INFORMED CONSENT DOCUMENT

Sponsor / Study Title:	**American Oncology Partners of Maryland, P. A., with the commercial name Center for Cancer and Blood Disorders (CCBD) / "Real-world assessment of AZD7442 efficacy in preventing SARS-CoV-2 infection in immunosuppressed cancer patients"**
Protocol Number:	**ESR 22-21698**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone No.:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

The study sponsor is American Oncology Partners of Maryland, P. A., with the commercial name Center for Cancer and Blood Disorders (CCBD). In this Informed Consent Document, the Sponsor will be referred to as the "Center for Cancer and Blood Disorders." This study is managed by MediMergent, LLC, a real-world data collection and analysis company headquartered in Rockville, Maryland.

We are asking you to voluntarily participate in the aforementioned research study. The purpose of the study is to evaluate the protective effect of the neutralizing antibody drug AZD7442 (Evusheld™) manufactured by AstraZeneca, L. P. in preventing COVID-19 infection in individuals with cancer who were previously vaccinated against COVID-19 infection with the Janssen, Moderna or Pfizer vaccines. A neutralizing antibody drug called AZD7442 (Evusheld™) will be administered in the study treatment.

Read this document carefully. Take the time you need to ask the study doctor or staff all the questions you may have about the study. The study doctor or staff will be able to explain any terms or information that you do not understand. Reading this document and speaking with the study doctor and staff will help you to decide whether or not you are willing to participate. If you decide to participate in this study, you must enter the date and sign your name at the end of this document.

Study Overview

Evusheld™, in intramuscular administration form, has been granted an Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA). Currently, it is the standard of care as preventative treatment for COVID-19 in individuals who are immunosuppressed due to medication or one or more underlying health conditions. In this study, Evusheld™ is considered investigational because it does not have full FDA approval. Evusheld™ authorized for use in individuals as a treatment for COVID-19 or as a protection against COVID-19 infection in the event of exposure to a person infected with SARS-CoV-2.

AstraZeneca has recently reported that Evusheld™ has a low neutralizing activity (prevention of infection) against the BA.1 and BA.1.1 Omicron variants of SARS-CoV-2. However, there was only a minimal impact on neutralizing activity against Omicron variants of the BA.2 variant. Therefore, the FDA requested that the dose of Evusheld™ be increased from 300 to 600 mg for everyone, which is the dose that you will receive in this study. The use in this study is to prevent COVID-19 infection or reduce all the related symptoms if you have received a positive test result for the infection. The purposes of this study are the following:

- To evaluate the efficacy of Evusheld™ in the prevention of the COVID-19 disease;
- To evaluate the efficacy of Evusheld™ in the reduction of symptoms in individuals who had a positive test result for COVID-19 infection;
- To measure Evusheld™ levels in blood nine times in order to determine whether your type of cancer (solid tumor or hematological malignancy) and your current or prior cancer treatment affect these levels.

The total duration of your participation in this study will be 12 months starting with your reference (initial) visit. During this period, you will complete nine medical visits in order to undergo blood tests. You will answer questionnaires related to your health about once per month from your home.

If you choose to enroll in the study, your personal information and all your survey answers will be provided to the study doctor, MediMergent, LLC, and the Center for Cancer and Blood Disorders, so that they can analyze the data. About 1,500 patients with cancer will participate in this study.

<u>Assessment</u>:

Prior to performing procedures or tests related to the study, you will be asked to read, sign and date this consent document. The following assessment procedures and tests will be performed to determine whether you qualify for this study:

- The study doctor will confirm whether you meet all the requirements in order to be enrolled.

- The study doctor will verify that you have received the Janssen, Moderna or Pfizer vaccines before beginning with the study.
- You will have blood drawn to complete a standard analysis and a test of RBD-IgG antibodies specific to SARS-CoV-2 (post-vaccination immunity).

If the study doctor confirms that you are eligible to participate, and you have signed and dated this consent, you will be allowed to proceed with the reference visit.

Reference Visit:
After completing the assessment visit, you will be asked to attend a reference visit where you will answer questions from the reference survey related to your health status after receiving Evusheld™. This survey is called the Experience/Clinical Outcome Assessment (COA). Your real-time responses will be compiled through a secure and confidential website.
You have the following options to answer the questions: (1) by telephone, (2) on a tablet computer in the doctor's office, (3) on your own tablet, desktop computer, or laptop at home, or (4) on your smartphone. If you are using your computer, tablet, or smartphone, you may have to sign in on a secure website. You will decide how you wish to respond to the survey questions. The results of each survey will be available immediately to the study doctor. In addition to the survey questions, you will get a rapid test for SARS-CoV-2 antigens. You must have a negative result before starting the study treatment with Evusheld™.

Once you have completed the reference survey and antigen test, you will be administered one dose of Evusheld™. In general, the dose is delivered through two intramuscular injections, either in the left and right thigh muscle, or in the left and right gluteus (buttocks). It may also be delivered through an intravenous infusion in your arm, depending on your platelet count or physical condition, or through a venous port. The study doctor will determine the administration method. It is important for you to be aware that, although the administration of Evusheld™ by intravenous infusion is not authorized or approved in the United States, and the risks of this administration method are not fully known for Evusheld™, the FDA has issued an Emergency Use Authorization (EUA) for other drugs of the same type (monoclonal antibodies) to be administered by intravenous (IV) infusion.

After receiving Evusheld™, either by intramuscular or intravenous infusion, you will have to stay at the study doctor's office under observation for 60 minutes to monitor your blood pressure, pulse, respiratory rate, and general condition. After that, you will be given a COVID-19 test home kit to check for COVID-19 infection at any time during the course of the study. Your participation in this study will last 12 months.

- Follow-Up Surveys: You will have to complete the Experience/Clinical Outcome Assessment (COA) follow-up surveys on days 2, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, and 360 at home after the reference visit.

- You will have to complete Quality of Life (QoL) assessments on days 2, 90, 180, 270, and 360 at home after the reference visit.
- Follow-Up Visits: At the study office, the study staff will draw blood from you to determine the serum concentration of Evusheld™ on days 30, 60, 90, 120, 150, 180, 210, 270, and 360 after the reference visit.
- At the study office, the study staff will draw blood from you to determine the level of RBD-IgG antibodies on days 90 and 180 after the reference visit.
- At the office, the study staff will draw blood from you for a T-cell test on day 30 after the reference visit.

COVID-19 Testing:
If you present any COVID-19 symptoms, such as fever, aches, chills, cough, loss of smell or taste, difficulty breathing, sore throat, or sneezing, we will ask you take a COVID-19 self-test at home. **If the result is positive, call the study doctor immediately.** You must also take a test locally to confirm the results. Go to the nearest approved testing pharmacy, urgent care center or laboratory to have a PCR (nasal) test. The study doctor can give you a list of approved testing centers. The results of this test will be sent to your study doctor. If you receive a positive PCR result, the study doctor will need to examine you as soon as possible to repeat the tests for Evusheld™ levels in blood, and quantities of RBD-IgG antibodies and T-cells. The study doctor will offer you treatment with the current standard of care for positive COVID-19 infections.

Side Effects of Evusheld
Reactions related to Evusheld™ and its administration have been observed. These occur during intramuscular injections and up to 24 hours after an injection. The signs and symptoms related to Evusheld™ may include the following:

- fatigue,
- headache,
- cough,
- pain at the injection site,
- swelling at the injection site,
- redness at the injection site,
- tenderness at the injection site,
- bleeding at the injection site,
- hypersensitivity reaction, which includes anaphylaxis (difficulty swallowing, hives, itching, difficulty breathing), and
- greater risk of heart attack and heart failure if you have risk factors.

There is no published information about whether or not there have been reactions related to the intravenous infusion of Evusheld™. Reactions occurring during or up to 24 hours after the

infusion have been observed with the intravenous infusion of **other similar drugs** known as COVID-19-neutralizing antibodies. The signs and symptoms of these infusion-related reactions included: fever, difficulty breathing, decrease in oxygen saturation, chills, fatigue, arrhythmia (such as atrial fibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental state, nausea, headache, bronchial spasms, hypotension (low blood pressure), hypertension (high blood pressure), angioedema (hives), throat irritation, rash including hives (redness), pruritis (itching), myalgia (muscle pain), vasovagal reactions (such as fainting or pre-fainting), dizziness, and diaphoresis (sweating).

Allergic Reaction

As with any medication, there is a risk of allergic reactions. If you have a very serious allergic reaction, it could be life-threatening. Some symptoms of allergic reactions are:

- rash,
- wheezing and difficulty breathing,
- dizziness and fainting,
- swelling around the mouth, throat or eyes,
- accelerated pulse, and
- sweating.

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

Risks of study procedures

Blood draws

You may have pain or bruising at the site from where your blood was drawn. You might feel dizzy. There is a possibility of infection at the extraction site.

Surveys

There are two types of surveys in this study. In one survey, you will be asked questions about your general health status and possible risk of COVID-19 infection. In the other, you will be asked questions about your quality of life. You must answer all the questions in both surveys. Although you can choose not to answer any question that may make you uncomfortable, this could result in your exclusion from the study.

Electronic App

We will e-mail you a copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the copy of this consent document is seen and/or saved on a personal electronic device (PED), especially if that device is shared with other users or is lost, hacked or subject to a search warrant or subpoena. In addition, it might not be possible to permanently remove the copy of the consent from the device. As part of this research, you

may need to use one or more of the following: a telephone or web site/application. When using these, your information may be gathered and shared with researchers or individuals not related to the study. These data may include your personal health information. Generally, you can find a complete description of the data gathered and shared by the application in the Privacy Policy related to the application. If you wish to read these documents, ask the study doctor for a copy or instructions on how to access that information. Although the Privacy Policy may include statements that limit your rights in the event of damages due to your use of the application in this study, you are not exempting the investigator, sponsor, institution, or agents from being responsible for errors. Furthermore, it does not imply that you are waiving your rights as a participant in the research study.

Risks to Pregnancy

At present, the side effects for women of reproductive age or who are pregnant or breastfeeding are unknown. Therefore, women of reproductive age who are not using a birth control method or who are currently pregnant or breastfeeding are excluded from this program. Women of reproductive age who currently are not pregnant or breastfeeding and who are using a birth control method may be included. Women will be required to use a birth control method throughout the entire study. If you become pregnant, the study staff will collect information about the pregnancy, its outcome, and the health of the newborn.

There may be risks to participating in the study that are currently unknown.

Benefits

You may benefit from participating in this study. However, it is not guaranteed. The information obtained in this study may help others in the future.

Confidentiality

The records of your participation in this study will be kept confidential, except when the law requires that the information be shared or as described in this informed consent. The study doctor, the sponsor (Center for Cancer and Blood Disorders), or people working on behalf of the sponsor and, in certain circumstances, the FDA and/or the Advarra Institutional Review Board (IRB) will be able to inspect and get copies of confidential study-related records that may identify you by name. An IRB is an independent ethics committee that has reviewed the ethical aspects of this study to help protect the rights and welfare of the study participants. If the results of this study are published or presented at meetings, you will not be identified.

MediMergent, LLC keeps the information safe by means of numerous security measures to protect the confidentiality and security of your medical information. In addition, there is a secure website where you can complete all the surveys. Security measures are also provided for

transmitting your medical information electronically. However, no security measure is perfect, and there is a possible risk of a confidentiality or security breach.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that may identify you. At the most, the website will provide a summary of the results. You may search this website at any time.

Access to Participants' Medical Information

MediMergent, LLC and/or the Center for Cancer and Blood Disorders must have access to any other medical information that identifies you. This includes information from your clinical history in printed or electronic form, information on dispensing of pharmaceutical products, and health care claims submitted within 6 months before and 12 months after your study enrollment date. For example, we will need to get information on other medications you are taking, other medical issues for which you receive treatment, and the results of specific tests, emergency room visits, urgent care center visits, and hospitalizations.

We will also ask you to sign and date a separate Authorization to Disclose Medical Information document allowing MediMergent, LLC and/or the Center for Cancer and Blood Disorders to receive any medical information that individually identifies you in order to use and further disclose it for the purposes of this study. Please be aware that, once MediMergent, LLC and/or the Center for Cancer and Blood Disorders remove data that individually identifies you or that might identify you (elimination of personal information) from your medical information, they will be able to use and disclose the rest of the information for any legal purpose without your authorization. Information without personal data will be included in study reports that may be shared with the FDA or other regulatory authorities, the Advarra IRB, AstraZeneca, L. P., and certain oncologists.

The technology that maintains the data from the reference and follow-up surveys is compliant with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and uses a cloud-based storage system. This technology is designed to preserve the security and safety of your protected health information (PHI). All your responses to the reference and follow-up surveys will be protected by this system. All the information entered in the surveys will be stored only in MediMergent, LLC's dedicated computers.

You will be able to see the results of this study. We will also provide you with certain information on an ongoing basis. We will share the full study results with you once all of the participants' information has been gathered and analyzed.

The Health Insurance Portability and Accountability Act (HIPAA) and any corresponding federal or state privacy laws will apply to this study and to your personal health information. Remember that by signing and dating this authorization, you accept the limited disclosures and

uses described here. No information that can be directly linked to you will be used for commercial purposes.

Your permission to use and share your medical information will expire in 50 years, unless you revoke (withdraw) it sooner. You can revoke your authorization at any time. To do so, you must contact the study doctor in writing at the address indicated on the first page of this document. If you revoke your Authorization for the Disclosure of Medical Information in writing for ongoing use or disclosure of medical information obtained previously in the study, analysis of this protected health information (PHI) will continue after your revocation only to the extent necessary to protect the integrity of the study. MediMergent, LLC and/or the Center for Cancer and Blood Disorders may continue to use and disclose information that does not individually identify you derived from your medical information, without your authorization, for any legal purpose, even after your revocation. By signing and dating the Authorization for the Disclosure of Medical Information document, you accept the use and disclosure of your protected health information as described above. You may not participate in the study if you decide not to sign and date this document.

Alternatives to Participating in the Study
The drug AZD7442 (Evusheld™) is available in compliance with an Emergency Use Authorization (EUA), and you can also access this medication outside of the study if you decide not to participate.

Compensation
You will receive no compensation for participating in this study. You will not have to pay anything to participate in this study.

Voluntary Participation
Your participation is voluntary. If you revoke your participation in the study, you will not have to complete any more surveys, blood tests, or other study-related activities. If you decide not to participate or decide to revoke your authorization, you will not have to pay any penalties, nor will you lose any rights or medical benefits that are not related to the study and to which you would otherwise be entitled to. However, please be aware that any information collected until your revocation cannot be eliminated from the study. Your participation in the study can terminate at any time and for any reason, such as MediMergent, LLC, the Center for Cancer and Blood Disorders, the FDA, or the Advarra IRB deciding to stop the study. You will be told about any new information discovered during the study that may affect your willingness to continue participating.

Compensation for Injuries

The study doctor will make every effort to prevent any injuries that might occur as a result of this study. To help prevent injuries, it is very important that you follow all the study instructions. The study does not affect your right to receive emergency care or other medical services, as needed. If you are injured due to your participation in the study, contact the study doctor immediately, who will treat you or refer you for treatment.

If any physical side effects, complications, or injuries occur that are determined to be a direct result of Evusheld™ or of any study procedure that you would not have received if you had not participated in the study, and if you did not cause an adverse event by failing to follow the instructions of the study staff and this informed consent, then MediMergent, after consulting with the study doctor, will pay the reasonable and customary costs of the emergency treatment required to treat such side effect, complication, or injury if the treatment costs are not covered by other health insurance, a government health program, or third-party health care coverage.

Neither MediMergent nor the sponsor will be able to provide compensation greater than that indicated in this informed consent document. No financial compensation or reimbursements are routinely offered in cases such as loss of earnings, property damage, disability or discomfort, or for preexisting illnesses, conditions, or disorders that are not related to Evusheld™. It is your obligation, in the event that you feel impaired in any way, to stop doing the activity that might cause harm to you, to any other person, or to property as a result of your participation in this study (such as driving a vehicle, operating machinery, or climbing a ladder). Remember that some insurance plans may not cover research-related injuries. You should contact your insurance company for more information. In order to pay for medical expenses that are not covered by your insurance company, as mentioned above, MediMergent and/or the sponsor will need certain information about you, such as your name, date of birth, the health insurance provider's name and your identification number. If Medicare provides your health insurance, the sponsor will need your Medicare beneficiary identification number. This is for MediMergent and/or the sponsor to verify whether you receive Medicare benefits and, if you do, they must inform Medicare of the payments that are made.

MediMergent, LLC, the Center for Cancer and Blood Disorders, and their representatives do not offer medical recommendations or advice. All medical recommendation, advice, and treatment must be provided by the study doctor and/or other health care provider(s).

Contact Information for Study-Related Matters

During the study, you may develop a medical problem, experience a research-related injury, or have questions, concerns, or complaints such as:

- whom you should contact in case of illnesses or injuries related to the research,
- your responsibilities as a study participant,
- whether you are eligible to participate in the study,
- the study doctor or staff's decision to exclude you from the program,
- the results of the tests or procedures.

In such cases, contact the study doctor at the telephone number given on the first page of this consent document.

If you seek emergency medical care or need to be hospitalized, tell your attending physician that you are participating in this study.

An Institutional Review Board (IRB) is an independent committee established to help protect the rights of study participants. If you have questions about your rights as a study participant, contact:

- By mail: Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- By phone **(toll-free)**: 877-992-4724
- Or by **e-mail**: adviser@advarra.com

Provide the following reference number when you contact the study participant's adviser: Pro00062998.

I have read this document and I have been able to ask questions about this study. The study doctor and/or staff answered all my questions. I voluntarily agree to participate in this study.

My digital signature below meets all the necessary conditions for electronic signatures in compliance with the provisions of the Health Insurance Portability and Accountability Act (HIPAA), the Federal Electronic Signature in Global and National Commerce Act (ESIGN Act), and the Uniform Electronic Transactions Act (UETA).

By signing and dating this document, I am not waiving any of my legal rights.

Participant	**Person obtaining the informed consent**
Name:_____	**Name:**_____
Signature:_____	**Signature:**_____
Date:_____	**Date:**_____