QIMR Berghofer
Medical Research Institute

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Participant Information Sheet/Consent Form – Parent/Guardian

Study Title:	Phase I clinical trial of adoptive transfer of multi-virus-specific T cells into TCRαβ$^+$/CD19$^+$-depleted haploidentical HSCT recipients
Short Title:	Multi-virus-specific T cell therapy for haplo-HSCT
Protocol Number:	P3505-QCHS
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 child's participation involve?

1. Introduction

We are asking the child in your care (from here on referred to as 'your child') to take part in this clinical trial. They are being asked to participate in the trial because a haploidentical haematopoietic stem cell transplant (haplo-HSCT) is planned as part of their clinical care. This trial is testing a new preventative therapy for infectious complications following the 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/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 your child 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 your child can take part, you might want to talk about it with a relative, friend or your child's local doctor.

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

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

- Understand what you have read
- Consent to your child taking part in the research project
- Consent for your child to have the tests and treatments that are described
- Consent to the use of your child's 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?

In this trial, a T cell therapy targeting a number of viruses will be created for each patient. A blood sample from the transplant donor will be used to grow these T cells. This therapy will then be given to the transplant recipient – your child. 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 who are at risk of uncontrolled viral infection.

The viruses we are targeting are Epstein–Barr virus, cytomegalovirus, BK virus and adenovirus. The T cell therapies that we grow will vary from donor to donor, as 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. 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 reproduce to strengthen the immune response. Once the T cells have been grown, we will freeze them in single-dose vials for future infusion into patients.

You may have heard of graft-versus-host disease (GvHD), which is a serious complication that can occur following transplantation. In GvHD, some of the T cells from the transplant (graft) attack the patient. To reduce the chance of this occurring, most of the T cells are removed from the transplant before a patient receives a haplo-HSCT. By removing most of the T cells, haplo-HSCT recipients are at low risk of developing GvHD. However, T cells are important for fighting viruses, and removing them means that the transplant recipient is at much higher risk of developing an infection. As part of this clinical trial, we will see if the T cells that we grow in the laboratory from the transplant donor can help to restore the transplant recipient's immune system. This may help to prevent serious infectious complications from developing.

T cell immunotherapy is an experimental treatment. This means that it has not yet been approved as a treatment for infectious complications following transplant in Australia. One of the possible risks of this treatment is that it could cause GvHD, as we are transferring another person's immune cells into patients. However, based on previous clinical trials of similar therapies, we believe this risk is low, and we will monitor all patients closely to ensure that any GvHD is identified and treated early.

This research has been initiated by Professor Rajiv Khanna at QIMR Berghofer Medical Research Institute, and is funded by the Children's Hospital Foundation and QIMR Berghofer Medical Research Institute.

3. What does participation in this research involve?

Before any study-related assessments are performed, this consent form must be signed to enable your child to be screened to determine their eligibility to participate in this study. You will be given a copy of this signed form to keep. If it is age appropriate, your child may also be involved in the process of deciding whether to participate in this study. This means they will be given a child/adolescent information sheet and assent form to review, and will be able to ask any questions about the study. The study doctor will give them answers to help them understand what is involved. If you decide that your child can participate in this research project, the study doctor will inform your child's local doctor.

Only children undergoing a haplo-HSCT will be enrolled in this study; however, this transplant is <u>not</u> being performed specifically for the purpose of this trial (i.e. it will be the standard treatment for your child, regardless of whether or not they participate in this study).

Screening assessment
For this assessment, we will use the results of tests that have already been recorded in your child's medical record, or via interview with you. No additional testing will be required. Information to be collected includes:

- Date of birth
- Sex
- Height/weight
- Tissue type
- Relevant medical history
- Full blood count results

If your child is eligible to participate in the trial, they will undergo the haplo-HSCT as per standard treatment. Blood for the T cell therapy will be taken from the haplo-HSCT donor prior to the transplant.

Infusion visits
Please be aware that there is a chance that the T cell therapy won't grow from the donor's blood, and in this case your child won't be able to continue in the trial.

If the T cell therapy is successfully grown, infusions will start at least 28 days following the transplant. The start date will be chosen by the study doctor, based on your child's clinical status. Before infusions begin, the clinical team will confirm that the transplant has been successful, there is no evidence of GvHD, and your child is generally well.

The infusions will be given at the hospital, and your child will then be monitored closely for any side effects that may result from the infusion, for at least 4 hours. If your child is receiving the infusion as an outpatient, they will need to stay at the hospital following each infusion until the treating doctor confirms that they can go home. Your child will receive the T cell therapy approximately every 2 weeks. Up to six doses will be given, but there may be fewer doses, depending on how well the T cells grow.

We will study the effects of this treatment by monitoring your child's signs and symptoms, and by blood tests. Blood tests will be done prior to each infusion visit. If possible, we will use the results from your child's medical record rather than repeat a test. In addition, blood samples will be obtained to study your child's immune system following the treatment. For this, around 5 mL of blood (approximately one teaspoon) will be obtained prior to each infusion, if it is clinically feasible. Your child will also be checked by the treating doctor for any adverse effects during these visits.

Follow-up visits
Follow-up visits will occur at approximately 2, 6, 10 and 14 weeks following the final infusion, and then as per standard of care until approximately 40 weeks following the final infusion. Standard-of-care visits are approximately every 2–3 months. Here, we will again study the effects of this treatment by monitoring your child's signs and symptoms, any adverse effects, and by blood tests, including measuring the amount (if any) of each virus present in your child's blood. A 5 mL blood sample will be obtained at each visit to study the immune response of the treatment. Your child's total length of involvement in the research will be approximately 12 months. The duration of participation might be longer if patients are consented further in advance of transplantation, if there is a delay in commencing infusions following transplantation, or due to clinical complications.

Long-term follow-up
Once your child has had their final follow-up visit, we will check your child's 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 their medical records. This will enable us to see how your child is progressing clinically, including whether or not they are experiencing any illness from the viruses that we are targeting.

Storage of blood samples for trial purposes
By signing the attached consent form, you are confirming that you agree to have your child's 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 child's blood will help researchers gain information about their 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.

It is important to tell the study doctor and the research staff about any treatments or medications your child may be taking, including non-prescription medications, vitamins or herbal remedies, and any changes to these during their participation in the study.

Future access to cell therapy
After this trial, there is no guarantee of future access to T cell therapy. However, if there are sufficient T cells left after your child has completed their infusion visits, we will store up to 12 additional doses for a 1-year holding period. If your child becomes critically ill and their doctors believe they would benefit from further treatment with T cell therapy, the hospital may apply for access to any remaining doses of cells via the Special Access Scheme of the Therapeutic Goods Administration. This scheme allows patients to access new treatments that haven't yet been approved for use in Australia.

If there are more than 12 additional doses, and subject to an assessment of risk (i.e. determining whether or not the donor's cells would be suitable for use in other patients), we would like to make the remaining cells available for other patients. This would only be done if the blood donor consents for their cells to be used in this way – the donor will be asked for their permission prior to blood collection for therapy generation. If they agree to this request, the cells would form part of a larger T cell repository, which could be used in future clinical trials, or for patients who require urgent treatment via the Special Access Scheme. In addition, we would move the additional doses of cells to the repository at the end of the 1-year holding period.

Please note that there is no guarantee that cells from the repository would be available specifically for your child. However, it will be in place for all patients with viral complications, if a suitable match is available and an application by the treating hospital is approved.

Additional costs
There are no additional costs associated with participation in this research project, apart from transport to and from the hospital for clinical trial visits. Where possible, these will be timed to coincide with your child's regular visits to the hospital. Neither you nor your child will be paid for being involved in the clinical trial. All medication, tests and medical care required as part of the trial will be provided to your child free of charge. This excludes the costs of any treatment that your child requires as part of their standard clinical management.

4. Other relevant information about the research project

We are aiming to recruit 20 transplant patients and their transplant donors for this study. Patients and donors will be recruited from the Queensland Children's Hospital in Brisbane, The Royal Children's Hospital Melbourne, and Sydney Children's Hospital. All participants will receive the same standard-of-care treatment for their haplo-HSCT transplant, and then the T cell therapy.

5. Does my child have to take part in this research project?

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

If you do decide that your child can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

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

6. What are the alternatives to participation?

Your child does not have to take part in this research project to receive treatment at this hospital. At any time you are free to withdraw consent for your child's participation in this study. It is important to understand that if you decide to withdraw your child from this study, you and your child will not be disadvantaged. Your child will continue to receive the standard care that their treating doctor has prescribed. Your child 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 child's local doctor.

7. What are the possible benefits of taking part?

We cannot guarantee that your child will receive any benefits from this research, as this is the first clinical trial of this T cell therapy and we do not yet know its impact on patients. However, it is possible that infusion of the T cell therapy may help restore your child's immunity against multiple viruses and help control viral infection and disease. We hope this study will tell us whether T cell infusion is a safe and feasible therapy that can 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. Your child may experience none, some or all of the side effects listed below, and they may be mild, moderate or severe. If your child has 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 your child has.

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 development or worsening of GvHD. These will now be discussed in detail.

The T cell therapy is grown in the laboratory and strict quality standards will be used in the manufacturing process. The cells are also tested for microbial contamination prior to infusion, which 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 your child could develop low blood pressure, fatigue, pain or a fever (up to 40 °C) following the infusion. However, during these cell infusions your child 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.

GvHD is a potential harmful effect of cell-based therapies. One of the challenges post transplantation is balancing harmful immune responses (which lead to GvHD) and beneficial immune responses (which help fight infections). 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 child's tissues to cause inflammation or GvHD. Previous clinical trials of similar T cell therapies targeting viruses in transplant recipients indicate that the risk of GvHD is low, and our laboratory will test for unwanted T cells before the therapy is given. However, we cannot completely rule out this risk, and we monitor your child closely for the development or worsening of GvHD, according to a standard grading system (grades 0–4). Any GvHD will be treated along standard lines by the study doctor, and if the GvHD becomes a higher grade (i.e. grade 3 or 4), infusions will be discontinued until it can be controlled.

This clinical trial will involve children up to the age of 18. 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 research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. Females of child-bearing potential must not participate in the research if they are pregnant or breast-feeding. If child-bearing is a possibility, the female participant will be required to undergo a pregnancy test prior to commencing the research project. If the participant is male, he should not father a child for at least 2 months after the last dose of study medication.

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

If a participant becomes pregnant during the research project, the study doctor must be advised immediately. The study doctor would then withdraw the participant from the research project and advise on further medical attention should this be necessary. A participant must not continue in the research if they become pregnant.

Similarly, if a trial participant fathers a child during the research project, the study doctor must also be advised immediately. The study doctor will advise on medical attention for the participant's partner should this be necessary.

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.

9. What will happen to my child's test samples?

To maintain your child's privacy and confidentiality throughout the clinical trial, they 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 your child from their unique code.

Blood collected for research laboratory analysis of your child's 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 child's samples. The immune studies on your child's 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.

By signing this consent form you agree to have your child's tissue samples (i.e., blood and T cells grown in the lab from your child's blood) stored at QIMR Berghofer for analysis as part of this project. 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 child's 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 child's samples to collaborators to allow this work to be done. Your child's tissue will not be sold by QIMR Berghofer.

As we are collecting very small volumes of blood for research, we don't anticipate that there will be samples remaining in storage at the conclusion of this project. However, if there are any blood samples or T cells remaining, 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 their date of birth, sex, clinical history related to transplantation and receipt of the T cell therapy, and their immune response against Epstein–Barr virus, cytomegalovirus, BK virus and adenovirus. No samples or data would contain your child's name – they would be linked only to your child's unique study code. The samples and clinical information would be used in future research projects investigating virus-related conditions or the development of immunotherapies.

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 child's 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 child's samples for future research, they will be stored at QIMR Berghofer indefinitely, until they are analysed. If you disagree, your child's remaining samples will be destroyed at the completion of the project.

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, the study doctor will tell you about it and discuss with you whether you want your child to continue in the research project. If you decide to withdraw your child, their study doctor will make arrangements for their regular health care to continue. If you decide that your child can continue in the research project, 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 child's best interests to withdraw them from the research project. If this happens, the doctor will explain the reasons and arrange for your child's regular health care to continue.

11. Can my child have other treatments during this research project?

Whilst your child is participating in this research project, they may not be able to take some of the medications or treatments they have been taking for their condition or for other reasons. It is important to tell the study doctor and the study staff about any treatments or medications that your child is 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 child's participation in the research project. The study doctor should also explain to you which treatments or medications need to be stopped for the time your child is involved in the research project.

It may also be necessary for the participant to take medication during or after the research project to address side effects or symptoms that they may have. You may need to pay for these medications and so it is important that you ask the study doctor about this possibility.

12. What if I withdraw my child from this research project?

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

The following occurrences will result in participant withdrawal from the study:
1. The T cell therapy does not meet the release criteria (this includes the cells not growing)
2. There are safety concerns for the participant
3. There is consistent non-compliance, as determined by the Investigators

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. If you choose to withdraw your child from the research project, or if they are withdrawn due to one of the above reasons, we will request your permission to allow long-term follow-up as described in Section 3 of this document. This will enable us to see how your child is progressing clinically until the trial has been completed, without requiring any more visits to the hospital for the purposes of this research project. Your response will be recorded in the withdrawal form attached to this document.

13. Could this research project be stopped unexpectedly?

This research project 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 research project ends?

At the end of this clinical trial, your child will continue to be cared for by their 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 patient has completed the study. 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 your child cannot be identified, except with your permission.

Part 2: How is the research project being conducted?

15. What will happen to information about my child?

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

In addition to your health information, samples of your child's blood will be collected and stored at QIMR Berghofer. All data and samples obtained by QIMR Berghofer will be labelled with your child's

unique trial enrolment code rather than their name, so research staff who analyse their data and samples but are not authorised to know your child's identity will not know who they are.

The Principal Investigator and Research Coordinators will be able to link these samples and data to your child 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 child's data and samples, for research purposes. Your child's information will only be used for the purpose of this research project and will only be disclosed with your permission, except as required by law.

Information about your child 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 child's participation in this clinical trial.

Your child's health records and any information obtained during the research project 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, or until the 25th birthday of the youngest participant, whichever is later. Written agreement from the Sponsor must precede destruction of same.

Information about your child's participation in this research project may be recorded in their health records. You have the right to request access to your child's 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 child's information.

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

16. Complaints and Compensation

You and your child will not be paid to participate in this study. In the event that your child suffers an injury as a result of taking part in this study, hospital care and treatment will be provided by the hospital at no extra cost to you. 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*. Please note that you also have the right to seek compensation through the legal system.

Whilst you are free to discuss your child's participation in this study with project staff (see list of contact persons below), if you would like to speak to someone not directly associated with the study you are welcome to contact a representative at the Children's Health Queensland Human Research Ethics Committee (HREC) via phone: (07) 3069 7002 or email: CHQETHICS@health.qld.gov.au. You may also contact the Secretary of the QIMR Berghofer HREC via: phone: (07) 3362 0259 or email: HREC.Secretariat@qimrberghofer.edu.au. These ethics committee representatives are available to answer questions about your child's rights in this study, or to record independent complaints.

17. Who is organising and funding the research?

This research project is being overseen by Prof Rajiv Khanna at QIMR Berghofer. Prof Khanna and a Co-Investigator on this project, 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 project. QIMR Berghofer may also benefit financially from this research project if, for example, the project 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 research project, you agree that samples of your child's 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 child's samples or from knowledge acquired through the analysis of your child's samples. You will not benefit financially from your child's involvement in this research project.

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, your child, or 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 child's involvement in this research project (other than their ordinary wages).

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 Children's Health Queensland HREC and QIMR Berghofer HREC (see contact details in Section 16).

This project is being carried out according to the *National Statement on Ethical Conduct in Human Research (2007), updated 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

This research study is being run concurrently by QIMR Berghofer, Queensland Children's Hospital (Brisbane), the Royal Children's Hospital Melbourne and Sydney Children's 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 study 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 study-related injury, or have more questions about the study, 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]

Research Coordinators (QIMR Berghofer):
Dr Michelle Neller or Dr Katherine Matthews, via email: immunotherapy@qimrberghofer.edu.au or phone: (07) 3362 0412.

QIMR Berghofer
Medical Research Institute

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Consent Form – Parent/Guardian

Study Title:	Phase I clinical trial of adoptive transfer of multi-virus-specific T cells into TCRαβ$^+$/CD19$^+$-depleted haploidentical HSCT recipients
Short Title:	Multi-virus-specific T cell therapy for haplo-HSCT
Protocol Number:	P3505-QCHS
Study Sponsor:	QIMR Berghofer Medical Research Institute
Principal Investigator:	Prof Rajiv Khanna (QIMR Berghofer)
Study Doctors:	*[Insert clinical investigator names]*
Location:	*[Insert site name]*

Declaration by Parent/Guardian

- 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 child's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to QIMR Berghofer concerning my child's 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 my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.
- I understand that I will be given a signed copy of this document to keep.

_____ _____

Name of child (please print) *Name of parent/guardian (please print)*

_____ _____

Signature of parent/guardian *Date*

Declaration by Study Doctor

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

_____ _____ _____

Name of Study Doctor (please print) *Signature* *Date*

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

QIMR Berghofer
Medical Research Institute

[Insert institution logo]

Extended Consent Form – Parent/Guardian: Long-term storage of donated tissue for future research

Study Title:	Phase I clinical trial of adoptive transfer of multi-virus-specific T cells into TCRαβ$^+$/CD19$^+$-depleted haploidentical HSCT recipients
Short Title:	Multi-virus-specific T cell therapy for haplo-HSCT
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Principal Investigator:	Prof Rajiv Khanna (QIMR Berghofer)
Study Doctors:	*[Insert clinical investigator names]*
Location:	*[Insert site name]*

Declaration by parent/guardian – please tick the appropriate box and sign below:

☐ I agree to the storage of my child's excess tissue (including blood components and T cells grown from blood) for use in future research projects investigating virus-related conditions or the development of immunotherapies. I agree for the following information to be used in conjunction with these samples: date of birth, sex, clinical history related to transplantation and receipt of the T cell therapy, and immune response against Epstein–Barr virus, cytomegalovirus, BK virus and adenovirus. I understand that all future research will first be approved by the relevant ethics committees and will abide by the relevant guidelines/regulations.

OR

☐ I do not agree to the storage of my child's excess tissue samples obtained over the course of this study (including blood components and T cells grown from blood) for use in future research projects. I understand that my child's samples will be destroyed at the completion of this study.

_____	_____	
Name of child (please print)	*Name of parent/guardian (please print)*	
	_____	_____
	Signature of parent/guardian	*Date*
_____	_____	_____
Name of Study Doctor or Delegate (print)	*Signature*	*Date*

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

QIMR Berghofer
Medical Research Institute

[Insert institution logo]

Form for Withdrawal of Participation – Parent/Guardian

Study Title:	Phase I clinical trial of adoptive transfer of multi-virus-specific T cells into TCRαβ$^+$/CD19$^+$-depleted haploidentical HSCT recipients
Short Title:	Multi-virus-specific T cell therapy for haplo-HSCT
Protocol Number:	P3505-QCHS
Study Sponsor:	QIMR Berghofer Medical Research Institute
Principal Investigator:	Prof Rajiv Khanna (QIMR Berghofer)
Study Doctors:	*[Insert clinical investigator names]*
Location:	*[Insert site name]*

Declaration by Parent/Guardian– please tick the appropriate box and sign below:

I wish to withdraw my child from participation in the above research project and understand that such withdrawal will not affect their routine treatment, relationships with those treating them or the relationship with *[insert site name]*.

☐ I give permission for the investigators to access my child's clinical data until trial closure. I understand that this will not require further contact with trial staff, as information will be collected from records made during standard care at this hospital, or by applying for reports from other treating hospitals.

OR

☐ I do not give permission for the investigators to access my child's future clinical data for trial purposes.

_____ _____

Name of child (please print) *Name of parent/guardian (please print)*

_____ _____

Signature of parent/guardian *Date*

In the event that the decision to withdraw is communicated verbally, check the box above that aligns with the parent/guardian's wishes, and provide a description of the circumstances of withdrawal:

_____

_____

Declaration by Study Doctor or Delegate

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

_____ _____ _____

Name of Study Doctor or Delegate (print) *Signature* *Date*

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