Informed Consent Document for Rugby Participants

University of Cape Town
Psychology Department
Telephone: +27 21 650-3430
Fax: +27 21 650-4104

Investigating the neuropsychological effect and long term outcomes of concussions among high school rugby players

Informed consent for your child to participate in research and authorization for collection, use, and disclosure of protected health information

The neuropsychological (relationship between the brain and behavior) effects of traumatic brain injuries (TBIs) are considered a public health concern, both in South Africa and around the world. A common form of TBI is concussion, which is known to be associated with neuropsychological (thinking and behavioural) difficulties. Some of the outcomes associated with concussion often include difficulties with attention and concentrating, higher order thinking skills (e.g., working with information in one's head), remembering information and the speed at which one thinks or processes information.

Some research suggests that exposure to concussive head injuries over a long period of time, especially when this starts at a young age like in the adolescent years, may result in permanent neuropsychological (thinking and behavioural) and emotional problems in the adult years. There have been some cases for which research has suggested that such long-term exposure to multiple concussions may also be associated with neurodegenerative (loss of structure and function of neurons (brain cells) over time) processes in later life.

Added to this, adolescent athletes seem to show more difficulties and longer recovery times compared to adults following concussion, suggesting that the injury and recovery process may be different between adolescents and adults. Therefore, investigating the effects of concussion among a young adolescent population (aged 16 to 19 years) is of particular interest in this study. Younger athletes (e.g., adolescents) may be at greater risk for difficulties as compared to adults, for several reasons: 1) the brain is still maturing and developing during childhood and adolescence and thus an injury during this developmental period can interfere with this development; second, the differences in how intense and how long symptoms last in adolescents compared to adults suggests that the adolescent brain is different to that of the adult brain.

One sport in which concussion is frequently reported is that of rugby. Although many people play rugby, little research has been done to investigate the long-term outcomes of concussive injuries in an adolescent rugby-playing sample.

In order to investigate this you are invited to allow your child to take part in a research study at your son's school with the University of Cape Town. This form provides you with information about the study and seeks your permission for the collection, use and disclosure of your child's neuropsychological and behavioural performance data, as well as other information necessary for the study. The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will also describe this study to you and answer all of your questions. Your child's participation is entirely voluntary. Before you decide whether or not your child may take part, read the information below and ask questions about anything you do not understand. Whether you do or do not allow your child to participate in this study you will not be penalized or lose any benefits to which you would otherwise be entitled.

This study will be conducted in a manner that adheres to the ethical guidelines and principles of the International Declaration of Helsinki (Fortaleza, Brazil, 2013).

1. Title of Research Study

Investigating the neuropsychological effect and long term outcomes of concussions among high school rugby players.

2. Principal Investigator(s) and Telephone Number(s)

Dr. Leigh Schrieff-Elson (Supervisor)
2.10 Department of Psychology
University of Cape Town
Rondebosch
7701
Tel: 021 650 3708
Email: leigh.schrieff-elson@uct.ac.za / leigh.e.elson@gmail.com

Postgraduate student involved in the study and working alongside the principal investigator:
Nicholas Reid
Psychology Department
University of Cape Town
082 567 6636
Email: nicholas.reid@alumni.uct.ac.za

3. Source of Funding or Other Material Support

National Research Foundation

Medical Research Council

4. What is a concussion?

A concussion is a traumatic brain injury that results in the changing of brain functioning. A concussion is typically caused by a direct impact to the head, but it can also occur when a force is applied to the body that results in the rapid rotation of the head. The most common symptoms of a concussion include headaches, dizziness, memory deficits, and balance disturbances.

5. What is the purpose of this research study?

The purpose of this research study is to investigate whether or not, and how, instances of concussions contribute to brain functioning in adolescents, whose brains are still developing. More specifically the research intends to find out how these injuries may affect the way that an individual thinks, feels and behaves, and whether/how it impacts on the brain. Also, the purpose is to observe how individuals who sustain concussions compare to people who have had no such injuries.

6. Who is taking part in this study?

Because we would like to compare to individuals who sustain concussions to individuals who have had no such injuries, there will be two groups of participants in this study: a rugby group and a non-contact sports playing matched control group.

Rugby is a sport that involves a lot of impacts to the head, neck, and shoulder areas. These forces can at times lead to a concussion. The rugby group will be analyzed to see the effect of these concussions on tests of behavior and cognitive (thinking) functioning, as well as the structure of the brain (using a brain scan). The non-contact sports group (the control group) will be included so that we can compare the outcomes of the rugby group to matched individuals who are not exposed to rugby and the associated injuries. By matched participants we mean that participants in the control group who are similar to participants in the rugby group based on their age, sex, baseline test scores and sport involvement.

7. How many people are expected to participate in the research?

Your son will be one of 120 school-aged rugby and 120 school-aged non-contact sport players in this study. The maximum number of participants who will be screened at the baseline testing will be 120

for each group; but only 16 participants per group will be requested to complete the full study procedures.

8. What will be done if you allow your child to take part in this research study?

During this study, your son will be asked to complete a number of questionnaires and tests to obtain individual demographic information, personal characteristics, an estimate of his ability to think, as well as the different ways in which he acts and feels. Following the start of the season, should your son sustain a concussion, he will then be contacted for repeated testing in the 24-72 hours following the injury, where he will be asked to undergo a brain scan. Following the conclusion of the rugby season, your child may be contacted for repeated testing in September/October, 2018, where he may be asked to undergo another brain scan. These testing procedures will be conducted in a private room at the Cape Universities Body Imaging Centre (CUBIC), Groote Schuur Hospital. By signing the consent form, you are consenting to your child's participation in the possible follow-up assessments as well. Your child will also be asked to give their assent at the start of all testing sessions.

Tests and questionnaires that will be given to your son:

Demographic and medical history questionnaire – This questionnaire asks for information about your son's age, height, weight, language ability, learning difficulties (if any), any current or previous concussions, any previous or current psychiatric disorder, and what (if any) medication your son is currently taking.

Alcohol Use Disorders Identification Test – This questionnaire measures your son's current and/or lifetime alcohol use. The researchers do not suspect your son of consuming alcohol, however previous research has shown a strong relationship between concussions and substance use.

Barratt Impulsiveness Scale – This questionnaire looks at how impulsive your son's behavior is, and how this may relate to concussion.

Beck Depression Inventory – This questionnaire looks at symptoms of depression. Concussion has been shown to be associated with depressive symptoms, and this questionnaire will be used to assess for any such symptoms.

General Health Questionnaire – This questionnaire is used to look at the overall psychological health in an individual. It will be used with the other psychological questionnaires to understand your son's general health.

Profile of Mood States (short form) – The profile of mood states is a measure of overall mood. Mood is different to psychological health because it is more variable. This will also be used to compliment the other psychological questionnaires.

State-trait Anger Expression Inventory – This questionnaire looks at the amount of anger expressed by your son.

State-trait Anxiety Inventory – This questionnaire looks at the levels of anxiety your son has, and how it is expressed.

The IMPACT – The IMPACT is a computerized test used to measure concussion symptoms. It has two parts to it. The first part measures the concussion symptoms of your son, such as nausea, sleep and headaches. The second part measures your son's cognitive performance.

Pocket Concussion Recognition Tool (PCRT). The PCRT, is a side-line evaluation which can be administered by medical or non-medical professionals to detect a probable concussion. A conclusion of a probable concussion should be made if one or more symptoms is present in the following categories: visible cues of suspected concussion (loss of consciousness, balance problems, dazed gaze), symptoms of a concussion (headache, dizziness, confusion), and poor memory function.

Brain Scan – Brain scans are computerized images of the brain generated by placing the participant on a padded plastic bed that slides into the scanner. The scan is non-invasive (does not enter or penetrate the body) and painless. These images are used to examine the brain for any possible abnormalities that may be causing some discomfort. The standard brain imaging techniques do not reveal any obvious big negative changes in the structure of the brain associated with concussions. However, recent research indicates that there may be smaller changes following a concussion. The brain scans will be conducted in order to see if there are any small changes to your son's brain structure as a result of the concussion. Any small structural changes after concussion will be recorded, and reports will be forwarded on to the medical teams employed by you and/or your son's school. If any abnormalities are discovered, a pediatric neurosurgeon will review the scans and advise you and your family on the best course of action. It is important to note that as with the other assessment measures, the brain scan is part of the research assessment and not part of clinical management of the concussion injury.

9. What are the exclusion criteria for this study?

The exclusion criteria for the study include: (a) being of the female sex, (b) being older than 19 years or younger than 16 years at time of recruitment, (c) scoring 21 or more on the Beck Depression Inventory-Second Edition (BDI-II), (d) prior or current diagnosed psychiatric illnesses, learning disabilities, or neurological disease, (e) any history of or current drug and/or alcohol abuse, (f) participants who do not have a clear referral process to an adequately qualified clinician following a concussive episode, for a formal diagnosis of concussion. Should your son meets any of these criteria, he will not be contacted to partake in the second phase of the study.

Discharge points

We have also included what we refer to as 'discharge' or exit points in the study. In their Concussion Guidance document, World Rugby (2017) note the following about multiple concussions: "Players with a history of two or more concussions within the past year are at greater risk of further brain injury and slower recovery and should seek medical attention from practitioners experienced in concussion management before return to play". Given the potential risk of a participant sustaining multiple concussions and the possibility that they may be returning to play prematurely following a concussion, and in an effort to adhere to the World Rugby guidelines which are in the player's best interest (i.e., for their protection), we will include the following discharge points in the study:

1) If an individual has previously been concussed in the year leading up to the study and is concussed again during the course of the study, and those two concussion points fall within a one-year period, then they will need to be discharged from the study in accordance with the World Rugby guidelines, mentioned before.

2) If an individual is concussed twice within the course of the study, then they will be discharged from the study thereafter, again, in accordance with the World Rugby guidelines, mentioned before.

3) If standard return to play guidelines, as put forward by World Rugby (as outlined in the information sheets distributed on return-to-play guidelines) (Gomez and Hergenroeder 2012, Kutcher and Giza 2014) are not followed before a player returns to play following a concussion, then they will also be discharged from the study. We will ask your son's attending doctor, managing the concussion, to oversee a return-to-play protocol checklist used in this study.

Again, these discharge points are included as a measure of precaution, with participants' best interest in mind.

10. If you choose to participate in this study, how long will your child be expected to participate in the research?

Your son will be asked to be available for each of the scheduled testing sessions – each session will take approximately 2 hours. The study will run over the course of 6 months. There will be only one testing session around the start of the season if your son does not sustain a concussion. Should your son sustain a concussion during the course of the rugby season, he will be asked to participate in the post-concussion and end-of-season assessments and brain scans.

11. What are the possible discomforts and risks for your child?

There is minimal risk associated with this study. Your son may be required to return for a repeated assessment in September/October 2018 at CUBIC, should he sustain a concussion during the season. You will be contacted by the Principal Investigator if this is the case. The testing procedures take approximately 1½ - 2 hours per person. Due to it being a lengthy process, your son may feel fatigued or irritable during testing. However, he will be given breaks where necessary, as well as refreshments. The follow-up session is not as time consuming.

All return-to-school and play decisions will be made by the medical team employed by your son's school, and not the researchers. Your son's testing results will be made available to the medical team, as well as comparisons between his baseline scores and his injury scores. Findings from the study are not primarily intended to determine whether your son returns to play or not - that is the goal of the clinical assessors. Clinical assessors might however use the data we collect to inform return-to-play decisions.

Some participants in the research study may feel anxious or claustrophobic with regards to the brain scan. To counter this, an assistant will explain the scanning procedure to your son. The research assistant will also allow your son to have a "mock scan" where he will experience what it is like to have a scan, before undergoing the actual scan. The scan will not hurt your son and it will not be dangerous in any way. Your son will however need to take the following precautions.

During the MRI neuroimaging assessment, certain metal objects, such as watches, credit cards, hairpins, and writing pens, may be damaged by the MRI scanner or pulled away from the body by the magnet. For these reasons, your son will be asked to remove these objects before entering the scanner. When the scanner takes the images, the bed may vibrate, and your son will hear loud banging noises. He will be given earplugs or earphones to protect his ears. Also, some people feel nervous in a small-enclosed space such as that of the scanner. Your son will be able to see out of the scanner at all times, and the radiographer will not start the procedure until he is comfortable. Your son will be able to stop the procedure at any time by squeezing a ball and he can talk to the radiographers using an intercom that is built into the scanner. There are no known harmful long-term effects of the scanner used in this study. Scans will take no longer than 1 hour.

In the process of testing and scanning, researchers may come across incidental findings. Incidental findings are discoveries that are made that do not relate to the research study, and may be potentially harmful. For example, these may relate to findings on brain scan, where, in the process of investigating the outcomes of concussion, researchers may come across other findings on the scan that may be of concern. (Below we include referral information in the event of such incidental findings).

If you wish to discuss the information above or any discomforts your son may experience, you may ask questions now or call the Principal Investigators listed on this form an any point in the study.

Because this study involves on-going brain scans and cognitive testing related to concussion, this may give you the incorrect impression or misconception that we are providing care for, or clinical management of, your son's concussion injury. It is important to note that this is however not the case as this is a research study and it is therefore not providing any clinical care or management of the concussion injury. We are not replacing any existing medical/care structures that the schools and/or you may have in place, but rather working in conjunction with them. All decisions on whether to return to school and play will be made by the medical structures already employed by the schools and/or you. Your son's test and brain scan results will be made available to the medical professionals employed by the you and/or your son's school should it be required, as well as comparisons between their baseline scores and their scores from any testing after a concussion. Before we collect any data, we will hold an information session with parents and participants to talk about this potential misconception.

It is important to note that if your child does suffer a concussion injury, findings from tests conducted as part of this research study might impact on your child's ability to continue playing rugby or other contact sports in the future. The implications of the test findings for thinking and behaviour and brain scan findings should be discussed with health professionals as part of the referral process (described below).

12. Referrals

Given that return-to-play decisions are the domain of the clinical assessors, we, as researchers, cannot and should not make any such decisions on the basis of our data. However, clinical assessors might however use the data we collect to inform return-to-play decisions. However, given that we are administering tests of thinking and behavior, post-concussion tests, and brain scans as part of the study, there may be outcomes following those tests, for which further follow-up by health professionals may be advisable. We will not impose these referrals but we provide the necessary information for parents as these follow-up consultations in the best interests of the child. We outline these referrals below.

Referrals related to baseline testing and exclusion criteria

We noted under point 8 above that there are certain exclusion criteria for this study and we outlined those points there. Two of these exclusion criteria related to participants' scores on a test of depression symptoms and a test related to alcohol usage. If participants score within certain

ranges on these tests, they will be referred to a Sports Psychologist at the Sports Science Institute of South Africa. In the event that your son scores 21 or more on the Beck Depression Inventory and/or reports any history of, or current drug and/or alcohol abuse, as reported on the AUDIT (see exclusion criteria), he will be referred to Clinton Gahwiler (see details below) by the Principal Investigator.

Psychological management:

Clinton Gahwiler (BA hons MA)

Sport Psychologist at Sport Science Institute of South Africa

Tel: 021 659 5655

Fax: 086 624 7988

Email: sportpsych@xsinet.co.za

Website: www.performingmind.co.za

Referrals related to concussion diagnoses and post-concussion testing

It is important to note that a suspected concussion requires a clinical assessment by a doctor skilled in the management of concussion. We include the details of doctors below, who specialize in concussion diagnoses and management, should your son or the school not currently have such a management system in place.

As noted, we will share your son's performances on the behavior and cognitive tests administered, and on the brain scan, with the health professional managing your son's concussion. That health professional will decide whether your son may need further medical management, either by the school's medical team or another medical team, should the school not have one.

Please note that the costs of referrals for further management will be for the personal account of parents/legal guardians and the participants.

In the event that your son's school does not have a medical team in place to assist in your son's care, please see the details below, which can be passed on to the health professional attending to your son.

Concussion management:

Sports Medicine department at the Sports Science Institute of South Africa

Tel: 021 659 5644

Email: info@cape-sportsmed.com

Neurosurgery Clinic (with Prof Anthony Figaji)

Red Cross War Memorial Children's Hospital

021 658 5434

Referrals related to incidental findings on MRI scans

Incidental findings are discoveries that are made that do not relate to the research study, and may be potentially harmful. A radiologist on the CUBIC staff and linked to this study, is going to review all the participants' brain scans for such incidental findings. In an unfortunate case of an incidental finding your son will be referred for further evaluation to Professor Anthony Figaji. Professor Figaji is a pediatric neurosurgeon, and he will undertake to consult, examine and counsel you and your son where necessary, as well as determine any further course of management that may be needed.

13. What if something goes wrong?

This research study is covered by an insurance policy taken out by the University of Cape Town if your son suffers a bodily injury because you are taking part in the study. The insurer will pay for all reasonable medical costs required to treat your son's bodily injury, according to the SA Good Clinical Practice Guidelines 2006, which are based on the Association of the British Pharmaceutical Industry Guidelines. The insurer will pay without your son having to prove that the research was responsible for your bodily injury. You may ask the study doctor for a copy of these guidelines.

The insurer will *not* pay for harm if, during the study, your son:

- Uses medicines or other substances that are not allowed
- Does not follow the study doctor's instructions
- Does not tell the study doctor that he had a bad side effect from the study medicine
- Does not take reasonable care of himself and his study medicine

If your son is harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs. However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court. It is important to follow the study doctor's instructions and to report straightaway if your son has a side effect from the study medicine.

14. What are the possible benefits of this study to your child, and others?

After the completion of each testing session, participants will be given a restaurant voucher as compensation for their time. In the event that your son sustains a concussion, the individual brain scans and test results will be sent to the medical team at your son's school following testing and imaging.

Overall, this research aims to contribute to practical information regarding return-to-play decisions, thresholds of concussion injuries, and diagnostic guides of concussion that are important for player safety. It will provide those involved with contact sport, including medical teams, information regarding the cognitive, behavioural and brain scan findings associated with concussion.

15. If you choose to let your child participate in this research study, will it cost you anything?

Participating in this research study will not cost you anything. However, the cost of any care arising from a concussion injury (over and above what is done in the study), i.e., the clinical management of a concussion, or the costs of referrals for further management, will be for the personal account of parents/legal guardians and the participants.

16. Can your child withdraw from this research study?

You and your child may withdraw your consent and assent and stop participating in this research study at any time, without any penalty to you or your child. At the beginning of each testing session your son will be asked if he wants to continue with the study. Should he say no, there will be no punishment or penalty placed on your son.

If you have a complaint or complaints about your son's rights and wellbeing as a research participant, please contact the Human Research Ethics Committee.

Tel: 021 406 6492

E-mail: sumaya.ariefdien@uct.ac.za

17. If your child withdraws, can information about you and your child still be used and/or collected?

Information that has already been collected will be removed from the data set. Should your son withdraw from the study, his data will be removed from the data set.

18. Once personal and performance information is collected, how will it be kept secret (confidential) in order to protect your privacy?

If you agree for your child to participate in this research study, it is possible that some of the information collected might be copied into a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify your son – his identity will remain confidential. Data will be labeled using participant numbers rather than names, so that they cannot be used to directly identify any particular individual. A separate and private log will be used simply to relate participant names to numbers in the event that a participant

needs to be contacted or contacts the Principal Investigator. This log will only be accessible to the Principle Investigator or Nicholas Reid.

All hard copy data collected will be stored in a locked filing cabinet in the access-controlled ACSENT Laboratory located in the Department of Psychology UCT. All electronic data will be stored on a password protected hard drive. Only the primary researcher and select individuals involved in the collection and analysis of the data will have access to these files. Your son's research records will not be released without your permission unless required by law or a court order. These measures do not however guarantee complete privacy, given the small cohort of rugby-playing participants, that players may be inherently identifiable. It may therefore not be possible to guarantee individual privacy. However, published data will not contain any identifiable information other than participant numbers.

19. How will the researcher benefit from your child participating in this study?

This study will be conducted as a part of a PhD degree at UCT. In addition, the researcher may choose to present this research at a conference or in a scientific journal.

20. Dissemination of research findings

You and your son's school will be provided with a report on the analysis of the data collected in this study. It is the aim that this report be published in an academic journal in order to widen the knowledge base of concussion in rugby. The report is based on the overall statistical findings, and will not reveal any personal details specific to your son.

21. Signatures

You have been informed about this study's purpose, procedures, possible benefits, and risks; and how your son's responses and performance and other data will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree for your child to participate in this study. You hereby authorize the collection, use and sharing of your son's performance and other data. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing Date

_____ _____

Relationship to child participating in the study: parent / legal guardian

_____

Name of Participant ("Study Participant" – the child)

_____

Authorization for _____ to participate in the study.

Parent / legal guardian cellphone number: _____

Parent / legal guardian email address: _____