Participant Information and Consent Form – Suspected Concussion

Full Project Title: Blood Biomarkers for Sport-Related Concussion Diagnosis Beyond the Day of Injury

Principal Investigators: Dr Stuart McDonald, Professor Terence O'Brien (Alfred Health), Dr Steven Mutimer (Sportsmed Biologic; Performe Sports Medicine)
Clinicians: Dr Blake Colman (Alfred Health), Dr Duncan Austin (Alfred Health), Dr Steven Mutimer (Sportsmed Biologic; Performe Sports Medicine)

1. Introduction

You have been invited to take part in this research project, as you have been identified by your Victorian Amateur Football Association (VAFA) or Eastern Football Netball League (EFNL) football club as having experienced a suspected concussion.
The diagnosis and management of sport-related concussion is challenging, primarily as it is heavily reliant on subjective signs and symptoms. As such, our research group has focused on discovering and validating objective tools to assist with concussion diagnosis and management. In recent published studies in emergency department and sports concussion cohorts, we have shown that measures of brain specific proteins in blood (i.e., blood biomarkers), hold great promise in assisting with this process. However, there are critical gaps in evidence that must be filled to advance the blood tests towards routine clinical use.
This *Participant Information and Consent Form* outlines the research project. Please read this information carefully, and feel free to raise any questions or concerns you may have. Participation is voluntary; therefore, you do not need to participate in the study if you do not wish to. Please note that you are required to be a participant of this study to receive booking access assistance to the concussion clinics from the research team. Please keep a copy of this *Participant Information and Consent Form* for your record.

2. What is the purpose of this research?

The aim of this study is to determine how existing and new candidate blood biomarkers (i.e. proteins found in blood that reflect a biological process, in this case brain injury) might be used to assist diagnosis of concussion at clinically relevant stages after injury. It recruits directly from adult Australian football teams from the VAFA and EFNL, rather than just from the subset that attend a hospital emergency department, and thereby generates data most reflective of the sports concussion spectrum. We aim to recruit 300 players with suspected concussion. By combining an injury report and referral from your football club, repeated symptom evaluation and blood biomarker testing at 24 hours and 48-72 hours, and an expert medical evaluation in a concussion-specific clinic, we aim to produce the high-quality evidence required to progress blood biomarkers towards routine clinical use to assist diagnosis in cases of potential or suspected concussion.
This research is conducted by the Department of Neuroscience at Monash University, and the Department of Neurology at Alfred Health. The research has been initiated by Dr Stuart McDonald, the Chief Investigator of this study. The research team will include an approved student researcher Dr Steven Mutimer, undertaking tasks under appropriate supervision for the purpose of obtaining a part of their PhD degree.
The research is funded by an Ideas Grant and Medical Research Future Fund grants awarded by the Australian National Health and Medical Research Council, and no member of the research team will obtain any financial benefit from their involvement in this project (other than their ordinary wages to help with data collection).

3. What does participation in this research involve?

The study consists of two visits and three online surveys.
Visit 1 will be undertaken at your premises the day after your suspected concussion (i.e., 24 hours after injury) at a time of your choosing, and features basic questions about your medical and sporting background, your injury, symptoms, and a small blood sample (15 mL; i.e. 3 teaspoons). This visit will require ~30 minutes.
For Visit 2, you will have the option to visit one of three affiliated concussion clinics:

1) ***The Alfred Concussion Clinic*** at the Caulfield Hospital, which is available on Mondays.
2) ***Sportsmed Biologic*** in Box Hill, which is also available on Mondays.
3) ***Performe Sports Medicine*** in Melbourne, which is available on Tuesdays.

The clinics are free to attend for participants. During this appointment, you will receive clinical evaluation and care by a medical doctor (i.e. a Neurologist at Alfred, and a Sports and Exercise Medicine Registrar at either Sportsmed Biologic or Performe). This medical appointment is standard clinical practice for these concussion clinics. We will securely share your Trainer/Physio Report, publicly available concussion footage, and your 24h symptom questionnaire results (SCAT6) with your treating doctor to potentially assist with the clinic visit. Upon completion of the standard clinical evaluation, with your consent the treating doctor will fill out a short survey regarding your injury signs, symptoms, and diagnosis. This information is used for research purposes only and

is not communicated to your football club. Additionally, a qualified and experienced researcher will collect a second small blood sample (~15ml) for the research. This visit will require ~60 minutes at the clinic. All three clinics are open to the public, however, please note that you are required to be a participant of this study to receive booking access assistance to the concussion clinics from the research team.
Finally, at 1-, 6-, and 18-months, you will be sent an online survey via a secured website to complete in your own time. This survey will contain information about your symptom recovery, return to training and matches, training and match completion, and future concussion incidence. Each survey requires less than 10 minutes to complete. You will not be paid in cash for your participation in this research, *but your contribution will be met with gratitude in the form of eGift vouchers to reimburse you for your time:*
For visit 1 (i.e., home visit to you), you will receive a **$50** voucher at the conclusion of the visit.
For visit 2 (i.e. visit to concussion clinic), you will receive a **$75** voucher. This voucher is also intended to indirectly, but potentially incompletely, reimburse you for any transportation costs
At the completion of each of the 3 follow-up surveys, you will receive a **$20** voucher.
Please note that Monash University may require the names of those receiving vouchers for internal auditing purposes.
Which clinic do I attend? You have the option to attend your choice of the clinics, subject to appointment and your availability.
Do I have to attend a clinic? The study aims are largely dependent on participants attending the clinic, however, should you not be able to book / attend an appointment, you can continue participation in this study by completing the follow up surveys.

4. What are the possible benefits?

a) *To participants:* Outside of being given the option to go to a concussion clinic, it is possible that you will receive no benefit from your participation. Data that is collected for research purposes will not influence your injury management.
b) *To society:* We anticipate that this research will help lead to a sensitive and specific blood test for sport-related concussion diagnosis and management.

5. What are the possible risks?

It is not expected that you will experience any harm from participating in the study. However, it is possible you may experience more than discomfort given the study asks you to provide two blood specimens. Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel. Rarely, there could be bleeding or a minor infection. If this happens, it can be easily treated. Some people may feel faint when having blood taken, and may occasionally faint. A percentage of the population is prone to fainting, and consciousness is usually regained in seconds. Unexpected fainting and falling may lead to injury, however our researchers are trained to manage this risk. Blood samples will not be assessed for illicit substances.
All data will be stripped of identifiers, meaning any data or samples collected from you will not be labelled with your name, date of birth, etc. No social, economic or legal risks are present. If you experience more than discomfort from participating in this study, please contact the research team, your doctor, your club health care professional, or Lifeline through their Lifeline National Telephone Crisis Line 13 11 14.

6. What if I get injured or have complication in the research?

Note that only Medicare cardholders are eligible to participate in this study. If you suffer any injuries or complications as a result of this research, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. As you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

7. Do I have to take part in this research project?

Participation in this research project is voluntary. You will only be enrolled in this study if you provide consent to partake in this study. If you do not wish to take part you don't have to, non-participation will not result in any negative ramifications from your VAFA or EFNL football club. Please note that you are required to be a participant of this study to receive booking access assistance to the concussion clinics from the research team.

8. What if I withdraw from this research project?

There will be no ramifications to you from withdrawing from the study. You can choose to withdraw from the study at any time. Withdrawals are documented with the Withdrawal Form, where you can actively withdraw the analyses and/or storage of your trainer/physio report, blood samples, and other data. You may choose to allow your data collected up to the time point to be analysed, or to be discarded in the Withdrawal Form. If you wish to withdraw from the study, please use the Withdrawal Form attached to this PICF, and you may also contact Dr McDonald on 0402 694 000 or stuart.mcdonald@monash.edu for more information.

9. How will I be informed of the results of this research project?

The findings of this study and any results from the clinic visit will be non-identifiable (i.e., not revealing individual information) and published in a widely accessible journal. You will not be able to get the results of your individual blood tests; however a lay summary of overall study findings along with the abstract of any publications will be communicated to you if you wish to receive this by email.

10. What else do I need to know?

- **What will happen to information about me?**

By signing the consent form, you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your Trainer/Physio Report, concussion footage and SCAT6 results shared securely with the doctor for your clinic visit will not contain your study code. All data and samples pertaining to you stored for research will be labelled with your study code (without any identifiers such as your name or date of birth) which only the research team will be able to re-identify. These results will be presented at conferences and incorporated in scientific publications in the same deidentified manner, this means that the results will not identify you or any other participants.

Publicly available video footage (of your incident, if available) from the VAFA or EFNL website, as well as all other data will be stored in secure files labelled only with participant codes, and only research members approved by the Ethics Committee will have access to these files. These files will be securely stored for 10 years according to the Archiving Guideline, or indefinitely into the future (with your consent). Hardcopy files are stored in a locked cabinet in Dr McDonald's office on level 6, Alfred Centre. All blood samples will also be labelled only with your study code (no identifiers such as name or date of birth) and stored for a maximum of ten years (with your consent) in the Department of Neurosciences laboratory, Level 1 Burnet building, Monash University (Alfred Hospital). These samples will be used for concussion-related blood tests in this project, and may be used in future such projects within the time period which you consent to. Blood samples will be analysed at specialist laboratories in Australia and overseas. Samples will not be used for other purposes and will be destroyed after the study period which you consent to. The results of this research will also be used partially by Dr Steven Mutimer to obtain a PhD degree.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified. This confidentiality will be maintained by presenting aggregate (grouped) data.

- **Is this research project approved?**

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2023) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies. This study has been approved by the Alfred Hospital Ethics Committee.

11. Who can I contact?

If you would like any further information concerning this project, you can contact:

- Dr Stuart McDonald on 0402 694 000 or stuart.mcdonald@monash.edu

For complaints: If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Complaints Officer, Alfred Health on P: (03) 9076 3619 | E: research@alfred.org.au

Please quote the following project number: **Project 106478**

Performe Sports Medicine Site Complaints:

- Molly Rayner (Business Manager) on (03) 84120048 or molly.rayner@performe.com.au

Sportsmed Biologic Site Complaints:

- Sam van Wetering (Practice Manager) on 1300 858 860 or samvw@sportsmedbiologic.com.au

12. Consent

Declaration by Participant

I have read this document and I understand the purposes, procedures and risks of this research project as described within it. I freely agree to participate in this research project as described, and I understand that I am giving my consent by completing this informed consent form.

I consent to the following (Please tick boxes).

- ☐ Video analysis of publicly available footage of any head impacts sustained in match play.
- ☐ Completion of a survey pertaining to my demographics, medical and sporting history at first home visit.
- ☐ Attending one of three Concussion Clinics at the agreed upon time, to receive clinical evaluation and care independent of the research study.
- ☐ The research team to securely share a copy of my Trainer/Physio Report, concussion footage, and 24h SCAT6 symptom results with my treating doctor at the Concussion Clinic for the purpose of potentially assisting with my clinic visit.
- ☐ My treating doctor completing a survey regarding my injury signs, symptoms, and diagnosis, to be shared with the research team for research purposes only.
- ☐ A small sample of blood (15 mL i.e. ~3 teaspoons) to be collected at each home and clinic visit.
- ☐ Completion of 3 follow up online surveys pertaining to symptom recovery, return to training and matches, training and match completion, and future concussion incidence.
- ☐ My blood to be analysed for biomarkers related to brain trauma in this study.
- ☐ I wish to receive a summary/abstracts of any findings from this research.
  Email:_____

Please tick ONE of the following:

- ☐ My blood/data to be stored and used in future (ethically approved) concussion-related studies. (Bloods discarded after 10 years, data stored indefinitely)
  or
- ☐ My blood/data to be used for this study only.
  (Blood and data discarded after completion of this study)

Participant full name: _____ Signature: _____ Date: _____

Witness name: _____ Signature: _____ Date: _____