The Sydney children's Hospitals Network
care, advocacy, research, education

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2 October 2019

Associate Professor Nicodemus Tedla
Department of Pathology
School of Medical Sciences
University of NSW

Dear Associate Professor Tedla,

HREC Reference:	**2019/ETH00151**
Project title:	**Discovery of serum biomarkers for the diagnosis of sport-related concussions in children**
Sites:	**University of NSW** **The Children's Hospital at Westmead**

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Children's Hospitals Network Human Research Ethics Committee ("the Committee") at its meeting **21 June 2019** and subsequently by the Executive of SCHN HREC on **9 September 2019** and on the **30 September 2019**.

The HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review, and by the National Health and Medical Research Council as a certified committee in the review of multi-centre clinical research projects..

This 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 *CPMP/ICH Note for Guidance on Good Clinical Practice.*

I am pleased to advise that the Committee has granted ethical approval of this research project. Your approval is valid for five (5) years, effective the date of this letter.

This application has been assessed in accordance with, and meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
REGIS Project Registration		Received 03 Jun 2019
Cover letter_Tedla		27 Apr 2019
HREA	Version 8	01 Oct 2019
Cover letter - Response to each question listed by the committee in a Q&A style		29 Aug 2019
Flowchart_Healthy control participants recruitment flowchart	Version 2	20 Aug 2019
Flowchart_Participants with concussion recruitment flowchart	Version 2	20 Aug 2019
Healthy control participants clinical history form	Version 1	28 Aug 2019
Cover letter_3rd response to each question listed by the committee in a Q&A style	Version 3	18 Sep 2019
Consent form participants and parents/legal guardians	Version 3	11 Sep 2019
Parents or Guardians PIS - healthy	Version 4	17 Sep 2019
Parents or Guardians PIS - patients with concussion	Version 4	17 Sep 2019
Leaflet_Advert for recruitment of healthy participants	Version 3	11 Sep 2019
Revocation of consent form by participants and parents/legal guardians	Version 4	27 Sep 2019
Spirit Template Non-Drug Device Protocol Research proposal	Version 7	11 Sep 2019
Young Person PIS with concussion	Version 3	11 Sep 2019

Document	*Version*	*Date*
Young Person PIS - healthy controls	Version 3	11 Sep 2019
Recruitment Flowchart - patients	Version 3	11 Sep 2019
Recruitment Flowchart - healthy controls	Version 3	18 Sep 2019
Flowchart obtaining consent from young persons	Version 3	18 Sep 2019
Questionnaire_ Concussion Recognition Tool 5	Version 5	26 Apr 2017
Westmead Post-Traumatic Amnesia Scale (A-WPTAS)		2007
Sport Concussion Assessment Tool (SCAT5)	Edition 5	26 Apr 2017
Pocket Concussion Recognition Tool	Version 1	11 Mar 2013

Please note the following conditions of approval:

1. The Coordinating Investigator will immediately report anything which may warrant review of ethical approval of the project in accordance with the SCHN adverse event reporting policy.

2. All proposed changes to the research protocol, including the conduct of the research, changes to site or personnel, or an extension to HREC approval, are to be provided to the HREC or its delegate for review before those changes can take effect.

3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. The co-ordinating investigator will provide an annual report to the HREC on the anniversary of this approval letter, and a final report on completion of the study.

5. Your approval is valid for five (5) years from the date of the final approval letter. If your project extends beyond that five year period and you are still actively recruiting you will be required to resubmit your application incorporating any amendments within six (6) months of that approval expiry date. If your project is in follow up on, or analysis, please submit an application for amendment to extend the approval period. Ethics approval can be extended for a period of twelve (12) months at a time.

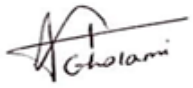
6. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

Should you have any queries about the HREC's consideration of your project please contact the Ethics Administration Assistant on (02) 9845 1253.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The SCHN HREC wishes you every success in your research.

Yours faithfully



Ms Asra Gholami
Executive Officer, Research Ethics
Sydney Children's Hospitals Network Human Research Ethics Committee

CC Gary Browne

***NB: All clinical trials must now be registered on a publicly accessible registry such as the Australian New Zealand Clinical Trials Registry. For further information please go to www.anzctr.org.au*. Please provide this office with a copy of your registration number for our records if you have not already done so.**