Version Date: 12/21/2020

CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: A SINGLE-CENTER, DOUBLE-ARM, PROSPECTIVE CLINICAL TRIAL TO COMPARE VISUAL PERFORMANCE OF NON-DIFFRACTIVE EXTENDED DEPTH OF FOCUS AND NEUTRAL ASPHERIC MONOFOCAL INTRAOCULAR LENSES

Principal Investigator: Seth Pantanelli, MD

Address: Penn State Hershey Medical Center, 500 University Drive, Department of Ophthalmology Research Suite 501, Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-1513. After hours call (717) 531-8521 and ask for the ophthalmology 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 considering surgery to remove your cataracts.

What is the purpose of this research study?

The purpose of this voluntary research study is to compare the vision of subjects that receive one of two intraocular lenses (IOLs), the Alcon Vivity or Bausch & Lomb enVista. These intraocular implants are inserted once the cataracts are removed.

How long will the research study last?

The research study will last 4 months.

What will I need to do?

If you choose to be a part of the research study, you will be randomized to receive either the Alcon Vivity or the Bausch & Lomb enVista intraocular lens. You will have follow up visits at specified time points, in the same way that patients are seen in the routine provision of care (i.e. the follow up time points are exactly the same for those that participate in the study as those that do not). At some of these visits, you will have your vision tested in ways that are important for the research study. These additional vision tests are not part of your normal visits and are done for the purpose of research.

What are the main risks of taking part in the study?

The risks to your participation in this study are the same risks associated with cataract surgery. These risks include infection, temporary or permanent vision loss, need for additional surgery, need for glasses or contact lenses to achieve your best possible vision, and need for reading glasses.

Intraocular lenses that seek to provide intermediate or near vision without glasses may be associated with additional risks that include blurry vision not correctable with glasses or contact lenses and subjective visual disturbances including starbursts, haloes, glare, hazy or blurry vision. In an FDA trial that compared similar lenses to the ones being evaluated in this study, these visual disturbances were severe or very bothersome in 3-4% of patients.

What are the possible benefits to me that may reasonably be expected from being in the research?

There is no direct benefit from participating in this research study.

Results of the study may benefit other people in the future by helping us learn more about the differences and benefits of the both lens used in the study.

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.

Instead of being in this research study, your choices may include having a cataract surgery with the lens chosen by the Ophthalmologist as felt to be most appropriate for your eyes.

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 investigate how patients see at far, intermediate, and near distances after cataract surgery with one of two intraocular lenses: Alcon Vivity or Bausch & Lomb enVista. Note that neither of these lenses are considered investigational devices; both lenses are FDA approved in the United States for implantation during cataract surgery.

Because you are considering surgery to remove your cataract, you are being asked to participate in the study of a FDA approved intraocular lens (IOL) called the Alcon Vivity or Bausch & Lomb enVista. The purpose of the study is to compare how the two different devices work. The Alcon Vivity and Bausch & Lomb enVista IOLs are permanent artificial lenses that replaces the cloudy natural lens that is removed during cataract surgery to restore vision. Both the Alcon Vivity and Bausch & Lomb enVista are made of a biocompatible acrylic material that can be folded for insertion through the same small incision used to remove the cataract.

Approximately 70 people will take part in this research study at Penn State Health.

2. What will happen in this research study?

Before you begin participation, the study must be explained to you and all of your questions must be answered to your satisfaction. Ask the study doctor or the study staff to explain any words or procedures you do not clearly understand and to answer any questions you may have about this study. You must take your time to read this informed consent carefully before signing. No activities for this study can be done until you sign this form. Afterwards, a copy of the signed informed consent form will be given to you. The activities that will occur at each scheduled visit in the study are summarized below.

Visit 1/Day 1 -Preoperative Visit - Regular scheduled visit and to determine your eligibility for the study

- You will be asked to provide information about yourself, including your date of birth, gender, race, ethnic origin, and personal data (information)
- You will be asked about your current overall health and the condition of both of your eyes. You will also be asked about any previous conditions or treatments you have had. You must be honest in providing information about your eyes and your overall health. Giving false or incomplete information could have serious health consequences.
- A list of the medications you are taking now and have taken in the past will be recorded.
- If you are female and able to become pregnant, you will need to take a urine pregnancy test. The pregnancy test must be negative for you to continue in this research.
- The vision in each of your eyes will be checked to determine how well you see.
- Numbing drops will be put in your eyes and your eye pressure will be measured by touching an instrument to your cornea, which is the clear front window of your eye. Because your eyes are numb, you should feel no pain during this procedure.
- The front part of both of your eyes will be examined using a bright light and a special microscope called a slit lamp.
- Dilating drops will be put in each of your eyes to enlarge your pupil (the black circle in the center of the colored part [the iris] of the eye). The study doctor will use a magnifying lens and a bright light to examine your retina, which is the back of your eye. The effect of these drops will last approximately 4 -5 hours and, during that time, you should not drive a car or operate machinery.
- The following additional exams will be performed:
  - The dimensions of your eye will be measured using a specialized instrument, to help the doctor determine the necessary IOL power to provide you with good vision.
  - The shape of your cornea (the front surface of your eye) will be measured using a separate device to confirm no irregularities.
  - A detailed picture of your retina (the back of your eye) will be measured using another device to confirm the absence of disease that would impact the outcome of the study.

Based on the information gathered during this exam, the study doctor will determine if you meet the criteria for further study participation. If you are qualified to continue in the study, you will be scheduled for cataract surgery and placement of one of the study devices. Both of your eyes will be selected to receive the same IOL (either Alcon Vivity or B&L enVista).

Visit 2/ #1 (first eye) and Visit 5/#2 (second eye) Cataract Surgery (to remove your cataract and place the study device)

- After study enrollment, but before surgery, you will be randomized to receive one of the two intraocular lenses. You will not be told which of the two devices you are scheduled to receive until 3 months after surgery in the second eye. This process is called blinding and is done to improve the quality of the research study. Dr. Pantanelli will be unblinded which means he will know which IOL you have been assigned.

Your cataract surgery will be performed in an operating room at a clinic or hospital. You should plan that you will be there for 2 – 4 hours. Please make certain someone is available to take you home after surgery.

You will have your cataract removed and if there are no complications, the study device will be placed in your eye in the location where the natural lens was located. After surgery, your study doctor may ask you to continue use of eye drops for about 4 weeks to reduce the chance for swelling and infection. The study doctor or study staff will provide instructions on how to use these drops.
Each eye will be done separately. There will be a period up to 30 days between each operation.

Post-Surgery Visits - Regular scheduled follow ups to evaluate your vision and the health and collect research information for the device
You will be scheduled to return for 4 clinic visits during the 3 months after your cataract surgery for each eye. These visits may each require 1.5-2 hours of your time. The visits must follow the schedule below:

- Visit 3/#1/Visit 6/#2: 1 day after surgery
- Visit 4: Approximately 1 week after surgery
- Visit 7: Approximately 1 month after surgery
- Visit 8: Approximately 3 months after surgery

The following study exams and procedures will be performed at these visits:

- After enrollment, you will be asked to complete two study related questionnaires. The questions will ask you how much difficulty you presently have seeing things at distance, intermediate and near. It will also assess which specific visual disturbances (eg blurry vision, glare) you are experiencing before surgery takes place.

- At each clinic visit, you will be asked how you are feeling and if you have had any changes in your health or medications used since your last visit

- For both eyes, the following additional tests will be performed:
  - The vision exam, to determine how well you see.
    - Your vision will be tested with and without a glasses prescription in place, and will be tested at various distances.

- A slit lamp exam will be performed to evaluate the condition of the front part of your eye. During this exam, the IOL position and clarity will also be evaluated.
- Numbing drops will be put into your eye, and your eye pressure will be measured.
- At the 1 Month Visit, dilating drops will be put in your eye to enlarge your pupil to examine the lens and your retina. The effect of these eye drops will last approximately 4 – 5 hours. Research related tests will be performed by a blinded examiner. Neither you nor the examiner will know which lens was placed in your eyes. The following test are for research; visual acuity (a similar exam you would have during a regular eye appointment), this will be performed 6 different ways.
- At the 3 Month Visit- You will be asked to complete two questionnaires. These are the same questionnaires you were given before surgery, and assess your dependence on glasses for tasks requiring good distance, intermediate, and near vision, as well as the presence of any visual disturbances. The research related tests performed at Month 1 will be repeated at this visit by the blinded examiner. You will have 1 additional research test on your eye also performed by the blinded examiner. At this visit, after all of the research related tests are completed (those tests that are specific to the lens placement that are not done as part of a normal post-surgical visit) you will be provided with a medical card that is standard of care after cataract surgery with detailed information of what IOL was implanted in your eyes.

At each scheduled visit, the study doctor and study staff will evaluate your vision and any health complications or complaints that may be related to the study device.

Unscheduled Visits

If you have any problems with your vision between scheduled follow-up visits, you should contact your study doctor who may request that you return for an unscheduled visit.

You may also be asked to return for 1 or more unscheduled visits if there are changes in the health of your eye during the study, or if you discontinue study participation for any reason. If you are asked to return for an unscheduled visit, some or all of the exams listed above may be performed. Your study doctor will decide which exams are appropriate during the unscheduled visit.

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

Taking part in a research study can be an inconvenience to your daily life. Please carefully consider the time commitments and responsibilities you will be undertaking. Your responsibilities as a study participant include:

- Tell the truth about your medical history, current conditions and any prescription or over-the-counter medications you are taking.
- Tell the study doctor if you have been in a research study during the past 3 months or are in another research study now. You will not be able to enroll in any other clinical study of an investigational drug or device until you have completed participation in this study.
- Go to all your scheduled study visits.
- Follow all instructions given by the study doctor and study staff.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- If you typically wear rigid gas permeable (RGP) contact lenses, you must not put them in the eye planned for surgery for at least 30 days before your pre-operative eye anatomy measurements are performed.

- If you are female and able to become pregnant, you will be asked to use medically acceptable birth control and to prevent pregnancy.

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

All subjects who decide to participate in this study will have cataract surgery. The risks and benefits for this procedure should have already been reviewed with you. There may be harmful effects that can occur from receiving the study device. Some effects may be mild and might not last long.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

These effects may include: a small amount of bleeding in your eye, mild eye infection, slight pain in or around the eye, or mild change in your vision.

You may experience complications that are more difficult to manage and may cause serious problems, such as: serious eye infection, bleeding inside the eye, wound healing problems, chronic pain, retinal detachment (detachment of a membrane at the back of the eye), inflammation of the gel that fills the eyeball, damage to the cornea (clear front window of the eye), damage to the iris (colored part of the eye), damage to lens capsule (transparent bag that surrounds the natural lens), damage to or dislocation of the IOL, malfunction of the IOL, unusually low or unusually high eye pressure, double-vision, loss of vision, drooping eyelids, persistent inflammation of the eye.

Intraocular lenses that seek to provide intermediate or near vision without glasses may be associated with additional risks that include blurry vision not correctable with glasses or contact lenses and subjective visual disturbances including starbursts, haloes, glare, hazy or blurry vision. In an FDA trial that compared similar lenses to the ones being evaluated in this study, these visual disturbances were severe or very bothersome in 3-4% of patients.

Some of these problems may create the need for further surgery or to remove the study device.

There may be rare or unknown side effects that could possibly occur, including life-threatening reactions. You should discuss these risks with your family doctor to see if he or she feels that you are a good candidate for this kind of surgery.

Risks to women who are pregnant or nursing are unknown. The study device might involve risks to the unborn baby, which are currently unforeseeable. If you suspect that you have become pregnant, you must notify the study doctor immediately.

Possible Risks or Discomforts of the Study Exams

In the exam where your eye pressure is measured, there is a risk that your cornea may receive a minor scratch from the instrument that touches the cornea. Minor scratches of this nature usually heal within 24 hours.

In the exam where eye drops are used to make your pupil large, there are risks of temporary glare and blurring of your vision. The eye drops could make your eye pressure higher. You may have an allergic reaction to these eye drops. You should avoid driving until your vision returns to normal. To protect your eyes until your

pupils return to normal size, you should wear sunglasses while outside. The study doctor will monitor your eye pressure closely and may take steps as necessary to reduce the pressure if it increases too much.

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.

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

4a. What are the possible benefits to me?

There is no direct benefit from participating in this research study.

4b. What are the possible benefits to others?

The results of this research may guide the future treatment of patients with cataracts.

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

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

- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition.
- Receive commercially available IOL lenses

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

The therapy offered in this research is available to you without taking part in this research study.

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

If you agree to take part, it will take you about 4 months to complete this research study. You will be asked to visit the research site 5 times total. This is the same number of times you would be asked to visit the clinic if you do not participate in the study.

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, initials, address, phone number, date of birth, medical record number, a code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Pantanelli's research office.
- Your research records will be labeled with: your code number, your initials, your date of birth, and will be kept in a safe area in Dr. Pantanelli's research office research office.
- A copy of this signed consent form will be included in your PSH medical record. This means that other PSH healthcare providers will know you are in this study.
- Results of some of the research-related clinical tests (including but not limited to cataract surgery) will be kept in your PSH medical record.

For research records sent to ALCON, you will not have any identifiers sent to the sponsor. .

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

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 sponsor(s) of this study, monitors and auditors, and other people or groups it hires to help perform this research
- A group that oversees the data (study information) and safety of this research
- Other: ALCON, sponsor of this clinical trial.

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?

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

-
- If you are randomized to receive the Alcon Vivity IOL it is provided from the company at no cost to you. Although this device is provided at no cost, there may be costs for the cataract surgery. You and your insurance company will be responsible for these costs.
- 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: study questionnaires, and the visual acuity and defocus curve testing at month 1 and month 3.

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

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research. This includes the Bausch and Lomb enVista lens and the cataract surgery no matter which lens you receive.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

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

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

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at 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.

Sponsor's compensation for injury

To pay these medical expenses, you will need to complete a form for the sponsor. This form will ask you for your name and if you have ever been enrolled in Medicare Part A or Part B. If you have been enrolled in Medicare you will also be asked to provide your date of birth and either your Medicare Claim Number or your Social Security Number. The sponsor will need to know this information about you because the sponsor has to report the payment it makes to Medicare. The sponsor will not use this information for any other purpose.

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 after completing month 1 and $60 after completing month 3 Visit. If you do not complete the study for any reason, you will be paid for the visits you have completed.

The payment will be provided by Greenphire Clincard. 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. 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."

10. Who is paying for this research study?

The sponsor ALCON is paying PSH/PSU for the research to be done. Dr. Pantanelli is a paid consultant for Bausch and Lomb one of the lens companies that you could be randomized to receive for this study.

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

Taking part in this research study is voluntary.

- You do not have to be in this research.

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

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

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

- Some possible reasons for this are: continuing the research would be harmful, your condition has become worse, you become pregnant, you did not follow the instructions of the study doctor, you experience serious side effects.
- 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 doctor for a final visit.

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

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

Please call the head of the research study (principal investigator), Dr. Pantanelli at (717) 531-1513 or the Ophthalmology 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 https://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