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Layman

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Nursing – Community Health

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Dental Graduate

Dr Howard Smith
Medical Graduate – Endocrinologist

Ms Jennifer Sullivan
Laywoman

Ms Shane Waterton
Laywoman

Dr Christine Wearne
Clinical Psychologist

Mrs Christina Whitehead
Research Co-Ordinator - RN

Research Office File No: **(5520)**

HREC Ref: HREC/18/WMEAD/3
SSA Ref: SSA/18/WMEAD/273

31 August 2018

Prof Philip O'Connell
Renal Medicine
Westmead Hospital

Dear Prof O'Connell

Research Proposal: A phase II, single arm multi-centre trial of thymoglobulin, belatacept and Sirolimus in pancreatic islet transplant recipients

We acknowledge your request for amendment and attached documentation in relation to the above study.

I am pleased to advise approval has been granted for the Request for Amendment / Modification for this **multicentre** research project being conducted at:

- Westmead Hospital (NSW) –Chief Investigator Prof Philip O'Connell
- Westmead Institute for Medical Research (NSW) – Principal Investigator Prof Philip O'Connell
- St Vincent's Hospital (VIC) – Principal Investigator A/Prof David Goodman
- Royal Adelaide Hospital (SA) – Principal Investigator Prof Patrick Coates

The following documentation has been reviewed and approved.

- Protocol Version 3, dated 14 August 2018
- PICF Master, version 3, dated 14 August 2018
- WSLHD Main PICF version 2, dated 14 August 2018
- Belatacept Investigator Brochure version 21, dated 6 June 2018
- Safety Monitoring and Reporting Protocol, version 1, dated 10 August 2018
- SAE Reporting Form version 1, dated 10 August 2018

This amendment has also been reviewed and authorised by the Research Governance Officer for Western Sydney Local Health District. For non-Western Sydney Local Health District sites please ensure that the Research Governance Officer for each site named on this study receives the updated approved documentation in relation to this amendment.

HUMAN RESEARCH ETHICS COMMITTEE

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HREC approval is granted for a period of 12 months and ongoing approval is contingent upon annual submission. Annual Reports for all studies should be submitted in November, they will be review, approved, and notified to the HREC. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.

We appreciate your keeping us informed and look forward to receiving your next annual report.

Yours sincerely



Mrs Pat Fa
Secretary
WSLHD Human Research Ethics Committee