If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **A Phase 1 Open Label Dose Ranging Study to Assess the Safety and Tolerability of N-Acetylcysteine (NAC) in Patients with Retinitis Pigmentosa (FIGHT-RP1 Study)**

Application No.: **IRB00103296** **NCT03063021**

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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- 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.

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This is a research study to see if a study drug called N-acetylcysteine can be safely used in the treatment of Retinitis Pigmentosa (RP) and whether it prevent disease progression. The information gathered from this study will help find out if N-acetyl cysteine can be used in the treatment of RP.

N-acetylcysteine has been approved by the Food and Drug Administration (FDA) as an oral and inhaled drug for facilitation of expectoration via mucolysis (helping to breakdown thick lung mucus to help people cough it up) and in an IV form for acetaminophen (Tylenol) overdose. N-acetylcysteine is not approved by the FDA for the use in the treatment of RP and its use in this study is considered investigational. The FDA is allowing for the use of N-acetylcysteine in this study.

This is a dose-escalation study in which 6 doses of N-acetylcysteine tablets are being tested:

- 600mg twice a day
- 600mg three times a day
- 1200mg twice a day
- 1200mg three times a day
- 1800mg twice a day
- 1800mg three times a day

Participants will be given the dose pre-determined for the group they enter upon enrollment. If a participant cannot tolerate the assigned dose of N-acetylcysteine due to nausea and/or vomiting, the dose will be reduced to the dose immediately below the current dose. If that dose cannot be tolerated, the dose will be reduced to the next lowest level. This will be done until a tolerated dose is identified and the participant will be maintained on that dose throughout the study. If a participant cannot tolerate the starting dose of 600mg twice a day, they will be reduced to 600mg once a day. If a participant cannot tolerate a dose of 600mg once a day, they will be removed from the study.

Adult patients diagnosed with RP can join this study.

How many people will be in this study?

This study will enroll 30 patients the clinic population of the Wilmer Eye Institute, Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Study Summary:

After inform consent is obtained, you will enter a screening period to find out if you qualify for the study. Following this you will enter the study drug administration period. The study drug N-acetylcysteine will be given to you in a tablet form. You will be responsible for taking the drug daily as recommended by your study doctor. You will be on the study drug for a total duration of 6 months. The study staff will also show you how to complete your study drug dosing diary. Upon completion of the study drug period, you will enter a 3 month observational period during which you will be screened for any adverse events related to the use of the study drug. If you choose to withdraw from this research study at any time, or your participation is terminated by Johns Hopkins for any reason, you will be asked

to complete an End of Study (EOS) assessment visit (all study procedures on the EOS assessment visit will be similar to those conducted on the month 9 visit) and the 3 months observational period.

Study Procedures:
The following is a list of the required visits which will happen during the study. For each of these visits you will visit the Wilmer Eye Institute.

Screening
Screening Visit: Office Visit 1
The screening visit will be performed prior to the baseline visit.

After obtaining informed consent and receiving a unique screening number, you will undergo a number of screening activities.

If possible all screening activities should be conducted on the same day. At the screening visit, the following activities/procedures will be performed:

- Review of eligibility criteria
- Record demographics, medical and ocular history; concomitant medications, smoking history, alcohol intake and supplement usage
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MP1 and MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
    - Optical Coherence Tomography (OCT), a noninvasive procedure to check the thickness of your retina
    - Fundus autofluorescence, a noninvasive test to check disease status
- Color pictures of the back of your eye
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood draw to look for biomarkers of disease activity
- Blood draw for RNA, DNA samples for future genotyping studies including next generation sequencing

  The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information.

  The law provides that health insurance companies and group health plans
  - may not ask for genetic information from this research and
  - may not use genetic information when making decision about eligibility or premiums

  The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

Study Drug Administration Period

Baseline Visit: Office Visit 2 (Day 1)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MP1 and MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
    - Optical Coherence Tomography (OCT), a noninvasive procedure to check the thickness of your retina
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity
- Blood Draw before as well as 1 and 2 hours after administration of oral NAC for measurement of drug levels in the blood. The 2 hour blood draw will be optional, based on the convenience of the subject and at the discretion of the investigator.
- Start of the study drug administration, first dose of NAC to be administered in the clinic

Four Week Visit (Week 4/ 28±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity

Eight Week Visit (Week 8/ 56±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye

- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity

Twelve Week Visit (Week 12/ 84±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
    - Optical Coherence Tomography (OCT), a noninvasive procedure to check the thickness of your retina
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity
- Blood Draw before as well as 1 and 2 hours after administration of oral NAC for measurement of drug levels in the blood. The 2 hour blood draw will be optional, based on the convenience of the subject and at the discretion of the investigator.
- NAC to be administered in the clinic

Sixteen Week Visit (Week 16/ 112±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity

Twenty Week Visit (Week 20/ 140±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye

- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity

Twenty-Four Week Visit (Week 24/ 168±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
    - Optical Coherence Tomography (OCT), a noninvasive procedure to check the thickness of your retina
    - Fundus autofluorescence, a noninvasive test to check disease status
- Color pictures of the back of your eye
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity and drug levels
- Blood Draw before as well as 1 and 2 hours after administration of oral NAC for measurement of drug levels in the blood. The 2 hour blood draw will be optional, based on the convenience of the subject and at the discretion of the investigator.
- NAC to be administered in the clinic

Observational period

Twenty-Eight Week Visit (Week 28/ 196±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina
    - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity

Thirty-Two Week Visit (Week 32/ 224±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
    - Visual Acuity Testing (testing the sharpness of your vision)
    - Slit Lamp examination of your eye
    - An examination of your retina

- MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye

- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity

Thirty-Six Week Visit (Week 36/ 252±7days)

- Record any change in medical and ocular history; concomitant medications, smoking history, alcohol intake, supplement usage and adverse events
- Vital sign measurements (blood pressure, pulse rate, temperature and respiratory rate)
- Eye and Vision Exams:
  - Visual Acuity Testing (testing the sharpness of your vision)
  - Slit Lamp examination of your eye
  - An examination of your retina
  - MAIA microperimetry, a noninvasive test to check for the quantity of light perceived by the eye
  - Optical Coherence Tomography (OCT), a noninvasive procedure to check the thickness of your retina
- Anterior chamber tap to look for biomarkers of disease activity (0.1ml of aqueous fluid obtained from the front of the eye and stored at -80℃)
- Blood Draw to look for biomarkers of disease activity

How long will you be in the study?

You will be in this study for a total of 9 months after treatment initiation.

4. What are the risks or discomforts of the study?

Possible Risks and Side Effects of the Study Drug (N-acetylcysteine)

The most frequent adverse events associated with the oral administration of NAC are gastrointestinal in nature and include vomiting, diarrhea, abdominal pain and nausea. Hypersensitivity reactions, difficulty in breathing, rash and pruritus have been reported less frequently.

In this study, we will use NAC 600 mg effervescent tablets which are generally more pleasant and more tolerable than large capsules; however, because the formulation contains sodium, there is a risk of increase in blood pressure. We will exclude patients with uncontrolled arterial hypertension defined as diastolic blood pressure >95 mm Hg or systolic blood pressure >160 mm Hg.

Risks from study procedures

Dilation Risks:

Dilating drops are used to dilate or enlarge the pupils of the eye to allow the doctor to take a better view of the inside of your eye. Dilating drops frequently blur vision for a length of time which varies from person to person and may make bright lights bothersome. Because driving may be difficult immediately after such an examination, it may be best if you make arrangements not to drive yourself. You should bring sunglasses to your appointment to avoid discomfort from bright lights for 2-4 hours after your visit. Dilating drops may trigger acute angle-closure glaucoma. This is extremely rare and treatable with immediate medical attention.

Intra-ocular pressure Risks:

When the pressure inside your eye is measured, there is a small chance that the instrument used could scratch the surface of your eye. If this does occur, this is usually minor.

Fundus Photography Risks:
During fundus photography, you may experience some brief discomfort and you may "see spots" from the flash bulb for a few minutes after these pictures are taken.

SD-OCT Risks:
The SD-OCT test uses a non-harmful, very thin laser beam to create a picture of the tissues at the back of your eye (the retina). It should not cause you any discomfort.

Eye fluid (Aqueous Humor) Sample Collection
The eye is swabbed with a brown fluid (Betadine) that is very good at killing germs, but can cause mild discomfort or burning for a few hours. While this medication is effective at eliminating germs, there is a small possibility that the combination of making a small opening into the eye and pressure or manipulation of the eye afterward could allow some residual germs to enter the eye and cause infection. This can be damaging to the eye and requires rapid treatment if it occurs. While the chance of this occurring is very small, it can lead to vision loss.

Anesthetic drops:
There may be some local irritation and stinging several hours after the instillation. The pupil may dilate with these drops. Rarely, a severe hyper allergic corneal reaction may occur. Allergic contact dermatitis with drying and fissuring (splitting or cracking) of the fingertips has been reported. Softening and erosion of the corneal epithelium and conjunctival congestion and hemorrhage (bleeding) have been reported.

Blood Sample Risks:
Blood samples will be taken as part of this study and will be taken by single needle sticks or involve the insertion of intravenous (IV) catheters. Some people have discomfort or pain with the needle stick, when an IV catheter is inserted or when blood is collected. There are people who feel faint or pass out when having blood taken. There is a risk of infection, redness, bleeding and/or bruising at the puncture site when blood is collected.

Confidentiality:
There is the risk that information about you may become known to people outside this study.

Genetic information is unique to you and your family, even without your name or other identifiers. Johns Hopkins follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

There may be side effects and discomforts that are not yet known.

5. Are there benefits to being in the study?

You may or may not benefit from being in this study. Information obtained from this study may help study doctors to learn more about the safety and effectiveness of NAC in patients with RP.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use your health information that they have already collected if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization

12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

13. What does a conflict of interest mean to you as a participant in this study?

A researcher had a financial or other interest in this study. Johns Hopkins has a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Dr . Mandeep Singh, at 410-502-2789. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Peter A. Campochiaro at 410-955-5106. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Peter A Campochiaro at 410-955-5106 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call 410-955-2159 and you will be able to get an on call retina doctor 24 hours a day. This physician will be able to contact Dr. Campochiaro.

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

16. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time
Signature of Participant	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.