**Participant Information Sheet**

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| HREC No: | **2016.33.213** |
| Project Title: | Prothrombotic changes associated with aortic valve management |
| Name of Researchers: | Dr. Jonathon Fanning, Dr. Karl Poon, Dr. Alexander Incani, Prof. John Fraser, Dr. John Keys, Dr. Stephen Fanning, Dr. Sarvesh Natani, Dr. Bruce Garlick, Dr. Shaun Roberts, Ms. Shannon Hoban. |

This information sheet is 7 pages long. Please make sure you have all pages.

1. **A lay title of the research study**

Changes in the clotting potential of the blood during aortic valve surgery and intervention.

1. **Invitation to participate in the study**

As a patient of St. Andrew’s War Memorial Hospital (SAWMH) who has elected to undergo either: i) a transcatheter aortic valve implantation (TAVI); or, ii) a percutaneous coronary intervention procedure (PCI); or, iii) an aortic valve replacement (AVR) surgery, you are invited to participate in this research project. Before you decide whether or not to be involved, we would like to give you more information about the study to openly and as clearly as possible explain its purpose and what participation will involve.

Your decision to participate in this study is completely voluntary. You may refuse or withdraw your involvement at any time during the study by notifying a member of the research team and/or submitting the “revocation of consent” form attached (page 7). Your medical care, relationship with treating medical personnel and relationship with SAWMH will not be affected by your decision.

Please read the Information Sheet carefully and feel free to ask questions about any information in the statement that you may need clarified. Once you understand what the project is about and if you decide to enrol in the study you will be asked to sign the consent form (page 5). By signing the consent form, you indicate that you understand the information and that you agree to participate in the research study. You will be given a copy of the Consent Form and this Information Sheet to keep as a personal record.

This research has been approved by the Uniting*Care* Health (UCH) Human Research and Ethics Committee who oversees all research conducted at SAWMH.

1. **Background**

As you have no doubt discussed with your doctor, bleeding and clotting are potential complications associated with your procedure or surgery. This occurs during your surgery or procedure as the result of: i) imbalance between factors in the blood that promote verse prevent clots; ii) efforts to overcome this with blood thinning medication during the procedure; and, iii) necessary trauma to body tissues (e.g., skin incision).

This study uses novel technology to measure these changes as they occur during the procedure or surgery. By characterising exactly what changes occur in the blood and when during the procedure we will be able to better understand the underlying risk of the procedure / surgery for clot related complications. This understanding will then be used to determine the most appropriate blood thinning medications to use with the aim of improving patient outcomes by minimising the occurrence and effects of suboptimal or excessive blood thinning medication. The information will also for a platform for larger studies testing the efficacy of different blood thinning regimes.

1. **What will happen to you during the study?**

*Routinely collected information*

All patients managed at SAWMH receive the highest level of care. This includes routine investigations and tests conducted as part of the work-up for and management during and following the operation. Should you decide to participate in this study it will allow the research team to access, record and analyse these results.

*Medical questionnaire*

In addition to the information routinely collected as described above, you will be asked to complete a standardised medical questionnaire if you choose to participate in this study.

*Blood tests*

In addition to routine care, your involvement in this study will mean that we will collect additional blood samples from you at specific times during your procedure or surgery. 10 mL of blood will be collected by trained research or clinical staff at 4 separate times during your procedure and again at 6 hours following your procedure for the purposes described as follows:

1. *Standard laboratory tests of clotting:* These samples will be prepared / processed by Queensland Medical Laboratories (QML).
2. *Novel point-of-care tests of clotting:* These samples will be processed at SAWMH by trained research staff at the time of collection.
3. *Processing and storage of blood for later processing:* Once recruitment of all participants required for this study is complete, stored samples will be processed for specialised clotting tests. These samples will not be used for any other purpose. Any unused or partly used samples will be discarded at the completion of processing. No sample will be stored beyond 12 months following collection.
4. **Benefits**

The information we obtain from this study is unlikely to have any direct benefit for you. However, by improving our understanding of the changes occurring in your blood this research has the potential to modify clinical practice and improve blood thinning medication use for future patients undergoing PCI, AVR and TAVI.

1. **Risks and Side Effects**

Blood collected is limited to the minimum required to successfully run tests proposed by the study and cannot be considered to pose a risk to the patients. Intraoperative blood tests will be obtained from access already in situ to minimise discomfort to patients (e.g. central venous catheter or arterial line indicated for clinical purposes). Where such access is not available, every attempt will be made to ensure study-specific blood tests are timed to coincide with routine collection.

This research will not interfere with your medical care and all management decisions remain at the discretion of your treating specialist in consultation with you. Your medical care, relationship with treating medical personnel and relationship with SAWMH will not be affected by your decision to participate, not participate or initially participate and subsequently withdraw from the study.

1. **Reimbursement**

You will not be paid for taking part in this study nor will there be any additional cost for taking part in the study. All assessments are coordinated so as to coincide with your hospital admission.

1. **Patient selection**

You have been selected to participate in this study as you and your treating cardiologist or cardiac surgeon have elected that your management involve either a transcatheter or surgical aortic valve procedure or a percutaneous coronary intervention. Not all patients having these procedures are automatically invited to participate.

Patients, like yourself, are identified by the treating cardiologists or cardiothoracic surgeon as being medically suitable to be involved in the study. The research team has then re-assessed your suitability for the project. You have been approached with an offer to participate in this study because you have been considered a good candidate for our project. However, the final decision to participate in this study is yours and you are welcome to refuse. Such a decision will in no way impact your medical care or relationship with your treating clinicians, SAWMH or UCH. If you do agree but change your mind, you are welcome to withdraw your involvement at any time during the study by notifying a member of the research team and / or submitting the “revocation of consent” form attached (page 7). In such a circumstance, you can elect to either allow the researchers to use the data already collected, or to have all your data removed from our research database.

1. **Confidentiality and Privacy**

Any information obtained in connection with this study will remain confidential. In any publication that arises from this research, information will be provided in such a way that you will not be identifiable. Medical confidentiality and protection of personal data will be ensured, and any access to the data will be made in a manner that respects and protects your privacy. In short, we will not tell anyone what you tell us or allow anyone access to the data we have collected except in the rare circumstance where someone might be hurt. If this situation arises, we will talk to you first about the best thing to do, where this is possible.

***Other study data will be kept confidential and will be stored by the chief investigator for approximately 15 years after the study is completed.*** By signing this consent form you grant permission for your original medical records to be made available to the study research personnel for the purposes of data collection, reporting and review. Following completion of this study the data collected may be accessed by the research team to answer specific research questions that may arise but following completion of this study additional UCH Human Research and Ethics approval will be sought and data only accessed if such approval is granted.

The SAWMH Director of Medical Services, on recommendation from the UCH Human Research Ethics Committee, has given approval for this study to proceed. UCH Human Research and Ethics Committee may wish to inspect the data collected at any time as part of its monitoring activities. In these circumstances, your identity may be disclosed.

1. **Disclosure**

None.

1. **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, including feedback following completion of the study, or if you have any medical problems that may be related to your involvement in the project (for example, any side effects), please contact:

Research contact person

|  |  |
| --- | --- |
| Name | *Dr. Jonathon Fanning* |
| Position | *Clinical Research Fellow* |
| Telephone | *0410408777* |
| Email | *jonathon\_fanning@icloud.com* |

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 also contact the Coordinator of Research and Ethics for UCH who will forward their concerns to the Chair of the Human Research Ethics Committee.

Uniting*Care* Health Human Research Ethics Committee contact

|  |  |
| --- | --- |
| Name | *Shannon Lytras* |
| Position | *Ethics Coordinator* |
| Telephone | *(07) 3232 7500* |
| Email | *ethics@uchealth.com.au* |

**Consent Form**

|  |  |
| --- | --- |
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| Project Title: | Prothrombotic changes associated with aortic valve management |
| Name of Researchers: | Dr. Jonathon Fanning, Dr. Karl Poon, Dr. Alexander Incani, Prof. John Fraser, Dr. John Keys, Dr. Stephen Fanning, Dr. Sarvesh Natani, Dr. Bruce Garlick, Dr. Shaun Roberts, Ms. Shannon Hoban. |

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(the participant), agree to participate in the above named project and in so doing acknowledge that:

* I have been informed as to the nature and extent of any risk to my health or well-being.
* I am aware that, although the project is directed to the expansion of medical knowledge generally, it is unlikely to result in any direct benefit to me.
* I have been informed that my refusal to consent to participate in the study will not in any way effect the quality of treatment provided by the treating team at St. Andrew’s War Memorial Hospital.
* I have been informed that I may withdraw from the study at any time and that this decision will not in any way affect my medical care, relationship with treating medical personnel or relationship with St. Andrew’s War Memorial Hospital.
* If I do decide to withdraw it will be my decision as to whether the information collected up to the time of withdrawal can be used by the investigators or must also be withdrawn.
* I have been advised that the Executive Director, St. Andrew’s War Memorial Hospital, on recommendation from the Uniting*Care* Health Human Research Ethics Committee, has given approval for this project to proceed.
* I am aware that I may request further information about the project as it proceeds.
* I understand that, in respect of any information obtained during the course of the project; confidentiality will be maintained to the same extent as for my medical records. In the event of any results of the project being published, I will not be identified in any way.

Patient’s name: …………………………………………

Outcome**: AGREE / DISAGREE to participate in the abovementioned**

 **study**

Feedback: **I DO / DO NOT wish to be contacted with feedback**

 **(including outcomes and results) following study**

 **completion**

Signature ………………….................................... Date: / /

 (Patient) DD/MM/YY

Name of Investigator:………………………………

Signature ………………….................................... Date: / /

 (investigator)DD/MM/YY

**Revocation of Consent Form**

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| --- | --- |
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* I hereby wish to **WITHDRAW** my consent to participate in the research project described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with St. Andrew’s War Memorial Hospital or Uniting*Care* Health.
* My decision regarding the data collected from me for study purposes up to this point is (please tick the option that best reflects your decision):

 Data collected by the study investigators must also be withdrawn

 Data collected by the study investigators may contribute toward the

 study and be further analysed as described in the original consent

Patient’s name: …………………………………………

Signature ………………….................................... Date: / /

 (Patient) DD/MM/YY

This Revocation of Consent should be forwarded to:

Dr. Jonathon Fanning

Intensive Care Unit

St. Andrew’s War Memorial Hospital

457 Wickham Terrace

Brisbane QLD 4001