Informed Consent Document for Non-rugby (Control) Participants

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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 authorisation 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 17 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)**

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   Rondebosch
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   Postgraduate student involved in the study and working alongside the principal investigator:
   Nicholas Reid
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   Psychology Department
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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 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. In this study, the matched control group includes non-rugby sports players who are similar (matched) in terms of age, sex, baseline test scores and sport involvement to the players in the rugby group so that we can compare rugby players in our study to similar aged non-rugby players.

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.

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. Your son may be one of 16 control participants invited to take part in the testing and brain scan component of the study at the end of the season (explained below).

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

The reason that we are including non-rugby playing participants is so that we can compare the performances of high school learners who play rugby (and who may or may not have sustained a concussion) to the performances of those who do not play rugby and have not sustained concussions.

At the start of 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.

At the end of the rugby season, we are going to do a similar set of tests to the baseline tests with rugby players that were concussed during the rugby season. Those players will also undergo a brain scan. At that point, we will also select and invite players from the matched control group who match the rugby players that were concussed during the season, on age, baseline testing, and sport involvement, to undergo the same tests and a brain scan so that we can have comparative data.

Therefore, following initial testing, the results of the baseline testing will be evaluated. Your son may be contacted to participate in another session of the same tests in September/October, 2017, where he may also be asked to undergo a brain scan, if he happens to match (in terms of age, baseline testing and activity levels) a rugby-playing participant at that time.

These testing procedures will be conducted in a private room at the Cape Universities Body Imaging Centre (CUBIC), Groote Schuur Hospital. We will ask for your son's assent again if he is asked to participate in the second set of assessments.

Tests and questionnaires that will be given to your son at the initial testing session and if your son if invited to participate in further testing at the end of the season:

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 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 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 in the brain that may be causing some discomfort. The standard brain imaging techniques do not reveal any gross structural abnormalities associated with concussions. However, recent research indicates that there may be small changes following a concussion. If your son is in the control group, the scan will be done in order to compare your son's brain structure to the rugby group participants'. If any abnormalities are discovered, a pediatric neurosurgeon will review the scans and advise you and your family on the best course of action.

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 17 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) control participants with a history of a previous concussion.

Should your son meet any of these criteria, he will not be contacted to partake in the second phase of the study.

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 the initial scheduled testing session – this session will take approximately 2 hours. The study will run over the course of 6 months. Your son will however only participate in the baseline testing session unless he is selected as a matched control to participate in the end of season assessment and brain scan.

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

There is minimal risk associated with this study. You***r*** child may be required to return for a repeated assessment in September/October at CUBIC. 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 child may feel fatigued or irritable during testing. However, your child will be given breaks where necessary, as well as refreshments. The follow-up session is not as time consuming.

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 child. The research assistant will also allow your child to have a "mock scan" where they 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 your son is comfortable. Your son will be able to stop the procedure at any time by squeezing a ball and 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 completing the scan at the end of the season for this research study (if you son is selected to participate in that component), 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 you may experience, you may ask questions now or call the Principal Investigators listed on this form.

12. Referrals

Given that we are administering tests of thinking and behavior 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 the 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 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 he is 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 Clinic§al Practice Guidelines 2006, which are based on the Association of the British Pharmaceutical Industry Guidelines. The insurer will pay without you having to prove that the research was responsible for your son's 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 has 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?

There is no potential for direct individual benefit by your son taking part in this study.

After the completion of each testing session, participants will be given a restaurant voucher as compensation for their time.

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 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. 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 Masters 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.

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.