PO BOX 509, BONDI, NSW 2026 Phone 02 8007 3903 Fax 02 9475 1321 www.necksafe.com.au

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

THE IDENTIFICATION OF SPORT RELATED CONCUSSION IN FOOTBALL BY COMPARING PRE-SEASON BASELINE MEASURES WITH IMPACT DATA AND POST-IMPACT REPEAT MEASUREMENTS

HREC project number 15/315

Invitation

You are invited to participate in a research study into assessing concussion in football.

The study is being conducted by Dr. Adrian Cohen from Necksafe, a charity which is recognised by the Australian Charities and Not For Profits Commission (ACNC) as a Health Promotion Charity (HPC) dedicated to the elimination of preventable head and neck injuries through advocacy, awareness, education and research. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

This study aims to collect pre and post injury data, and assess the severity of the impact and resultant diagnosis of concussion using objective testing measures of force (via Impact Sensors/accelerometers)and balance. The results of this study will be presented at national / international conferences and submitted to peer-reviewed journals.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study because you are a footballer over 18 years of age.

3. What does participation in this study involve?

If you agree to participate in this study you will then be asked to complete a pre-competition concussion history questionnaire, a sports concussion assessment baseline evaluation, undertake a physical examination of your head and neck and to complete a number of computerised cognitive tests over approximately one hour at the principle researcher's offices in Kensington. This information will be collected at the beginning of your enrolment in the study. These questionnaires and tests will be repeated after a concussion or suspected concussion has occurred in order to be able to compare your performance to the baseline tests. This information may also be passed onto other healthcare services should there be a medical situation where you are required to be referred for further care and management. You will be asked to wear an acelerometer fitted patch behind your ear while you participate in football matches. The patch will be applied on a hypo-allergenic, adhesive material during your preparation for the game, and will be removed when you leave the field. You may also be asked to supply saliva samples before and after matches. Any information obtained in connection with this research project that can identify you will remain confidential. If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

4. What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

5. How is this study being paid for?

The study is being paid for by the charity NeckSafe.

6. Are there risks to me in taking part in this study?
The only foreseeable risk/s in taking part in this study are those discomforts and risks that normally occur from participating in football match activities. There is a small risk of dislodgement of the accelerometer which may cause minor inconvenience of the your time if ti has to be reapplied.

7. What happens if I suffer injury or complications as a result of the study?
If you require treatment or suffer loss as a result of the negligence of any of the parties involved in the study you may be entitled to compensation; the cost of your treatment would have to be paid out of such compensation.

8. Will I benefit from the study?
This study aims to further medical knowledge and may improve future treatment of concussion however it may not directly benefit you. Information gained from this research has potential to help shape training and game strategies to prevent concussion, and develop indicators of potential concussion to protect you from injury.

9. Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything, nor will you be paid.

10. How will my confidentiality be protected?
The data from the project will be coded and held anonymously in secure storage under the responsibility of the principal investigator of the study in accordance with the requirements of the Australian Privacy Principles (APPs) (March 2014).

All reference to participants will be by code number only in terms of the research thesis and publications. Identification information will be stored on a separate file and computer from that containing the actual data.

Only the investigators will have access to computerised data.

Should a situation occur where you become injured then your identified next-of-kin / legal guardian / parent that has been recorded and/or signed the consent form will be contacted to advise them of the injury, the care provided and where you have been transferred to. The information obtained will also be passed onto the healthcare service as part of the on-going management of your medical care.

11. What happens with the results?
If you give us your permission by signing the consent document, we plan to discuss/publish the Information gained from this research to prevent concussion, and develop prognostic indicators of value to athletes, clinicians, physical conditioners and coaches

In any publication, information will be provided in such a way that you cannot be identified.

12. What should I do if I want to discuss this study further before I decide?
When you have read this information, the researcher Dr. Adrian Cohen will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him 0418253333

13. Who should I contact if I have concerns about the conduct of this study?
This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee.

Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants.
You should contact them on 02 9382 3587, or email RSOseslhd@sesiahs.health.nsw.gov.au and quote HREC project number 15/315.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

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CONSENT FORM

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1. I,.....of..... agree to participate in the study described in the participant information statement set out above.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the club.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Dr. Adrian Cohen on telephone 0418253333 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email RSOseslhd@sesiahs.health.nsw.gov.au.

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____
Signature of investigator	**Please PRINT name**	**Date**
_____	**Adrian Cohen**	_____

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REVOCATION OF CONSENT

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I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the club or my medical attendants).

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____

The section for Revocation of Consent should be forwarded to

Dr. Adrian Cohen
PO Box 509
Bondi
NSW 2026