OFFICE USE:
FILE NO._____
DATE REC'D: __/__/__

CSR, Incorporated

Submission for Institutional Review Board Approval: Revised Protocols, Expedited Review

Initial Approval Granted 6/23/2014

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.

John A. Foster-Bey

Digitally signed by John A. Foster-Bey
DN: cn=John A. Foster-Bey, o=CSR, Incorporated, ou=President/CEO, email=jfosterbey@csrincorporated.com, c=US
Date: 2015.02.27 11:44:27 -05'00'

PRINCIPAL INVESTIGATOR

02/27/2015
DATE

INSTITUTIONAL APPROVAL:

UNIT DIRECTOR_____ DATE_____

IRB PROVISIONAL (INITIALS)_____ DATE_____

IRB APPROVED (SIGNATURE) _____DATE February 27, 2015

EXECUTIVE OFFICE_____ DATE_____

IRB USE: Received:_____ Reviewed:_____ By:_____
For record---IRB Meeting _____

OFFICE USE:
FILE NO._____
DATE REC'D: __/__/__

The IRB Chair was presented with documentation indicating changes to the previously approved study protocols. The Chair determined that an expedited review should take place due to the following factors:

1) Changes in the population studied, e.g. including minors as well as adults; 2) Changes in study recruitment procedures; 3) Change in the amount of compensation provided to participants; and 4) Addition of personnel who will interact with human participants or have responsibility for research data.

Materials were reviewed and the IRB determined the following:

- Soccer coaches involved in the revised study are now more specifically identified as non-school club soccer coaches. The ages of the youth they coach remains the same.
- The revised study identifies a sample of parent/guardian-athlete dyads rather than a sample of youth players and parents of players. This change is an improvement and will allow for more specific data about the role of parents in Return to Play issues. This will also streamline consent issues because the parent/guardian must consent to participate in order for the athlete/youth soccer player to participate. The parent will then provide contact information for the athlete and consent for them to participate if they are under 18.
- The researchers expect the same number of eligible athletes per team (15) and expect an eligible sample of 5,400 athlete-parent dyads
- If an athlete ceases to play, they will not be followed up with by the researchers. This remains the same in the revised study.
- In the revised study, there will be two comparison groups made up of 14 states each —states with no specific requirement for athletes to return to play after a concussive injury event (the control group) and states that require approval from a trained healthcare professional before returning to play (the treatment group). In the original IRB application the sample was stratified into three state groups. In addition to the two groups described in the revised plan, the third group in the original plan would have included states which required RTP clearance from a licensed health professional (with no requirement that the health care professional have training in TBI management).
- The revised research does not offer any incentives for participation (the original plan called for incentives in the form of Amazon gift cards in different amounts to be provided to coaches, parents, and youth soccer players. Even though the amounts on the gift cards were relatively small (25, 10, and 5 $), removing the use of incentives reduces the possibility of any kind of coercion.
- The revised study added a baseline survey in addition to 10 weekly reports.
- The expected participation rate of 28% seems reasonable.
- The identities of the parents and youth athletes will be protected by the use of a randomly generated ID number. The files linking study participant names and ID numbers will only be accessible to the contractors/researchers. This will provide adequate protection for the participants.
- The revised research plan expands on how information about a concussive event will be handled. The study team will receive automatic emails of any positive responses so no positive responses will be missed. Parents and athletes will receive separate phone calls within 24 hours of a reported injury, determine the severity of the event using a standardized scale, determine whether the athlete continued to play and whether or not the injury was reported (and to who it was reported). Data will be gathered on medical care received and instructions about RTP. Athletes and parents will be called weekly while symptoms continue. Physician research team members will review the interviews and follow up assessments. Parents will be notified if concussion symptoms are identified and suggest follow up with the athlete's doctor.

IRB USE: Received:_____ Reviewed:_____ By:_____
For record---IRB Meeting _____

OFFICE USE:
FILE NO._____
DATE REC'D: __/__/__

- The research plans adequately protect the health of the athlete and notify parents of any possible concussive event.

The members of the IRB committee have changed due to a previous member becoming part of the research team. This change was made as soon as the IRB Chair was notified.

As such, this revised study has been approved.

IRB USE:	Received:_____	Reviewed:_____	By:_____
For record---IRB Meeting _____			