

Human Research Ethics Committee

Research Ethics Unit
Level 8 HSB – Room 8322
Austin Hospital

TO: Dr Mathis Grossmann
Department of Medicine
University of Melbourne

PROJECT: Testosterone Replacement Therapy in Men with Type 2
Diabetes Mellitus and Low Testosterone Levels

PROTOCOL NO:

PROJECT NO: H2008/03198

FROM: Ms Jill Davis Research Ethics Unit Manager

DATE: 4th July 2008

RE: Protocol (incorporated in Module 1)
Participant Information and Consent Form Version 4 dated 3
July 2008

Approval Period: 4th July 2008 – 4th July 2011

Agenda Item: 5.4 (April)

Further to my letter dated 24th April 2008 concerning the above detailed project, I am writing to acknowledge that your response to the issues raised by the Human Research Ethics Committee at their meeting on 19th June 2008 is satisfactory. This project now has full ethical approval for a period of three years from the date of this letter.

Before the study can commence you must ensure that you have a signed CTA and indemnity. For sponsored Phase III studies, the indemnity and insurance certificate, in conjunction with the CTA, should be approved by Corporate Counsel. Where appropriate a copy of CTN approval from the TGA is to be forwarded to the Research Ethics Unit. No CTN trial may commence until the CTN form has been forwarded to the TGA by the investigator.

For trials involving radiation to volunteers, the research must be added to the Austin Health Research with Human Volunteer's licence issued by the Department of Human Services – Radiation Safety Section prior to commencement. The HREC must be notified when the research has been added to the licence

Also, it is now your responsibility to ensure that all people associated with this particular project are made aware of what has actually been approved. Any changes to the original application will require a submission of a protocol amendment to the

Committee for consideration as this approval only relates to the original application as detailed above.

The Committee has requested me to make arrangement for progress reports to be submitted by the Investigator to the Committee at the end of twelve (12) months, or sooner if the project is completed within twelve (12) months. Should your study not commence twelve (12) months from the date of this letter this approval will lapse. A resubmission to the Human Research Ethics Committee would then be necessary before you could commence.

The Committee wishes to be informed immediately of any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers.

DETAILS OF ETHICS COMMITTEE:

It is the policy of the Committee not to release personal details of its members. However I can confirm that at the meeting at which the above project was considered, the Committee fulfilled the requirements of the National Health and Medical Research Council in that it contained men and women encompassing different age groups and included people in the following categories:

Chairperson

Lay Man

Lay Woman

Minister of Religion

Lawyer

Person with Research Experience

Person with Counselling Experience

Additional members include:

- Nurse Administrator
- Surgeon
- Pharmacologist
- Pharmacist

I confirm that the Principal Investigator or Co-Investigators were not involved in the approval of this project. I further confirm that all relevant documentation relating to this study is kept on the premises of Austin Health for more than three years.

The Committee is organised and operates according to the Note for Guidance on Good Clinical Research Practice (CPMP/ICH/135/95) annotated with TGA comments, and the National Statement on Ethical Conduct in Human Research (NHMRC The National Statement) and the applicable laws and regulations; and the Health Privacy Principles in The Health Records Act 2001.

PLEASE NOTE: The Committee requests that the Research Support Unit (ethics@austin.org.au) is informed of the actual starting date of the study as soon as the study commences. A written notice (e-mail, fax or letter) is considered the appropriate format for notification.

Jill Davis