

## Application Approval

Dr Jane Nikles  
University of Queensland  
St Lucia

UnitingCare Health Human Research Ethics Committee  
Ground Floor Moorlands House  
The Wesley Hospital  
451 Coronation Drive, Auchenflower QLD 4066  
PO Box 499 Toowong QLD 4066  
Phone: 3232 7500  
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Our Ref: **1702**  
Your Ref:

4 April 2017

Dear Dr Nickles

**Project Title:** Melatonin for better sleep in Parkinson's Disease  
**Sponsor:** Pharmanord  
**Investigators:** Dr Jane Nickles, A/Prof John O'Sullivan, Prof Geoff Mitchell, Dr Susanna Mantovani, Dr Alex Ritchie, A/Prof Simon Smith, Dr Hugh Senior and A/Prof James McGree

I am pleased to advise that the UnitingCare Health Human Research Ethics Committee have reviewed the above named research proposal and granted ethical and governance approval on 10 March 2017

Approval of this project from UnitingCare Health HREC is valid from the approval date to 31 January 2020 subject to the guidelines on page 3 of this letter.

The approved documents include:

Document	Version	Date
<b>Initial application for Ethical Review</b>		
PICF	2	Feb 2017
Eligibility Screen and Registration Form A	2	Feb 2017
Protocol	2	Feb 2017
Sleep Diary	3	15/12/16
Form B	3	15/12/16
Run-In Diary	1	Dec 2016
Parkinson's Flyer		
Parkinson's Pamphlet		
Follow Up Telephone Call Proforma	1	Dec 2016
Product Information	1	Dec 2016
Safety Information Card		

The UnitingCare Health Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Human Experimentation and Supplementary Notes

As your project involves inpatients and/or the use of hospital facilities, the Director of Medical Services at both The Wesley Hospital and St Andrew's War Memorial Hospital, have also given approval for your application. Please refer to point 3 of the Guidelines enclosed with this letter.

It is a strict condition of approval that any departure from the protocol detailed in the proposal submitted for approval be reported immediately to the UCH HREC. If there is any change to the status of the project, this should also be reported.

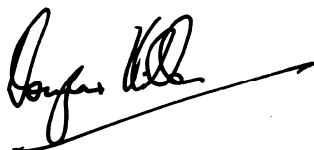
Approval for the project is given subject to your agreement to UnitingCare Health requirements for the monitoring of research (see overleaf), which have been based on the Australian Health Ethics Committee guidelines. Please note the requirement to submit a report annually or at the completion of the project, as appropriate.

The Investigator was not a member of the UnitingCare Health HREC at the time the above-mentioned study was reviewed and approved. The UnitingCare Health Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Human Experimentation and Supplementary Notes.

In all future correspondence please quote the UCH HREC number.

Please accept our very best wishes for the success of this study.

Yours sincerely

A handwritten signature in black ink, appearing to read "Douglas V Killer", with a long horizontal line extending to the right.

Douglas V Killer MBBS FRACP  
Executive Officer  
UnitingCare Health Human Research Ethics Committee

## UnitingCare Health Human Research Ethics Committee Guidelines

### Information for Researchers Gaining Scientific & Ethical Approval for Research Projects

#### Monitoring of Research

The Australian Health Ethics Committee now requires institutional ethics committees to monitor research projects to which they have given ethical approval. The principal reason for the monitoring of research projects is to ensure that their conduct does not jeopardize the rights and interests of those who have consented to take part as subjects in them. By monitoring the projects to which approval has been given, Ethics Committees will also be helping to ensure that researchers are practising responsible science and that the good reputation of the institution that is the setting for the research is maintained.

#### UnitingCare Health Requirements

Within UnitingCare Health, researchers who have approval from the Human Research Ethics Committee for their respective projects will undertake the following:

- 1 A report on the approved project will be provided at least annually and a final report is to be submitted on completion of the study. This does not preclude the Ethics Committee from asking for a report at more frequent intervals. Provision of relevant reports will be the responsibility of the applicant. In the case of multi-centre research, a report from the principal investigator may suffice. However, it is the applicant who is responsible for submitting the report to the Ethics Committee.

The report should provide details of the following:

- Status of the project (completed/in progress/abandoned/not commenced).
  - Compliance with the conditions of ethical approval, including security of records and procedures for consent.
  - Compliance with any special conditions stated by the Ethics Committee as a condition of ethical approval.
- 2 Applicants (or principal investigators) are responsible for notifying the Ethics Committee immediately of matters that might affect continued ethical acceptability of the project including:
    - Serious adverse effects of the project on subjects and of steps taken to deal with these.
    - Changes in the research protocol, together with an indication of ethical implications (if any).
    - Any plan to extend the duration of the project past the approval period.
    - The current principal investigator's inability to continue as coordinating principal investigator and will provide the name of the contact information for a replacement.
    - Abstracts, presentations, publications as they occur
    - Other unforeseen events.

Where the above requirements are not adhered to, the Ethics Committee may withdraw ethical approval for a project.

- 3 Any costs associated with the study performed at The Wesley Hospital and St Andrew's War Memorial Hospital are the responsibility of the Chief Investigator, and this includes Hospital costs. For an indication of hospital costs please contact the Director of Medical Services Office.

As a guide the following are examples of typical costs:

- Medical records including retrieval, off site costs and storage costs.
- Clinical and non clinical staff costs.
- Clinical and non clinical – consumables.