Title: Preventing Anaphylaxis With Acalabrutinib

NCT number: NCT05038904

Date: March 21, 2022

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

COMBINED RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Preventing Life-Threatening Allergic Reactions with Acalabrutinib, an FDA-Approved BTK Inhibitor

Application No.: IRB00223615

Funded By: AstraZeneca Pharmaceuticals, LLP
National Institutes of Health

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

- This study is testing whether acalabrutinib (the "study drug") can prevent systemic allergic reactions including anaphylaxis to peanuts and/or tree nuts in allergic people, and to gather additional information about the safety of the drug.
- You are being asked to participate in this research study because you have a life-threatening allergy to peanuts and/or tree nuts. This is an open-label study, which means that you, the study doctor and the study staff will know that you will receive acalabrutinib.
- If you choose to be in the study, and you qualify for the study, you will be in the study for at least 3 months and you will have to make at least 3 visits to the Johns Hopkins Bayview Clinical Research Unit (CRU) (the "study site").

- At the first and second visits, oral food challenges (OFC) will be done, where you will eat small, controlled amounts of a food you are allergic to (or a placebo, i.e. a food you are not allergic to) until you have an allergic response or until you have had one full serving without a reaction. Emergency medications will be immediately available within the exam room should you have a severe reaction. All OFCs will be conducted by trained personnel and supervised by a doctor with experience in performing OFCs and in the treatment of anaphylaxis, a serious reaction. Skin prick testing (allergy testing) to peanut or tree nuts will also be done on your arm or back.
- Between the first and second visits, you will be asked to take the study drug twice a day for 2 days by mouth at home.
- At least 3 blood samples will be taken during the course of the study. At least 45 mL of blood (about 3 tablespoons) will be taken at each visit. Extra blood samples may be required if any of your laboratory tests are not normal, or if the study doctor thinks it is necessary for watching your health.
- The risks of participating include having a severe reaction during the OFC, which could result in hospitalization and/or death.
- There is no benefit to you for participating. There is no cost to you for participating. You will be paid for the study visits that you complete, up to $520.
- Your participation is completely voluntary. You can choose to stop the study at any time. Your medical care will not be affected if you choose not to participate.

2. Why is this research being done?

There are no known therapies that can prevent allergic reactions, including anaphylaxis (a systemic allergic reaction) to foods. This research is being done to test whether the investigational drug called acalabrutinib can prevent systemic allergic reactions including anaphylaxis to peanuts and/or tree nuts in allergic people, and to gather additional information about the safety of the drug.

Are there any investigational drugs/devices/procedures?

Acalabrutinib is approved by the Food and Drug Administration (FDA) for the treatment of B cell malignancies. It is not approved for use in food allergy. The FDA is allowing the use of acalabrutinib in this research study.

Who can join this study?

People 18 years or older with a history of peanut and/or tree nut allergy may join.

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:

Screening/Baseline Visit (Visit 1):

To help the study doctor determine if you are eligible to participate in this study, you will be asked to come to the study site for a screening visit. The entire Visit 1 will last approximately 8 hours. The screening will happen at the beginning and last approximately 1 hour. The following tests and procedures will be performed:

- You will be asked to read and sign this consent form.
- A complete physical examination will be performed and your vital signs (blood pressure, body temperature, breathing, and pulse rate), and height and weight will be taken.
- A review of your health and medical history, your demographics (such as your gender, race, and other background information), and any medications (prescription, nonprescription, and over-the-counter herbal and dietary) you have taken and are currently taking will be done. The study doctor or study staff will also review with you what medications you are not allowed to take during the study.

- If you are a female capable of becoming pregnant, a urine pregnancy test will be done.

If you meet the requirements to participate in the study and agree to take part, the study doctor and staff will perform a food challenge to confirm your food allergy. This will last approximately 7 hours. The following tests and procedures will be performed:

- About 3 tablespoons (45 mL) of blood will be taken for laboratory tests (such as complete blood count and kidney and liver function tests, and tests to determine the normal level of substances in your blood that indicate an allergic response).
- If you have asthma, a spirometry (breathing) test will be performed to check your lung function. You will be asked to take a deep breath and breathe out hard into a tube attached to a machine called a spirometer. This machine measures how fast and how much air moves out of the lungs over a period of time. You may be asked to blow into the spirometer several times.
- You will have skin prick testing done with the food that you are allergic. During this test, the study team will put a drop of solution containing the food allergen on your skin. They will use a small plastic probe or needle to gently scratch your skin to let the solution enter the surface. The use of the needles in this test is usually not painful and will last about 30 minutes.
- You will have an electrocardiogram (ECG), which is a test that records the rhythm of the heart. You will be asked to lie flat on a table and several small electrode pads (like stickers) will be placed on the body. This test takes about 10 minutes.
- An oral food challenge (OFC) will be performed. This involves you eating increasing amounts of the food to which you are allergic. Some doses will contain the food you are allergic to, and others will contain something you are not allergic to (called a placebo). You will not know which you are eating, but the study doctor will. See below for the procedures performed during an OFC:
    - An IV needle will be placed in a vein (most likely in your arm). This is for your safety so that emergency medications can be given to you immediately if you have a severe allergic response.
    - Your vital signs and the amount of oxygen in your blood will be measured multiple times, including before, during and after the OFC.
    - The OFC will begin. You will take by mouth a very small amount of a food allergen (like a nut flour or nut butter) that will be mixed with another food to mask the taste (like pudding). Controlled, increasing doses of the food allergen will be given to you every 15-30 minutes under the supervision of a board-certified allergist.
    - The procedure will stop as soon as clear allergic symptoms are seen, or until you eat a full serving of the food. All symptoms will be treated as medically appropriate.
    - You will be watched for 2 hours or more following your last dose of the food allergen or placebo.

If 1 - 3 days before this visit you have asthma symptoms, seasonal allergy symptoms, fever, infection, rash, or change in a medical condition, the OFC procedure will be rescheduled for another day.

If you do not have a reaction to the oral food challenge at this first visit, then this will be your last visit and you will not take the study drug. If you do react to the oral food challenge, you will be given a supply of study drug to take home. There is no placebo drug in this study – both you and your doctor will know that you are receiving the study drug. You will take 100 mg of the study drug twice a day for two days, swallowed with a glass of water.

You should not take the study drug while you are taking certain medications that can affect its metabolism. The study team will tell you which medications you cannot take while participating in this study.

Study Visit 2:
On the second day of the study drug, you will be asked to return to the study site for Visit 2, (which will be at least 4 weeks following your Screening/Baseline Visit) to see if the study drug stopped allergic reactions. The study team will let you know what day to return to the study site.

This visit will last approximately 8 hours. The following tests and procedures will be performed:
- A review of any illness or medical events you have had and any medications (prescription and over-the-counter) that have changed since your last visit.
- A complete physical examination will be performed and your vital signs (blood pressure, body temperature, breathing, and pulse rate), and height and weight will be taken.
- If you are a female capable of becoming pregnant, a urine pregnancy test will be done.
- You will have skin prick testing done.
- About 3 tablespoons (45 mL) of blood will be taken for laboratory tests (such as complete blood count, kidney and liver function tests, and tests for an allergic response).
- You will have an electrocardiogram (ECG).
- If you have asthma, spirometry will be done.
- An OFC will be performed. Please see above visit for a full description of this procedure.

If 1 - 3 days before any of these visits you have asthma symptoms, seasonal allergy symptoms, fever, infection, rash, or change in a medical condition, we may ask you to stop taking the study medication, and the OFC procedure will be rescheduled for another day.

Follow-Up Visit(s):
1 month after completion of Visit 2, you will be asked to return to the study site for a safety follow-up visit. This visit will last approximately 30 minutes and will include the following procedures:
- A review of any illness or medical events you have had since your last visit.
- If you are a female capable of becoming pregnant, a urine pregnancy test will be done.
- About 2 tablespoons (30 mL) of blood will be taken for laboratory tests (such as kidney and liver function tests and tests for an allergic response).
- You will have skin prick testing done.

If any of your labs are abnormal, you may be asked to return for another follow-up visit in another 3 months for a repeat of the above procedures.

Early Termination Visit:
If you and/or the study doctor decide that you will no longer be in the study before your Visit 2, you will be asked to complete the Early Termination Visit. This visit will last approximately 1 hour. The following tests and procedures will be performed:
- A review of any illness or medical events you have had and any medications (prescription and over-the-counter) that have changed since your last visit.
- A complete physical examination will be performed and your vital signs (blood pressure, body temperature, breathing, and pulse rate), and height and weight will be taken.
- You will have skin prick testing done.
- About 2 tablespoons (30 mL) of blood will be taken for laboratory tests (such as kidney and liver function tests and tests for an allergic response).
- You will have an electrocardiogram (ECG).
- If you are a female capable of becoming pregnant, a urine pregnancy test will be done.

Will research test results be shared with you?
This study involves research tests that we do not expect will be useful for your clinical care. We will not share these results with you.

How long will you be in the study?
You will be in this study for 3 months.

4. What happens to data and biospecimens that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

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.

If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from these efforts.

What testing or procedures may be done with your biospecimens?
Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes basophil (white blood cell) activation, testing for IgE antibodies to peanut and/or tree nuts, and testing markers of activation from your white blood cells.

How will your data and/or biospecimens be shared now and in the future?
Sharing data and/or biospecimens is part of research and may increase what we can learn from this study.

Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data and/or biospecimens may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data/biospecimen sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data/biospecimens, we limit the uses of the information and whether these data/biospecimens can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Johns Hopkins researchers may also use the biospecimens collected in this study for future research purposes, which may include gene sequencing and genetic testing. Each cell contains your complete DNA. Gene sequencing of your DNA provides researchers with the code to your genetic material. This future research may be unrelated to the current study and may include outside collaborators.

Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data/biospecimens in future research, you may not want to participate in this study.

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

You may have some side effects and discomfort while in this research. If you have any side effects, you should tell the study doctor or staff as soon as possible. They will monitor you closely. This research may also have risks or side effects that are not well known or understood at this time.

Risks related to acalabrutinib (the study drug):

All drugs may cause certain side effects and discomforts. The following reported side effects were mostly mild and seen in patients taking acalabrutinib for lymphoma cancer and may not appear with the same frequency for the short time you take the study drug. The most common and likely side effects and discomforts reported for acalabrutinib are anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain, which can occur in 30% or more of patients taking it chronically. Additional rare, but serious, side effects include bleeding, abnormal heart rhythms, and cancers. The most frequently-reported secondary cancer was non-melanoma skin cancer (caused by too much sun exposure over many years). The risk of cancer from taking 2 days of this drug in people without cancer is not known.

To date, only people with cancer have received acalabrutinib. The cancers being treated with this drug tend to be cancers of older adults, and most of the patients have been over the age of 50, with many aged 65 or older. All have received drug for months to years. Most have received acalabrutinib after failing other treatments, or in addition to other treatments for their underlying cancer. In this study, you will receive 4 doses (2 days of the study drug).

If you have any problems, you should tell the study doctor or staff as soon as possible. They will watch you closely. If it is best for you, the study doctor may decide to take you out of the study. If you are taken out of the study, the study doctor may want to continue checking on you.

The study drug may have side effects that are unknown today and may include your food allergies getting worse. This is why it is very important for you to report any reactions or changes in your health to the study doctor.

The study staff will monitor any side effects that you have during the study. If necessary, you will be withdrawn from the study for your safety.

Allergic Reactions:

An allergic reaction to the study drug is unlikely if you have never taken it before this study. As with any drug, there is a risk of an allergic reaction to the study drug ingredients. It is important to tell the study doctor if you are having an allergic reaction.

If you have a very serious allergic reaction, you may be at risk of death.

Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- A rash (red or itchy skin)
- Having a hard time breathing
- Wheezing when breathing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Not able to breathe without help
- A feeling of dread
- Swelling around the mouth, throat, eyes or other parts of the body
- Fast pulse
- Sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

In the event of an emergency, dial 911 immediately. If you require emergency care, be sure to tell the emergency care provider about your participation in this study.

Oral Food Challenge (OFC):
Oral food challenges involve eating increasing amounts of the food that you are allergic to. When you have a reaction, the challenge will be stopped, and you will receive medical treatment. It is important to tell the study doctor if you are having an allergic reaction. The risks of an allergic reaction are described above, including a very rare, but serious, risk of having a serious allergic reaction is death.

Blood Draw and IV Placement:
Taking blood and placing an IV tube in your arm may both cause discomfort. Likely symptoms include bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting or an infection at the site.

Skin Testing:
Skin prick testing with food extracts will be performed on your forearm or back. Likely side effects of skin testing include redness, itchiness and a sometimes a rash or hive at the testing site, which typically lasts for less than a day. Less likely, a delayed reaction can occur, which involves mild swelling, itching, and sometimes pain at the testing site a day later. Rare, but serious, side effects of skin testing include systemic reactions like shortness of breath, hives all over the body, nausea, vomiting, or diarrhea.

Spirometry:
Spirometry is used to measure the amount of air taken into and exhaled from the lungs and requires forceful breathing. Discomforts of this procedure are likely to include mild dizziness or a feeling of being light-headed afterwards, which typically lasts for only a few minutes.

Electrocardiogram (ECG):
The pads used for ECGs have adhesive to help them stick to your skin, which can cause irritation or a mild rash.

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

6. Are there risks related to pregnancy?

It is unknown whether this research may hurt an embryo or fetus. The effects of the study drug on the reproductive system (sperm, eggs) or to an embryo/fetus are unknown. It is important that females (women) do not become pregnant while in this study. Males (men) should not father a baby while in this study. Females who are pregnant or nursing will not be allowed to take part in this study. All participants in this study must agree to use a reliable method of birth control or not have sexual intercourse during the study. The study doctor/staff will talk about this with you and provide information on the best methods of birth control.

Women will have a pregnancy test before starting the study drug. A pregnancy test may also be required at other study visits when you are in this study. During the course of the study, if there is any chance you may be pregnant (late or missed menstrual period), please contact the study doctor right away. If a woman becomes pregnant when taking part in this study, she may be asked to stop the study. However, follow-up visits to review the effects on her and/or the baby may be needed.

7. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

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

There are no alternative treatments capable of preventing allergic reactions including anaphylaxis. You do not have to join this study. An alternative is to not take part in this study. If you do not join, your medical care at Johns Hopkins will not be affected.

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

No. 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.

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

You will be paid $1,050 for taking part in this study. You will receive $500 per each of the first 2 completed study visits and $50 for the follow up visit, in the form of a prepaid Visa card. You will only be paid for completed study visits. You will also be reimbursed for parking charges and travel expenses for study visits.

You will be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. Because your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. 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 share your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. 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 need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- 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 or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Only the study staff will have access to your identifiable information. You will be assigned a unique study number, which will be used to label all of your samples. This study number will allow us to analyze your samples without disclosing your name or other identifiable information. The key that matched your study number to your name, plus all paper documents containing your identifiable information, will be kept in a locked cabinet in the study doctor's office, which is locked when not in use. Electronic information will be password-protected and encrypted on Johns Hopkins approved computers and/or drives.

14. 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, such as your allergist.

15. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

16. 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.

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

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

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.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the study coordinator, Dr. Ragha Suresh, at 410-803-3104, or the principal investigator, Dr. Melanie Dispenza, at 410-550-1815. If you wish, you may contact the principal investigator by letter. The address is 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 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Melanie Dispenza at 410-550-1815 during regular office hours and at 703-477-6413 after hours and on weekends. If this doctor is not available, the operator will page the "on call physician."

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

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, 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

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 AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

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

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).