MAIN INFORMED CONSENT FORM
AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute of Allergy and Infectious Diseases / "Adaptive Platform Treatment Trial for Outpatients with COVID-19 (Adapt Out COVID)"**
Protocol Number:	**ACTIV-2/A5401**
Principal Investigator: (Study Doctor)	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

SUMMARY

PURPOSE

This is a research study and your participation in this study is voluntary. The purpose of this study is to evaluate the ability of various experimental drugs to improve health outcomes for people with COVID-19. We also want to see if these study drugs are safe, and if these study drugs can stop the disease process and prevent hospitalization. This study is designed to quickly identify safe and effective drugs that may treat COVID-19.

STUDY DRUG

Study drug will be either an active drug or a placebo. A placebo looks like a "real" drug, but it does not have any active drug in it.

As drugs are recommended for the treatment of COVID-19 symptoms, some of them will be selected for testing in this study. Therefore, there may be different study drugs being used as part of the study at different times. You will receive information about specific study drugs being tested at this time in a separate consent form. Regardless of how many study drugs are being tested, you will only receive one study drug (or placebo).

	If, during the course of the study, a standard treatment for COVID-19 is identified, that treatment will be substituted for placebo.
NUMBER OF PARTICIPANTS	For each study drug being tested, a minimum of 110 people will receive that study drug and an equal or smaller number will receive placebo. If a study drug appears to be safe and effective when 110 people have received it, then more people will be enrolled so that up to 1000 receive that drug. Again, an equal or smaller number will receive placebo.
LENGTH OF STUDY	Your participation in this study will last between 24 weeks (6 months) and 72 weeks (18 months), depending on which study drug you receive.
REQUIRED ACTIVITIES	If you are in this study, the following study procedures are required: • you will record your symptoms • you will provide blood samples • you will provide self-collected nasal swab samples • you may have nasopharyngeal swabs (deep nasal swabs) collected by a study staff person
RISKS	There are some risks that are specific to the study drug that you might receive. We will tell you about those risks in the second part of this consent process.
BENEFITS	If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. It is also possible that you will receive no benefit from being in this study. Information learned from this study may help others who have COVID-19.
OTHER CHOICES	Instead of being in this study, you have the option of: • treatment with prescription drugs available to you through your health care provider • treatment with other experimental drugs, if you qualify • no treatment

INTRODUCTION

You are being asked to take part in this research study because you have been diagnosed with SARS-CoV-2 and have symptoms of the disease it causes, which is commonly known as COVID-19. This study is sponsored by the National Institutes of Health (NIH). The study doctor in charge of this study at this site is listed on the first page of this form. Before you decide if you want to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign and date this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

SARS-CoV-2 is a new virus that has caused a widespread outbreak of an illness called COVID-19. In some people, it causes a mild to moderate symptoms, like a "cold." In others, this virus can cause a pneumonia (an inflammation of the lungs), which can be serious and life threatening. There is no proven treatment for COVID-19 for people who are not sick enough to be hospitalized.

For each study drug that is tested in this study, there could be two study parts. In the first part, we will see if the study drug is safe. We will also see if it can decrease how long people have COVID-19 symptoms and if it can help get rid of SARS-CoV-2 virus more than the placebo. Study drugs that appear to be safe and to work better than the placebo in the first part of the study will be tested in the second part of the study.

In the second part of the study, we will continue to test how safe the study drug is. We will also continue to compare it to a placebo to see if it can reduce the number of people who have to go into the hospital or who die from COVID-19.

You will be told which part of the study is open for enrollment during this consent process. At each stage, new study drugs may be added (in other words, multiple study drugs may be studied at one time).

The study is designed to rapidly evaluate new therapies for COVID-19. This could mean that the study finds that a study drug that you were started on will not be studied further. If this happens, we will tell you. If you agree we would like you to continue to participate in the study and have all of the study visits, but this is your choice. We will not ask you to stay on the study drug if early results suggest that the study drug is not safe.

If you are randomized (assigned by chance, like flipping a coin or rolling dice) to an active study drug in the first part of the study that is selected to be tested in the second part of the study, you will not be notified of this decision.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

Location of Study Visits

Your study visits will take place in person or remotely. You and the study staff at your site will discuss the location for each visit.

- In-person visits will take place at the clinic, at your home, or at another non-clinic location
- Remote visits will take place over the phone or via telemedicine systems approved for use at your site

Information Collected at Screening

There is some information that we collect on everyone who is screened for this study. As part of your screening visit, some demographic (for example, age, gender, race), clinical (for example, disease condition, diagnosis), and laboratory values will be collected from you.

We will collect this information even if you do not enroll in this study. This information is collected so that researchers may determine whether there are patterns and/or common reasons why people do not join a study.

Blood Drawn
The site staff can tell you how much blood will be collected at any particular visit.

Screening Visit
If you would like to be in this study, after you have read, signed and dated this consent form, you will have a screening visit to make sure you meet the requirements for joining the study. This visit will take about 1 hour.

At this visit:
- study staff will review your history and confirm that you have tested positive for SARS-CoV-2 infection.
- you will be asked about symptoms you are experiencing.
- study staff will ask you about any health conditions you have and questions about your health in general.
- study staff will ask you about your medication history and any medications you are taking.
- you may have a brief physical exam if your screening visit takes place in person.

Entry Visit
If you qualify for the study, you will have an entry visit. This visit might occur on the same day as your screening visit. At this visit, you will be randomly assigned (like flipping a coin or rolling dice) to a study group. You and the study staff will not be able to choose which study treatment group you are in. You will not know whether you are receiving active study drug or placebo. We will tell you more about the study treatment groups that you might be in during the second part of this consent process.

Also at the Entry visit:
- you will have a physical exam and answer questions about your medical history and any medications you are taking or have taken in the past.
- you will be asked about symptoms you are experiencing.
- you will be asked about your smoking status and history.
- the study staff will ask if anyone else in your household has been diagnosed with SARS-CoV-2 infection.
- you will be asked to provide your home address.
- you will be asked to provide contact information for people the study staff could contact in case we cannot reach you for a study visit. You will need to tell these people that you are in the study, and that they could receive a call from study staff. If study staff cannot reach you after two tries (separated by 24 hours), they will call one of the people you have identified.
- you will be asked to provide your health care provider contact information, like your regular physician or commonly used clinic and hospital.
- you will receive a kit that includes information about the study, instructions and supplies for self-collection of certain samples, a diary in which you will record how you are feeling, instructions on what to do if you have worsening symptoms, and contact information for the study staff.
- you will complete your first entry in the study diary with the study staff to make sure that you understand how to complete the study diary.
- a swab will be collected from your nose. This swab is used to detect viruses. You will place a swab in each nostril and rotate the swab several times. Study staff will provide you with further instructions about the nose swabs.

- you will have blood drawn. This blood will be used for the following tests:
    - to find out the levels of SARS-CoV-2 virus, inflammation markers, and clotting factors in your blood.
    - for future study-required testing.
- you will start study drug. Details of this are provided in the next part of the consent.

If you participate in the first part of the study:

- you will have a second swab collected from your nose. For this swab, the site staff will insert a different kind of swab into your nostril. The swab will be placed deep towards to the back of your throat. The swab will be left in place for several seconds and then slowly removed. This procedure is uncomfortable and it might make you gag or make your nose bleed.

Study Visits

After the Entry visit, your study visits and evaluations will be different depending on whether you are in the first part of the study or the second part of the study.

IF YOU ARE IN THE FIRST PART OF THE STUDY:

Daily on Days 1-14

You will collect a nose swab every day on days 1-14. On some of these days, you will collect the swab on your own and save it at home. You will record the time you collected your nose swab. You will be given instructions for how and when to return the swabs to the study staff.

Daily on Days 1-28

You will record your symptoms in your study diary at about the same time every day. If you are not feeling well, someone can help you by writing the responses down for you, but the responses should come from you.

You will receive a reminder every day on days 1-28 to complete your study diary. This reminder may be by telephone, text message, email, or other method that you give permission for.

Study Visits on Days 3, 7, 14, 28

At these visits:

- you will have a brief physical exam and answer questions about any medications you are taking.
- the study staff will ask you if there are any updates to the contact information for the people you have identified.
- you will review the entries in your study diary with study staff. On day 28, the study staff will collect your diary.
- the study staff will ask you if anyone else in your household has been diagnosed with SARS-CoV-2 infection. (Day 28)
- you may have blood drawn. This blood will be used for the following tests:
    - to find out the levels of SARS-CoV-2 virus, inflammation markers, and clotting factors in your blood.
    - for future study-required testing.
- the site staff will collect a nasal swab as described above.
- you will also collect your own nasal swab

Study Visits at Weeks 12 and 24
At these visits:

- you will have a brief physical exam (Week 24)
- you will answer questions about any medications you are taking.
- at week 12, the study staff will ask you if there are any updates to the contact information for the people you have identified.
- the study staff will ask you if anyone else in your household has been diagnosed with SARS-CoV-2 infection.
- you will answer questions about any potential COVID-19 related symptoms or conditions you have experienced.
- at week 24, you will have blood drawn. This blood will be used for the following tests:
    - to find out the levels of inflammation markers and clotting factors in your blood.
    - for future study-required testing.

Additional Study Visits
Study visits may be required after week 24. This will depend on the study drug/placebo you received. Details are listed in the consent which discusses the study drug you might receive.

IF YOU ARE IN THE SECOND PART OF THE STUDY:

Days 3, 7, and 14
You will collect a nose swab on each of these days. You will collect the swabs on your own and save them at home. You will be given instructions for how and when to return the swabs to the study staff.

Daily on Days 1-28
You will record your symptoms in your study diary at about the same time every day. If you are not feeling well, someone can help you by writing the responses down for you, but the responses should come from you.

You will receive a reminder every day on days 1-28 to complete your study diary. This reminder may be by telephone, text message, email, or other method that you give permission for.

Study Visits on Days 3, 7, and 14
At these visits:

- you will answer questions about how you are feeling and any medications you are taking.
- the study staff will ask you if there are any updates to the contact information for the people you have identified.
- you will review the entries in your study diary with study staff.

Study Visit on Day 28
At this visit:

- you will have a brief physical exam and answer questions about any medications you are taking.
- the study staff will ask you if there are any updates to the contact information for the people you have identified.
- you will review the entries in your study diary with study staff and the study staff will collect your diary.

- the study staff will ask you if anyone else in your household has been diagnosed with SARS-CoV-2 infection.
- you will collect a swab from your nose as described above.
- you will have blood drawn. This blood will be used for the following tests:
    - to find out the levels of inflammation and clotting factors are in your blood.
    - for future study-required testing.

Study Visits at Weeks 12 and 24

At these visits:

- you will have a brief physical exam (Week 24)
- you will answer questions about any medications you are taking.
- at week 12, the study staff will ask you if there are any updates to the contact information for the people you have identified.
- the study staff will ask you if anyone else in your household has been diagnosed with SARS-CoV-2 infection.
- you will answer questions about any potential COVID-19 related symptoms or conditions you have experienced.
- at week 24, you will have blood drawn. This blood will be used for the following tests:
    - for future study-required testing.

Additional Study Visits

Study visits may be required after week 24. This will depend on the study drug/placebo you received. Details are listed in the consent which discusses the study drug you might receive.

Early Discontinuation

If at any point in the study you want to stop participating in the study, you must contact the study site immediately. The study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

If you have not withdrawn consent but must discontinue participation in the study after starting study drug, the study site will attempt to obtain information regarding vital status (whether you are living or have died) from other sources, such as family members, other secondary contacts that you have provided, or clinical records.

WILL I RECEIVE THE RESULTS OF ANY TESTS?

Some of the blood that is collected from you will be stored and tested later. Some of these tests will be done after you are done with the study, and other tests are not yet approved by the FDA and are still considered “research” tests. For these reasons, you will not receive the results of the tests to:

- check levels of SARS-CoV-2 in your blood and nasal swabs.
- check how well your blood clots.
- check the level of inflammation markers and clotting factors in your blood.
- check if your body developed antibodies to SARS-CoV-2.

You will be told of any new information learned during the course of the study that might cause you to change your mind about staying in the study.

At the end of the study, you will be told when study results may be available and how to learn about them. As with all studies, if we find out important information that may affect your care, you will be provided with those results.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

In the first part of the study, 110 people will receive each study drug and a similar number of people will receive placebo. If the study proceeds to the second part for a particular study drug, up to 1000 participants will receive that study drug and a similar number will receive placebo.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study between 24 weeks (6 months) and 72 weeks (18 months), depending on which study drug you receive.

WHY WOULD THE STUDY DOCTOR TAKE ME OFF THIS STUDY EARLY?

The study doctor may need to take you off the study early without your permission if:
- the study is stopped or cancelled.
- your health care provider requests that you stop participating in the study.
- you do not receive the first dose of study drug when you start the study.

The study doctor may also need to take you off the study drug without your permission if:
- you are taking other medications that should not be taken with the study drug.
- continuing the study drug may be harmful to you.

If you must stop taking the study drug before you are finished with the study, the study doctor will ask you to continue to be part of the study and return for study visits and procedures.

WHAT HAPPENS IF I DECIDE TO PERMANENTLY STOP TAKING THE STUDY DRUG(S)?

If you must permanently stop taking study drug before your study participation is over, the study staff will discuss other options that may be of benefit to you.

WHAT HAPPENS WHEN I FINISH THE STUDY?

After you have completed your study participation, the study will not be able to continue to provide you with the study drug you received on the study.

If continuing to take these or similar study drugs/agents would be of benefit to you, the study staff will discuss how you may be able to obtain them.

WHAT ARE THE RISKS OF THE STUDY?

<u>Risks and Discomforts associated with the Study Drug</u>
There are risks to taking part in any research study. The effectiveness of the study drug is not known. One risk is that the study drug may not stop you from becoming sicker, being hospitalized, or dying from SARS-CoV-2.

There is a risk of serious and/or life-threatening side effects when non-study medications are taken with the study drug. For your safety, you must tell the study doctor or study nurse about all medications you are taking before you start the study.

Since the study drug, or use of the study drug, is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

There are some risks that are specific to the study drug that you might be assigned to. We will tell you about those risks in the second part of this consent process.

Risks of Blood Draw

Having blood drawn may cause some discomfort, bleeding, bruising, and/or swelling where the needle enters the body, and in rare cases it may result in fainting. There is a small risk of infection.

Risks of Nose Swabs

Nose swabs might make you gag or sneeze. They may also cause discomfort or cause your nose to bleed.

Effect on Future Vaccination

Vaccines against the virus that causes COVID-19 are becoming available. It is currently unknown how long people should wait to receive a COVID-19 vaccine after having COVID-19, since the body's own immune response may offer protection for several months. We also do not know how your body’s immune response to COVID-19 vaccines may be affected by the study drugs being evaluated in this study. If there are potential effects and recommendations for a given study drug, they will be reviewed with you.

Risks of Transmitting Personal Information over the Internet

As part of this study you may be asked to use an electronic study diary. The electronic diary used in this study will transmit your personal information via the internet. You may also be asked to communicate with researchers via text message, email, or using a Website. The diary and all other digital or web-based technologies used in this study are designed to secure your personal information from accidental loss and from unauthorized access, use, alternation, and disclosure.

Unfortunately, however, the transmission of information via the internet and mobile platforms is not completely secure and the security of your personal information transmitted using the study diary or Website cannot be guaranteed.

ARE THERE RISKS RELATED TO PREGNANCY AND BREASTFEEDING?

In the second part of the consent process we will tell you about the specific drugs that you might receive and whether they have any risks related to pregnancy and breastfeeding.

If you become pregnant while on study, the study staff would like to obtain information from you about the outcome of the pregnancy (even if it is after your participation in the study ends).

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. It is also possible that you may receive no benefit from being in this study. Information learned from this study may help others who have COVID-19.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?

Instead of being in this study you have the choice of:

- treatment with prescription drugs available to you from your health care provider.
- treatment with other experimental drugs, if you qualify.
- no treatment.
- There may be a COVID treatment available to you through a US FDA Emergency Use Authorization (EUA). Under an EUA, the FDA may allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions Your site will tell you about any COVID treatments that might be available to you through an EUA.

Please talk to your study doctor about these and other choices available to you. Your study doctor will explain the risks and benefits of these choices.

WHAT ABOUT CONFIDENTIALITY?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have gotten a Certificate of Confidentiality from the US Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Any publication of this study will not use your name or identify you personally.

Your records may be reviewed by the US Food and Drug Administration (FDA), the AIDS Clinical Trial Group (ACTG), the US Office for Human Research Protections (OHRP), or other local, US, and international regulatory entities as part of their duties, Advarra IRB (institutional review board, a committee that protects the rights and safety of participants in research), National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, and their designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

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.

When samples are no longer needed for this study, the ACTG may want to use them in other studies and share them with other researchers. These samples are called “extra samples.” The ACTG will only allow your extra samples to be used in other studies if you agree to this.

Identifiers will be removed from your samples and from any private information that has been collected about you. This means that no one looking at the labels or at other information will be able to know that the samples or information came from you.

You will not be paid for your samples. Also, a researcher may make a new scientific discovery or product based on the use of your samples. If this happens, there is no plan to share any money with you.

If you agree to these extra samples to be used for future studies, you will be asked to sign and date a separate consent form.

WHAT IF THE SITE CAN NO LONGER REACH ME DURING THE STUDY?

If you cannot be reached after two attempts to contact you (with 24 hours between attempts), study staff may try to contact you through the family, friends, or acquaintances you provided at screening and updated at each visit.

If you are still unable to be reached, we will attempt to obtain information about your status (whether you are living or have died) by contacting your health care provider (if you agree) or by accessing publicly available records (you do not have to give your permission for us to access these records).

WHAT ARE THE COSTS TO ME?

There will be no cost to you for study-related visits or procedures. If you require medical care as a result of taking study drug, it is possible that your insurance company will not pay for these costs because you are taking part in a research study. Costs related to acute care/hospitalization will not be covered by the study.

WILL I RECEIVE ANY PAYMENT?

You will be paid [redacted] each for Screening, Study Entry/Day 0, Day 3, Day 7, Day 14, Day 28, Week 12, and Week 24. You will be paid following each completed visit.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

If you have any questions regarding your compensation for participation, please contact the study staff.

WHAT HAPPENS IF I AM INJURED?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries.

The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the NIH.

You will not be giving up any of your legal rights by signing and dating this consent form.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study drug used in this study. Participants using the study drug in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. If funds are appropriated by Congress, compensation for injuries may be available to you under this Countermeasures Injury Compensation Program (CICP). To find out more about the Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your decision will not have any impact on your participation in other studies and will not result in any penalty or loss of benefits to which you are otherwise entitled.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants.

If you have any questions about your rights as a research participants, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00045266.

Contacting Your Health Care Provider

With your permission, for which you would need to sign a waiver, study staff may contact your health care provider or hospital(s) where you might receive care to determine if you have been hospitalized or died while in the study, and the cause of death. You can still participate in this study even if you do not give us permission to contact your health care provider or hospital(s).

Will you allow us to contact your health care provider or hospital(s) to obtain this information?

_____ YES (initials)

_____ NO (initials)

If you said Yes, please list the names of your health care provider and the hospitals you would likely be admitted to, below:

_____
_____
_____
_____

Would you like us to contact your primary health care providers to inform them of your participation in this study?

_____ YES (initials)

_____ NO (initials)

If you said Yes, please list the names of your health care provider, below, and we will inform them of your participation in this study:

_____
_____
_____
_____

Genetic Testing

Your body, like all living things, is made up of cells. Cells contain deoxyribonucleic acid, also known as "DNA". DNA is like a string of information put together in a certain order. Parts of the string make up "genes". Genes contain instructions on how to make your body work and fight disease. Differences or changes in DNA explain some of the physical differences among people. These differences partly explain why some people get diseases like cancer or diabetes while others do not. Genetic testing looks at the differences in people's DNA. This testing also looks at how differences affect health and the body's response to disease and treatment.

If you agree, some of your blood that is collected may be used to study whether there are genetic differences in how sick people get when they are infected with SARS-CoV-2 or how they respond to study drugs. This genetic testing might include whole genome sequencing (WGS). "Sequencing" is looking at the order of a person's genes to see how this order is different from the order of most people.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

You do not have to agree to participate in this genetic testing. Even if you do not agree, you can still participate in the rest of the study.

Please put your initials below to indicate your choice:

_____ (initials) I understand and I agree to this use of my samples

OR

_____ (initials) I understand but I do not agree to this use of my samples

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below and date it.

Participant's Name (print)	Participant's Signature and Date
Participant's Legally Authorized Representative (As appropriate)	Legally Authorized Representative (print) Signature and Date
Study Staff Conducting Discussion (print)	Study Staff's Signature and Date Consent
Witness's Name (print)	Witness's Signature and Date (As appropriate)

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the National Institute of Allergy and Infectious Diseases.
- Representatives of PPD.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study.
- A data safety monitoring board which oversees this study.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.

- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____	_____
Participant's Name (print)	Participant's Signature and Date
_____	_____
Participant's Legally Authorized Representative (As appropriate) (print)	Legally Authorized Representative Signature and Date
_____	_____
Witness's Name (print) (As appropriate)	Witness's Signature and Date