**Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Adult providing own consent*

Austin Health

|  |  |
| --- | --- |
| **Title** | Does *Mycobacterium ulcerans* colonise skin prior to clinical Buruli ulcer? |
| **Short Title** | Buruli skin swab study |
| **Protocol Number** | Not available at this time |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Paul Johnson |
| **Associate Investigator(s)** | Anita Velink |
| **Location** | Austin Health |

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

**1 Introduction**

You are invited to take part in this research project, ‘Does *Mycobacterium ulcerans* colonise skin prior to clinical Buruli ulcer?’. This is because you are a friend or relative of a patient who was diagnosed with *Mycobacterium ulcerans* infection (Buruli ulcer) and was treated at the Austin Hospital. The research project is aiming to investigate whether the bacteria *Mycobacterium ulcerans* is present on the skin of those who live in or visit a Buruli ulcer endemic area (Mornington and Bellarine Peninsulas).

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?**

Buruli ulcer is a destructive disease of the skin and soft tissue that is caused by the bacteria *Mycobacterium ulcerans.* There is currently a major outbreak of Buruli ulcer in Victoria, specifically in the Mornington and Bellarine Peninsulas. It is unclear how humans acquire the disease. Further information regarding how Buruli ulcer is transmitted may help to prevent the disease and its complications.

This study is investigating whether people who live or visit endemic areas carry the bacteria on their skin. This has implications for how Buruli ulcer is transmitted. Participants will self-collect swabs of their skin (e.g. of backs of elbows, ankles), which will be tested for the presence of *Mycobacterium ulcerans.*

The results of this research will be used by the study researcher Anita Velink to obtain a Doctor of Medicine degree.

This research has been initiated by the study doctor, Professor Paul Johnson.

This research has been funded by the Department of Infectious Diseases, Austin Health.

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

Participation in this research will involve self-collection of swabs of certain areas of your skin (e.g. of backs of elbows, ankles. Instructions will be provided). You will also complete a short questionnaire regarding where you were and what you were wearing on the day of swab collection, what outdoor activities you undertook, and if you have ever had Buruli ulcer. You will complete the swabs where and when it is suitable for you according to the instructions, and then send them in the mail in the provided pre-addressed envelope. Participation is estimated to involve a time commitment of approximately 30 minutes. There is no risk to your health of taking the swabs.

The consent form must be signed before any study assessments are performed.

Your answers to the questionnaire and swab results will be used as data in this study.

You will receive a phone call to obtain the results of your swab (i.e. whether it was positive or negative for the bacteria we tested for). In your swab is positive, you will be offered a timely medical review and follow up by a Buruli expert (Professor Paul Johnson) or referral to another specialist of your choice. This will be free if you are eligible for Medicare.

PLEASE NOTE: Having the bacteria on your skin does not necessarily mean that you have Buruli ulcer. If you don’t have any clinical disease (e.g. an ulcer), only observation will be required. If you do have clinical disease, Buruli ulcer is a treatable condition and you will receive the follow-up and medical care needed to treat the disease. This may involve tablet antibiotics and or surgery.

We will inform you of the overall results of the study when available.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

There are no costs associated with participating in this research project, nor will you be paid. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit up to a value of $15.00

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

To participate in this study you need to return this consent form in the pre-addressed envelope, along with the completed questionnaire and self-collected swabs. We will ask you to collect the swabs after spending at least half the day (4 hours) partaking in your usual outdoor daily activities in your local area (e.g. gardening, walking the dog, sitting outside or working in an outdoor occupation), but before you shower or swim. This is expected to take 30 minutes. We will also ask you to mention this study to friends and relatives who spend time with you on the Mornington or Bellarine Peninsula so we can contact them to consider participation. We will provide you with a flyer describing the study and a number to call if they would like to proceed.

You should continue to take your regular medication.

Participating in this study does not involve any dietary or lifestyle restrictions.

You may still donate blood.

The consent form must be signed before any study assessments are performed.

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

There will be up to 60 participants overall in this research project. Some participants are ‘control’ participants who do not live or visit endemic areas of Buruli ulcer (Mornington and Bellarine Peninsulas) and will also undertake the questionnaire and swab collection.

This project involves collaboration with Austin Health and the Peter Doherty Institute for Infection and Immunity. The Doherty institute will test the swabs for the presence of the bacteria.

**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 Austin Health.

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

We cannot guarantee or promise that you will receive any benefits from this research, however possible benefits may include detecting Buruli ulcer earlier than it otherwise would have been. This may shorten the duration of treatment required.

This project may increase our understanding of how Buruli ulcer is transmitted, and therefore help to control the disease.

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

This study will not expose you to any medications or radiation. There will be no side effects or harm to your current or future health or fertility. There is **no increased risk** of acquiring Buruli ulcer from participating in this study.

You may become anxious or distressed as a result of being told that your skin swab is positive for the bacteria. However you will receive expert medical care if you do have a positive result, and early detection may shorten the duration of your treatment (if treatment is required).

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

The self-collection of swabs is a key part of participating in this research project. If you do not wish to take the swabs, you do not have to take part in this project.

Your swabs will be stored in a locked compartment in the Doherty Institute until they are tested for presence of the bacteria. This will be a period of less than 3 months. Once the swabs have been tested, they will be disposed of. The swabs will not have your name or personal information written on them, however will have a number that corresponds to your name and questionnaire information.

Your swabs will be used for this research project only.

**10 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. There are no implications for you if you choose to withdraw from this research project.

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.

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

This research project may be stopped unexpectedly for a variety of reasons. This may include serious illness of the study investigators.

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

When this research project ends, there will no follow-up required unless you have been found to have a positive skin swab result. If this is the case you will continue to receive medical care if required until the resolution of your Buruli ulcer (if you have Buruli ulcer that is detected as a result of this study).

If you wish, you may receive a copy of the study investigator’s report of the study results, expected to be available in July 2019. The study investigator will ask you if you would like to receive a copy of this report.

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

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

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Consent forms will be kept in a locked filing cabinet located at the Austin Hospital. Questionnaire and swab results will be stored without your name or identifying information on a password-protected computer which will only be accessed by the research team. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The data will be stored for a period of 7 years on the password protected computer to allow for audit and verification by authority bodies. After this period all data will be deleted.

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

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.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**14 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.

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

This research project is being conducted by Professor Paul Johnson and medical student Anita Velink.

The project is funded by the Department of Infectious Diseases, Austin Health.

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

**16 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 Austin Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**17 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 at any time the principal study doctor **Professor Paul Johnson** on**0438 324 913**or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Ms Anita Velink |
| Position | Research Associate |
| Telephone | 0490092473 |
| Email | anita.velink@unimelb.edu.au |

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: :

**Complaints contact person**

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| --- | --- |
| Name | Dr. Sianna Panagiotopoulos |
| Position | Manager, Office for Research |
| Telephone | 9496 5088 |
| Email | research@austin.org.au |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Does *Mycobacterium ulcerans* colonise skin prior to clinical Buruli ulcer? |
| **Short Title** | Buruli skin swab study |
| **Protocol Number** | N/a |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Professor Paul Johnson |
| **Associate Investigator(s)** | Anita Velink |
| **Location** | Austin Health |

**Declaration by Participant**

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

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

I 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.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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|  | | | | | | | |
|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  | |
|  | | | | | | | |
|  | Signature |  | | Date |  | |  |
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\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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

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

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

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

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

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

|  |  |
| --- | --- |
| **Title** | Does *Mycobacterium ulcerans* colonise skin prior to clinical Buruli ulcer? |
| **Short Title** | Buruli skin swab study |
| **Protocol Number** | N/a |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/Principal Investigator** | Professor Paul Johnson |
| **Associate Investigator(s)** | Anita Velink |
| **Location** | Austin Health |

**Declaration by Participant**

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

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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 |  |  |
|  | | | | | | |

† 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.