IRB# [redacted]

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	A Phase 1, Open-Label, Single Center, Dose Escalation Study of the Safety and Pharmacokinetics of mAb AZD5396 and mAb AZD8076 delivered as dMAbs in Healthy Adults
Principal Investigator:	Pablo Tebas, MD [redacted]
Emergency Contact:	[redacted]
Regulatory Sponsor	Pablo Tebas, MD
Funding Sponsor	U.S. Department of Defense

Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at [redacted] for assistance (an IRB is a committee responsible for making sure that the study follows the guidelines for the protection of human research subjects).

The research study is being conducted to determine if an investigational way to deliver an antibody against COVID-19 is safe in humans. If you agree to join the study, you will be asked to complete research procedures including blood draws, physical exams, vital signs, ECGs and receive the study drug injections.

Your participation will last for about 72 weeks.

You are not expected to receive any benefit from participation. The most common risks of participation are:

- Injection site reactions (such as redness, pain, inflammation, swelling, hardness, itchiness)
- Not feeling well, tiredness, muscle aches, joint pain, or headache

These side effects (if they occur) are generally brief in duration (up to a few days). Your alternative is not to be in this study.

We encourage you to be vaccinated against COVID-19. Being vaccinated against COVID-19 will not keep you from participating in this study. If you have not been vaccinated already talk to your primary doctor if interested in approved COVID-19 vaccines. The currently authorized or approved vaccines have shown to be effective against COVID-19 while the effectiveness of this experimental new way to deliver antibodies is not known.

Please note that there are other factors to consider before agreeing to participate such as

additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Introduction

You are being invited to participate in a research study of two products called dMAbAZD5396 and dMAbAZD8076, given separately with a device called CELLECTRA® 2000, for the prevention of COVID-19. These products are pieces of DNA that carry all the information for your body to make 2 different antibodies against COVID-19. This study is a clinical research trial to find out whether the administration of the two investigational (not approved by the US Food and Drug Administration (FDA)) products with the investigational device (CELLECTRA® 2000) is safe, tolerated, and can produce enough antibodies in your blood that may indicate the ability to prevent infection from COVID-19.

Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about any information or terms that you do not understand. If you decide to participate, you will be asked to sign this form.

The doctor in charge of this study at this site is Dr. Pablo Tebas. Dr. Pablo Tebas is from the University of Pennsylvania and is the Principal Investigator overseeing the entire study. Funding for this research study comes from the Department of Defense.

Why Is This Study Being Done?

The COVID-19 disease pandemic is a global health crisis. COVID-19 symptoms can be mild-to-severe respiratory illness including fever, cough, and difficulty breathing, and in the most severe cases can require mechanical ventilation or even lead to death. In the US alone there are more than 80 million confirmed cases of COVID-19 and almost 1 million deaths as of April 2022. The COVID-19 pandemic has had a severe impact on the health systems and will likely have lasting social and economic impact. Medical countermeasures are urgently needed.

While there are already vaccines approved and available so you make antibodies against COVID-19, there is a need for vaccines that will provide protection in patients that are immunosuppressed and will not mount a response to regular vaccines. This study is being done to test a new COVID-19 approach that will give your muscle cells the information to make antibodies against COVID-19 to see if it is safe and makes your muscle cells make antibodies to protect against COVID-19 in your body.

Cells contain a type of molecule called deoxyribonucleic acid (DNA). Your genes are made of DNA. DNA is different in each person. You can think of genetic characteristics as composing a large instruction book that your body reads to understand how it should be built and function. The words that make up this instruction book are represented by your DNA.

dMAb AZD5396 and dMAb AZD8076 are DNA vaccines that have been created in a lab using the DNA sequence that encodes (provide the instructions) for 2 different antibodies that have activity against SARS-CoV-2. The DNA vaccines will be injected into your muscle and electroporated (a small electrical current) to increase the amount of DNA that gets into your cells making them produce more antibody.

Once the DNA is inside the muscle cell, they use the injected DNA instructions to make antibodies against SARS-CoV-2. This DNA disappears with time and does not become part of your DNA. This is not gene therapy.

The DNA vaccines used in this study also differ from other approved COVID-19 vaccinations in the timing of receiving the 2 vaccinations, which are given only days apart (Day 0 and Day 3, as described on page 4 “Dosing and Follow-Up Evaluations” section) as compared to months apart for other available COVID-19 vaccines.

Because the vaccine is made of a gene that encodes for antibodies, and not the whole or part of the SARS-CoV-2 virus, the vaccine itself cannot cause you to become infected with the SARS-CoV-2 virus. It is not known whether receiving the vaccine in this trial will prevent you from getting infected with SARS-CoV-2 during the study or in the future. It is also not known whether receiving the vaccine in this trial will prevent you from getting infected with any of the SARS-CoV-2 variants (e.g., alpha, beta, delta, and Omicron variant, etc.).

How long will I be in the study?

24 people will take part in this study. Your participation in the study will be around 18 months. If you participate in the study, you cannot have any standard of care vaccines within 14 days from the last administration of the study vaccine.

What am I being asked to do?

Before you can start the study, the study doctor or study staff will talk to you about the study and give you time to read this consent form. If you decide to take part in this research study, you will be asked to sign this consent form. Once you sign this consent, tests will be done at the screening visit to see if you are eligible to join the study.

Screening Visit:

During the screening visit the following procedures will occur:

- Health and medication questionnaire: You will answer questions about your health, your medical history, and the medications you take.
- Physical Assessment: The study doctor or nurse practitioner will do a physical exam.
- Record Vital Signs: Study staff will check your blood pressure, heart rate, listen to you breathe in and out, check your height and weight, and take your temperature.
- Electrocardiograms (ECGs): Study staff will attach leads (electrical sensing devices) to your chest to measure the electrical activity of your heart.
- Collect 30-50 mLs (2-4 tablespoons) of blood for safety testing of your blood counts, chemistry, liver and kidney functions, antibody testing for Human Immunodeficiency Virus (HIV, the virus that causes AIDS), hepatitis B and C (viruses that affect the liver), and pregnancy testing (blood, for women who are able to have children).
    - If you test positive for HIV or hepatitis B or C, by law we have to report the positive test results to the City of Philadelphia Health Department and/or the PA Department of Health. Personal identifiers such as your name, sex, date of birth,

address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements of reporting infectious diseases to the PA Health Department, please visit www.health.pa.gov and type 'Reportable Diseases' into the site search bar.

- Collect urine for urinalysis.
- A nasopharyngeal (nose) swab to rule out active COVID-19 infection.

You will be permitted to enter the study if you meet the study criteria and if study related test results are satisfactory, which will be decided by the study investigator.

Dosing and Follow-Up Evaluations

If you qualify to be in this study, you will be assigned to one of five groups (A1, A2, B, C, or D) to receive dMAb AZD5396 and dMAb AZD8076 with the CELLECTRA device, which is also investigational, and the following procedures will be complete:

Day 0 and Day 3

Evaluations will be performed on Day 0 (all groups) and Day 3 (only groups B, C, and D). The following evaluations will be performed only prior to investigational product administration:

- You will answer questions about any present or new or ongoing health conditions and medications you may be taking
- Physical examination and ECG.
- Record vital signs pre injection including heart rate, respiratory rate blood pressure, oral temperature
- Collect urine for urinalysis
    - For women who are able to become pregnant, a urine pregnancy test will be performed
- Blood collection
- Provide Memory Aid
    - You will be given a diary to record:
        - Your temperature for 4 days after each injection.
        - Any injection side effects for 7 days after each injection.
        - Any rash or skin irritation around and/or in the middle of the injection site.
        - Any medications taken.
    - The diary will be given to you at the entry visit (the day of the first investigational product administration and electroporation procedure). It will take you about 10-15 minutes to complete the diary each day. You will bring the diary back to the clinic at your next visit and at every visit afterwards until the Day 10 follow-up visit. The diary will be collected by the study staff.

You will then receive the investigational products and electroporation.

The following will be done on Day 0 and Day 3 after the investigational product administration:

- Immediately after and at 5 and 10 minutes following each injection, you will rate the amount of discomfort you experienced during the injection and at the 5 and 10-minute time points.
- Study staff will assess the injection site 30 minutes after the injection
- Your vital signs - heart rate, respiratory rate, blood pressure, and temperature will be taken

- You will have an ECG performed

You will be expected to return to the clinic for the follow up visits:

Day 7 (all groups) & Day 10 (only groups B, C, D)
The following evaluations will be performed at this visit:

- Study staff will assess the injection site to look for injection reactions
- You will answer questions about any present or new or ongoing health conditions including COVID and medications you may be taking
- Physical examination and blood collection
- Record vital signs pre injection including heart rate, respiratory rate, blood pressure, oral temperature
- An electrocardiogram
- Collect urine for urinalysis
    - For women who are able to become pregnant a urine pregnancy test will be performed

Weeks 2, 3, 4, 5, 6, 8, 12, 16, 24, 52, and 72
The following evaluations will be performed at this visit:

- You will answer questions about any present or new or ongoing health conditions including COVID and medications you may be taking
- Physical examination and blood collection
- Record vital signs pre injection including heart rate, respiratory rate, blood pressure, oral temperature
- An electrocardiogram
- Collect urine for urinalysis
    - For women who are able to become pregnant a urine pregnancy test will be performed

Weeks 32, 42, and blood testing
The following will be done at weeks 32 and 42:

- You will answer questions about any new or ongoing health conditions including COVID
- Blood collection

You may be asked to come in for repeat blood testing between Weeks 52 and 72 if needed.

CELLECTRA® Procedure (Electroporation)
To improve the effectiveness of the vaccine, instead of a regular needle and syringe, a small, hand-held device called CELLECTRA® will be used to inject the vaccine into your upper arm or thigh muscle. [redacted] This study procedure will occur with each administration of vaccine at Day 0 (all groups) and Day 3 (only groups B, C, D). The study personnel will insert the needles from

the investigational CELLECTRA® device into the muscle on your arm and then inject the vaccines. [redacted]

You will stay in the research center for a minimum of half an hour following the injection to be monitored closely for any side effects.

Below is a schedule of procedures:

Schedule of procedures:

Tests and Observations	Screen	Day 0	Day 3 (B-D) ±1d	Day 7 ±1d	Day 10 (B-D) ±1d	W2 ±2d	W3 ±2d	W4 ±2d	W5 ±2d	W6 ±2d	W8 ±2d	W12 ±7d	W16 ±7d	W24 ±7d	W32 +8w	W42 ±2w	W52 ±7d	Blood tests	W72 ±7d	Early Termi-nation
CLINICAL Assessments																				
Consent	X																			
Eligibility Assessment	X																			
Demographics	X																			
Medical history	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
Medication review	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
Vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
Physical Exam	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
ECG	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
LABORATORY Assessments																				
Blood draw	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy test	X	X	X																	
Urine Collection	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
COVID swab test	X																			
OTHER Assessments and Procedures																				
Vaccination + Electroporation		X	X																	
Diary, Pain & Discomfort Ratings		X	X																	
Injection Site Reactions		X	X	X	X															

What are the possible risks or discomforts?

Risks of dMAb AZD5396 and dMAb AZD8076 and Hylenex® Recombinant (Hyaluronidase) Delivered IM with EP using CELLECTRA® 2000

Reactions observed in patients who have received DNA vaccinations followed by electroporation with the use of the CELLECTRA® device are summarized below.

Frequency	Event
Very Common (≥10%)	• Mild Injection site pain or tenderness • Moderate Injection site pain or tenderness • Injection site redness • Injection site swelling, hardness, or scabbing • Itchiness at injection site • Not feeling well (tiredness, muscle aches, joint pain, or headache)
Common (≥1% to <10%)	• Fever
Uncommon (≥0.1% to <1%)	• Severe Injection site pain or tenderness • Injection site bruising • Nausea, lightheadedness, or dizziness
Rare (≥0.01% to <0.1%)	• None
Very Rare (<0.01%)	• Allergic reaction

Risks of hypersensitivity/anaphylaxis

Serious (but rare) hypersensitivity reactions, including anaphylaxis, have been observed when using monoclonal antibodies similar to dMAb AZD5396 and dMAb AZD8076. Allergic reactions can happen during and after injection of dMAb AZD5396 and dMAb AZD8076. Contact the study team or get medical help right away if you get any of the following symptom of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion feeling tired, wheezing, swelling of your lips, face or throat, rash including hives, itching, muscle aches, dizziness and sweating. These reactions may be severe or life threatening.

Risks of clinically significant bleeding

As any other intramuscular injections, dMAb AZD5396 and dMAb AZD8076 should be given with caution to individuals with any coagulation disorder or low blood platelet counts also called thrombocytopenia. This is important as platelets help stop bleeding by clumping and forming plugs in blood vessel injuries. The study team will review your platelet count prior to you receiving the injection. This will occur during the screening visit.

Risks of cardiovascular events

Serious cardiac adverse events have been observed in injections similar to dMAb AZD5396 and dMAb AZD8076, but these events were not common. It is not known if these events are related to the injection or underlying medical conditions. People who have a history of or are at risk of cardiac events (including history of heart attack) may be more likely to have injection related cardiac events and that is why these people are excluded from this study. Contact the study team or get medical help right away if you get any of the symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach or jaw, as well as shortness of

breath, feeling tired or weak (fatigue), feeling sick (nausea), or swelling in your ankles or lower legs.

Risks of blood draws

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body, and in rare cases, fainting or infection.

Unknown/Unforeseeable Risks and Discomforts

You may have side effects while participating in the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. The research may involve risks that are currently unknown. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away. In some cases, side effects can be serious, long lasting, or may never go away.

In addition to the risks listed above, there may be some unknown or infrequent (rare) and unforeseeable risks associated with the use of this study medication, including severe or life-threatening allergic reactions or interactions with another medication. There also is a risk of death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Reproductive Risks

Although antibodies for the treatment of COVID-19 are used during pregnancy, there are unknown effects for unborn babies. You must agree not to become pregnant or make a woman pregnant. Because of the risk involved, you and your partner must use an acceptable method of birth control that you discuss with the study staff. You must continue to use birth control until six months after you have received the investigational products. Acceptable birth control methods are listed below:

- Birth control drugs that prevent pregnancy given by pills, shots or placed under the skin
- Spermicide with barrier methods
- Male or female condoms with or without a cream or gel that kills sperm - diaphragm or cervical cap with a cream or gel that kills sperm
- Intrauterine device

If you can become pregnant, you must have a pregnancy test before you enter this study. The test must show that you are not pregnant. If you think that you or your partner may have become pregnant during the study, it is important that you inform the study doctor immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility, and may request to track your pregnancy and will report the pregnancy to the Sponsor and the IRB. You will not be allowed to breast-feed during this study. If you become pregnant, the health of your baby will be followed for a year after birth.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

There is the possibility that your body makes anti-SARS-CoV2 antibodies, which may be protective against COVD-19, but this is not known, or you may receive no direct benefit from being in this study. Information learned from this study may help those who are at risk for SARS-CoV-2 infection.

What other choices do I have if I do not participate?

Your alternative is not to be in this study and continue your normal care. If you have not been vaccinated against COVID-19, you should ask your primary doctor about receiving approved alternative COVID-19 vaccines.

Will I be paid for being in this study?

To compensate you for your time, transportation or other expenses you may incur as a participant you will receive:

[redacted]

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number to the study team. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year. If you earn more than $600 per year as a research participant, you may incur income tax liabilities.

Will I have to pay for anything?

You will not have to pay for any procedure or laboratory test related to the study itself. You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in this consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the FDA has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.

What may happen to my information and samples collected on this study?

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens

Your identifiable information and samples will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study. No personal identifiers will be retained with your information and samples. Instead, your information and samples will be identified with your unique Study ID number, and the link for this code will only be known by the study team. The study team will store the code linking your name, date of birth, and medical record number with their research study files.

Your information and samples may be stored and used for future research purposes for an indefinite amount of time. There are no plans to tell you about any of the specific research that will be done.

We may share your information and samples with other researchers within Penn. Any samples and information shared outside of the study team will not contain any personal identifiers, and no one outside the study team will have access to your identifiable information. Your samples and information may be shared with other research institutions, as well as pharmaceutical, device, or biotechnology companies. We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation. We will not share the results of any future testing that may be performed on your samples.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by maintaining all hard-copy identifiable records in a double locked environment with the study team and all electronically stored information will be maintained the University servers and University-approved platforms (like Penn Box or MicroSoft Teams).

You will likely not directly benefit from future research with your information and samples. Research with your identifiable information and samples may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information and samples, or have changed your mind, you can contact Dr. Pablo Tebas at [redacted]. Withdrawal of consent for sample storage may not be possible after the study is completed.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have

access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call [redacted].

Will I, as a subject, have access to research related information within the EMR?
The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

Will I receive the results of research testing that may be relevant to my health?

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?

The following personal health information will be collected, retained, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, email address
- Personal and family medical history
- Dates directly related to you, such as date of birth and clinic visits
- Results of tests and procedures you will undergo during this research
- Social Security Number, medical record number
- Questionnaires
- Current and past medications or therapies

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and

stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures.

This information may be disclosed to those listed below:

- AstraZeneca
- INOVIO Pharmaceuticals
- Wistar Institute
- Data Safety Monitoring Board will receive data to monitor if the trial is safe.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration (FDA) and the Department of Defense for them to evaluate the safety and efficacy of the treatments being used in this study. Representatives of the U.S. Department of Defense will have access to research records as part of their responsibilities for human subjects protection oversight of the study.

Oversight organizations

- The U.S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania’s Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending a written notice to: [redacted]. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date

MD Investigator Consent

The risks, alternatives and benefits have been reviewed with me by the investigator, and I understand what we have discussed.

Name of Subject (Please Print)	Signature of Subject	Date

I verify I have reviewed risks, alternatives, and benefits with this subject, who demonstrates good understanding.

MD Investigator (Please Print)	Signature	Date

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	A Phase 1, Open-Label, Single Center, Dose Escalation Study of the Safety and Pharmacokinetics of mAb AZD5396 and mAb AZD8076 delivered as dMAbs in Healthy Adults
Principal Investigator:	Pablo Tebas, MD [redacted]
Emergency Contact:	[redacted]
Regulatory Sponsor	Pablo Tebas, MD
Funding Sponsor	U.S. Department of Defense

Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at [redacted] for assistance (an IRB is a committee responsible for making sure that the study follows the guidelines for the protection of human research subjects).

The research study is being conducted to determine if an investigational way to deliver an antibody against COVID-19 is safe in humans. If you agree to join the study, you will be asked to complete research procedures including blood draws, physical exams, vital signs, ECGs, and study drug injections.

Your participation will last for about 18 months (1½ years).

You are not expected to receive any direct benefit from participation. The most common risks of participation are:

- Injection site reactions (such as redness, pain, inflammation, swelling, hardness, scabbing, itchiness)
- Not feeling well, tiredness, muscle aches, joint pain, or headache

These side effects (if they occur) are generally brief in duration (up to a few days). Your alternative is not to be in this study.

We encourage you to be vaccinated against COVID-19. Being vaccinated against COVID-19 will not keep you from participating in this study. If you have not been vaccinated already talk to your primary doctor if interested in approved COVID-19 vaccines. The currently authorized or approved vaccines have shown to be effective against COVID-19 while the effectiveness of this experimental new way to deliver antibodies is not known.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time.

Introduction

You are being invited to participate in a research study of two products called dMAbAZD5396 and dMAbAZD8076, given separately with a device called CELLECTRA™ 2000, for the prevention of COVID-19. These products are pieces of DNA that carry all the information for your body to make 2 different antibodies against COVID-19. This study is a clinical research trial to find out whether the administration of the two investigational (not approved by the U.S. Food and Drug Administration (FDA)) products with the investigational device (CELLECTRA™ 2000) is safe, tolerated, and can produce enough antibodies in your blood that may indicate the ability to prevent infection from COVID-19.

Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about any information or terms that you do not understand. If you decide to participate, you will be asked to sign this form.

The doctor in charge of this study at this site is Dr. Pablo Tebas. Dr. Tebas is from the University of Pennsylvania and is the Principal Investigator overseeing the entire study. Funding for this research study comes from the Department of Defense.

Why Is This Study Being Done?

The COVID-19 disease pandemic is a global health crisis. COVID-19 symptoms can be mild-to-severe respiratory illness including fever, cough, and difficulty breathing, and in the most severe cases can require mechanical ventilation or even lead to death. In the U.S. alone, there were more than 100 million confirmed cases of COVID-19 and more than 1 million deaths as of March 2023. The COVID-19 pandemic has had a severe impact on the health systems and will likely have lasting social and economic impact. Medical countermeasures are urgently needed.

While there are already vaccines approved and available so you make antibodies against COVID-19, there is a need for vaccines that will provide protection in patients that are immunosuppressed and will not mount a response to regular vaccines. This study is being done to test a new COVID-19 approach that will give your muscle cells the information to make antibodies against COVID-19 to see if it is safe and makes your muscle cells make antibodies to protect against COVID-19 in your body.

Cells contain a type of molecule called deoxyribonucleic acid (DNA). Your genes are made of DNA. DNA is different in each person. You can think of genetic characteristics as composing a large instruction book that your body reads to understand how it should be built and function. The words that make up this instruction book are represented by your DNA.

dMAb AZD5396 and dMAb AZD8076 are DNA vaccines that have been created in a lab using the DNA sequence that encodes (provide the instructions) for 2 different antibodies that have activity against SARS-CoV-2. The DNA vaccines will be injected into your muscle and electroporated (a small electrical current) to increase the amount of DNA that gets into your cells making them produce more antibody.

Once the DNA is inside the muscle cells, they use the injected DNA instructions to make antibodies against SARS-CoV-2. This DNA disappears with time and does not become part of your DNA. This is not gene therapy.

The DNA vaccines used in this study also differ from other approved COVID-19 vaccinations in the timing of receiving the vaccinations, which are given only days apart (as described on page 4, "Dosing and Follow-Up Evaluations" section) as compared to months apart for other available COVID-19 vaccines.

Because the vaccine is made of a gene that encodes for antibodies, and not the whole or part of the SARS-CoV-2 virus, the vaccine itself cannot cause you to become infected with the SARS-CoV-2 virus. It is not known whether receiving the vaccine in this trial will prevent you from getting infected with SARS-CoV-2 during the study or in the future. It is also not known whether receiving the vaccine in this trial will prevent you from getting infected with any of the SARS-CoV-2 variants (e.g., alpha, beta, delta, and omicron variant, etc.).

How long will I be in the study?

Around 39 people will take part in this study. Your participation in the study will be around 18 months (1½ years). If you participate in the study, you cannot have any other vaccines within 14 days from the last administration of the study vaccine.

What am I being asked to do?

Before you can start the study, the study doctor or study staff will talk to you about the study and give you time to read this consent form. If you decide to take part in this research study, you will be asked to sign this consent form. Once you sign this consent, tests will be done at the screening visit to see if you are eligible to join the study.

Screening Visit:

During the screening visit the following procedures will take place:

- Health and medication questionnaire: You will answer questions about your health, your medical history, and the medications you take.
- Physical Assessment: The study doctor or nurse practitioner will do a physical exam.
- Record Vital Signs: Study staff will check your blood pressure and heart rate, listen to you breathe in and out, check your height and weight, and take your temperature.
- Electrocardiograms (ECGs): Study staff will attach leads (electrical sensing devices) to your chest to measure the electrical activity of your heart.
- Collect 30-50 mLs (2-4 tablespoons) of blood for safety testing of your blood counts, chemistry, liver and kidney functions, HbA1c (average blood sugar over past 3 months), antibody testing for Human Immunodeficiency Virus (HIV, the virus that causes AIDS), hepatitis B and C (viruses that affect the liver), and pregnancy testing (blood, for women who are able to have children).
    - If you test positive for HIV or hepatitis B or C, by law we have to report the positive test results to the City of Philadelphia Health Department and/or the PA

Department of Health. Personal identifiers such as your name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements of reporting infectious diseases to the PA Health Department, please visit www.health.pa.gov and type "Reportable Diseases" into the site search bar.

- Collect urine for urinalysis.
- A nasopharyngeal (nose) swab to rule out active COVID-19 infection.

You will be permitted to enter the study if you meet the study criteria and if study-related test results are satisfactory, which will be decided by the study investigator.

Dosing and Follow-Up Evaluations:

If you qualify to be in this study, you will be assigned to one of 3 groups (E, F, or G) to receive dMAb AZD5396 and dMAb AZD8076 with the CELLECTRA™ 2000 device, which is also investigational. Cohort E will receive a higher dose level than other cohorts in the study. The following procedures will be done:

Day 0 (all groups), Day 3 (all groups), Day 28 (group G only), and Day 31 (group G only):

The following will be done before you get the study injections:

- You will answer questions about any new or ongoing health conditions and medications you may be taking
- Physical examination and ECG.
- Record vital signs pre injection including heart rate, breathing rate, blood pressure, & oral temperature
- Urine testing
  - For women who are able to become pregnant, a urine pregnancy test will be done.
- Blood collection
- Provide Memory Aid
  - You will be given a diary to record:
    - Your temperature for 4 days after each injection.
    - Any injection side effects for 7 days after each injection.
    - Any rash or skin irritation around and/or in the middle of the injection site.
    - Any medications taken.
  - The diary will be given to you at the entry visit (the day of the first vaccine injections). It will take you about 10-15 minutes to complete the diary each day. You will bring the diary back to the clinic at your next visit and at every visit afterwards until the Day 10 follow-up visit. The diary will be collected by the study staff.

You will then receive the investigational products and electroporation (vaccine injections).

The following will be done after the study injections:

- Immediately after and at 5 and 10 minutes following each injection, you will rate the amount of discomfort you feel
- Study staff will check the injection site 30 minutes after the injection
- Your vital signs (heart rate, breathing rate, blood pressure, and temperature) will be taken
- Another ECG

You will be expected to return to the clinic for the follow-up visits:

Day 7 and Day 10:
The following will be done at these visits:

- Study staff will check the injection site to look for injection reactions
- You will answer questions about any new or ongoing health conditions including COVID and medications you may be taking
- Physical examination and blood collection
- Record vital signs including heart rate, breathing rate, blood pressure, and temperature
- ECG
- Urine testing
    - For women who are able to become pregnant, a urine pregnancy test will be done

Weeks 2, 3, 4, 5, 6, 8, 12, 16, 24, 52, and 72
The following will be done at this visit:

- You will answer questions about any new or ongoing health conditions including COVID and medications you may be taking
- Physical examination and blood collection
- Record vital signs including heart rate, breathing rate, blood pressure, and temperature
- ECG
- Urine testing
    - For women who are able to become pregnant, a urine pregnancy test will be done

Weeks 32, 42, and blood testing
The following will be done at weeks 32 and 42:

- You will answer questions about any new or ongoing health conditions including COVID
- Blood collection

You may be asked to come in for repeat blood testing between Weeks 52 and 72 if needed.

CELLECTRA™ 2000 Procedure (Electroporation):
To improve the effectiveness of the vaccine, instead of a regular needle and syringe, a small, hand-held Applicator will be used to inject the vaccine into your upper arm or thigh muscle. [redacted] This study procedure will take place with each administration of vaccine at Days 0 and Day 3 (all groups), and on Days 28 and 31 (group G only). [redacted]

You will stay in the research center for a minimum of half an hour following the injection to be monitored closely for any side effects.

Schedules of procedures:

Groups E and F:

	Screen	Day 0	Day 3	Day 7	Day 10	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 8	Wk 12	Wk 16	Wk 24	Wk 32	Wk 42	Wk 52	Extra blood tests	Wk 72	Early Ending
Consent	X																			
Eligibility	X																			
Medical history	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
Medication review	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
Physical exam	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
ECG	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
Blood draw	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy test	X	X	X																	
Urine test	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
COVID test	X																			
Vaccine injections		X	X																	
Diary, pain ratings		X	X																	
Injection site checks		X	X	X	X															

Group G:

	Screen	Day 0	Day 3	Day 7	Day 10	Wk 2	Wk 3	Day 28	Day 31	Wk 5	Wk 6	Wk 8	Wk 12	Wk 16	Wk 24	Wk 32	Wk 42	Wk 52	Extra blood tests	Wk 72	Early Ending
Consent	X																				
Eligibility	X																				
Medical history	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X
Medication review	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
Physical exam	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
ECG	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
Blood draw	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pregnancy test	X	X	X					X	X												
Urine test	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X		X	X
COVID test	X																				
Vaccine injections		X	X					X	X												
Diary, pain ratings		X	X					X	X												
Injection site checks		X	X	X	X			X	X												

What are the possible risks or discomforts?

Risks of dMAb AZD5396 and dMAb AZD8076 and Hylenex® Recombinant (Hyaluronidase) Delivered IM with EP using CELLECTRA™ 2000

Reactions observed in patients who have received DNA vaccinations followed by electroporation with the use of the CELLECTRA™ 2000 device are summarized below.

Frequency	Reaction
Very Common (≥10%)	• Mild injection site pain or tenderness • Moderate injection site pain or tenderness • Injection site redness • Injection site swelling, hardness, or scabbing • Itchiness at injection site • Not feeling well (tiredness, muscle aches, joint pain, headache)
Common (≥1% to <10%)	• Fever
Uncommon (≥0.1% to <1%)	• Severe injection site pain or tenderness • Injection site bruising • Nausea, lightheadedness, or dizziness
Rare (≥0.01% to <0.1%)	• None
Very Rare (<0.01%)	• Allergic reaction

Risks of hypersensitivity/anaphylaxis

Serious (but rare) hypersensitivity reactions, including anaphylaxis, have been observed when using monoclonal antibodies similar to dMAb AZD5396 and dMAb AZD8076. Allergic reactions can happen during and after injection of dMAb AZD5396 and dMAb AZD8076. Contact the study team or get medical help right away if you get any of the following symptom of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, fast or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness, and sweating. These reactions may be severe or life threatening.

Risks of clinically significant bleeding

As with any other intramuscular injections, dMAb AZD5396 and dMAb AZD8076 should be given with caution to people with any coagulation (clotting) disorder or low blood platelet counts, also called thrombocytopenia. This is important as platelets help stop bleeding by clumping and forming plugs in blood vessel injuries. The study team will check your platelet count before you receive the injections. This will take place during the screening visit.

Risks of cardiovascular events

Serious cardiac adverse events have been observed in injections similar to dMAb AZD5396 and dMAb AZD8076, but these events were not common. It is not known if these events are related to the injection or underlying medical conditions. People who have a history of or are at risk of cardiac events (including history of heart attack) may be more likely to have injection-related cardiac events and that is why these people are excluded from this study. Contact the study team or get medical help right away if you get any of the symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach, or jaw, as well as shortness of breath, feeling tired or weak (fatigue), feeling sick (nausea), or swelling in your ankles or lower legs.

Risks of blood draws
Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body, and in rare cases, fainting or infection.

Unknown/Unforeseeable Risks and Discomforts
You may have side effects while participating in the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. The research may involve risks that are currently unknown. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away. In some cases, side effects can be serious, long lasting, or may never go away.

In addition to the risks listed above, there may be some unknown or infrequent (rare) and unforeseeable risks associated with the use of this study medication, including severe or life-threatening allergic reactions, interactions with another medication, or death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Reproductive Risks
Although antibodies for the treatment of COVID-19 are used during pregnancy, there are unknown effects for unborn babies. You must agree not to become pregnant or make a woman pregnant. Because of the risk involved, you and your partner must use an acceptable method of birth control that you discuss with the study staff. You must continue to use birth control until six months after you have received the investigational products. Acceptable birth control methods are listed below:

- Birth control drugs that prevent pregnancy given by pills, shots, or placed under the skin
- Spermicide with barrier methods
- Male or female condoms with or without a cream or gel that kills sperm - diaphragm or cervical cap with a cream or gel that kills sperm
- Intrauterine device (IUD)

If you can become pregnant, you must have a pregnancy test before you enter this study. The test must show that you are not pregnant. If you think that you or your partner may have become pregnant during the study, it is important that you tell the study doctor right away. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility, and may request to track your pregnancy and will report the pregnancy to the Sponsor and the IRB. You will not be allowed to breast-feed during this study. If you become pregnant, the health of your baby will be followed for a year after birth.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
There is the possibility that your body makes anti-SARS-CoV2 antibodies, which may be protective against COVD-19, but this is not known, or you may receive no direct benefit from

being in this study. Information learned from this study may help those who are at risk for SARS-CoV-2 infection.

What other choices do I have if I do not participate?

Your alternative is not to be in this study and continue your normal care. If you have not been vaccinated against COVID-19, you should ask your primary doctor about receiving approved alternative COVID-19 vaccines.

Will I be paid for being in this study?

To compensate you for your time, transportation, or other expenses you may incur as a participant, you will receive:

[redacted]

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number to the study team. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year. If you earn more than $600 per year as a research participant, you may incur income tax liabilities.

Will I have to pay for anything?

You will not have to pay for any procedure or laboratory test related to the study itself. You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and bloodwork. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed on page 1 of this consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the FDA has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.

What may happen to my information and samples collected on this study?

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens

Your identifiable information and samples will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study. No personal identifiers will be retained with your information and samples. Instead, your information and samples will be identified with your unique Study ID number, and the link for this code will only be known by the study team. The study team will store the code linking your name, date of birth, and medical record number with their research study files.

Your information and samples may be stored and used for future research purposes for an indefinite amount of time. There are no plans to tell you about any of the specific research that will be done.

We may share your information and samples with other researchers within Penn. Any samples and information shared outside of the study team will not contain any personal identifiers, and no one outside the study team will have access to your identifiable information. Your samples and information may be shared with other research institutions, as well as pharmaceutical, device, or biotechnology companies. We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation. We will not share the results of any future testing that may be performed on your samples.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by maintaining all hard-copy identifiable records in a double-locked environment with the study team and all electronically stored information will be maintained on the University servers and/or University-approved platforms (like Penn Box or Microsoft Teams).

You will likely not directly benefit from future research with your information and samples. Research with your identifiable information and samples may help others by improving our understanding of health and disease, improving healthcare, making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information and samples, or have changed your mind, you can contact Dr. Pablo Tebas at [redacted]. Withdrawal of consent for sample storage may not be possible after the study is completed.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e., your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call [redacted].

Will I, as a subject, have access to research related information within the EMR?
The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

Will I receive the results of research testing that may be relevant to my health?

Many tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?

The following personal health information will be collected, retained, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, email address
- Personal and family medical history
- Dates directly related to you, such as date of birth and clinic visits
- Results of tests and procedures you will undergo during this research
- Social Security Number (in order to pay you)
- Medical record number
- Questionnaires
- Current and past medications or therapies

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical research management system (CRMS). A clinical research management system (CRMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CRMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and study teams
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures.

This information may be disclosed to those listed below:

- AstraZeneca
- INOVIO Pharmaceuticals
- Wistar Institute
- Data Safety Monitoring Board will receive data to monitor if the trial is safe.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration (FDA) and the Department of Defense for them to evaluate the safety and effectiveness of the treatments being used in this study. Representatives of the U.S. Department of Defense will have access to research records as part of their responsibilities for human subject protection oversight of the study.
- The U.S. Office of Human Research Protections (OHRP)
- Greenphire

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a

purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending a written notice to: [redacted] If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page 1 of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date

MD Investigator Consent

The risks and benefits of the investigational products have been reviewed with me by the investigator, and I understand what we have discussed.

Name of Subject (Please Print)	Signature of Subject	Date

I verify I have reviewed risks and benefits of the investigational products with this subject, who demonstrates good understanding.

MD Investigator (Please Print)	Signature	Date