St Vincent's Hospital

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3 May 2016

Prof Lesley Campbell
Garvan Institute of Medical Research
384 Victoria St
Darlinghurst NSW 2010

Dear Lesley

SVH File Number: 15/291
Project Title: The effects of a new GLP-1 agonist on appetite and gastric emptying in Prader-Willi syndrome
Short Title: ENGAGE PWS
HREC Reference Number: HREC/15/SVH/437

Thank you for your letter, dated **4 April 2016**, responding to issues raised regarding the above project, which was first considered by the St Vincent's Hospital HREC at its meeting held on **3 December 2015.** 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 out of session Executive meeting on **2 May 2016** has granted ethical and scientific approval of the above **multi centre** project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note as this clinical trial involves patients who cannot provide independent informed consent in an ongoing manner the NSW Civil and Administrative Tribunal – Guardianship Division must approve a clinical trial before any adult who cannot consent to their own treatment can take part in that clinical trial. Once approval has been granted from the NCAT Guardianship Division a copy of the approval letter must be forwarded to the HREC before the study can commence in NSW.

The project is approved to be conducted at **St Vincent's Hospital, Sydney and Garvan Institute**

Radiation safety assessment report has been noted by the HREC for the following sites:

- **St Vincent's Hospital, Sydney**

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 25 March 2016
- Participant Information Sheet and Consent Form – Main for self, Version 4, dated 2 May 2016
- Participant Information Sheet and Consent Form – Person Responsible, Version 4, dated 2 May 2016 (changes may be required pending outcome of NCAT - Guardianship Division decision)
- Questionnaire, dated 28 September 2007

- Product Information – Bydureon (exenatide), dated 2015
- Consumer Medicine Information – Bydureon (exenatide), dated May 2014

The National Ethics Application Form (NEAF) document reviewed by the HREC was NEAF **AU/1/A6B226**

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **2 May 2021.** The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an annual progress report beginning in **May 2017**, 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 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.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

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

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: 8382-2075, email SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/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

Please quote **SVH File Number: 15/291** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,

Sarah Charlton
HREC Executive Officer
St Vincent's Hospital Research Office
Level 6, de Lacy Building

TRIM REF: D/2016/26548