



STREAMLINED ETHICAL REVIEW

RESEARCH GOVERNANCE | Site Specific Approval

3 November 2017

Mr Iouri Banakh
Senior Pharmacist
Peninsula Health
PO Box 52
FRANKSTON VIC 3199

Dear Mr Banakh

Ultrarapid iron polymaltose infusion for iron deficiency anaemia: a pilot safety study

HREC Reference Number: HREC/17/PH/30

Protocol: Version 3: 28 September 2017

Thank you for submitting the above project which was first considered by the Peninsula Health Human Research Ethics Committee (HREC) on Wednesday 20 September 2017 in accordance with the National Statement on Ethical Conduct in Human Research (2007). Following review of requested clarifications, amendments and approval by the Drugs and Therapeutics Committee I am pleased to advise that full approval to commence has now been granted.

The documents reviewed and approved at Peninsula Health include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
NEAF:		23 June 2017
VSM:		13 July 2017
Protocol:	Version 3	28 September 2017
Participant Information and Consent Form:	Version 3	24 October 2017
Data Collection Form:		16 August 2017

Please note the following requirements of the Peninsula Health HREC:

- The principal investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - any serious or unexpected adverse events
 - unforeseen events that might affect continued acceptability of the project.
- Proposed changes to the research protocol, conduct of the research, or research completion date will be provided to the Human Research Ethics Committee (HREC) for review in the specified format.
- The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. The principal investigator will provide an annual report to the HREC and at completion of the study a final report, in the specified format.

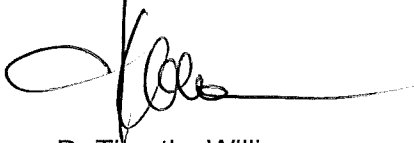
Should you have any queries about the consideration of your project please contact Ms Lee-Anne Clavarino, Manager, Office for Research. Details of review processes and guidelines are available on the Peninsula Health website <http://www.peninsulahealth.org.au/research-and-education/human-research-ethics-and-governance/>.

Please quote the Peninsula Health Project Number in all correspondence.

The Committee wishes you every success in your research

Yours sincerely

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A handwritten signature in black ink, appearing to read 'Tim Williams', with a long horizontal flourish extending to the right.

Dr Timothy Williams
Executive Director Medical Services
Executive Sponsor Research