



# St Vincent's Hospital

A facility of St Vincent's  
& Mater Health Sydney

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19 December 2016

Prof. Anne Keogh  
Heart and Lung Transplant Unit  
St Vincent's Hospital  
390 Victoria Street  
Darlinghurst NSW 2010

Dear Anne,

**SVH File Number: 11/181**  
**Project Title: Australian and New Zealand Hypertension Patient Registry**  
**Short Title: PHT Patient Registry**  
**HREC Reference Number: LNR/11/SVH/178**

Thank you for submitting a request for an extension of HREC approval for the above project. The project was first approved by St Vincent's Hospital HREC on 7 November 2011. St Vincent's Hospital HREC (EC00140) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. 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.

This project meets the requirements of the National Statement on Ethical Conduct in Human Research. I am pleased to advise that the Committee at an Executive meeting on 6 December 2016 has granted an extension of ethical and scientific approval until 6 December 2021.

If the project is expected to continue beyond this date a new submission is required to be submitted to the HREC prior to 6 December 2021. Please contact the Research Office to discuss your project and submission requirements.

*Extension of approval has been granted in order to complete long-term data collection.*

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. 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 sites:

- St Vincent's Hospital, Sydney
- Royal Prince Alfred Hospital
- John Hunter Hospital
- Nepean Hospital
- Liverpool Hospital
- Austin Hospital
- St George Hospital

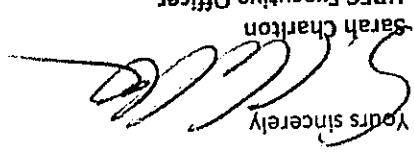
Please note the following conditions of approval:

- The Co-ordinating Investigator is required to notify the HREC 6 months prior to the 6 December 2021 if the project is expected to extend beyond the extended approval date at which time the HREC will advise of the requirements for ongoing approval of the study.

- The Co-ordinating Investigator will continue provide an annual progress report, to the HREC as well as a final study report at the completion of the project in the specified format.
- The Co-ordinating Investigator will immediately report anything which 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.
- Projects that are undertaken by investigators holding an academic appointment (including conjoint appointments) or by students as part of a University course may also be required to notify the relevant University HREC.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries regarding this project please contact the Research Office, Tel: 8382-4960, email SVHS.Research@svhs.org.au The HREC Terms of Reference, Standard Operating Procedures, National Statement on Ethical Conduct in Human Research (2007) and the CPM/ICH Note for Guidance on Good Clinical Practice and standard forms are available on the Research Office website: <https://svhs.org.au/home/research-education/research-office>

Yours sincerely  
  
 Sarah Charlton

HREC Executive Officer  
 St Vincent's Research Office  
 Translational Research Centre, 97-105 Boundary Street

cc: Carolyn Corrigan  
 TRIM REF: D/2016/114693