QIMR Berghofer
Medical Research Institute

[Insert institution logo]

Participant Information Sheet and Consent Form

Study Title:	Phase I open-label clinical trial of allogeneic multi-virus-specific T cells for the treatment of viral complications in transplant recipients
Short Title:	Virus-specific T cell therapy for transplant recipients
Protocol Number:	P3645-QMVT01
Study Sponsor:	QIMR Berghofer Medical Research Institute
Principal Investigator:	Prof Rajiv Khanna (QIMR Berghofer)
Study Doctor(s):	*[Insert name of site clinical investigators]*
Location:	*[Insert site name]*

Part 1: What does my participation involve?

1. Introduction

We are asking you to take part in this clinical trial. You are being asked to participate in the trial because you have had a solid organ transplant and are experiencing viral complications following the transplant. This trial is testing the safety of a new therapy for infectious complications following receipt of an organ transplant. The new treatment is called T cell immunotherapy, and it aims to use T cells (a type of immune cell) to fight disease.

This Participant Information Sheet and Consent Form tells you about the clinical trial, and explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in this clinical trial.

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 you would like to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this clinical trial is voluntary. If you do not want to take part, you do not have to. You will receive the best possible care whether or not you participate in this clinical trial.

If you decide you want to take part in the clinical trial, you will be asked to sign the consent section of this form before any study assessments are conducted. By signing it, you are telling us that you:

- Understand what you have read
- Consent to taking part in the clinical trial
- 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 clinical trial?

The Tumour Immunology Laboratory at QIMR Berghofer has grown a number of T cell therapies from the immune cells of healthy donors. The T cells from these healthy donors are grown in the lab (further details provided below) to turn them into 'T cell therapies'. These T cell therapies are designed to target up to four different viruses that can cause health problems in people who have received an organ transplant. In this trial, based on your clinical condition and tissue type, we will select the best-matching T cell therapy available and give you up to four infusions of the therapy. The main aim of this clinical trial is to see whether this new T cell therapy is safe for transplant patients. In addition, we would like to see the effect of these cells when they are infused into transplant recipients with viral complications.

The viruses that we are targeting are Epstein–Barr virus, cytomegalovirus, BK virus and adenovirus. These viruses are very common in the general population and in most cases don't cause health issues. However, they can cause problems for people who have received a transplant or are immune suppressed for other reasons, as the immune system isn't able to effectively fight the viruses. Because these viruses are common, healthy people can develop strong immune responses against them. This allows us to grow T cell therapies from blood samples collected from these healthy donors. The therapies vary depending on the blood donor, since different people have different immune responses against these viruses. For example, the blood we collect from a particular donor may not have an immune response against cytomegalovirus, but it might still have very good responses against the other viruses that we are targeting.

To make the therapy, we stimulate the anti-viral T cells to multiply by exposing them to small synthetic proteins known as 'peptides'. These peptides look like viruses to the T cells (although they are not infectious), which causes the cells to multiply to strengthen the immune response. Once the T cells have been grown, we freeze them in single-dose vials for future infusion into patients.

T cell immunotherapy is an experimental treatment. This means that it has not yet been approved in Australia as a treatment for infectious complications following transplant. This clinical trial has been initiated by Professor Rajiv Khanna at QIMR Berghofer Medical Research Institute, and is funded by the National Health and Medical Research Council.

3. What does participation in this clinical trial involve?

If you agree to participate in this clinical trial by signing the attached consent form, we will undertake some tests and review your medical history to see if you are eligible to participate in this trial. This is called 'screening'. You will be assigned a unique study code for the purposes of this trial, so that any information and research blood samples collected from you during the trial are not directly linked to your name. Only authorised staff will be able to identify you from your code.

Screening assessment

We will collect some demographic information (e.g. name, sex, date of birth, height and weight), review your medical history, and conduct a physical examination and some blood tests to determine if you meet the eligibility criteria. Where possible, we will collect information from your medical records rather than repeating tests. The blood tests that may be conducted are:

- Tissue typing
- Biochemistry
- Full blood count
- Viral serology (this confirms past exposure to the virus(es) of interest)
- Viral load (testing how much virus is present in your blood)
- Pregnancy test if you are female and able to bear children
- Collection of approximately 36 mL (approximately two tablespoons) of blood for research studies

Infusion visits
If you are found to be eligible to participate in the trial, we will identify the most appropriate T cell therapy based on your tissue type and history of viral complications. You will receive four intravenous infusions of this T cell therapy. The first infusion will generally start within 2–3 weeks after your eligibility is confirmed. The start date will be chosen by the study doctor, based on your clinical status. Infusion two will be given 2 weeks after infusion one, and the final two infusions will be given weekly.

The infusions will be given at the hospital, and you will then be monitored closely for any side effects that may result from the infusion, for at least 4 hours. If you are receiving the infusion as an outpatient, you will need to stay at the hospital following each infusion until the treating doctor confirms that you can go home.

We will study the effects of this treatment by monitoring your signs and symptoms, and by blood tests. Blood tests for full blood count, biochemistry, and viral load will be done prior to each infusion visit. We will also look at the numbers of different types of white blood cells in your blood (known as lymphocyte subset analysis) before your first infusion. In addition, around 36 mL of blood (approximately two tablespoons) of blood will be obtained prior to each infusion for research studies at QIMR Berghofer. This will enable analysis of how your immune response changes over time. You will also be checked by the treating doctor for any adverse effects during these visits.

Follow-up visits
Your first follow-up visit will occur approximately 2 weeks following the final infusion, and then you will have three more visits at approximately monthly intervals. Here, we will again study the effects of this treatment by monitoring your signs and symptoms, any adverse effects, and by the blood tests described above. A 36 mL blood sample will be obtained at each visit to study the immune response of the treatment. Your total length of involvement in the clinical trial will be approximately 4 months. The duration of participation might be longer if there are clinical complications.

After your fourth follow-up visit, we will check your progress remotely every 4–6 months until the trial has been completed. This will not require any additional visits to the hospital or interactions with the study team; we will collect information from your medical records. This will enable us to see how you are progressing clinically, including whether or not you are continuing to experience complications from the virus that we targeted with the T cell therapy.

Storage of blood samples for trial purposes
By signing the attached consent form, you are confirming that you agree to have your blood cells stored at QIMR Berghofer for analysis as part of this trial. The samples that are collected for research will be assigned a unique code that is used throughout the clinical trial. Studying your blood will help researchers gain information about the immune response to the viruses we are studying, and measure whether or not this changes over the course of the trial. This information might also help develop new vaccines or therapies for virus infections following transplants in future.

Ongoing medical care
If you decide to participate in this clinical trial, the study doctor will inform your local doctor. Throughout the trial it is important to tell the study doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies. You must also inform them of any changes to these medications during your participation in the clinical trial.

Additional costs

There are no additional costs associated with participation in this clinical trial, apart from transport to and from the hospital for trial visits. Where possible, these will be timed to coincide with your regular visits to the hospital. You will not be paid for taking part in this clinical trial, but reimbursement of reasonable local travel expenses related specifically to the trial will be considered. Any requests for the reimbursement of these local travel costs will need to be approved by the sponsor (QIMR Berghofer) prior to payment. As such, payment will be processed following each clinical trial visit. You will not be entitled to any payment in regard to commercialisation of the product. You will not be entitled to any payment related to intellectual property or any discovery during the conduct of this trial. All medication, tests and medical care required as part of the trial will be provided to you free of charge. This excludes the costs of any treatment that you require as part of your standard clinical management.

4. Other relevant information about the clinical trial

This is the first trial of this particular T cell therapy in the solid organ transplant setting; however, other types of T cell therapy have been tested in the past. Our group has recently completed a clinical trial of a T cell therapy targeting only cytomegalovirus in solid organ transplant recipients. No serious side-effects related to the therapy were seen in the 12 patients who participated in the trial. However, the T cell therapy was grown from each patient's own blood, whereas in the current trial, healthy unrelated adults are donating blood for the therapy. The potential benefits and risks of taking part in this clinical trial are detailed in sections 7 and 8, below.

We are aiming to recruit 25 participants in this clinical trial, from The Prince Charles Hospital, Princess Alexandra Hospital, Royal Brisbane and Women's Hospital (all in Brisbane), and the Royal Adelaide Hospital. Clinical trial participants will have received a kidney, lung, heart or liver transplant (or a combination of these).

5. Do I have to take part in this clinical trial?

Participation in any research project is voluntary. If you do not wish to take part in this trial, you do not have to. If you decide that you want to take part and later change your mind, you are free to withdraw from the trial at any stage.

If you decide to take part in this clinical trial, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Whether you decide to take part in this trial or not, or you decide to participate but then decide to withdraw, it will not affect your routine treatment, relationship with those treating you, or your relationship with QIMR Berghofer Medical Research Institute or the hospital.

6. What are the alternatives to participation?

You do not have to take part in this clinical trial to receive treatment at this hospital. At any time you are free to withdraw consent for your participation in this clinical trial. It is important to understand that if you decide to withdraw from this clinical trial, you will not be disadvantaged. You will continue to receive the standard care that your treating doctor has prescribed. You may also be eligible to participate in other clinical trials. It is important that you speak with the treating doctor to determine which alternative treatments are available. You can also discuss the options with your local doctor.

7. What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this clinical trial, as it is the first trial of this T cell therapy and we do not yet know the therapy's impact on patients. However, it is possible

that infusion of the T cell therapy may help restore your immunity against multiple viruses and help control viral infection and disease. We hope this clinical trial will tell us whether T cell infusion is safe and should be studied further for use in the management of infectious complications following transplantation. It will give us useful knowledge on how we can try to improve immunity post transplant, and could potentially lead to new treatment approaches.

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

Medical treatments often cause side effects. You may experience none, some or all of the side effects listed below, and they may be mild, moderate or severe. If you have any of these symptoms, or you are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms that you have. If you experience any severe medical symptoms while not at the hospital, call '000' or present to the emergency department of your nearest hospital.

Many side effects go away shortly after treatment ends; however, sometimes they can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop T cell infusions. The study doctor will discuss the best way of managing any side effects with you.

The main risks are: the acquisition of communicable diseases, microbial contamination, infusion reactions, and the potential for the T cells to attack healthy cells. These will now be discussed in detail.

The risk of blood-borne infection has been reduced by testing each blood sample used to grow the T cell therapies. Each sample is tested for human immunodeficiency virus (the virus that can cause AIDS), hepatitis B and C, syphilis and human T-lymphotropic virus. However, the presence of other infectious agents cannot be ruled out.

The T cell therapy is grown in an accredited cell therapy manufacturing laboratory and strict quality standards are adhered to. The cells are tested for microbial contamination before they are approved for infusion. There is a risk that contamination could be introduced when the cells are thawed and prepared for infusion; however, this will be minimised by preparing the therapy for infusion in a sterile cabinet in a qualified laboratory. These precautions should greatly minimise, though not completely eliminate, the possibility of microbial contamination.

Any transfusion of cells can be associated with reactions. These are usually mild, but more severe reactions can occur and can include rash, difficulty breathing, and rarely, circulatory collapse (failure of the circulation, which could lead to organ failure or death). It is possible you could develop low blood pressure, fatigue, pain or a fever (up to 40 °C) following the infusion. However, during these cell infusions you will be closely monitored by clinical staff and any signs of these symptoms will be immediately treated within the hospital facility at no charge to you.

A potential harmful effect of this therapy is 'off-target' effects, where some of the infused T cells might attack healthy cells in your body, including your transplant. The process we use to make the T cell therapy allows us to specifically increase the number of virus-specific T cells from within the original blood sample. However, other T cells will still be present in the cell therapy that don't target the viruses we are trying to control. This may include T cells that could theoretically attack your tissues to cause inflammation or rejection of your transplant. Previous clinical trials of similar T cell therapies targeting viruses in transplant recipients indicate that this risk is low, and our laboratory will test for unwanted T cells before the therapy is given. However, we cannot completely rule out this risk.

We will monitor you closely for any off-target effects of the T cells, including any negative impact on your transplant. After the first infusion of T cells, there will be a 2-week break before the second infusion, to allow time to detect any early impact on your transplant. If these effects are detected, T cell infusions will be discontinued until this issue can be controlled.

The infusion of T cells or the collection of a blood sample may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

Please be aware that the effects of T cell therapy on the unborn child and on the newborn baby are not known. Because of this, it is important that clinical trial participants are not pregnant or breast-feeding and do not become pregnant during the course of the trial. Women of child-bearing potential must not participate in the trial if they are pregnant or breast-feeding. If you are a woman who is able to bear children, you will be required to undergo a pregnancy test prior to commencing the clinical trial. If you are male, you should not father a child for at least 2 months after the last dose of T cells.

Both male and female participants are strongly advised to use effective contraception during the course of the clinical trial and for a period of 2 months after trial completion. You should discuss methods of effective contraception with the study doctor.

If you become pregnant during the clinical trial, you must advise the study doctor must immediately. The study doctor will withdraw you from the trial and advise on further medical attention should this be necessary. You must not continue in the trial if you become pregnant.

Similarly, if you father a child during the trial, you must also advise the study doctor immediately. The study doctor will advise on medical attention for your partner, should this be necessary.

9. What will happen to my test samples?

To maintain your privacy and confidentiality throughout the clinical trial, you will be assigned a unique coded patient identifier for use on all documents, clinical samples and therapeutic preparations. Only authorised staff will be able to identify you from your unique code.

Blood collected for research laboratory analysis of your immune system will be analysed in the laboratory of Prof Rajiv Khanna at QIMR Berghofer. Blood components will be isolated and stored for immunological analysis and to determine the quantity of virus DNA in your samples. The immune studies on your blood will include: measuring the size of the immune response against each virus over the course of the trial, studying the characteristics of different types of T cells in the blood, and determining which viral proteins these cells can recognise. We will also study your genetic material (i.e. DNA or RNA) and how your body controls which of your genes are made into proteins. These studies will be related to your immune system and how this system is controlled. We will not conduct studies of genetic material that could result in information about future risks to your health, possible genetic disorders within children you may have, or which could be relevant to the health of family members who are not participating in this clinical trial.

By signing this consent form you agree to have your tissue samples (i.e., blood and T cells grown in the lab from your blood) stored at QIMR Berghofer for analysis as part of this trial. The samples that are collected for research will be assigned a unique code that will be used throughout the clinical trial. During this trial, we may wish to conduct immune studies on your samples that we are not equipped to do ourselves, or that other research groups at QIMR Berghofer or other institutes/universities may be more specialised in undertaking. In such cases, we will transfer your samples to collaborators to allow this work to be done. We may also ask the collaborators to analyse your de-identified data. No identifying details will be shared, and your tissue will not be sold by QIMR Berghofer.

If there are any blood samples or T cells remaining at the conclusion of the trial, we would like to ensure that these valuable samples don't go to waste. Therefore, we request permission for long-term storage and future use of any remaining samples, and the clinical data associated with them. This clinical data includes your date of birth, sex, clinical history related to transplantation and receipt of the T cell therapy, and your immune response against Epstein–Barr virus, cytomegalovirus, BK virus and adenovirus. No samples or data would contain your name – they would be linked only to your unique study code. The samples and clinical information would be used in future research projects investigating virus-related conditions or the development of immunotherapies. As with the current project, any future projects would not include genetic studies that could result in information about future risks to your health of the health of your family.

Any future research projects utilising samples from this trial will be approved by the appropriate human research ethics committee(s) prior to their commencement. Your samples would not be used for any other purposes, except where ethics approval has been granted. You can indicate your agreement or disagreement with this long-term storage on the extended consent form below. If you agree to the use of your samples for future research, they will be stored at QIMR Berghofer indefinitely, until they are analysed. If you disagree, your remaining samples will be destroyed at the completion of the project.

10. What if new information arises during this clinical trial?

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

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

11. Can I have other treatments during this clinical trial?

Whilst you are participating in this trial, you may not be able to take some of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell the study doctor and the study staff about any treatments or medications that you are taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the study doctor about any changes to these during your participation in the clinical trial. The study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the trial.

12. What if I withdraw from this clinical trial?

You may voluntarily withdraw from the trial at any time. In addition, you may be withdrawn at the discretion of the study doctor. Withdrawal from the trial will not affect your standard clinical care, which will continue to be provided.

The following occurrences will result in your withdrawal from the clinical trial:

1. A suitable T cell therapy based on your medical history cannot be identified
2. The study doctors are concerned about your safety
3. You regularly do not comply with the clinical trial requirements (e.g. you miss appointments).

If you decide to withdraw from the clinical trial, please notify a member of the study team before you withdraw. This notice will allow that person to discuss any health risks or special requirements linked

to withdrawing, which may vary depending on the point in the study at which you withdraw. If you withdraw from the trial, personal information that has already been collected will be retained to ensure that the results of the trial can be measured properly, and to comply with law.

If you choose to withdraw from the trial, or if you are withdrawn due to one of the above reasons, we will request your permission to allow us to check your progress remotely every 4–6 months until the trial has been completed. This will not require any additional visits to the hospital or interactions with the study team; we will collect information from your medical records. This will enable us to see how you are progressing clinically, including whether or not you are continuing to experience complications from the virus that we targeted with the T cell therapy. Your response will be recorded in the withdrawal form attached to this document.

Please note that if a suitable T cell therapy cannot be identified, you can still be re-assessed at a later date for inclusion into the trial if new T cell therapies are grown.

13. Could this clinical trial be stopped unexpectedly?

This clinical trial may be stopped unexpectedly for a variety of reasons. These may include reasons such as the observation of unacceptable side effects.

14. What happens when the clinical trial ends?

At the end of this clinical trial, you will continue to be cared for by your usual medical team. The results of the trial will be analysed and then published for legitimate scientific purposes, including use in future medical or pharmaceutical research, as soon as possible after the final participant has completed the clinical trial. The results will be published in the form of journal articles and presentations at scientific and medical meetings. At your request, we will provide you with a copy of any articles we publish in scientific and/or medical journals following the completion of the trial. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Part 2: How is the clinical trial being conducted?

15. What will happen to my information?

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for this clinical trial or the future research described in Section 9 (if you provide additional consent for future studies). Any information obtained in connection with this clinical trial that can identify you will remain confidential. At your treating hospital, only the staff who work on the trial or who are involved in your ongoing clinical care will have knowledge of your involvement in this clinical trial. At QIMR Berghofer, this study's Principal Investigator and Project Managers will know your identity.

In addition to your health information, samples of your blood will be collected and stored at QIMR Berghofer. All data and samples obtained by QIMR Berghofer will be labelled with your unique trial enrolment code rather than your name, so research staff who analyse your data and samples but are not authorised to know your identity will not know who you are.

The Principal Investigator and Project Managers will be able to link these samples and data to you using a secure trial enrolment log, which is not accessible to other staff. All trial data will be kept in locked cabinets or in secure electronic folders, and stored tissue samples will be kept at QIMR Berghofer in facilities that are protected with keycard access. Only authorised trial staff will have access to your

data and samples, for research purposes. Your information will only be used for the purpose of this clinical trial and will only be disclosed with your permission, except as required by law.

Information about you may be obtained from their health records held at this and other health services, for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this clinical trial.

Your health records and any information obtained during the clinical trial are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor (QIMR Berghofer), the institution relevant to this Participant Information Sheet (*[insert name of institution]*), or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. All study-related documents and records are to be retained for a minimum of 15 years following trial completion. Written agreement from the Sponsor must precede destruction of same.

Information about your participation in this clinical trial may be recorded in your health records. You have the right to request access to your information that has been 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.

As described in Section 14, it is anticipated that the results of this clinical trial will be published and/or presented in a variety of forums. Your unique study number will be used in any publication or presentation, so you cannot be identified, except with your permission.

16. Complaints and Compensation

You will not be paid to participate in this clinical trial. If you suffer any injuries or complications as a result of this trial, 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. In accordance with the guidelines for running clinical trials issued by the Therapeutic Goods Administration and the Australian National Health and Medical Research Council, clinical trial insurance will be maintained by the Sponsor. The Sponsor adheres to the *Medicines Australia Guidelines for Compensation*.

You do not give up any legal rights to compensation for your injury or compensation by participating in this trial. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the trial. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the trial (for example, the researcher, the hospital, or the study doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

Whilst you are free to discuss your participation in this clinical trial with study staff (see list of contact persons below), if you would like to speak to someone not directly associated with the trial you are welcome to contact the Secretary of the QIMR Berghofer HREC via: phone: (07) 3362 0117 or email: HREC.Secretariat@qimrberghofer.edu.au. *[For Royal Adelaide Hospital, add:* You may also contact a representative of the Central Adelaide Local Health Network HREC via phone: (08) 7117 2229 or email: Health.CALHNResearchEthics@sa.gov.au*]*. An ethics committee representative will be available to answer questions about your rights in this trial, or to record independent complaints.

17. Who is organising and funding the clinical trial?

This clinical trial is being overseen by Prof Rajiv Khanna at QIMR Berghofer. Prof Khanna and a Co-Investigator on this trial, Assoc Prof Corey Smith, hold patents on some of the peptides that we use to grow T cell therapies. This means that they could potentially benefit financially from the outcomes of this clinical trial. QIMR Berghofer may also benefit financially from this clinical trial if, for example, the trial results in intellectual property, which may be used to develop a commercial product. Any commercial product developed as a result of this research will remain the property of the Sponsor/Investigators. By taking part in this trial, you agree that samples of your blood (or data generated from the analysis of these samples) may be provided to QIMR Berghofer. QIMR Berghofer and the research team may directly or indirectly benefit financially from your samples or from knowledge acquired through the analysis of your samples. You will not benefit financially from your involvement in this trial.

Even if knowledge acquired through this research leads to discoveries that are of commercial value to QIMR Berghofer, the study doctors or their institutions, there will be no financial benefit to you, or your family from these discoveries. Aside from the potential for future development of a commercial product based on the outcomes of this research, no member of the research team will receive a personal financial benefit from your involvement in this trial (other than their ordinary wages).

18. Who has reviewed the clinical trial?

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 clinical trial have been approved by the QIMR Berghofer HREC *[For Royal Adelaide Hospital, add:* and the Central Adelaide Local Health Network HREC*]* (see contact details in Section 16).

This clinical trial is being carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. 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

This clinical trial is being run concurrently by QIMR Berghofer, The Prince Charles Hospital, Princess Alexandra Hospital, Royal Brisbane and Women's Hospital (all Brisbane) and the Royal Adelaide Hospital, and is sponsored by QIMR Berghofer. All parties are bound by the Australian National Health and Medical Research Council guidelines for research in human participants. The clinical trial is being conducted according to the principles of Good Clinical Practice as recognised by the Therapeutic Goods Administration.

If you have a problem, encounter any clinical trial-related injury, or have more questions about the clinical trial, you may contact one of the study staff listed below:

Study Doctor(s):
[Add site-specific Clinical Investigator name(s) and phone number(s); email address optional]

Clinical Trial Coordinator:
[Add site-specific Clinical Trial Coordinator name(s) and phone number(s); email address optional]

Emergency Clinical Contact Person (available 24 hours):
[Provide the name and contact details of a 24-hour clinical contact person]

Project Managers (QIMR Berghofer):

Dr Michelle Neller or Ms Hilary Reddiex, via email: immunotherapy@qimrberghofer.edu.au or phone: 0408 884 169.