

ADDRESS FOR ALL CORRESPONDENCE
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ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050



Health
Sydney
Local Health District

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REFERENCE: X17-0382

19 March 2018

Dr Adrienne Gordon
Level 2 D17 The Hub
Charles Perkins Centre
The University of Sydney
Camperdown NSW 2050

Dear Dr Gordon,

Re: Protocol No X17-0382 – "PRE-PLAN: Impact of pre-conception weight loss for overweight and obese women: a pilot randomised controlled trial"

HREC/17/RPAH/579

SSA/18/RPAH/94

Thank you for submitting a Site Specific Assessment Form (AU/2/9334315) for this study. I am pleased to inform you that the Chief Executive has granted authorisation for it to be undertaken at the **Royal Prince Alfred Hospital**.

The following documents are authorised for use at the site:

- **Protocol (version 1.2, 13 November 2017)**
- **Participant Information Sheet (CPC-RPA Clinic Version 1, 8 March 2018) based on Master Version 1.1, 13 November 2017**
- **Participant Consent Form (CPC-RPA Clinic Version 1, 8 March 2018) based on Master Version 1, 2017**
- **Trial Flyer (Version 1.0, 14 February 2018)**

The following conditions apply to this research study. These are additional to those conditions imposed by the human research ethics committee (HREC) that granted ethical approval:

1. Please use the Information and Consent Form footers as detailed above.
2. **NB:** A copy of the annual report and any other reports to the approving HREC, accompanied by a copy of the HREC's acknowledgement letter, *must be provided to me for review*.
3. The appropriate documentation must be submitted to me for authorisation before any external researcher is authorised to be on-site for the project.
4. Proposed amendments to the research protocol or conduct of the research, which may affect the ethical acceptability of the study and which are submitted to the lead HREC for review, must be copied to me.
5. Proposed amendments to the research protocol or conduct of the research, which may affect the ongoing site acceptability of the study, must be submitted to me.

I wish you every success in your research.

Yours sincerely,

Maree Larkin
Research Governance Officer
SLHD (RPAH Zone)

RGO - Maree\CORRES\X17-0382

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