PARTICIPANT INFORMATION SHEET Version 3.2 (Concussion Clinic Birmingham)

**Title of project: Repetitive Concussion in Sport (RECOS)**

**IRAS Project ID: 216703**

# Part 1

## Introduction to the research and invitation to take part:

You are being invited to take part in a research study. It is important that you understand why the research is being done and what it will involve before you decide whether or not to take part. Please read the following information carefully, and please discuss this with others if you wish. Feel free to ask us if there is anything that is not clear or if you would like more information.

## What is the purpose of the study?

The study will investigate what happens to the brain after concussion (head injury). The study will be examining the relations between components in your blood, saliva and urine along with imaging of your brain through Magnetic Resonance Imaging (MRI) and functional Near-Infrared Spectroscopy (fNIRS). Furthermore, there will be tests to assess your memory, concentration, attention and coordination.

## What kinds of tests will I have?

We would like to carry two brain imaging techniques, functional Near-Infrared Spectroscopy (fNIRS) and Magnetic Resonance Imaging (MRI) scan. Before undertaking these two brain imaging techniques, female participants will take a pregnancy test. In case of positivity of this test you will be excluded from the study. We would also like to carry neurological tasks which assess your memory, concentration, attention and coordination. These tasks will be done on a computer or using pencil and paper. Some of these tasks will be performed while you are undertaking the fNIRS. If you agree, we will also ask you for a blood sample, which will be taken by a trained practitioner, and saliva and urine samples. All tests will be repeated when you are fit to return to work or play. You will be able to withdraw from the study at any time.

## Do I have to take part?

No. It is up to you whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. Withdrawing from the study will not affect you in any way (e.g., your future medical treatment).

## What will happen to me if I take part?

You will undergo a Magnetic Resonance Imaging (MRI) scan, during which you will be asked to lie still and reduce any mental effort in the scanner. During a part of the MRI scanning, we will propagate small waves into your brain. You will feel vibrations on the back of your head which are necessary to produce these waves. The scanning session will last about 1 hour.

You will undergo to an functional Near-Infrared Spectroscopy (fNIRS) monitoring. You will wear a headgear connected with probes and we will ask you to stay still or to do physical and neurocognitive tasks. This assessment will last about 1 hour.

We will take saliva and urine samples and 25 ml blood sample during your clinical assessments in the Concussion Clinic in the Queen Elizabeth Hospital Birmingham until your recovery.

You will be asked to do physical and neurocognitive tasks during your evaluations in the Queen Elizabeth Hospital Birmingham to follow your recovery.

All these tests can be useful to better assess your brain and can potentially predict when athletes may be ready to return to play and train.

## I have been checked immediately after I got concussed, will the results of those tests be part of the study?

Yes, we may use the results of your clinical assessment on the pitch side.

## Can I drive after concussion?

No, it would be preferable that you not drive after an episode of concussion until said otherwise by a medical doctor. Concussion can affect your balance, vision and reaction speed. All of these are really important to drive; therefore we would advise you not drive to the clinic.

## How can I reach the Concussion Clinic Birmingham in the Queen Elizabeth Hospital Birmingham if I cannot drive?

The local sport club can arrange the travelling for you. Otherwise you have to reach the Concussion Clinic Birmingham in the Queen Elizabeth Hospital Birmingham by your own. The study does not include a service to carry the patients to the Concussion Clinic Birmingham in the Queen Elizabeth Hospital Birmingham.

## Will I be refunded of the expenses of travelling to the Concussion Clinic Birmingham in the Queen Elizabeth Hospital Birmingham?

No, unfortunately we are unable to refund your travel expenses.

## What is Magnetic Resonance Imaging (MRI)?

Magnetic Resonance imaging uses a magnetic field to measure the structure and function of the tissues. When the brain is scanned, we can derive information about both brain structure and function. During the MRI scan there will be also performed a technique named Magnetic Resonance Elastography (MRE) which measures the stiffness of the brain tissue by analysing the propagation of small waves of vibration in the brain. During the MRE, you will feel your head slightly vibrate.

The procedure is non-invasive and carries no known harm outside of safety issues for operating in a high magnetic field (e.g., if you have a cardiac pacemaker). For this reason, you will be asked to go through a safety questionnaire with a scan operator prior to being allowed to proceed into the scanning environment

## What is functional Near-Infrared Spectroscopy (fNIRS)?

A functional Near-Infrared Spectroscopy (fNIRS) utilizes a type of light named Near-Infrared to detect the brain activation. In the clinical practice, the Near-Infrared Light is used routinely on fingers to measure the level of oxygenation in the blood (e.g., pulse oximetry). We can use the fNIRS to map how different areas of the brain work at rest and during physical and neurocognitive tests.

## What tests of memory, concentration, attention and coordination will I have?

We will carry out the Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) which is a computerised test for sports-concussion related cognitive impairment. A paper and pencil assessment (the Screening Module of Neuropsychological Assessment Battery, NAB-S) will also be administered by trained health professional researchers. They take about 40 minutes to complete and assess different areas of cognition with a series of short tasks covering orientation, memory, spatial attention and executive functioning, as well as pre-morbid general ability.

Coordination will be tested using the Nine Hole Peg Test. This is a 5-minute test of fine motor coordination and hand/eye coordination where you will be asked to pick up and replace pegs into holes, one at a time, using your dominant hand only.

Balance assessments and gait analysis will also be conducted including a short Balance Error Scoring Sheet (BESS) test whereby you will be required to remain as still as possible whilst performing numerous stances with your eyes closed. Additionally, a Virtual Reality based balance assessment will also be conducted. You will be required to stand on a balance platform wearing a pair of virtual reality goggles in order to become immersed in a virtual environment whilst completing a short neuropsychological task.

These tests will be carried out because research has shown that concussion can cause a temporary impairment of various aspects of our cognitive abilities and coordination. The results of these tests will allow us to interpret the MRI findings.

## Will the googles used to simulate Virtual Reality be safe to wear?

The googles used to simulate a Virtual Reality are used for videogames. They have a small risk of seizures. Continuous monitoring from trained staff will be done during the usage of the googles.

## Why do you need a blood test and urine and saliva sample?

Certain chemicals that are produced in the brain after injury may appear in the bloodstream, in the saliva and urine after a few minutes or hours. Measuring these compounds may offer us the opportunity to identify new biomarkers of head trauma that can track brain recovery without resorting to a brain scan in the future.

## Are you going to do genetic tests on the samples?

Yes, we are going to do analyses on the RNA. In particular, on small molecules of RNA called microRNA. We may also use the samples to look for genes may influence recovery from concussion. We are not interested in the whole genome (e.g. to look for genetic conditions that have nothing to do with concussion). These further genetic analyses will not be used to make decisions about you and you can opt out of these further tests if you prefer.

## What are the possible benefits of taking part?

By learning more about brain recovery, by using MRI, we will be able to develop better ways of advising athletes, soldiers and NHS patients on when they can return to previous activity. At present, we do not have an objective test to track brain recovery, which means that some people may risk another injury to their brain before they are fully recovered, while other people may be unnecessarily stopped from activity or play for a long period of time.

**What will happen to my samples?**

The samples will be transferred to the University of Birmingham, where they will be analysed. Any residual volume of sample left after the analysis will be stored for up to five years. These residual samples may be used to look for further biomarkers of injury or genetic testing. These further analyses may be carried out in other labs outside the University of Birmingham and the samples may also be used for the development of commercial tests by third parties. Rest assured that at no point we will pass on any personal information about you.

**Data confidentiality**

We will ensure that your personal data remain strictly confidential. We will confidentially access information from other databases, such as the RFU’s Injury Surveillance Programme, but this link will only be used to collect meaningful injury data for the statistical analysis. The data will be stored securely in an encrypted folder on the University of Birmingham server behind several firewalls. Your personal information will only be shared with very few approved researchers on the study and nobody else.

## What happens at the end of the research study?

The results will be written for scientific publication. In addition, we will report them in a newsletter

that we will distribute to all participants and to hospitals. All data will be reported anonymously.

## What if there is a problem during these tests?

It is possible that lying in the MRI scanner might cause some back or neck pain, and it is possible to feel a burning sensation. If you experience any discomfort you can press the emergency buzzer and you will be brought out of the scanner immediately.

During the assessment with the fNIRS it is possible to feel some neck pain due to the still position. Trained members of the research group will continually assess you, they will minimise as much as possible any discomfort and they will stop the test if needed.

Blood sampling is a routine aspect of hospital care, is relatively uncomfortable and carries with it small risks of haematoma.

Any complaint about the way the study has been conducted or any possible harm you may have suffered will be addressed. The detailed information on this is given in Part 2.

## What if during these tests (e.g, MRI) there will be an incidental discovery of a pathology?

If we find a pathology that you were not aware of, you will be notified of it. If you consent to it, we will refer this finding to your GP or medical team at your sport club. All your data will be kept confidential.

## Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact Details:

**Mr David Davies,** School of Medicine, University of Birmingham (0121 371 6741, david.davies@uhb.nhs.uk)

**Prof. Belli**, School of Medicine, University of Birmingham (a.belli@bham.ac.uk)

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision**.**

# Part 2

## What will happen if I do not want to carry on with the research study?

You are free to withdraw from the study at any time until completion of your follow-up assessments, including following data collection, without giving a reason. After completion of your last assessment it would be unfeasible to us to remove your anonymised data from the analysis.

If the data collected until the time of withdrawal could be used, you will specifically be asked to give your consent to having the data included in any analysis.

## What if there is a problem?

If you have any problems with the conduct of the study then you can do any of the following:

1. Phone the Research Governance Committee of the University of Birmingham, who have considered this project, on 0121 414 7618, who will arrange for your concerns to be investigated.
2. Write to Research Governance, University of Birmingham, Room 119, Aston Webb Building, University of Birmingham, Edgbaston B15 2TT
3. Email researchgovernance@contacts.bham.ac.uk
4. Contact any of the researchers listed above in Part 1.

Citizen Advice (<https://www.citizensadvice.org.uk/>) can provide independent advice if you are unhappy with any aspect of the process.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence then you may have grounds to claim compensation against the University of Birmingham, but you may have to pay your legal costs.

## Will my taking part in this study be kept confidential?

Our procedures for handling, processing, storing and destroying your data are all compliant with the Data Protection Act 1998. All information that is collected about you during the course of the research will be kept strictly confidential.

## Who is organising and funding the research?

The research is organised by the University of Birmingham.

## Who has reviewed the study?

This study was given a favourable ethical opinion by the East of England Research Ethics Committee (Essex Research Ethics Committee).

You will be given a copy of the information sheet and a signed consent form to keep.

Thank you for considering taking part and taking the time to read this sheet.