BC Children's Hospital Research Institute | The University of British Columbia
F508 4480 Oak Street |Vancouver BC | V6H 3V4 Canada
Phone +1 (604) 875-3776 | Fax +1 (604) 875-3569
bcinjury1@cw.bc.ca | www.injuryresearch.bc.ca

Adolescent Information and Assent Form

Title: **Surveillance in High Schools to Reduce Concussions and Consequences of Concussions in Canadian Youth – SHRed Concussions**

Short Title: **SHRed Concussions**

Who is in charge of this study?

The investigator in charge of this study is Dr. Carolyn Emery, at the University of Calgary, where all information from the study will be electronically stored on a secure server. In BC, the investigators in charge of the study are Dr. Ian Pike and Dr. Shelina Babul. They are being helped by Dr. Cheryl Wellington, Dr. Paul van Donkelaar, Dr. Jackie Whittaker, and Dr. Bruce Bjornson. Information that identifies me will be stored in a locked cabinet, in a locked office, at BC Children's Hospital. I can learn more about how my information will be collected and stored in the 'confidentiality' section of this form. The researchers will answer any questions I have about the study. I can call the Study Coordinator by phone (604-875-2000 extension 5478) or email (shred@bcchr.ca) if I have questions or need help.

Invitation

I am being invited to participate in this study because I am a high school student who plays at least one sport that carries a higher risk of concussion injury. The following pages explain the study so that I can decide if I want to take part or not. It is up to me if I want to be in this study. No one will make me be part of the study and no one will get mad at me if I don't want to be part of this study.

Do I have to be in this study?

I do not have to participate in this study if I don't want to. If I choose to participate, I can stop being in the study at any time. My doctors will take care of me as they have in the past, regardless of whether I am in the study or not.

If I want to be in the study, I will be asked to sign this form. My parent/guardian will need to sign a consent form before I join the study, but I do not have to participate even if they sign the consent form. The researchers will not enroll me into the study unless I agree.

I should take time to read the following information carefully and to talk it over with my family, and if I wish, with my doctor, before I decide. I understand that I should feel free to talk to the study doctors if anything is not clear. I can choose to be in the study, not be in the study, or take more time to decide. Even if I agree now to be part of the study, I can change my mind later. I can ask the study doctor or study coordinator any questions I may have at any time during my study participation.

Why are we doing this study?

Concussion is a form of mild traumatic brain injury (TBI). Among youth, concussions often happen during sport participation. Past studies of concussion among youth athletes are limited and therefore it is still not well understood why some youth recover quickly and others continue to have symptoms for a long time. Symptoms may include headaches, dizziness, foggy thinking, sleep problems, and emotional distress. These symptoms can make it difficult for youth to return to school and sports. We need better information about sport-related concussion in youth to improve the ways we recognize, manage and prevent concussions.

Why are you inviting me to be in this study?

I am being invited to be in the study because I am between the ages of 13 and 17, I attend a public or Catholic or private high school in British Columbia, and play at least one of the following sports: basketball, football, ice hockey, ringette, lacrosse, rugby, soccer, volleyball, cheerleading, alpine skiing, sledge hockey, or wrestling.

The purpose of this study is to establish a national picture of the burden of sport-related concussion among youth in Canada, and to improve the ways in which concussions are prevented, recognized, managed and treated. This study will involve 6,000 high school athletes from across Canada (1,200 from BC) who will be in the study for 3 years.

What will happen to me in this study?

If I decide to be in the study, the activities that I will be asked to do depend on whether or not I get a concussion during the school year.

Once I am in the study, I will be given a website link to an online site called REDCap. This site (also called a 'portal') will let my parent make an account, and invite me to make one, so I can fill out information about myself, my injury/medical history, and my sport participation. Moving forward, this portal will be where I report injuries to the SHRed concussion team.

I will be asked to complete a single 2-hour baseline testing session at the start of each school year for 3 years. This baseline testing session will take place at UBC Vancouver, BC Children's Hospital, or at participating school/club facilities. The researchers will test my fitness, balance, coordination, reaction times and ask me questions about how I feel about school, what sports I play and if I've had any sport-related injuries in the past. I will also be asked if I want to do an optional blood test at the baseline testing session. If I choose to do the blood test, a nurse will use a needle to take blood (about 2 teaspoons) from my arm for some tests to measure the level of certain proteins in my blood.

After the baseline has been done, I will log into an online portal once each week to report how much time I spent playing sports that week and if I got injured at all. This will take about 5 minutes of my time and I can do this at home. If I forget to log in and fill out the form, I will get a call, text or email from the study coordinator to remind me to fill it out. My parent/guardian will also fill out two short questionnaires about me.

As a study participant, I will also be able to see an athletic therapist or physiotherapist at my school if I get any injuries during the school year. They will help me with my injuries. If I get an injury that is not a concussion while I am in the study, I should see my family doctor for help.

Optional blood draws: Blood collection is an optional portion of this study meaning I do not have to participate if I do not want to. Blood samples will be drawn by a trained phlebotomist or nurse, who can help answer any questions, concerns or anxiety I may have about the blood test. If I am uncomfortable or anxious about the blood test, or if I want to stop for any reason, I can ask the phlebotomist/nurse to stop. A maximum of two attempts to draw blood will be made at each session. Blood draws that are conducted off-site (for example, at schools or club facilities or community fields) will be done so in areas that have been sterilized, and all safety measures will be followed.

Blood will be processed within 4 hours of collection into serum and plasma. DNA and genetic material will be removed from the sample, meaning only the serum and plasma will be used for analysis. The serum/plasm samples will be stored in a biobank (a lab space for storage of blood and/or it's components) for analysis. If I consent to blood draw, my samples will be stored for up to 7 years following the study.

Because research on concussions and information from blood is developing, and new types of blood tests will be available later, SHRed researchers will be asking my permission to store serum/plasma specimens in a biobank for as long as they can be used for research. If I am interested in allowing my samples to be stored in the biobank, I will sign a separate form.

<u>If I get a concussion while I'm in the study</u>

If I experience any of the following red flag symptoms I should call 911 immediately:

- neck pain or tenderness
- double vision
- weakness or tingling/burning in your arms or legs
- severe or increasing headache
- seizure or convulsion
- loss of consciousness
- deteriorating conscious state
- vomiting
- increasingly restless, agitated or combative

These are signs that I need **immediate** medical attention at the nearest Emergency Department. After I get out of the hospital, I can report my concussion and book my first study visit by calling the Study Coordinator.

If I get a concussion, I will come to BC Children's Hospital to see the study doctor – who is a sports concussion specialist— or go to their office, at the earliest possible time after my injury. If my parent and I would like to see my family doctor for concussion care, I can come to see the study doctor for research appointments only. The study doctors will be giving me medical treatment for my concussion and helping collect research data. My medical care will **always** be their first priority. The study doctor will inform me about which assessments are being conducted as part of usual clinical concussion care, and which are being done for research purposes.

I will see the study doctor 3 times following my injury: (1) within approximately 72 hours of getting a concussion; (b) 1-2 weeks after getting a concussion; and (3) and 30 days after getting a concussion. The first and third visit will each take 3 hours and the second visit will take one hour. If my recovery takes longer than 30 days, I will come back to see the doctor every 2 weeks until they think I can return to my activities.

If my parent and I choose, the study doctor will take care of all of my medical care for my concussion. I will go to my family doctor for anything else that is not related to my concussion.

Some of the tests I did at the baseline testing session will be repeated, and I will be asked if I want to do a scan of my brain. My parent/guardian will be asked to fill out the same questionnaires that they did at the baseline session at each of the three follow up visits. I will continue to report my sport participation and any new sport-related injuries online every week. If at any time during the testing I feel unwell, or my symptoms increase, the tests will be immediately stopped. I can refuse to do any tests I don't want to do and still be part of the study.

This table shows the tests I will be asked to do if I decide to be part of the study:	**All participants**		**Concussion follow-up ONLY at BCCH**				
	Every Year	Every Week	Within 72 hrs	Around 7 days	Around 30 days	Every 2 weeks*	Around 90 days
Questionnaires (may include): Questions about demographics, injury history, activity history, concussion knowledge & beliefs, sleep, quality of life, coping and strengths, experiences & feelings post-injury	✓		✓	✓	✓	✓	
Concussion symptoms: Sport Concussion Assessment tool 5 (SCAT5) virtual or in person	✓		✓	✓		✓	
Clinical tests: Head, neck, vision, balance, and attention	✓		✓			✓	
Fitness testing: Grip strength, vertical jump height, and 20-m shuttle run,	✓		✓			✓	
Blood test: Blood sample of 2 teaspoons	✓		✓	✓		✓	
Equipment check: Mouthguard use, helmet fit	✓		✓				
Weekly exposure forms: Self-report of sport participation and injury*** (all complaints, including suspected concussion)		✓					
Imaging: 1-hour MRI scan at BC Children's Hospital			✓		✓		✓

**I will only be seen every two weeks if I am still not feeling well 30 days after my concussion*
***A certified athletic therapist or physiotherapist will come to the school once a week to assess any reported injuries in person*

There is a possibility that MRI may show an unexpected abnormality, also called an "incidental finding." The radiologist will review every scan. This means that a medical record will be created for me, but my participant ID will not be on any scans. Only the research team will know which participant ID is mine. If the radiologist thinks there is an abnormality in my scan, they will contact the study doctor, who will then contact me and my parent(s), and with our permission, my family doctor and help him or her arrange the right follow-up for me.

Sub-Studies

There are additional sub-studies I can participate in if I want to. For each optional study, I will be provided with an assent form that describes the details. I will be asked to sign those forms if I want to participate. I can take part in the main study and not take part in these optional studies.

If I decide not to take part in any or all of the optional studies, my participation in this study and my medical care will not be affected.

Can anything bad happen?

As with any physical activity, there is the possibility of a muscle strain for tests, such as running. Some testing may result in dizziness or muscle fatigue for a short time following the tests. If I feel unwell, or if I wish to stop the testing for any reason, I should let the study staff know right away and the tests will be stopped.

Although very rare, there is a possibility of local infection within days of having blood taken. There is a possibility of a slight bruise at the needle site. There is also a remote possibility of fainting. If you dizzy or faint, tell the nurse or phlebotomist right away.

Magnetic resonance imaging (MRI) is a technique that uses magnets and radio waves, not radiation, to take pictures of the body. MRI has no known harmful effects as long as I have none of the risk factors that will be screened for by the MRI technologist. Specifically, I should not have an MRI if I have any metal inside my body, and I will also need to remove all metal from my clothing and pockets. No metal can be brought into the magnet room at any time, since the magnet is always "on". During the MRI session, I will lie on a padded table and be asked to hold as still as possible while pictures are being taken. I will hear a loud knocking noise (like a drum beat) that can change at times during the scan. If I cannot lie still, if I am uncomfortable or anxious, or want to stop for any reason, I will be removed from the scanner immediately. I should tell the MRI technologist if I am feeling too anxious to enter the scanner.

What are the potential benefits of participating?

No one knows whether or not I will benefit from this study. The study doctors hope that the information learned from this study can be used in the future to benefit other people who have concussions.

Who will know I am in the study?

The study team will not release any information to anybody else that could be used to identify me, unless they are required to do so by law. For example, researchers are required to report if a participant is believed to be at risk for harming him/herself or others. As part of the study I will fill out some questionnaires that will ask me about how I am feeling. If the study doctors are worried about me they will contact my family doctor if I have given them permission to do so and they will contact my parents to make sure that I get any additional care that is needed.

I will be identified by specific study codes that apply only to me. Any paper forms that are part of the study will use this code rather than my name. Dr. Shelina Babul and Dr. Ian Pike will keep the file linking your identifying information to this code at the local study site (BC Children's Hospital, BC Injury Research and Prevention Unit), in a locked file cabinet. Computer files are password protected and stored in a secure server at BC Children's Hospital, BC Injury Research and Prevention Unit, and will only be accessed by the research team at this location.

For this study, the researchers will be collecting my full name, age, month and year of birth, phone number, email, city, school, and relevant sports organizations I play for, for the research described in this form. Although steps have been taken to protect my identity, this could increase the risk of other researchers finding out I am. My information will only be available to SHRed researchers at BC Children's Hospital and the University of Calgary. Researchers outside of the local site would not normally have access to my personal information; this is unique to this study. The team at University of Calgary has signed a confidentiality form, and researchers at BC Children's Hospital have done privacy training. My personal information will not be used to contact me about joining future research studies without your consent, and all future contact will be made directly by the BC research team. All of my identifying information will be deleted from the Calgary-based REDCap portal by the earliest possible date, which is August 31, 2024. The researchers at BC Children's Hospital will keep the file linking my ID to my identifying information in a locked cabinet, in a locked office, for 5 years after the study is completed.

What will the study cost me?

There will be no financial costs to me as a participant in this study. I will be reimbursed for parking or transit when I attend study visits. Juice and snacks will be offered to me at the time of each blood test. I will not be paid for participating.

Who do I contact if I have questions about the study during my participation or to report an injury?

UBC Co-Investigators: Dr. Ian Pike (604) 875-3425 Dr. Shelina Babul (604) 875-3682
Study Coordinator: (604) 875-2000 ext. 5478

Who do I contact if I have questions or concerns about my rights as a research participant?

If I have any concerns or complaints about my rights as a research participant and/or my experiences while participating in this study, I should contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). I should reference the study number (H19-00037) when contacting the Complaint Line so the staff can better assist me.

Surveillance in High Schools to Reduce Concussions and Consequences of Concussions in Canadian Youth – SHRed Concussions

My signature on this assent form means:

- I have read and understood this adolescent information and assent form.
- I have had enough time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had acceptable answers to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing the quality of care that I receive.
- I understand that I can continue to ask questions, at any time, regarding my participation in the study.
- I understand that if I put my name at the end of this form, it means that I agree to be in this study.

Are you willing to be contacted by the BC Children's Hospital researchers for future studies?

YES ☐

NO ☐

I will receive a signed copy of this assent form for my own records.

I agree to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date