



5 November 2018

A/Prof Leo Pinczewski  
North Sydney Orthopaedic and Sports Medicine Centre  
Suite 2 The Mater Hospital  
3-9 Gillies Street, Wollstonecraft NSW 2065

Dear Leo,

**SVH File Number: 18/225**  
**Project Title: Survival of ACL Reconstruction in Athletes**

Thank you for submitting the above project for ethical and scientific review.

Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD2010\_055 'Ethical and Scientific Review of Human Research in NSW Public Health Organisations', this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

This project meets the requirements of the National Statement on Ethical Conduct in Human Research. I am pleased to advise that the Committee at an Executive meeting on **2 November 2018** has granted ethical and scientific approval of the above **single centre** project.

The project is approved to be conducted at **North Sydney Orthopaedic & Sports Medicine Centre**.

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documents have been approved:

- Study Protocol: Survival of ACL Reconstruction in Athletes, Version 1 dated October 2018
- Assessment Form: Survival of ACL Reconstruction in Athletes, Version 1 dated October 2018
- Participant Information Sheet: Survival of ACL Reconstruction in Athletes, Version 1, October 2018

The Human Research Ethics Application Form (HREA) reviewed by the HREC was HREA **AU/1/8AE8316**

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **5 November 2023**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.

**St Vincent's Hospital  
Sydney Limited**  
ABN 77054038872

390 Victoria Street  
Darlinghurst NSW 2010

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- The Co-ordinating Investigator will provide an Annual Progress Report beginning in **November 2019**, to the HREC as well as a Final Study Report at the completion of the project in the specified format.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.
- Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.
- The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

This letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed **Site Specific Assessment Form** and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note that it is not considered best practice to store research data on personal hardware. No identifiable participant data can leave a site. There always needs to be data security measures in place and a clear plan for permanent destruction of data needs to be adhered to at completion of the project.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries regarding this project please contact the Research Office, Ph: (02) 8382-4960 or by E-mail: [SVHS.Research@svha.org.au](mailto:SVHS.Research@svha.org.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 web-site to be found at: <https://svhs.org.au/home/research-education/research-office>

St Vincent's Hospital HREC (EC00140) 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 Certification Scheme. 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.

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Please quote **SVH File Number: 18/225** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,

**Dr Pamela Blaikie**  
**Research Office Manager**  
**St Vincent's Hospital Research Office**  
Translational Research Centre, 97-105 Boundary Street

cc: Lucy Salmon  
TRIM REF: D/2018/85615

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