Version Date: 12-10-23

CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: Effect of oral black raspberry administration on oral cell DNA adducts in smokers

Principal Investigator: Dr. Karam El-Bayoumy, PhD

Address: Penn State Hershey Medical Center
500 University Dr., MC CH69
Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-1005.

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 the potential effects that black raspberry lozenges may have on reducing the damage caused from cigarette smoke in mouth cells in adult smokers, which may be useful in reducing health risks associated with smoking.

How long will the research study last?
It will take you about 13 weeks to complete this research study.

What will I need to do?
Following one week of being in the study you will be given black raspberry lozenges to take 5 times daily for 8 weeks. Afterwards you will participate in the study for an additional 4 weeks for a 'wash-out' period where no lozenges are given. During study visits you will be asked to complete questionnaires, provide a urine sample, and a mouth cell sample by swabbing your cheek. You will smoke as you normally do

throughout the study. You will record cigarette and lozenge use every day. You will complete 2 phone call interviews about your 24-hour food intake during the beginning and the end of the study.

What are the main risks of taking part in the study?
Some participants with stomach sensitivities to berries may experience stomach discomfort (examples: nausea, vomiting) when consuming the lozenges, although these complaints have been uncommon. There is a chance that you may experience irritation on the inside of the moth when brushing your cheeks for mouth cells.

What are the possible benefits to me that may reasonably be expected from being in the research?
There are no benefits to you from taking part in this research. Results of the study may benefit other people in the future by helping us learn more about disease prevention using black raspberry lozenges.

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.

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 the potential effects that black raspberry lozenges may have on reducing the damage caused from cigarette smoke in mouth cells in adult smokers. This research uses investigational black raspberry lozenges and will help us determine if black raspberries may be useful in reducing health risks associated with smoking.

Approximately 75 people will take part in this research study at Penn State Health.

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

1. Urinary pregnancy test to confirm that you are not pregnant (female participants only). If the test is positive, you will be alerted to the results and will not be allowed to continue in the study.
2. Oral cancer screening done by a trained study team member who will look into your mouth for any unusual spots or infections (if a team member is not available during the first visit the oral cancer screening may be done at Visit 2)
3. Exhaled carbon monoxide sample where you will blow through a plastic tube for up to 5 seconds. This sample measures the amount of carbon monoxide in your body from smoking cigarettes

After the screening, if you are eligible to continue in the research, your participation will continue today and consists of 3 Phases over 13 weeks that includes 8 study visits:

	PHASE 1	**PHASE 2**	**PHASE 3**
Duration	*1 week*	*8 weeks*	*4 weeks*
Number of visits	2	4	2

Version Date: 12-10-23

PHASE 1

Visit 1: Week 0

Allow a researcher to take the following additional measurements at this appointment:

- **Heart rate and blood pressure**
- **Height and weight**
- A **Mouth cell sample** will be obtained to test for smoking related damage: You will first rinse your mouth with distilled water. Mouth cells will be collected by gently brushing the inside of your cheeks (both sides) with a soft bristle toothbrush. You will rinse your mouth once again with salt water and spit the rinse into a collection vial.

You will not receive the results of the research tests at any visit.

A research coordinator will conduct a short interview with you regarding questions on demographics, medical history, menstrual cycle history (women only), current alcohol use, current cigarette use and dependence, and current medications you are taking. You are free to skip any questions you do not wish to answer. This interview will take approximately 35 minutes.

Study materials will be provided to you to complete during the week:

You will be asked to tally all smoked cigarettes **every day** on a daily study log provided to you, beginning today, until you return to the clinic for your next visit. You will also be asked to tally any alcoholic drinks you consumed. Only smoke your usual brand cigarettes. If you do use other nicotine or tobacco products please report it to study staff

Visit 2: Week 1

At this visit you will:

- Bring in completed daily study log.
- Receive new daily study logs to keep track of the cigarettes you smoke and any alcoholic drinks each day. You must bring these back to your next study visit.
- Only smoke your usual brand cigarettes. If you do use other nicotine or tobacco products please report it to study staff.
- Provide a mouth cell sample by brushing the inside of your cheeks with a soft toothbrush and rinsing with salt water. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Provide a urine sample to look at nicotine and other chemicals from cigarettes.
- Provide an exhaled carbon monoxide sample by blowing through a plastic tube. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Provide your weight, blood pressure, and pulse.
- Complete several questions on health and possible changes since your last visit.

At this visit, you will be starting the second phase of the research study. In this phase you will be given a four week supply of black raspberry lozenges and instructed to consume 1 lozenge, 5 times/day by placing the lozenge in your mouth and slowly sucking on it until it is fully dissolved (~10-12 min). Please do not eat or drink 15 minutes following lozenge use. You will be asked to tally all lozenges each day on the daily study log provided to you, beginning today, until you return to the clinic for your next visit.

2 Phone Call Interviews
During Phase 1, you will receive two unannounced phone calls by a trained nutritionist who will interview you regarding the food you have eaten over the past 24 hours. Each call will typically last 15 minutes or less.

PHASE 2

Visit 3, 4 and 5: Week 4, 5 and 8
At these visits you will:

- Return completed daily study log
- Receive new daily study log to keep track of the cigarettes you smoke, any alcoholic drinks, and your lozenge use each day. You must bring these back at your next study visit.
- Only smoke your usual brand cigarettes. If you do use other nicotine or tobacco products please report it to study staff.
- Return all un-used black raspberry lozenges.
- Provide your weight, blood pressure, and pulse.
- Provide a mouth cell sample by brushing the inside of your cheeks with a soft toothbrush and rinsing with salt water. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Provide a urine sample (Visit 4 only) to look at nicotine and other chemicals from cigarettes. For female participants, a urine pregnancy test will also be completed.
- Provide an exhaled carbon monoxide sample by blowing through a plastic tube. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Complete several questions on health and possible changes since your last visit.

2 Phone Call Interviews
During the last week of Phase 2, you will receive two unannounced phone calls by a trained nutritionist who will interview you regarding the food you have eaten over the past 24 hours. Each call will typically last 15 minutes or less.

Phone Call Reminders
You will be contacted midway between visit 2 and visit 3 and between visit 4 and visit 5 to remind you to complete your daily study log, and to confirm the schedule for your next visit to the clinic. The call will typically last 5 minutes or less.

Visit 6: Week 9
At this visit you will:

- Return completed daily study log.
- Receive new daily study log to keep track of the cigarettes you smoke and any alcoholic drinks each day. You must bring this back at your next study visit.
- Only smoke your usual brand cigarettes. If you do use other nicotine or tobacco products please report it to study staff.
- Return all un-used black raspberry lozenges.

- Provide a mouth cell sample by brushing the inside of your cheeks with a soft toothbrush and rinsing with salt water. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Provide a urine sample to look at nicotine and other chemicals from cigarettes. For female participants, a urine pregnancy test will also be completed.
- Provide an exhaled carbon monoxide sample by blowing through a plastic tube. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Provide your weight, blood pressure, and pulse.
- Complete several questions on health and possible changes since your last visit.

At this visit you will be starting the final phase of the study. You will discontinue use of the black raspberry lozenges and will no longer complete the lozenge use portion of the log. All other aspects of the study will remain the same.

Phone Call Reminders
You will be contacted midway between visit 6 and visit 7 to remind you to complete your daily study log, and to confirm the schedule for your next visit to the clinic. The call will typically last 5 minutes or less.

Visit 7 and 8: Week 12 and 13
At these visits you will:

- Return completed daily study log .
- Receive new daily study log to keep track of the cigarettes you smoke and any alcoholic drinks each day. You must bring this back at your next study visit (Visit 7 only).
- Only smoke your usual brand cigarettes. If you do use other nicotine or tobacco products please report it to study staff.
- Provide a mouth cell sample by brushing the inside of your cheeks with a soft toothbrush and rinsing with salt water. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Provide your weight, blood pressure, and pulse.
- Provide a urine sample (Visit 8 only) to look at nicotine and other chemicals from cigarettes. For female participants, a urine pregnancy test will also be completed.
- Provide an exhaled carbon monoxide sample by blowing through a plastic tube. Instructions will be provided to you to collect this sample at home if masking mandates are currently in place that restrict sample collection during your visit.
- Complete several questions on health and possible changes since your last visit.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities include:

- Use black raspberry lozenges daily as directed
    - For your safety, you must tell the study doctor or nurse about all the prescription drugs, herbal products, over-the-counter drugs (OTC), vitamins and other supplements you are taking. Check with the study doctor before starting any new medicines (including prescription, OTC drugs, vitamins and herbal supplements) or changing doses of medications that you are already taking.
- Return all un-used lozenges
- Attend study visits at Penn State Health Dental Clinic and Clinical Research Center

- Provide urine, exhaled carbon monoxide, and mouth cell samples at study visits
- Fill out surveys, including the daily study logs
- Complete short diet interviews over the phone on off clinic weeks (4 total)

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

The black raspberry lozenges are non-toxic and available over-the-counter as a dietary supplement (BerriProducts LLC, Corvallis, OR). Each lozenge contains 1 g of freeze-dried black raspberries (equivalent to ~5 black raspberries) in the form of dissolvable slow-release black raspberry lozenges. The daily dose of 5 lozenges contains 5 grams of freeze-dried black raspberries (equivalent to ~25 black raspberries). Some participants with stomach sensitivities to berries may experience stomach discomfort (examples: nausea, vomiting) when consuming the lozenges containing black raspberries, although these complaints have been uncommon. If you think the lozenges are causing any stomach issues please discontinue lozenge use and notify the study team.

Additional potential risks include:

- **Smoking cigarettes:** Smoking is dangerous to your health. If at any time during the study you decide to quit smoking, your decision will be encouraged.

- **Risk to fetus:** Smoking is known to be harmful to the developing human fetus. Women who are pregnant or are nursing a child may not participate in this research study. If you are a female capable of becoming pregnant, a pregnancy test will be required before you begin the research. You must agree to take reasonable and necessary precautions (hormonal or barrier method of birth control; abstinence) against becoming pregnant during the period of the investigation. The investigator will discuss appropriate precautions with you. If at any point during the research you believe there is any possibility that you may be pregnant, you must notify the research team immediately.

- **Risk with mouth cell collection:** The soft bristle toothbrush used for this collection is sterile and non-invasive (it shouldn't break the skin). However, the gentle rubbing of the brush may cause minor irritation on your inner cheeks if you have a pre-existing area that is already irritated. This area can be avoided during the collection procedure, just let the research staff know.

- **Questionnaires:** It is possible that some of the questions in the questionnaires may make you uncomfortable. You will be instructed that you are free to skip any questions that make you uncomfortable.

- **Loss of confidentiality:** There is a risk of loss of confidentiality if your information is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening, including coding of data in the secure database. 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?

You will not benefit from this research study.

4b. What are the possible benefits to others?

Findings from this study may benefit others by helping researchers develop effective prevention and intervention strategies to reduce the health impact of cigarettes in the general population.

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

6. How long will I take part in this research study?
If you decide to participate in this study, your participation will last 13 weeks. During this time, you will be asked to complete 8 on-site study visits that will last approximately 30-45 minutes each.

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, email address, date of birth, and a code number.

A list that matches your name with your code number will be stored electronically in REDCap and will not be destroyed. The PI, study coordinator, lab manager, and other required research personnel will have access to the data and specimens.

All study data will be collected and managed using REDCap (Research Electronic Data Capture). Data in REDCap are stored and encrypted on a secure server at Hershey Medical Center and will not be destroyed. Access to the database requires authentication (a unique username and password) and a user matrix will be used to ensure that only appropriate data are accessed based on the individual's role on the project. Every interaction with the data is logged in REDCap creating an audit trail. Your paper research records will be labeled with your code number and will be kept in a safe area in the research offices of the study team. Your research samples will be labeled with your code number and will be stored in a locked research lab.

Your research records may be sent to Dr. Susan Mallery from Ohio State University for review of health related events that may occur during the study. Your research records will be sent through the Penn State Secure File Transfer to protect your confidentiality. Your records will be identified by name, initials, code number, dates (including date of birth).

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 the National Cancer Institute 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 Subjects Protection Office at (717) 531-5687.

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. 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. oral cancer screening), you are found to have an abnormal finding, 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 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)
- Other researchers and medical centers outside of PSU and Penn State Health that are part of this study and their IRBs
- A group that oversees the data (study information) and safety of this research

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.

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.

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.

PSH/PSU compensation for injury

- 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 $35 for each study visit for your participation in this research study for a total of $280. If you complete all of the study visits you will receive an additional $100, for a total compensation of $380. 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 $5 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 National Institute 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, or you experience serious side effects.
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

If you stop participating in the study, already collected data may not be removed from the study database.

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), Karam El-Bayoumy at (717) 531-1005 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.

Version Date: 12-10-23

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

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