Participant Information Sheet/Consent Form

Observational Study - *Adult providing own consent*

Monash Health

Title	SerOzNET: SARS-CoV-2 post-vaccine surveillance studies in Australian adults with cancer
Protocol Number	RES-21-0000337A
Coordinating Principal Investigator/ Principal Investigators	Professor Eva Segelov
Associate Investigator(s)	Dr Elizabeth Ahern/ Professor Stephen Opat/ Dr Amy Body
Location	Monash Health

Part 1 What does my participation involve?

Dear Participant,

You are invited to participate in this research project to help us better understand how vaccination against COVID19 (Coronavirus) works in patients with cancer. You have been invited because you are currently receiving or have recently received treatment for cancer (including blood cancer).

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. Your decision whether or not to participate will not affect your relationship with your doctors or with Monash Health.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Background:

The COVID19 pandemic has been a global event causing severe illness and death for millions of people worldwide. As a result there has been major disruption to normal life and to provision of health care globally.

In countries with high rates of COVID19 infection, patients with cancer have been more likely to suffer severe illness or death from COVID19. This is due to multiple reasons:

- Many cancer treatments lower the immune system response and ability to fight off infections
- Cancer itself can affect how well the immune system works
- If you catch COVID-19, having another illness such as cancer can reduce the body's reserve to withstand another illness.

There are now a number of different vaccines around the world that protect against COVID-19 infection, illness and death. The Australian government has a program to provide vaccination free of charge to all persons in Australia. Because of the risk of serious illness with COVID-19, patients with cancer are strongly recommended to get vaccinated and have been prioritized to be vaccinated early in the COVID19 vaccine rollout.

Research done overseas shows that cancer patients may not have as strong of an immune response to the COVID19 vaccine as other people. What we don't know at present is how significant this effect is, whether it affects all or only some patients with cancer, and what more we could possibly do to make sure cancer patients have adequate protection against COVID19.

What this study will add

This study will look at cancer patients who are having their COVID-19 vaccination as per the Government recommendations. This study covers vaccination with either of the currently authorised vaccines, known as "Pfizer' and "Astra Zeneca (AZ). The study consists of doing blood tests at certain time points before and after vaccination, and asking you to answer some questionnaires for us to understand how your immune system responds to the COVID-19 vaccine.

This study will keep a record of what type of cancer and what kind of treatment you have, so that we can understand if certain treatments affect vaccine response more than others.

This information will help us to work out how to best protect people with cancer against COVID-19 in future years- for example whether a booster dose of vaccine might be needed, or a certain vaccination type. This information might also help us plan protection for patients with cancer against other infectious diseases in the future.

In addition, this study will collect information from participants regarding any side effects that you have experienced from the vaccination and any effect that the vaccination has on your quality of life or day-to-day function. We also ask you to complete a survey at the beginning of the study, which asks about your attitude towards vaccination. This survey has been used in other studies around the world. This information will allow us to provide better advice to patients with cancer in the future about what to expect from COVID-19 vaccination, and will help health care providers understand whether additional checking of patients with cancer is required for the COVID-19 vaccination program.

3 What this study will involve for me

Vaccination- standard of care

The vaccination you will receive will be under the standard government funded program, just as if you were not on the study. The government policy is to give the vaccine appropriate for your age group, either Pfizer (Comirnaty) or Astra Zeneca (COVID-19 Vaccine Astra Zeneca). This is supplied free of charge by the Australian government and will be given at one of the vaccination centres at Monash Health, or a clinic of your choice that is offering COVID-19 vaccinations. There is no change or impact for you getting the vaccine if you choose not to participate in the research study. The vaccination centre will give you a patient information form regarding the vaccine itself, as routine, whether you are participating in this study or not. The vaccine itself is a routine part of patient care and will be given as per current government recommendations. Please be sure to discuss your participation in this vaccination study with your usual treating doctor or GP.

If you have any side effects from the vaccine, you should report these to your usual doctor just as if you were not on the study. You will be given information about how to do this at the vaccine centre.

Study activities:

Blood tests

This study will involve 5 blood tests. The first test is taken up to a week before your first vaccination. The other 4 blood tests are taken during the next 6 months. Approximately 9 teaspoons of blood taken each time.

The total number of blood tests in the study is 5. The first blood test is done before the first vaccine and the last blood test is approximately 6-7 months after enrolment (depending on which vaccine you receive). The full schedule is listed in the tables below. The reason we need to take blood tests at many different time points is to compare the response of cancer patients to non-cancer patients from other studies. Cancer patients may have the same or delayed immune response, so having several time points will allow this comparison.

Surveys

We will also ask you to complete one brief survey before your vaccination and several other short surveys at different times after the vaccination. These are all standard questionnaires used in this type of research. One survey is looking at the effect of the vaccine on your quality of life and another asks about your attitudes towards the vaccine. We will also ask you about any side effects that you had. Please note these surveys can be completed online or we can give you a paper survey to take home- you do not have to attend in person on days when there is a survey but no other tests.

Study schedules

For patients receiving Pfizer vaccine

	Up to one week before vaccination	Day 1	Day 7	Day 21	Day 28-35	1 month post 2nd dose (Day 49)	3 months post 2nd dose	6 months post 2nd dose
Vaccine is given		X		X				
Blood test	X			X (can be up to 3 days earlier)		X	X	X
Survey about how you are feeling (quality of life)	X		X	X	X		X	
Survey asking what side effects you had			X		X			
Survey asking about your attitudes to the vaccine	X							

Total study duration approximately 7 months

For patients receiving Astra Zeneca vaccine

	Up to one week before vaccination	Day 1	Day 7	Day 21	12 weeks post 1st dose (Day 84)	7-14 days post 2nd dose	1 month post 2nd dose	3 months post 2nd dose
Vaccine dose		X			X			
Blood test	X			X (can be up to 3 days prior)	X (can be up to one week prior)		X	X
Survey about how you are feeling (quality of life)	X		X		X	X		X
Survey asking what side effects you had			X			X		
Survey asking about your attitudes to the vaccine	X							

Total study duration approximately 6 months

Medical record access

By agreeing to participate in this study, you also agree to the study investigators (Monash Health employees who are part of the Oncology department and Monash University) accessing your medical records to record information about your health relevant to your cancer diagnosis, cancer treatment and general health during the study period.

4 What benefit is there to me from participating in this study?

There is no immediate benefit to you from participating in this study, as we will wait until we have blood from many patients before we start the analysis. The study will not give any results that will affect any individual participant or make any change from the routine vaccination program.

However, there are benefits to patients with cancer (including yourself) in the future. Results of this study will allow us to better inform patients with cancer about what to expect fromCOVID-19 vaccination, including how cancer treatments might affect both vaccine side effects and the response to vaccines. It will also help us understand the attitudes of cancer patients towards the

COVID-19 vaccine. This information will also help us better protect patients with cancer from COVID-19 in future, by informing us how cancer patients are protected from COVID-19 by routine vaccinations.

Examples of what this research may tell us whether in the future cancer patients, or certain groups of cancer patients, need extra doses of the COVID-19 vaccine, or if the response to vaccine wears off after time in a way different to people without cancer. This will help us plan COVID-19 prevention to best protect patients with cancer in the future.

Future use of your blood samples

We and/or our collaborating researchers will also seek your consent to use blood samples which will be obtained through this research in future cancer or vaccine research. This is because it is likely that some tests or analyses that researchers may wish to perform in the future have not yet been developed. This is called "unspecified consent" and means that we will be able to use these samples to perform future research that we might not have thought of yet. If you consent to this, you will allow us or our collaborating researchers to use your blood and tissue samples in the future for research related to this project, without seeking your specific consent each time. Human Research Ethics Committee approval will be sought for all future studies in which samples or data collected from SerOzNET will be used.

Costs and fees

There are no additional costs associated with participating in this research project, nor will you be paid. All tests and medical care required as part of the research project will be provided to you free of charge.

Where participant(s) are experiencing financial hardship, reimbursement for parking/travel will be provided.

5 Other relevant information about the research project

This research will be conducted at Monash Health and Monash University. The study aims to recruit between 250-600 participants during 2021-2022. The researchers involved are based at Monash University and Monash Health but may involve collaborations with other researchers for the different analyses of the immune response.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Monash Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive your usual cancer treatment at this hospital, or your COVID-19 vaccine. If you decline participation in this study, you will still be offered COVID-19 vaccination as per the government program. The study doctor or nurse will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible risks and disadvantages of taking part?

Having blood samples taken may cause some discomfort, bruising, minor infection or bleeding. If this does occur, it can be easily treated and will be done so free of charge.

Very common (>10%)

- Pain or discomfort at the site that the needle goes into the vein. This is usually mild and self limited and can be treated with simple painkillers such as paracetamol.
- Bleeding or bruising may occur.

Uncommon (1-10%)

- Feeling faint or sweaty

Rare (<1%)

Fainting (losing consciousness). This is usually related to position and resolves quickly once the person is moved to a lying down position.

The total amount of blood collected during this project will measure in total a maximum of 225mLs during the different time points over a period of 6 to 7 months. This amount would be naturally replaced by your body as each test is taken, because only a small amount is taken each time. Blood cells are normally replaced by your body every few months, which means blood taken at the start of the study will already have been replaced naturally before blood is taken later in the study.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Qualified staff who are not members of the research project team will provide any counselling or support if necessary. This counselling will be provided free of charge.

If you have any concerns, talk with your study doctor or nurse. They will answer any questions you have regarding risks of involvement.

9 What will happen to my test samples?

Blood samples obtained will be stored at Monash Health in the Monash Health Translational Precinct (Monash Medical Centre Campus), Victoria. Storage does not involve any additional procedure on your behalf. Samples will be kept for as long as the investigators are doing research and for at least 5 years after publication of any results. There are no plans to destroy these samples, but some of them may be used up in the process of testing them. The purpose of storing your blood samples is to have them available for cancer or vaccine research undertaken currently and in the future by clinical investigators at Monash Health and Monash University. This is called "unspecified consent" and means that we will be able to use these samples to perform future research that we might not have thought of yet, but which is relevant to this study. Additional Human Research Ethics Committee approval will be obtained for all future research involving use of your samples or data collected from the SerOzNET study.

We may also share these materials with collaborating researchers to cover all the immune studies relevant to COVID-19, but the samples will not be able to be identified as coming from you.

All material collected from you will be stored in a coded format to protect your identity. Only those authorised to access health information by Monash Health will be able to access this if relevant or necessary for the research (the principal investigator and their delegates). Results generated from this study will be presented in grouped format, so that no individual participant will be identified.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

11 Can I have other treatments during this research project?

This research does not alter your treatment; it only monitors you while you receive it. If you participate in this research project, you will still be able to take the medications or treatments you have been using for this or any other medical condition.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing (including sub-points *(i)* & *(ii)* described below).

You will continue normal treatment as discussed with your doctor even if you withdraw during the study.

(i) If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect any additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

(ii) If you do withdraw your consent during the research project, we will stop collecting blood and surveys from you. We will ask for your consent to use your biological materials which have already been collected, as part of our future research. If you refuse, no further new use or analysis of your collected material will be undertaken by researchers. It is important to note that it may not be possible to prevent the use of some of the materials which has already been collected prior to your withdrawal (for example if it has been pooled with material / data of other patients, or if it has already been used to generate data, or if it has been sent to a collaborator), but in such instances if it does remain as part of the study, it will only be used in a de-identified way. All physical material collected from you that can be located and destroyed will be destroyed under the supervision of the Principal Investigator.

13 Could this research project be stopped unexpectedly?

This research project may be stopped if:

- Patients are experiencing harm.
- There is a lack of funding for continuation of the project.
- Methods used for analysis of blood samples are deemed inadequate or need refinement

14 What happens when the research project ends?

Upon conclusion of the study, you will no longer require the study-specific blood samples to be taken. You will continue care as determined by yourself and your treating doctor.

A newsletter outlining results from samples and data collected from SerOzNET participants will issued to participants at the end of the study, when all data has been analysed.

Results may be published in a peer-reviewed journal and presented at both national and international conferences.

You may request access to personal information Monash Health keeps about you from your study doctor at any point in the study or via http://www.monashhealth.org/page/Access_my_records.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The information will be stored for 15 years.

Information about your participation in this research project may be recorded in your health records.

Once in the laboratory, your sample(s) will not be identified with any individual identifiers (e.g. name, date of birth) or, if it is, all identifiers will be permanently removed prior to storage.

Your health records and any information collected and stored by the study doctor during the research project may be reviewed for the purpose of verifying the procedures and the data. This review may be done by the ethics committee which approved this research project, regulatory authorities and authorised representatives of this organisation, Monash Health or Monash University or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information as noted above.

By signing the consent form, you consent to the study doctor and relevant research staff sharing results from this project with other researchers in other hospitals and academic centres. Any information obtained in connection with this research project that can identify you will remain confidential. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your written permission. You will not be named in any reports, publications, or presentations that may come from this study.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

16 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. If

you have any complaints regarding the conduct of the study or those involved, please contact the complaints contact person.

17 Who is organising and funding the research?

This research project is being conducted by Professor Eva Segelov who has a joint appointment at Monash Health and Monash University. The study is funded by specific funding from Cancer Australia, the Australian Government body responsible for overseeing cancer care throughout Australia.

By taking part in this research project, you agree that samples of your blood (or data generated from analysis of these materials) will be provided to Monash Health and Monash University. Monash Health and Monash University may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Monash Health and Monash University. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Monash Health and Monash University, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

There are no additional declarations of interest of study doctors, sponsors and institutions.

18 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Monash Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects from blood tests), you can contact the principal study doctor Dr Amy Body on 03 8572 2392 or any of the following people:

Clinical contact person

Name	Dr Amy Body
Position	Medical Oncologist, Monash Health
Telephone	03 8572 2392
Email	AmyLouise.Body@monashhealth.org

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Ms Deborah Dell
Position	Manager, Human Research Ethics Committee, Monash Health
Telephone	03 9594 4605
Email	Deborah.Dell@monashhealth.org

Consent Form - *Adult providing own consent*

Title	SerOzNET SARS-CoV-2 post-vaccine surveillance studies in Australian adults with cancer
Protocol Number	RES-21-0000337A
Coordinating Principal Investigator	Professor Eva Segelov
Associate Investigator(s)	Dr Elizabeth Ahern, Professor Stephen Opat and Dr Amy Body
Location	Monash Health

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash Health concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I understand that, if I decide to discontinue the study, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the storage and use of blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for to use in the current and future cancer research projects.

In addition:

I understand that blood will be stored in the laboratory and may be used in future related research by the study investigators or their collaborators and I consent to this:

☐ Yes
☐ No

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Where required. Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	SerOzNET SARS-CoV-2 post-vaccine surveillance studies in Australian adults with cancer
Protocol Number	RES-21-0000337A
Coordinating Principal Investigator	Professor Eva Segelov
Associate Investigator(s)	Dr Elizabeth Ahern, Professor Stephen Opat and Dr Amy Body
Location	Monash Health

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Monash Health. Please indicate ONE of the following TWO statements:

☐ **I consent that biomaterials (blood) and data that has already been collected from me can be stored and used as part of the research project.**

☐ **I wish to withdraw consent for the use and storage of blood collected for the purposes of this research project**

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.