



**BC INJURY** research and prevention unit



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## Parent Information and Consent Form

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

**Short Title:** **SHRed Concussions**

**Sponsor:** **National Football League's Scientific Advisory Board**

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## **Invitation**

Sport is good for youth, but there is always a chance of getting injured. One of the injuries that can happen is a concussion, which is a type of injury to the brain. Past research has looked at why some youth may be more likely to get a concussion, what affects the amount of time it takes to recover from concussion, and ways to prevent concussions in sports. This helps researchers and health professionals develop strategies that can be used to educate teachers, coaches, parents, and students in schools about concussions.

Your child is being invited to participate in this study because they are a high school student who plays at least one sport that carries a higher risk of concussion injury.

## **Your participation is voluntary**

You have the right to refuse to have your child participate in this study. If you decide to participate, you may still choose to withdraw your child from the study at any time by contacting the Study Coordinator. If you decide to withdraw your child from the study, you can also request to withdraw your child's data from the study as well. Your child's involvement in their school and their team(s) will not be affected if you or your child decide not to take part in this study.

You should be aware that there is a difference between being a patient and being a research participant. As a patient all medical procedures and treatments are carried out for your child's benefit only according to standard accepted practice. As a research participant you and your doctor must also take into account the requirements for the research study. These may include tests that are not part of standard practice. This consent form describes the extra tests that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish for your child to be part of the research and sign this consent only if you accept your child being a research participant.

If your child wishes to participate in this study, you will be asked to sign this form. Please take time to read the following information carefully and to discuss it with your child before you decide.

## **Who is conducting the study?**

SHRed Concussions is a national study being led by Dr. Carolyn Emery at the University of Calgary, where all identifying information and study data will be electronically stored on a secure server. In BC, this study is being conducted by Co-Principal Investigators Dr. Ian Pike and Dr. Shelina Babul who are being supported by Co-Investigators located at the University of British Columbia in Vancouver and UBC Okanagan. Local participants' identifying information will also be stored in a locked cabinet, in a locked office, at BC Children's Hospital (BCCH). Collection and storage of identifying information is explained in detail in the 'confidentiality' section of this consent form. This study is funded by the National Football League's Scientific Advisory Board.

## **Background**

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.

### **What is the purpose of the study?**

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.

### **Who can participate in this study?**

Students are eligible if they are between the ages of 13 and 17, presently enrolled in a public, Catholic or private high school in British Columbia, and participate in at least one of the following sports: basketball, football, ice hockey, ringette, lacrosse, rugby, soccer, volleyball, cheerleading, alpine skiing, sledge hockey, or wrestling.

### **Who should not participate in this study?**

Students who have a health condition (disease, recent surgery or injury) that prevents them from participating in one of the above sports, or students whose parents do not agree for them to be in the study.

### **What does the study involve?**

This study will involve 6,000 high school athletes from across Canada (1,200 from BC – 1000 from Vancouver and 200 from Kelowna) who will be in the study for 2-3 years. If your child decides to join the study, the activities that they will be asked to do depend on whether or not they get a concussion during the school year.

### **Activities for all participants**

If your child is eligible for the study, you will be asked to provide us with contact information that includes your first name, your preferred phone number, and your child's full name. We will use this information to contact you and explain the details of the study as well as allow you time to ask any questions you may have. Once you have agreed to participate in this study, you and your child will be enrolled.

Once enrolled, you will be given a website link to an online data portal called REDCap. This portal/website allows you to create an account for you and your child where you will fill out information regarding your demographics, your child's injury/medical history and your child's sport participation. Moving forward, this portal will be where you or your child will report injuries to the SHRed concussion team.

Your child 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 baseline tests are described in the table below.

After the baseline has been done, all participants will be asked to report how much time they spent in practices and games during the week, as well as any sport-related injuries they might have had that week, every week for 3 years. This part is completed online on a secure portal and will take about 5 minutes per week to do. If your child forgets to fill out their form, you or your child may get a phone call, text or email from a study staff member to remind them to fill it out. A team designate will also be present at games/practices to record SHRed participants' attendance and any sustained injuries. The maximum time to participate in the baseline and weekly online reporting will be 7 hours per year, for a total of 21 hours over the entire study period. As a study participant, your child will also have access to a physiotherapist or athletic therapist (or individual with similar experience) who will come to their school/club once a week to assess any injuries that they may have sustained while playing sports during the school year. SHRed study doctors will not be conducting medical assessments with participants who do not get a concussion during the study (i.e., care for any other injuries/conditions should be sought from your general practitioner).

You will be asked to complete two short questionnaires about your child that will take approximately 5 minutes each, at the time of baseline. You can do them online at home, if you prefer.

Optional blood draws: Blood collection is an optional portion of this study meaning your child is not required to participate if you/your child do not want to. Blood samples will be drawn by a trained phlebotomist or nurse, who can help answer any questions, concerns or anxiety you or your child may have about the blood test. If you/ your child are uncomfortable or anxious about the blood test, or if they want to stop for any reason, they may do so. A maximum of two attempts will be made at each session. Blood draws that are conducted off-site (e.g., 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 for analysis. If you and your child consent to blood draw, your child's deidentified samples will be stored for up to 7 years following the study.

As concussion research surrounding fluid biomarkers from blood is still evolving and new types of blood tests will be available later, SHRed researchers will be asking your permission to store deidentified serum/plasma specimens in a biobank for as long as they can be used for research. A separate consent form will be provided to you for this biobank if you are interested in this component of the study.

### **What are my responsibilities?**

It is very important that we are notified as soon as possible in the event that your child sustains a sport-related concussion during the study period, so that we can arrange their first follow up visit within 72 hours.

To report a concussion and book your first study visit, call the Study Coordinator at: (604) 875-2000 ext. 5478.

### **If your child experiences any of the following red flag symptoms, 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 your child needs **immediate** medical attention at the nearest Emergency Department. After they get out of the hospital you can report your child's concussion and book their first study visit by calling the Study Coordinator.

### **Activities that apply only to those who sustain a sport-related concussion:**

If your child gets a sports-related concussion, contact the study coordinator at the earliest possible time after a concussion has occurred, to schedule your child's appointment with the study doctor – who is a sports concussion specialist – within 72 hours of their injury.

If you choose, you may take your child to their family doctor following their concussion (prior to seeing our study doctor). The SHRed study doctor is experienced in concussion management and will take over clinical care, related to their concussion, if you and your child agree. If you would like clinical care related to the concussion to continue with your family doctor, you may meet with the study doctor solely for research purposes. In cases where the study doctor will be assuming clinical care for your child's concussion, we would like to emphasize that the study doctors have two roles: 1) clinical care and 2) gathering research information. Clinical care of your child will **always** be first priority. The study doctor will inform you and your child which assessments are being conducted as part of standard clinical concussion care, and which are being done for research purposes.

Your child will see the study doctor (at BC Children's Hospital or their offices) 3 times following their injury: (1) within approximately 72 hours post injury; (2) 1-2 weeks post injury; and (3) 30 days post- concussion. If your child's recovery takes longer than 30 days, they will be asked to come to the clinic every 2 weeks until their doctor clears them to return to playing sports. During

these visits, your child will be assessed by the study doctor, and some of the baseline tests will be repeated. Visits 1 & 3 will last approximately 2.5-3 hours each. Visit 2 and the bi-weekly visits will take approximately 1 hour each. You will be asked to repeat the same two questionnaires about your child at Visit 1 and Visit 3. You can choose to do these in-person at the clinic, or you can do them online at home if you prefer.

If you and your child choose, the study doctors will assume full responsibility of coordinating all of the appropriate follow-up and medical management of the concussion injury. All other unrelated (to the concussion) medical care should be sought by your family physician.

This study does not involve any new treatments. The study doctor will provide your child with the same medical care that your child would receive if they saw a concussion specialist outside of the study. If at any time during the testing your child feels unwell, or their symptoms increase, the tests will be stopped immediately. They can refuse any tests they do not want to do and still continue to be part of the study.

This table shows the tests your child will be asked to do if they decide to participate in 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 until cleared*	Around 90 days
<b>Questionnaires (may include):</b> Questions about demographics, injury history, activity history, concussion knowledge & beliefs, sleep, quality of life, coping and strengths, experiences & feelings post-injury	✓		✓	✓	✓	✓	
<b>Concussion symptoms:</b> Sport Concussion Assessment Tool 5 (SCAT5) virtual or in person	✓		✓	✓		✓	
<b>Clinical tests:</b> Head, neck, vision, balance, and attention	✓		✓			✓	
<b>Fitness testing:</b> Grip strength, vertical jump height, and (at baseline only) 20-m shuttle run	✓		✓			✓	
<b>Blood test:</b> Blood sample of 2 teaspoons	✓		✓	✓		✓	
<b>Equipment check:</b> Mouthguard use, helmet fit	✓		✓				
<b>Weekly exposure forms:</b>		✓					

Self-report and monitoring of sport participation and injury** (all complaints, including suspected concussion)						
<b>Imaging:</b> 1-hour MRI scan at BC Children’s Hospital			✓		✓	✓

*\*If your child is experiencing symptoms beyond 30 days, we will ask them to come in for assessments every 2 weeks until they are cleared to return to their activities.*

*\*\*A certified Athletic Therapist or Physiotherapist or individual with similar experience will come to your child’s school/club once a week to assess any reported injuries in person*

### Optional studies

The following studies are optional. For each optional study, you will be provided with a separate consent that describes the details, and which you will be required to sign if your child wishes to participate. Your child can take part in the main study and not take part in these optional studies. If you decide not to take part in any or all of the optional studies, your child’s care will not be affected.

- A. SHRed imaging sub-study:** A very small number of non-concussed participants may be invited to do a 1-hour MRI scan at BC Children’s Hospital once during the study. Your child might be invited if they “match” (by age, sex, and primary sport) another participant who sustained a concussion.
- B. Fluid bio-markers sub-study:** Your child might be invited to partake in an optional blood draw if they “match” (by age, sex, and primary sport) another participant who sustained a concussion.
- C. Biobank:** All participants in SHRed will be asked if they would like to make their blood samples available to a biobank at UBC for future concussion studies. This sub-study uses leftover blood samples from the main study and does NOT require additional blood draws.
- D. Long-term use of data for future studies:** With your permission, de-identified data from this study may be used to answer sports-related concussion research questions in future studies. No medical data outside of study data collected in this study will be accessed by the research team. You can withdraw your consent for future use of data at any time by contacting the Study Coordinator without affecting your child’s participation in SHRed.

### What are the possible harms and discomforts?

#### *Physical Assessments*

All physical assessments will be done under close supervision and every effort will be made to ensure your child’s safety. 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. The neck, balance, vestibular, eye movement and other clinical tests are ones that are typically used in clinical practice. If an increase in discomfort occurs above what is typically expected during testing, if your child has any injury symptoms at any time, or if they wish to stop testing, they should let the study staff know right away and the tests will be stopped.

### *Blood tests*

The blood tests will be done following standardized laboratory procedures by a trained nurse or phlebotomist. 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 your child feels dizzy or faint, they should tell the nurse or phlebotomist right away.

### *Imaging*

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 your child has none of the risk factors that will be screened for by the MRI technologist. Specifically, they should not have an MRI if they have a pacemaker or certain other metal objects inside their body (including dental braces), because the strong magnets in the MR scanner might cause these to heat up or move, causing harm. Your child will also need to remove all metal from their clothing and pockets; otherwise, these objects could be pulled into the magnet and cause harm. No metal can be brought into the magnet room at any time, because the magnet is always “on”. During the MRI session, your child will lie on a padded table and be asked to hold as still as possible while pictures are being taken. The MRI technologist will be carefully monitoring the session and will answer any questions or concerns that you or your child may have during the session. When the scan begins, your child will hear a loud knocking noise (like a drum beat) that can change at times during the scan. If they cannot lie still enough to complete a high-quality scan, if they are uncomfortable or anxious, or want to stop for any reason, your child will be removed from the scanner immediately. Further, MRI will not be performed if they feel too claustrophobic to enter the scanner.

### **What are the potential benefits of participating?**

There may or may not be direct benefits to your child from taking part in this study. Your child will have access to follow-up with a study doctor with expertise in youth sport-related concussion within approximately 72 hours of sustaining a suspected concussion. It is possible that you may learn more about sport-related injuries and concussions, and that staff at your child’s school/club may become more knowledgeable about concussions.

### **Incidental findings**

In the unlikely scenario that a researcher observes an unexpected abnormality (called an ‘incidental finding’) in your child’s results (i.e., images, questionnaires), the study doctor will be notified immediately. He or she will make a determination of its potential significance to your child’s health and welfare. If considered to be a finding of potential clinical significance, you will be informed and the physician will make recommendations for follow-up, including contacting your child’s family doctor and working with him or her to make sure that your child receives the appropriate medical care. If you do not have a family doctor, the study doctors will make appropriate referrals for your child’s care.



The MRI scan being done is designed to answer research questions, not examine your child's brain medically. This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, there is a possibility that MRI may show incidental findings. For this reason, a neuroradiologist will review every scan. The scan and neuroradiologist's review results will become part of your child's medical record, which will be kept locally at BC Children's Hospital. Scans and medical records will not include your child's participant ID, therefore they will not be linked to any research data. If the radiologist thinks that there may be an abnormality in your child's MRI scan, we will contact the SHRed study doctor, who will then contact you and with your permission, your family physician and help him or her get the right follow-up for your child.

**Primary care physician (family doctor) notification**

Please indicate, by checking the applicable box, whether you want us to notify your child's primary care physician(s) of their participation in this study. This is not a consent to release medical information.

Yes, I want the study investigator to advise my child's primary care physician(s) of my child's participation in this study.

My child's primary care physician(s) name(s) is/are: \_\_\_\_\_

The name of the medical clinic my child attends is: \_\_\_\_\_

Parent Initials: \_\_\_\_\_

No, I do not want the study investigator to advise my child's primary care physician(s) of my child's participation in this study.

Parent Initials: \_\_\_\_\_

My child does not have a primary care physician or specialist.

Parent Initials: \_\_\_\_\_

I understand that if I choose not to advise my child's primary care physician(s) of my child's participation in this study, there may be potential medical consequences which may affect my child's comprehensive medical care or treatment. I understand that the study investigator may not be responsible for these consequences.

Parent Initials: \_\_\_\_\_

**What are the alternatives to the study treatment?**

This study does not involve treatments beyond the standard of care. If you choose not to take part in this study, your child's medical care will not be affected.

**What if new information becomes available that may affect my decision to participate?**

You will be informed if new information becomes available that may affect your willingness to remain in this study.

**What happens if I decide to withdraw my consent to participate?**

You can decide to withdraw your child from the study at any time and you do not have to give a reason. Contact the Study Coordinator to withdraw from the study. The Study Coordinator will communicate with you to confirm that your child has been withdrawn and if you have requested that your child's data be withdrawn and any samples destroyed, the Study Coordinator will communicate with you to confirm that this has been done also.

**Can my child be asked to leave the study?**

If your child is not able to follow the requirements of the study or for any other reason, the study doctor may withdraw your child from the study and, if they are receiving concussion follow ups at that time, the doctor will arrange for your child's care to continue. If your child is asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

**How will my and my child's information in this study be kept confidential?**

You and your child's privacy will be respected at all times. Unless you provide permission, the study team will not disclose that your child is in or has been a part of this study. They will not release any information that could be used to identify your child, 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 your child will fill out some questionnaires that will ask about how he/she is feeling. If the study doctors are worried about your child they will contact you and/or your child's family doctor if you have given them permission to do so, and they will contact you to make sure that your child gets any additional care that is needed.

You and your child will each be identified by specific study codes that apply only to you or him/her. Any paper forms that are part of the study will use this code rather than you or your child's name. The Principal Investigators will keep the key file linking you and your child's 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, accessible to the research team at this location only.

A larger than usual number of identifiers are being collected and stored in a secure, online data server (REDCap). This is to allow for interface personalization (e.g., your name to appear on the online portal), the central storage of data, and data completeness. REDCap uses authentication for users, encryption, and password protection in accordance with Personal Health Information Protection and Privacy Act (HIPPA) guidelines, and in accordance with University of Calgary information Security Control Requirements approval, and stored on an OVH Canada dedicated server in compliance with University of Calgary requirements. REDCap is housed by the University of Calgary and can only be accessed by Dr. Carolyn Emery and her research staff, as well as the BC Children's Hospital SHRed Research Team. Members of the University of Calgary

team are required to sign a confidentiality agreement, and research staff at UBC complete Privacy and Information Security training.

For this study we will be collecting personal identifiers which include: Parent and child full name, age, month and year of birth, phone number, email, city, school/club, and relevant sports organizations to which your child belongs for the research purposes described in this consent form. Although steps have been taken to protect your privacy, this could increase the risk of your re-identification. Identifying information will be accessible to BC Children's Hospital and University of Calgary SHRed study personnel only. Researchers outside of the local site would not normally have access to personal identifiers; this is unique to this study. Your personal information will not be used to contact you for recruitment into future research studies without your consent and all future contact will be made directly by the BC research team. All identifying information will be removed from the Calgary-based REDCap portal one year following study completion, which is the earliest possible date to do so. The local investigators (BC Children's Hospital, BC Injury Research and Prevention Unit) will retain the file that links identifiers to the study ID code for 5 years following the end of the study, in a locked cabinet in a locked office, as per UBC policy requirements.

We are asking to collect your email address because it is required for creation of an online SHRed Concussions account, and access to the portal. We will also use your email to contact you about scheduling calls/appointments when necessary. Although you may not be aware of this fact, emails sent to some webmail services (e.g. Gmail, Hotmail, etc.), may be stored/routed outside of Canada (for example, in the United States). Due to the fact that future emails will contain personal information about you, including your name, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before we continue. We will only send your personal information to the email address you have provided to us. All of the information which you provide to us will be kept completely confidential. Providing your email address means that you voluntarily agree and give your consent for the study team to email your personal information to you.

**I have read, understand, and approve that my and my child's identifying information will be available via a secure online portal to SHRed researchers at BC Children's Hospital (the Principal Investigators and study coordinators) and the University of Calgary (Principal Investigators, data management coordinator, technical coordinator, national coordinator, and statistician).**

Parent Initials: \_\_\_\_\_

**What happens if something goes wrong?**

By signing this form, you do not give up any of your legal rights and you do not release the principal investigator, participating institutions, or anyone else from their legal and professional duties. In the event that your child suffers an injury as a direct result of participating in this study, the research team will ensure that they are connected with medical care. The costs of your medical treatment will be paid by your provincial medical plan.

### **What will the study cost me?**

There will be no financial costs to you as a participant in this study. We will reimburse you for parking or transit when your child attends study visits. Juice and snacks will be offered to your child at the time of each blood test. You will not be paid for participating in this study.

### **Who do I contact if I have questions about the study during my child's participation or to report an injury?**

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

### **Who do I contact if I have questions or concerns about my child's rights as a research participant?**

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

### **After the study is finished**

All identifying information for all participants will be removed from the REDCap portal by the earliest possible date, which will be one year following study completion. All study-related documents will be maintained after the study ends at UBC, or in an off-site secure storage location such as is used by legal and government firms, for 7 years; after that the documents will be destroyed. Study results will be communicated to schools/clubs in annual progress updates, or as required by the schools/clubs or school districts.



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

My signature on this consent form means:

- I have read and understood the information on this consent form.
- I have had enough time to think about the information provided and discussed it with my child.
- I have been able to ask questions and have had satisfactory responses 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 purposes.
- I understand that my child’s participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw my child from this study at any time, and that this will not change the quality of care that my child receives, or affect their involvement in their school or team(s).
- I understand that I am not waiving any of my child’s legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to my child.
- I have received a copy of this form for my own records.
- I consent to my child’s participation in this study.

Please check this box if you are willing to be contacted by investigators at the local site for future studies about sport-related concussion among youth. Checking this box does NOT obligate you to participate.

This consent form was read by the parent(s)/guardian(s)/substitute decision-maker (legally authorized representative), and both the person reading this consent form and the investigator are satisfied that:

- The study information was accurately explained to, and apparently understood by, the child/participant.
- The child/participant was given an opportunity to ask questions, and all questions have been answered.
- The child/participant assents to participating in the research.

\_\_\_\_\_  
Participant Name

\_\_\_\_\_  
[Parent]/[Representative’s] Signature      Printed name      Date

\_\_\_\_\_  
Signature of Person Obtaining Consent      Printed name      Study Role      Date