

20th December 2016

Dr Robyn O'Sullivan
Suite 3a, Administration Building
Greenslopes Private Hospital
Newdegate Street
GREENSLOPES Q 4120

Dear Dr O'Sullivan

Protocol 16/71

Can mandibular advancement improve CPAP effectiveness in patients sub-optimally treated with CPAP using an oronasal mask?

The following correspondence was considered by the Greenslopes Research and Ethics Committee at the meeting held on Monday, 19th December, 2016.

- Application form
- Patient Information and Consent Form, Version 1.0, dated 30th November 2016
- Research Proposal, Version 1.0 dated 30th November 2016

After reviewing these documents the Committee granted ethical approval for this study to be conducted at Greenslopes Private Hospital.

The Greenslopes Research and Ethics Committee is constituted and functions in accordance with the National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015.

Greenslopes Research and Ethics Committee continuing approval is subject to the following conditions being met:

1. Conditions

- The Greenslopes Research and Ethics Committee will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Coordinating Investigator will provide an annual report to the Greenslopes Research and Ethics Committee and at completion of the study in the specified format.
- It is important that you inform the Ethics Committee immediately of any problems which arise during the course of the project which may have implications relating to the ethics of continuing the project in its present form.
- Approval is conditional upon the commencement of the project within twelve months of the date of approval being granted. If the project does not commence within this time limit then a new protocol will require to be submitted to the Greenslopes Research and Ethics Committee.
- The Greenslopes Research and Ethics Committee is to be advised when the project is completed.

- All Visiting Medical Officers are advised to check with their Medical Defence Organisation re personal indemnity for any research work about to be undertaken.
- Any public recruitment information, publicity or press releases are to be approved by the committee before release.

2. Reporting

- An annual report is required to be submitted to the Ethics Secretary in a timely manner. A review questionnaire will be circulated to you annually to keep the Ethics Committee informed of the progress of the project.
- The Coordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including any unforeseen events that might affect continued ethical acceptability of the project.
- Serious Adverse Events must be notified to the Committee. In addition, the Coordinating Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Participant Information Sheet and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

3. Amendments

Amendments to the protocol should be forwarded to the Ethics Secretary for consideration at a committee meeting.

A copy of this letter should be presented when required as official confirmation of the approval of the Greenslopes Research and Ethics Committee. We wish you every success in your research.

Yours sincerely



Terry McLaren
Deputy Chair
Greenslopes Research and Ethics Committee