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

(OMB no. 0920-1240 exp. date 08/31/2021)

Proposed Changes: Justification and Overview 01/04/2019

Justification

This non-substantial change request is related to the ICR entitled, "Validation of a Case Definition for Parent- or Self-Reported Traumatic Brain Injury (TBI)," OMB control number 0920-1240. This Non-Substantive change requests does not include changes to the currently approved burden surveys and/or costs.

This Non-Substantive change request is to allow text message correspondence to sampled survey participants. The original protocol specifies that adult participants can respond to a voicemail or missed call by dialing back to a help desk. However, it did include a plan for contacting adolescent respondents via text message to provide the web survey link. It did not anticipate, though, that text messaging would be a communication avenue for those potential adult respondents that had received a phone call. As a result a communication plan to respond to these potential respondents via text message must be added to the protocol.

During Wave 1 of data collection, CDC received over 900 text messages from potential adult respondents who had *not* been originally contacted via text message. These potential respondents had been called from the survey line and instead of calling back to verify the caller's identity or set up an appointment to conduct the interview, they text messaged the survey line. However, the current protocol does not specify a procedure for responding to these text messages, forgoing a potentially powerful method. This engagement from potential respondents creates a unique opportunity to increase response rates, answer their requests for additional information, and discern more quickly their intentions related to participation, including refusals. The current lack of a protocol to communicate with respondents via text message may contribute to non-response bias as it is possible we are missing a segment of the population who will not respond to interview requests via phone call but may via text message.

This document outlines our proposed changes to the original protocol to include respondent engagement via text message. This change does not represent any change in burden; the same number of participants will be surveyed using the approved instruments. This Non-Substantive change request does not include changes to the currently approved instruments or surveys.

Project Description

Current estimates of traumatic brain injury (TBI) in the United States underestimate the burden. As a preliminary step in the development of a national surveillance system, 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:

A case definition for TBI will be validated using the proposed data collection. TBI will be classified into three tiers, based on the certainty that a TBI was sustained. The proposed three tiers indicate a descending level of certainty about whether a TBI occurred using a combination of signs and symptoms that correspond to injury severity. People who sustain a head injury, and do not report any symptoms, will be classified as a non-case head injuries. Data collected will be used to evaluate the proposed three-tiered case definition among adults and children in three ways: (1) construct validity will be tested by assessing associations between each of the three tiers and non-case head injuries and TBI outcomes; (2) concurrent validity will be tested by comparing estimates of TBI based on the proposed case definition to other nationally representative 12-month estimates of TBI; and (3) reliability of parents reporting TBI on behalf of adolescents will also be tested by assessing correspondence between parent proxy and adolescent self-reports of TBI.

Methods to be used to collect data:

Data for both adults and children will be collected 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.

Proposed Changes

As noted above, the original protocol includes no process for responding to those participants who are originally contacted via phone to participate in the survey, but subsequently contact ICF via text message. The adjustment sought through this change request is to add a protocol for responding to text messages. The contractor's survey software platform will house the text messages and allow staff to respond to those that contact the contractor via text message. Text messages will be checked twice a day (once in the morning, and once in the afternoon) during normal business hours (8am-5pm EST), Monday thru Friday. On Monday, staff will catch up on the text messages that were received over the weekend first thing in the morning. Text messages will be addressed as they are checked.

Inbound Text Message Protocol

Inbound text messages received during Wave 1 can be classified into four categories and we have drafted potential text message responses for each.

Inbound message category	Description of category	Common inbound messages received	Draft outbound responses
Request to stop	Request that	"Please stop	Text responses will not be issued to these

contact	CDC cease calling and/or texting	calling me"	respondents; they will be dispositioned as "refusals" and no more attempts will be made to contact them via telephone.
Requests for aid	Communicating a need for assistance	"I need help"	CDC will not respond via text but use the phone number listed to better understand the need for help, engaging the crisis protocol if needed. If the respondent is not experiencing a crisis event, we will address their question/concern if applicable to the survey, and attempt to schedule a time to complete the survey. A text response will only be used if respondent does not answer the telephone. "This is the survey response number for a nationwide head injury survey administered on behalf of the Centers for Disease Control and Prevention. If you are experiencing an emergency, please call 911."
Requests for additional information	Respondent is looking for additional information as to the purpose of the phone call	"Who is this?" "Why are you calling me?"	Introductory text response: "Thank you for contacting us. We are conducting a nationwide study about head injuries in children and adults on behalf of the Centers for Disease Control and Prevention. The survey should take no more than 10-15 minutes to complete. Please let us know a time when we can call you to conduct the interview." Follow-up if non-response from intro text and respondent did not provide some form of terminal communication: "Hello – we wanted to follow-up to ask whether you had any further questions regarding the head injury study. The survey should take no more than 10-15 minutes to complete. Please let us know a time when we can call to conduct the interview."
Other	Message that does not fit into a previous category	"I'll be right there," "Jane isn't here"	Clarifying text (if warranted): "This is ICF text messaging support. We're conducting a nationwide study about head injuries in children and adults on

behalf of the Centers for Disease Control and Prevention. We are hoping you would be willing to participate. Please let us know a time when we can call to conduct the interview."
Should a respondent request a time to be called, the scheduled callback will be provided to the call center and rotated into the dialing rotation. The respondent will be sent a confirmation text affirming the appointment time.

At any point during the text messaging engagement, if the client requests to not be contacted again, the communication will be terminated, and the respondent dispositioned as a "refusal". Outside of the one follow-up after three days of non-response, no additional communications will be sent if not initiated by the respondent.

Change to Burden or Cost

This change does not represent any change in burden; the same number of participants will be surveyed using the approved instruments. This Non-Substantive change request does not include changes to the currently approved burden and/or costs and therefore a cross-walk is not included in this request.