CONSENT FOR RESEARCH

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

Title of Project: Measuring Neuroadaptations in Response to Very Low Nicotine Content Cigarettes

Principal Investigator: Andrea L. Hobkirk, PhD

Address: 500 University Drive, Box CH69, Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-0003 x286415.

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 indicated that you are a regular smoker, who is not planning to quit in the next 3 months. The research is being done to evaluate how brain function changes when smokers switch to cigarettes that contain a very low level of nicotine. Specifically, we will be looking at how your brain responds to smoking-related odors, images and monetary rewards.

Approximately 90 people will take part in this study at the Hershey Medical Center.

You will be randomly assigned to one of the 2 groups. This means whichever group you are assigned to will be determined purely by chance. One group will receive study cigarettes with a nicotine content that is similar to the nicotine content in their usual cigarettes and the second group will receive study cigarettes that contain very low levels of nicotine content. Two out of every three participants will be assigned to very low nicotine content cigarettes. One out of every three participants will be assigned to cigarettes containing a usual nicotine content. Neither you nor the research team will know to which group you have been assigned, but the research team will be able to get this information quickly if it is needed to ensure your safety. The Food and Drug Administration (FDA) reviewed the proposed investigational use of the cigarettes as described in the study protocol. The cigarettes used in this study are not available outside of the study.

If you choose to participate in this study, you will complete a magnetic resonance imaging (MRI) scan. MRI uses strong magnetic fields and radio waves to make pictures of the body. Radiofrequency exposure is monitored throughout the study and maintained below the limits determined to be safe by the FDA. You will be screened before the MRI scan to make sure that you do not have metal in or on your body, which can be dangerous if brought near the large magnet contained in the MRI scanner.

2. What will happen in this research study?

The study will include switching to a research cigarette for 6 weeks, completing 3 remote visits, 2 phone calls, and 2 MRI visits at the Hershey Medical Center. The study involves magnetic resonance imaging (MRI) of the brain. Details about the procedures at each visit can be found below:

We will ask you to abstain from smoking for 14 hours before coming to each MRI Scan visit.

You will be randomized to one of two groups prior at your first MRI visit. One group will receive cigarettes that contain a nicotine content similar to their usual brand cigarette, and the other group will receive cigarettes that contain a very low nicotine content. You will be asked to use these cigarettes for six weeks, but you will not be told which type of cigarettes you are being given.

We will create a schedule of study visits and you should make every effort to keep these appointments. If you are not able to keep an appointment, you should call the study center to reschedule as quickly as possible. You should know that if you miss a visit (including rescheduled visits), you could be withdrawn from the study. You may also be withdrawn from the study for using other tobacco products.

MRI visit 1:

1. We will first review this consent form and you will have time to ask questions. If you choose to sign the consent form, we will continue with the study procedures.
2. We will test your exhaled carbon monoxide (CO) to monitor your levels during the course of the study.
3. We will collect urine for cotinine analysis and pregnancy testing if you are a women of childbearing age.
4. We will collect two saliva samples using swabs. The first swab will be used as a back-up method to analyze cotinine in case we cannot get an accurate measure from your urine and the second swab will be used for future research including micro RNA (miRNA) biomarker investigations.
5. You will complete three computer tasks. For the first task, you will choose between two pictures that each include a certain amount of money and a specified time when you would receive the money (e.g., in 2 weeks). In the second task, you will observe images on the screen that correspond to odors that you will smell at the same time. No other action is needed during this task. In the final task, you will press a button as quickly as possible or stop yourself from pressing the button when you images with different colored borders.
6. You will complete surveys asking about your nicotine withdrawal symptoms, smoking urges and cravings. You will also complete a rating of the scents you are presented while in the MRI.
7. We will assess your safety to undergo MRI and then complete an MRI.

To date, over 150 million MRI studies have been performed around the world. MRI has been shown to be extremely safe as long as proper safety precautions are taken. MRI uses strong magnetic fields and radio waves to make pictures of the body. This study will use a 3.0 Tesla MRI scanner. There is no exposure to x-rays or radioactivity during an MRI scan. All scans that we will perform pose no more than minimal risk because the instantaneous and cumulative energy levels are within the FDA established safety limits.

You will be asked to leave metal objects and personal belongings in lockers provided in the prep room of the MRI center. You will also be asked to remove any articles of clothing with metal inserts or clasps before entering the MRI room. Please ask the experimenter if you are unsure about any items.

You will be asked to lie on a bed that slides into the long tube of the scanner. You will be given earphones and/or earplugs for hearing protection since the MRI scanner makes loud noises during normal operation. You will be asked to remain very still at these times. For scans of the head, we may put cushions around your head and we may lightly tape your head to keep it from moving. You will have a plastic tube placed near your nose for the smell test. You will be able to talk to the MRI technologist by an intercom, and he/she will be able to see you and hear you at all times. You will also be given a squeeze-ball signaling device. If at any time you would like to discontinue the study, you can tell the investigators over the intercom or press the squeeze-ball signaling device and you will be removed immediately from the scanner. You can discontinue the study at any time without penalty.

During the one-hour MRI scan, you will first complete an anatomical scan to obtain a high-resolution image of your brain structures. This scan will last for about 10 minutes and you will be asked to lie still with your eyes open. Next you will complete a functional scan that allows us to measure activity in your brain while you complete three tasks. During this scan, images will be displayed on the monitor that is visible from inside the scanner. We will provide you with MRI safe glasses to partially correct your vision if necessary. If you have normal vision or wear contacts, you will not need to wear the glasses. We will also ask you to wear a sensor on your abdomen to monitor your breathing rate during the scans. You will use a button box inside the scanner to indicate your choices on the tasks. Each task will last approximately 15 minutes. The tasks include:
1. Monetary choice task. You will choose between two pictures that each include a certain amount of money and a specified time when you would receive the money (e.g., in 2 weeks). At the end of the study, one of your choices will be chosen at random and honored.
2. Smell task. You will be presented with three different smells that will alternate. You won't know when the smell is coming. You will be asked to pay attention to the smells during this task. You will rate how much you are craving cigarettes using the button box and monitor before and after the task.
3. Go/NoGo task. During this task you will be presented with pictures surrounded by blue or yellow borders. One of the colors will signal you to push a button as quickly as possible on the button box, while the other color signals that you should do nothing.

None of the scans done during this study are designed to detect or evaluate any medical condition you may have. They are intended solely for research purposes.

You will be given research cigarettes to smoke for the next six weeks and you will be asked to return in 6 weeks for your next MRI visit. The amount of cigarettes given to you will be more than the number of cigarettes you usually smoke over a six week period. You will be asked to continue using the paper cigarette log to track the number of cigarettes you smoke each day and to complete the online surveys in the evening. You will be asked to bring all opened, unopened and empty cigarette packs to the study center at each visit. If you are accurate with returning close to all the packs that you received and you complete the cigarette log between study visits, you will be eligible for an additional compliance payment at the end of the study.

It is important that you do not smoke any non-research cigarettes or use other tobacco products or illegal drugs. If you do, however, you should report this to the study staff. Accurate reporting of your cigarettes, other tobacco products or other substances will help with the accurate interpretation of the study results. If you use other tobacco products too often, you may not be able to continue with the study.
Frequent use of other tobacco products could result in you being withdrawn from the study.

Remote visit 1:

1. You will complete questionnaires on the computer asking about your current mood and stress, smoking habits and preferences, social support, and health symptoms and behaviors.
2. You will complete two computer tasks. For the first task you will choose between two pictures that each include a certain amount of money and a specified time when you would receive the money (e.g., in 2 weeks). In the second task, you will choose what color the words on a computer screen are printed in.
3. We will assess your current medications and adverse events.
4. You will complete some questionnaires about your smoking, health, substance use, and medical history.

Phone call 1:
In the week following your first MRI scan we will call you to confirm that you are still able to make it to your next appointment. We will also ask you about any challenges with smoking only research study cigarettes or problems completing your log. We will do the best we can to help problem-solve if you are finding study participation difficult.

Remote visit 2:
1. You will complete questionnaires on the computer asking about your current mood and stress, smoking habits and preferences, social support, and health symptoms and behaviors.
2. You will complete two computer tasks. For the first task you will choose between two pictures that each include a certain amount of money and a specified time when you would receive the money (e.g., in 2 weeks). In the second task, you will choose what color the words on a computer screen are printed in.
3. We will assess your current medications and adverse events.

Phone call 2:
After the first MRI and remote visits, we will call you to confirm that you are still able to make it to your next appointment. We will also ask you about any challenges with smoking only research study cigarettes or problems completing your log. We will do the best we can to help problem-solve if you are finding study participation difficult.

Remote visit 3:
You will repeat the same procedures that you did at remote visits 1 & 2, including questionnaires, computer tasks and an assessment of current medications and adverse events. In addition, you will complete a perceived health risk rating questionnaire.

MRI visit 2:
You will repeat the same procedures that you did at MRI visit 1 including exhaled CO, saliva, and urine collection, questionnaires, computer tasks, MRI safety check, and MRI scan.

At the end of the visit, you will return all opened, unopened, and empty packs of cigarettes to the researcher. You will complete answer questions about your interest in quitting smoking and will be given a smoking cessation manual that will provide you with optional self-guided exercises for you to do on your own.

12-Week Text Message Survey:
Twelve weeks after your last visit you will receive a final text message asking about your current smoking status and any quit attempts you made have made since we saw you last. If we do not hear from you, another text message will be sent. If you elected to take the survey by phone we will call you.

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

- Abstaining from smoking for 14 hours prior to the MRI visits.
- Accurately reporting how many research cigarettes and how many non-research cigarettes you smoke each day.
- Returning all research cigarette packs either open, unopened or empty.
- Smoking only the research cigarettes that we give you.
- Not using any other tobacco products (including cigars, pipes chew, snus, dip, snuff, electronic cigarettes, hookah or dissolvables).
- Providing saliva, urine and exhaled CO samples at each MRI visit.

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

The cigarettes that we give you have been previously tested and found to be of no greater risk than cigarettes you are already using. Any changes in your health will be documented by study staff. The study PI may withdraw you at any point during the study for safety reasons.

Risk of injury is very low during an MRI scan. However, MRI is not safe for everyone. It may not be safe for you to have an MRI scan if you have any metal containing iron in or on your body. This is because metal containing iron can pose a safety risk when in the presence of strong magnetic fields. Radiowaves may also heat the body and metallic objects within or on the body, possibly resulting in burns. Before you are allowed in the scanner room, you will be asked a set of questions to determine if it is safe for you to have an MRI scan at this time. For example, it may not be safe to have an MRI scan if you have a cardiac pacemaker, aneurysm clips, an intrauterine device (IUD), etc. For your safety, it is very important that you answer all questions truthfully.

It is possible that you may feel uncomfortable or confined once inside the scanner. This feeling usually passes within a few minutes as the experimenters talk with you and the study begins. You might experience dizziness, mild nausea, or tiny flashing lights in your field of vision. These sensations are mostly due to movement while inside the magnet and can be minimized by holding still. All of these sensations should stop shortly after you leave the magnet.

There are no known risks of MRI apart from those described above. However, there is always the possibility that there are unknown risks associated with this procedure. Because MRI has not been proven to be safe during pregnancy, it is important that a baby developing in the uterus not be exposed to any unnecessary risks. Therefore, in order to participate in this study, you must not be pregnant at the time of your scan.

The scans done during this study are NOT designed to detect or evaluate any medical condition you may have. They are intended solely for research purposes. The investigators for this project are not trained to perform medical diagnosis, and the scans to be performed in the study are not optimized to find abnormalities. On occasion, a member of the research team may notice a finding on a scan that seems abnormal. When a finding is noticed, one of the investigators may consult a physician specialist, such as a radiologist or neurologist, as to whether the finding merits further investigation. If the specialist recommends further follow-up, the investigator or another member of the research team will contact you within **48 hours** of the recommendation and suggest that you contact your private medical provider for follow-up. To facilitate follow-up care, you may be given a copy of your images upon written request. Being told about a finding may cause anxiety as well as suggest the need for additional tests and financial costs. Medical insurance may be affected whether or not

the finding is ultimately proved to be of clinical significance. Costs for clinical follow-up are not covered in the cost of research. The decision as to whether to proceed with further examination or treatment lies with you.

Although the risks of the study are minimal, other possible risks include:

- **Cigarette smoking is dangerous to your health:** If at any time during the study, you decide to quit smoking, your decision will be encouraged.
- **Increased compensatory smoking:** If you start smoking a lot more cigarettes than you usually do, you may receive higher levels of chemicals from cigarettes. Your cigarette consumption and exhaled carbon monoxide will be monitored throughout the trial.
- **Nicotine withdrawal symptoms:** Decreased nicotine cigarettes and abstaining from smoking may result in nicotine withdrawal symptoms (e.g. irritability, anxiety, restlessness, depressed mood, increased appetite, fatigue, insomnia/sleep problems, impatience, headache, difficulty concentrating, frustration, anger, craving for sweets, constipation, coughing, dizziness, nausea and sore throat).
- **Pregnancy/Birth Control:** If you are pregnant or breastfeeding a baby, you cannot participate in this study. Smoking is known to be harmful to the developing human fetus, either from cigarettes or at the recommended therapeutic dose of the nicotine replacement gum or lozenge. For this reason, we ask that women of child-bearing potential agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and during the study. Should you become pregnant or suspect you are pregnant while you are participating in this study, you should inform the study staff immediately and you will be withdrawn from the study. In addition, we will be performing urine pregnancy tests regularly throughout the study.
- **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 to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.
- **Randomization in clinical trials:** You will be assigned to a cigarette group by chance. You have higher chance of being assigned to the very low nicotine cigarette group (2/3) than the usual nicotine cigarette group (1/3).
- **Questionnaires:** It is possible that some of the questions in the questionnaires may make you feel uncomfortable. You are free to skip any individual questions that make you uncomfortable.

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 the possibility of reduced nicotine dependence. You will receive information on smoking cessation at the end of the trial and may choose to quit smoking.

4b. What are the possible benefits to others?

The main benefit to society and others from the study is the possibility of a greater scientific understanding of the effect of very low nicotine content cigarettes on brain function.

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

You may choose not to be in this research study. Because it is investigational, the procedures offered in this research is only available to you if you take part in the research study. If you feel that you are ready

to quit smoking soon then you should not participate in this study. You can obtain advice on quitting by calling 1-800-QUIT NOW.

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

If you agree to take part, it will take you about 6 weeks to complete the MRI visits and 18 weeks to complete all parts of the study. During this time, you will be asked to return to the research site for 2 study visits including today's MRI visit.

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. In our research files at The Milton S. Hershey Medical Center (HMC) 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.

- A list that matches your name with your code number will be kept in a password protected electronic file on a secure server through Penn State accessible only by study team members.
- Your research records will be labeled with a code number, initials and visit number and will be kept in a safe area in Dr. Hobkirk's laboratory.
- Your saliva and urine samples will be labeled with a code number, initials and visit number and will be stored in a locked research lab in HMC before being sent to an HMC lab for analysis.

To help protect your privacy, a Certificate of Confidentiality has been obtained from the federal government. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used to for checking or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate, however, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not prevent the principal investigator from taking steps, including reporting to appropriate authorities, to prevent serious harm to yourself or others, such as child abuse or threats of violence.

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.

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?

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:

- HMC/PSU research staff involved in this study
- 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. or foreign government bodies that oversee or review research)
- The HMC/PSU pharmacy
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Twilio.com, San Francisco, CA (the company that will temporarily receive your phone number in order to send you the scheduled study text messages)
- A group that oversees the data (study information) and safety of this research

- 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 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 research cigarettes will be provided by the National Institute on Drug Abuse 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: MRI scanning, pregnancy testing, urine cotinine analysis.

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.

HMC/PSU compensation for injury

- 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 $30 for the screening visit (which you have already completed) and $85 for each MRI visit that you complete. If you accurately return your study cigarette packs, complete all of the cigarette logs, and complete all study visits, you will receive an additional $75. You will also receive a $15 payment for each scheduled phone call along with $65 for the remote visit 2.

The total compensation you can receive including transportation is up to $370. If you do not complete the study for any reason, you will be paid for the visits you have completed.

Payments will be made adding the amount to your Greenphire Clincard when it has been earned.

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, date of birth 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.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Institute on Drug Abuse and a grant from Brain & Behavior Research Foundation 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.

The principal investigator 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 for the study, you experience serious side effects from smoking a lot more cigarettes than you usually do, or you develop or acquire MRI safety contraindications like a metal implant in the body.
- Also, the sponsor of the research may end the research study early.
- If your participation ends early, you may be asked to visit the research team 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.

If you will be in another clinical research study at Hershey Medical Center or elsewhere while in this research, you should discuss the procedures and/or treatments with your physician. This precaution is to protect you from possible side effects from interactions of research drugs, treatments or testing.

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), Andrea Hobkirk at 717-531-0003 x286415 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