotape an assessment of eating behavior and attitudes and current and past history of psychological issues for the sole purpose of receiving consultation from a supervisor.

I understand that recording will be used in accordance with the ethical standards of confidentiality that govern licensed psychologists. The recording will eventually be destroyed.

I further understand that I have the right to withdraw permission for the recording at any time.

_____

Name (printed) Date

_____

Name (signature) Date

_____

Witness Date

IRB Approval From: 10/24/2018 to 10/23/2019

Title of research: Psychosocial and Behavioral Aspects of Bariatric Surgery (Protocol#: 23492)

Investigator and Department:

David Sarwer, Ph.D.
Center for Obesity Research and Education
Temple University
3223 N. Broad Street, Suite 175
Philadelphia, PA 19140
215-707-8632

Why am I being invited to take part in this research?

We invite you to take part in a research study 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).

What should I know about this research?

- Someone will explain this research to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to about this research?

If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team at:

Center for Obesity Research and Education
Temple University
3223 N. Broad Street, Suite 175
Philadelphia, PA 19140
215-707-8633

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at 215-898-2614 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

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 this research?

We expect that you will be in this research for 24-30 months (depending on scheduling and how quickly the screening procedures for your surgery are completed).

How many people will be studied?

We expect about 300 people will take part in the research.

What happens if I agree to be in this research?

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 Temple University 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 Temple University Hospital 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 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 Temple University Hospital (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 my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for completing the 4 study visits.

What happens if I agree to be in this research, but I change my mind later?

At any time you may withdraw or take away your permission to be part of this research study. 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.

Is there any way being in this research could be bad for me?

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.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

The particular treatment or procedure may involve risks to the subject that are currently unforeseeable.

Will being in this research help me in any way?

We cannot promise any benefits to you or others from taking part in this research. However, possible benefits include that 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 happens to the information collected for this research?

To the extent allowed by law, we limit the viewing of your personal information to people who have to review it. We cannot promise complete secrecy. The IRB, Temple University, Temple University Health System, Inc. and its affiliates, and other representatives of these organizations may inspect and copy your information. This study is also being conducted at the University of Pennsylvania. Authorized members of the study team may also inspect your information. Dr. Dale Bond at the Warren Alpert Medical School of Brown University will review information on study progress.

The sponsor and its agents (if applicable), monitors, auditors, the IRB, and the National Institutes of Health will be granted direct access to the portion of your medical records which are related to this research study for verification of the research procedures and date. By signing this document you are authorizing this access. You will also need to sign a separate “Authorization to use and disclose your protected health information” to be a part of this research. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Federal law provides additional protections of your personal information. These are described in an attached document titled “Authorization to use and disclose your protected health information”.

Can I be removed from this research without my OK?

The person in charge of this research or the sponsor can remove you from this research without your approval. Possible reasons for removal include:

- Dr. David Sarwer (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.

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

What will I be paid for taking part in this research?

If you agree to take part in this research, we will pay you $100 at the first visit (baseline), $50 at the 6 and 12 month visits, and $100 for the 24 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. You may also receive compensation for parking and travel (SEPTA tokens) for study-related assessment visits for your time and effort. Federal tax law requires to you to report this payment as income to the Internal Revenue Service.

You may be asked to tell us your social security number. If payments are more than $599.00, we will report them to the Internal Revenue Service and send you a Form 1099-MISC. If you do not give us your social security number, you may take part in this research if you agree to not be paid.

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.

Signature Block for Adult Subject Capable of Consent

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Título de la investigación: Aspectos psicológicos y psicosociales de la cirugía bariátrica (Protocolo No.: 23492)

Investigador y Departamento:

David Sarwer, Ph.D.
Center for Obesity Research and Education (Centro de Investigación y Educación sobre Obesidad)
Temple University
3223 N. Broad Street, Suite 175
Philadelphia, PA 19140
215-707-8632

¿Por qué se me invita a participar en esta investigación?

Lo invitamos a participar en un estudio de investigación porque reúne los requisitos para participar en este estudio. Es una persona adulta de entre 18 y 65 años de edad y tiene un índice de masa corporal (IMC) y un perfil de salud que lo hacen candidato para una cirugía bariátrica (cirugía para adelgazar) (es decir, un IMC de al menos 40 o de al menos 35 sumado a problemas de salud relacionados con el peso).

¿Qué debo saber acerca de esta investigación?

- Alguien le explicará esta investigación.
- La decisión de participar o no participar es suya.
- Puede optar por no participar en el estudio.
- Puede aceptar participar y modificar su decisión en el futuro.
- Su decisión al respecto no se considerará en su contra.
- Puede hacer todas las preguntas que desee antes de tomar una decisión.

¿Con quién puedo hablar acerca de esta investigación?

Ante cualquier pregunta, duda o queja, o si cree que la investigación le ha provocado algún daño, póngase en contacto con el equipo de investigación:

Center for Obesity Research and Education (Centro de Investigación y Educación sobre Obesidad)
Temple University
3223 N. Broad Street, Suite 175
Philadelphia, PA 19140
215-707-8633

Esta investigación ha sido revisada y aprobada por un Comité de Revisión Institucional. Puede comunicarse con dicho comité llamando al 215-898-2614 por cualquiera de los siguientes motivos:

- El equipo de investigación no responde a sus preguntas, dudas o quejas.
- No puede comunicarse con el equipo de investigación.
- Quiere hablar con otra persona además del equipo de investigación.
- Tiene preguntas sobre sus derechos como sujeto de investigación.

- Desea obtener información o realizar comentarios sobre esta investigación.

¿Por qué se lleva a cabo esta investigación?

Este estudio examinará la relación entre su funcionamiento psicosocial anterior a la cirugía en relación con los cambios en el peso y el estado psicosocial en los dos primeros años después de la cirugía bariátrica. Utilizaremos tareas de computadora, encuestas, entrevistas, análisis de orina y medidas de altura/peso. Llevaremos un registro de cómo los factores sociales y psicosociales antes de la cirugía se relacionan con los cambios en el peso y de estos mismos factores psicológicos y sociales después de la cirugía. Este estudio es patrocinado por los Institutos Nacionales de la Salud (National Institutes of Health, NIH).

¿Cuánto tiempo participaré en esta investigación?

Prevemos que participará en esta investigación durante un período de 24 a 30 meses (dependiendo de su programación de citas y la rapidez con que complete los procedimientos de selección para su cirugía).

¿Cuántas personas participarán en este estudio?

Prevemos que unas 300 personas participen en este estudio.

¿Qué sucede si acepto participar en esta investigación?

Sus decisiones respecto de la cirugía para adelgazar (someterse a ella o no y qué tipo de cirugía podría realizarse) y su elegibilidad para la cirugía no se relacionan de ninguna manera con su participación en este estudio. Esta sección solo aborda su participación en este estudio de investigación y no trata sobre la cirugía en sí misma.

A fin de participar en este estudio de investigación, se le pedirá que acuda a Temple University para completar varias visitas. La primera visita será una visita de selección para determinar si usted reúne los requisitos para participar en el estudio. Las cuatro visitas subsiguientes serán visitas de evaluación. Lo que hará en cada una de ellas se describe a continuación.

Visita de selección
El propósito de esta visita es explicarle el estudio y ver si usted reúne los requisitos para participar. Esta visita durará aproximadamente 30 minutos. Si acepta participar en este estudio, revisaremos su expediente médico para confirmar que usted reúne los requisitos de índice de masa corporal (IMC) y otros requisitos médicos del estudio. Se reunirá con el coordinador de investigación del estudio quien confirmará que usted tiene las características físicas apropiadas para participar en el estudio. El profesional de enfermería (o médico) del estudio revisará los resultados de sus antecedentes clínicos y de su examen físico, completados como parte del proceso de evaluación médica para la cirugía, a fin de confirmar que usted reúne los requisitos médicos para participar en el estudio. Una vez que se confirme su elegibilidad, se le suministrará un enlace para que complete cuestionarios en su casa antes de la fecha de la evaluación inicial que se haya programado para usted.

Visitas de evaluación
Completará un total de cuatro visitas de evaluación. Cada visita durará unas 4 horas y tendrá lugar en el consultorio de cirugía de Temple University Hospital. La primera visita consistirá en

una evaluación inicial. Intentaremos programar su evaluación inicial lo más cerca posible de la fecha de cirugía, aproximadamente de 2 a 6 semanas antes de su cirugía. Las visitas de evaluación de seguimiento tendrán lugar los meses 6, 12 y 24 después de la fecha de cirugía. Los procedimientos a completar en cada visita de evaluación son idénticos y se describen a continuación.
Llegará al programa de Cirugía Bariátrica de Temple University Hospital (su ubicación podría variar según dónde atienda su cirujano). Se le medirá el peso, la altura y la circunferencia de cintura y deberá proporcionar una muestra de orina (para análisis de uso de drogas). Antes de cada evaluación, se le suministrará un enlace a los cuestionarios que deberá completar en su casa antes de acudir a sus visitas con el Programa de Cirugía Bariátrica.

Cuando llegue al Programa de Cirugía Bariátrica, se le pedirá que complete 3 tareas de computadora en una sala tranquila; estas tareas le llevarán aproximadamente 25 minutos. También realizará una entrevista clínica con un profesional de investigación calificado para evaluar su funcionamiento psicosocial y sus hábitos de alimentación. Esta entrevista durará aproximadamente 3 horas. En caso de no haber completado los cuestionarios que se le suministraron antes de cada visita, se le pedirá que los complete en la computadora en cada visita. Estos cuestionarios indagarán sobre sus hábitos de alimentación, su actividad física y otras áreas del estado psicosocial.

Si su evaluación inicial tiene lugar más de 3 meses antes de su cirugía, es posible que se le pida que regrese a la clínica para completar las tareas de computadora y el diario de alimentos de 24 horas.

¿Cuáles son mis responsabilidades si participo en esta investigación?

Si participa en esta investigación, deberá completar las 4 visitas del estudio.

¿Qué sucede si acepto participar en esta investigación pero posteriormente cambio de opinión?

Puede retirarse o retirar su permiso para participar en este estudio de investigación en cualquier momento. Para hacerlo, debe enviar una notificación por escrito a los Investigadores Principales del estudio a la dirección que figura en la primera página. Aun si usted retira su permiso, la información médica personal que hayamos recabado antes de recibir su solicitud escrita podría seguir siendo utilizada y divulgada, según sea necesario a los fines del estudio.

¿Hay alguna posibilidad de que participar en esta investigación resulte perjudicial para mí?

No existen riesgos conocidos asociados a las tareas de computadora que se le pedirá que complete durante el estudio. Asimismo, los cuestionarios y las entrevistas que se le pedirá que complete presentan muy poco riesgo. Podría cansarse un poco al realizar estas tareas.

El cirujano bariátrico y/o el médico de atención primaria controlará/n su estado general de salud. Si el personal del estudio de investigación advierte estos u otros problemas médicos durante una visita del estudio, se alentará al paciente a que comunique estas observaciones a su médico. Es posible que durante el transcurso del estudio de investigación, el personal de investigación realice alguna observación inesperada. En dicho caso, tal observación/tales observaciones

será/n considerada/s por el personal correspondiente y el investigador principal le brindará información al respecto, en caso de ser necesario. Estas posibles observaciones podrían ser significativas o no y podrían generarle ansiedad respecto de su estado y requerir más exámenes por parte de su médico.

Usted y su compañía de seguro médico deberán pagar por los servicios de atención médica que normalmente serían responsables de pagar. En algunos casos, el seguro no pagará por los servicios normalmente cubiertos ya que estos servicios se prestan en un estudio de investigación. Usted debe comprobar con su compañía de seguros cuáles servicios estarán cubiertos dentro de su seguro y cuáles deberá pagar.

El tratamiento o procedimiento particular podría implicar riesgos para el sujeto que son hoy imposibles de prever.

El hecho de participar en esta investigación, ¿me ayudará de alguna manera?

No podemos prometer beneficios para usted u otras personas por participar en esta investigación. Sin embargo, uno de los posibles beneficios consiste en que los resultados de esta investigación aumenten los conocimientos científicos que se tienen en relación con los cambios en el peso, la psicopatología, los trastornos alimentarios y la impulsividad vinculados con la cirugía bariátrica. Estos conocimientos podrían contribuir al desarrollo de formas para mejorar los resultados de la cirugía para adelgazar.

¿Qué ocurre con la información obtenida para esta investigación?

En la medida en que lo autoriza la ley, solo permitimos que las personas a cargo de revisar su información personal sean quienes accedan a ella. No podemos prometer una confidencialidad completa. El Comité de Revisión Institucional (IRB), Temple University, Temple University Health System, Inc. y sus filiales, así como otros representantes de estas organizaciones, pueden inspeccionar y copiar su información. Este estudio también se lleva a cabo en la Universidad de Pensilvania. Los miembros autorizados del equipo del estudio también podrían inspeccionar su información. El Dr. Dale Bond de la Warren Alpert Medical School de Brown University revisará la información sobre el progreso del estudio.

El patrocinador y sus agentes (si corresponde), los supervisores, los auditores, el IRB y los Institutos Nacionales de la Salud tendrán acceso directo a la parte de su historia clínica que esté relacionada con este estudio de investigación, para verificar los procedimientos del estudio y las fechas. Al firmar este documento, usted autoriza este acceso. Para poder participar en esta investigación, usted también deberá firmar una Autorización por separado para usar o divulgar su información médica protegida. Podríamos publicar los resultados de esta investigación. Sin embargo, mantendremos la confidencialidad de su nombre y de otro tipo de información de identificación.

La legislación federal brinda protecciones adicionales para su información personal. Estas se describen en un documento adjunto titulado “Autorización para usar y divulgar información médica protegida”.

¿Pueden retirarme de esta investigación sin mi consentimiento?

La persona a cargo de esta investigación o el patrocinador pueden retirarlo de esta investigación sin su aprobación. Los posibles motivos del retiro incluyen:

- El Dr. David Sarwer (Investigador Principal del estudio) lo considera necesario para su salud o seguridad. Si bien tal medida no requeriría su consentimiento, usted será informado en caso de que se tome dicha decisión y se le explicará la razón.
- Usted no ha seguido las instrucciones del estudio.
- El Patrocinador, o los Investigadores Principales, han decidido suspender el estudio.

Le haremos saber sobre cualquier nueva información que pudiera afectar su salud, bienestar o elección de continuar participando en esta investigación.

¿Se me pagará por participar en esta investigación?

Si acepta participar en esta investigación, le pagaremos $100 en la primera visita (inicial), $50 en la visita a los 6 y 12 meses y $100 por la visita a los 24 meses. Si completa todas las visitas, recibirá una compensación de $300 en total. En caso de que se le pida que regrese a la clínica porque su evaluación inicial tiene lugar más de 3 meses antes de su cirugía, recibirá $25 adicionales por completar esta visita. También podría recibir compensación para estacionamiento y transporte (fichas para SEPTA) por concurrir a las visitas relacionadas con el estudio en agradecimiento por su tiempo y esfuerzo. La ley tributaria federal exige que usted declare este pago como ingreso ante el Servicio de Impuestos Internos.

Podríamos pedirle su número de seguro social. Si los pagos exceden el total de $599.00, los declararemos al Servicio de Impuestos Internos y le enviaremos un Formulario 1099-MISC. Si no nos suministra su número de seguro social, puede participar en esta investigación si acepta hacerlo sin recibir pago alguno.

Declaración de dinero recibido fuera del estudio:

El Dr. Sarwer, miembro del equipo del estudio, recibe dinero adicional de BARONova y Medtronic (compañías que fabrican dispositivos médicos y quirúrgicos) por servicios de consultoría que no forman parte de este estudio. Si desea obtener más información, hable con los investigadores o con el coordinador del estudio.

Sección de firmas para el sujeto adulto con capacidad de proporcionar consentimiento
Mediante su firma, usted deja constancia de su autorización para participar en esta investigación.

Firma de la participante	Fecha
Nombre de la participante en imprenta	
Firma de la persona que obtiene el consentimiento	Fecha
Nombre en letra de imprenta de la persona que obtiene el consentimiento	

College of Public Health

David B. Sarwer, Ph.D.
Associate Dean for Research
Director, Center for Obesity Research and Education
3223 N. Broad Street, Suite 175
Philadelphia, PA 19140

Phone **215-707-8630**
Fax 215-707-6462
Email ***dsarwer@temple.edu***
Web *www.cph.temple.edu*

Permission to Audiotape

Investigator's Name: David B. Sarwer, PhD
Department: Center for Obesity Research and Education
Project Title: Psychopathology, Disordered Eating, and Impulsivity as Predictors of Outcomes of Bariatric Surgery

Subject: _____ Date: _____

I give the Psychosocial and Behavioral Aspects of Bariatric Surgery study team permission to audiotape me. This audiotape will be used only for the following purpose (s):

(Choose one)

___ CLINICAL

This audiotape will be used as part of my treatment. It will not be shown to anyone but my treatment team, my family, and myself.

___ EDUCATION

This audiotape may be shown to education professionals outside of _____ for educational purposes. At no time will my name be used.

_X_ RESEARCH

This audiotape will be used as a part of a research project at Temple University . I have already given written consent for my participation in this research project. At no time will my name be used.

___ MARKETING/PUBLIC INFORMATION

This audiotape will be used to promote _____ to educational or health professionals, referral sources, and/or the general public. At no time will my name be used.

___ OTHER

Description:

WHEN WILL I BE AUDIOTAPED?

I agree to be audiotaped during my participation in the study beginning on _____ until my 24 month research assessment.

HOW LONG WILL THE TAPES BE USED?

I give my permission for these tapes to be used from during my participation in study beginning on _____ and until my 24 month research assessment.

Data will be stored for (3) years after completion of the study.

WHAT IF I CHANGE MY MIND?

I understand that I can withdraw my permission at any time. Upon my request, the audiotape(s) will no longer be used. This will not affect my care or relationship with Temple University in any way.

OTHER

I understand that I will not be paid for being audiotaped or for the use of the audiotapes.

FOR FURTHER INFORMATION

If I want more information about the audiotape(s), or if I have questions or concerns at any time, I can contact:

Investigator's Name: David Sarwer, PhD

Department: Center for Obesity Research and Education

Institution: Temple University

Address: 3223 North Broad Street, Suite 175
Philadelphia, PA 19140
Phone: (215) 707-8633

This form will be placed in my records and a copy will be kept by the person(s) named above. A copy will be given to me.

Participant Name (please print): _____

Participant Signature: _____

Staff Name (please print): _____

Staff Signature: _____

Date: _____

IRB Approval From: 10/24/2018 to 10/23/2019

TEMPLE UNIVERSITY®

College of Public Health

David B. Sarwer, Ph.D.
Associate Dean for Research
Director, Center for Obesity Research and Education
3223 N. Broad Street, Suite 175
Filadelfia, PA 19140

Phone **215-707-8630**
Fax 215-707-6462
Email ***dsarwer@temple.edu***
Web *www.cph.temple.edu*

Permiso Para Grabación en Audio

El Nombre del Investigador: David B. Sarwer, PhD
Departamento: Center for Obesity Research and Education
El Título de Proyecto: Psicopatalogía, Comer Desordenado y La Impulsividad Como Predictores de los Resultados de la Cirugía Bariátrica

Participante: _____ La Fecha: _____

Yo le doy permiso al equipo de estudio de Psicopatología y Aspectos Conductuales de la Cirugía Bariátrica en cinta de audio. Esta cinta de audio se utilizará solo para el/los siguiente(s) propósito(s):

(Elegir una)

___ CLÍNICO

Esta cinta de audio se utilizará como parte de mi tratamiento. No se mostrará a nadie solo mi equipo de tratamiento, mi familia y yo.

___ EDUCACIÓN

Esta cinta de audio puede ser mostrada a los profesionales de la educación fuera de _____ para los propósitos educativos. En ningún momento utilizará mi nombre.

_X_ INVESTIGACIÓN

Esta cinta de audio se utilizará como parte de un proyecto de investigación en Temple University. Yo he dado consentimiento para mi participación en este proyecto de investigación. En ningún momento se utilizará mi nombre.

___ MÁRKETING/INFORMACIÓN PÚBLICA

Esta cinta de audio se utilizará para promover _____ en educación o profesionales de la salud, fuentes de referencia, y/o público en general. En ningún momento se utilizará mi nombre.

___ OTRA

Descripción:

¿CUANDO SERA GRABADO EL AUDIO?

Estoy de acuerdo en ser grabado/a en audio durante mi participación en el inicio del estudio en _____ y hasta mi evaluación de investigación de 24 meses.

¿CUÁNTO TIEMPO SE UTILIZARÁ LAS CINTAS?

Doy mi permiso para que estas cintas sean utilizadas de durante mi participación en el studio que comienza en _____ y hasta mi evaluación de investigación de 24 meses.

Los datos se almacenarán por 3 años después de la terminación del estudio.

¿QUÉ PASA SI CAMBIO DE OPINION?

Entiendo que puedo retirar mi autorización en cualquier momento. A mi petición, ya no se utilizerán las cintas de audios. Esto no afectará mi cuidado o relación con Temple University.

OTRO

Yo entiendo que no me pagarán por ser audio grabado/a o para el uso de las cintas de audio.

PARA MÁS INFORMACIÓN:

Si quiero más información sobre las cintas de audio, o si tengo preguntas o dudas en cualquier momento, puedo contactar:

Nombre de Investigador: David Sarwer, PhD

Departamento: Center for Obesity Research and Education (CORE)

Institución: Temple University

Dirección:
3223 North Broad Street, Suite 175
Philadelphia, PA 19140
Phone: (215) 707-8633

Este formulario se colocará en mi expediente y se mantendrá una copia de la persona nombrada arriba. Se me dará una copia para mi.

El nombre del participante (en letra de molde): _____

La firma del participante: _____

El nombre del personal (en letra de molde): _____

La firma del personal: _____

La fecha: _____

Autorización para usar y divulgar información médica personal para investigaciones en Temple University, proveedores de Temple University Health System y Temple University Clinical Faculty Practice Plan

Recopilación y divulgación de su información

Durante el transcurso de este estudio de investigación, el cual es descrito por título en el formulario de consentimiento adjunto y el **documento específico sobre el estudio,** cierta **información médica personal** será recopilada y divulgada a los **destinatarios** identificados en este documento. Es importante que sepa que su información médica personal podrá identificarle por su nombre, dirección, número de teléfono, fotografía, número de seguro social, número de plan de seguro médico, fecha de nacimiento, fechas referentes a diversas pruebas y procedimientos, y otro tipo de información de identificación personal. Esta información se podrá obtener de sus expedientes médicos, exámenes físicos y procedimientos: (a) para determinar si usted es elegible para participar en el estudio de investigación, o (b) generada como resultado de su participación en el estudio de investigación.

Utilización y divulgación de su información

Al firmar este formulario de autorización, usted le da a Temple University, los proveedores de Temple University Health System, Temple University Clinical Faculty Practice Plan, Temple University Institutional Review Board y los investigadores nombrados en el documento de estudio-específico adjunto permiso para que utilicen su información médica personal y para divulgar dicha información a los destinatarios que se indican a continuación (si corresponde):patrocinante, los agentes del patrocinante, las agencias gubernamentales que supervisan la investigación en los Estados Unidos y en el extranjero, entre las cuales se podría incluir, en los Estados Unidos, a la Administración de Drogas y Alimentos y el Departamento de Salud y Servicios Humanos. Es importante que usted sepa que los destinatarios de la información, y sus agentes o representantes, harán todo lo posible para mantener su información médica personal en confidencialidad, y tomarán las medidas de protección apropiadas para evitar que personas no autorizadas usen o divulguen su información médica personal. No obstante, una vez que su información médica personal sea divulgada a los destinatarios entonces su información médica personal ya no continuara siendo protegida por las leyes y regulaciones federales sobre privacidad. Además, existe la posibilidad de que esta información sea divulgada nuevamente. Sin embargo, las leyes del Estado de Pensilvania o del estado donde usted reside pueden brindar protección adicional de privacidad.

Como usted puede tener acceso a su información

Usted debe saber que usted tiene derecho a ver y recibir una copia de la información médica personal que fue recopilada de usted durante el estudio de investigación mientras que Temple University y el investigador principal mantengan dicha información. Sin embargo, mientras el estudio de investigación esté en curso y a fin de proteger la integridad de la investigación, usted no podrá tener acceso a su información médica personal. Usted tendrá acceso a dicha información una vez finalizado el estudio. Pude que haya un cargo asociado por las copias de estos materiales.

Como revocar su autorización

Usted también tiene que saber que usted puede revocar su autorización para divulgar su información médica personal en cualquier momento, enviando una notificación por escrito al investigador principal y a Temple University a la dirección **indicada en el documento** específico sobre el estudio adjunto a la presente. Si usted decide revocar su autorización, Temple University y el investigador principal dejarán de recopilar su información médica relacionada con el estudio. En adición, Temple University y el investigador principal dejarán de utilizar y divulgar su información médica personal, excepto cuando dicha información haya sido obtenida antes de recibir su revocación. Por ejemplo, Temple University, el investigador principal, los destinatarios de la información, y sus agentes o representantes, podrán utilizar la información que se obtenga antes de que usted revoque su autorización a fin de proteger la integridad científica del estudio de investigación.

Notificaciones importantes

Usted recibirá una copia de esta autorización para que confirme que presta su consentimiento para que Temple University y el investigador principal revelen información médica personal acerca de usted. Si usted no firma la presente autorización o si la revoca, el investigador principal y Temple University no podrán permitirle participar o seguir participando en el estudio de investigación identificado en el documento específico sobre el estudio adjunto a la presente.

DOCUMENTO ESPECÍFICO SOBRE EL ESTUDIO

1. ESTUDIO DE INVESTIGACIÓN: Aspectos psicológicos y psicosociales de la cirugía bariátrica

2. INVESTIGADOR PRINCIPAL: David B. Sarwer, Ph.D.

3. FECHA DE VENCIMIENTO: Esta autorización no perderá validez.

4. PARA EXPEDIENTES DE VIH, SALUD MENTAL O ABUSO DE SUSTANCIAS ÚNICAMENTE (SI CORRESPONDE):

VIH: Comprendo y reconozco que mis expedientes de VIH serán utilizados y divulgados como parte de la investigación. Autorizo tal uso o divulgación por un período de: _____.

Firma del participante: _____ Fecha: _____

Salud mental: Comprendo y reconozco que mis expedientes de salud mental serán utilizados y divulgados como parte de la investigación. Autorizo tal uso o divulgación por un período de: _____.

Firma del participante: _____ Fecha: _____

Abuso de sustancias: Comprendo y reconozco que mis expedientes de abuso de sustancias serán utilizados y divulgados como parte de la investigación. Autorizo tal uso o divulgación por un período de: _____.

Firma del paciente: _____ Fecha: _____

5. INFORMACIÓN ADICIONAL:

_____
_____
_____

_____
Firma del paciente Fecha

_____
Nombre en imprenta del paciente

_____
Firma del representante personal del paciente Fecha

_____
Nombre del representante personal en letra de imprenta y su relación con el paciente

_____
Firma de la persona que obtiene la autorización Fecha

_____
Nombre de la persona que obtiene la autorización en letra de imprenta

Instrucciones para completar el Documento específico sobre el estudio

NO INCLUIR ESTA PÁGINA EN LOS MATERIALES QUE SE ENTREGAN AL PACIENTE

1. ESTUDIO DE INVESTIGACIÓN:	Enter the full title of the research protocol including identification number assigned to the protocol
2. INVESTIGADOR PRINCIPAL:	Enter the name, department affiliation and address of the PI
4. VIH, salud mental o abuso de sustancias:	If the research will involve the use and/or disclosure of any HIV, mental health or substance abuse records, the subject MUST indicate the duration for authorization of release of such information and provide a separate signature and date where indicated.
5. INFORMACIÓN ADICIONAL:	If applicable, enter any special elements of PERSONAL HEALTH INFORMATION that will be used, created and/or disclosed, and also indicate whether any samples of blood, urine or tissue will/may be stored for additional laboratory testing/storage for research at a later date.

Authorization to use and disclose personal health information for research at Temple University, Temple University Health System Affiliates, and Temple University Clinical Faculty Practice Plan

Information that will be collected from you and disclosed

During the course of this research study, which is described by title in the attached consent form and **study-specific document,** certain **personal health information** will be collected and disclosed to **recipients** identified in this document. It is important for you to know that your personal health information may identify you by name, address, telephone number, photograph, social security number, health plan number, and date of birth, dates relating to various tests and procedures, or other personally identifiable information. This information may be obtained from your medical records, physical examinations and procedures: (a) to determine if you are eligible to participate in the research study or (b) created as a result of your participation in the research study.

How your information will be used and to whom it will be disclosed

By signing this authorization form, you give Temple University, Temple University Health System affiliates, and Temple University Clinical Faculty Practice Plan, Temple University Institutional Review Board, and the investigator(s) named in the attached study-specific document, permission to use your personal health information and to disclose this information to the following recipients (as applicable): sponsor; sponsor's agents; governmental entities overseeing research in the United States and abroad, which may include in the United States, the Food and Drug Administration and the Department of Health and Human Services. It is important for you to know that the recipients, and their agents or representatives, will take all reasonable efforts to maintain your personal health information in confidence, and to use appropriate safeguards to prevent further use or disclosure by those not authorized to use or disclose your personal health information. However, once your health information is disclosed to the recipients, then your personal health information may no longer be protected by federal privacy laws and regulations and there is a potential for re-disclosure of this information. However, the laws of the Commonwealth of Pennsylvania or your state of residence may provide further privacy protection.

How you can access your information

You should know that you have the right to see and receive a copy of your personal health information that was collected from you during the research study for as long as this information is maintained by Temple University and the principal investigator. However, while the research study is in progress, you will not be able to access your personal health information in order to preserve the integrity of the research. You will be able to access this information when the study is completed. There may be associated charges for copying these materials.

How to revoke your authorization

You should also know that you can revoke your authorization to disclose your personal health information at any time by sending a written notice to the principal investigator and Temple University at the address listed in the attached study-specific document. Should you decide to revoke your authorization, Temple University and the principal investigator will stop collecting your study-related health information. In addition, Temple University and the principal investigator will stop using and disclosing your personal health information, except to the extent such information was collected prior to your revocation. For instance, Temple University, principal investigator, recipients, and their agents or representatives may use the information obtained before you revoked your authorization in order to preserve the scientific integrity of the research study.

Important notices

You will receive a signed copy of this authorization to acknowledge your approval for Temple University and the principal investigator to the release your personal health information**.** If you do not sign this authorization or if you revoke this authorization, the principal investigator and Temple University cannot allow you to participate in or to continue to participate in the research study identified in the attached study-specific document**.**

STUDY-SPECIFIC DOCUMENT

1. RESEARCH STUDY:
Psychosocial and Behavioral Aspects of Bariatric Surgery (Protocol#: 23492)

2. PRINCIPAL INVESTIGATOR:
David Sarwer, Ph.D.
Center for Obesity Research and Education
Temple University
3223 N. Broad Street, Suite 175
Philadelphia, PA 19140
215-707-8632

3. EXPIRATION DATE: This Authorization does not expire.

4. FOR HIV, MENTAL HEALTH OR SUBSTANCE ABUSE RECORDS ONLY

Signature of Subject: _____ Date: _____

Mental Health: I understand and acknowledge that my mental health records will be used or disclosed as a part of the research. I consent to such use or disclosure for a period of: _____.

Signature of Subject: _____ Date: _____

Substance Abuse: I understand and acknowledge that my substance abuse records will be used or disclosed as a part of the research. I consent to such use or disclosure for a period of: _____.

Signature of Subject: _____ Date: _____

_____
Signature of Subject Date

_____
Printed Name of Subject

_____
Signature of Personal Representative of the Subject Date

_____
Printed Name of Personal Representative of the Patient and Relationship to Subject

_____
Signature of Person Collecting Authorization Date

_____
Printed Name of Person Collecting Authorization

IRB Approval From: 10/24/2018 to 10/23/2019

Instructions for Completing the Study-Specific Document:

DO NOT INCLUDE THIS PAGE IN THE MATERIALS GIVEN TO SUBJECT

1. RESEARCH STUDY:	Enter the full title of the research protocol including identification number assigned to the protocol
2. PRINCIPAL INVESTIGATOR:	Enter the name, department affiliation and address of the PI
4. HIV, Mental Health or Substance Abuse:	If the research will involve the use and/or disclosure of any HIV, mental health or substance abuse records, the subject MUST indicate the duration for authorization of release of such information and provide a separate signature and date where indicated.
5. OTHER INFORMATION:	If applicable, enter any special elements of PERSONAL HEALTH INFORMATION that will be used, created and/or disclosed, and also indicate whether any samples of blood, urine or tissue will/may be stored for additional laboratory testing/storage for research at a later date.