

MACKAY HEALTH SERVICE DISTRICT

Enquiries to: HREC Administrator
Telephone: 4968 6481
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Email: MACKAY_ETHICS@health.qld.gov.au
Our Ref: Ethics – 12-08

8 September 2008

A/Professor Herwig Drobetz
Mackay Base Hospital

Dear Dr Drobetz

PROTOCOL NUMBER: 13-08
PROTOCOL NAME: Volar Locking Plate versus External Fixator/Cast Fixation for the treatment of Distal Radius Fractures. A randomised controlled prospective study.

Thank you for your application for approval of the above study.

At their meeting on 3 September 2008 the Mackay Health Service District Human Research and Ethics Committee provided ethical approval for the commencement of your research project with the following clauses:

- 1) Changes to Disclosure from wording to clarify that names or other identifying information will not be published or included in publications.
- 2) People with English as a second language will not be excluded and interpreter services would not be at any cost to patient.

The Committee requires that the investigator is responsible for notifying the Committee of any adverse effects or substantial changes in the protocol, or of any unforeseen events.

A summary, written by the Researcher and signed by a nominated local Monitor, is required when submitting any amendments to the protocol.

Notifications of Serious Adverse Reactions are to include the following information:

1. The number of people in the study.
2. The number of similar adverse reactions of an unexpected or expected nature and the timeframe over which these have occurred.
3. The investigator's assessment of the significance in context of continuance or modification of the study.

In addition, you are required to:

- Address all correspondence quoting the protocol number and name.
- Provide a written report signed by the Monitor to the Committee in six months time (**2 March 2009**).

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- Provide a final report signed by the Monitor on completion of the project detailing the status of the project, its compliance with the conditions imposed upon it by this Committee, as well as details concerns data security.
- Provide a summary, (written by the Researcher and signed by the Monitor) of any protocol amendments.

If you have any queries, please contact me on (07) 4968 6248.

Yours sincerely



Dr David Farlow
A/Chairperson
Mackay Health Service District Human Research Ethics Committee

10/9/08