ADDRESS FOR ALL CORRESPONDENCE
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CAMPERDOWN NSW 2050

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REFERENCE: X16-0340 & HREC/16/RPAH/467

Health
Sydney
Local Health District

25 October 2016

A/Professor L Mileshkin
C/- Ms A Livingstone
NHMRC Clinical Trials Centre
UNIVERSITY OF SYDNEY
Locked Bag 77
CAMPERDOWN NSW 1450

Dear Professor Mileshkin,

Re: Protocol No X16-0340 & HREC/16/RPAH/467 - "PEARL – A randomised phase 3 trial of Palliative care Early in Advanced Lung Cancers"

The Executive of the Ethics Review Committee, at its meeting of 20 October 2016 considered Ms A Livingstone's correspondence of 6 October 2016. In accordance with the decision made by the Ethics Review Committee, at its meeting of 14 September 2016, ethical approval is granted.

The proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research.*

This approval includes the following:

- NEAF (AU/1/D6F7219)
- NSW Privacy Addition to National Ethics Application Form
- Victorian Specific Module (signed 25 August 2016)
- Protocol (Version 1.0, 5 August 2016)
- Participant Information Sheet/Consent Form (Master Version 1.1, 6 October 2016)
- Participant Form for Withdrawal of Participation (Master Version 1.1, 6 October 2016)
- Caregiver Information Sheet/Consent Form (Master Version 1.1, 17 October 2016)

- Caregiver Form for Withdrawal of Participation (Master Version 1.1, 17 October 2016)
- Patient Good Days Diary (Master Version 1.0, 5 August 2016)
- Patient Questionnaire to be completed 3 to 4 weekly for first 24 weeks then 6-8 Weekly thereafter (Master Version 1.0, 5 August 2016)
- Patient Questionnaire to be completed at baseline then every other visit (Master Version 1.0, 5 August 2016)
- Carer Questionnaire to be completed at Baseline (Master Version 1.0, 5 August 2016)
- Carer Questionnaire to be completed at 6-12 weeks following patient death (Version 1.1, 6 October 2016)
- Carer Questionnaire to be completed at every other visit (Master Version 1.0, 5 August 2016)
- Carer Questionnaire to be completed every 3 to 4 weeks until week 24 then 6-8 weekly thereafter (Master Version 1.0, 5 August 2016)

You are asked to note the following:

- **This letter constitutes ethical approval only.**
- **You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.**

  On the basis of this ethics approval, authorisation may be sought to conduct this study within any NSW/QLD/VIC/SA/ACT public health organisation and/or within any private organisation which has entered into an appropriate memorandum of understanding with the Sydney Local Health District, Sydney Local Health Network or the Sydney South West Area Health Service.

  The Committee noted that authorisation will be sought to conduct the study at the following sites:

  - Royal Prince Alfred Hospital (NSW)
  - The Chris O'Brien Lifehouse (NSW)
  - Royal North Shore Hospital (NSW)
  - Peter MacCallum Cancer Centre (VIC)
  - Monash Medical Centre (VIC)
  - St Vincent's Hospital, Melbourne (VIC)
  - The Prince Charles Hospital (QLD)

- This approval is valid for four years, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **November 2017.** If recruitment is ongoing at the conclusion of the four year approval period, a full re-submission will be required. Ethics approval will continue during the re-approval process.

- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and 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*.

- You must 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.

- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.

- You must notify the HREC and other participating sites, giving reasons, if the project is discontinued at a site before the expected date of completion.

- If you or any of your co-investigators are University of Sydney employees or have a conjoint appointment, you are responsible for informing the University's Risk Management Office of this approval, so that you can be appropriately indemnified.

- 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.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney Local Health District website.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The Ethics Review Committee wishes you every success in your research.

Yours sincerely,

Falleiro

Sharon Falleiro
Executive Officer
Ethics Review Committee (RPAH Zone)

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