

St Vincent's Hospital

A facility of St Vincents
& Mater Health Sydney

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5 October 2012

Dr Craig Waller
Suite 405
St Vincent's Clinic
438 Victoria Street
Darlinghurst NSW 2010

Dear Craig

SVH File Number: 11/199

Project Title: Effectiveness of the KineSpring Single Spring Absorber with PEEK in Improving Pain and Function in Patients with Knee OA: A Multi-centre, Single Arm Pilot.

Thank you for your letter dated 11 September 2012 submitting a response to HREC request for further information for an amendment dated **18 July 2012** to the above project. This was considered by the St Vincent's Hospital HREC at its Executive meeting held on **27 September 2012**. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the documents reviewed and approved at the meeting were:

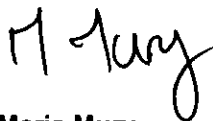
- Protocol KINE-1102 Version 2 dated 12 July 2012
- KineSpring Investigator's Brochure Version 2 dated 12 July 2012
- St Vincent's Hospital Patient Information Sheet Version dated 31 August 2012
- KineSpring Surgical Technique Guide – Draft 2012
- Overall Treatment Evaluation dated 10 July 2012
- Knee Society Score dated 5 September 2012

Please note the Clinical Trial Notification (CTN) Form signed by HREC has been forwarded to Study Coordinator, Jo Price.

For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents.

Should you have any queries about your project please contact the Research Office, Tel: 8382-2075, email research@stvincents.com.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: www.stvincents.com.au/researchoffice or internal at <http://exwwwsvh.stvincents.com.au/researchoffice>

Yours sincerely



Maria Mury
Acting HREC Executive Officer
Research Office

CC: Jo Price
TRIM Ref: D/2012/43874