Document Section Cover Sheet

Official Title: The Efficacy of Suvorexant in Treatment of Patients With Substance Use Disorder and Insomnia: A Pilot Open Trial

NCT number: NCT03412591

Document: Informed Consent Form

Document date: 3/14/2023

Version Date: 16 February 2023

CONSENT FOR RESEARCH
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: The Efficacy of Suvorexant in the Residential Treatment of Patients with Substance Use Disorder and Insomnia: A Pilot Open Trial

Principal Investigator: Scott Bunce, PhD

Address: 500 University Drive, Hershey PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (215) 510-8295.

Caron Study Coordinator (24-hour)
Erin Deneke, PhD
610-743-6242
edeneke@caron.org

Subject's Printed Name: _____

We are asking you to be in a research study.

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.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

We are asking you to be in this research study because you are being treated for opiate or alcohol dependence at The Caron Foundation.

This research is being done to find out if suvorexant helps in treating insomnia in substance dependent patients. The evaluations will include sleep, stress hormones, as well as daily reports of mood, feelings of stress and craving for drugs/alcohol.

Suvorexant is an FDA approved medication for treatment of trouble falling asleep and staying asleep in adults with Primary Insomnia, but it is not specifically approved for the treatment of sleep disturbance in patients with substance dependence disorders. Therefore, its use in this research should be considered "investigational".

Approximately thirty-six (36) patients admitted to the Caron Foundation for treatment of addiction to opioids or alcohol will take part in this research study which is being conducted at the Caron Foundation in conjunction with Penn State Hershey Medical Center.

2. What will happen in this research study?

If you agree to participate in this research, you will first read and sign this consent document before any study-related tests or procedures are performed. Your decision to participate in the research will not affect your treatment at the Caron Foundation. All decisions about your clinical care, including its duration, will be made by you and the members of your clinical team at the Caron Foundation.

The study coordinator at Caron Foundation will complete the following tests and procedures on an electronic tablet and on paper forms. This will be reviewed with the study coordinator and the Principal Investigator at Penn State College of Medicine which will help us to determine if you qualify to continue in the research study:

- The M.I.N.I. International Neuropsychiatric Interview screen (M.I.N.I. 7.0.2) which provides psychiatric diagnosis.
- The Hamilton Depression scale (HAM-D) will be used to provide a measure of depressive symptomatology.
- Form 90-DI or AI to determine your recent and lifetime history of drug and alcohol use.
- A modified Pittsburgh Sleep Quality Index (PSQI) scale assessed to measure sleep quality.
- A modified Insomnia Severity Index (ISI) to measure insomnia symptoms.

You cannot take part in this study if you are pregnant or breastfeeding a baby. If you test positively for pregnancy at admission to Caron, you may not participate in this research study.

The tests and procedures listed below will be performed if you remain eligible to continue in the research study after completing the screening part of the research and you choose to continue. The tests/procedures described in the following section will occur during a 10 day (9 night) period.

- Sleep- Actigraphy: Your objective sleep will be assessed for 9 nights using an actigraph. This involves wearing a small, watch-like wrist band that measures your movement while you sleep. Each evening and morning you will complete a log to indicate your bedtime and morning awakening, as well as to record periods of activity and inactivity. In addition to the actigraph, you will complete the Insomnia Severity Index (ISI) scale to measure your subjective sleep at the beginning and the end of the study (day 0 and 9). The actigraphs will be transferred to Penn State, Hershey to download the data and further analyze it.
- Daily Surveys: You will be asked to report your sleep, mood, drug/alcohol craving, perceived stress, and pain 4 times each day for 9 consecutive days using rating scales on a smart phone that will be issued to you for your use only during the research. The data will be transmitted directly to a secure database from the smart phone without any identifying information. You will be asked how you feel (e.g., happy, sad, frightened, stressed, etc.) and if you have any drug/alcohol craving. These surveys will take about 5-6 minutes each. The smart phones are programmed only to administer these surveys, and cannot be used to make phone calls or connect to the internet in any way. Such collected data will be transferred electronically to University Park for further analysis. You will receive reminders on the smart phones to complete the surveys.

- Saliva Collections: Your saliva will be collected to measure the level of a hormone called cortisol in your body. You will collect your saliva on 2 consecutive days at the beginning and two consecutive days at end of the study (Days 1&2, 7&8) at 5 different time points throughout the day (8:00 am before breakfast, noon before lunch, 3:00, 6:00 and 9:00 pm). You should not eat or drink anything or brush/floss your teeth for 30 minutes prior to saliva collection. You will hold an absorbent cotton swab in your mouth to saturation (about 90 sec) and deposit the cotton swab in a tube that we will supply to you. Salivary samples will be transferred to Penn State, Hershey by the HMC study coordinator where it will be stored and analyzed at the end of the study.
- Abuse liability- You will be asked to complete questions about abuse liability about 30 min after medication administration on study nights 1 and 7 and the morning following it. It includes questions if you like the drug (drug liking), if the drug had an effect (drug effects questionnaire), questions related to drug value (drug value questionnaire). You will also categorize the drug effect according to one of 7 classes of psychoactive medications which will be done on the morning of day 2 & 8. In addition to the above, the nurse who administers the medication, will complete a questionnaire based on her observation about 30 min after you take the medication. Data will be entered and transferred electronically to Penn State, Hershey using REDCap.
- *Optional* saliva sample for genetic analysis (only for opioid use disorders) In addition to collecting saliva for cortisol measurement as described above, an optional saliva sample can be collected for genetic material. The saliva sample will be collected once at the beginning of the study. The sample will be stored at Dept. of Psychiatry, Penn State Hershey and later send to University Park at the end of the study for further analysis by Dr. David Vandenbergh.. A separate optional area to sign is at the end of the consent form.

- Study Medication: For the first 2 nights, you will continue your current medication (melatonin or sedating antidepressant). You will then receive study medication, suvorexant for 7 consecutive nights. Both medications will be administered by a trained nurse.
The nurse will evaluate you on the Observer Rated Questionnaire. You will complete the self-report abuse liability assessments 30 minutes after drug administration on study nights 1&7, and mornings 2&8.

Table 1. Day time questionnaires and procedures.

Study Day	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Consent and Screening (Form 90 AI/DI, MINI 7.0.2, HAM-D)	**X**									
EMA		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Modified ISI	**X**									**X**
Modified PSQI	**X**									
*DNA Collection**	**X**									
Cortisol Collection		**X**	**X**					**X**	**X**	
Abuse Liability Battery – Morning			**X**						**X**	

Table 2. Night time questionnaires and procedures.

Study Night	0	1	2	3	4	5	6	7	8
Suvorexant			1	2	3	4	5	6	7
*Baseline***	X	X							
Suvorexant Administration			X	X	X	X	X	X	X
Actigraphy/Logs	X	X	X	X	X	X	X	X	X
Abuse Liability Battery - Evening		X						X	
Observer Rated Questionnaire		X						X	

*For patients with opioid use disorder only
**Current medication regimen including antidepressants/melatonin

Abbreviations: MINI, MINI international neuropsychiatric interview; HAM-D, Hamilton Depression Rating Scale; EMA, ecological momentary assessment; ISI, Insomnia Severity Index; PSQI, Pittsburgh Sleep Quality Index.

What are my responsibilities if I take part in this research?

If you take part in this research, your major responsibilities will include:

1. Read and understand the informed consent. Discuss with the Caron based study coordinator if you have any questions about the study before signing and agreeing to participate in the study.
2. To complete the screening tests and procedures with the Caron based study coordinator which helps us to determine if you are eligible to continue in the study.
3. Take the study medication for 9 nights of the study period. This includes 2 nights on the current medication including trazodone or other sedating anti-depressant or melatonin for first two nights followed by suvorexant 20 mg for the next 7 nights. Report any side effects to your staff at Caron Foundation so that they are appropriately addressed.
4. Wear the actigraph to measure objective sleep for 9 nights of the study. Complete an actigraph log each evening and morning to indicate bed and wake up times and to record periods of activity and inactivity.
5. Complete the surveys regarding your sleep, mood, drug/alcohol craving, perceived stress and pain four times a day for 9 consecutive days of the study period on a smart phone issued to you for the study period.
6. Provide saliva samples five times a day for two days at the beginning (Days 1 &2) and at the end of the study (Days7 & 8).
7. Complete questionnaire related to abuse liability about 30 min after drug administration on study nights 1 and 7 and the morning following it.
8. Provide saliva sample for genetic analysis which is optional. You may wish to participate in the main part of the study without agreeing for the optional saliva collection for genetic analysis.

3. What are the risks and possible discomforts from being in this research study?

Medication: Adverse reactions with suvorexant include common and less common serious reactions. Common reactions include: excessive daytime sleepiness, headache, dizziness, abnormal dreams, diarrhea, dryness of the mouth, upper respiratory infection, cough, temporary inability to

move, speak or react when falling asleep or waking up (sleep paralysis), and sudden loss of muscle tone associated with strong emotions like laughter or excitement while awake (cataplexy). Less common but serious reactions include: impaired mental alertness, memory problems (CNS depression), abnormal sensory experiences (hallucinations), sleep walking, talking or acting out dreams (abnormal sleep behavior), worsening depression, higher risk of abusing the medication and suicidal thoughts.

There may be risks that are not known at this time or are currently unforeseeable.

You will report any of the side effects to your providers at Caron Foundation. Side effects will also be monitored by the medication nurse.

We will be employing a modified abuse liability protocol to assess the relative risk of developing possible dependence on suvorexant. Neither tolerance nor withdrawal effects were observed in the pre-marketing studies.

It is possible that you may be allergic to any medication involved in the study. Signs of an allergic reaction to a medication include: hives, difficult breathing, swelling of the face, lips, tongue or throat. If you have any of these signs please seek emergency medical help.

Actigraphy: There is no known risk to wearing the wrist actigraphs. A minor skin rash may develop from the wristband, but this risk is very slight.

Questionnaires: The interviews and forms are routine, standardized forms for sleep research and psychology research. They pose no known risks, although certain questions may be mildly upsetting because they may probe sensitive psychological areas and/or alcohol and substance use patterns. If there are any areas of concerns, appropriate referrals can be arranged at the Caron Foundation. You are free to skip any questions that make you uncomfortable. All patients who express any suicidal thoughts will be referred for follow-up mental health counseling.

The risks to an unborn baby or a nursing child from the study drugs are largely unknown, though some animal studies suggest adverse events. Limited use in pregnant women has not demonstrated any fetal abnormalities or adverse events. Women who are pregnant or are nursing a child may not participate in this research study.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include an improvement in your ability to fall asleep and stay asleep. It is important that you remain on the study medication over the course of 7 nights since it is possible that the effectiveness may be delayed if your insomnia is related to the continuing withdrawal effects related to your substance use disorder.

4b. What are the possible benefits to others?

The results of this research may guide the future treatment of insomnia in patients with opioid or alcohol dependency.

5. What other options are available instead of being in this research study?

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive commercially available treatments, including behavioral techniques, same or another sleep medication.
- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition.

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

6. How long will I take part in this research study?

If you agree to take part, it will take you 10 days (9 nights) to complete this research study while you are a patient at The Caron Foundation. The screening will take about 2 hours. Responding to the queries from the smart phone will take 5-6 minutes, 4 times a day for 9 days. On days 1, 2, 7, and 8 it will take about 2-3 minutes to collect saliva samples at each of the 5 time points.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law. In our research files at Caron foundation and at The Milton S. Hershey Medical Center (HMC) and the Penn State College of Medicine (PSU) we will include these identifiers: your name, date of birth, medical record number, actigraph/device identifier and a code number.

- A list that matches your name and date of birth with your code number will be kept in a locked file at the Caron Foundation and at HMC/PSU.
- Your research records will be labeled with your study ID code and will be kept in a safe area in the research office at Caron and at HMC/PSU.
- Your research samples will be labeled with your study ID code and will be stored in a freezer in a locked room at the research laboratory at HMC/PSU in the Department of Psychiatry.

For research records and specimens sent to researchers working on this study at the University Park Campus of Penn State University you will be identified by your study ID code.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to personnel of the United States Government in order for it to evaluate or audit the research, or prevent disclosures required to meet FDA requirements. For additional information ask the principal investigator or a member of the study team or contact the Human Research Protection Program at (814) 865-1775.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information and samples may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement, if applicable, to ensure it continues to be used under the terms of this consent and authorization.

7b. How will my identifiable health information be used?

We may use your research information and your biological samples in future studies or may share your information or biological samples with other investigators for future research without your additional informed consent. Before we use or share your information or samples we will remove any information that shows your identity.

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. We will use and disclose your information only as described in this form and in the HMC Privacy Notice.

The research team may use the following health information:

- Past, present, and future medical records
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- Research staff involved in this study at HMC/PSU and The Caron Foundation
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office
- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. government bodies that oversee or review research)

- The Synergy Pharmacy
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Researchers from other campuses of Penn State University who are part of this study
- A group that oversees the data (study information) and safety of this research
- Clinical Trial Monitoring Team from the Department of Public Health Sciences at Penn State Hershey College of Medicine
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original Caron/PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to
- take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The suvorexant will be provided at no cost to you while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include: Actigraphy, cortisol testing, Daily Diary Collection and the optional collection of saliva for genetic analysis.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at Caron. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the medical staff at Caron, who will report the event to a doctor on staff. The Principal Investigator at Penn State listed on the first page of this consent form will be informed within 12 hours.

<u>HMC/PSU compensation for injury</u>

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will receive a $10 gift card for each day you complete the study. Upon completion of the entire medication period, you will get a bonus of a $50 gift card. The total amount you will receive for completing the entirety of the study will be $150 in gift cards.

It is possible that your research information and/or specimens may be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

10. Who is paying for this research study?

The institution and investigators are not receiving any funds to support this research study. The study is internally funded by the Department of Psychiatry at Penn State University, Hershey to support this research.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

The research doctor at Penn State may take you out of the research study without your permission.

- Some possible reasons for this are: you did not follow the instructions of the study.
- If your participation ends early, you may be asked to visit your doctor for a visit.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the Caron study coordinator, Dr. Erin Deneke, at 610-743-6242 (24-hour), or the head of the research study (principal investigator and clinical psychologist), Dr. Scott Bunce, 215-510-8295 (cell), if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and

- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

Optional part(s) of the study (Opiate Patients Only)

In addition to the main part of the research study, there is another part of the research. You can be in the main part of the research without agreeing to be in this optional part.

Collection of Saliva Sample for genetic analysis

Cells in your body contain a type of molecule called deoxyribonucleic acid, or DNA for short. DNA contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child. We would like to collect DNA from you by asking you to donate an additional saliva sample.

DNA obtained from your saliva samples will be housed in a in a freezer in a locked room at the research laboratory, Department of Psychiatry and will be analyzed at the end of the study. At the end of the study, the collected salivary samples will be safely transported, stored and analyzed at Dr. Vandenbergh's laboratory at University Park. The researchers will ensure that the material is safely transported and stored in a freezer before analysis at Dr. Vandenbergh's laboratory. This will allow investigators to pair clinical information with genetic data for research questions about the biological basis of opioid use disorder. Using the research data along with saliva samples, we may be able to find out how and why diseases start, and improve tests to diagnose diseases. The saliva sample for the genetic analysis is optional. You may wish to participate in the main part of the study without agreeing for the optional part.

We will study your DNA for research only. We will learn your genotype at many points in your DNA, and these genotypes will then be compared to the data you give us, such as the questionnaires, actigraph, and smart phone, in the study. We will also study the changes in your DNA that are related to a biological process known as epigenetics. The genetic research data will not be used for your medical care. Neither your doctor nor you will receive results of these research tests. If you are interested in clinical genetic testing, there are clinical labs to which you may send your saliva or other biological samples and get the clinical testing done for a price. If any results are found that may be clinically relevant for your care, the investigator will apply to the Penn State ethics committee to make a decision on the necessity and procedure of return of results to you.

Potential Risks and the Genetic Information Non-Discrimination Act (GINA): There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at Penn State Hershey, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

You should initial below if you agree to provide DNA saliva samples for genetic testing for this research.

I agree to provide DNA saliva samples for genetic testing for this research **only**.
_____ Yes _____ No

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the optional part(s) to the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

Signature of Person Giving Informed Consent

Signature of Subject

By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part(s) of the research study.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name