SCREENING CONSENT TO TAKE PART IN THE SCREENING PROCESS FOR A RESEARCH STUDY
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor/ Study Title:	**FHI Clinical (FHIC)/Joint Program Executive Office (JPEO) of the U.S. Department of Defense (DoD) / "Early Treatment and Post-Exposure Prophylaxis of COVID-19 - Adaptive Platform Trial (PROTECT-APT 1)"**
Protocol Number:	**PCO6**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This screening consent form describes information on procedures that you will undergo during the screening process for this study. The information collected during the screening process will help you and the study doctor to decide whether you will or will not be eligible to take part in this study.

If you have questions at any time during the screening process or about the study, we encourage you to ask the study staff. The study staff will answer any questions you may have to completely understand while deciding to continue with the screening process. After all your questions have been answered, if you still wish to take part in the screening process, you will be asked to sign and date this screening informed consent form.

Why have you been asked to take part in the screening process for this study?
You are invited to take part in the screening portion of the study because you may have COVID-19 and are having symptoms OR you have been in contact with someone who has tested positive for COVID-19. To participate in the study, you need to go through the screening process.

Based on the results of the screening process, the study doctor and/ or study staff will determine if you qualify for the study. If you qualify for the study, and you decide to continue with the study enrollment, you will be enrolled in the study.

Once your eligibility is confirmed, additional information will be given to you about the study drug and whether you will receive a study drug or placebo. A placebo looks identical to the study drug being tested but it does not have any active drug in it.

What is the purpose of screening?
The purpose of screening for this study is to see if individuals like yourself who are interested are also eligible to participate. In this study, we want to test new drugs to treat or prevent COVID-19 infection. We also want to learn more about the disease and how we can better care for and treat people with COVID-19.

Based on the results of your screening process and as we begin more studies, there may be multiple study drug options you could receive if you decide to participate. These study drug(s) are not approved by the United States Food and Drug Administration (FDA) for general use by the public. However, we have told the FDA about this study, and they have given us permission to conduct this study.

What will you be asked to do if you decide to do the screening part of the study?
If you agree to be screened, you will be asked to sign and date this Screening Informed Consent form and the Authorization to Use and Disclose Protected Health Information before any study activities are started. The screening visit may be conducted remotely (over the phone or via a video call) or in person.

During the first step of the screening process, the study doctor or study staff will ask you some questions about your health history, demographics, vaccination history, the medications you may be taking and your present condition, including your exposure to COVID-19 or sickness due to COVID-19. You do not have to answer any questions if you do not want to answer and may stop this interview at any time. The study staff will do a physical exam to check your vitals, height, and weight. They will also take a blood draw and ask you for a pregnancy test (when applicable). A nasal swab will be collected to test for COVID-19. You will be informed of the results of your COVID test. If your screening visit is done remotely, the nasal swab will need to be collected at the study site within 24 hours after screening. The study doctor may be required by law to report the results of these tests to the local health authority. You will be asked to complete a questionnaire daily for the first 4 weeks of the study and periodically until the end of your participation. You may either do the screening part remotely and then come in the next day to finish enrolling or you can complete both the screening and enrollment activities on the same day you visit the study site.

If you agree to participate and are found eligible for the study, you will be assigned to a study drug group. Each study drug group includes a drug being studied (study drug) or a control (placebo). Your assignment to a study drug group is random, like the "flip of a coin." As this research study can test more than one study drug at a time, there may be more than one study drug group available. If that is the case, you will have an equal chance of being assigned to one of the study drug groups that you are eligible for. For example, if you are eligible for 3 study drug groups, you will have a 1 in 3 chance of being assigned to a particular study drug group. Each study drug group may have additional screening tests or procedures to figure out if you are eligible for that group or not. The study staff will provide you information about each of the study drugs that you may be eligible for, and you will receive a separate consent form for each study drug group before completing these tests or procedures. If you are still eligible, you will be assigned to a study drug group.

You will then be assigned to either the study drug or the control within the study drug group are assigned to. Your assignment to the study drug or control is also random. Your chance of being

assigned to the study drug or control will depend on the number of study drug groups available in this research study and if they are sharing the control group. If there is only one study drug group available or if they are not sharing the control group, you will have a 1 to 1 (or equal) chance of being assigned to the study drug or the control. If two study drug groups are available and they are sharing the control group, you will have a 2 to 1 chance of receiving the study drug or the control. If three study drug groups are available and they are sharing the control group, you will have a 3 to 1 chance of receiving the study drug or control, and so forth.

You will not be able to choose the study drug group you are assigned to or whether you are assigned to the study drug or control within that group. Once you are enrolled in a study drug group, neither you, your study doctor, and the study staff at your study site will know whether you are receiving the study drug or control.

After your enrollment visit, there will be up to seven (7) follow-up visits in the study. Depending on the visit, these visits may be completed in person or remotely. In person visits will take place at the study site, while remote visit may take place outside the study site. In conclusion, the study staff may require you to provide blood and/or nasal swab samples, clinical assessments, and complete study questionnaire, as needed. You will be able to contact study staff with questions at any time during the study.

Who may participate in the screening process?
Adults, 18 years or older, who have COVID-19 or have been near someone with COVID-19 are eligible to participate in the study. Your participation in the screening process is completely voluntary on your part. Should you decide not to participate, it will not affect your relationship with study site or your right to receive medical care or any service you are entitled to. Should you decide to participate, you are free to withdraw your consent and stop your participation at any time without affecting your care at the study site.

If you choose to join the study, your participation will last for 3 months (12 weeks). This is a multi-center study that will be conducted in both domestic and international study sites.

Am I providing my identifiable health information or my identifiable sample as part of this screening process?
You will be asked to provide us with your full legal name, your address, your email address, and your phone number so that our study staff members may reach you in case it becomes necessary during the screening process. Your health information and samples will be assigned a unique numerical code that will not contain any personally identifying information during the screening process. This is done to protect and keep your information confidential. Some of your deidentified transcriptomics, laboratory data, and associated metadata may be deposited into databases maintained by the U.S National Institutes of Health. Access and use of these data will require approval of ethics regulatory bodies.

What are the risks and/or discomforts you might experience if you take part in the screening part of this study?
Potential risk from the screening process includes possible discomfort or mild bleeding from the nasal swab. The nasal swab may also cause you to gag, cough or vomit. You may feel dizzy or faintish from the blood draw or bruising, bleeding, soreness at site where blood was drawn.
Since these are study drugs, there may be other risks that are unknown. In addition, there may be some possible side effects with taking the study drug or medications that may interact with the study drug. The study staff will thoroughly go over each side effect and medications that may interact with the study drug during once you have been assigned to a study drug.

Although efforts are made to protect the information collected during the screening process, there is always a risk that someone could get access to the personal information in your medical records or other information the study staff have stored about you. The study staff will do their best to make sure that your medical information is kept private and confidential. (See the Authorization to Use and Disclose Protected Health Information for more information). If you agree to participate and are found eligible for the study, additional risk may be possible and will be outlined in the product specific consent form.

After declaring COVID-19 to be a public health emergency, the US Department of Health and Human Services issued a public health declaration called the Public Readiness and Emergency Preparedness Act Declaration for Countermeasures Against COVID-19 (PREP). Since being issued in March 2020, PREP has limited 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.

The ending of the public health emergency on May 11, 2023, does not automatically terminate PREP coverage for activities related to COVID-19. Whether PREP can continue to limit the legal rights of subjects participating in a COVID-19 clinical study after the public health emergency ends depends on a number of complex factors that can be subject to change. If PREP limitations on subjects' legal rights apply to this study drug, subjects using the study drug in the study may have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

Are there risks related to pregnancy and nursing?
The study staff will also discuss with you any risks related to pregnancy and nursing.

If you are pregnant, planning to become pregnant or to father a child within a certain timeframe of taking the study drug, or are nursing, you cannot participate in this study. If you become pregnant while on the 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 any benefits or alternatives to taking part in the screening part of the study? There is no direct benefit from participating in the screening process. If you take part in the screening process, you may receive your results from the COVID-19 test quicker. You may choose to not participate in the screening process, and you may still receive a COVID-19 test at the site location.

Also, you may be eligible for treatment with any currently available and approved drugs for COVID-19 infection, even if you do not participate in the screening or additional parts of the study.

What are my rights if I decide to take part in the screening process?
You have the right to ask questions about any part of the screening consent for this study at any time. You should not sign and date this form unless you have had a chance to fully discuss any questions and all your questions have been answered. Participating in the screening process does not affect your right to get your regular medical care.

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 such as:

- Whom to contact in the case of a research-related injury or illness
- Payment or compensation for being in the study, if any
- Your responsibilities as a research participant
- Eligibility to participate in the study
- The study doctor's or study site's decision to exclude you from participation
- Results of tests and/or procedures

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 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 participant, 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: **Pro00062062.**

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE STUDY DOCTOR BEFORE SIGNING AND DATING. YOU MAY CONSULT WITH YOUR PERSONAL DOCTOR OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing and dating below, I agree that I have been provided time to read the information describing the screening process in the consent form. The content and meaning of this information have been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this screening process.

By signing and dating this form, I have not given up any of my legal rights as a screening participant.

☐ Check box if Verbal Screening Consent was completed and refer to completed Screening Consent Form Checklist. Only "Printed Name of Participant" should be completed below.

_____
Printed Name of Screening Participant

_____ _____
Signature of Screening Participant Date (MM/DD/YYYY)

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date (MM/DD/YYYY)

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date (MM/DD/YYYY)

Authorization to Use and Disclose Protected Health Information

If you decide to be in this study, the study doctor and study staff will collect and share your health information as part of this research study. This information is kept at the site and will not be shared except when authorized users visit the site to monitor the study procedure or if requested by authorized users. Health information may include:

- Your name
- Address
- Telephone number
- Date of Birth
- Email address
- Other facts that could identify the health information as yours such as:
    - Medical records (only related to this study from any doctor, hospital, or other healthcare provider)
    - Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests

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

Several people and organizations may review or receive your information. They will need this information to:

- Conduct the research
- To assure the quality of the data
- To review the data or samples
- For other research activities related to the study

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

- Representatives of The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF)
- Representatives of FHI Clinical (FHIC)
- Representatives of the manufacturer of the study drug
- Study site staff
- People from agencies and organizations that perform independent oversight of research such as:
    - US Food and Drug Administration (FDA) and other US federal and state agencies

- The US Department of Defense (DoD) Human Research Protections Office
- Advarra Institutional Review Board (IRB)
- Local Institutional Review Board (IRB)
- External safety monitoring board
- JPEO and other representatives from the US DoD who are funding the study
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries involved in the research.
- 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 study doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study.

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Once your health data have 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.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date (MM/DD/YYYY)

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date (MM/DD/YYYY)