INFORMED CONSENT FORM

Sponsor / Study Title:	**American Oncology Partners of Maryland d/b/a Center for Cancer and Blood Disorders / "Real World Evaluation of the Effectiveness of AZD7442 for Prevention of SARS-CoV-2 Infection in Immuno-Suppressed Cancer Patients"**
Protocol Number:	**ESR 22-21698**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

The Sponsor of the study is American Oncology Partners of Maryland, P.A. d/b/a Center for Cancer and Blood Disorders. Throughout the rest of this Informed Consent Form, the Sponsor will be called, "Center for Cancer and Blood Disorders". This study is being managed by MediMergent, LLC, a real-world data collection and analytics company headquartered in Rockville, Maryland.

You are being asked to voluntarily participate in the above 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 the prevention of a COVID-19 infection in people with cancer who have been previously vaccinated for COVID-19 infection with either the Janssen, Moderna, or Pfizer vaccines. You will be given study treatment with the neutralizing antibody drug AZD7442 (Evusheld™) on two occasions.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

Study Overview

Evusheld™ when administered by intramuscular administration has been granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) and is now the standard of care as a preventive treatment for COVID-19 for people who are immune-suppressed due to either medication and/or underlying medical condition(s). Evusheld™ is considered investigational in this study because it does not have full FDA approval. Evusheld™ is not authorized for use in individuals for the treatment of COVID-19 or to protect you from a COVID-19 infection if you have been exposed to someone infected with SARS-CoV-2. AstraZeneca has recently reported that Evusheld™ had reduced neutralizing activity (infection prevention) against the Omicron SARS-CoV-2 variants BA. 1 and BA 1.1, however, neutralizing activity against the Omicron variant BA. 2 was only minimally impacted. As a result, the FDA requested that the dose of Evusheld™ in all people be increased from 300 mg to 600 mg, which is the dose that you will receive in this study. As a result of a recent change submitted to the FDA by AstraZeneca, the dose of 600 mg will now be administered at two time points within the study. The first dose will be administered at baseline with the repeat dose at 6 months after the first dose. Its use in this study is to prevent you from getting a COVID-19 infection or to reduce all of the symptoms in the event that you test positive for the infection. The purposes of the study are to:

- Evaluate the effectiveness of Evusheld™ in the prevention of COVID-19 infection
- Evaluate the effectiveness of Evusheld™ in the reduction of symptoms in people that test positive for COVID-19 infection
- Measure blood levels of Evusheld™ at 9 timepoints to determine if your cancer type (solid tumor or hematologic malignancy) as well as current or prior cancer treatment affect these levels

The total length of your participation in this study will be 12 months after the Baseline (initial) visit has been completed. During this time, you will have 9 clinic visits for blood tests, and will complete survey questionnaires approximately monthly which can be done from your home. If you choose to enroll in the study, your personal information and responses to all survey questions will be provided to your study doctor, MediMergent, LLC and Center for Cancer and Blood Disorders for data analysis. About 1,500 cancer subjects will participate in this study.

<u>Screening</u>:

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- The study doctor will confirm that you meet all requirements to be enrolled in this study.

- The study doctor will verify that you have received either of the Janssen, Moderna or Pfizer COVID Vaccines prior to starting the study.
- You will have blood drawn for standard testing as well as SARS-CoV-2 specific RBD-IgG antibody (post-vaccination immunity).
- You will have a nasal swab for SARS-CoV-2 antigen testing

If the study doctor confirms that you are eligible for participation, and you have signed and dated this consent, you will be allowed to proceed to the baseline visit.

Baseline Visit:

After completing your screening visit, you will be asked to attend a baseline visit where you will respond to baseline survey questions regarding your health status after receiving Evusheld™. This survey is called the Experience/Clinical Outcome Assessment (COA) survey. Your real time responses will be collected through a confidential secure web portal.
These questions may be answered: (1) by telephone, (2) on a tablet computer at the doctor's office (3) on your tablet, laptop or desktop computer at home or (4) on your smartphone. To answer by computer, tablet or smartphone you may need to log on to a secure web portal. It is your choice as to how you want to answer the survey questions. The results of each survey are immediately available to your study doctor. In addition to the survey questions, you will have a rapid SARS-CoV-2 antigen test done, which must be negative before you receive the Evusheld™ study treatment.

After completing the RBD-IgG antibody level and SARS-CoV-2 antigen test, you will be given a dose of 600 mg of Evusheld™. This will usually be administered by two intramuscular injections into either your left and right thigh muscle, or your left and right gluteal (butt) muscle. It could also be given by an intravenous infusion in your arm depending on your platelet count or physical condition; or through a venous port. The choice of which form of administration will be made by study doctor's decision. It is important to note that although Evusheld™ administered by intravenous infusion is not authorized or approved in the United States, and that the risks of this mode of administration are not fully known for Evusheld™, the FDA has granted Emergency Use Authorization (EUA) for several other drugs of the same type (monoclonal antibodies) which are given by IV infusion.

After receiving Evusheld™ either in your muscles, or as an intravenous infusion, you will need to remain at your study doctor's office in order to be observed for 60 minutes during which time your blood pressure, pulse, respiratory rate and overall feeling will be monitored. During this 60 minute time period, you will have the opportunity to complete the baseline survey in the study doctor's office. At the end of this time, you will be given a COVID-19 home test kit to check for any COVID-19 infection during the course of the study. Your participation in this study will last 12 months.

- Follow-Up Surveys: You will complete follow-up Experience/COA surveys on days 2, 30, 60, 90, 120, 150, 180, 181, 210, 240, 270, 300, 330 and 360 post-baseline at home.
- You will complete Quality of Life (QoL) assessments on days 2, 90, 180, 270, and 360 post-baseline at home.
- Follow-Up Visits: The study staff will obtain blood for serum concentration of Evusheld™ at days 30, 60, 90, 120, 150, 180, 210, 270 and 360 post-baseline in the study office.
- Study staff will obtain blood for RBD-IgG antibody level at days 90, 180, 270 and 360 post-baseline in the study office.
- Study staff will obtain blood for T-cell assay at Day 30 and 210 post-baseline in the office.
- Follow-Up Study Drug Administration: The study staff will administer a repeat dose of Evusheld™ 600 mg at day 180 post-baseline in the study office. The dose will be given either intramuscularly (IM) or intravenously (IV) in the same manner as the first dose. You will be asked to remain in the study office for 60 minutes following administration of the repeat dose. During this 60-minute time period, you will have the opportunity to complete the day 180 survey in the study doctor's office.

COVID-19 Testing:

If you develop any COVID-19 symptoms such as fever, aches, chills, cough, loss of smell or taste, shortness of breath, sore throat or sneezing, we will ask that you take a home COVID-19 test. **If the results are positive, please call your study doctor right away.** You will also need to have a test done locally to confirm the results. Please go the nearest approved testing pharmacy, Urgent Care Center or laboratory and have a nasal PCR test performed. Your study doctor can provide you with a list of approved testing centers. The results of this test will be sent to your study doctor. If you have a positive PCR test, you will need to be seen by your study doctor as soon as possible in order to repeat the Evusheld™ blood level, RBD-IgG antibody level and T-cell test. Your study doctor will offer you treatment with the current standard of care for COVID-19 positive infections.

Evusheld Side Effects

Evusheld™ related reactions, occurring during an injection into your muscles and up to 24 hours after injection, have been observed with administration of Evusheld™. Signs and symptoms related to Evusheld™ may include:

- 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 including anaphylaxis (trouble swallowing, hives, itching shortness of breath)
- Increased risk for heart attack and heart failure if risk factors present

There is no published information as to whether there are or are not any intravenous infusion-related reactions with Evusheld™. Intravenous infusion-related reactions, occurring during the infusion and 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 such infusion-related reactions have included: fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (for example, atrial fibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension (low blood pressure), hypertension (high blood pressure), angioedema (hives), throat irritation, rash including urticaria (redness), pruritus (itching), myalgia (muscle pain), vaso-vagal reactions (for example, pre-fainting or fainting), dizziness, and diaphoresis (sweating).

Allergic Reaction

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.

Risks of Study Procedures:

Blood draws

You may have pain or bruising at the site where the blood is drawn. You may feel faint. An infection at the site of the blood draw is possible.

Surveys

There are two types of surveys in this study. One survey will ask questions about your overall health status and possible risk of COVID-19 infection and the other survey asks questions about your quality of life. It is required that you answer all of the questions in both surveys. You may choose not to answer any questions that make you feel uncomfortable, however this may result in you being removed from the study.

Electronic App

You will be emailed 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 form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the copy of the consent may not be able to be permanently removed from a PED. As part of this research, you may be required to use one or more of the following: a phone or web application/site. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information. A complete description of the data collection and sharing for an application, can commonly be found in the Privacy Policy associated with the application. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor. While the Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app in this study, you do not release the Investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research subject.

Pregnancy Risks
The side effects for women who are of childbearing potential, pregnant or breastfeeding are unknown at present. Therefore, women who are of childbearing potential and not using contraception, or currently pregnant or currently breastfeeding are excluded from this program. Women who are of childbearing potential, not currently pregnant, not currently breastfeeding and are using contraception may be included. Women will be required to use contraception for the duration of the study. If you become pregnant, the study staff will collect information about the pregnancy, its outcome, and the health of the child after birth.

There may be risks to participating in this study that are unknown at this time.

Benefits
You may benefit as a result of your participation in this study. While all subjects will receive Evusheld™ (there is no placebo treatment), there is no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

Confidentiality
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the Sponsor (Center for Cancer and Blood Disorders) or persons working on behalf of the Sponsor, and under certain circumstances, the FDA and/or the Advarra Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which 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 study subjects. If the results of this study are published or presented at meetings, you will not be identified.

MediMergent, LLC maintains information security that includes numerous safeguards to protect the confidentiality and security of your health information. A secure web portal is maintained where you may complete all surveys. There are safeguards provided in transmitting your health information electronically. However, no security measure is perfect and there is a possible risk of breach of confidentiality or security.

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.

Access to Subject Health Information
MediMergent, LLC and/or Center for Cancer and Blood Disorders will also require access to other health information that identifies you including information from paper and electronic

medical records, pharmacy fill/refill information and healthcare claims information for the 6 months before and the 12 months after the date of your enrollment. For example, we will need to receive information about other medications you are taking, other medical conditions for which you are being treated, and the results of specific tests, emergency room visits, urgent care center visits and hospitalizations.

We are asking you to sign and date a separate Authorization for Release of Health Information Form to allow for MediMergent, LLC and/or Center for Cancer and Blood Disorders to receive any health information that identifies you, and to use and further disclose it for purposes of this study. Please note, after all information that does or can identify you is removed (de-identified) from your health information by MediMergent, LLC, and/or Center for Cancer and Blood Disorders, the remaining information may be used and disclosed by either MediMergent, LLC and/or Center for Cancer and Blood Disorders for any lawful purpose without your authorization. De-identified information will be included in study reports that may be shared with the FDA or other regulatory authorities, Advarra IRB, AstraZeneca, L.P. and certain oncology physicians.

The technology that holds the study baseline and follow-up survey data is Health Insurance Portability and Accountability Act (HIPAA) compliant and uses a cloud-based storage system. This technology is engineered to keep your Protected Health Information (PHI) safe and secure. All of the responses to the baseline and follow-up surveys that you enter are secured under this framework. All of the survey information entered is uploaded onto MediMergent, LLC dedicated computers only.

You will be able to see the results of this study. Certain information will be provided to you on an ongoing basis. Once all of the information from all subjects has been collected and analyzed, the full study results will be shared with you.

The Health Insurance Portability and Accountability Act (HIPAA) and any other applicable state or federal privacy laws will apply to this study and your personal health information. Keep in mind that by signing and dating this authorization, you are agreeing to the limited disclosures and uses as described. No information that can be directly related to you personally will be used for commercial purposes.

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 withdraw your authorization at any time by contacting the study doctor in writing at the address listed on the first page of this form. If you revoke your Authorization for Release of Health Information in writing for continued use or disclosure of health information that was already obtained in the study, analysis of that Protected Health Information (PHI) will continue after your withdrawal only to the extent necessary to protect the integrity of the study. MediMergent, LLC and/or Center for Cancer and Blood Disorders may

continue to use and disclose de-identified information derived from your health information without your authorization for any lawful purpose, even after your withdrawal. By signing and dating the Authorization for Release of Health Information Form, you are agreeing to the use and disclosure of your PHI as described above. If you decide not to sign and date this form, you will not be able to take part in the study.

Alternatives to Study Participation
AZD7442 (Evusheld™) is available under Emergency Use Authorization and can also be accessed outside of the study if you choose not to participate.

Compensation

«Compensation»

You will not be paid for taking part in the study. There will be no cost to you for your participation in this study.

Voluntary Participation
Your participation is voluntary. If you withdraw from participation in the study, you will not be required to complete any additional surveys, blood tests or other study-related activities. If you decide to not participate or you decide to withdraw, you will not suffer any penalty, loss of rights, or loss of medical benefits that are unrelated to the study to which you are otherwise entitled. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study. Your participation in the study may stop at any time for any reason, such as if MediMergent, LLC, Center for Cancer and Blood Disorders or the FDA or Advarra IRB decides to stop the study. You will be told about any new information found during the study that may affect whether you want to continue to participate.

Compensation for Injury
The study doctor will make every effort to prevent any injury to you resulting from this study. To help avoid injury, it is very important to follow all study directions. The study does not affect your right to receive emergency and/or other medical services, if needed. In case of an injury from participating in the study, please contact the study doctor immediately who will provide or refer you to treatment.

If you have physical side effects, complications or injuries that are determined to be a direct result of Evusheld™ or any study procedure that you would not have otherwise received if you had not been participating in the study and, you did not cause an untoward event by failing to follow the directions of the study personnel and this informed consent, MediMergent in consultation with the study doctor, will pay the reasonable and customary costs of the

necessary urgent treatment for such side effect, complication, or injury if the costs of treatment are not covered by any other health insurance, government health program, or other third party providing coverage for health care.

Neither MediMergent nor the Sponsor can provide other compensation beyond that which is listed in this informed consent document. Neither financial compensation nor reimbursement for such things as pre-existing conditions, illness, or disease unrelated to Evusheld™, lost wages, property damage, disability, or discomfort is routinely offered. It is your obligation, in the event you feel impaired in any way, to cease activity that may cause injury to yourself, to any other person, or to property as a result of participating in this study (such as, driving a vehicle, operating machinery, or climbing a ladder). Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information. To pay the medical expenses that are not covered by your health insurance as listed above, MediMergent and/or the Sponsor will need to know some information about you like your name, date of birth, the name of your Health Insurance Provider and your ID#. If your health insurance is provided by Medicare, the sponsor will need your Medicare Beneficiary Identifier (ID #). This is because MediMergent and/or the Sponsor has to check to see if you receive Medicare benefits and if you do, to report any such payment it makes to Medicare.

Neither MediMergent, LLC, nor Center for Cancer and Blood Disorders nor any of its representatives provide any medical advice or recommendations. All medical advice, recommendations and treatment should be provided only by your study doctor and/or other healthcare provider(s).

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 such as:

- Whom to contact in the case of a research-related injury or illness
- Your responsibilities as a research subject
- 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 subjects. If you have any questions about your rights as a research subject, 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: Pro00062998.

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

My digital signature below complies with all conditions necessary for e-signatures under HIPAA Rules, the Federal Electronic Signature in Global and National Commerce Act (ESIGN Act) and the Uniform Electronic Transactions Act (UETA).

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

Subject	**Person Obtaining Informed Consent**
Name:_____	**Name:**_____
Signature:_____	**Signature:**_____
Date:_____	**Date:**_____