

HHS/CDC/NCIPC
SUPPORTING STATEMENT FOR
OMB INFORMATION COLLECTION REQUEST

Supporting Statement A

March 23, 2015

**Improving the Understanding of Traumatic Brain Injury through
Policy and Program Evaluation Research**

Supported by:

Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Injury Prevention and Control
Division of Unintentional Injury Prevention

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SUMMARY TABLE

- **Goal of the study:** To determine whether the return-to-play policies followed by club soccer teams make a difference in the proportion of boys and girls ages 14–18 who return to play with symptoms after a concussion injury. A secondary goal is to assess the relationship between CDC's Heads Up Initiative and concussion knowledge among youth soccer coaches, parents, and athletes
- **Intended use of the resulting data:** To improve efforts focused on youth athlete concussion prevention, evaluation, and management to prevent the potential catastrophic and short- and long-term effects of continuing to play after sustaining a traumatic brain injury, including concussion.
- **Methods to be used to collect data:** A multistage, stratified data collection strategy will produce an eligible sample of the population. Data will be collected preseason from all subpopulation samples and weekly from youth soccer athletes and their parents using a two-group study design over the course of a single soccer season.
- **The subpopulation to be studied:** Boys and girls ages 14–18 playing club soccer, their parents, and coaches.
- **How data will be analyzed:** Simple and multiple logistic regression models will be used to examine differences in the likelihood of returning to play with symptoms between two return-to-play policy groups.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

CDC requests OMB approval for 1 year for this new data collection to examine whether the evaluation and management of youth sports-related concussion varies by type of State legislation or organizational policy governing youth sports organizations. Authority for CDC's National Center for Injury Prevention and Control to collect these data is granted by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A). This act gives Federal health agencies, such as CDC, broad authority to collect data and carry out other public health activities, including this type of study.

Background

In 2009, Washington State was the first to enact legislation focused on reducing the overall impact of concussions (a type of traumatic brain injury or TBI) among youth athletes. Known as the Lystedt Law, this State law includes four key elements regarding education and management of youth athletes participating in school sports. These elements include:

1. Parents and athletes must sign a concussion information sheet before the start of each sports season in order to participate.
2. Educational materials on concussion in sports provided to coaches, parents, and athletes

3. An athlete who exhibits signs and symptoms of a concussion must be removed immediately from practice or play (“remove from play,” or RFP).
4. To return to play (RTP) after a concussive event, an athlete must have written clearance from a licensed healthcare provider trained in the evaluation and management of concussions.

Since the passage of the Lystedt Law, all 50 States and the District of Columbia (DC) have enacted similar legislation related sports-related concussions among youth athletes. These laws are primarily focused on improving concussion identification and management in an attempt to prevent the potential health consequences of continuing to play while exhibiting signs and symptoms of a concussion. Although there is considerable variation among State requirements, these laws generally include the four of the elements found in the Lystedt law. Harvey (2013) systematically searched and identified various components of the State laws and was able to code these components. The coded law information is available through Temple University’s Public Health Law Research Web portal [1, 2].

To best understand how policies can affect the key variable of interest—return-to-play decisions(e.g., returning to play while symptomatic vs. asymptomatic), we have classified the State laws into one of two groups:

1. Laws with no specific requirements governing an athlete’s RTP after a suspected concussion injury in a game or practice (No Specific RTP).
2. Laws that require clearance from a licensed healthcare provider with training in the evaluation and management of concussions prior to allowing an athlete to RTP after a suspected concussion injury in a game or practice (Specific RTP).

It is critical to note that these laws vary in their applicability to youth sports activities. For instance, some State laws may only apply to school-sponsored athletic activities, whereas others may include youth athletic organizations.

In States where the law does not cover all organized youth athletic activities, organizations such as the United States Youth Soccer Association (USYSA) and their State associations have to decide which policies to use to govern play under their jurisdiction. If a State law only extends its coverage to school-based athletics, club and recreational teams and organized leagues must decide on their own whether to follow the State law or to implement a different policy. For example, USYSA specifies RTP requirements that apply during national events; however USYSA State associations enforce their own RTP requirements for other events and regular league play. The RTP requirements enforced by each USYSA State association are subject to State law. Specifically, if a USYSA State association is located within a State whose law includes youth athletic organizations, then the RTP policy enforced by the State association must include, at minimum, the RTP requirements outlined by the State law. Thus, when analyzing how RTP decisions and youth outcomes are associated with policy, it is important not only to consider the State policy but also the organizational policies that govern play. Attachment Q provides a break down of the selected States’ legal RTP requirements, whether youth organizations are subject to the State law, the USYSA RTP requirements, and which policy governs USYSA play within that state.

In an pilot study of the Lystedt Law, Rivara et al. (2014) (the “Lystedt Law study”) found that 3 years after the passage of the Lystedt Law, girls soccer coaches were receiving substantial concussion education, often through multiple modalities. Moreover, high school coaches scored on average more than 95 percent on a concussion knowledge test administered by the research team. However, concussion education for parents and athletes was found to be less extensive [4].

Aside from the Lystedt Law study [1], there has been no systematic examination to date on the impact of youth sports concussion management policies on how RTP is handled after an injury. Moreover, there has been no systematic analysis of whether these policies are associated with improved concussion knowledge and training for coaches, athletes, and parents.

One of the primary challenges in assessing the relationship between the concussion management policies and their impact on RTP decisions and management is the lack of timely and accurate data on youth sports-related concussions. Because youth athletes may not recognize that their symptoms are consistent with a concussion and may fail to report them, team and medical personnel may have an inaccurate picture of how many of these injuries occur. Moreover, injured athletes may be reluctant to report symptoms for fear of being kept out of competition. Data from the Lystedt Law study indicate that a concussed athlete’s coach was aware of the injury only 40 percent of the time [3].

By collecting data on concussions directly from the athletes and parents, we believe that, based on the findings from the Lystedt Law pilot study, we can greatly improve the understanding of the effectiveness of RTP policies at the state and organizational level. Given the current data limitations on youth sports-related concussions, any study that relates the State laws and organizational policies to concussion evaluation and management will require new, primary data collection. This information collection request would attempt to address this objective.

This information collection request will also allow for a supplementary assessment of how education and awareness efforts that attempt to reduce harm caused by concussion can complement State laws and youth organization policies. CDC’s Heads Up education campaign (<http://www.cdc.gov/concussion/HeadsUp/youth.html>) focuses on raising awareness of the signs and symptoms of concussions and improving the management of concussions among youth athletes. The campaign includes materials for health professionals, sports coaches, school professionals, and parents and guardians. CDC has partnered with more than 85 organizations, including health and medical organizations, school organizations, youth- serving organizations, sports organizations, and Federal agencies. There has been tremendous saturation of CDC Heads Up materials: Since the beginning of the initiative, more than 3 million print copies of the Heads Up materials have been disseminated, and more than 1.3 million high school coaches have completed the National Federation of State High School Associations Concussion in Sports Training that was developed in partnership with CDC Heads Up. Numerous other youth sports coaches have been trained through other Heads Up courses. The CDC Heads Up materials are freely available to sports organizations for adoption and implementation within their own unique programs. Thus, in addition to exposure to sports organization policies driven by State legislation, coaches, athletes, and parents may be exposed to local education and awareness efforts. It is important to understand exposure to the CDC Heads Up education and awareness program as well as State policy.

In summary, this data collection will examine whether the evaluation and management of youth sports-related concussions varies by type of State legislation or organizational policy governing youth sports organizations such as USYSA. This study has been directly informed by the Harvey (2013) analysis of State policy components, which allowed for the development of the strata for sampling and analysis. In addition, this study has been directly informed by the previous pilot study in Washington State (the Lystedt Law study).[3] The Lystedt Law study has provided insights on assessment of outcomes, sampling strategies, and expected effect sizes that can inform a more robust evaluation of State laws and youth sports organization policies.

A.2. Purpose and Use of the Information Collection

The primary purpose of this proposed study is to assess whether the evaluation and management of youth sports-related concussions varies by type of State legislation and sports organization policy governing youth sports organizations, as described in A1 above. The goal of the State youth sports concussion laws and youth organization concussion policies is secondary prevention. That is, these policies seek to promote awareness, increase knowledge on the signs and symptoms of concussion, and encourage youth athletes to seek proper diagnosis and treatment if a concussion is suspected to prevent further injury. We will use the data collection to investigate the following research question: Does the frequency of concussed athletes returning to play while still experiencing symptoms vary between States with policies (at the State or organizational level) that have no specific RTP requirements (No Specific RTP) and those that require RTP clearance from a healthcare professional trained in concussion evaluation and management (Specific RTP)? In addition to this primary research question, this data collection will allow CDC to gain additional knowledge on:

1. The training of club soccer coaches, parents, and youth athletes in concussion recognition and management, including exposure to CDC Heads Up training and education/awareness efforts; and
2. The level of concussion knowledge among club soccer coaches, parents, and athletes.

The data collected during this study will produce an estimate of the number of boys and girls ages 14–18 playing soccer on organized club and recreational teams that experience concussive events and how many of them return to play while still experiencing symptoms. The study also will provide data that will allow for an analysis of how characteristics such as demographics; past history of concussions, and the use of concussion education materials by the athlete, parent, and coach correlate with:

- The probability of returning to play after a concussion injury while still symptomatic; and,
- Concussion knowledge

In addition to identifying the prevalence of injured athletes who return to play while continuing to experience symptoms of a concussion, this study will seek to identify important predictors of this behavior. The proposed data collection will obtain high-quality data from a national sample that will produce valuable information for coaches, parents, athletic trainers, medical

professionals, school officials, other researchers, and decision makers interested on ways to improve evaluating and managing risks associated with sports-related concussion. Moreover, the data collected during this study will be used to help CDC strengthen the quality and reach of its existing flagship sports concussion education initiative—Heads Up. In the absence of the proposed data collection, CDC will be forced to rely on incomplete datasets that suffer from underreporting.

During recruitment, participant names and contact information will be obtained to facilitate follow up throughout the study and to create unique identifiers for each study participant. Participants will use the unique identifier to respond to the study, allowing the research team to keep participants' responses and personally identifiable data in separate databases with limited access.

Data on participants' age, gender, race, ethnicity, and soccer experience will be collected on the preseason survey (Attachments C, D, and E). Race and ethnicity will be collected in accordance with OMB requirements.[5] These data will allow the research team to investigate the relationship between these demographic characteristics and the outcomes of interest.

The preseason survey will also collect data on concussion education/training—including the use of the Heads Up program—as well as concussion knowledge, attitudes, and behaviors. The research team will use these data to examine differences in these characteristics between the coach sample and the athlete-parent sample.

In the weekly surveillance reports collected from athletes and parents over a 10-week period, the research team will gather data on the number of athletic exposures faced by the athlete the previous week as well as any injuries and TBI symptoms they may have suffered. These data will be used to identify potential concussions for follow-up. Researchers will contact injured athletes who have been determined to have potentially suffered concussions to discover whether they return to play with symptoms or sit out until any symptoms are resolved.

A.3. Use of Improved Information Technology and Burden Reduction

We will use an online survey tool to collect preseason baseline data from coaches, athletes, and the athletes' parents or guardians. A paper survey instrument will be available to participants who prefer to respond in that manner, although based on the Lystedt Law study, we expect only a small proportion of respondents will choose this option.

Weekly surveillance data collection from athletes and parents will be done over the phone using an interactive voice response (IVR) system. This brief survey will allow athletes and parents to respond at their convenience using an automated phone system. Further follow-up of injured athletes and their parents will be completed through phone interviews (Attachment H).

A.4. Efforts to Identify Duplication and Use of Similar Information

At this time, no Federal agency has conducted a study similar to the one we propose. However, there have been non-Federal efforts to collect data on youth sports-related concussions. These non-Federal data collection efforts are often limited for the following reasons:

- A significant problem with ascertaining how youth sports-related concussion evaluation and management varies across States is that no good, large-scale database on concussions exists.
- Only a small and thus potentially highly biased sample of youth athletes with sports-related concussions seeks care in hospital emergency departments (EDs) [6,7,8] and there is no universal standard definition used by EDs to diagnose concussions. Additionally, national administrative databases such as the National Electronic Injury Surveillance System,[8] Healthcare Cost and Utilization Project,[9] have limitations. Some of these limitations include limited sample sizes, lack the ability to obtain sports-related concussion visits outside the ED (e.g., physician offices), and they do not allow for the accurate determination if the visit was sports-related and at what level (e.g., school-based, youth sports organization based, recreational).
- Dr. Dawn Comstock has developed the Reporting Information Online Surveillance System for high school sports (HS RIO) [9,11,12,13]. However, it is limited to approximately 100 high schools with certified athletic trainers (CATs), athletic trainers are not present at all practices or competition, and reporting of concussions into the system depends on CAT uploading data based on observed events and athlete reporting of symptoms. HS RIO is also limited to school based athletics. Given its design, the HS RIO system would not provide data on the variables proposed for study in this project.

Given the limitations of the existing data, we will instead use primary data collection. For the following reasons, our approach includes club and community sports teams rather than school-based teams:

- More athletes ages 14–18 are enrolled in club and community teams than in high school teams, and more coaches are involved.
- There is somewhat less structure to their oversight than in school-based teams.
- Club and community teams tend to be more accessible than school-based teams. As such, the process for gaining approval for the study and recruiting participants should be easier and more efficient than doing a similar study using school-based teams.
- The recruitment process will be facilitated because coaches, athletes, and parents communicate primarily via e-mail. The research team has already established a formal partnership with the premier club association in the country—the US Youth Soccer Association—through a formal written agreement to assist in participant outreach, recruitment and follow up once the study is approved by OMB.

This study will also allow us to examine the utility of available concussion training and education materials, such as CDC’s national Heads Up initiative (HUI). Previous investigations have focused on how exposure to Heads Up materials and training influences attitudes, beliefs, and intended behavior change. [14,15,16,17] However, to date, there have been no attempts to evaluate the behavior or health outcome effects of CDC’s HUI, primarily because of the lack of

data on the program's reach, adoption, or implementation. This makes primary data collection a necessity.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

As described in section A.4, existing data to address the research questions examined in this study are limited. Not conducting the proposed collection would force researchers to rely on incomplete data, limiting the usefulness of any conclusions. The proposed study design includes a preseason survey of coaches, athletes, and their parents related to their knowledge and understanding of concussions and a 10-week surveillance phase during which data would be collected weekly from athletes and their parents. Because athletes who return to play while symptomatic are the main population of interest in the proposed study, it is critical for the research team to identify and confirm concussion injuries. Employing techniques utilized in the Lystedt Law study, the weekly surveillance reports taken of athletes and their parents will provide an accurate and timely accounting of injuries.[3] Each week, athletes and their parents will call into an automated system to report on the number of practices and games in which the athlete participated that week, along with any injuries and concussion symptoms they may be experiencing. The study has designed a protocol to follow up with athletes and their parents should they report symptoms that might be indicative of a concussion. Final determination of whether an athlete has suffered a concussion will be made by a medical doctor on the research team after reviewing all reported symptoms and the follow-up information. Suspected concussions will be reported to athletes and their parents. Based on the results from the Lystedt Law study, we believe this approach will improve the identification of concussion injuries while minimizing the risk of recall error. Waiting to collect data until the end of the playing season may result in athletes failing to report minor injuries or misremembering the severity of symptoms, thus affecting the quality of the data. The brief weekly reports will provide real-time, high-quality data while imposing a low burden on respondents.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A.8.1. Federal Register Notices

A 60-day Federal Register Notice was published in the *Federal Register* on April 30, 2014, vol. 79, No. 83; pp. 24431–32 (see Attachment B). One nonsubstantive public comment was received during this review time (Attachment B), and the standard CDC response was sent.

A.8.2. Efforts to consult outside the agency

The study will be pursued in collaboration with a team of experts from the University of Washington who conducted the study on the Lystedt Law in Washington, funded by the Robert Wood Johnson Foundation Public Health Law Project. The Principal Investigator and researchers from the University of Washington for this proposed study also led the research team on the study of the Lystedt Law.

The methodology proposed by the contractor to CDC for this study is based substantially on the approach employed in the Lystedt Law study. We believe that the involvement of these researchers offers CDC the opportunity to build on the investigators' knowledge of the topic and experience with recruiting participants, data collection, and data analysis of a comparable study. This approach will also involve collaboration with USYSA to support the research team's participant recruitment and data collection efforts.

University of Washington Team of Experts

Frederick P. Rivara, M.D., M.P.H., Seattle Children's Guild Endowed Chair in Pediatrics; Professor of Pediatrics and adjunct Professor of Epidemiology at University of Washington; Chief of the Division of General Pediatrics; Vice Chair of the Department of Pediatrics in the University of Washington School of Medicine.

Ali Rowhani-Rahbar, Ph.D., M.D., M.P.H., Assistant Professor in the Department of Epidemiology at University of Washington, School of Public Health.

Sara P.D. Chrisman, M.D., M.P.H., Assistant Professor in the Division of Adolescent Medicine, Department of Pediatrics, University of Washington; Seattle Children's Hospital; and the Harborview Injury Prevention and Research Center.

Stanley Herring, M.D., Clinical Professor in the Departments of Rehabilitation Medicine, Orthopedics and Sports Medicine, and Neurological Surgery; Director of Spine, Sports and Musculoskeletal Medicine at University of Washington; Co-medical director of the Seattle Sports Concussion Program; and member of the National Football League's Head, Neck and Spine Committee.

A.9. Explanation of Any Payment or Gift to Respondents

No payments or gifts of any kind will be provided in exchange for survey participation.

A.10. Privacy Impact Assessment Information

The applicable System of Records Notice (SORN) is 09-20-0160, "Records of Subjects in Health Promotion and Education Studies."

A.10.1 Overview of the Data Collection System.

This evaluation of State youth sports-related concussion laws and organizational policies will investigate the relationship between policies governing the evaluation and management of sports-related concussions among youth athletes participating in USYSA and what parents and athletes report about the actual handling of youth athletes who experience a suspected concussion. Information will be collected via self-report surveys administered to coaches, athletes, and their parents or guardians in 27 selected States (see Part B for a detailed description of the sampling strategy). Coaches, athletes, and parents will all complete an online preseason

survey. Athletes and parents will then complete a brief surveillance report once a week for 10 weeks using an automated phone system. Athletes who report suffering a hit with associated concussive symptoms and the parent of such an athlete will be administered an additional phone follow-up interview about the athlete's symptoms and management.

Information about the RTP requirements of the State youth sports-related concussion laws and organizational concussion policies have been obtained using data collected from Temple University's Public Health Law Research (PHLR) Web portal [2], State legislature Web sites, and USYSA State soccer association Web sites. The PHLR Web site provides data on the requirements of several components of State youth sports-related concussion laws as outlined by Harvey (2013). These data were used as the basis for determining the appropriate RTP stratum for each State. When gaps about the laws were found in the PHLR, State legislature Web sites were consulted for clarification. USYSA State association Web sites were also consulted to identify concussion policies governing youth soccer teams within the State that may differ from the parent State law. This information allowed us to determine which policy (State or USYSA) applied to each State sampled for this study.

Data collected will be stored physically and electronically at the office of the contractors collecting the data. Hard copies of data will be stored in locked file cabinets. Electronic data will be secured in encrypted databases on password-secured data platforms. Electronic de-identified databases will be transferred to CDC upon completion of the contract. Any hard copies of data collected will be kept in a locked cabinet at the contractor's office for 5 years after completion of data collection, as specified by Federal guidelines.

A.10.2 Items of information to be collected.

The preseason surveys administered to coaches, athletes, and parents collect information about concussion and TBI knowledge, attitudes, and behaviors; history of concussions; and use and awareness of concussion education materials. The weekly surveillance report is designed to capture concussive events the athlete experiences during the season. This report will collect information about the presence of concussion symptoms after a collision as well as number of games and practices played that week (athlete exposures). When an athlete's symptoms indicate that he or she may have suffered a potential concussion injury, the research team will follow up to confirm the symptoms reported and determine the severity of symptoms. During the follow-up interview, the research team will notify parents and athletes if symptoms reported to the IVR are identified as those consistent with a possible concussion. The interviewer will suggest that any medical concerns that arise should be addressed by the child's doctor. Further action will be left up to the parent. A medical professional on the research team will review the information to make a determination as to whether the athlete may have experienced a concussion. In addition, the research team will obtain information related to any medical treatment sought and the management of the injury, whether the athlete was removed from play, whether he or she has returned to play, and under what conditions the athlete returned to play.

Personally identifiable information will be collected from coaches, athletes, and parents to contact participants to administer surveys. Identifiable information will also allow the research team to identify athlete/parent pairs and track athletes and parents over the course of the season and to link athletes to coaches and teams. This will require collecting the participant's name,

telephone number, e-mail address, and soccer team name. Unique identifier codes will be created and given to each coach, athlete, and parent participant; one tracking database will contain the participants' personally identifiable information, a second database will contain the participants' actual survey data identified only by the unique identifier code, and a third database will contain the link between the participant identity (participant name, phone number, e-mail address, team, and State) and the unique identifier code. These data will be collected and stored by the contractor during the contract.

A.10.3 How the information will be shared.

All publication of this data will be in aggregate form. No respondent would be able to be identified from the information provided to the public at the aggregate level. In addition to data and reports shared with CDC, results from the current study will also be disseminated in various ways that may include publication in peer-reviewed journals and presentations to a wide range of audiences: injury researchers, coaches and athletic trainers, policy and/or governing organizations representing the athletic community, and the public health community.

A.10.4 Impact of proposed collection on respondent's privacy.

The proposed collection will have a minimal impact on respondents' privacy. The respondents' names, e-mail addresses, and phone numbers will be collected and used to facilitate survey responses and schedule interviews as needed. All data collection and data management staff will be well trained in maintaining information security at all stages of the data collection and data management process. Protocols for data collection will ensure that names, addresses, and all other personally identifiable information are kept secure during all stages of data collection. Recruitment lists and survey data will be kept in locked, secure facilities by the contractor.

Data will be stored in encrypted databases on password-secured data platforms. Data will be linked only with a unique identifier code and be kept in a separate database from personally identifiable data, and a third database with limited personnel access will contain information linking participants with their unique identifier codes. Identified data will be stored and maintained by the evaluation contractor, and only de-identified data will be given to CDC at the conclusion of the contract. The contractor will be required to destroy all data within 6 months of the end of the contract, provided that the data have been safely and successfully handed over to CDC and CDC has had an opportunity to verify the accuracy and completeness of the data.

A.10.5. Whether people are informed that providing the information is voluntary or mandatory.

Respondents will be informed that their participation in any or all parts of the study is voluntary, as indicated in the informed consent information that will be provided to participants (Attachment N).

A.10. 6. Opportunities to consent, if any, to sharing and submission of information.

Information about the Web-based preseason survey and the weekly IVR reports will be distributed to each parent on selected teams (see survey samples in Attachments E and G). Each

parent will be asked to provide his or her name and contact information to be used for follow-up and weekly IVR reminders (Attachment R). At this time, parents will also be presented with an online informed consent document (Attachment N) and will be asked to click a check-box to indicate they are voluntarily agreeing to participate in the study. Parents will be asked to provide contact information for their athlete (child) and to provide consent for their athlete to participate by clicking a separate check-box if their athletes are under age 18. Athletes will be contacted directly to obtain their consent/assent. Using the contact information provided by parents, the research team will send study invitations to athletes. The study invitation will include a link to an online informed consent document (Attachment N). Athletes will be asked to click a check-box indicating they are voluntarily assenting (if under age 18) or consenting (in age 18 or over) to participate in the study. No athlete under the age of 18 will be allowed to participate in the study without parental consent, and no athlete under the age of 18 will be expected to participate in the study without providing formal assent. All participants will be provided with informed consent information (Attachment N) detailing how information will be shared. Data on the coaches and athlete-parent dyads will be publicly shared only in aggregate. However, information collected from individual dyads may be shared with both members (parent and athlete) of the dyad. For instance, if the researchers discover an athlete-study participant has a potential concussion, that information will be shared with both the athlete and the parent.

A.10.7. How the information will be secured.

Securing data collected during the study is among our highest priorities. All data collected during this study will be collected and maintained by the evaluation team on a secure server with restricted access during the study period. A copy of the final de-identified dataset, survey instruments, and final analysis will be prepared and delivered to the CDC Contracting Officer's Representative as part of the final report.

All data collection and data management staff will be well trained in maintaining information security at all stages of the data collection and data management process. Protocols for data collection will ensure that names, phone numbers, addresses, and all other personally identifiable information are kept secure during all stages of data collection. Recruitment lists and all survey data will be kept in locked, secure facilities by the contractors. Data will be stored in encrypted databases on password-secured data platforms. Data will be linked only with a unique identifier code and be kept in a separate database from personally identifiable data, and a third database with limited personnel access will contain information linking participants with their unique identifier codes.

Respondents will receive a randomly generated identification number that will be used to complete the online and phone surveys. The database linking these identification numbers to participant data will only be available to a limited number of evaluation contractor staff. Identified data will be stored and maintained by the evaluation contractor, and only de-identified data will be given to CDC at the conclusion of the contract.

The contractor will employ database security measures compliant with CDC information security guidelines, including ITSO Encryption Best Practice (Version 1.00.11 of September 21, 2010) and National Institute of Standards and Technology (NIST) Guide to Protecting the Confidentiality of Personally Identifiable Information (NIST Publication 800-122). Databases

will be encrypted and kept on password-secured platforms, and hard-copy data will be kept in locked storage cabinets. At the end of the contract, the evaluation contractor will give CDC the de-identified database as a contract deliverable. Data deliveries to CDC will be encrypted in compliance with Federal Information Processing Standard (FIPS) 140-2, Level 2. The contractor will destroy all the data within 6 months of the end of the contract, after it has been safely and successfully handed over to CDC and after CDC has had an opportunity to verify the accuracy and completeness of the data. Only selected people on the research team (e.g., database manager) will have access to the tracking database and the survey data database. Fewer identified people at the contracting firm will have access to the third database linking participants with their unique identifier codes.

A.10.8. Whether a system of records is being created under the Privacy Act.

This project is subject to the Privacy Act. The applicable System of Records Notice (SORN) is 09-20-0160, "Records of Subjects in Health Promotion and Education Studies."

Institutional Review Board Approval

The CDC NCIPC Human Subject Coordinator has determined that CDC is not engaged in this research as all CDC employees will not obtain data by intervening or interacting with participants and will not have access to identifiable (including coded) private data or biological specimens; therefore, approval by the CDC Institutional Review Board (IRB) is not required (Attachment L2). The contractor has addressed prior OMB comments on the IRB approvals (Attachment L). New revised IRB approval has been obtained by the contractor (see Attachment L1).

A.11. Justification for Sensitive Questions

The weekly reports and follow-up interviews with injured athletes may contain potentially sensitive questions. We will ask about the occurrence of any concussion or head injury as well as any symptoms. Athletes who do not want their parent or coach to know about any injury for fear they will not be allowed to continue to participate may withhold this information from us. However, because symptom-free return to play is a key outcome of interest, it will be necessary to gather information on injuries and symptoms. We will explain to athletes and parents at the outset of the study that their responses will not be shared with the coach. This will be important to ensure honest reporting, especially by the athletes. Notifying coaches of an athlete's potential concussion could not only affect the willingness of athletes to report concussion symptoms, but would also violate their privacy by sharing their medical information with someone other than a parent/guardian.

A.12. Estimates of Annualized Burden Hours and Costs

Burden estimates for hours and costs were derived based on the experience of the members of the research team in using similar data collection instruments in their Lystedt Law study. We have also taken into account the fact that revisions to the preseason survey instruments have resulted in a slightly shorter survey than the one used in the Lystedt Law study. The number of

respondents was based on the sampling plan and power analysis (supporting statement part B) for the main hypotheses.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
USYSA Soccer Coach	Preseason survey (Attachment C)	180	1	10/60	30
Parent	Preseason survey (Attachment E)	2,025	1	10/60	338
Parent	Weekly surveillance report (Attachment G)	1,518	10	3/60	759
Parent	Injury follow-up survey (Attachment H)	683	1	10/60	114
Athlete	Preseason survey (Attachment D)	2,025	1	10/60	338
Athlete	Weekly surveillance report (Attachment F)	1,518	10	3/60	759
Athlete	Injury follow-up survey (Attachment H)	683	1	10/60	114
Total					2,452

The respondent burden has been estimated based on the number of respondents enrolled in the study, the number of times each of these respondents needs to be contacted, and the estimated amount of time required for a respondent to provide the requested information. The total estimated burden for this request is 2,452 hours.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
USYSA Soccer Coach	Preseason survey (Attachment C)	180	1	10/60	30	\$24.21	\$726.30
Parent	Preseason survey (Attachment E)	2,025	1	10/60	338	\$24.21	\$8,182.98
Parent	Weekly surveillance report (Attachment G)	1,518	10	3/60	759	\$24.21	\$18,375.39
Parent	Injury follow-up survey (Attachment H)	683	1	10/60	114	\$24.21	\$1,839.96
Athlete	Pre-season survey (Attachment D)	2,025	1	10/60	338	\$7.25	\$2,450.50
Athlete	Weekly surveillance report (Attachment F)	1,518	10	3/60	759	\$7.25	\$5,502.75
Athlete	Injury	683	1	10/60	114	\$7.25	\$826.50

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
	follow-up survey (Attachment H)						
Total							\$37,904.3

The respondent burden has been estimated based on the number of respondents enrolled in the study, the number of times each of these respondents needs to be contacted, and the estimated amount of time required for a respondent to provide the requested information. This calculation of the total amount of time required of the respondents is then multiplied by an estimated hourly wage for the respondent population affected by the particular data collection instrument/processes. The product of the total amount of time required and the applicable estimated hourly cost to each respondent yields an estimate of the total respondent cost across multiple data collection instruments/processes. Given the age range of the athlete respondents, the Federal minimum wage was used to calculate the respondent cost for that group. The respondent cost for coaches and parents was calculated using the average hourly earnings for January 2014, as reported by the Bureau of Labor Statistics [18]. Because the current study will include adults from many industries and professions and can include respondents from many States and Washington, DC, a national average was used as an estimate. Total respondent cost for this evaluation is \$37,904.38.

A.13. Estimates of Other Total Annualized Cost Burden to Respondents and Record Keepers

Respondents will incur no capital or maintenance costs.

A.14. Annualized Cost to the Federal Government

Two types of government costs will be incurred: (1) contracted data collection, and (2) government personnel. The total cost to the Federal government is \$707,281.27.

CSR, Incorporated, and its partners, the University of Washington and Avar Consulting, Inc., have assigned a Project Manager, a Principal Investigator, Co-Principal Investigators, Survey Methodologists, an Epidemiologist, a Statistician, Research Analysts, and Research Assistants to plan, conduct, and oversee this data collection. The contractor costs for this project are \$696,361.12.

The costs for CDC personnel are \$10,920.15.

Item	Cost
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Federal Employee Monitoring—Science 5% of 104,403.00	\$5,220.15
Federal Employee Monitoring—Budget 5% of 114,000.00	\$5,700.00
CDC TOTAL	\$10,920.15

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation, Analysis, and Publication, with Project Schedule

Quantitative measures, including proportions and means, will be used to describe findings from the surveys of coaches, athletes, and parents regarding their concussion knowledge and attitudes. We will use the data to answer the key research question: are differences in State and organizational youth athletic policies concerning the evaluation and management of concussion injuries associated with the probability of athletes returning to play while still injury symptomatic?

The analysis will involve discerning whether there is a statistically significant difference in RTP with symptoms between the two groups. We will use both bivariate and multivariate techniques to analyze the data. For example, we plan on using both multiple and simple logistic regression analysis as well as contingency tables to analyze whether differences exist between the groups.

Using the two-group design, we also will examine differences in concussion training, education, and knowledge. Do coaches, parents, and athletes in the robust RTP group have greater concussion knowledge than the comparable populations in the No RTP group? Are there differences in the types and amount of exposure to concussion training and education between the two groups? We will use descriptive, bivariate, and multivariate analyses to examine differences between the two groups. We also will stratify the analysis to examine subpopulations—for example, between group differences for coaches—where sufficient sample sizes exist.

Finally, we will assess the scope, reach, and usefulness of the CDC Heads Up Initiative among the subpopulations included in the study. We will investigate differences in exposure to the HUI between subgroups within the samples. Research questions will include: (1) Have coaches had more exposure to HUI than parents or athletes? (2) Are there gender, race, or ethnicity differences in the exposure to HUI among the study group? (3) Is there any association between exposure to HUI and concussion knowledge among study population?

A time schedule for this study with deadlines and publication dates is presented below.

Project Time Schedule

Activity	Deadlines and Publication Dates
Letters sent to respondents	Within 1 month of OMB approval
Data collection	2–6 months after OMB approval. Data collection must coincide with the fall soccer season, which may begin as early as August.
Data validation	7–8 months after OMB approval
Analyses	9–12 months after OMB approval
Final report	13–14 months after OMB approval

The research team will work with CDC to develop reports for publication following data collection and analysis. These reports may be published through a number of channels, including peer-reviewed journals, CDC’s Website, and the contractor’s Website. Attachment O includes sample table shells to illustrate the analysis that we plan on conducting using the data we will collect. These table shells are based on tables presented as part of the previous Lystedt Law study. Other tables not depicted in the attachment may also be generated.

A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

1. Harvey, H.H. (2013). Reducing traumatic brain injuries in youth sports: youth sports traumatic brain injury state laws, January 2009–December 2012. *Am J Public Health*, 103, 1249–1254.
2. Public Health Law Research. (December 31, 2014). Youth Sports Concussion Laws Map. Retrieved from <http://lawatlas.org/query?dataset=sc-reboot>.
3. Rivara, F.P., Schiff, M.A., Chrisman, S.P., et al. (2014). The effect of coach education on reporting of concussions among high school athletes after passage of a concussion law. *Am J Sports Med*, 42(5), 1197–1203.
4. Chrisman, S.P., Schiff, M.A., Chung, S.K., et al. (2014). Implementation of concussion legislation and extent of concussion education for athletes, parents, and coaches in Washington State. *Am J Sports Med*, 42(5), 1190–1196.
5. Agency for Healthcare Research and Quality. (October 2014). Chapter 3: Defining Categorization Needs for Race and Ethnicity Data: Race, Ethnicity, and Language Data: Standardization for Health Care Qu. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from <http://www.ahrq.gov/research/findings/final-reports/iomracereport/reldata3b.html>
6. Bazarian, J.J., McClung, J., Cheng, Y.T., Flesher, W., & Schneider, S.M. (2005). Emergency department management of mild traumatic brain injury in the USA. *Emerg Med J*, 22(7), 473–477.
7. Meehan, W.P., 3rd, & Mannix, R. (2010). Pediatric concussions in United States emergency departments in the years 2002 to 2006. *J Pediatr*, 157, 889–893.
8. Gilchrist, J., Thomas, L., Xu, L., McGuire, C., & Coronado, V.G. (2011). Nonfatal traumatic brain injuries related to sports and recreation activities among persons ≤ 19 years—United States, 2001–2009. *MMWR*, 60(39), 1337–1342.
9. Marar, M., McIlvain, N.M., Fields, S.K., & Comstock, R.D. (2012). Epidemiology of concussions among United States high school athletes in 20 sports. *Am J Sports Med*, 40(4), 747–755.
10. Guise, K.S., Cassidy, L.D., & Oldham, K.T. (2007). Traumatic injury and children: a national assessment. *J Trauma*, 63(6Suppl), S68–80; discussion, S81–86.
11. Covassin, T., Swanik, C.B., & Sachs, M.L. (2003). Sex differences and the incidence of concussion among collegiate athletes. *J Athl Train*, 38, 238–244.
12. Yard, E.E., & Comstock, R.D. (2009). Compliance with return to play guidelines following concussion in US high school athletes, 2005–2008. *Brain Inj*, 23, 888–898.
13. Rechel, J.A., Yard, E.E., & Comstock, R.D. (2008). An epidemiologic comparison of high school sports injuries sustained in practice and competition. *J Athl Train*, 43(2), 197–204.
14. Covassin, T., Elbin, R.J., & Sarmiento, K. (2012). Educating coaches about concussion in sports: evaluation of the CDC’s “Heads Up: Concussion in Youth Sports” initiative. *Journal of School Health*, 82(5), 233–238.
15. Chrisman, S.P., Schiff, M.A., & Rivara, F.P. (2011). Physician concussion knowledge and the effect of mailing the CDC’s “Heads Up” toolkit. *Clinical Pediatrics*, 0009922811410970.
16. Sarmiento, K., Mitchko, J., Klein, C., & Wong, S. (2010). Evaluation of the Centers for Disease Control and Prevention's concussion initiative for high school coaches: “Heads Up: Concussion in High School Sports.” *Journal of School Health*, 80(3), 112–118.

17. Sawyer, R. J., Hamdallah, M., White, D., Pruzan, M., Mitchko, J., & Huitric, M. (2008). High school coaches' assessments, intentions to use, and use of a concussion prevention toolkit: Centers for Disease Control and Prevention's "Heads Up: concussion in high school sports." *Health Promotion Practice*, 11(1), 34–43.
18. Bureau of Labor Statistics. Table B-3: Average hourly and weekly earnings of all employees on private nonfarm payrolls by industry sector, seasonally adjusted [Table]. Accessed February 20, 2014.