COVER LETTER/PROJECT DETAILS – CHILD (8-12YO)
PLEASE READ AND KEEP THIS COPY

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INVITATION TO PARTICIPATE: As an Athletic Trainer and clinical researcher from South Dakota State University, I am excited for our research team to partner with your school organization to implement an innovative program to better evaluate and manage concussion/head injuries. *The project is entitled:* ***Evidence-Based Diagnosis and Care Improves Patient Centered Outcomes in Concussed Rural Children (IRB-1107002-EXP).*** The program will assist you (parent and child) as well as your medical provider in more effectively evaluating and treating head/injuries, namely sport-concussions. This letter provides information related to the service being offered to student-athletes. We would also like to ask that you consider allowing the data collected as part of the service to be used in research that will help us better describe concussions in youth.

Due to the nature of sport, it is difficult to prevent every concussion; however, we can ensure that if a student-athlete receives a blow to the head, he or she is evaluated using the most current accepted practice. Research has shown that the best way to diagnose, monitor and manage a concussed child is to utilize multiple "brain function" tests over different times in the healing process. We will be implementing a protocol for baseline testing (pre-injury) for all student-athletes, as well as a post-injury protocol for those participants who receive a head injury/concussion.

(1) The purpose of the project is to investigate the effects of sport related concussions on the pediatric athlete (12-18yo). Specifically we will be addressing three questions (1) Does a proposed rural SC protocol using multiple measurements result in an increased number of concussion diagnoses when compared with traditional physician based methods of concussion assessment?; (2) At the time of physician-recommended return to play (RTP) decision, do impairments described by the SC still exist? **AND** (3) Do concussed children self-report lower health-related quality of life (HRQoL) compared to healthy children?

(2) If you give permission/assent to participate, the participant will complete baseline testing for injury history, cognitive function, balance, smoothness of eye movement and quality of life at the beginning of their competitive sport season at your school. Baseline testing includes completion of the Immediate Post-Concussion Assessment and Cognitive testing (ImPACT™) software program, postural stability testing (Balance Error Scoring System) and eye movement/tracking (King-Devick Test). The tests described are commonly used in the evaluation and management of concussions. The ImPACT™ software is a non-invasive test set up in "video-game" type format. It is simple, and actually many athletes enjoy the challenge of taking the test. Essentially, the ImPACT™ test is a preseason physical of the brain. It tracks information such as memory, reaction time, speed, and concentration. It is not an IQ test. **Baseline testing takes approximately 60 minutes to complete.** Again, these are non-invasive procedures and are commonly used strategies to assess head injuries.

(3) If the participant suffers a head injury, the research team will be notified and work with your school district to arrange post injury testing. Information will be collected minimally: (1) within 24-72 hours post- concussion and (2) when the decision is made by the medical provider to return the participant to play. Additional testing may occur according to your provider as well as follow-up at 6 months following return to play and 12 months following return to play. Each of these assessment points will take approximately 30-45 minutes.

(4) Student-Athletes will receive the testing services regardless of whether they provide assent/consent to participate in the research aspect of the study. Participation in this research project is voluntary. The participant has the right to withdraw at any time without penalty.

(5) Risk at baseline testing: Electronic neurocognitive testing ImPACT ™ testing, postural testing and eye movement tests are common and accepted procedures in the assessment and management of concussions. Risk is no greater than minimal for student-athletes testing for their baseline scores. If the student-athlete completes an invalid test, they may be asked to re-test to earn a valid baseline score. This will take an additional 20-30 minutes but again, beyond delay of starting practice, there is no greater than minimal risk.

(6) Risk with Post-Concussion Testing: Concussed student-athletes (as with other types of injuries) typically follow initial assessment and re-assessment after injury using history, cognitive, balance and eye movement testing. When these tests are delivered, signs, symptoms and altered behaviors may increase. If your student-athlete demonstrates an increase in the signs, symptoms and behaviors during testing, the test will be terminated and the student-athlete will be referred to their medical provider.

(7) Student-athletes will not receive any compensation for their participation in the study; however, the data collected from the procedure will be made available, at no cost, to students, parents and medical providers of the student's choice to assist in evaluation and management and with your permission.

(8) Student-athletes will benefit from the information collected from this battery of tests since these tests are consistent with expert/evidence based recommendations for evaluation and management of concussion in youth (self-report symptomology, cognitive function and postural assessment). The information collected for the post-concussed student-athlete (including the baseline information) will be provided to the student-athlete's medical provider for consideration in the evaluation and management of their condition. The information compiled from all participants will add to the body of knowledge that is helping to explain concussions in youth.

(9) Participant findings recorded during baseline and follow up testing are strictly confidential. Files are maintained in a secure location on the campus of SDSU. When the data and analysis are presented, participant data will be reported in aggregate and no individual data will be identified by name, title or any other identifying item.

(10) Participants will be informed of all research activities and will be given the choice to participate. If the participant at any time indicates that participation in the project is causing stress or that participation is no longer voluntary, their involvement in the project will immediately be terminated.

(11) If you have any questions regarding this study, you may contact the project director. If you have questions regarding your rights as a participant, you can contact the SDSU Research Compliance Coordinator at (605) 688-6975 or sdsu.irb@sdstate.edu.

We are excited to implement this program given that it provides us the best available information for managing concussions and preventing potential brain damage that can occur with multiple concussions. Our research team, administration, coaching, and athletic training staffs are striving to keep the health and safety of participants at the forefront of the student athletic experience. **Please use this letter for your reference.**

ID: _____
Date: _____
Office Use Only

PLEASE COMPLETE AND RETURN WITH BASELINE TESTING

STUDENT ASSENT/PARENT PERMISSION: Please read the follow statements and discuss as parent and child. If you agree with these statements, please check the boxes to the left of the statement. There is a column for both the parent and child to check.

Parents Name: (Please Print)	Child's Name: (Please Print)

Parent	Child	Statement
		I give my permission to complete baseline and post-concussion testing including ImPACT™ (Immediate Post-concussion Assessment and Cognitive Testing), balance testing and eye movement tracking in conjunction with your school or sport organization policy. This information will be kept in a secure file with the researchers at SDSU. I understand there is no charge for the testing.
		l agree to allow the data collected to be included as part of the research project.

Parent/Guardian Signature:	Date:
Participant Signature:	Date:
This form was read and filed by:	Date:

CONTACT INFORMATION: This general contact information is for record keeping purposes and to help facilitate any post-concussion follow-up as necessary. It will be kept in a secure location.

CHILD'S NAME: Last:_____ Middle Initial:_____ First:_____

SCHOOL District: _____

PARENT/GUARDIAN NAME (Primary Contact):_____

Preferred Phone Number: _____ **Second Phone Number: _____**

Email Address: _____

Address: _____

STREET ADDRESS CITY STATE ZIP CODE

CHILD'S PHONE (if different from parents): _____

CHILD'S birth date? Month: _____ Day: _____ Year: _____

CHILD'S year in school: 7th 8th 9th 10th 11th 12th

CHILD'S current age? _____ **Circle gender**: male female

Sport	Position	High School or Junior High?	Years of Experience at this Level?

ID: _____ Date: _____ *Office Use Only*

HISTORY: Please answer the following questions to prepare for baseline testing.

_____ Height (ft./inches) _____Weight (pounds) Handed ness: Right (R) Left(L) Ambi (both R AND L)

(1) Ethnicity: ___ American Indian ___ Asian ___ Black or African American ___ Hispanic or Latino
___ Native Hawaiian or other Pacific Islander ___ White

(2) Check any of the following that apply:
___ Received speech therapy ___ Attended special education classes ___ Repeated one or more years at school
___ Diagnosed with a learning disability ___ Diagnosed with attention deficit disorder or hyperactivity

(3) While in school, what type of student are you:
___ Below Average (< C average) ___ Average (mostly C) ___ Above Average (Mostly A/B)

(4) Number of Times Diagnosed with a Concussion: _____

(5) If you have been diagnosed with a concussion:

	Total number of concussions that resulted in loss of consciousness
	Total number of concussions that resulted in confusion
	Total number of concussions that resulted in difficulty remembering events occurring immediately after the injury
	Total number of concussions that resulted in difficulty remembering events occurring immediately before the injury
	Total number of games missed as a direct result of all concussions combined

(6) Please list your (five) most recent concussions, if applicable; you may use approximate dates:

Concussion 1	Month:	Year:
Concussion 2	Month:	Year:
Concussion 3	Month:	Year:
Concussion 4	Month:	Year:
Concussion 5	Month:	Year:

(7) Indicate whether you have experienced the following:

YES	**NO**	
		Treatment for headache by a physician
		Treatment for migraine headaches by physician
		Treatment of epilepsy/seizures
		Treatment for brain surgery
		Treatment for meningitis
		Treatment for substance/alcohol
		Treatment for psychiatric condition (anxiety/depression)

(8) Have you ever been diagnosed with any of the following conditions? (check all that apply)
_____ ADD/ADHD _____ Dyslexia _____ Autism

(9) Date of last concussion (most recent): _____ Month _____Day _____Year

(10) Current Medications:

ID# _____

Date:_____

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

CHILD REPORT (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has this been for you …*

ABOUT MY HEALTH AND ACTIVITIES ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. I have trouble getting along with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

ABOUT SCHOOL ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

ID# _____

Date:_____

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

PARENT REPORT for **CHILDREN** (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month,** how much of a **problem** has your child had with …*

PHYSICAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

