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19 June 2015

PETER MACCALLUM CANCER CENTRE AUTHORISATION TO CONDUCT A RESEARCH PROJECT

Peter Mac Project No: 13/73L

Project Title:

Surgical thromboprophylaxix: Impact of a newly developed risk stratification model

Principal Investigator: Ms Marliese Alexander

Approval Date: 19 June 2013 Approval Expiry:

I am pleased to advise that the above project has received ethical approval and satisfies Peter Mac research governance requirements and may now be conducted at Peter MacCallum Cancer Centre. Conduct of the project is subject to compliance with the conditions set out below.

Approved Documents:

- Project Protocol Version, as included in the Low Risk Application Form
- Outcome Measure and CRF
- Surgical thromboprophylaxis ppt

In order to comply with the National Statement on Ethical Conduct in Human Research (2007), Guidelines for Good Clinical Research Practice and local research policies and guidelines, you are required to notify the Peter MacCallum Cancer Centre Ethics Committee Secretariat of:

- Any proposed amendments to the project including any proposed changes to any of the approved documents;
- Any unexpected developments in the project with ethical implications;
- Your inability to continue as Principal Investigator and any other change in research personnel involved in the project at Peter MacCallum Cancer Centre;
- Any proposed extension to the duration of the project, past the above stated approval date;
- Any decision taken to end the project prior to the expected date of completion.

You are also required to submit to the Ethics Committee Secretariat:

- An Annual Progress Report every 12 months for the duration of the project.
 Note: Continuation of ethics approval is contingent on submission of an annual report in a timely manner, and
- A Final Report upon completion of the project.

The Peter MacCallum Cancer Centre Ethics Committee may conduct an audit of the project at any time.

Patron: The Honourable Alex Chernov, AC, QC - Governor of Victoria

Please refer to the Peter MacCallum Cancer Centre Ethics Committee Secretariat website (www.petermac.org/ethicscommittee) for access to forms, policies and guidelines and other information and news concerning research at Peter MacCallum Cancer Centre.

The Peter MacCallum Cancer Centre Ethics Committee is organised and operates according to the NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007) and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and the Health Privacy Principles enumerated in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Please be advised that the Principal Researcher and any Associate Researchers named on the application did not participate in deliberative discussions or decision-making regarding the project.

Yours sincerely,

Dr. Dianne Snowden Ethics Coordinator

Ethics Committee Secretariat

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