Metro South Health

Enquiries to: Metro South
Human Research Ethics Committee
Phone: 07 3443 8049
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HREC Ref: HREC/15/QPAH/688
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Prof Elizabeth Powell
Director, The Centre for
Liver Disease Research
University of Queensland
Level 5, West Wing
Translational Research Institute
37 Kent Street
Woolloongabba Qld 4102

Dear Prof Powell

HREC Reference number: HREC/15/QPAH/688
Project Title: Medication Management and Medication-Related Problems in People With Chronic Liver Disease

Thank you for submitting the above research protocol to the Metro South Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 3 November 2015.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Metro South Chief Executive or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the Chief Executive or Delegate to conduct this research at the Princess Alexandra Hospital.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

I am pleased to advise that the HREC has granted approval of this research protocol. The documents reviewed and approved include:

Document	Version	Date
MSF31 Submission Checklist Form		15 October 2015
NEAF		15 October 2015
Protocol	1	6 October 2015
Participant Information and Consent Form	3	8 December 2015
Baseline Survey Part 1	1	6 October 2015
Baseline Survey Part 2	1	6 October 2015
Pharmacist-Patient Interview at Baseline	1	6 October 2015
Medication Reconciliation	1	6 October 2015
Medication Related Problems identified AFTER week 0	1	6 October 2015
Pharmacist-Patient Phone Contact (Week 4 and Week 13)	1	6 October 2015
Final Survey	1	6 October 2015
Patient Satisfaction Survey	1	6 October 2015

Chart data collection tool	1	6 October 2015
Entecavir classification of side effects		
Frusemide classification of side effects		
Lactulose classification of side effects		
Propranolol classification of side effects		
Rifaximin classification of side effects		
Spironolactone classification of side effects		
Tenofovir classification of side effects		
Letter in response to HREC comments		27 November 2015

This HREC approval is valid from 10 December 2015 until 10 December 2018.

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol. Serious Adverse Events must be notified to the HREC as soon as possible. In addition the 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 Patient Information 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 the event.
2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Amendments should accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard copies of the cover letter and all relevant updated documents, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP.
3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the HREC Coordinator. These should include a cover letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
7. The Principal Investigator will provide at least, an annual report to the HREC on the anniversary of the approval and at completion of the study in the specified format.
8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Should you have any queries about the HREC's consideration of your protocol please contact the Metro South HREC Office on 07 3443 8049.

Please note that the Metro South HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition (Attachment I).

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attached) and return to the Metro South Human Research Ethics Committee.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

A/Prof Richard Roylance
Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Centres for Health Research
Princess Alexandra Hospital

10/12/15

C.c. L Horsfall, Centre for Liver Disease Research