



St Vincent's Hospital

25 May 2010

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A facility of
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Dear David

SVH File Number: 10/055

**Project Title: Screening for pancreatic cancer in high risk individuals
(HREC Ref: HREC/10/SVH/33)**

Thank you for submitting the above project for ethical and scientific review. The project was first considered by the St Vincent's Hospital HREC at its meeting held on 15 April 2010. This HREC has been accredited by NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at an Executive meeting on 20 May 2010 has granted ethical and scientific approval of the above multi-centre project.

You are reminded that this letter constitutes *ETHICAL* approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The project is approved to be conducted at the following NSW Public Health sites:

- St Vincent's Hospital
- Royal North Shore Hospital
- Prince of Wales Hospital
- Westmead Hospital

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

- Protocol Version 2 dated May 2010
- Participant Information Sheet and Consent Form Master Version 0.3 dated May 2010
- Invitation Letter Version 02 dated May 2010
- Advertisement Version 1 dated May 2010

The National Ethics Application Form (NEAF) document reviewed by the HREC was:
NEAF Lock /AB/16287/1/AU/16287/11018/1/856.

Please note the following conditions of approval:

- This approval is valid for five years, and the Committee requires that you furnish it with annual reports on the study's progress beginning in May 2011.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.
- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- The Co-ordinating Investigator will provide a progress report, in the specified format, annually to the HREC as well as at the completion of the study.
- HREC approval is valid for 5 years from the date of this letter.

Investigators holding an academic appointment (including conjoint appointments) at the University of New South Wales are required to provide a copy of the application form, all approved documents and a copy of this letter to the UNSW HREC for ratification. These documents should be sent to UNSW, Ethics Secretariat, Research Services, Rupert Myers Building, 3rd floor, Kensington 2052.

Please note it is the responsibility of the sponsor or the principal (or co-ordinating) investigator of the project to register this study on a publicly available online registry (eg Australian Clinical Trial Registry www.actr.org.au).

Should you have any queries about your project please contact the Research Office, Tel: 8382-2075, email research@stvincents.com.au. The HREC Terms of Reference, Standard Operating Procedures, HREC Membership and standard forms are available via the research/education link on the St Vincent's Hospital website: internal address: <http://exwwwsvh.stvincents.com.au> external address: <http://wwwsvh.stvincents.com.au>

Please quote **SVH File Number 10/055** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely



Sarah Charlton
HREC Executive Officer
Research Office
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D/2010/7354