ST. VINCENT’S HOSPITAL (MELBOURNE)

Research Governance Unit

**‘Changing Members of a Research Team’**

**   **

**Principal Investigator:**

**Contact Person / Study Coordinator:**

**Contact Person / Study Coordinator** **email:**

**Contact Person / Study Coordinator** **Phone Number:**

**Department/ institution:**

**HREC reference number:**

**SERP HREC Reference Number (If applicable):**

**Study title:**

**The following amendment is requested:**

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| *\* If the Principal Researcher is changing please ensure declaration is* *counter signed by the current Principal Researcher.**\*\*Only the name of the Principle investigator and Contact Person should appear in the ‘Participant Information and Consent Form’ (PICF). Should either change, an updated PICF should be submitted with this form.* |
| Title and Name |  |
| Appointment |       |
| Department |       |
| Institution |       |
| Mailing address |       |
| Describe the role of the investigator in this project |       |
| Brief summary of relevant experience for this project |       |
| Phone |       | Fax:  |  |
| Mobile/pager |       | Email: |  |

**The following amendment is requested:**

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| *\* If the Principal Researcher is changing please ensure declaration is* *counter signed by the current Principal Researcher.**\*\*Only the name of the Principle investigator and Contact Person should appear in the ‘Participant Information and Consent Form’ (PICF). Should either change, an updated PICF should be submitted with this form.* |
| Title and Name |  |
| Appointment |       |
| Department |       |
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| Describe the role of the investigator in this project |       |
| Brief summary of relevant experience for this project |       |
| Phone |       | Fax:  |  |
| Mobile/pager |       | Email: |  |

**Declaration by Researchers:**

I/WE, the researcher(s) agree:

* To only start this research project after obtaining final approval from the Institution’s Human Research Ethics Committee (HREC);
* To conduct this research project in accordance with the protocols and procedures as approved by the HREC;
* To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
* To provide additional information as requested by the HREC;
* To provide progress reports to the HREC as requested, including a final report and a copy of any published material at the end of the research project;
* To maintain the confidentiality of all data collected from or about project participants;
* To notify the HREC in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;
* To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;
* To agree to an audit if requested by the HREC;
* To only use data and any tissue samples collected for the study for which approval has been given;
* To only grant access to data to authorised persons; and
* To maintain security procedures for the protection of privacy, including (but not restricted to): removal of identifying information from data collection forms and computer files, storage of linkage codes in a locked cabinet and password control for access to identified data on computer files.

**I have read the NH&MRC *National Statement on Ethical Conduct in Human Research* (2007) and will observe the principles set out in that document and in the *Declaration of Helsinki and ICH Good Clinical Practice.***

**Name of Researcher: Sign: Date:**

**Certification by Principal Researcher**

“I accept full and total responsibility for the conduct of this research project according to the principles of the National Statement on Ethical Conduct in Research Involving Humans published by the National Health & Medical Research Council (2007). I certify that all researchers and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training to fulfil their role in this project. I will also take responsibility for the confidential maintenance of records for 7 years after completion of the project (15 years in the case of drug trials).”

**Name of Principal Researcher: Sign: Date:**