

## Participant Information Sheet

### **PROJECT TITLE: Use of human immune cells develop new immune therapies**

You are invited to take part in a research study, and we would be grateful if you could take the time to read the following information carefully. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve for you. If you wish, please feel free to discuss this information with friends or relatives, or your doctor, before you decide whether to participate.

### **1. What is the research study called?**

The title of this study is: “Use of human immune cells to develop new immune therapies”. As the title implies, we would like to use immune cells from the blood of healthy volunteers to develop new therapies for cancer and disorders of the immune system, as well as preventative vaccines for infectious diseases. As part of this research we will also develop tests to detect cellular immunity (natural exposure or by vaccination) to viruses that are common in the general population (eg cold viruses (HCoV), glandular fever (EBV), influenza, COVID-19, Cytomegalovirus (CMV)) to investigate their effects on immune cell function.

### **2. Who is organising the research study?**

The study is being organised by the University of Auckland. The department of Auckland University involved is the School of Biological Sciences, where the project will be based, under the principal investigator Dr. Hilary Sheppard and co-investigators Professor Rod Dunbar, Dr Anna Brooks and Dr. Catherine Angel. Members of the Dunbar, Sheppard, Brooks and Angel research laboratories will carry out the research in Auckland.

### **3. Why is the research study being carried out?**

New therapies are needed for infectious diseases and cancer. There is good evidence that some types of human immune cells can attack cancer. The research team is especially interested in how these cells might be activated to find and destroy any cancer cells present in the body. Better knowledge of human immune cells and the effects of common viral infections, is needed to develop new therapies for patients with cancer, such as vaccines that can stimulate cancer-attacking cells. We will also establish immune tests to detect presence of viral immunity so we can better understand the effects of common viruses on immune cell function. Results from this project will also help in the development of new vaccines for infectious diseases where effective vaccines are not yet available, and in developing therapies for disorders of the immune system.

#### **4. Who is funding the research study?**

Our research is mostly funded by the University of Auckland, using funds allocated for public good (that is, non-commercial) research, and other public good and charitable funding sources. However, as some of our work moves toward clinical trials, companies may support aspects of the research (e.g. the new start-up company SapVax LLC, formed to take some of our vaccine designs into the clinic). You have the option to consent to the use of your blood sample for such commercially funded research. If you do not consent to your blood being used for commercially funded research you can still consent to the use of your blood sample for public good, non-commercial research. In making this choice it is important to know that while any company funding our research is helping progress it into the clinic, it will also aim to deliver financial benefit to its shareholders, who may include the University of Auckland, and university staff or students who discovered the new therapy being tested.

#### **5. What will it involve if I decide to take part?**

If you decide to take part you would first be asked to fill out a short questionnaire and sign a consent form by staff or appointed delegates of the Auckland Regional Tissue Bank. You can ask the staff any questions you may have about the study before you sign the consent form. If you require further information you can contact a member of the research team directly – their contact details are on page six of this form. They will ask you a few questions to record in our database, including details provided in the questionnaire (relating to COVID-19 exposure and/or vaccination) as well as your name, date of birth, age, gender, self-identified ethnicity, contact details, as well as contact details for your primary care physician, and confirmation that you are currently healthy and not suffering from any infectious disease, and not a pregnant or lactating woman. (If you have any ill health that might exclude you from contributing to the study, no information about you will be recorded or stored in our database, so there will be no record that you were excluded due to ill health.) In addition, they will ensure that you are not regularly donating blood to the NZ Blood Service nor have donated >100 mls blood for any purpose within the last 28 days. At a time convenient for you, staff from the Auckland Regional Tissue Bank or appointed delegates would take up to 100ml (seven table-spoons) of blood from you. This will involve only the minor discomfort of having a needle introduced into your arm, in the same way as for blood tests at a doctor's surgery or pathology service collection centre. Staff trained in first aid will be available should there be any problem, eg if you should feel faint as a result of having the blood taken.

Your blood sample will then be coded so you cannot be identified by laboratory staff, and your sample would be sent to our laboratory where we would separate the white blood cells from the other components of the blood. We would store the samples in our laboratory for use in our studies. Your involvement in the study can end immediately after this first blood sample is taken.

However, we may be interested in taking further blood samples from you, for example if your blood contains particularly high numbers of the particular cells we need to study. If you were agreeable to this, then we would contact the Auckland Regional Tissue Bank with the details of your "code", and they will contact you to ask if you would be interested in donating further blood samples. After being contacted by them, you would be free to choose the times when you wished to provide further blood samples to us,

provided these were at least 4 weeks apart. Each time the procedure would be the same – you would sign a further consent form, and have up to 100ml blood sample taken. You would be free to provide as many blood samples as you wished, at times of your choosing.

If you decide to take part, whether by providing a single blood sample or multiple blood samples, you will always have the right to change your mind and withdraw completely from the study. If you do decide to withdraw, you need simply to notify the Auckland Regional Tissue Bank who will notify the Principal Investigator or their teams, and all samples from you will be immediately destroyed, without further question. You do not need to give any explanation if you decide to withdraw – this decision is entirely your own choice, and will be fully respected.

## **6. What will happen to the samples I give?**

As part of this project, the samples will be tested and analysed over the next 3 years, so they need to be preserved and stored after they reach our laboratory. Most of the sample material will be used up within 3 years, but in some cases it may be very helpful to continue storing cells from your samples beyond that time. Your samples may contain cells that have unique properties, for example white blood cells capable of killing tumours, or virally infected cells and these cells may allow important discoveries in the future that we cannot yet predict. For this reason we are seeking your consent to store cells derived from your samples for up to 20 years, to allow maximum scientific benefit to be derived from them. Some of this use may involve sharing your cells with other researchers at leading international research institutes. So if you decide to participate, when you sign the consent form you have the option of granting us 3 years or 20 years use of your sample, after which any remaining material will be destroyed by using established guidelines for discarding biohazard waste. If you are Māori and would like to request a specific tikanga (Māori custom) process, please feel free to talk with the research team about this. Please note that if you consent to the storage and use of your sample for up to 20 years, no future research project can use your sample for projects different from what is described here without first gaining the permission of the University of Auckland Human Participants Ethics Committee.

## **7. Does the study involve any genetic testing?**

Yes it may – but only on a very small region of your DNA. In some cases we may want to know your “tissue type” (technically your “HLA” type, or “MHC” type). You may have heard about tissue types being determined to see whether people are compatible for organ transplantation, but in the case of this research project, we want this information to understand how white blood cells called T cells respond to infectious agents and cancer cells. The best way to determine your tissue type is by sequencing your DNA over the very small region that encodes your tissue type. If you consent to us determining your tissue type, it is possible that the information we find may have implications for your health – for example, people with certain tissue types have a higher risk of certain diseases. If you would like us to share this information with you so you can discuss it with your primary care physician, you can indicate this on the Consent Form, and we will send any tissue type results that we obtain to you via the Auckland Regional Tissue Bank. (However please note that in many cases we will not need to determine your tissue type,

so if you consent to the possibility of tissue typing, we will not necessarily have any information to share with you.)

### **8. Does the study involve any genetic modification?**

Some of our studies may include using gene editing tools to modify the genome of cells to understand the function of genes and DNA variants that influence cellular behaviour. When compared to unmodified cells, the gene edited cells will help us to understand the consequences of particular DNA mutations and genes, which may help us to identify new ways to treat disease. However it is important to recognise that gene editing of your cells will create living cells that have been genetically modified – and technically these are regarded as Genetically Modified Organisms. On the Consent Form you therefore have the option to consent to genetic modification of your cells – but this is not necessary to enable us to perform many other useful studies on your cells that do not involve genetic modification.

If we do carry out gene editing on your cells with your consent, we will also use DNA sequencing to confirm that the correct sequence has been disrupted (“knock-outs”) or introduced (“knock-ins”). There is a very small possibility that this very limited DNA sequencing may discover variants in your DNA that have health implications for you and your family members. We will check the results against an internationally-agreed list of these variants, in consultation with a clinical genetics specialist. If we find any variant that has clear implications for your health, we will ask the Auckland Regional Tissue Bank to contact you and your primary care physician with this information. If you do not want to be informed of incidental findings then we would advise you not to take part in this study.

### **9. Will my taking part be confidential?**

If you consent to take part in the study we will need to record the details mentioned above (name, date of birth, age, gender, self-identified ethnicity, contact details, physician contact details, and COVID-19 exposure and/or vaccination history) for the purpose of analysing our results, and if you are interested in providing more than one blood sample, the Auckland Regional Tissue Bank will also record your phone contact details. All information collected about you during the course of the research will be kept strictly confidential, and access to computerised records of that information will be restricted to staff or direct delegates of the Auckland Regional Tissue Bank. The Principal Investigator and the research team under her direct control will have no direct access to this information, and can only request de-identified details from the Auckland Regional Tissue Bank, such as your age, gender and self-identified ethnicity, based on the information you provide them. In this way you will remain completely de-identified to the laboratory carrying out the studies. The records in the Auckland Regional Tissue Bank will be kept for 6 years, to allow time for data publication in peer-reviewed journals, but after that time the files will be deleted – unless you consent to sample storage and use over 20 years, when data will be kept for that length of time. Each sample stored will be labelled with a coded number, and by using coded numbers, you will also remain de-identified if we need to publish results, or share data or samples with other laboratories for the purposes of this or any subsequent study.

## 10. What will happen to the results of the research?

The aim of our research is to gain a better understanding of the role of white blood cells in patients with cancer or with infectious diseases. The information that we obtain will be preliminary and will contribute to an overall understanding of immune cells, which we hope will help in the design of new treatments in the future. Since the results we obtain using your samples will have no relevance to your health, you would not receive any of the individual research results that we generate. However, we can offer to send you an overall summary of findings written in non-academic language, but it is important to realise that it may take several years to finalize the outcomes from this study. You can indicate on the consent form if you would like to be sent a summary and there is space to provide a postal or email address for that purpose. In addition, the overall findings of our studies will be available to you through public sources, since we aim to publish the results of our research in a leading medical journal with a particular focus on cancer or the immune system. You will be able to identify future publications on this work by searching on the internet for publications that include the names of the Principal Investigator or co-investigators in the author list. Results will also be shared with the Faculty of Science's Kaiārahi, our advisor for all Māori cultural issues.

There is a small possibility that some of the results from our studies may lead to products that are commercially valuable. For example, if we purify a cell from your blood that can kill cancer cells, the molecules from those cells may be useful to treat patients with infectious disease or cancer, and may therefore have commercial value. Should this happen, you would not receive any financial benefit from these discoveries, but some value may accrue to the University and its staff and students. In the Consent Form you have the option of consenting to the commercialisation of products from your cells or molecules derived from them, but should you not wish to consent to this use, we can still perform valuable work using your donated cells.

## 11. Summary of benefits, risks, and safety

If you agree to participate in the study, there will be no immediate benefit to you. You will not receive any compensation or payment for your participation. However, this research aims to develop safe new therapies for cancer and infectious disease, and as such it may help you and your community indirectly or even directly in the future.

The risks involved in participating are minimal, since you are only asked to consent to the provision of one or more small blood samples. Participation in the study will not result in any other inconvenience or cost to you in any way. In the extremely unlikely event of a physical injury as a result of your participation in this study, you will be covered by the accident compensation legislation with its limitations. If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this study.

As mentioned above, there is a very small chance that DNA analyses may identify genetic information that has known implications for your health and/or that of your family members. This information, often referred to as an “incidental findings” that are considered to have clinical significance, based on the nature of the genetic variant and the published evidence of its link to disease, will be discussed with team advisor and clinical geneticist, Dr. Patrick Yap. If Dr. Yap deems the genetic finding to be clinically

significant, then you and your primary care physician will be notified with the recommendation that you be referred to Genetic Services to discuss the genetic finding and for genetic counselling. If you do not want to be informed of incidental findings then we would advise you not to take part in this study.

### Finally ...

Thank you for reading this and considering participation in the study.

If you have any questions, or if anything is not clear to you, please do not hesitate to contact the Principal Investigator, the co-investigators or their Head of Department.

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### Co-investigators:

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If you want to talk to someone about any Māori cultural issues you may have about this project, you can contact :

Mr. Jason Tutara, the University of Auckland Faculty of Science's kaiarahi on:  
Phone: 09 3737 599 x 87253 Email: [j.tutara@auckland.ac.nz](mailto:j.tutara@auckland.ac.nz)

For any queries regarding ethical concerns you may contact:

**The Chair**  
**The University of Auckland Human Participants Ethics Committee**  
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**APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE FOR 3 YEARS ON OCT 2019, REFERENCE NUMBER 023815**