Informed Consent Form

Multiple-Arm Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of XmAb20717 in Combination with Standard of Care Treatment in Patients with Metastatic Castration Sensitive Prostate Cancer

NCT Number: NCT05733351

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EMORY UNIVERSITY | Institutional Review Board
Research Administration

EMORY | WINSHIP CANCER INSTITUTE
National Cancer Institute-Designated Comprehensive Cancer Center

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 30 people who are being studied, at Emory.

Why is this study being done?

This study is being done to answer the question: is the addition of XmAb20717 immunotherapy to the standard of care treatment of advanced prostate cancer safe and potentially effective? You are being asked to be in this research study because you were diagnosed with advanced prostate cancer.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will require visits every 3 weeks. The researchers will ask you to do the following: you will receive XmAb20717 infusion for up to one year in addition to the standard treatment of advanced prostate cancer. Some of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. Potential benefit for you includes early access to the study drug, XmAb20717.

What are the risks or discomforts you should know about before deciding?

The study will take time. The study drug that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Diarrhea, fatigue, itching, rash

- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled “What are the possible risks and discomforts?”

Alternatives to Joining This Study
The alternatives to joining this study include receiving standard of care treatment for advanced prostate cancer outside the setting of the clinical trial.

Costs
The study sponsor will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care.

There is more information in the “Costs” section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: Multiple-Arm Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of XmAb20717 in Combination with Standard of Care Treatment in Patients with Metastatic Castration Sensitive Prostate Cancer

IRB #: STUDY00004688

Principal Investigator: Bassel Nazha, MD

Sponsor-Investigator: Bassel Nazha, MD

Study-Supporter: Xencor

Introduction

You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

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.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?

The proposed study is a Phase I trial of patients with advanced of metastatic prostate cancer who would receive one of three standard of care treatment regimens (Cohort A: abiraterone/prednisone, Cohort B: enzalutamide, Cohort C: abiraterone/prednisone and docetaxel) plus Xmab20717, a novel immunotherapy agent that is not FDA approved and whose use is experimental. The study is non-randomized and will be at Emory University – Winship Cancer Institute (WCI) clinical care sites. The included subjects should have not had progression of disease while receiving standard of care hormonal treatment for prostate cancer.

What will you be asked to do?
You will be asked to enroll into one of three cohorts, based on cohort availability, sequence of enrollment set in the protocol, anddiscussion with your treating physician.

First, once all your questions have been answered and you feel comfortable that you understand what this study involves, you will need to sign this informed consent.

Screening
To find out if you can take part in this study, you will go through a Screening process. In this process, you will be asked about your general health and your medical history. You will also be asked about medicines, prescriptions and any over-the-counter drugs and supplements you are taking right now or have taken within 28 days prior to the first dose of study drug.

If any of the tests required at screening were performed prior to signing consent, as part of your routine care, and if they fall within the time allowed by the study, they may be used and need not be repeated.

This screening evaluation process may take up to a maximum of 28 days prior to starting the study and will include the following:

- Review your current condition, your medical history, and any medications you may be taking.
- A physical examination (including Performance assessment, vitals, obtaining your height and weight)
- Approximately one tablespoon of blood will be drawn for blood tests (electrolytes, kidney function, liver function, thyroid function), complete blood count (white blood cells, red blood cells, and platelets), and coagulation tests (PT, PTT).
- You must not be planning to have children in order to join the study.
- Radiologic imaging studies to evaluate tumor status: Have a computerized tomography (CT) scan or magnetic resonance imaging (MRI) to see tumor in the chest, abdomen and pelvis. A CT scanner is used to take a series of X-rays of your body at slightly different angles. A computer puts these together to produce a very detailed picture of the inside of your body. Magnetic resonance imaging (MRI) uses a strong magnetic field and radio waves to produce detailed pictures of the inside of your body. The pictures produced by the CT scans and the MRIs provide doctors with information to help them assess the extent of your cancer. CTs will be performed with intravenous (IV) contrast; MRIs will be performed with IV contrast. This means that you may have to receive a special dye by injection into a vein that will highlight areas of disease involvement more easily for a doctor who is reviewing your scans.
- Nuclear medicine imaging studies: a bone scan, PSMA PET scan (with IV contrast), and FDG PET scan (with IV contrast).
- A stool sample for research purposes
- A blood sample of 60mL for research purposes.

Treatment schedule
If you are found to be eligible for the study, and agree to participate, you will be enrolled into one of three cohorts, based on a discussion with your doctor.

Cohort A consists of treatment with XmAb20717 intravenous infusion every 3 weeks for up to one year in addition to standard of care abiraterone plus prednisone oral pills and androgen deprivation therapy (ADT).

Cohort B consists of treatment with XmAb20717 intravenous infusion every 3 weeks for up to one year in addition to standard of care enzalutamide oral pills and ADT.

Cohort C consists of treatment with XmAb20171 intravenous infusion every 3 weeks for up to one year, in addition to standard of care docetaxel intravenous infusion every 3 weeks, abiraterone plus prednisone oral pills and ADT.

On Day 1 of every cycle (and at the time of discontinuation of study treatment), you will go through the following assessments:

- Review medications you may be taking.
- Perform a physical exam and take your vital signs and weight.
- Collect blood samples for blood cell counts, blood sugar, and organs functions

Research blood samples
Your blood samples will be used to study cells, genes and proteins present in the liquid portion of the blood (serum). This study will attempt to find differences in the blood between patients and before and after treatment. It might help us understand changes in biomarkers induced by the treatment. Samples will be collected at Baseline, every 3 weeks the first two months, and one last sample will be collected at the end of treatment period (study discontinuation). Each sample will be of 60 mL. Those samples are for research purposes and are not part of your standard clinical care.

Research stool sample
A research stool sample will be collected at baseline, after 12 weeks of treatment, and at the end of treatment to study the treatment effect on gut microbiome.

Imaging studies (CT or MRI) and bone scan
Computed tomography (CT) or magnetic resonance imaging (MRI) of the chest/abdomen/pelvis and bone scan.

- Baseline imaging studies must be performed within 4 weeks of study start
- Radiologic imaging studies every 12 weeks to evaluate your tumor status.

At every clinic visit, we will be assessing for side effects. If the side effects are severe and do not come under control, you may be withdrawn from the study if the study doctor feels this is in your best interests.

How will your study drug be provided?
The study drug that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the study drug to you. If you have questions about the study drug, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have

questions about the study drug. The number for the pharmacy is included on your study drug package, if given one.

Note: The research team for this study includes non-licensed team members who may obtain your consent, or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study.

What are the possible risks and discomforts?

Risks Associated with XmAb20717

XmAb20717 has been tested as a single therapy in 145 participants with various types of advanced cancer participating in a different ongoing, clinical study. Based on the experience in that study, XmAb20717 may cause 1 or more of the side effects listed below. Because testing of XmAb20717 has been done mostly in that study, other side effects that are not yet known may also occur. You should tell your study doctor or nurse right away about any possible side effects that you experience. There is limited information regarding the safety of XmAb20717 in combination with other anticancer therapies. Therefore, there are unknown risks of the combination of XmAb20717 and other treatments that will be used in this study.

The side effects that have occurred most frequently in the ongoing study of XmAb20717 are listed below. XmAb20717 may potentially result in other side effects not yet seen in the ongoing study.

Occurred in 5% or More of Study Participants

- Fatigue
- Decrease in red blood cells (anemia)
- Itchy skin
- Rash, including rash covered in bumps
- Fever
- Chills
- Constipation
- Nausea
- Vomiting
- Diarrhea
- Pain in the belly
- Cough

- Shortness of breath
- Headache
- Dizziness
- Swelling in lower legs or hands
- Decreased appetite
- Weight loss
- Changes in laboratory measurements in blood, including:
    - Elevations in blood sugar, liver enzymes, creatinine (which may indicate impaired kidney function), alkaline phosphatase (a protein), and enzymes secreted from the pancreas (which may indicate inflammation of the pancreas)
    - Decreases in electrolytes, albumin (a protein), platelets (cells that help the blood to clot), and lymphocytes (a type of white blood cell important for fighting infection)
- Joint pain
- Back pain
- Pain in arms or legs
- Muscle aches
- Low blood pressure
- High blood pressure
- Rapid heart rate
- Dry mouth
- Vomiting blood
- Inflammation of the lungs, which can cause shortness of breath and difficulty breathing
- Pneumonia
- Acute kidney injury
- Hypothyroidism (thyroid gland does not produce enough thyroid hormone)
- Infusion-related reaction (a strong immune response to receiving a drug intravenously [into the vein])
- Fall
- Flu-like illness

Safety information is available from 6 patients who have been treated with XmAb20717 plus chemotherapy (carboplatin plus either cabazitaxel or docetaxel) in this study. Many of the side effects that have occurred most frequently in this study have been similar to the ones listed above. In addition, the following side effects have also been seen in at least 2 patients in this study:

- Muscular weakness

- Indigestion

Immunotherapy-Related Adverse Events

XmAb20717 is in a class of drugs known as cancer immunotherapy, a type of therapy that uses a person's immune system to fight cancer. Immunotherapy can cause side effects, many of which happen when the immune system, which has been activated to fight the cancer, also acts against healthy cells and tissues in your body. These types of side effects can occur in any part of the body and include some of the more common side effects listed above for XmAb20717. The following are important but infrequently reported immunotherapy-related adverse events that have been seen with other immunotherapies, and have been reported in approximately 3% or fewer patients in the studies of XmAb20717:

- Pancreatitis: inflammation of the pancreas (an organ that produces digestive juices and certain hormones, including insulin), causing symptoms including pain in the upper abdomen, nausea, and vomiting
- Gastrointestinal tract-related events, such as enterocolitis (small bowel inflammation) and/or colitis (large bowel inflammation) causing symptoms including, but not limited to, abdominal pain, diarrhea, and/or constipation
- Myocarditis: inflammation of the heart causing symptoms such as chest pain, shortness of breath, and/or palpitations
- Hepatitis: inflammation of the liver that can impair liver function
- Guillain-Barré syndrome: a disorder in which the body's immune system attacks the nerves, which can weaken your arm and leg muscle strength

Infusion-Related Reactions

The symptoms of an infusion-related reaction include fever, shaking, chills, tiredness, headache, or nausea. In some cases, an infusion-related reaction can lead to shortness of breath and low blood pressure. This type of reaction, if it is severe, may be life-threatening when it occurs and requires immediate treatment. Your study doctor will have emergency equipment nearby each time you receive an infusion so that treatment is immediately available if you have a severe reaction.

Reproductive Risks

XmAb20717 has not been studied in laboratory and animal experiments to see if it causes problems with pregnancy or birth defects. It is not possible to say that nothing bad will happen when a woman gets pregnant while taking it. There is no Information about available at present about harm to developing babies or harm that may result from breastfeeding. Because many medicinal products, including antibodies, can be secreted in human milk, a risk to newborns/infants cannot be excluded. Participants should agree to use an adequate method of birth control from the time the consent is signed until 120 days after the last dose of XmAb20717.

XmAb20717 may potentially result in other side effects not yet seen with these types of antibodies.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

If it is biologically possible for you to make someone pregnant: the effect of the study drug on sperm is not known. To protect against possible side effects, you should not get a sexual partner pregnant while taking the study drug and for 120 days after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will take the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

Radiation-Related Risks
You will be exposed to radiation from nuclear medicine and CT scans. These procedures are necessary for your medical care and will occur even if you do not participate in this study. The radiation dose estimate that you will receive is equal to or less than the radiation exposure allowed to be received by a radiation worker for 2 years. The principal risk associated with a radiation dose is the possibility of developing radiation-induced cancer later in life. Although the risk from radiation is cumulative it is not expected to adversely affect your condition or treatment. The Emory University Radiation Safety Committee has reviewed and approved the use of radiation in this research study.

Risks Associated with Abiraterone/Prednisone
The most common adverse reactions (≥10%) are fatigue, joint pain, elevated blood pressure, nausea, swelling of the legs, low potassium levels, hot flush, diarrhea, vomiting, upper respiratory infection, cough, and headache. The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, elevated triglyceride, low white blood counts, elevated cholesterol, elevated glucose levels, and low potassium levels.

Risks Associated with Enzalutamide
The most common adverse reactions (≥ 10%) are fatigue, back pain, decreased appetite, constipation, joint pain, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, shortness of breath, musculoskeletal pain, weight decrease, headache, hypertension, and dizziness/vertigo.

Risks Associated with Docetaxel
The most common adverse reactions are infections, low neutrophil count, anemia, hypersensitivity, low platelet count, neuropathy, changes in taste, shortness of breath, constipation, anorexia, nail disorders, fluid retention, fatigue, pain, nausea, diarrhea, vomiting, mucositis, loss of hair, skin reactions, and muscle pain.

Risks Associated with Trial Participation
You may be foregoing therapies known to prolong survival to participate in this trial. Those are the standard of care treatments for advanced prostate cancer as used outside of a clinical trial. There are multiple drugs that are approved for the treatment of advanced prostate cancer, including abiraterone/prednisone, enzalutamide, apalutamide, docetaxel, docetaxel plus abiraterone, and docetaxel plus darolutamide.

Will you benefit from the study?
You may not benefit from joining the study. Your condition may improve while you are in this study or it may get worse. The study results may be used to help others in the future.

Will you be paid for your time and effort?
You will not be compensated for being in this study.

What are your other options?
If you choose not to join this study, you can get care outside of this study. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information
We will store all the data and specimens that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data and specimens may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory and Saint Joseph's Hospital, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory and Saint Joseph's Hospital. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee the anonymity of your data.

We will use your specimens and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

Medical Record

If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory Atlanta and Saint Joseph's Hospital provider or facility gives you any services or procedures for this study.

We will take reasonable steps to keep copies of this form out of Emory's and Saint Joseph's Hospital medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

Emory and Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Saint Joseph's Hospital medical records. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory and Saint Joseph's Hospital places may not become part of your Emory and Saint Joseph's Hospital medical records. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Bassel Nazha at telephone number [redacted] You should also let any healthcare provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital will help you to get medical treatment. Neither Emory, Saint Joseph's Hospital nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory and Saint Joseph's Hospital, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Saint Joseph's Hospital employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a negligence claim.

Costs

The study supporter will pay for certain items and services that you may receive if you take part in this study.

The study drug, Xmab20717, will be provided to you at no cost.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover. Emory

and Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory, Saint Joseph's Hospital and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- If you develop a serious side effect from your treatment
- If your clinical assessment or imaging scans suggest that your cancer is not responding to treatment
- If you choose to receive care at another institution

If you withdraw from the study, you can request in writing at any time that your samples be destroyed. However, data already obtained from your samples or de-identified samples will continue to be kept and used for the purposes described in this document.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study in which you may choose to participate.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study-related treatment.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to get payment for study-related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Bassel Nazha, MD is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study

administration and billing. These include the Emory IRB, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - Study-Supporter: Xencor
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI 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.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly, and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. Bassel Nazha [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted]

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at [redacted]

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ ___:___ am / pm
Signature of Subject (18 or older and able to consent) **Date** **Time (please circle)**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ ___:___ am / pm
Signature of Person Conducting Informed **Date** **Time (please circle)**

Optional Study of Data and/or Specimens for Future Research

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI for the optional study. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study, but you can still be in the main research study.

Consent and HIPAA Authorization for Optional Study/Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study previously described:

SAMPLES FOR FUTURE RESEARCH STUDIES

_____ I agree my samples and related information may be kept for use in future health research.