Version Date: 11-29-23

PID: _____

CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: Randomized trial of low nicotine cigarettes plus electronic cigarettes in smokers

Principal Investigator: Jonathan Foulds, Ph.D.

Address: Penn State University, 500 University Drive, Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-3504. After hours call (717) 531-8521. Ask for the General Internal Medicine doctor on 24-hour call.

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, and there will be no penalty or loss of benefits to which you are entitled.

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.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?
We are asking you to take part in this voluntary research study because you are an adult smoker.

What is the purpose of this research study?
The purpose of this voluntary research study is to learn about adult smoker's experiences using study cigarettes with different amounts of nicotine in combination with e-cigarettes containing different amounts of nicotine.

How long will the research study last?
It will take you about 6 months to complete this research study.

What will I need to do?
During the first two weeks of the study you will smoke study cigarettes similar in nicotine to your own brand of cigarettes. Afterwards you will be randomly assigned to one of two study cigarette groups AND one of two e-cigarette groups for 16 weeks. You will use these products throughout the study. During study visits

you will be asked to complete questionnaires, provide urine samples, and complete other health measurements. You will record your cigarette and e-cigarette use every day.

What are the main risks of taking part in the study?
The main risk for this study is that you may experience nicotine withdrawal symptoms or nicotine dependence depending on the nicotine content in your study cigarettes/e-cigarette. Additionally, there have been reported risks related to the use of e-cigarettes, including serious lung illnesses and seizures. E-cigarettes containing THC and e-cigarettes purchased off the street (not from retailers) have been linked with most of the cases involving lung illnesses. The e-cigarettes provided in this study do not contain THC.

What are the possible benefits to me that may reasonably be expected from being in the research?
There are no benefits to you for taking part in this study. However, depending on the cigarette/e-cigarette group you are assigned to, you may experience decreased toxicant exposure and decreased addiction to cigarettes if you are able to reduce your cigarette use.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

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DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?

This research is being done to learn about adult smokers' experiences using study cigarettes with different amounts of nicotine in combination with e-cigarettes containing different amounts of nicotine. We are also interested in learning about the potential effects of using these products on stress and mental health.

Approximately 300 people will take part in this research study at Penn State Health in Hershey, Pa.

2. What will happen in this research study?

If you agree to participate in this research, you will sign this consent form before any research-related tests or procedures are performed. The following screening procedures will be done to determine if you are eligible to continue in the research:

1. If you are a female participant, we will do a urine pregnancy test to confirm that you are not pregnant. If the test is positive you will not be allowed to continue in the study.
2. Collect blood pressure and heart rate measurement.
3. Provide an exhaled carbon monoxide sample by blowing through a plastic tube. This test will not be completed if a mandate on mask removal is currently in place at the time of your visit.

If you are eligible to continue in the research, your participation in the study will continue today starting with Phase 2 and consist of 2 more phases:

Phase #	**Phase 2**		**Phase 3**				**Phase 4**
Description	Smoke study cigarettes similar to your usual brand cigarettes for 2 weeks.		Randomly assign you to: a) one of two study cigarette groups AND b) one of two e-cigarette groups				Follow- up
Study Visit #	2	3	4	5	6	7	8
Visit Type	In-person	In-person	In-person	In-person	Remote	In-person	Remote
Study Week #	-2	0	4	8	12	16	20
Questionnaires	X	X	X	X	X	X	X
Daily Cigarette Log	X	X	X	X	X	X	X
Daily E-cig Use Log			X	X	X	X	X
Urine Collection		X		X		X	
Exhaled Carbon Monoxide	X	X	X	X	X	X	X

Blood Pressure and Heart Rate	X	X	X	X	X	X	
Lung Function Test	X	X	X	X	X	X	
Weight	X	X	X	X	X	X	
Height	X						
Pregnancy Test (Women only)	X	X		X		X	

Phase 2

In Phase 2, you will be asked to smoke study cigarettes that contain the normal amount of nicotine as conventional cigarettes. The cigarettes will be matched to your menthol or non-menthol flavor preference. We will give you more than enough cigarettes to replace the ones you smoke each day. This phase lasts 2 weeks and consists of two study visits. Based on the visit, you will also:

1. Allow a researcher to collect your blood pressure, heart rate, and weight measurements.
2. Collect a urine sample at the study visit to look at nicotine and other chemicals from cigarettes. If you are a female participant we will also do a urine pregnancy test to confirm you are not pregnant.
3. Provide an exhaled carbon monoxide sample by blowing through a tube into a machine. This test will not be completed if a mandate on mask removal is currently in place at the time of your visit.
4. Complete a lung function test, where you will be asked to breathe hard into a machine that measures how much air you exhale after taking a deep breath. This test will not be completed if a mandate on mask removal is currently in place at the time of your visit.
5. Complete several questionnaires on smoking habits, cigarette liking, stress, mood, and daily living experiences. You are free to skip any questions that you would prefer not to answer. Questionnaires will be sent to you via a survey link before your study visit. You will be asked to complete the questionnaires 2 hours before your visit, but if that is not possible you will have up to 24 hours after your study visit to complete them.
6. Collect your daily cigarette logs and study cigarette packs (unopened, opened or empty) from your previous visit.
7. Receive daily e-cigarette and cigarette logs to complete at home to keep track of your use. You must bring these back at your next study visit.

Phase 3

In Phase 3, you will start the randomized phase which lasts 16 weeks and consists of 4 study visits (3 in-person and one remote) and one phone call. You will be randomly assigned to one of four groups (see table below). This means whichever group you are assigned to will be determined purely by chance. You

will have an equal chance of being in each group. Neither you nor the research team will know which cigarette group you are in, but the research team will be able to get this information quickly if it is needed to ensure your safety.

	Nicotine Containing E-cigarette	**Zero Nicotine E-cigarette**
Normal Nicotine Cigarettes	Group 1	Group 2
Very Low Nicotine Cigarettes	Group 3	Group 4

The e-cigarette (JUUL) used in this study is being used because research shows that it delivers lower levels of toxicants than other e-cigarettes. Because we are using JUUL in this study does not mean that it is safe for everyone to use. E-cigarettes and nicotine should never be used by youth or young adults. Please take care to keep your e-cigarette out of the hands of others.

We will call you one week after you are randomized into one of the four groups to check in with you. We will collect information on your use of the study cigarettes and e-cigarette.

Depending on the visit, you will also be asked to do the following during Phase 3:

1. Allow a researcher to collect your blood pressure, heart rate, and weight measurements. Your waist and hip ratio measurement will be collected at the last visit of this phase.
2. Collect a urine sample at study visits to look at nicotine and other chemicals from cigarettes and e-cigarettes. If you are a female participant we will also do a urine pregnancy test at every other visit to confirm you are not pregnant.
3. Complete several questionnaires on smoking habits, study product liking, stress, mood, and daily living experiences. You are free to skip any questions that you would prefer not to answer. Questionnaires will be sent to you via a survey link before your study visit. You will be asked to complete the questionnaires 2 hours before your visit, but if that is not possible you will have up to 24 hours after your study visit to complete them.
4. Provide an exhaled carbon monoxide sample by blowing through a tube into a machine. This test will not be completed if a mandate on mask removal is currently in place at the time of your visit.
5. Complete a lung function test, where you will be asked to breathe hard into a machine that measures how much air you exhale after taking a deep breath. This test will not be completed if a mandate on mask removal is currently in place at the time of your visit.
6. Collect your daily e-cigarette and cigarette logs from your previous visit. We will also collect e-cigarette cartridges (used and unused) and study cigarette packs (unopened, opened or empty) from your previous visit.
7. Receive daily e-cigarette and cigarette logs to complete at home to keep track of your use. You must bring these back at your next study visit.
8. Receive new study cigarette packs and e-cigarette cartridges to last until your next visit. You must bring these back at your next study visit.

Phase 4

In Phase 4, you will complete a final follow-up study visit remotely, either over the telephone or through teleconferencing. We will collect information on your cigarette, e-cigarette, or nicotine product use since your last study visit. We will send you questionnaires on smoking habits, mood, and daily living experiences via a survey link before your study visit. You will be asked to complete the questionnaires 2 hours before your visit, but if that is not possible you will have up to 24 hours after your study visit to complete them. If you report being abstinent from cigarettes in the past 7 days at the last visit, we will follow up with a carbon monoxide reading using an individual CO monitors that can be mailed to your house. You will use the personal devices to complete a CO measurement through teleconferencing with the researcher.

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

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

- Willingness to replace your cigarettes with the study e-cigarette
- Attend study visits regardless of how successful you are at reducing smoking or using the study cigarettes/e-cigarette
- Keep track of daily cigarette and/or e-cigarette usage
- Complete in-person study visits at Penn State Health in the Clinical Research Center and remote visits through teleconferencing or over the phone
- Complete study procedures and questionnaires
- Return your used and unused study products at each in person visit

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

Switching cigarette brands: Before being randomized in the study you will switch from your usual brand of cigarettes to study cigarettes that are similar in nicotine to your own brand of cigarettes to smoke for 2 weeks. The cigarettes you are given throughout this study may have different characteristics (i.e. nicotine level, ventilation, length, etc.) than your usual brand. So you could experience symptoms related to different strength or sensory effects from the study cigarettes, such as harshness in your throat or chest.

Increased compensatory smoking: You may be given cigarettes that have very low levels of nicotine in them which may lead to compensatory smoking and in turn increased levels of toxicant exposure. In prior studies, compensatory smoking was minimal and higher levels of toxicant exposure were generally not observed. Cigarette consumption and exhaled carbon monoxide will be monitored throughout the trial.

E-cigarette use: There may be some unknown risks related to the use of e-cigarettes. Side effects associated with using an e-cigarette include changes in taste, dehydration, mucus in throat/sinus, dry mouth, dry cough, throat irritation, mouth irritation, sore throat, mouth ulcers, dizziness, headache, nausea, and hiccups.

- There are reports that some people who use e-cigarettes have experienced seizures, with most involving youth or young adult users. If you have a history of seizures or take medications to prevent seizures you should not be in the study.
- There have been some reports of serious lung illnesses among those who used e-cigarettes, and even some cases of death as a result. The cause of all deaths has not been identified. The investigations being conducted by the Centers for

Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have found that the majority of people experiencing these illnesses were using e-cigarette products that contained tetrahydrocannabinol (THC) and/or products that were bought off the street and not from retail establishments. It is important that you avoid these products. The e-cigarette products used in this study do not contain THC. Nonetheless, please call your doctor immediately if you experience cough, shortness of breath, chest pain, nausea, vomiting, diarrhea, or fever after using your e-cigarette. Please ONLY use the e-cigarette and liquid cartridges given to you by our researchers. Do not tamper with your e-cigarette and do not use other liquids with your e-cigarette device.

- E-cigarette liquid contains vegetable glycerin, propylene glycol, and flavorings. It is possible that you may have an allergy to one of more of these ingredients. The most common reported allergic reaction to these substances is a rash.
- The contents of the e-cigarette cartridges should not be ingested. If they are swallowed, chewed, or eaten, contact a poison control center immediately.

Nicotine addiction: You may be given an e-cigarette that contains nicotine, which is an addictive substance. The amount of nicotine you receive from this product depends on what product you are given and how you use it.

Nicotine withdrawal symptoms: Stopping nicotine may result in nicotine withdrawal symptoms such as irritability, anxiety, restlessness, depressed mood, increased appetite, fatigue, insomnia/sleep problems, impatience, headache, and difficulty concentrating. It is possible that nicotine withdrawal symptoms could affect a pre-existing mental health condition. These symptoms will be monitored at each visit.

New pregnancy or intention to become pregnant: Nicotine, from cigarettes and from e-cigarettes, is known to be harmful to the developing human fetus. Females capable of becoming pregnant will be administered a pregnancy test prior to beginning the research. If you are female you must agree to take reasonable and necessary precautions against becoming pregnant during the period of the investigation. If, at any point during the research, you believe there is any possibility that you may be pregnant, you must notify the research staff immediately.

Spirometry: Risks associated with spirometry may include shortness of breath, dizziness, headache, and on rare occasions fainting while doing the breathing test. Every effort will be made to limit these effects during the procedure.

Loss of confidentiality: 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 as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

Randomization in clinical trials: You will be assigned to a research intervention by chance. The intervention you receive may prove to be less effective or to have more side effects than the other research treatment(s) or other available treatments.

Questionnaires: It is possible that some of the questions in the questionnaires may make you feel uncomfortable. You can skip any questions that make you uncomfortable. In addition, we will provide you with a list of phone numbers for organizations that can provide information and referrals for you should you need them.

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 participation in this study. However, depending on the cigarette/e-cigarette group you are assigned to you may experience decreased toxicant exposure if you are able to reduce your cigarette use and experience reduced dependence on cigarettes.

4b. What are the possible benefits to others?
Findings from this study may benefit others by helping researchers develop effective strategies to reduce the health impact of cigarettes among the smoking population.

5. What other options are available instead of being in this research study?
You may choose not to be in this research study. Electronic cigarettes are available outside of this study.

6. How long will I take part in this research study?
If you agree to take part, it will take you about 6 months to complete this research study. During this time, you will be asked to complete 5 in-person and 2 remote study visits that will last approximately 1 ½ hours. You will also be asked to complete 1 phone call interview that will last about 15 minutes.

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 Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: your name, address, phone number, date of birth, email address, and a code number. Your paper research records will be labeled with your code number and your initials and will be kept in a safe area in locked file cabinets in Dr. Foulds' research offices. The electronic research data collected for this study will be entered directly into our research database called REDCap. REDCap is a secure, web-based application designed to help with data capture for research studies.

Your research samples will be labeled with your code number and will be stored in freezers inside locked research labs at PSU.

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.

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

7b. What will happen to my research information and/or samples after the study is completed?
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. The research data will be kept in REDCap and research samples will be kept in freezers inside locked research labs at PSU. Before we use or share your information or samples we will remove any information that shows your identity.

Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies. They share this information with each other by putting it into scientific databases. Your coded research information may be put in one or more databases and used for future research. Your information stored in these databases will not include any identifying information such as your name, address, telephone number, or social security number. Your research data will only be available to researchers who have received approval from data access committees and/or Institutional Review Boards. Some of these databases are maintained by PSH/PSU, some are maintained by the federal government, and some are maintained by private companies and other institutions.

This study is not designed to diagnose any disease or condition. However, if during the course of conducting clinical procedures (e.g., blood pressure, lung function), you are found to have a result outside of clinical norms, the result will be discussed with you at the visit where the result is identified. For women only: if you test positive for pregnancy, the results will be shared with you, you will be withdrawn from the study, and you will be advised to follow up with your doctor for prenatal medical care.

Most tests done on samples (urine) in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

7c. How will my identifiable health information be used?
In general, under federal law (including the Health Insurance Portability and Accountability Act – HIPAA or privacy laws) your health information is private. By signing this form, you are authorizing us to collect, use, and disclose your identifiable health information, sometimes referred to as "Protected Health Information" or "PHI" under HIPAA, for the purposes of this research study. We will use and disclose your information only as described in this form, in the PSH Privacy Notice, and as may be required or allowed under the applicable privacy laws.

The research team may use the following health information:

- Past, present, and future medical records, including identifiable information
- 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:

- PSH/PSU research staff involved in this study
- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Subjects Protection Office
- The PSH/PSU Research Quality Assurance Office

- Non-research staff within PSH/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. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- 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)
- The PSH/PSU pharmacy

These groups may also review and/or copy your original PSH/PSU 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.

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

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

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.

You should know that it is our ethical responsibility to report current situations of abuse or neglect of a child, dependent adult or elder to the appropriate authorities. Suspected abuse includes, but is not limited to, physical, sexual, emotional, and financial abuse or neglect. If we have a reason to believe someone is being abused or neglected, we will report it to the Pennsylvania Department of Human Services through the ChildLine (1-800-932-0313). We will also report current, suspected abuse to the Penn State College of Medicine administration.

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?

There is no cost to you for taking part in this study. The study cigarettes, e-cigarette, and e-cigarette cartridges are provided at no cost.

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 any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

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

- There are no plans for PSH/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 $60 for Visits 2-8, for a total of $420. You will receive an additional $20 at each in-person visit to cover travel expenses to the study site. If you complete the entire study you will receive a compliance payment of $30 included in your last visit payment. The total payment for participating in the study is $550. If you do not complete the study for any reason, you will only be paid for the visits you have completed. This reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.

When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, and Social Security Number.

You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your Mobile Phone Number and/or E-mail Address.

Payment received as compensation for participation in research is considered taxable income. If payments from Greenphire exceed $600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of Penn State.

It is possible that your research information and/or specimens (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

10. Who is paying for this research study?
The institution and investigators are receiving a grant from the Food and Drug Administration and National Institutes of Health 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.

Your research doctor may take you out of the research study without your permission.

- Some possible reasons for this are: continuing the research would be harmful, you become pregnant, you did not follow the instructions of the study, you experience serious side effects, or you missed your study visits
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

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.

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 head of the research study (principal investigator), Jonathan Foulds at (717) 531-3504 or the General Internal Medicine doctor on 24-hour call at (717) 531-8521 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 PSH 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, complaints 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, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions 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

Version Date: 11-29-23

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

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name