Health
Hunter New England
Local Health District

11 July 2016

Professor Ian Harris
Whitlam Orthopaedic Research Centre
Ingham Institute for Applied Medical Research
1 Campbell Street
Liverpool NSW 2170

Dear Professor Harris,

Re: CROSSFIRE: A Combined Randomised and Observational Study of Surgery for Fractures In the distal Radius in the Elderly (16/02/17/3.04)

HNEHREC Reference No: 16/02/17/3.04
NSW HREC Reference No: HREC/16/HNE/10

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Hunter New England Human Research Ethics Committee. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has determined the variation meets the requirements of the National Statement on Ethical Conduct in Human Research and has granted ethical approval for the following amendment requests:

- For the addition of Nepean Hospital as study site;
- For the addition of Dr Manish Gupta as Principal Investigator at Nepean Hospital;
- For the addition of Prince of Wales Hospital as study site;
- For the addition of Dr Bernard Schick as Principal Investigator at Prince of Wales Hospital;
- For the addition of Gosford Hospital as study site;
- For the addition of Wyong Hospital as study site
- For the addition of Dr Ian Incoll as Principal Investigator at Gosford Hospital and Wyong Hospital;
- For the addition of St George Hospital as study site;
- For the addition of Dr Geoff Smith as Principal Investigator at The Sutherland Hospital and St George Hospital;
- For the addition of Campbelltown Hospital as study site;
- For the addition of Dr Sameer Viswanathan as Principal Investigator at Campbelltown Hospital;
- For the addition of Princess Alexandra Hospital as study site;

- For the addition of Dr Nicola Ward as Principal Investigator at Princess Alexandra Hospital;
- For the addition of Nambour Hospital as study site;
- For the addition of Dr Kim Latendresse as Principal Investigator at Nambour Hospital;
- For the addition of Cairns Hospital as study site;
- For the addition of Dr Chris Morrey as Principal Investigator at Cairns Hospital;
- For the addition of Western Hospital as study site;
- For the addition of Dr Phong Tran as Principal Investigator at Western Hospital;
- For the addition of Wagga Wagga Base Hospital as study site;
- For the addition of Dr Angela Hatfield as Principal Investigator at Wagga Wagga Base Hospital;
- For the addition of Toowoomba Hospital as study site;
- For the addition of Dr Leo Zeller as Principal Investigator at Toowoomba Hospital;
- For the addition of Mr Andrew Lawson as student researcher;
- For the deletion of Dr Peter Tamblyn as an Investigator at Flinders Medical Centre site;
- For the Protocol (Version 20 dated 25 May 2016); and
- For the Summary of Changes v-18-v20 (dated 14 June 2016)

For the protocol**: CROSSFIRE: A Combined Randomised and Observational Study of Surgery for Fractures In the distal Radius in the Elderly [Protocol Version 18 dated 10 March 2016]**

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of **3** years from the date of the approval letter of your initial application, after which a renewal application will be required if the protocol has not been completed. The above protocol is approved until **March 2019.**

Approval has been granted for this study to take place at the following sites:

- **Campbelltown Hospital, NSW**
- **Gosford Hospital, NSW**
- **John Hunter Hospital, NSW**
- **Liverpool Hospital, NSW**
- **Nepean Hospital, NSW**
- **Prince of Wales Hospital, NSW**
- **St George Hospital, NSW**
- **The Sutherland Hospital, NSW**
- **Wagga Wagga Base Hospital, NSW**
- **Wyong Hospital, NSW**
- **Cairns Hospital, QLD**
- **Mackay Base Hospital, QLD**
- **Nambour Hospital, QLD**
- **Princess Alexandra Hospital, QLD**
- **Toowoomba Hospital, QLD**
- **Flinders Medical Centre, SA**
- **Royal Adelaide Hospital, SA**
- **Royal Melbourne Hospital, VIC**
- **Western Hospital, VIC**

The *National Statement on Ethical Conduct in Human Research (2007)* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is **March 2017.** A proforma for the annual report will be sent two weeks prior to the due date.

- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.

- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

    - any serious or unexpected adverse events

        - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure.

        - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Ethics Officer of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.

        - Copies of serious adverse event reports from other sites should be sent to the Hunter New England Human Research Ethics Committee for review as soon as possible after being received.

        - Serious adverse events are defined as:

            - Causing death, life threatening or serious disability.
            - Cause or prolong hospitalisation.
            - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

    - Unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, the Manager, Research Ethics & Governance Office as soon as possible.

The Hunter New England Human Research Ethics Committee also has delegated authority to approve the commencement of this research on behalf of the Hunter New England Local Health District. This research may therefore commence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per the contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Hunter New England Local Health District website.

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
New Lambton NSW 2305
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

Please quote **16/02/17/3.04** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

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