**Participant Information Sheet/Consent Form**

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| --- | --- |
| **Title** | CHIP-MI: Investigating the role of clonal haematopoiesis of indeterminate potential (CHIP) in the inflammatory system after myocardial infarction (MI). |
| **Project Sponsor** | Monash University, Wellington Road, CLAYTON, VIC 3800 |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Stephen Nicholls/ Dr Kristen Bubb |
| **Location**  | Monash Health / Victorian Heart Hospital |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in a research study because you are aged 65 years or older and have been hospitalised for a heart attack

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

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

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

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

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

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

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

**2 What is the purpose of this research?**

Cells are the basic building blocks of all living things. The human body is composed of trillions of cells. They provide structure for the body, take in nutrients from food, convert those nutrients into energy, and carry out specialised functions. Specialised cells called Haematopoietic Stem Cells (HSCs) are the stem cells that trigger the formation of other blood cells. Our genetics play a role in regulating HSCs and their function and as we change, our genes can naturally change, or mutate When mutations occur to the genes regulating HSCs, this can lead to increased numbers of HSCs, a process that is called clonal haematopoiesis of indeterminate potential, or CHIP. Research indicates that CHIP is present in a minority people who have had a heart attack or have experienced cardiovascular disease, with age also known to be a risk factor of developing cardiovascular disease (CVD).

The purpose of this study is to assess whether patients who have confirmed CHIP display high levels of biomarkers that promote inflammatory processes compared to those without CHIP after having experienced a heart attack, and the role of these biomarkers in your recovery. By understanding how CHIP promotes CVD we can develop new approaches to risk prediction and triage patients to more intensive use of established preventive therapies and develop specific therapies to achieve more effective reductions in risk.

**3 What does participation in this research involve?**

Taking part in this project will involve providing consent for your clinical information and a blood sample to be collected for testing. You will continue to receive the same care you would have received if you chose not to participate in this research. During your participation, if any new clinically significant finding arises that may have an effect on your health, this information will be communicated to you by your treating doctor, so they can advise you on the best treatment options available to you.

* If you choose to take part, blood samples will be taken at one timepoint which is when you provide consent. Blood samples will be collected to assess your current health status, which are routinely performed as part of standard of care. Blood samples of interest to the study team, will also be collected and using this blood, the study team will test it to determine if you have CHIP.
* No more than 20mL (approximately 1 tablespoon) will be collected from you.
* Information about you and your heart attack will be accessed and collected by the study team from the medical records

Before participating in this project, you will be asked to sign a ‘Participant Consent Form’. By signing the form, you are telling us that you:

* Understand what you have read
* Consent to take part in the project as described
* Consent to the use of your personal and health information as described.

There are no costs associated with participating in this research project, nor will you be paid.

**4 What do I have to do?**

If you decide to take part in this study, it is important that you agree to inform your study doctor or the study staff when asked about any changes in your health status, your cardiovascular health, or changes in your medications, even if you think none of these are related to the study. It is also important to tell your study doctor or study staff if you change your mind about taking part in the study.

**5 Other relevant information about the research project**

This research has been initiated by Professor Stephen Nicholls. This research is being conducted by Monash University. This study intends to enrol up to 200 participants over the space of 5 years.

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

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

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

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

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include receiving standard of care treatment which may include medication and regular follow up with your doctor. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

**8 What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research. You may receive information about your health from medical tests performed in this study. Information collected in the study will add to what is known about inflammatory responses after heart attack in patients who have confirmed CHIP compared to those without CHIP.

**9 What are the possible risks and disadvantages of taking part?**

There are possible risks and discomforts from the procedures you may experience during the study. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your 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 your study doctor immediately about any new or unusual symptoms that you get.

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

*Risks associated with blood collection (common):*

Blood will be collected from you using a needle and syringe. Risks associated with blood draws or infusions can include temporary discomfort or pain from the needle, bleeding, bruising at the site where blood is drawn, and in rare cases, local infection. Dizziness and fainting can also occur in some cases due to drawing blood.

**10 What will happen to my test samples?**

Samples of your blood obtained for the purpose of this research project will be transferred to the Victorian Heart Institute, Monash University. The samples will be stored for testing. The values provided will be recorded in the study database.

During the study, up to 20 mL of blood (1 tablespoon) will be collected at Monash Health laboratory to assess your health status. Tests results will be made available to members of the study team. Once the results are available, these samples will be destroyed at the local laboratory.

In order to determine whether or not you have CHIP, the study team will sample a portion of this blood for genetic material that would indicate if you have CHIP. Once processed and a result is provided, this sample will be destroyed.

Depending on your blood sample result regarding your mutation, you may be asked to return for follow-up blood sample collection and other assessments which would have been performed at earlier visit.

If you choose to provide consent for a blood sample to be collected for Future Biomedical Research, approximately 10 mLs (2 teaspoons) of your blood will be collected additionally at time of consent. Your consent to use the study data does not have a specific expiration date, but you may withdraw your consent at any time without providing any reason by notifying the Study Doctor. You have the right to refuse. If you withdraw your consent when a sample has been taken but before it has been sent for analysis, the sponsor and the study doctor will ensure that your blood sample is destroyed. However, if analysis has already been performed, Monash University, the local Sponsor, is not obliged to destroy results of this research. If you withdraw your consent after your blood sample has been sent for genetic research the sponsor and the study doctor will ensure that your blood sample and any DNA that has been extracted from it are destroyed. However, if genetic research has already been performed the sponsor is not obliged to destroy results of this research. In this case only the blood sample and any DNA extracted will be destroyed.

Samples collected for future biomedical research that could provide useful information will be stored indefinitely. As technology and scientific knowledge evolves, the researchers may be able to perform extra tests that have not been outlined in the current protocol. These samples are valuable to medical research and may help identify a cure for disease or identify a biomarker to help with the treatment of disease. Any future tests will be performed in samples that are coded with a study ID and therefore do not contain any identifiable or sensitive information about you.

Your samples will not be sold or used directly to produce commercial products. In case of any commercial gain based on research results from your samples, Monash University will have the ownership of the research results and may file patents. The research performed with your samples may help to develop new products, new medical tests or treatments in the future that have commercial value. There will be no financial benefit to you for any commercial findings or products because of your sample use. By agreeing to take part in this clinical research study, you agree to give up your rights for any commercial value resulting from your samples and data.

Reports about research performed with your samples will not be recorded in your health/medical record and will be kept confidential to the best of our ability within the law.

In the future, researchers studying your samples may need to know more about you, such as whether you smoke or not, and other information such as your age, gender, race. If this information is already available because you are taking part in a study, it may be given to the researcher, but it will not contain information that might reveal your identity.

You will be asked whether you would like to participate in this additional Future Biomedical Research and a separate information sheet and consent form will be provided. Your participation is optional and not mandatory in order to take part in this main study. Health Authorities may request more testing on your samples in order to generate more study data. In such a case, the sponsor, Monash University will be required to perform the requested testing.

**11 What if new information arises during this research project?**

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

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

If you are confirmed to have CHIP, you will be informed that you are CHIP positive or CHIP negative and you will be provided with information on CHIP and possible cardiovascular risks. Testing positive for CHIP is specific to you only and it is not considered hereditary, or an issue for your members of your family. Qualified members of the study team will discuss this with you and will answer any questions you have regarding this.

**12 Can I have other treatments during this research project?**

You should continue to take all of the medications that your doctor prescribes for you during this research project.

**13 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the Investigators up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**14 Could this research project be stopped unexpectedly?**

It is unlikely that this project will be stopped unexpectedly, however in the event it is, you will be informed of this any your study doctor will plan for continuation of your care.

**15 What happens when the research project ends?**

At the conclusion of the research project your study doctor will be able to advise you of the outcome of the study. They may do this by contacting you via email, or by mail or in person if they are still involved in your care. They will be able to provide a document outlining the study results. Please note, the results of the study may be published in medical literature, but you will not be identified.

**Part 2 How is the research project being conducted?**

**16 What will happen to information about me?**

Your data or samples cannot be used without your consent. Therefore, you will not be able to take part in the study if you do not give your consent to use your personal information. Any information collected in this study will not be published in any manner that could identify you as an individual, during or after the conclusion of this study. We will only publish group data. Your personal and health information which we will collect as part of this study is reported in an online database by the study staff. Your name is not recorded on these forms. You are only identified by your initials and a study-specific number assigned by research staff. All forms will be stored in a safe and secure place with appropriate measures in place to protect them from unauthorised access.

All information obtained in connection with this study that can identify you will remain confidential.  It will only be accessible to research staff and it will only be used as outlined in this participant information sheet and consent form, except as required by law.

When the data are published and/or presented, all information will be in a coded format and will not reveal your identity.

By signing the attached consent form, you are agreeing to the release of your medical records held by your doctor or hospital. This information will be collected, stored and analysed only for the purposes of this study and will be limited to the medical details related to this study. Any information collected from your clinic about you will be overseen by the clinic doctors.

Your 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 Monash Health, the institution relevant to this Participant Information Sheet, 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.

It is anticipated that the results of this research project may be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

All information collected for this study will be retained for a period of no less than 15 years following the completion of the study. Hardcopy information will be shredded and destroyed, and electronic data will be deleted from the secure database after a period of no less than 15 years after the completion of the study, in accordance with Good Clinical Practice.

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

**17 Complaints and compensation**

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

**18 Who is organising and funding the research?**

This research project is being funded and conducted by the Victorian Heart Institute at Monash University.

If knowledge acquired through this research leads to discoveries that are of commercial value to Monash University, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project.

**19 Who has reviewed the research project?**

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

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

**20 Further information and who to contact**

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

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor using the details below:

 **Clinical contact person**

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| --- | --- |
| Name | *Dr Kristen Bubb* |
| Position | *Senior Research Fellow**Lead, Translational Vascular Therapeutics Group* |
| Telephone | *03 7511 1857* |
| Email | *kristen.bubb@monash.edu* |

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

|  |  |
| --- | --- |
| Reviewing HREC name | Monash Health Human Research Ethics Committee |
| HREC Executive Officer | HREC Executive Officer |
| Telephone | +61 3 9594 4611 |
| Email | research@monashhealth.org |

**Participant Consent Form**

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| **Coordinating Principal Investigator/ Principal Investigator** | Professor Stephen Nicholls/ Dr Kristen Bubb |
| **Location**  | Monash Health / Victorian Heart Hospital |

**Declaration by Participant**

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

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

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

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

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

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

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

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

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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

**Form for Withdrawal of Participation**

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| --- | --- |
| **Title** | CHIP-MI: Investigating the role of clonal haematopoiesis of indeterminate potential (CHIP) in the inflammatory system after myocardial infarction (MI). |
| **Project Sponsor** | Monash University, Wellington Road, CLAYTON, VIC 3800 |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Stephen Nicholls/ Dr Kristen Bubb |
| **Location**  | Monash Health / Victorian Heart Hospital |

**Declaration by Participant**

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

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher†**

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

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

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

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