Contact: Sydney Local Health District Human Research Ethics Committee – CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: (02) 9767 5622
Email: crgh.ethics@sswahs.nsw.gov.au

Our Ref:

CONCORD
REPATRIATION GENERAL
HOSPITAL

16 June 2017

Professor Lisa Horvath
C/- Dr Blossom Mak
Chris O'Brien Lifehouse
119-143 Missenden Road
CAMPERDOWN NSW 2050

Dear Professor Horvath,

Re: HREC/17/CRGH/97 CH62/6/2017-063
Statins in Metastatic Castration-Resistant Prostate Cancer

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 25 May 2017. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry 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.*

I am pleased to advise that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and final ethical approval has been granted.

The documents reviewed and approved include:

	IDENTIFICATION NUMBER	**DATE**
National Ethics Application Form (NEAF)	**Submission code AU/1/20FC217**	**31/03/2017**
Protocol	**Version 1**	**23/02/2017**
Master Participant Information Sheet & Consent Form	**Version 2.1**	**15/06/2017**
Data Collection Sheet	**Version 2**	**07/06/2017**

The HREC has provided ethical and scientific approval for the following sites:

1. Chris O'Brien Lifehouse
2. Concord Repatriation General Hospital
3. St Vincent's Hospital
4. Olivia Newton-John Cancer Centre
5. Adelaide Cancer Centre
6. Baker Heart and Diabetes Institute

Please forward a copy of this letter to all site investigators for submission to the relevant Research Governance Officer

Please note the following conditions of approval:

1. You 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, (including Serious Adverse Events).

2. 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.

3. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. You will provide an annual report to the HREC, and at completion of the study in the specified format.

5. You agree that you will not commence the trial named above until the Clinical Trial Notification (CTN) has been submitted to the Therapeutic Goods Administration (TGA) using the online form. This HREC approval letter fulfils the documentation required to indicate the approval of the Human Research Ethics Committee responsible for monitoring the trial. A copy of the TGA acknowledgment of receipt of a CTN must be submitted to the CRGH Research Office as soon as it is available.

6. You will adhere to the study protocol at all times.

7. It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number.

8. Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.

9. HREC approval is granted on the assumption that all students and early career researchers are adequately supervised by the principal and senior investigators on a project. This supervision would ensure that all privacy concerns are met (including the completion of confidentiality agreements by participating students) and that both students and participants are supported in the conduct of the study in line with the approved research protocol.

HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the Concord Hospital Research Office by **30/06/2018.**

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: www.sswahs.nsw.gov.au/concord/ethics.

We wish you every success in your research.

Please quote the above file number in all correspondence.

Yours sincerely,

Professor Andrew McLachlan
Chairman
Sydney Local Health District Human Research Ethics Committee – CRGH

Please complete the boxes below and return a copy of this page to the Concord Hospital Research Office:

☐	***I acknowledge and accept the Conditions of Ethical Approval.***

☐	***I will not commence this project at any site until separate written authorisation from the Chief Executive or delegate of that site has been obtained***

_____	_____	_____
Printed Name	**Signature**	**Date**
Chief Investigator		