 HREC Project Number: **H-2016-0190**

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Priority Research Centre for Stroke & Brain Injury

LOCATION:
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Participant Information Statement for the Research Project
A validation study of a computerised neuropsychological test for concussion
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You are invited to take part in a research project defined above, which is being conducted by researcher Dr Andrew Gardner from the Priority Research Centre for Stroke and Brain Injury, University of Newcastle. You are being asked to participate in this study to validate a computerised neuropsychological test for concussion.

Why is this research being done?
The purpose of the research is to determine the clinical utility of a newly developed computerised neuropsychological test design to detect cognitive deficits post-concussion.

Previous research has shown that deficits in cognition (thinking skills) occur in concussed athletes. Alterations in memory, attention, processing speed, reaction time, inhibitory control and decision-making have all been demonstrated in athletes with concussion. In order to detect and monitor recovery of these deficits to inform return to play decisions it is important to have valid and reliable measures of cognitive function post-concussion.

Who can participate in the research?
We are seeking male and female athletes, of every level who are aged between 11 years and 35 years and who are NOT colour-blind to participate.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you, nor will it affect any current or future relationship that you have with The University of Newcastle, or your sporting organisation or club.

If you do decide to participate, you may withdraw from the project at any time without giving a reason, and have the option of withdrawing any data that identifies you.

What would you be asked to do?
If you agree to participate, you will be asked to complete a 45-minute assessment of your thinking skills. This will involve two elements including:
(a) A clinical interview asking about personal information including: your age, education level and concussion history.
(b) A neuropsychological assessment that includes tests of memory, attention, and cognitive functioning.

Some participants will also be asked to complete the computerised testing a second time this second assessment will be decided firstly on a random basis and on your availability. This second assessment with us will help us to calculate the test's 'test re-test reliability.' The time between the two testing sessions will vary from 1-2 weeks duration; 8-10 weeks duration; or 23-26 weeks duration. If you are asked to be re-tested, then when you are assigned to a re-test group you will be informed of the time duration for the second testing session.

We will also ask you to consent to us keeping your contact details on file for at least five years, so that we can approach you during the season should you sustain a concussion, to invite you to participate in another round of this testing.

How much time will it take?
The estimated time to complete this assessment is approximately 45 minutes.

What are the risks and benefits of participating?
There are few risks associated with the study, but should you become distressed while completing any assessments, the researcher working with you at that time can provide information and advice regarding additional support and/or referral for your particular concerns.

We cannot promise you any personal benefit from participating in this research. You are able to request an individual summary of your assessment results, which might be beneficial to you in terms of your medical history.

How will your privacy be protected?
Information provided by you for the project will have your name replaced by a participant code number and will be securely stored on password protected computers and in the secure office in the office of Dr Andrew Gardner. Only the researchers listed on this sheet will have access to your information. Identifying information linking your participant code number with your name will be kept entirely separately from your assessment results on password protected computers and in the secure office in the office of Dr Andrew Gardner.

Any information collected by the researchers that might identify you will be stored securely on password protected computers and in the secure office in the office of Dr Andrew Gardner and only accessed by the research team named on this Information Statement, except as required by law.

All data collected as a result of this study will be kept for 15 years in accordance with recommended practice. This includes names and addresses to allow for longer-term follow-up.

How will the information collected be used?
Information provided by you as a result of your participation in this project will only be reported in group format, with no individual participant being identified. Study results may be presented at academic conferences and published in professional journals, again, only using summarised, and not individual, results. Individual participants will not be identified in any reports arising from the project.

Individual feedback on your own assessment results is available to you, and only you, upon request.

What do you need to participate?
Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the research team.

If you would like to participate, please contact the research team member. A member of the research team will then contact you directly to arrange an appointment, convenient to you, where the assessments will be completed. The consent form will be completed prior to testing.

Further information
If you would like further information, please contact Sarita Kidson (sarita.kidson@students.mq.edu.au).

Thank you for considering this invitation.

Dr Andrew Gardner
Conjoint Senior Lecturer, School of Medicine and Public Health, University of Newcastle

Research Team
Dr Andrew Gardner
Dr Susanne Meares
Courtney Phillips
Sarita Kidson
Vanessa Chase
Kathy Gurr

Complaints about this research
This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2016-0190.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

If you would like to participate, please contact Sarita Kidson at sarita.kidson@students.mq.edu.au