The National Institute of Integrative Medicine Human Research Ethics Committee

**STANDARD CONSENT FORM**

**FOR PEOPLE WHO ARE PARTICIPANTS IN A RESEARCH PROJECT**

1. I, ……………………………………………………………… *(please print name)*

 have read the attached Information Sheet for Participants entitled:

 **The Effect of Surgery on Plasma Vitamin C and Cognitive Function** and consent to take part in this research project

*This project is being conducted by a PhD research student who is enrolled at Swinburne*

*University. This study will be conducted at the place of your surgery and NIIM, in collaboration*

*with researchers at NIIM, The Avenue Hospital and Swinburne University of Technology. Your personal data will be known only to the study team and de-identified results will be analysed by the research team and written up for submission to a peer reviewed journal and potentially presented at conferences.*

2. *I will have blood taken before and after surgery, a procedure that will be undertaken by a trained*

*nurse/phlebotomist in the hospital. In addition, I understand that I am required to attend 5 testing*

*sessions in total. These will be conducted 1-2 weeks before surgery and 4-6 weeks, 3 months and 6*

*months after my surgery, at the National Institute of Integrative Medicine (NIIM) in Hawthorn.*

*One testing session will be conducted within 1 week after surgery, at the hospital. Testing will*

*involve having my cognitive function, vitamin C and vitamin B12 levels measured together with*

*other measurements such as pain, mood, food frequency, sleep, wound healing, pulse wave*

*velocity and hair cortisol.*

4. *I give permission for my blood to be stored and used for analysis of inflammatory markers*

*(TNF- α, IL-1, IL-6) linked to surgery and cognitive function.*

5. *I give permission for the researcher to obtain from me available information regarding the*

*Length and type of surgery/anaesthesia*

5. *I consent to have my data combined with other data sets. Data collected immediately before and*

*after surgery (from this study) may be added to data collected in a previous study* (Titled: *The*

*effects of surgery on plasma vitamin C and serum B12 levels) that only collects blood levels of*

*Vit C etc immediately before and after surgery.*

7. I have had the project, so far as it affects me, fully explained to my satisfaction by the research worker. My consent is given freely.

8. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

9. I have been informed that, while information gained during the study may be published, I will not be identified and my personal results will not be divulged.

10. I understand that I am free to withdraw from the project at any time and that this will not affect medical advice in the management of my health, now or in the future.

11. I am aware that I should retain a copy of this Consent Form, when completed, and the attached Information Sheet

 I can be contacted by phone: \_\_\_\_\_\_\_\_\_\_\_\_\_ or by email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant: ………………………………………………………………………………………

 *(signature) (date)*

Investigator: …………………………………………………………………………………………

If you would like us to send you your test results at the completion of the trial, then please complete your details:

[delete this section if not relevant]

**Address**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**State**: \_\_\_\_\_\_\_\_\_\_\_\_\_**Postcode**:\_\_\_\_\_\_\_\_\_\_

**Form for Withdrawal of Participation – Person Responsible**

**Declaration by Person Responsible**

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect their routine treatment, relationship with those treating them or relationship with *[Institution]*.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Participant (please print) |  |  |
|  |  |  |  |
|  | Name of Person Responsible (please print) |  |  |
|  |  |  |  |
|  | Relationship of Person Responsible to Participant |  |  |
|  |  |  |  |
|  | Signature of Person Responsible |  | 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.*

|  |
| --- |
|  |

**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 person responsible for 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.