THE UNIVERSITY OF QUEENSLAND

Institutional Human Research Ethics Approval

Project Title:	Biliary Strictures In Liver Transplant Recipients In Queensland, Australia: A Retrospective Study
Chief Investigator:	Miss Janske Reiling
Supervisor:	Prof Johathan Fawcett
Co-Investigator(s):	Prof Johathan Fawcett, Mrs Geraldine Lipka
School(s):	School of Medicine
Approval Number:	2013000930
Granting Agency/Degree:	PhD
Duration:	31st December 2013

Comments:

Expedited review on the basis of approval from the Metro South HSD HREC (PAH), dated 27/06/2013

Note: if this approval is for amendments to an already approved protocol for which a UQ Clinical Trials Protection/Insurance Form was originally submitted, then the researchers must directly notify the UQ Insurance Office of any changes to that Form and Participant Information Sheets & Consent Forms as a result of the amendments, before action.

Name of responsible Committee:
Medical Research Ethics Committee
This project complies with the provisions contained in the *National Statement on Ethical Conduct in Human Research* and complies with the regulations governing experimentation on humans.

Name of Ethics Committee representative:
Professor Bill Vicenzino
Chairperson
Medical Research Ethics Committee

Signature _____ Date 24/7/2013

THE UNIVERSITY OF QUEENSLAND

Institutional Human Research Ethics Approval

Project Title:	Biliary Strictures In Liver Transplant Recipients In Queensland, Australia: A Retrospective Study - 30/07/2015 - AMENDMENT
Chief Investigator:	Janske Reiling
Supervisor:	Prof Johathan Fawcett
Co-Investigator(s):	Prof Johathan Fawcett, Mrs Geraldine Lipka, Elizabeth Forrest
School(s):	School of Medicine
Approval Number:	2013000930
Granting Agency/Degree:	PhD
Duration:	31st December 2015

Comments/Conditions:

Note: if this approval is for amendments to an already approved protocol for which a UQ Clinical Trials Protection/Insurance Form was originally submitted, then the researchers must directly notify the UQ Insurance Office of any changes to that Form and Participant Information Sheets & Consent Forms as a result of the amendments, before action.

Name of responsible Committee:
Medical Research Ethics Committee
This project complies with the provisions contained in the *National Statement on Ethical Conduct in Human Research* and complies with the regulations governing experimentation on humans.

Name of Ethics Committee representative:
Professor Bill Vicenzino
Chairperson
Medical Research Ethics Committee

Signature _____ Date 5 Aug 2015

Metro South Health

Enquiries to: Metro South
Human Research Ethics Committee
Phone: 07 3443 8049
Fax: 07 3443 8003
HREC Ref: HREC/13/QPAH/382
E-mail: PAH_Ethics_Research@health.qld.gov.au

Ms Janske Reiling
3/27 Browning Street
South Brisbane QLD 4101

Dear Ms Reiling

HREC Reference number: HREC/13/QPAH/382
Protocol Title: Biliary strictures in liver transplant recipients in Queensland, Australia: A retrospective study

Thank you for submitting the above research protocol to the Metro South Health Human Research Ethics Committee for ethical and scientific review. This protocol was considered by the Low Risk Review Panel of the Human Research Ethics Committee (HREC) on 19th June 2013

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 District CEO 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 CE or Delegate to conduct this research at the Princess Alexandra Hospital

I am pleased to advise that the Low Risk Review Panel of the HREC has granted approval of this research protocol and a waiver of consent. The documents reviewed and approved include:

Document	Version	Date
LNR Form		7.6.13
Letter of Support form Prof Jonathan Fawcett		7.6.13

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. Major amendments should be reflected in a revised online NEAF (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 revised NEAF, the cover letter and all relevant updated documents, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP. (Further advice on submitting amendments is available at http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf http://www.health.qld.gov.au/pahospital/research/amendments.asp
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 or Study Co-ordinator 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 Coordinating Principal Investigator will provide an annual report to the HREC 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/

This HREC approval is valid for 3 years from the date of this letter.

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat 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 with specialty and affiliation with the Hospital (Attachment I).

The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the following websites:
http://www.health.qld.gov.au/pahospital/research/ethics.asp
http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

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,


pp

A/Professor Richard Roylance
Deputy Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Centres for Health Research
Princess Alexandra Hospital
27.6.13