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**Participant Information Sheet/Consent Form**

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

The Alfred Hospital

|  |  |
| --- | --- |
| **Title** | Seizure Detection Using Electrocardiogram Recordings and Kaoskey TRIO Software |
| **Short Title** | Seizure Detection Using ECG and Kaoskey TRIO software |
| **Protocol Number** | KAOSKEY-K-001 |
| **Project Sponsor** | Kaoskey Pty Ltd |
| **Principal Investigator** | Professor Terence O’Brien |
| **Associate Investigator(s)** | Professor Patrick Kwan, Associate Professor Piero Perucca, Dr Shobi Sivathamboo, Ms Lyn Millist, Ms Georgia Grant, Mr Max Cowey, Mr Jack Germaine |
| **Location** | The Alfred Hospital |
| **HREC Reference** | HREC-61886-Alfred-2020 |
| **Local Project Number** | 91/20 |

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

**1 Introduction**

You are invited to take part in this research project. This is because you have been admitted for video-EEG monitoring because you may be having ongoing seizures. The research project is testing a device that may help detect seizures using heart rate and rhythms. There are two separate devices that work together to achieve this. These are called the eMotion Faros Sensor, which records heart rate and rhythm data, and the TRIO software, which analyses this data.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 your 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 have the tests and treatments that are described

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

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

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

Epilepsy is one of the most common serious brain disorders in the world, affecting over 70 million people worldwide. Over a third of patients with epilepsy will not achieve seizure control with the use of antiepileptic drugs. Uncertainty around the predictability of seizure occurrence can have a negative financial, physical and emotional impact on people with epilepsy.

The purpose of this study is to see if heart rhythms can be used to accurately detect seizures. Participants will have their heart rhythms recorded using a wearable device (“eMotion Faros Sensor”). These recordings are called echocardiograms (ECGs). These ECGs will be interpreted by using software called TRIO.

The development of a wearable device that can detect seizures would have universal applications for patients, carers, clinicians, and researchers. This would allow for high-quality monitoring of patients with epilepsy outside the hospital setting, which would improve clinical care. Having an accurate way of documenting seizures may also allow for a better understanding of the effectiveness of therapies on seizure frequency in individual patients.

Medications, drugs and devices have to be approved for use by the Australian Federal Government through the Therapeutic Goods Administration (TGA)

The eMotion Faros Sensor is approved in Australia to record heart rate and motion in adults and children. However, it is not approved to detect seizures. Therefore, it is an experimental device for detecting seizures. This means that it must be tested to see if it is effective in detecting seizures.

The TRIO software is an experimental device. This means that it is not approved for detecting seizures or any other purpose in Australia.

This research is being conducted and sponsored in Australia by Kaoskey Pty Ltd. In addition, Kaoskey Pty Ltd are the developer and owner of the TRIO software.

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

If you agree to take part in this study and the study is suitable for you, your participation in the study is expected to last up to five days (while you are being monitored in the video-EEG monitoring unit).

We will ask you to wear a device (called the “eMotion Faros Sensor”) that monitors heart rate and rhythm during the (up to) five-day video-EEG monitoring period. It is a small non-invasive sensor. The approximate size of the sensor is 5cm x 3cm x 1cm and is worn on the chest. In some patients, a fabric stretchable band and additional ECG electrodes (up to 5) may be placed on the chest, in order to improve recording quality.

The TRIO software then analyses this data once this has been collected. You will not come into contact with this device.

This study will not impact the clinical care that you receive in any way.

Your participation in this study will end once you are discharged from the video-EEG monitoring unit.

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

There are no additional costs associated with participating in this research project, nor will you be paid. The device and related medical care required as part of the research project will be provided to you free of charge.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

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

If you decide to participate:

* You need to wear the device (“eMotion Faros Sensor”) during the five-day video-EEG monitoring period.
* You need to inform your study doctor about any health problems, accidents or medical interventions that happen while you are in the study, even if you think it is not important.
* You need to inform the study doctor if you decide not to continue in the study. You don’t have to give a reason for your decision.

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

About 100 people at The Alfred hospital in Australia will take part in this research study. This study will take approximately 12 months to complete.

**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 The Alfred Hospital.

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

You do not have to take part in this research project to receive treatment at this hospital.

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

There will be no clear benefit to you from your participation in this research. However, this may potentially lead to the development of a wearable device that can accurately identify seizures, which would have universal applications for patients, carers, clinicians, and researchers in the future. This would allow for high quality monitoring and improved clinical care outside of the hospital. Having an accurate way of documenting seizures may also allow for an improved understanding of the effectiveness of therapies on seizure frequency in individual patients.

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

Medical treatments often cause side effects. 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.

|  |  |  |  |
| --- | --- | --- | --- |
| Side Effect | How often is it likely to occur? | How severe might it be? | How long might it last? |
| Skin irritation | Low | Minor | A few hours to days |
| Electromagnetic emissions or electric disturbances, (e.g. discharges or surges, such as surgical equipment or with a defibrillator) | Low | Minor | A few seconds |

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.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

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

This study will not impact your treatment in any form.

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

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss 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 sponsor 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.

**12 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:

• Unacceptable side effects.

• The device being shown not to be effective.

• The device being shown to work and not need further testing.

• Decisions made by local regulatory/health authorities.

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

The study will end once you are discharged from the video-EEG monitoring unit. You will not be required to do anything further. At the end of the study, we will send you a summary of the findings. This will be in the form of grouped results, not related to individual participants.

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

**14 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.

Any information about you that is sent out of the hospital will be labelled with a code and will not include your name or address, or any information that directly identifies you. 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.

Kaoskey Pty Ltd will received completely anonymised data. This includes demographic data (e.g. age, sex) and relevant clinical information collected during the hospital admission (e.g. the primary diagnosis) which will be in an excel spreadsheet, and ECG recordings. This does not include any identifying data such as your name, address or hospital number when sent to the sponsor, and cannot be to trace back to the individual it came from. Kaoskey Pty Ltd will keep this data for a minimum of 15 years, after which time it may be securely destroyed. Anonymised ECG recordings will be analysed at Kaoskey Pty Ltd in Sydney, Australia. All ECG recordings and analyses will be stored in secured Google Drive servers. All servers are secured via domain level password protection in a secure location and no patient identifying records will be stored on any of these servers. In addition, all servers will only be accessible to authorised staff only.

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

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 the Human Research Ethics Committee that reviewed this project, The Alfred Hospital, 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 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. You will not be named in any reports, publications, or presentations that may come from this study.

Information about your participation in this research project may be recorded in your health records.

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

If you are not satisfied with how your personal information has been handled (as laid out in the Privacy Act, 1988), then you can make a complaint to the Office of the Australian Information Commissioner (OAIC). Please refer to <http://www.oaic.gov.au/privacy/privacy-complaints> for more 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.

**15 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.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

* The medical technology industry has set up a compensation process, with which the Sponsor Kaoskey Pty Ltd of this research project has agreed to comply. Details of the process and conditions are set out in the *Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Investigation*. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request.
* You may be able to seek compensation through the courts.

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

This research project is being conducted, sponsored and funded in Australia by Kaoskey Pty Ltd.

Kaoskey Pty Ltd may benefit financially from this research project if, for example, the project assists Kaoskey Pty Ltd to obtain approval for a new device.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Kaoskey Pty Ltd, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Alfred Health will receive a payment from Kaoskey Pty Ltd for undertaking this research project. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**17 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 Alfred 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.

Approval has been given by The Alfred hospital, where this research will be carried out.

**18 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 on 0418 370 566 or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr Shobi Sivathamboo |
| Position | Research Fellow |
| Telephone | 0479 041 282 |
| Email | S.Sivathamboo@alfred.org.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Position | Complaints Officer |
| Telephone | (03) 9076 3619 |
| Email | Complaints Officer |

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 | Alfred Hospital Ethics Committee |
| Position | HREC Executive Officer |
| Telephone | (03) 9076 3619 |
| Email | research@alfred.org.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

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

|  |  |
| --- | --- |
| **Title** | Seizure Detection Using Electrocardiogram Recordings and Kaoskey TRIO Software |
| **Short Title** | Seizure Detection Using ECG and Kaoskey TRIO software |
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| **Location** | The Alfred Hospital |
| **HREC Reference** | HREC-61886-Alfred-2020 |
| **Local Project Number** | 91/20 |

**Consent Agreement**

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 doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The Alfred Hospital concerning my 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 participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

**Declaration by Participant – for participants who have read the information**

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Declaration - for participants unable to read the information and consent form**

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| Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* 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** | Seizure Detection Using Electrocardiogram Recordings and Kaoskey TRIO Software |
| **Short Title** | Seizure Detection Using ECG and Kaoskey TRIO software |
| **Protocol Number** | KAOSKEY-K-001 |
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| **Location** | The Alfred Hospital |
| **HREC Reference** | HREC-61886-Alfred-2020 |
| **Local Project Number** | 91/20 |

**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 The Alfred Hospital.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

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.