**Participant Information Sheet/Consent Form**

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

*Alfred Hospital*

**Title:** Facial recognition to predict pain and opioid requirement after surgery

**Short title:** Facial recognition for pain and opioids

**Project number:** 251/20

**Project Sponsor:** Strong Room Technology Pty Ltd

**Principal Investigator:**

Dr Alex Konstantatos

**Associate Investigators:**

Professor Paul Myles

Mr Max Mito

Mr Christopher Durre

Dr Sadi Vural

**Location:**

Alfred Hospital

Melbourne, Australia

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

**1 Introduction**

You are invited to take part in this research project. This is because you will have a major elective operation. The research project is testing a new technique for preventing pain and excessive opioid requirement following surgery. The new technique is called facial recognition 3-dimensional mapping.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the 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?**

The purpose of this study is to explore whether facial recognition 3-dimensional mapping can be used to measure pain prior to waking and whether it can be used to predict opioid requirement following surgery. All participants in the study will receive facial recognition 3-dimensional mapping. This project will recruit 120 participants and will take place only at The Alfred Hospital.

Medications, drugs and devices must be approved for use by the Australian Federal Government. Facial recognition 3-dimensional mapping is an experimental treatment. This means that it is not an approved treatment for pain after surgery or prolonged opioid requirement after surgery in Australia.

The two main researchers are doctors working in clinical practice, Dr Alex Konstantatos and Professor Paul Myles. Alex and Paul came up with the idea for the research. They will be working with three people who are specialists in information technology, Mr Max Mito, Mr Christopher Durre and Dr Said Vural, who are from Strong Room Technology.

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

You will be participating in a study where your standard of care for surgery, anaesthesia and pain management will not change. We seek your consent to obtain video footage of your facial expressions before, during and after your anaesthesia and surgery. Your facial expressions will then be interpreted and compared to expressions of other participants by computer experts involved in this research project. We will also conduct surveys which will help us measure your emotional expressivity before your operation and guide us in how much opioid is needed after your surgery, as well as measure your overall recovery from surgery. The same researcher conducting these surveys will measure your pain intensity using a behavioural scale as you begin to wake from surgery.

The video recordings of your face will occur several times (a minimum of 3 times) during your stay in the operating theatre using a small portable video camera positioned just above your bed. Firstly, we will obtain video footage of your face before the commencement of your anaesthetic to obtain a reference recording of your facial features. The second recording will take place before your anaesthetic commences and several minutes after you have been given a dose of opioid medication through an intravenous drip. It is usual practice to receive opioid medication prior to hypnotic medications required to initiate anaesthesia. The third recording will take place when your operation has finished as you begin to wake from your anaesthetic. You are unlikely to be awake enough to be able to remember the third recording taking place. The fourth video will take place only if you require a dose of opioid medication through the intravenous drip to control pain after waking from surgery in the post anaesthesia care unit.

Each video recording will take place for approximately one minute and will obtain information about the relative position, size, and shape and movements of your facial features such as your eyes, nose, cheekbones, and jaw. The objective of the study will be to see how these facial features change after you receive opioid medication before and after your operation and also to try and detect whether your face shows evidence of pain before you are sufficiently awake to indicate that you have pain. Once we have recordings of your facial expressions, they will be stored securely under password control at the site where the computer analyst researchers work, Strong Room Technology. They will only be accessible by the researchers involved in this project. The videos will then be analysed by a special computer program which will look for patterns of facial expression that could be linked to perception of pain and reactions to receiving opioid therapy.

In addition to the video recordings, we will also conduct surveys that measure how much opioid you might need after surgery, and measure your emotional expressivity before your operation. We will also use a behavioural scale to estimate your pain intensity as you wake from surgery. The purpose of these surveys is to help us to evaluate the effectiveness of the facial recognition 3-dimensional mapping in predicting pain and opioid requirements following surgery.

We will also collect information about your previous health history, age, gender, ethnicity, weight, type and duration of your operation, your pain intensity ratings, potential side effects from analgesic (and other) medications and the quantity and duration of opioid medications that you will require following your operation. Some of this information can only be collected after you leave hospital, so we will continue to contact you after your discharge from hospital. Most of this information will relate to the amount and duration of your opioid therapy after you leave hospital and whether you have experienced any complications following your surgery.

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

You will be reimbursed for any reasonable travel, parking, and other expenses associated with the research project visit up to a total of $30.

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?**

There will be no restrictions in your lifestyle, diet, or ongoing requirement for medications that you were taking prior to your admission. There are no restrictions to the therapy that you will receive while in hospital, including your anaesthetic and your pain management.

**5 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

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

You do not have to take part in this research project to receive treatment at this hospital. You will receive your anaesthetic, surgery and postoperative care as organised by the doctors managing your care. The only difference is that you will not be participating in the preoperative surveys, have your pain intensity measured by behavioural pain assessment, or participate in video measurement and assessment of your facial features.

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

We cannot guarantee or promise that you will receive any benefits from this research. People in future may stand to benefit from your participation through improved pain care following surgery and better management of opioid therapy to treat pain following surgery

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

You might feel anxious after conducting some of the surveys or as a result of participation in the video. Tell your study doctor immediately if you suffer from these symptoms. Your study doctor will discuss the best way of managing any side effects with you.

Your participation in this study may uncover a psychological illness as a result of participating in one of the surveys or having video footage taken of your facial expressions. In the event that this happens, we will organise for you to see someone who can manage your psychological illness. If you become upset or distressed as a result of your participation in any other part of 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.

This research project involves the collection of information about your use of drugs. The information will be stored in 2 ways. Both ways ensure that your personal details and responses are protected: in a locked cabinet only accessible by the researchers and through password protection and in a computer document accessible only by the researchers. In the event that The Alfred Hospital is required to disclose that information, it may be used against you in legal proceedings or otherwise. The implications of signing consent to participate in our study are explained in more detail in paragraph 12 of this consent form.

**9 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 health risks or 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 when you withdraw from the research project. In the event that you withdraw consent and do not wish for your video to be included in the research analysis then your video will be erased in accordance with your wishes.

**10 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 not to work and need further testing

• Decisions made in the commercial interests of the funding body or by local regulatory/health authorities.

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

Once this research project is completed, the researchers will evaluate the effectiveness of the facial recognition 3-dimensional mapping I.e. the ability for facial recognition technology to predict pain early after surgery and predict opioid requirement following surgery. If proven to be effective, further research will take place to help define a role for the facial recognition 3-dimensional mapping. In the event that the facial recognition 3-dimensional mapping proves to not be effective as first thought, clinicians will continue to manage pain and susceptibility to opioids as they do currently, by using existing measures of pain intensity and careful history taking and taking surveys to assess for susceptibility to opioids.

Results of the overall results of this study will be made available to you as a report after the project is completed. We hope that this will be approximately 6- 18 months after you have participated in the project. The report will either be mailed to you by letter or by e-mail to the address recorded in your participant details.

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

**12 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. This will be achieved by protecting your name in the data collection form (replacing your name with a number) and storing paper-based documents in a designated filing cabinet to which only the researchers have access by lock and key. Electronic information generated by this research, including video footage and analysis will also be stored in a way where your identity is protected and saved in a secure database by Strong Room Technology. The password will only be known by the researchers. Your information will only be used for the purpose of this research project and to help with future research projects. However, you should be aware that should you become involved with a criminal or civil case, in certain limited circumstances, a court of law may be persuaded to order disclosure of particular information relating to you that would otherwise remain confidential

Information about you will be obtained from your health records held at the Alfred Hospital 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 Sponsor, Strong Room Technology, the institution relevant to this Participant Information Sheet, Alfred Hospital, or in compliance with the 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. All presentations will not directly refer to The Alfred Hospital and will not use the names or specific results of any individual participant.

Information about your participation in this research project will 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.

Any information obtained for the purpose of this research project and any future projects that arise as a result of this specific projectthat can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

**13 What if I get injured in the research?**

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. As 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 pharmaceutical industry has set up a compensation process, with which the Sponsor, Strong Room Technology, involved with this research project has agreed to comply. Details of the process and conditions are set out in the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. 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.

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

This research project will be conducted by Dr Alex Konstantatos*.* It is funded in Australia by Strong Room Technology.

Strong Room Technologies may eventually benefit financially from this research project. For example, the project may assist them to introduce facial recognition 3-dimensional mapping products to medical practice because we prove it helps with measurement of early pain levels and prediction of opioid therapy after surgery.

By taking part in this research project you agree that data generated from analysis of facial videos and survey information may be provided to Strong Room Technology.

You will not benefit financially from your involvement in this research project even if, for example, your data (or knowledge acquired from analysis of your data) prove to be of commercial value to Strong Room Technology.

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

Alfred Hospital will receive a payment from Strong Room technology 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).

**15 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 Alfred Hospital Ethics Committee.

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.

**16 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 90763176 or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr Alex Konstantatos |
| Position | Chief Investigatorand Specialist Anaesthetist/Head of Alfred Hospital Pain Service |
| Telephone | 90763176 |
| Email | [A.Konstantatos@alfred.org.au](mailto:A.Konstantatos@alfred.org.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:

**HREC Office/Complaints contact person**

|  |  |
| --- | --- |
| Position | Complaints Officer, Office of Ethics & Research Governance, Alfred Health |
| Telephone | (03) 9076 3619 |
| Email | research@alfred.org.au |

Please quote the following project number: 251/20

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

**Title:** Facial recognition to predict pain and opioid requirement after surgery

**Short title:** Facial recognition for pain and opioids

**Project number:** 251/20

**Project Sponsor:** Strong Room Technology

**Principal Investigators:**

Dr Alex Konstantatos

Professor Paul Myles

**Associate Investigators:**

Mr Max Mito

Mr Christopher Durre

Dr Sadi Vural

**Location:**

Alfred Hospital

Melbourne, Australia

**Consent Agreement**

I have read the Participant Information Sheet

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 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 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.

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

**Title:** Facial recognition to predict pain and opioid requirement after surgery

**Short title:** Facial recognition for pain and opioids

**Project number:** 251/20

**Project Sponsor:** Strong Room Technology

**Principal Investigator:**

Dr Alex Konstantatos

**Associate Investigators:**

Professor Paul Myles

Mr Max Mito

Mr Christopher Durre

Dr Sadi Vural

**Location:**

Alfred Hospital

Melbourne, Australia

**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 Alfred Health.

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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.

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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.