27 November 2017

The Chair

Human Research Ethics Committee

St Vincent’s Hospital

Translational Research Centre

97-105 Boundary Street

Darlinghurst NSW 2010

Dear Prof Brien,

***[Renewal of if applicable]* Ethics Committee endorsement for the purpose of becoming an Authorised Prescriber of the an unapproved product under subsection 19(5) (drugs) / Section 41HC (devices) [delete as appropriate] of the Therapeutic Goods Act**

Include a short background statement relating to the product for which endorsement is being sought, relevant clinical experience of the prescriber, and why it is necessary to seek access to an unapproved product (eg. no equivalent product is available in Australia). Where possible, also include information about the registration status of the product in other countries.

Please provide a plan for how you will monitor for and investigate and report potential adverse events.

I/we wish to seek endorsement from the St Vincent’s Human Research Ethics Committee to apply to the TGA for Authorised Prescriber status for the following:

**Prescribers seeking endorsement:** [only complete this section where there are multiple prescribers seeking endorsement]

**Unapproved product:** [include dosage/route of administration as listed on the TGA “Agreement to Treatment form”]

**Indication for use:** [list specific details]

**Site/s for which endorsement is requested:** [list all sites at which the product will be prescriber, eg. St Vincent’s Hospital and St Vincent’s Private, or private rooms]

Renewal applications:

* Provide a report outlining the number of patients who have been treated and any adverse event or product defect reports
* Provide details of any new information relating to the product.

Included with this letter are the following [delete/insert as appropriate]:

* Consumer medical information if the product is approved in another country
* Relevant literature regarding product use
* For devices, a copy of the manufacturer instructions for use
* Any other documents relevant to submission

Electronic copies of the above, and of this letter, have been emailed to SVHS.Research@svha.org.au .

Yours sincerely,

Applicant Signature