SUPPORTING STATEMENT: PART A

OMB No. 0920-XXXX

VALIDATION OF A NEW CASE DEFINITION FOR PARENT- OR SELF-REPORTED TRAUMATIC BRAIN INJURY (TBI)

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A. SUMMARY TABLE

Goal of the study:

The goal of this Case Definition Validation Study is to test the validity of a three-tiered case definition designed to assess whether a TBI was sustained among adults and children during the last 12 months using parent- and self-report.

Intended use of the resulting data: Understand whether the proposed case definition and its underlying hypotheses are reflective of the data collected. In addition, the analysis should illuminate the extent to which current databases over and under estimate current TBI estimates. If validated, the new case definition will be communicated to health care professionals and researchers.

Methods to be used to collect data:

A questionnaire will be administered to a varied national sample of both adults and children through a household, random digit dial telephone survey utilizing both landline and cellphones. Adult respondents will be asked about their own TBI history during the past 12 months, and adult respondents with children 5-17 years of age will also serve as proxy reporters and answer questions about their children's TBI history during the past 12 months. Adolescents 13-17 years of age will be asked directly about their own TBI history during the past 12 months and will be offered both telephone and web options as response modes.

How data will be analyzed:

Comparisons of means (e.g. ANOVA, t-test) will be used to analyze differences in severity indicators (e.g. school or work functioning) across Tier 3 TBI, Tier 2 TBI, Tier 1 TBI and non-cases. Non-parametric tests (e.g. Kruskal-Wallis, Wilcoxon Rank-Sum) will be used where

A. JUSTIFICATION

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

The Centers for Disease Control and Prevention (CDC) requests Office of Management and Budget (OMB) approval for two years for this NEW data collection to validate a new case definition for parent- or self-reported traumatic brain injury (TBI). CDC's authority to collect information for this preliminary step in the development of the TBI Surveillance System is provided by Section 301 of the Public Health Service Act (42 U.S.C. 241) [280-1a] (Attachment A-1). More recently, the Traumatic Brain Injury Reauthorization Act of 2014 authorizes traumatic brain injury prevention and surveillance systems or registry programs (Attachment A-2).

TBIs are a significant public health concern in the United States. In 2013, TBIs contributed to an estimated 2.5 million Emergency Department (ED) visits, 282,000 hospitalizations, and 56,000 deaths in 2013 (1). These national estimates, however, are likely a significant underestimate of the burden of TBIs in the U.S. because they are based on healthcare administrative data that only capture information on the number of ED visits, hospitalizations, and deaths identified as TBI-related (2, 3). They do not account for: TBIs treated by physicians during office visits or other outpatient settings (2); TBIs that are identified by athletic trainers (4); or undiagnosed TBIs (4-6). The majority of TBIs are mild and may not involve seeking care from a health provider (7), making an accurate estimate of undiagnosed TBIs critical. Given the limitations of identifying TBI in clinical settings, especially mild TBIs, the only way to approach comprehensive estimates of TBI in the United States is through using self-report.

Self-report through a national survey can provide a mechanism for identifying people who are not currently reported in administrative databases such as ED visits, hospital discharges, or death certificate date. However, the validity of self-reported data, including for a case definition of TBI, has not been assessed. Current self-reported data collections of TBI have limitations, in part due to constraints on the amount of space for TBI-related questions. Examples of these include questions that require the respondent to only report about TBIs for which they received a diagnosis (8) or ask about TBIs using single question that includes a list of multiple symptoms (9, 10) that frequently do not include the full range of symptoms that may be experienced following a TBI. This has likely led to underreporting, particularly in the case of mild TBI, if the respondent did not seek care for the injury or their symptoms were not among those assessed. On the other hand, more generalized symptoms such as headaches, nausea, or dizziness may be falsely attributed to a TBI, resulting in false positive cases.

A potential way to ameliorate these challenges is through employing a classification system that utilizes a tiered classification system based on severity of symptoms, number of symptoms, and proximity of symptoms to the head impact to evaluate the certainty that a TBI occurred. This approach has been employed previously in clinical research in order to classify TBIs according to severity and certainty (11). For example, symptoms that indicate disruption of brain functions indicate a high level of certainty that a TBI occurred (e.g., loss of consciousness, altered consciousness or confusion and amnesia) (7, 12) Other symptoms may be associated with TBI, but may not be unique to TBI, and thus will confer less certainty.

The case definition we propose includes three tiers corresponding to the level of certainty (e.g. "Probable" or "Possible") that a TBI occurred. The case definition will be validated based on questions contained within the survey (e.g. diagnosis by a healthcare professional). We will also compare our estimates to external datasets that assess TBI to explore the extent to which current databases over and under estimate current TBI estimates. Additionally, the reliability of parents reporting TBI on behalf of

adolescents 13 to 17 years of age will be assessed. A validated case definition that may result from this collection could potentially be used for future TBI surveillance efforts at CDC, as well as other agencies. We sought feedback about the collection request and received the support of the Department of Defense, the National Institute for Occupational Safety and Health, and the United States Consumer Product Safety Commission.

A.2 PURPOSE AND USE OF INFORMATION COLLECTION

The goal of the proposed data collection is to validate a new case definition for TBI and compare these data to external datasets to explore the extent to which current databases over and under estimate current TBI estimates. Secondarily, we will also examine whether parents can accurately report if their adolescent has sustained a TBI. Given the challenges of identifying patients with mild TBI as compared to moderate and severe TBI, a goal of the TBI case definition is to be comprehensive enough to identify milder cases, while incorporating the assumption that some symptoms confer less certainty that a TBI occurred. Of key importance is that symptoms should result from the head impact and not from other causes (7) and the injury should contribute to physiological disruption of the brain (7, 12). The American Congress of Rehabilitation Medicine (ACRM) definition of mild TBI includes any period of loss of consciousness, any loss of memory before or after the accident, any alteration in mental state at the time of the accident and any focal neurological deficits (12). Similarly, the World Health Organization (WHO) includes one or more of the following as criteria for mild TBI: confusion or disorientation, loss of consciousness for 30 minutes or less, posttraumatic amnesia for less than 24 hours and other transient neurological abnormalities (13). The Mayo TBI Severity Classification System incorporated a category below mild TBI called “symptomatic” or possible TBI, which includes symptoms other than loss of consciousness and amnesia such as blurred vision, dizziness and headache (11). This category allowed for the possibility, but not the certainty, of TBI.

Case Definition for Parent- and Self-Reported TBI

For the purpose of this collection:

Tier 3: Probable TBI corresponds to the highest level of certainty that a TBI occurred as it includes symptoms that indicate physiological disruption of brain function (such as temporary loss of consciousness and/or loss of memory) (11-13).

Tier 2: Possible TBI includes TBIs characterized by symptoms that may or may not indicate disruption of brain function, but when they occur immediately or minutes after impact to the head, increase the likelihood that symptoms are due to TBI (e.g., nausea, headaches) (11).

Tier 1: Delayed Possible TBI includes cases of TBI that only involve symptoms that manifest sometime after the injury. Since it is harder to definitively ascertain whether symptoms that do not appear until sometime after the head impact are due to a TBI, this delay in presentation creates a lower level of certainty that a TBI occurred. Tier 1 also includes behavioral symptoms that do not present immediately after head injury (e.g., difficulty learning new things).

Non-case head injuries include head injuries without symptoms, which are not considered TBI.

Having three or more symptoms in a lower tier will elevate the TBI to the next higher tier because a greater number of symptoms confers greater certainty that a TBI occurred. The case definition is described in detail in Table A.2.1.

Table A.2.1. TBI Case Definition

The proposed case definition requires the report of **a bump, blow or jolt to the head** and the endorsement of at least one sign or symptom as a result of that head injury, with cases delineated further by the Tiers described below.
• **<u>Tier 3.</u> Probable TBI:** At least one of the following symptoms are reported: confusion, memory loss, or loss of consciousness *immediately or in the minutes after injury*, or three symptoms from Tier 2.
• **<u>Tier 2.</u> Possible TBI:** At least one of the following symptoms are reported: nausea, headache, balance problems, blurred vision, or trouble concentrating *immediately or in the minutes after injury*, or three symptoms from Tier 1.
• **<u>Tier 1.</u> Delayed Possible TBI:** At least one of the following symptoms are reported: difficulty learning new things, sensitivity to light or noise, change in temperament, or changes in sleep *sometime after the injury.* Additionally, any Tier 2 symptom that does not develop *in the minutes after the injury* is classified as a Tier 1 symptom due to the possibility that it may be attributable to an event or health condition other than the head injury in question.
• **<u>Non-Cases:</u>** Head injuries with no reported signs or symptoms.

Types of Validation

There are two types of validation employed in this study. Given that certainty and severity vary together (11), construct validity will be tested using the hypothesis that greater severity corresponds to greater certainty that a TBI occurred. As part of this process, we will conduct a sensitivity analysis to examine the appropriateness of using a three symptom threshold to elevate a TBI case to the next highest tier. It is possible that a higher (e.g. four symptoms) or lower (e.g. two symptoms) cutoff will improve construct validity. Sensitivity analyses also will be conducted with previously collected data sources of individuals with TBI that include symptoms and outcomes. Comparisons will be explored by comparing estimates of Tier 3, Tier 2 and Tier 1 TBI to other methods that estimate TBI in national populations (e.g. healthcare administrative datasets and datasets using single questions to assess multiple symptoms). Type of validation assessed using existing external data sources is summarized in Table A.2.2. In addition, we will compare parental report to the adolescent report to ascertain the reliability of having parents report TBI on behalf of adolescents. Indicators of construct validity and the external data sources used in validity exploration are described below, followed by the Specific Aims and Hypotheses.

Construct Validity Indicators

TBI outcomes that serve as indicators of severity include: time to symptom resolution or persistent symptoms (14), time to return to play (15) and hospitalization (16, 17). Other indicators of a more severe outcome include: receipt of post-TBI examination and/or TBI diagnosis (18); having a reason (e.g. cost of examination) other than the perception the head injury was not serious when asked why

they did not seek care or tell anyone (18); and impact to self-reported social, school, and work functioning subsequent to the head injury (19, 20). Summary of survey questions, including indicators of severity are described in Table A.2.3.

Table A.2.2 External Data Sources Used to Test Construct Validity and Compare Estimates

Collection Type	Analysis	Population	Data Source Name	Setting of Collection
Research Study: symptom presentation and outcomes among diagnosed TBI	Construct	Children 5 to 17 years of age	Pediatric Emergency Research Canada network (PERC)	Emergency Department
Research Study: symptom presentation and outcomes among identified TBI	Construct	Children 14 to 18 years of age	High School RIO: Reporting Information Online: National High School Sports-Related Injury Surveillance Study	Organized High School Sports
Healthcare Administrative: Diagnosed TBI	Compare Estimates	Adults and children 5 years of age and older	Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP – NIS)	Hospital
Healthcare Administrative: Diagnosed TBI	Compare Estimates	Adults and children 5 years of age and older	Healthcare Cost and Utilization Project Nationwide Emergency Department Sample (HCUP – NEDS)	Emergency Department
Healthcare Administrative: Diagnosed TBI	Compare Estimates	Adults and children 5 years of age and older	National Electronic Injury Surveillance System – All Injury Program (NEISS – AIP)	Emergency Department
Healthcare Administrative: Diagnosed TBI	Compare Estimates	Children 5 to 17 years of age	Truven Health Analytics MarketScan Research Databases: Medicaid and Commercial Claims	Emergency Department, Urgent Care Centers, Office/Clinic visits and Outpatient visits
Survey: Self-Reported TBI	Compare Estimates	Children 14 to 18 years of age	Youth Risk Behavior Surveillance System (YRBSS), 2017	High School-Based Self-Report

Specific Aims and Hypotheses for the Planned Data Collection

Aim 1: Explore validity of Proposed Case Definition with the Proposed Data Collection

1. Test construct validity by analyzing TBI outcomes that serve as indicators of severity
    a. Tier 3 cases will be associated with greater severity compared to Tier 2 and Tier 1 cases.
    b. Respondents with self-reported Tier 3, Tier 2, and Tier 1 TBIs will be more likely to report a definitive diagnosis, reduced social, work and school functioning, and have a reason for not seeking health care (other than lack of head injury severity) compared to non-cases
2. Test reliability of parents reporting TBI on behalf of adolescents by comparing parent proxy report and adolescent self-reports of TBI in the past 12 months
    a. Concordance of >= .70 and a kappa of >= .66 will be considered evidence of concurrent validity
    b. Concordance will increase with level of certainty as defined by the case definition

Aim 2: Compare Proposed Case Definition Estimates from the Proposed Collection with Externally Collected Data Sources

1. TBI Research Studies: Explore construct validity using existing data sources of study populations diagnosed by clinicians or identified by athletic trainers.
    a. Tier 3 cases will be associated with greater severity compared to Tier 2 and Tier 1 cases.
2. Healthcare Administrative TBI: Explore potential over and under estimation and its sources by comparing 12-month estimates to estimates based on administrative data for diagnosed 12-month TBI
    a. TBIs identified through health care administrative datasets will be comparable to estimates of Tier 3 and Tier 2 TBI
    b. Generate hypotheses about why different measures and approaches to data collection might give different estimates
3. Self-Reported TBI: Explore potential over and under estimation and its sources comparing 12-month estimates to estimates based upon self-reported 12-month TBI
    a. The 2017 National Youth Risk Behavior Surveillance System will be comparable to an estimate that includes Tier 3, Tier 2, and Tier 1 TBIs.
    b. Generate hypotheses about why different measures and approaches to data collection might give different estimates

Details for Hypothesis Testing for the Current Collection

The specific questions in the survey and related hypotheses for the current collection are described Table A.2.3. Associations in the expected direction for Tier 3 TBI, Tier 2 TBI, Tier 1 TBI, and non-cases with indicators of severity will be considered evidence of construct validity.

For testing the reliability of parents reporting TBI on behalf of adolescents, the adolescent report will be considered to be the correct report given that some TBI-related symptoms cannot be seen externally (21) and parents may not have witnessed the event. Concordance and kappa will be computed to assess level of agreement between parent and adolescent. The level of concordance and kappa outlined in our hypotheses above are considered evidence of concurrent validity based on previous work in this area

(22) and inter-rater agreement cutoffs more generally (23), and will allow us to conclude that parents are adequate reporters for TBI among adolescents 13 to 17 years of age. We will also calculate concordance and kappa by tier to assess whether agreement increases with level of TBI certainty.

Details for Hypothesis Testing for the Research Studies

We are using two previously collected datasets to assess construct validity of the Case Definition. The Pediatric Emergency Research Canada network (PERC) is a study of persistent post-concussive symptoms in a clinical setting that includes nine pediatric emergency departments (EDs). Participants in this study presented to the ED with a head injury and were diagnosed with a TBI (n = 3,063) (24). Data were collected from August 2013 through September 2014 and from October 2014 through June 2015. High School RIO: Reporting Information Online, the National High School Sports-Related Injury Surveillance Study is an ongoing study in which participants are assessed by Certified Athletic Trainers. We will include all athletes included in High School Rio who were determined to have sustained a TBI (n = 15,421) (25). Data have been collected every year since the 2005-2006 academic year. Symptoms for cases reported in these studies will be mapped onto the Case Definition and cases will be classified in accordance with the definition. Similar to the proposed data collection, associations between cases with higher level of TBI certainty and indicators of increased severity will be considered evidence of construct validity.

Details for Comparing with National Healthcare Administrative Data

Healthcare Administrative data sources, such as HCUP classify TBIs based on the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) (1). In order to compare HCUP-NEDS, which collects data on ED visits and HCUP-NIS which collects data on hospitalizations, we will restrict our proposed data collections to match the administrative sample population. (see Table A.2.3). HCUP-NIS and HCUP-NEDS also include external cause of injury codes (26), which classify injuries by mechanism, such as falls or motor vehicle crashes. Thus, we also will be able to compare estimates of TBI by mechanism of injury between our proposed data collection and available data sources. (see Table A.2.3). For the National Electronic Injury Surveillance System – All Injury Program (NEISS – AIP), coders abstract data from the ED record, including diagnosis and anatomic region of injury which are used to identify TBI cases. In addition, there is an algorithm developed for NEISS – AIP that identifies injuries as sports- and recreation- related (SRR) and further classifies them according to the specific SRR activity the respondent was engaged in at the time of the injury (3). Further restricting our analysis to SRR TBI will allow us to compare our estimates to estimates of TBIs classified by SRR activity in NEISS—AIP.

Truven Health Analytics MarketScan Research Databases, a source of Medicaid and Commercial Claims that also classifies TBI using the ICD-9-CM cases definition, is not, by design, a nationally representative data source for all healthcare visits. We will restrict this dataset and our sample to those 5 to 17 years of age for a comparison of estimates. We will also calculate Marketscan estimates by type of visit (e.g. emergency department, urgent care center, office/clinic or outpatient) for comparison to our sample, which will be similarly classified using questions on the survey that identify where the respondent sought care for their child (see Table A.2.3).

Details for Comparing with National Self-Reported Data

The Youth Risk Behavior Surveillance System (YRBSS) is a national school-based survey that is conducted every two years. On the 2017 YRBS, a question about SRR concussions was added to the standard questionnaire. The question is preceded by a definition of concussion[1] and asks, "During the past 12 months, how many times did you have a concussion from playing a sport or being physically active?" Response categories range from 0 times to 4 or more times. An additional question available on the YRBS in 2017 addressed specific activity: "During the past 12 months, what were you doing when you had your most recent concussion from playing a sport or being physically active?" Response options included: "I did not have a concussion during the past 12 months from playing a sport or being physically active", "I was playing on a sports team run by my school", "I was playing on a sports team being run by a community group", and "I was playing a sport or being physically active for fun or exercise, but not as part of a school or community sports team." Restricting our analysis to adolescents of high school age (i.e. 14 to 18 years of age) and our estimate to SRR-TBI will allow a comparison to the findings of the 2017 YRBS. For comparison to the YRBS question addressing specific activity, we will calculate estimates based on two questions on our survey that identify whether the respondent was participating in a school-based team sport, a non-school-based sports league, or neither of these (see Table A.2.3).

Overlapping confidence intervals between the estimates produced through the proposed collection with healthcare administrative and self-report data sources will suggest that the estimates are similar.

Specific statistical tests and variables for each hypothesis and comparison are described in Section A.16.

[1] A concussion is when a blow or jolt to the head causes problems such as headaches, dizziness, being dazed or confused, difficulty remembering or concentrating, vomiting, blurred vision, or being knocked out.

Table A.2.3. Summary of Survey Questions, Purpose and Hypothesis Direction and Interpretation

Question(s)	Question(s) Description	Purpose Related to the Case Definition Type of Validity, Comparison or Reliability Assessed	Hypothesized Direction/ Interpretation
Eligibility Landline (ISADLT – PRIVRES)	Verify respondent eligibility	N/A	
Household Roster/Selection Landline (ADTS – THREEADLT	Randomization, assess number of proxy interviews	N/A	
Eligibility Cellphone (CISADLT – UNSAFE)	Verify respondent eligibility, appropriate time to talk	N/A	
Household Roster Cellphone (CPRENUMC – CINFOR)	Assess number of proxy interviews	N/A	
Weighting Demographics (TRANS1 – CELLPH)	Questions used to weight the data	Prepare for comparisons to national estimates.	
Past 12 Months TBI (RECALL – INJTOT)	Whether or not the respondent experienced a head injury in the past 12 months, regardless of whether they sought care	Determination of sustaining a head injury in the past 12 months	
Injury Description (PREINTX – INJOPNB)	Brief description of injury in the case of multiple injuries – used to prompt the respondent	Increase accuracy of survey through making clear to the respondent which injury is being discussed.	
Timing of Injury Occurrence	Assessment of recall bias	Internal Validity	This variable will allow us to test the feasibility of using a 6-month recall

(QYEAR – SIXMO)			period in a future data collection effort (vs. the proposed 12 month period). Specifically, we will compare the size of 6-month vs. 12 month estimates. Also, we will compare the characteristics (e.g., severity) of head injuries within 6 months of the survey to those 6-12 months preceding the survey to identify whether there are differences in the type of TBIs that are recalled over a longer recall period.
Signs/Symptoms (PRESYMMU – SYM12)	Assess sign/symptoms and time to manifestation.	Classification as head injury without signs or symptoms or as Tier 1, Tier 2 or Tier 3	
Mechanism of Injury --Sports- and Recreation- Related (SRR) (SRRX – SRRSET3X, SSRSET1BX)	Assessment of SRR as a mechanism, specific type of sport or activity, whether the sport was an organized school sport or organized non-school sport or neither of these and level of school (e.g elementary, middle or high school)	Compare Estimates	Comparisons of the case definition to criterion measure produced by YRBS and NEISS. The expectation is that confidence intervals will overlap. Differences for which there are no plausible explanation will warrant further study.
Mechanism of Injury –Assault	Assessment of assault as a mechanism	Compare Estimates	Comparisons of the case definition to criterion measure produced by HCUP-NIS and HCUP NEDS. The expectation is that confidence intervals will overlap. Differences for which there are no plausible explanation will warrant further study.
Mechanism of Injury – Bike (TXMOST – BIKE4X)	Assessment of bike as a mechanism	Compare Estimates	Comparisons of the case definition to criterion measure produced by NEISS. The expectation is that confidence intervals will overlap. Differences for

			which there are no plausible explanation will warrant further study.
Mechanism of Injury –Motor Vehicle, Fall (MVX – CAUSEX)	Assessment of motor vehicle and fall as mechanisms	Compare Estimates	Comparisons of the case definition to criterion measure produced by HCUP-NIS and HCUP NEDS. The expectation is that confidence intervals will overlap. Differences for which there are no plausible explanation will warrant further study.
Practice, Competition or Performance (SRRPCPX)	Where the mechanism is SRR during organized sports, practice vs competition is assessed.	Construct Validity	TBIs sustained during competition are more likely to be more severe (28) and therefore the proportion of TBI experienced during competition should be greater for higher levels of certainty compared to head injuries experienced during practice.
Use of Helmet During Injury (HELMETX – HELMET1X)	Where the mechanism is SRR, depending on the specific activity, helmet use at the time of the injury is assessed.	Construct Validity	TBIs sustained while not wearing a helmet are more likely to be more severe (28), and therefore the proportion of TBIs experienced while not wearing helmets should be greater for higher levels of certainty compared to head injuries experienced while wearing helmets.
Still Experiencing Signs/Symptoms (SYMSTILL-SYMRECA)	If symptoms have resolved, the length of time to resolution is assessed.	Construct Validity	Experiencing symptoms for a greater length of time is associated with greater severity (14), and therefore the average number of symptoms experienced should be greater for higher levels of certainty of TBI.
Proxy Questioned About Symptoms During Call (CHILDPRES)	For proxy interviews, it is determined whether the child was asked about signs and symptoms during the call.	Reliability of Parents Reporting on Behalf of Adolescents	Asking a child about their symptoms will be considered a possible contamination of the proxy interview for the levels of agreement study and concordance and kappa tests will be conducted with and without these cases.

Receipt of Initial Evaluation (PREMED – EVWHOXA) (DASSESSED – DBYWHOB for Direct Adolescent Interview)	Receipt of medical evaluation is assessed for adult/proxy interviews. Being checked out is assessed for direct adolescent interviews.	Construct Validity	TBIs sustained by those who were evaluated by a medical professional are more likely to be more severe and therefore the proportion of TBIs that received a medical evaluation should be greater for higher levels of certainty compared to head injuries that did not receive a medical evaluation (18). Head injuries without subsequent symptoms are less likely to have been evaluated by a medical professional than head injuries with subsequent symptoms.
Timing of Initial Evaluation (EVTIMEX)	The timing of the evaluation is assessed	Construct Validity	The proportion of TBIs for which evaluation occurred more quickly should be greater for higher levels of certainty.
Place of initial and subsequent evaluation/care (EVWHEREX – CAREFX)	The place where care was received, for the initial evaluation and follow up care (e.g. doctor's office, emergency department, urgent care clinic) is assessed.	Compare Estimates	Comparisons of the case definition to criterion measure produced by NEISS, HCUP and Marketscan will require that head injuries be categorized by where care was sought. The expectation is that confidence intervals will overlap. Differences for which there are no plausible explanation will warrant further study.
Diagnosis (TBIDX)	Whether the TBI was diagnosed by a medical professional is assessed	Construct Validity	TBIs diagnosed by a medical professional are more likely to be more severe and therefore the proportion of TBIs that were diagnosed by a medical professional should be greater for higher levels of certainty compared to head injuries that were not diagnosed as TBIs (18). Head injuries without subsequent symptoms are less likely to have been diagnosed by a medical professional than head injuries with subsequent symptoms.

Not Seeking Care (WHYNOCAREX) (PRETELL – NOTELLWHY for Direct Adolescent Interview)	If the head injury was not evaluated by a medical professional (e.g. difficulty paying, did not have transportation, did not think it was serious), the reason is assessed for adult/proxy interviews. Why the adolescent did not tell is assessed for the direct adolescent interviews.	Construct Validity	TBIs for which care was not sought because it was not thought to be serious are less likely to be severe and therefore the proportion of TBIs for which care was not sought because it was not thought to be serious should be greater for lower levels of certainty compared to TBIs for which care was not sought for some other reason (18). Head injuries without subsequent symptoms are more likely to be head injuries for which care was not sought because it was not thought to be serious compared to head injuries with subsequent symptoms.
Type of Treatment (HOSPSTAX – RECSERVX)	Those who received their initial evaluation or subsequent care in a hospital are asked whether they were admitted, for how long, whether they were discharged to a rehabilitation center or if they received additional services.	Construct Validity	TBIs that resulted in hospitalization, discharge to a rehabilitation center or receipt of additional services are more likely to be more severe and therefore the proportion of head injuries discharged to a rehabilitation center or that received additional services should be greater for higher levels of certainty compared to TBIs that did not result in hospitalization, or were not discharged to a rehabilitation center or received additional services (16, 17). TBIs that result in a greater length of time in the hospital are also more likely to be more severe and therefore the average time in the hospital should be greater for higher levels of certainty.
Removal from Play (REMPLAYX – RETWHENX)	Proxy interviews and selected adults age 18-22 who play school-based organized sports are asked if they were removed from	Construct Validity	More severe TBIs have a greater likelihood of being identified, making removal from play more likely for those cases compared to less severe TBI that may go unrecognized, and therefore the

	play and for how long.		proportion of head injuries that resulted in removal from play should be greater for higher levels of certainty compared to head injuries that did not result in removal from play. TBIs that result in a greater length of time out of play are also more likely to be more severe and therefore the average time out of play should be greater for higher levels of certainty.
Returning to school (INSCHO – ACPERF3)	Proxy interviews are asked about missing school, receipt of assistance, decline in grades since the injury, and working harder for grades he or she had prior to the injury.	Construct Validity	TBIs that resulted in missing school, receipt of assistance, declining grades due to the injury or working harder for grades since the injury are more likely to be more severe (29) and the proportion of TBI that resulted in missing school, receipt of assistance, declining grades due to the injury or working harder for grades since the injury should be greater for higher levels of certainty compared to TBIs that did not result in missing school, receipt of assistance, declining grades due to the injury or working harder for grades since the injury. TBIs that resulted in a greater length of time out of school or receiving assistance are also more likely to be more severe and therefore the average time out of school or receipt of assistance should be greater for higher levels of certainty.
Missing work (PREWKMISSX – WKMISSX)	Adults are asked if the injury caused them to miss work.	Construct Validity	TBIs that resulted in missing work are more likely to be more severe (20) and therefore the proportion of TBIs that resulted in missing work should be greater for higher levels of certainty compared to TBIs that did not result in missing work.
Functioning	Adults, proxy interviews	Construct Validity	TBIs that resulted in interference with

(FUNCS – FUNCSA)	and direct adolescent interviews are asked the extent to which the injury interfered with social activities. Adults are asked the extent to which the injury interfered with work. Proxy interviews and direct adolescents are asked the extent to which the injury interfered with school activities.		functioning are more likely to be severe (19, 20) and the average effect on functioning should be greater for higher levels of certainty. Head injuries without subsequent symptoms are less likely to result in interference with functioning and should demonstrate lower average effects on functioning compared to head injuries with subsequent symptoms.
Insurance (HINS, CHINS)	Adults and proxy interviews with TBI will be asked about their type of insurance.	Compare Estimates	Comparisons of the case definition to criterion measure produced by Marketscan will require that TBIs be categorized by insurance type.
Proxy Relationship (RELATION)	Adults who serve as proxy interviews are asked their relationship to the child.	Reliability of Parents Reporting on Behalf of Adolescents	Proxy interviews conducted with parents or legal guardians will have greater concordance in the levels of agreement study.
Child demographics (CHINS, CRACEA)	Adults who serve as proxy interviews are asked their child's ethnicity and race	Additional weight variables for comparison to national estimates	
Adolescent Interview (ADOL – ASKEMAIL)	Adults who serve as proxy interviews for at least one child 13 to 17 years of age will be asked for permission to interview their child in order to assess level of agreement between parents and adolescents	Reliability of Parents Reporting on Behalf of Adolescents	Proxy interviews in households with at least one child 13 to 17 years of age will be eligible for a direct adolescent interview.
Reaching Selected Adult (CBTWOADULT –	If the selected adult and the knowledgeable adult are different, a time to call	N/A	

CBTHREEADULT)	the second interview back is established.		

We collaborated in the design of this project with other federal agencies through soliciting feedback regarding the purpose of the system and, when applicable, specific questions. These agencies include the Department of Defense, the National Institute for Occupational Safety and Health, and the United States Consumer Product Safety Commission. These consultations are described in more detail in Supporting Statement A, Section A.8.b. We also considered how the development of validated case definition for TBI may support the research agendas of the National Institutes of Health, the Department of Defense, and the Department of Veterans Affairs. These agencies and departments may find a validated case definition and a self-report instrument useful in future research that assesses short- and long-term cognitive, emotional, behavioral, neurobiological, and neuropathological consequences of TBIs, as well as repetitive head impacts over the life span.

This project is a preliminary step in the development of a TBI Surveillance System, which will ultimately aid in the formulation of policies and prevention strategies related to TBIs among adults and children. The validation of a case definition for TBI among adults and children and comparison to previously reported estimates will contribute to the accuracy of a potential future data collection. In addition, more accurate estimate of TBI incidence will provide critical information for federal, state, and local entities, including state and local health departments, to monitor trends, estimate resource needs for treatment, and target prevention strategies. Academic researchers will also be able to incorporate the case definition for TBI as well as the instrument itself into their own work. This will foster consistency in the collection and interpretation of self-reported TBI. Failure to develop a validated case definition for TBI will result in continued inconsistency in measurement and consequently continued underestimation of the true public health and economic burden of TBIs in the United States. This further inhibits the development and evaluation of programs designed to address this problem.

The contract number for the data collection is HHSD2002013M53944B. The project is currently funded and the option year for the contract was exercised on 5/10/2017. The contract is firm fixed-price and non-severable. We anticipate seeking a no-cost extension.

A.3 USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

Data collection will use a CATI system that collects responses 100% electronically. They also perform a number of functions prone to error when done manually by interviewers, including:

- Providing correct question sequence;
- Automatically executing skip patterns based on prior question answers (which decreases overall interview time and consequently the burden on respondents);
- Recalling answers to prior questions and displaying the information in the text of later questions;
- Providing random rotation of specified questions or response categories (to avoid bias);
- Ensuring that questions are not skipped accidently;
- Rejecting invalid responses or data entries.

The CATI system lists questions and corresponding response categories automatically on the screen, eliminating the need for interviewers to track skip patterns and flip pages. Moreover, the interviewers enter responses directly from their keyboards, and the information is automatically recorded in the computer's memory.

CATI allows the computer to perform a number of critical quality assurance routines that are monitored by survey supervisors, including tracking average interview length, refusal rate, and termination rates for each interviewer, and performing consistency checks for inappropriate combinations of answers.

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

As described in Supporting Statement A, Section A.1, current sources of TBI incidence estimates, such as those based on healthcare administrative data, likely underestimate the true public health and economic burden among both adults and children (2, 3, 30, 31), and a validated case definition for self-reported data does not exist (32).

For example, TBI incidence is currently estimated using healthcare administrative data, such as the Healthcare Cost and Utilization Project (HCUP) and the National Electronic Injury Surveillance System – All Injury Program (NEISS – AIP). These systems provide national estimates, and cover individuals of all ages and based on medical diagnoses. There is a lack of detail regarding the TBI circumstances and these data sources do not include persons who seek care in primary care, urgent care, or specialty care settings, nor do they capture those who do not seek care at all, necessitating an alternate approach that can allow for self-report data using a validated case definition. Additionally, as described previously, different levels of training and infrastructure across medical settings (33) introduces potential unmeasured variability.

Two large scale collections that collect data about SRR-TBIs, High School RIO: Reporting Information Online (HS RIO) and the National Collegiate Athletic Association (NCAA) Injury Surveillance System, collect details related to the concussion such as prior concussions, use of protective equipment, and signs and symptoms of concussion experienced. A benefit of these sources is that they capture data outside of the healthcare setting. However, these data are limited to high school and NCAA athletes. For these systems, certified athletic trainers (ATC) diagnose the athletes. Therefore, these systems miss all concussions experienced prior to high school and those experienced outside of organized, school-based sports for which an ATC is available. These settings include organized sports not affiliated with a school, sports played only for fun, and recreational activities (e.g., bicycling, skateboarding, playground injuries).

CDC's Behavioral Risk Factor Surveillance System (BRFSS) and Youth Risk Behavior Surveillance (YRBS) System collect information on U.S. residents regarding their health-related risk behaviors, chronic health conditions, and use of preventive services. While these surveys assess a wide range of health conditions, national estimates cannot be produced for TBI using the BRFSS because TBI questions are not part of the core survey. While several states have collected TBI-related data, a validated case definition was not applied and the level of detail about the injury collected by the BRFSS is limited. The YRBS TBI questions have varied among the few states that have included them and, similar to the BRFSS, a validated case definition was not applied. The 2017 national YRBS includes a single question about sport and recreation TBI, but is also limited in that it does not incorporate a validated case definition and it only includes SRR-TBI. Similarly, although the Maternal and Child Health Bureau of the Health Resources and Services Administration administers the National Survey of Children's Health every four years, the questions addressing TBI do not apply a validated case definition and do not assess the activity or action the respondent was engaged in when they were injured.

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

The planned data collection does not involve small businesses or other small entities.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

Data are only being collected once from participants.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINE 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.a Federal Register Announcement

A 60-Day Federal Register Notice was published in the *Federal Register* on June 13, 2016, volume 81, number 113, pp. 38182 (see Attachment B-1). No comments were received.

A.8.b Consultations

To support this effort, the CDC solicited feedback from experts on the proposed questions related to TBI signs and symptoms as well as how those questions mapped onto a proposed case definition. Feedback was solicited and received from experts in the fields of neurology, neuropsychology, pediatrics, sports medicine, and athletic training. The feedback was synthesized and themes were developed to guide improvements to the questions and the case definition.

In order to develop the most appropriate research protocol and instrument for the collection of TBI signs and symptoms and TBI related data, two leading experts in the field of TBI research, John Corrigan, PhD, and Dawn Comstock, PhD, were retained for the preparation phase of the project (August 2015 to May 2016). Dr. Corrigan is the project director for the Ohio Regional Traumatic Brain Injury Model System longitudinal research program funded by the National Institute on Disability and Rehabilitation Research. He is also editor-in-chief of the Journal of Head Trauma Rehabilitation. Dr. Comstock is a nationally known expert in the surveillance of sports and recreation injuries. She originated the National High School Sports-Related Injury Surveillance System (HS RIO, or High School Reporting Information Online) that has been used to support policy decisions among federal, state and non-governmental sporting organizations. It is also the official injury surveillance system for the National Federation of State High School Associations. Dr. Corrigan and Dr. Comstock met weekly with the TBI team at CDC to develop and review the list of data elements to be collected in order to refine the survey instrument for content and clarity. They also contributed to discussions regarding the methodology and sampling design based on their experience with large-scale data collection on this topic.

As part of our review of duplicate information and consultation about our planned data collection, we shared the instrument and sought specific feedback on the purpose of the system, recommendations for data elements to be collected, and the wording of questions from other federal agencies. Feedback was provided by Samantha Finstad, Strategy, Plans and Programs Chief and Yll Agimi, Lead Surveillance Epidemiologist, both of the Department of Defense. In addition, the following experts provided feedback: Audrey Reichard, an Epidemiologist with the National Institute for Occupational Safety and Health; Jonathan Midgett, Developmental Psychologist and Coordinator of the Children's Hazards Team; and Jana Fong-Swamidoss, Chief of Staff and Chief Counsel to Chairman Elliot F. Kaye at the United States Consumer Product Safety Commission.

Through feedback from our retained consultants, input from experts on the case definition, and experts in other federal agencies, we added, dropped, or edited data elements. There were no major unresolved issues. Contact information for our retained consultants, and those from government agencies who were consulted, are included in Attachment C-1.

During the course of survey development, the TBI team at CDC consulted more generally with a number of well-known professionals in the field of TBI, as well as representatives of professional and non-profit organizations, about the purpose of the system, the importance of data elements to be included, and the consideration of survey burden on the respondents. CDC consulted the following for guidance related to specific data elements: Madeline Joseph, MD, Pediatric Chair of the American

College of Emergency Physicians; Fred Rivara, MD, MPH, Professor of Pediatrics and Adjunct Professor of Epidemiology at the University of Washington; and Karen McAvoy, PhD, clinical psychologist at Rocky Mountain Hospital for Children. Several sports medicine professionals were consulted related to specific data elements, including: Ruben Enchemendia, PhD, Director of the National Hockey League's Neuropsychological Testing Program, Co-Chair of the NHL's Concussion Working Group, Chair of Major League Soccer's concussion program, and the consulting clinical neuropsychologist to the U.S. Soccer Federation and the U.S. Soccer National Teams; Steve Marshall, an epidemiologist at the University of North Carolina's Injury Prevention Center; and representatives from the American College of Sports Medicine and Exercise Science, the National Athletic Trainers Association, and U.S. Lacrosse. Injury non-profit organizations were also contacted regarding specific data elements and survey burden and these include: the National Safety Council; the National Association of State Head Injury Administrators; and One Mind.

In addition to consulting with leading TBI researchers and partners, CDC has also contracted with ICF International to conduct the data collection. ICF International has extensive experience with data collection, data analysis, and statistical methods, particularly with respect to national surveillance systems. ICF has supported the CDC in the collection of data for the BRFSS for twenty years and has provided particular expertise in CATI administration involving complex landline and cell samples. For this project, ICF augmented their technical team with experts in TBI symptomatology and parent-child dyad reports, SRR-TBI and surveillance among youth, instrument development, school-based surveillance, and the characterization of SRR-TBI and other TBI.

A.9. EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS

No payment or gift will be provided to respondents participating in the data collection.

A.10. PROTECTION OF THE PRIVACY AND CONFIDENTIALITY OF INFORMATION PROVIDED BY RESPONDENTS

A.10.a. Privacy Act

The Office of the Chief Information Officer has determined that the Privacy Act does not apply, as records are not retrieved by personally identifiable information (PII) (see Attachment D-1 and D-2). During data collection, the contractor collects first names, alternate phone numbers and email addresses of adolescent respondents for the purpose of completing the adolescent interviews over the phone or through the web. At no time is this information linked or linkable to survey information that will be transmitted to the CDC. At no time does CDC have access to, or receive PII. An Authority to Operate (ATO) under the Federal Information Security Modernization Act (FISMA) has been completed. All data will be maintained in a secure manner throughout the data collection and data processing phases in accordance with National Institute of Standards and Technology (NIST).

The data are collected using a random digit dialing (RDD) landline and cell phone survey of English and/or Spanish speaking with the Web as an option for the adolescent respondents. Information will be collected in one-time anonymous interviews or Web survey. Although PII will be collected (specifically, an alternate phone number, email address, and first name of adolescent), these data will be stored separately from other survey response data, and will not be transmitted to CDC.

All data will be maintained in a secure manner throughout the data collection and data processing phases in accordance with Office of the Chief Information Security Officer OCISO requirements. Only the

contractor conducting the study will have study-specific temporary access to information that could potentially be used to identify a respondent (i.e., the telephone number, email and name). While under review, data will reside on directories that will only be accessible to project staff that need access. These staff persons include the project manager, CATI/Web programmers, and a sampling statistician. All computers will reside in a building with electronic security and are ID and password protected.

A.11. INSTITUTIONAL REVIEW BOARD (IRB) AND JUSTIFICATION FOR SENSITIVE QUESTIONS

The CDC/NCIPC Human Subject Contact has determined that this activity is research involving human subjects but CDC/NCIPC is not involved. CDC/NCIPC will NOT obtain data by intervening or interacting with respondents or have access to identifiable data (PII).

A verbal informed consent protocol is used for telephone interviews. After a single adult respondent in the household is randomly selected to participate, the interviewer administers the verbal informed consent, which provides information on the voluntary and confidential nature of the survey, the benefits and risks of participation, the survey topic and the telephone numbers to speak with staff from the CDC. The process is the same for an adult consenting to conduct a proxy interview or an adolescent assenting to conduct a phone interview. Adolescents completing the survey via Web will see a written assent page on which they will provide assent. All potential respondents, regardless of mode, are informed 1) of the purpose for the data collection; 2) that their data will be treated in a secure manner and will not be disclosed; and 3) that their name will never be linked to their responses.

ICF has its own IRB, which meets all of the Federal requirements as specified in 45 CFR 46, is registered with the Office for Human Research Protections, and has a Federal Wide Assurance (#FWA00000845). This ensures that all of its projects involving human subjects comply with Federal regulations. The ICF IRB approval letter that incorporates changes made to the instrument in order to be able to compare cases to head injuries without self-reported symptoms as part of the effort to validate the case definition is included as Attachment D-3.

Questions related to experiencing a head injury are not commonly considered sensitive or private by institutional review boards. Therefore, the data collection is anticipated to have little or no effect on the respondent's privacy. Nevertheless, some respondents may feel that some of the questions are sensitive in nature if the questions elicit memories of a painful injury, or difficult circumstances surrounding a head injury. Thus, safeguards will be put in place to ensure that all collected data remain private. Additionally, all respondents are made aware that participation is completely voluntary, and that they may refuse to answer any questions with which they feel uncomfortable. If the interviewer senses any discomfort or reluctance to answer any question, the interviewer will be instructed to remind the respondent that he/she may choose not to answer the question.

There are demographic questions in the survey. Two of these ask about race and ethnicity. OMB considers questions about race and ethnicity to be sensitive; however, they are important in determining whether disparities exist in health behavior, health status, and access to health services among those experiencing a TBI. Such disparities have been demonstrated in previous research (34-36). Lack of insurance at the time of injury is asked, but is also considered to be important due to potential disparities.

A.12. PROVIDE AN ESTIMATE IN HOURS OF THE BURDEN OF THE COLLECTION OF INFORMATION

The estimated burden for this information collection is based on timed tests of burden derived from internal testing. The planned information collection involves contacting and screening approximately 10,000 eligible adults and 1,440 eligible adolescents 13 to 17 years of age.

We estimate that to reach our target of 10,000 completed household interviews, we will need to make contact with 11,567 households. Of these, we anticipate that 1,567 will only receive eligibility screens that take, on average, 2 minutes to complete. Reasons for ineligibility include being under age 18, not living in a private residence, or being on a cell phone in a place that is unsafe to talk. Among the 10,000 households that are contacted and screened as eligible, we estimate that 85% or 8,500 adult respondents will not report a head injury in the past 12 months and will not complete any additional questions about their head injuries in the past 12 months. We expect that the interview for this subset of adults to take 14 minutes to complete on average, with a range of 9 minutes to 42 minutes. The reason for the variability is that the minimum assumes an adult respondent does not have any children in his/her household and does not report a head injury in the past 12 months. The maximum assumes an adult parent with three children in the household, so the adult would report on his/her TBI history, as well as provide proxy information for all children. The maximum time scenario also assumes two of the three children in the household reporting at least one sign or symptom of a TBI and thus meeting the minimum case definition for a TBI in the last 12 months. The 14-minute average is based on a number of assumptions that affect the length of the survey. First, we are accounting for the probability of having children based on national estimates and assuming that households with children have an average number of children. Second, we are assuming that any individual child has a 25% chance of having at least one head injury in the past 12 months (with 40% of those endorsing at least one sign or symptom and meeting the minimum case definition for a TBI). Among the estimated 1,500 adult respondents who report that they have experienced a head injury in the past 12 months, we estimate that the survey will take 23 minutes to complete on average, with a range of 14 minutes to 51 minutes. The reason for the variability is that the minimum assumes no children in the household and that the adult does not meet the minimum case definition of a TBI based on responses to the symptom questions. The maximum assumes the adult has had a head or neck injury in the past 12 months that meets the minimum case definition for a TBI, and reports as a proxy for three children in the household—one of whom also had a head injury that meets the minimum case definition for a TBI. The 23-minute average is based on a number of assumptions that affect the length of the survey. First, we estimate that 40% of the adults that report a head injury in the past 12 months will endorse at least one sign or symptom and meet the case definition for a TBI. Second, we are accounting for the probability of having children based on national estimates and assuming that households with children have an average number of children, each with a 25% chance of having at least one head injury in the past 12 months (with 40% of those endorsing at least one sign or symptom and meeting the minimum case definition for a TBI). Related to the levels of agreement study, we expect that there will be approximately 1,440 of the 10,000 households with at least one adolescent 13 to 17 years of age. We estimate that 75% (or 1,080) will not report a head injury in the past 12 months and will only complete the TBI screening, which takes, on average, 5 minutes to complete. Among the 360 who report having experienced a head injury in the past 12 months, we estimate that 56% will endorse at least one sign or symptom and complete the full survey, which is expected to take 15 minutes on average with a range of 8 minutes to 17 minutes. The reason for the variability is that the minimum assumes the adolescent does not meet the case definition for a TBI. The maximum assumes the adolescent meets the case definition for a TBI, and receives additional follow-up questions as a result. The estimated annualized burden hours are in the table below.

Table A.12.1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Adults 18 or older	Eligibility Screener	783	1	2/60	26
	Adult-Proxy Screener	4250	1	14/60	992
	Adult-Proxy Survey	750	1	23/60	287
Adolescent 13 to 17 years of age	Adolescent Screener	540	1	5/60	45
	Adolescent Survey	180	1	15/60	45
				Total Annual Burden Hours	1397

For this information collection, there are no direct costs to the respondents themselves. However, the cost to adult respondents can be calculated in terms of the time it will take to respond to the survey. Table A.12.2 illustrates the total calculation of costs to respondents for the survey. The estimated respondent burden hours have been multiplied by an estimated average hourly salary for adults. The estimated burden cost in terms of the value of time adults spend in responding is based on information provided by the U.S. Department of Labor, Bureau of Labor Statistics, at http://www.bls.gov/oes/current/oes_nat.htm, which estimates the latest (May 2015) mean hourly earnings among adults across all occupations of $23.23/hour. The adolescent hourly rate of $10.98 is the mean hourly rate for food preparation and serving-related occupations. At that hourly rate, the total annual cost burden for the time spent by respondents is $31,307.

Table A.12.2. Estimated Annualized Burden Cost

Type of Respondent	Form Name	Total Burden Hours	Average Hourly Wage Rate (in dollars)	Total Respondent Costs
Adults 18 or older	Eligibility Screener	26	$23.23	$604

	Adult TBI Screener	992	$23.23	$23,045
	Adult/Proxy Survey	287	$23.23	$6,668
Adolescent 13 to 17 years of age	Adolescent TBI Screener	45	$10.98	$495
	Adolescent Survey	45	$10.98	$495
Total Annual Burden Cost				$31,307

A.13. ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS

No capital or maintenance costs are expected.

A.14. ANNUALIZED COST TO THE GOVERNMENT

During data collection, additional costs will be incurred indirectly by the government as personnel costs of staff involved in the study oversight and data analysis. It is estimated that 3 CDC employees will be involved for approximately 20%, 20%, and 50% of their time (for federal personnel 100% time = 2,080 hours annually). The three salaries are $47.53, $40.09, and $49.53 per hour. The direct annual costs in CDC staff time will be approximately $87,960.70 annually.

The estimated annualized cost to the government will be $991,722 + $ 87,961 = $1,079,683.

Table A.14.3. Annualized Cost to the Government

Type of Cost	**Annualized Cost**
Contractor Costs	$991,722
Federal Employee Time Costs	$87,961
Total Annual Estimated Costs	$1,079,683

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

This is a new program.

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

Data Tabulation Plans

Aim 1: Explore validity of Proposed Case Definition <u>with the Proposed Data Collection</u>

Aim 1.1. Test construct validity by analyzing TBI outcomes that serve as indicators of severity

For Aim 1.1, comparisons of means will be used to analyze difference in outcomes across head injuries classified based on the case definition. Non-parametric tests will be used (e.g. Kruskal-Wallis, Wilcoxon Rank-Sum) where applicable (e.g. to compare ordinal indicators of severity measures across tiers). These are described in Table A.16.1.

Table A.16.1. Analyses to Compare Outcomes Across Head Injuries Based on the Case Definition

Indicators of Severity	Analysis	Population	Comparisons
Outcomes			
Time to Symptom Resolution	ANOVA	Adult/Proxy, Adolescent	Tier 3, Tier 2, Tier 1
Time to Return to Play	ANOVA	Adult/Proxy, Adolescent	Tier 3, Tier 2, Tier 1
Hospitalization	ANOVA	Adult/Proxy	Tier 3, Tier 2, Tier 1
Receipt of Post-TBI Examination	ANOVA, T-tests	Adult/Proxy	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases
TBI Diagnosis	ANOVA, T-tests	Adult/Proxy	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases
Reason for Not Seeking Care (other than lack of head injury severity)	ANOVA, T-tests	Adult/Proxy	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases
Checked Out For TBI	ANOVA, T-tests	Adolescent	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases
Reason for Not Telling Anyone (other than lack of head injury severity)	ANOVA, T-tests	Adolescent	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases
Social Functioning[b]	Kruskal-Wallis, Wilcoxon Rank-Sum	Adult/Proxy, Adolescent	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases
Work Functioning[b]	Kruskal-Wallis, Wilcoxon Rank-Sum	Adult	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases
School Activities[b]	Kruskal-Wallis, Wilcoxon Rank-Sum	Proxy, Adolescent	Tier 3, Tier 2, Tier 1; TBI[a]/Non-Cases

[a] Includes Tier 3, Tier 2 and Tier 1

[b] Subsequent functioning will be measured using questions adapted from the Short Form Health Survey (SF-36) (37).

Aim 1.2. Test reliability of parents reporting TBI on behalf of adolescents by comparing parent proxy report and adolescent self-reports of TBI in the past 12 months

Previous studies comparing concordance between child reports of TBI to parent reports of TBI have ranged from moderate (38) to strong (22, 38). Kappa is used to assess percentage of agreement as it adjusts for agreement due to chance (39). One study among adolescent female soccer players and male football players found that the kappa for female soccer players was .60 and the kappa for male football players was .62 for weekly reporting of head injuries and at least one symptom (22). As stated

previously, based on the possibility of the parent not being present for the injury and the possibility of TBI-related symptoms that cannot be seen externally (21), we consider the direct adolescent reports to be the more accurate.

Table A.16.2. Parameters for Comparison of Adolescent Report to Parent Proxy Reports

	Adolescent Report		
Parent Proxy Report	Yes	No	Total
Yes	p_{11}	p_{12}	$p_{1.}$
No	p_{21}	p_{22}	$p_{2.}$
Total	$p_{.1}$	$p_{.2}$	$p_{..}$

CDC researchers have determined that 70% is the target minimum level of agreement for parent proxy reporting, meaning that 70% of the positive responses reported by the parent are confirmed by the adolescent ($p_{11}/p_{1.}=70\%$) and 70% of the adolescent positive responses are confirmed by the parent ($p_{11}/p_{.1}=70\%$). Using the assumption that the percentage of the sub-population of study reporting a head injury with at least one symptom will be 13% (see Supporting Statement B, Section B.2 for details), a minimum of 9.1% of the responses will be positive response by both the parent and adolescent. This level of agreement indicates a Cohen's kappa of about 0.66. The acceptable range of κ is considered to be .40 to .75 (23).

We hypothesize that concordance will increase with level of certainty, and therefore will examine the impact of excluding Tier 1, the lowest level of certainty, on percent agreement and kappa. The calculations for the sample size required are described in Supporting Statement B, Sections B.2.

Aim 2. Compare Proposed Case Definition Estimates from the Proposed Collection <u>with Externally Collected Data Sources</u>

Aim 2.1. TBI Research Studies: Explore construct validity using existing data sources of populations diagnosed by clinicians or identified by athletic trainers

For Aim 2.1, comparisons of means will be used to analyze differences in outcomes across classification of TBI based on the case definition. Non-parametric tests will be used (e.g. Kruskal-Wallis, Wilcoxon Rank-Sum) where applicable (e.g. ordinal measures). These are described in Table A.16.3.

Table A.16.3. Analyses to Compare Outcome Across Case Definition Tiers

Dataset	**Outcome**	**Analysis**
High School RIO	Time to Symptom Resolution[a]	Kruskal-Wallis
High School RIO	Time to Return to Play[b]	Kruskal-Wallis

PARC Study	Persistent Symptoms	ANOVA

[a] Response options are ordinal, ranging from "<15 minutes" to "22 days or more"
[b] Response options are ordinal, ranging from "Returned to activity in less than 1 day" to "Returned to activity in 22 days or more"

Aim 2.2. and 2.3 Healthcare Administrative TBI: Explore potential over and under estimation and its sources by comparing 12-month estimates to estimates based on administrative data for diagnosed 12-month TBI*; and Self-Reported TBI:* Explore potential over and under estimation and its sources by comparing weighted 12-month estimates to estimates based on self-reported 12-month TBI

The analyses will use external databases to understand why there are differences in TBI rates derived from different databases by comparing rates for sub-populations defined by certain demographic, economic, and activity characteristics. Generating hypotheses to explain differences will help to determine which databases over and under estimate in which subpopulations and allow us to refine our proposed measure accordingly.

Weighted and unweighted estimates of TBI based on the case definition for comparability purposes (12-month TBI among adults and children 5 years of age and older, 12-month SRR-TBI among children 14 to 18 years of age, 12-month TBI among children and adolescents 5 to 17 years of age) will be calculated.

Drafts of table shells for each Aim and subaim are included in Attachment G.

Additional Analyses for Aim 1 (Data from the Current Collection)

Comparison of Mode: We are also proposing to compare the web and telephone modes for adolescents. First, we will compare levels of agreement across mode. However, we anticipate a greater number of cases collected via web and that there will not likely be enough cases to calculate kappa for telephone alone. Therefore, we will examine percent agreement and kappa results first with all adolescent cases (telephone and web) and then again after removing the telephone cases to ascertain the impact on percent agreement and kappa. This will provide insight as to whether mode influences level of agreement between proxy reports and adolescent reports and if one mode may be preferred by adolescents for reporting TBI (e.g., the web mode may have higher reports of TBI from adolescents compared to parent proxy reporters, and this may indicate adolescents are more willing to report using this mode).

Assessment of Recall Bias (Internal Validity): Additionally, for all of these analyses, we will compare 6-month estimates to 12-month estimates to assess recall bias. We will examine the risk of recall bias on both the recalling of whether a TBI occurred and the ability for the respondent to recall the details of a TBI. The TBI survey asks the respondent to report whether they have experienced any head injuries in the past twelve months. If yes, then the survey collects details about the head injury, including the month and year that the injury occurred. This information allows us to classify whether the injury occurred in the past six months or whether it occurred more than six months ago (but less than twelve months). From this, we can calculate estimates of head injuries that occur in the six months prior to the interview date and estimates of head injuries that occur up to twelve months prior to the head injury and ascertain if the comparability of the estimates varies by population, specific activity engaged in at the time of injury (e.g. all activities compared to SRR only) or case definition tier classification.

If the 6-month estimate includes enough cases to be considered a stable estimate, we will use 6-month and 12-month estimates to assess the magnitude of forward telescoping bias, or the over-reporting of TBIs occurring in the past twelve months. Forward telescoping occurs when the respondent recalls the event as happening more recently than it actually did. To assess for evidence of telescoping bias, we will compare the retrospective 12-month estimate with double the retrospective 6-month estimate. If the twelve-month estimate is significantly higher, we will conclude that the magnitude of the telescoping bias may be enough to warrant using six months as a recall period in future collections.

Further, we will evaluate the details provided by the respondent when the TBI happens within six months versus six to twelve months. We will look at proportions of missing data (Don't know/Refused) for questions describing the TBI—how it occurred and whether the respondent sought care, to assess whether recall of the TBI circumstances are affected by the length of the recall period.

A.16.b. Publication and Dissemination Plans

All analyses will be developed into publications that address the specific aims of the data collection. The data will not be used to produce nationally representative incidence or prevalence estimates. All publications will be submitted to peer-reviewed journals, published as government reports and/or presented at scientific conferences. The publications will include detailed descriptions of the applicable aspects of the methodology. All publications will be available via links on the Division of Unintentional Injury Prevention TBI website (http://www.cdc.gov/traumaticbraininjury/ncss/index.html).

A.16.c. Schedule for the Project

The timeline for the collection was scheduled to be May 2017 through April 2018 under the current contract. We will submit a modification to include a no-cost extension once OMB approval is received to move the timeline forward.

Table a.16.c. Project Time schedule

Activity	Time Period
Conduct analyses using other data	1 – 6 months after OMB approval
Implement data collection	1 – 24 months after OMB approval
Develop Data Dictionary and Submission of Initial Datasets from ICF to CDC	1 – 3 months after OMB approval
Provide Quality Checks of all Data Deliverables	1 – 24 months after OMB approval
Develop Detailed Data Analysis Plan and Analysis	1 – 6 months after OMB approval
Survey Implementation Status Reporting	1 – 24 months after OMB approval
Draft Report	23 months after OMB approval
Final Data Submission from ICF to CDC	24 months after OMB approval
Final Report from ICF to CDC	24 months after OMB approval

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

The expiration date of OMB approval of the data collection will be displayed.

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT

No exemptions from the certification statement are being sought.

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