

COVER LETTER/PROJECT DETAILS – TEEN (13-18YO) 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.**

PLEASE COMPLETE AND RETURN WITH BASELINE TESTING

ID:	
Date:	
Office Use Only	

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				Child's Name:			
(Please F	Print)			(Please Print)			
					1		
Parent	Child	Statement					
		I give my permission to complete		•			
		(Immediate Post-concussion Asse			llance testing and eye movement y. This information will be kept in		
		a secure file with the researchers			•		
					2		
	l agree to allow the data collected to be included as part of the research project.						
Parent/0	Parent/Guardian Signature: Date:						
Dawiii	+ C' -				Data		
Participa	ant Signa	ature:			Date:		
This form	m was re	ead and filed by:			Date:		
CONTAC	T INFOR	MATION: This general contact in	formation	is for record keeping p	urposes and to help facilitate any		
post-cor	ncussion	follow-up as necessary. It will be	kept in a	secure location.			
CHILD'S N	IAME: La	ast:	Midd	le Initial: First	:		
CHOOL I	District:						
PARENT/	GUARDI	AN NAME (Primary Contact):					
Preferred	l Phone	Number:		Second Phone Numl	ber:		
Email Ado	dress:						
auui ess.		REET ADDRESS		CITY	STATE ZIP CODE		
	31	REET ADDRESS		CITY	STATE ZIP CODE		
CHILD'S P	PHONE (i	f different from parents):					
CHILD'S b	irth dat	e? Month: Da	y:	Year:			
CHILD'S y	ear in so	chool: 7 th 8 th 9 th 10 th	th 11 th	12th			
CHILD'S c	urrent a	ge?		Circle gender: mal	e female		
Sport		Position	High Sch	ool or Junior High?	Years of Experience at this Level?		
					LCVCI:		
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					ID:	Date:	Office Use Only			
НІ	STORY: PI	ease ans	wer the following	questions to prepa	re for baseline	testing.				
	He	ight (ft./i	inches)	Weight (pound	s) <u>Handed n</u>	ess: Right (R) Left(L) A	mbi (both R AND L)			
(1)	Ethnicity:	Ar Na	nerican Indian ative Hawaiian or ot	Asian her Pacific Islander	Black or African	American Hispanic or La	atino			
	Received s	peech the	• • • • • • • • • • • • • • • • • • • •	•		Repeated one or more yea disorder or hyperactivity	ars at school			
			at type of student a (< C average)		c)	Above Average (Mostly A/	'B)			
(4)	Number o	f Times D	iagnosed with a Coi	ncussion:						
(5)	If you have		agnosed with a concussio	cussion: ons that resulted in los	ss of consciousn	ess				
		1 0 00011		ns that resulted in co						
		Total n injury	umber of concussio	ns that resulted in dif	ficulty rememb	ering events occurring imme	ediately after the			
			umber of concussio	ns that resulted in dif	ficulty rememb	ering events occurring imme	ediately before the			
		Total n	Total number of games missed as a direct result of all concussions combined							
1 6 \	Dloaco list	vour (five	a) most recent cons	ussions, if applicable;	vou may uso ar	anrovimato datos:				
(0)	Concussi		Month:	ussions, ii applicable,	Year					
	Concussi	on 2	Month:		Year	<u> </u>				
	Concussi	on 3	Month:		Year	<u> </u>				
	Concussi	_	Month:		Year					
	Concussi	on 5	Month:		Year	:				
/ 7 \	Indiants		h	d the felleridge.	-					
(/)		NO	ou have experience	a the following:						
	120		Treatment for heada	che by a physician						
				ine headaches by phy	sician					
			Treatment of epileps							
		1	Treatment for brain	surgery						
		٦	Treatment for menir	ngitis						
		1	Treatment for substa	ance/alcohol						
		٦	Treatment for psych	iatric condition (anxie	ty/depression)					
		_ADD/ADI	HD D	y of the following coryslexiaAutism	n	all that apply) Year				
(10) Curre	nt Medica	ations:							

ID#	
Date:	



Version 4.0

TEEN REPORT (ages 13-18)

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
I have trouble getting along with other teens	0	1	2	3	4
2. Other teens do not want to be my friend	0	1	2	3	4
3. Other teens tease me	0	1	2	3	4
4. I cannot do things that other teens my age can do	0	1	2	3	4
5. It is hard to keep up with my peers	0	1	2	3	4

ABOUT SCHOOL (problems with)	Never	Almost Never	Some- times	Often	Almost Always
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:	



Version 4.0

PARENT REPORT for TEENS (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for **your teen** 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 teen had with ...

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

SCHOOL FUNCTIONING (problems with)	Never	Almost Never	Some- times	Often	Almost Always
Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
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