Contact: Sydney Local Health District Human Research Ethics Committee – CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: *(02) 9767 5622*
Email: SLHD-ConcordEthics@health.nsw.gov.au
Local Ref: *CH62/6/2018-201*

CONCORD
REPATRIATION GENERAL
HOSPITAL

24 January 2019

Professor David Handelsman
C/- Sasha Savkovic
Andrology Department
CONCORD RGH

Dear Professor Handelsman,

Re: **Local reference number:** CH62/6/2018-201
HREC reference number: HREC/18/CRGH/295
Project title: Detection of Testosterone Microdosing in Women

Thank you for submitting the above research proposal for single ethical and scientific review. This project was first considered by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 13 December 2018. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

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.*

I am pleased to advise that final ethical approval has been granted on the basis of the following:

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

The documents reviewed and approved include:

	IDENTIFICATION NUMBER	**DATE**
Human Research Ethics Application (HREA)	Submission code AU/1/85F9317	18/01/2019
Protocol	Version 1.0	26/11/2018
Master Participant Information Sheet and Consent Form	Version 3.0	24/01/2019
Case Report Form	Version 1.0	30/11/2018
Recruitment Advertisement	Version 1.0	30/11/2018
Recruitment Advertisement	Version 2.0	03/12/2018
Product Information - Testogel	–	24/10/2014

The HREC has provided ethical and scientific approval for the following sites:

1. Concord Repatriation General Hospital, NSW

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until you have submitted a Site Specific

Assessment (SSA) Form to the Research Governance Officer (RGO) and received separate authorisation from the Chief Executive or delegate at that site.

Please note the following conditions of approval:

1. HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the HREC by **31/01/2020.** You must also provide an annual report to the HREC upon completion of the study.

2. You will adhere to the study protocol at all times.

3. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review.

4. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.

5. You will immediately report anything which might warrant review of ethical approval of the project, including unforeseen events that might affect continued ethical acceptability of the project, (including Significant Safety Issues).

6. You agree that you will not commence the trial named above until the Clinical Trial Notification (CTN) has been submitted to the Therapeutic Goods Administration (TGA) using the online form. This HREC approval letter fulfils the documentation required to indicate the approval of the Human Research Ethics Committee responsible for monitoring the trial. A copy of the TGA acknowledgment of receipt of a CTN must be submitted to the CRGH Research Office as soon as it is available.

7. It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number.

8. Where appropriate, the Committee recommends that you consult with your Medical Defence Organisation or relevant governing body to ensure that you are adequately covered for the purposes of conducting this study.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: https://www.slhd.nsw.gov.au/concord/Ethics/Ethics.html

We wish you every success in your research.

Please quote the local reference number at the top of this letter in all correspondence.

Yours sincerely,

Professor David Le Couteur
Chair
Sydney Local Health District Human Research Ethics Committee – CRGH

CC: Lucy Nigro, Concord Hospital Clinical Trials Pharmacist