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IRB Approval Letter

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CSR, Incorporated

Submission for Institutional Review Board Approval

PROJECT TITLE: Improving the Understanding of Traumatic Brain Injury through Policy and Program Evaluation Research

PRINCIPAL INVESTIGATOR:

NAME & TITLE: John Foster-Bey, D.L.S., M.B.A., M.P.A., President and CEO, CSR Incorporated

DEPARTMENT:

CO-INVESTIGATOR(s):

Robin LaVallee, M.P.P., Research Associate, CSR Incorporated

FUNDER(s): Centers for Disease Control and Prevention (CDC)

The information submitted herewith is complete and accurate to the best of my knowledge.



 PRINCIPAL INVESTIGATOR

6/24/2014

 DATE

INSTITUTIONAL APPROVAL:

UNIT DIRECTOR _____

DATE _____

IRB PROVISIONAL (INITIALS) _____

DATE _____

IRB APPROVED (SIGNATURE)  _____

DATE June, 24, 2014_

EXECUTIVE OFFICE _____

DATE _____

Recommendations:

1. The IRB requested additional clarification regarding the physician follow-up process. In reading the short description provided in the revised protocol, the process remains unclear. It is recommended that the research team provide a more detailed, step-by-step explanation of the role of the physician review. This explanation should include how the research team will notify the physician to review the file, the steps the physician will take when reviewing the file, the factors they will consider in making a concussion diagnosis, and the resulting actions following a diagnosis of a concussion, as it relates to both data ((i.e. how that diagnosis will be coded in the data) and study participants (i.e. who will be informed of the diagnosis).

2. The review panel asked for more information about the assent/consent process for study participants (Specific Comments on IRB application, Page: 3, bullet #2). While both the process of assent and consent are mentioned in

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later sections of the protocol, it would be advantageous to also provide an overview of the process in the “Data Collection Strategy” section. Additional information should also be provided to more clearly outline what will occur in the event that an athlete’s parent consents to study participation but the athlete/child does not assent to be part of the study.

3. The review panel asked for clarification about how families with multiple study-eligible children would be handled (Specific Comments on IRB application, Page: 3, bullet #2). Explicit language on how this situation will be dealt with (i.e. data will be collected from one child per family) should be added to the protocol.

4. The review comments suggested adding information to the protocol and distributed materials (i.e. invitation letters, pre-season surveys) about the length of the survey and the amount of time it will take to complete (Specific Comments on IRB application, Page: 3, bullet #3). The revised protocol and study materials do now include information about the amount of time it is expected to take to complete the survey instruments but do not mention the length of the survey. To address the reviewer concern, it is recommended that information about the length of the survey be added (i.e. number of questions).

5. Reading level of surveys, flyer, and letters. On page 3, the researchers state that the surveys are a modified version of pilot materials. The IRB is concerned about the reading level of the material which seems to be too high for parents and children, especially the survey questions for children, for example, “sensitivity to light.” There may also be parents in the study who speak English as a second language who will have difficulty understanding some of the words and phrases. If the surveys have been tested with a similar population, a statement about this being used previously and not causing comprehension problems would be helpful.

6. If during the course of the study information about the coach is discovered that may affect the children’s health and safety, the research team has an obligation to address the information with appropriate law enforcement or other agencies. The coach is part of the study and thus, this is the responsibility of the research team.

7. “the research team feels a responsibility to ensure parents are aware of a potentially serious injury in their child. This information will not be shared with coaches.” The IRB is concerned that coaches will not be informed of potentially serious injuries to the child. What happens if the child has symptoms of concussion, the parent is notified, and then the parent allows the child to continue playing? In this instance, not notifying a coach would endanger the child.

8. The researchers state that a positive response that could indicate symptoms of concussion will trigger an email to the researchers and a follow up phone call within 24 hours. The IRB recommends adding a sentence making it clear that email will be monitored over the weekend so if a possible injury is reported on a Friday evening or over the weekend, a researcher will see the email and respond within the designated time.

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Submitted: Dr. Monica L. Robbers (Chair), CSR Incorporated
Dr. Patricia San Antonio, CSR Incorporated
Dr. James Hyman, Independent Consultant
Dr. Rachel Brushett, CSR Incorporated
Dr. Stephen H. Haas, Office of Research and Strategic Planning, West Virginia Government

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ABSTRACT OF THE PROPOSED STUDY

Describe in non-technical language the objectives, methods, procedures and duration of the study. Include anticipated risks and benefits to the individuals involved and/or society.

Traumatic brain injury (TBI) is one of the highest priorities in public health because of its magnitude, economic and human impact, and preventability. Improving the recognition and management of mild TBIs—such as concussions that occur during youth sports—can help reduce the harm caused by such injuries and prevent future consequences.

More than 7 million U.S. high school students participate in organized sports each year. Sports-related concussions are common injuries among youth and have potentially serious consequences.^{1 2 3 4 5} CDC’s public health efforts have included the development of the Heads Up education campaign, which focuses on raising awareness of the signs and symptoms of concussions and improving the management of concussions among youth athletes.

However, individual states and the District of Columbia have taken the initiative and passed laws aimed at improving the management of youth sports-related concussions. In 2009, Washington State enacted the first such law to manage youth sports-related concussions—the Lystedt Law. Since there is currently no model law for managing youth sports-related concussions, 49 other states and the District of Columbia developed their own laws independently. While there are similarities across the states, an examination of the laws shows considerable variation in the breadth and scope of the laws. Despite the proliferation of state laws and the dissemination of concussion education materials, little is known about the reach, use, and effectiveness of these laws in improving the management of youth sports-related concussions. The major danger faced by young athletes who have experienced a concussive event is that they are allowed to return to play while still experiencing symptoms. If the state laws are effective, they should reduce the number of athletes who return to play while symptomatic.

The primary goal of the current proposal is to examine the relationship between state laws aimed at managing youth sports-related TBIs and youth athletes returning to play while symptomatic. In addition, the study also intends to assess variations in knowledge, attitudes, and behavior regarding concussions; the use of concussion education materials, including Heads Up; and state policies governing requirements for identification and management of concussions in youth athletics. CDC will use the outcome data to examine the factors at the individual, team, and state levels that may be associated with an increased likelihood of returning to play while symptomatic. By identifying injured athletes who return to play while continuing to experience symptoms of a concussion, the research team seeks to identify important predictors of this behavior. This will enable CDC to make recommendations for improving state policies and improve the agency’s Heads Up concussion education training program.

¹ Yeates KO, Swift E, Taylor HG, et al. Short- and long-term social outcomes following pediatric traumatic brain injury. *J Int Neuropsychol Soc* 2004; 10:412–426.
² Anderson V, Catroppa C, Morse S, Haritou F, Rosenfeld J. Recovery of intellectual ability following traumatic brain injury in childhood: impact of injury severity and age at injury. *Pediatr Neurosurg* 2000; 32:282–290.
³ Belanger HG, Spiegel E, Vanderploeg RD. Neuropsychological performance following a history of multiple self-reported concussions: a meta-analysis. *J Int Neuropsychol Soc* 2010; 16:262–267.
⁴ Fay TB, Yeates KO, Wade SL, Drotar D, Stancin T, Taylor HG. Predicting longitudinal patterns of functional deficits in children with traumatic brain injury. *Neuropsychology* 2009; 23:271–282.
⁵ Gessel LM, Fields SK, Collins CL, Dick RW, Comstock RD. Concussions among United States high school and collegiate athletes. *J Athl Train* 2007; 42:495–503.

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The proposed study is based on a pilot study funded by the Robert Wood Johnson Foundation (RWJF). The pilot study assessed variation in degree of implementation of the Lystedt Law and whether implementation methods affected the proportion of concussive injuries reported by athletes to coaches and the likelihood athletes played with concussive injuries. Nearly all studies have relied on reporting of concussions to team personnel or medical personnel. However, youth may not recognize that their symptoms are consistent with a concussion. They may also be hesitant to report symptoms for fear of being kept out of competition. The Lystedt Law pilot study methods were able to remove many of the obstacles to accurate and truthful reporting of concussions.

This study will be conducted using three national subsamples: (1) soccer coaches, coaching boys and girls ages 14–18 on club soccer teams; (2) boys and girls youth soccer players ages 14–18 playing club soccer; and (3) parents of boys and girls ages 14–18 who are club soccer players. The samples will be drawn from U.S. Youth Soccer, a national youth soccer organization with over 3 million youth players. The sample will be drawn using a multistage stratified random sampling approach.

First, states will be stratified into three groups, based on characteristics of their youth sports TBI laws:

- *Stratum 1:* The law does not specify requirements for Return to Play (RTP). (3 states)
- *Stratum 2:* RTP clearance must come from a licensed health professional. (13 states and Washington, DC)
- *Stratum 3:* RTP clearance must come from a licensed health professional with training in TBI management. (34 states)

This will be a prospective cohort study in which the effectiveness of the laws will be compared across the strata.

Because stratum 1 includes only 3 states, all were selected. States in stratum 2 and 3 were alphabetized within their respective strata and every other state was selected using a random start point. This resulted in 7 states selected from stratum 2 and 17 states from stratum 3. U.S. Youth Soccer member clubs within each selected state will be identified through each state’s official association website. Once all clubs have been identified, they will be alphabetized within state and 400 will be randomly selected from each stratum. A team will then be randomly selected from each club, with an equal number of girls’ and boys’ teams being selected.

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IRB Recommendations

1. The IRB requested additional clarification regarding the physician follow-up process. In reading the short description provided in the revised protocol, the process remains unclear. It is recommended that the research team provide a more detailed, step-by-step explanation of the role of the physician review. This explanation should include how the research team will notify the physician to review the file, the steps the physician will take when reviewing the file, the factors they will consider in making a concussion diagnosis, and the resulting actions following a diagnosis of a concussion, as it relates to both data (i.e. how that diagnosis will be coded in the data) and study participants (i.e. who will be informed of the diagnosis).

The IVR system will automatically notify the study team by e-mail of positive responses about injuries that could indicate concussion symptoms. Research assistants will then call the athlete and parent separately within 24 hours to determine the date of the injury, whether it was during a practice or a game, what the severity rating of symptoms is using a standardized, validated assessment of concussion based on a 0 to 6 scale (higher scores indicating more severe symptoms) on the day of injury and in the 24 hours before interview, whether the athlete continued to play with symptoms, and if and to whom the athlete reported symptoms. We will also ask about medical care for the injury and instructions on return to play. For athletes who report continued concussion symptoms at the time of the initial call, both athletes and parents will continue to be called weekly until symptoms are resolved.

All injury interviews and follow-up assessments will be reviewed by one of the physician members of the research team. The physician will review the participant's responses and a diagnosis of concussion will only be assigned if the athlete experienced more than just headache symptoms, if symptoms were rated as being more than mild, and if the symptoms lasted more than 1 day. If a concussion is diagnosed, the research team will notify the parent that the child meets the criteria for a concussion and suggest a visit to the child's doctor. The athlete will also be coded in the dataset as having been diagnosed with a concussion.

2. The review panel asked for more information about the assent/consent process for study participants (Specific Comments on IRB application, Page: 3, bullet #2). While both the process of assent and consent are mentioned in later sections of the protocol, it would be advantageous to also provide an overview of the process in the "Data Collection Strategy" section. Additional information should also be provided to more clearly outline what will occur in the event that an athlete's parent consents to study participation but the athlete/child does not assent to be part of the study.

In the event that a parent consents but an athlete does not assent, data will not be collected from that parent. Both the child and parent must agree to participate in the study.

3. The review panel asked for clarification about how families with multiple study-eligible children would be handled (Specific Comments on IRB application, Page: 3, bullet #2). Explicit language on how this situation will be dealt with (i.e. data will be collected from one child per family) should be added to the protocol.

Data will only be collected from one child per family. If more than one child in a given family assents to participate, one child will be randomly selected to participate.

4. The review comments suggested adding information to the protocol and distributed materials (i.e. invitation letters, pre-season surveys) about the length of the survey and the amount of time it will take to complete (Specific Comments on IRB application, Page: 3, bullet #3). The revised protocol and study materials do now include information about the amount of time it is expected to take to complete the survey instruments but do not mention the length of the survey. To address the reviewer concern, it is recommended that information about the length of the survey be added (i.e. number of questions).

The introduction included in the online survey instruments has been updated to include the number of items in the survey.

5. Reading level of surveys, flyer, and letters. On page 3, the researchers state that the surveys are a modified version of pilot materials. The IRB is concerned about the reading level of the material which seems to be too high for parents and children, especially the survey questions for children, for example, "sensitivity to light." There may also be parents in the study who speak English as a second language who will have difficulty understanding some of the words and phrases. If the surveys have been tested with a similar population, a statement about this being used previously and not causing comprehension problems would be helpful.

The survey instruments and other materials were used and tested in the previous Washington State Pilot Study of high-school aged athletes. The list of concussion symptoms, including "sensitivity to light," that are asked about in several survey instruments are from the Sports Concussion Assessment Tool 3 (SCAT 3), which has been approved for use in athletes 13 and older. This is a standardized assessment and we are unable to change the wording of any individual items without affecting its validity.

6. If during the course of the study information about the coach is discovered that may affect the children's health and safety, the research team has an obligation to address the information with appropriate law enforcement or other agencies. The coach is part of the study and thus, this is the responsibility of the research team.

While they will be asked to participate in the online, pre-season survey, coaches are not a part of the weekly surveillance reports. The current research protocol requires that the research team alert parents to any injuries to their child that meet the criteria for being considered a concussion. Beyond that, it is out of the scope of the research team's responsibility to become involved in any issues arising with the coach, team, other players etc.

7. "the research team feels a responsibility to ensure parents are aware of a potentially serious injury in their child. This information will not be shared with coaches." The IRB is concerned that coaches will not be informed of potentially serious injuries to the child. What happens if the child has symptoms of concussion, the parent is notified, and then the parent allows the child to continue playing? In this instance, not notifying a coach would endanger the child.

The research team will notify parents and suggest a visit to the child's doctor if a concussion is diagnosed by a study physician. Further action will be left up to the parent. Coaches will not be notified of any athlete or parent responses. Notifying coaches of a child's potential concussion could not only affect the willingness of children to report concussion symptoms, but would also violate the child's privacy by sharing their medical information.

8. The researchers state that a positive response that could indicate symptoms of concussion will trigger an email to the researchers and a follow up phone call within 24 hours. The IRB recommends adding a sentence making it clear that email will be monitored over the weekend so if a possible injury is reported on a Friday evening or over the weekend, a researcher will see the email and respond within the designated time.

The email account will be monitored over the weekend, allowing the research team to contact injured athletes within 24 hours of their reported injury.