

# **Measuring Preferences for Quality of Life for Child Maltreatment**

## **Supporting Statement A**

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

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## **Attachments**

Attachment A: Relevant Portion of the Public Health Service Act

Attachment B: Published 60-Day Federal Register Notice

Attachment C: Survey Invitation from Knowledge Networks

Attachment D: Survey Instrument

Attachment E: Survey Instrument Screenshots

Attachment F: IRB Consent Form

Attachment G: IRB Approval

Attachment H: Knowledge Networks Privacy Policies

Attachment I: 2<sup>nd</sup> Round Pretest Report

## **A. Justification**

### **A.1 Circumstances Making the Collection of Information Necessary**

This supporting statement is for an ICR packet classified as new.

The Division of Violence Prevention (DVP) at the National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC), requests approval of a new exploratory research study to collect stated preference (SP) data from the public on the impacts of child maltreatment on health-related quality of life.

These data are needed for research by DVP/NCIPC to fulfill its mission under Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment A**).

Child maltreatment (CM) is a major public health problem in the United States, causing substantial morbidity and mortality (DHHS, 2010), and the prevalence for any of the three major types of CM (physical abuse, sexual abuse, and neglect) is estimated at approximately 28% (Hussey et al., 2006). The lifetime prevalence of any of five types of CM (physical abuse, sexual abuse, physical neglect, emotional neglect, and emotional abuse) is estimated at 45.6% (Corso et al. 2008). Additionally, the *annual* incidence of any type of CM among children and adolescents 0-17 has been estimated at nearly 14%, while physical and sexual abuse are estimated at 3.7% and 0.6%, respectively (Finkelhor et al., 2005). CM has been shown to have lifelong adverse physical and mental health consequences for victims (Felitti et al., 1998), including behavioral problems (Felitti et al. 1998; Repetti et al. 2002), mental health conditions such as post-traumatic stress disorder (PTSD) (Browne and Finkelhor, 1986; Holmes and Sammel, 2005; Moeller and Bachman, 1993), increased trouble with interpersonal relationships (Fang and Corso, 2007), increased risk of chronic diseases (Browne and Finkelhor, 1986), and lasting impacts or disability from physical injury (Dominguez et al. 2001). The consequences of CM have a direct impact, through reduced health, as well as an indirect impact, through reduced health-related quality of life (HRQOL, or simply QoL), the state of “utility” or satisfaction that a person experiences as a result of their health (Drummond et al. 1997).

The CDC requests approval of an exploratory survey-based research study to measure the Health-Related Quality-of-Life (HRQOL) impacts resulting from child maltreatment (CM) using a quantitative, preference-based approach. The US Department

of Health and Human Services, among many others, has identified child maltreatment as a serious U.S. public health problem with substantial long-term physical and psychological consequences. Despite considerable qualitative research on the consequences of CM in adults, few studies have utilized standardized HRQOL techniques and none have quantified childhood HRQOL impacts. This gap in the literature means the full burden of CM on HRQOL has not been measured, inhibiting the evaluation of CM intervention programs and comparisons to other public health issues. This exploratory research study will improve public health knowledge and economic evaluation of the HRQOL impacts of CM, including effects specific to juvenile and adolescent victims, through the development and fielding a preference-based survey instrument.

CDC has developed an exploratory survey instrument to quantify the HRQOL impacts of child maltreatment following standardized HRQOL methods. The survey was developed based on findings from a literature review of CM outcomes, focus groups with adults who were CM victims, and expert review of outcomes by clinician consultants who work with children and/or adults who were victims of CM, or who are researchers in the field of CM. The survey is designed to quantify two types of data. The main objective is the HRQOL decrement attributable to CM, measured as the difference in HRQOL scores by CM victimization history. A secondary objective is a statistical evaluation of these decrements, based on respondent preferences over a series of comparisons that will be shown to survey respondents.

The survey will be fielded to a nationally-representative sample of 1850 US adults by an online survey. The survey will include HRQOL questions to capture the two types of data above, as well as select items on sociodemographics. Past exposure to CM will be measured using the Child Trauma Questionnaire (CTQ), the briefest and most nonintrusive set of scientifically validated questions to identify 5 types of past child abuse and neglect.

The results of this exploratory research study will provide an estimate of the HRQOL burden of child maltreatment in the United States. Because this is the first quantitative research on the HRQOL burden of child maltreatment, the results will constitute a methodological contribution that advances scientific knowledge. Analysis and results of the survey data may provide suggestive information on the impacts of CM

to the scientific and public health communities to help determine whether future studies using similar methods should be conducted after this exploratory study. Such future studies may be required before comprehensive evaluation and comparison of CM intervention programs can occur.

Health economists quantify health-related utility impacts using Health-Related Quality of Life (HRQOL), a composite measure of health and well-being used to evaluate health problems and diseases. HRQOL can be assessed in a variety of ways, and not all of these are comparable or standardized. For this exploratory research study, HRQOL will be measured using economic tools, which scale the health-related utility impacts on a common 0.0-1.0 utility range, and which can be used in economic evaluations of health interventions, such as cost-utility analysis. Few studies to date have attempted to quantify the HRQOL burden among adults using scientific methods for measuring HRQOL, and no studies have quantified the impact of CM on HRQOL among child victims. Thus, with this proposed research study, CDC seeks to address a major research gap on the full impacts of child maltreatment to advance both the field of CM research and the use of HRQOL measures to measure burden of disease.

A 2006 report for CDC (Prosser and Ravenscroft, 2006) explored the feasibility of using preference-based HRQOL methods to estimate the impact of CM and conducted a literature review of published research in this area. The authors found few relevant studies and concluded that the primary reason for the lack of research in this area is that existing, generic HRQOL instruments are inadequate and do not capture the relevant impacts of CM. This finding was expanded upon in a published literature review (Prosser and Corso, 2007) and was updated in a recent, unpublished review by members of a current research team from RTI International under contract for CDC. The only additional studies found (Afifi et al. 2007) were not preference-based measures of HRQOL, so they do not report utilities or map back to a 0.0-1.0 utility range. Common generic instruments (e.g., EQ-5D, QWB, SF-6D, HUI) are not able to accurately assess CM-related HRQOL because they are not designed to capture the relevant domains affected by CM and because they do not capture impacts relevant to childhood and adolescent ages. These reviews concluded that attempts to use existing generic instruments to measure CM-related HRQOL impacts would inaccurately measure the

burden of health, biasing any conclusions drawn from such efforts.

Based on these critical reviews and the impacts of CM on physical and mental health (Felitti et al., 1998), CDC recognizes the need for a new HRQOL instrument and research study to measure the HRQOL burden of CM across the lifecycle. A new HRQOL instrument for child maltreatment was developed over the past 2 years following standardized HRQOL methods, including a literature review, focus groups with adult victims of CM, and expert review. CDC now proposes a national collection of an exploratory research survey to: (1) measure HRQOL impacts associated with CM, and (2) elicit preferences over health states and HRQOL to convert the impacts into standardized economic utility values. The combined results will be used to assess how HRQOL methods can be used to measure burden of CM. RTI International is under contract with CDC to conduct this research study, analyze data, and report results.

CDC has not solicited a previous data collection on this subject. Previous systematic literature reviews on this topic have established there are no significant existing studies in this area, and that there is a clear need for a new instrument and data collection on this topic (Prosser & Corso 2007).

## **Privacy Impact Assessment**

### **Overview of the Data Collection System**

The goal of this information collection is to field an exploratory national research survey to: (1) measure HRQOL impacts associated with CM, and (2) elicit preferences over health states and HRQOL to convert the impacts into standardized economic utility values. The survey data will be collected online over the internet using Knowledge Networks (KN) as a data collection partner (subcontractor to RTI International). Data will be maintained in de-identified form by RTI and CDC in accordance with IRB approvals for this study for an IRB-approved duration. The online survey sample of n=1850 respondents will be drawn from the general U.S. adult population ages 18 and older. This sample will capture data from both those with and without a history of abuse or child maltreatment.

### **Items of Information to be Collected**

Collected data are survey responses to a CM-specific HRQOL instrument. Over the past two years, RTI has developed survey questions based on standardized HRQOL methods, including a literature review, focus groups with adult victims of CM, and reviews by experts from a variety of disciplines, with professional titles of psychologist, psychiatrist, physician, clinician, decision scientist, and economist. The instrument will ask a short series of questions on current health status, and on a retrospective assessment of health status during childhood and adolescence, to identify the QoL scores. To convert these scores into standardized economic utility values, respondents will then be asked to evaluate a series of health states (defined by pre-filled responses to the HRQOL instrument) using time-tradeoff (TTO) methods embedded in a discrete choice experiment (DCE) methods (Ratcliffe et al., 2009). Standard sociodemographic data, including age, race, ethnicity, income, employment status, marital status, and education will be collected as control variables for data reporting. Finally, a widely used and validated instrument, the Childhood Trauma Questionnaire short form (CTQ-SF) (Bernstein et al., 2003), and a short series of questions on other adverse childhood experiences from related research studies will be included at the end of the survey to measure a respondent's past exposure to CM or adverse experiences as a child or adolescent. The full survey instrument to be collected is appended to this document as **Attachment D**.

### **Website and Content Directed at Children Under 13 years of Age**

This IC involves web-based data collection methods but is limited to respondents ages 18 and older. Data will be collected through an online questionnaire created and maintained for this study only by an online survey data collection partner, Knowledge Networks (KN). RTI's data collection subcontract with KN will specify a sampling frame of adults ages 18 and older, which KN identifies through the use of basic demographic data that it maintains for its survey panels. KN will not sample or send survey invitations to any individual under age 18. Further, the data collection will begin with an IRB consent form (Attachment F) which requires a respondent to confirm that they are ages 18 and older when they provide informed consent (or decline to participate). The survey website that KN creates for this study will therefore not contain any content or pages

directed at children less than 13 years of age. A unique URL and password are required to access the survey website, further limiting access to the sampled individuals ages 18 and older. KN uses persistent cookies on respondents' computers to facilitate survey collection. This is discussed further in the KN privacy policy (Attachment H), but the information stored in cookies is not linked to any identifiable information submitted while on the KN website.

## **A.2 Purpose and Use of the Information Collection**

The purpose of gathering data and information from the proposed survey administration activities is to address the following research questions:

- What is the effect of CM on quality of life from childhood to late adulthood?
- How do quality of life impacts vary by type of abuse and sociodemographics of victims?
- How do preferences for health states related to quality-of-life impacts of CM differ between CM victims, non-maltreated, and the general public?

Exploratory survey data to answer the above research questions will be collected by an internet-survey partner, Knowledge Networks under subcontract to CDC's contractor for this study, RTI International. This is a one-time administration to a national sample of the general public.

The primary purpose of investigating these research questions is for CDC and RTI to advance the scientific literature on CM by writing research manuscripts on the HRQOL burden of child maltreatment; this research gap was previously identified and called for action (Prosser and Corso, 2007). Because this is the first quantitative research on the HRQOL burden of child maltreatment, the results will constitute a methodological contribution that advances scientific knowledge. CDC anticipates that future scientists working on studies of CM will use the results to report HRQOL impacts for other study populations, or will cite this study when describing the range of impacts of CM. A secondary purpose is for CDC to conduct exploratory economic analysis of the QoL burden of child maltreatment when reporting on the consequences of CM in a given study population. CDC may also use these results to conduct exploratory comparative analysis of CM intervention and treatment programs. Thus, collecting these exploratory data will

address a major research gap in the field of CM research, which has mostly relied on qualitative methods, not quantitative QoL methods. These data will substantially increase the scientific understanding of consequences of CM and its effects across the life cycle. The results of this exploratory research study will lay the foundation for significant future studies examining how to reduce the occurrence of child abuse and maltreatment, and how to mitigate the burden of CM in the U.S. for individuals, the healthcare system, and the economy. Future studies that build off of this exploratory research study may be required before comprehensive evaluation and comparison of CM intervention programs can occur.

Not collecting these data will limit advancement of the field of CM research and continue to require researchers and decision-makers to rely on qualitative methods when assessing the burden of CM. Quantitative data on the HRQOL burden of CM will not be available. Other fields have widely adopted HRQOL methods and these data are increasingly being requested by experts, decision-makers, and the public. CDC is not aware of any other active effort to apply HRQOL methods to CM at this time. Thus, not collecting these data will impede research on the HRQOL impacts of CM. The current state of incomplete information on HRQOL impacts of CM would continue and policies regarding CM interventions or prevention strategies will be based on incomplete evidence.

### **Privacy Impact Assessment Information**

Individuals' survey responses are being collected in order to conduct a new exploratory research study on the HRQOL burden of CM. Only de-identified data will be transmitted to RTI from KN for use in statistical analysis. Although Knowledge Networks maintains and safeguards information in identifiable form (IIF), IIF is not being collected anew for this study and will not be shared with RTI or CDC. The survey instrument does not include the collection of IIF. A national sample including CM victims and non-maltreated is necessary to estimate a statistical model of the differences in QoL by CM exposure history. To convert the QoL impacts into a common 0-1 utility scale, additional questions to elicit preference weights for CM-related QoL health states will be collected using TTO embedded in a DCE. To statistically identify differences in

HRQOL scores by past exposure to child maltreatment, validated questions to detect CM history are also required.

The proposed collection will have no effect on respondent privacy. The survey instrument will not collect IIF. The data collection partner, Knowledge Networks (KN), maintains Information in Identifiable Form (IIF) on its web survey panel (the KnowledgePanel) to help it draw samples for research studies. This information is not being collected anew in any way for this research study. Under subcontract to RTI, KN will use age and contact information to draw a nationally representative survey sample and to issue unique, secure invitations to sampled individuals. IIF will not be included in the data released to RTI or CDC. Most of the survey collects only non-sensitive information: sociodemographics, current and retrospective health states defined by the QoL questions, and valuations for a series of health states, identified by the DCE questions. See section A.11 for a discussion of sensitive information to be collected. Questions pertaining to CM history may prove to be sensitive to some respondents. These potentially sensitive questions are required for statistical identification of the impacts of CM, and include a small set of questions on if a respondent ever experienced emotional, physical, or sexual abuse and emotional or physical neglect. We are using the briefest and most nonintrusive set of scientifically validated questions to identify past child abuse and maltreatment, the Child Trauma Questionnaire short form (CTQ-SF) (Bernstein et al., 2003).

Prior studies in the literature confirm that the CTQ-SF questions can be collected with no adverse impact on respondents. Walker et al. (1997) collected the CTQ-SF, and other more sensitive questions, by mail from 500 adult female participants. A three-item evaluation of respondent experiences of satisfaction, upset and regret was used to identify possible respondent distress to these potentially sensitive instruments; the majority of respondents who completed their survey did not experience distress, and distress experienced by relatively few was “within tolerable limits.” RTI’s IRB reviewed the survey instrument, the study protocol, and the Walker et al. (1997) results before granting approval for this data collection.

In the event that participant data is disclosed, people who are CM victims and would prefer that others did not know about that part of their personal history may feel

uncomfortable if someone was to find out this information without their consent. The data collection partner, Knowledge Networks (KN), will be strongly reminded of the sensitivity of the CM history questions. RTI has also pre-negotiated subcontract language and steps with KN to safeguard the data. To ensure no breaches when the data are delivered by KN to RTI, KN will generate a de-identified dataset protected with 256-bit AES encryption and strong passwords transmitted by telephone.

Participants who become part of KN's panel, and therefore become eligible to complete surveys, are given a copy of the KN Privacy and Term of Use Policy outlining what information is collected and how it is used, and data security procedures. The document also explains how panel members can update, restrict, or remove their personal information and how they can quit the panel and ask for data to be destroyed.

The data collection partner, KN, also allows respondents to resume a survey that is suspended if respondents feel uncomfortable or need to take a break in the middle of the administration. Because all respondents are at least 18 years of age, they cannot be forced by a parent or guardian to provide these responses or to answer the questions in a false manner directed by a parent or guardian. Finally, since respondents use their own computers (or computers provided by KN) to complete surveys, they are able to complete the survey at their leisure, selecting the most convenient time and comfortable setting from which to complete the survey. Online administration of the child maltreatment history questions provides greater privacy relative to other electronic methods (e.g., telephone), which restrict respondents on the time, place, and setting in which they could respond.

Only de-identified information will be provided to RTI or CDC.

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

This information collection will exclusively use electronic methods (100% of responses). This exploratory research survey will be collected online over the internet, administered by the data collection partner (subcontractor), KN. The mode of internet survey data collection was selected in order to minimize respondent burden and to facilitate the highest quality responses to the DCE questions, which are more difficult for respondents to complete using alternative survey modes that do not include visual

displays (Ratcliffe et al., 2009; Bijlenga et al. 2009). Partnering with Knowledge Networks also facilitates a high-quality address-based sampling frame representative of the United States.

This research survey will be completed by respondents ages 18 and older from the convenience of their own personal computers over the internet. Sampled respondents will receive a survey invitation from KN which they can open and complete at their leisure, allowing them to select the most convenient time and comfortable setting from which to complete the survey. The online survey increases privacy relative to other electronic methods (e.g., telephone), which may reduce participant discomfort and increase the quality of data responses. Other electronic methods would restrict respondents on the time, place, and setting in which they could respond. Further, the DCE questions on the survey are best completed when a visual display is available (Ratcliffe et al., 2009; Bijlenga et al. 2009). Administering these questions by telephone is difficult for respondents and is more time-consuming and would increase the respondent burden. Finally, skip patterns, or computer-adaptive testing (CAT), will be used where possible to reduce burden by eliminating any logically irrelevant material from the survey in real-time based on individuals' responses.

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

No similar data to this exploratory research study are available. CDC seeks to measure the burden of child maltreatment and its effects on health-related quality of life (HRQOL) over the lifespan using validated HRQOL methods. Prior to developing the proposed data collection and this new research study, CDC commissioned a structured literature review of the use of HRQOL methods to quantify the burden of CM. A report (Prosser and Ravenscroft, 2006) and published review (Prosser and Corso, 2007) failed to demonstrate any datasets, instruments, or published research that could be used for the purposes of this study. This finding was also confirmed during an unpublished systematic review of the literature conducted by RTI in 2009. These reviews pointed out major limitations of existing "generic" HRQOL instruments such as the SF-36, EQ-5D, etc. and their failure to capture relevant domains and impacts of CM. The report and literature review also included expert consultation from two clinicians active in the field of CM

research, who confirmed the nonexistence of studies or instruments to meet measure the burden of child maltreatment and its effects on HRQOL over the lifespan using validated HRQOL methods.

Under contract for CDC to conduct this new research study, RTI has developed a new exploratory HRQOL instrument to measure the burden of CM over the lifespan using validated HRQOL methods. The HRQOL burden of CM in children has not previously been measured; therefore, this information has not previously been collected. For review during the instrument development process, RTI contacted 11 experts; all confirmed that no similar studies or instruments existed and provided general feedback on the scientific content.

We identified only one published study by Corso et al. (2008) on the quality of life of adults who were victims of CM; however this study does not meet the current needs of the proposed collection and is not duplicative of the proposed collection. First, the study used a generic measure of HRQOL, the SF-36, which was shown by Prosser and Ravenscroft (2006) and Prosser and Corso (2007) to have significant shortcomings and to omit many of the known HRQOL impacts of CM. To address this, the proposed study will use a new exploratory HRQOL measure developed specifically for this effort by RTI for CDC. Second, the Corso et al. (2008) paper estimated the burden only among adult respondents for their “current” health state. The proposed collection includes a retrospective assessment of health states experienced during childhood and adolescence. Third, the Corso et al. (2008) paper used a poor measure of child maltreatment, non-validated and vague questions about CM. The proposed collection improves on this by using validated questions accepted by CM researchers, the Child Trauma Questionnaire short form (CTQ-SF) (Bernstein et al., 2003). Fourth, the Corso et al. (2008) study used a convenience sample of respondents from a managed health care plan in California, not a national sample as in the proposed collection, and thus their results cannot be generalized.

#### **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**

This request is for a one-time survey. Sampled respondents will be invited to respond to the data collection one time only. Additional collections are not required to meet CDC goals and objectives for this new research study.

Without this data collection, decision makers will continue to lack estimates of the full burden of CM, including its impacts on HRQOL and may therefore make decisions based on incomplete information. Specifically, they will not be able to estimate changes in HRQOL that may result from successful interventions aimed at reducing the incidence of CM or the adverse health consequences of CM. The current lack of data on the HRQOL impacts from CM inhibits comparisons between alternative CM prevention and treatment programs, and between programs targeted at CM and those targeted at other health problems, for which considerable HRQOL data exists. For example, the HRQOL impacts of cancer (Doni et al. 2010) and diabetes (Laffel et al. 2003) have been used in evaluations of treatments for these conditions (Howard et al. 2010; Wolowacz et al. 2008). CDC proposes to use this study to quantify reductions in HRQOL related to CM using a common measurement in the HRQOL literature, health-state utilities.

If the collection is not conducted, the HRQOL impacts of child maltreatment will remain largely unmeasured and an important scientific research gap will remain. As noted in section A.4, the HRQOL burden of CM in children has not previously been measured. This instrument has not been previously collected and this study will expand the body of scientific knowledge on CM. Because this is the first quantitative research on the HRQOL burden of child maltreatment, the results will constitute a methodological contribution that advances scientific knowledge.

Furthermore, if the collection is not conducted, the HRQOL estimates from the proposed research will not be available to inform evaluation and effectiveness research by CDC, the scientific community, or other organizations. Valid cost-effectiveness research requires reliable HRQOL estimates (Drummond et al., 1997). CDC anticipates that future scientists working on studies of CM will use the results to report HRQOL

impacts for other study populations, or will cite this study when describing the range of impacts of CM. However, future studies that build off of this exploratory research study may be required before comprehensive evaluation and comparison of CM intervention programs can occur.

There are no legal obstacles to reduce the burden.

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

This project fully complies with all guidelines of 5 CFR 1320.5.

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

##### **A. 60-day Federal Register notice**

A 60-day Federal Register Notice was published in the *Federal Register* on November 1, 2010, vol. 75, No. 210, pp. 67092-67093 (see **Attachment B**). There were no public comments.

##### **B. Efforts to Consult Outside Agency**

During 2010, RTI International contacted the following experts outside of CDC to obtain their views on the study design: CM-specific HRQOL instrument developed for this study, the availability of data or alternatives, disclosure, reporting format, and on the data elements to be reported.

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

All respondents to the national sample for this exploratory research study will be recruited from an online research panel (the “KnowledgePanel®”) maintained by the data collection partner, Knowledge Networks (KN). Individuals join the KN panel only after being directly recruited; they may not voluntarily opt-in. Those who join are given, as necessary, a computer, internet access, and ongoing technical support. These services are provided to facilitate the data collection methodology, but respondents are allowed to freely use their computing resources for personal use. Thus, these benefits are also used as an incentive for recruiting potential panel members.

Research participants will be offered a small non-cash incentive by KN to complete the proposed research survey. KN requires that any survey to its panelists provide such “points,” which can be redeemed for raffle entries, various gifts, or cash at regular intervals. The total monetary equivalent of the points for this one-time survey will not exceed \$10. This honorarium is intended to recognize the time burden placed on the participants, encourage their cooperation, and to convey appreciation for contributing to this important study. Numerous empirical studies have shown that honoraria can

significantly increase response rates (Abreu & Winters, 1999; Shettle & Mooney, 1999). The decision to use honoraria for this study is based on findings reported in current research publications and several projects conducted by Knowledge Networks and RTI, which found that use of an honorarium increases response rates among adults.

All participant remuneration has been approved by the RTI International IRB. IRB approval is provided in **Attachment G**.

#### **A.10 Assurance of Confidentiality Provided to Respondents**

RTI and CDC will only receive information in de-identified form.

The data collection partner, Knowledge Networks (KN), maintains Information in Identifiable Form (IIF) on its web survey panel (the KnowledgePanel) to help it draw samples for research studies. This information is not being collected anew in any way for this research study. Under subcontract to RTI, KN will use age and contact information to draw a nationally representative survey sample and to issue unique, secure invitations to sampled individuals. IIF will not be included in the data released to RTI or CDC.

#### IRB Approval

RTI International's Institutional Review Board (IRB) has reviewed informed consent materials (Attachment F) and procedures for the proposed information collection to ensure that the rights of individuals participating in the study are safeguarded. The study received IRB approval as protocol #12324. The proposed survey instrument (Attachment D) was reviewed by RTI's IRB and approved as an amendment to the overall study protocol on November 29, 2010. The IRB for all study activities was renewed on February 21, 2012 (**Attachment G**). CDC staff for this study are considered "non-engaged" after review by the NCIPC Human Subjects/OMB coordinator.

All IRB standards for securing participant data will be maintained for data collections between participants and RTI or CDC. KN's privacy policy for collecting and storing participant information will be effective between KN and survey participants. Additional information describing Knowledge Networks privacy policies is described in **Attachment H**.

## **Privacy Impact Assessment**

### **A.10.A. Privacy Act Determination**

*This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply.*

### **A.10.B. How the Information will be Secured**

The project does not include an Assurance of Confidentiality or non-disclosure agreement. RTI will maintain restricted access to all data.

Knowledge Networks (KN) employees who have access to Information in Identifiable Form (IIF) are contractually required to keep the information secured. KN also secures and grants access to data to authorized users only. IIF and demographic information are maintained in separate databases from other information for added protection and only authorized employees and agents are given access to those databases. All employees of KN are required to sign a confidentiality agreement requiring him or her to secure personally indefinable information. Employees who violate the confidentiality agreement are subject to disciplinary action.

KN has developed a secure transmission and collection protocol, including the use of system passwords and two separate sets of firewalls to prevent unauthorized access to the system. Only de-identified data will be transmitted to RTI via an encrypted FTP server, with passwords transmitted separately by telephone. The data file itself will also be encrypted with 256-bit AES encryption with the password transmitted separately by telephone.

Technical controls used by RTI on the servers applicable for this study are: user identification, passwords, firewall, virtual private network (VPN), and encryption.

Physical controls used by RTI on the buildings applicable to project staff and servers are: guards, identification badges, key cards, and closed circuit TV (CCTV) cameras.

Administrative controls used by RTI for this study are: a system security plan, frequent backups stored onsite for 1 month and offsite for a period of 1 year (renewable up to 5 years, upon request by project directors), personnel training, least privilege methods, and records retention and destruction policies. This project will conform to an IRB-approved data security and destruction policy, as well as being in compliance with

contractual regulations between RTI and CDC for the overall study. RTI maintains restricted access to all data. All data files on multi-user systems will be under the control of a database manager, with access limited to project staff for this study only and on a “need-to-know” basis.

Planned controls used by RTI for this study: The process for handling security incidents is defined in the system’s Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events will be directed to the component’s Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

RTI’s data collection subcontract with KN will include a requirement that KN purge all data from this survey research study within 30 days of the completion of data collection and secure delivery of the de-identified data files to RTI. This 30-day period will allow RTI to conduct data cleaning, quality checks, and verification to confirm that there are no issues with the files. If KN must correct and re-ship a data file, the 30-day period will be reset to allow for additional verification. This procedure was developed in response to a request by RTI’s Institutional Review Board (IRB).

De-identified data will be delivered to CDC. The Science Officer, Curtis Florence, will manage the data files and requests to access and analyze the data. The data files will be stored on the secure CDC network in a folder with restricted access. Access to the folder will be permitted on a case by case basis. Researchers who request access to the folder will be required to submit a concept proposal which includes a security pledge and supervisory support.

#### **A.10.C. Respondent Consent**

All respondents recruited for the online national research survey will be required to read, review, and click a box indicating that they are 18 years of age or older and that they are providing informed consent to begin the survey. If a respondent does not indicate that he or she is 18 years of age or older, or does not provide informed consent, the online consent will go to a termination screen and the survey will not be collected from the

respondent. The consent form has been reviewed and approved by RTI's IRB and is included here as **Attachment F**.

#### **A.10.D. Informing Respondents of the Voluntary of Mandatory Nature of Their Response**

The IRB-approved consent form (**Attachment F**) includes text explaining that responding to the survey is voluntary.

#### **A.11 Justification of Sensitive Questions**

The only sensitive, or potentially sensitive, questions in this information collection are a small set of survey questions about CM history. These will consist of questions to determine if a respondent ever experienced emotional, physical, or sexual abuse and emotional or physical neglect. We are using the briefest and most nonintrusive set of validated question as possible that are accepted by CM researchers, the Child Trauma Questionnaire short form (CTQ-SF) (Bernstein et al., 2003).

Responses to these potentially sensitive questions from a national sample including CM victims and non-maltreated are necessary to estimate a statistical model of the differences in QoL by CM exposure history. A brief explanation of these questions will be provided to respondents in the IRB-approved consent form (**Attachment F**). The steps taken to obtain a respondent's consent are IRB-approved are discussed under section A.10.C above.

#### **A.12 Estimates of Annualized Burden Hours and Costs**

The estimated hour burden estimates for this data collection are shown in Table A.12-1. All respondents will be adults ages 18 and older. The survey instrument (**Attachment D**) will be sent to adults who respond affirmatively to a survey invitation (**Attachment C**). An IRB-approved consent form (**Attachment F**) must be completed by respondents before they are allowed to begin the survey.

Survey invitations (**Attachment C**) will be sent by the data collection partner, Knowledge Networks (KN), who will randomly draw a sample of U.S. adults ages 18 and older from its standing panel (Knowledge Panel). A random sample of n=750 will be limited to persons ages 18-29 and another random sample of n=1100 will include all

persons ages 18 and older (see Statement B.2). Both groups will complete the full survey. KN maintains basic demographic data on this population and will limit survey invitations to adults ages 18 and older. Adults who read the survey invitations and desire to participate will be re-directed to a secure, password-protected website hosted by KN which contains the next two forms.

An IRB-approved consent form (**Attachment F**) must be completed by respondents before they are allowed to begin the survey. Respondents will be asked to read basic information about the research study, the study purpose, procedures, duration of the survey, possible risks or discomforts from the survey, benefits of participating, incentive for participation, privacy, individuals' rights, and who to contact with questions. Respondents will then be required to click a box indicating that they have read the information, confirm that they are 18 years of age or older, and that they voluntarily consent to participate in the study or decline to participate. Only those who consent and certify that they are 18 years of age or older will continue to the full survey instrument.

Estimates for the time burden and number of respondents in Table A.12-1 are based on an in-person pretest of all materials with n=9 individuals in the Raleigh-Durham, NC area in May 2011. A second round of pretests, reflecting changes to the instrument discussed with OMB, was held in March 2012. Additional data for this table was derived by KN for RTI based on a 23-minute RTI public health survey fielded by KN in June 2010 to a national sample of U.S. adults ages 18 and older. To obtain a final count of n=1850 (1100 ages 18+, 750 ages 18-29) respondents to the full survey, n=1917 (1140 ages 18+, 777 ages 18-29) respondents will review the IRB consent form (96.5% consent and eligibility rate). To reach n=1917 adults for the consent form, n=2255 (1341 ages 18+, 914 ages 18-29) survey invitations will be sent by KN (85% response rate). (The overall response rate is 82%). Finally, KN has also reviewed the RTI survey instrument for length and estimated an average response time of 27 minutes.

The total estimated burden in time for this research study is 833 hours, based on 1850 respondents and up to 27 minutes per response.

**Table A.12-1: Estimated Annualized Burden Hours**

| <b>Type of Respondent</b> | <b>Form Name</b>                 | <b>No. of Respondents</b> | <b>No. Responses per Respondent</b> | <b>Average Burden per Response (in hours)</b> | <b>Total Burden Hours</b> |
|---------------------------|----------------------------------|---------------------------|-------------------------------------|---|---------------------------|
| Adults, age 18-29         | Survey Instrument (Attachment D) | 750                       | 1                                   | 27/60   | 338                       |
| Adults, age 18+           | Survey Instrument (Attachment D) | 1100                      | 1                                   | 27/60   | 495                       |
| <b>Total</b>              |                                  |                           |                                     |   | 833                       |

The annualized costs to respondents for the burden hours for administering this survey are included in Table A.12-2. Average wage rates for all adults are calculated from the *Statistical Abstract of the United States: 2011* (U.S. Census Bureau, 2010), Table 687. The average annual earnings for all men (hourly and salaried workers, full time) 18 years and older as of March 2009 are reported as \$61,783; the average annual earnings for all women (hourly and salaried workers, full time) 18 years and older as of March 2009 are reported as \$43,305. Assuming 48.6% of respondents are male and 51.4% female (based on the Census population estimates for ages 18+ in 2010) and 2000 hours worked per year, the population-weighted average hourly wage rate for all adults age 18+ is estimated at \$26.15. Similar estimates for wages and population for the age 18-29 group yield an average hourly wage rate of \$17.83.

The total estimated burden in time costs for this research study is \$18,971.

**Table A.12-2: Estimated Annualized Burden Costs**

| Type of Respondents | Form Name                        | No. of Respondents | No. Responses per Respondent | Avg. Burden per Response (in hours) | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---------------------|----------------------------------|--------------------|------------------------------|-------------------------------------|--------------------|------------------|------------------------|
| Adults, age 18-29   | Survey Instrument (Attachment D) | 750                | 1                            | 27/60                               | 338                | \$17.83          | \$6,027                |
| Adults, age 18+     | Survey Instrument (Attachment D) | 1100               | 1                            | 27/60                               | 495                | \$26.15          | \$12,994               |
| <b>Total</b>        |                                  |                    |                              |                                     |                    |                  | \$18,971               |

**A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There are no other direct costs to respondents or record keepers.

**A.14 Annualized Cost to the Government**

This is a contracted data collection, led by RTI International under contract for CDC. (RTI is subcontracting data collection to a partner, Knowledge Networks.) The total cost of the contract is \$599,938 over 4 years (July 2009 to July 2013). A CDC technical monitor and science officer devote 20% of their FTE for an estimated total cost of \$128,817.60 over 4 years. The average annualized cost is \$182,188.90 (\$149,984.50 contract + \$32,204.40 CDC labor).

**A.15 Explanation for Program Changes or Adjustments**

This is a new data collection.

### **A.16 Plans for Tabulation and Publication and Project Time Schedule**

The time schedule for the entire research project is shown in table A.16-1 below, including beginning and end dates, the completion of the report and publication dates. Survey invitations to respondents will be sent by KN 2 months after OMB approval. The survey fielding period will be completed 3 months after OMB approval. Analyses and publication will be completed 12 months after OMB approval.

**Table A.16-1:** Project Time Schedule

| <b>Activity</b>                        | <b>Time Schedule</b>           |
|--|--------------------------------|
| Survey invitations sent to respondents | 2 months after OMB approval    |
| Fielding period                        | 2-3 months after OMB approval  |
| Analyses                               | 3-12 months after OMB approval |
| Publication                            | 6-12 months after OMB approval |

A final report for this exploratory research study will be written by RTI International and delivered to CDC no later than 12 months after OMB approval. The report will be for internal use at CDC and will contain a detailed description of all aspects of the survey and HRQOL instrument development, data collection, and results. A list of tables for the report are included below as Tables A.16-2 through A.16-8.

CDC and RTI also anticipate writing two scientific manuscripts from this exploratory research study and submitting these to peer-reviewed journals in the fields of health economics, child maltreatment and abuse, public health, or quality-of-life research. The manuscripts will be excerpted from the final project report. One manuscript will report on a detailed description of all aspects the HRQOL instrument development and the estimation of the health-state utilities (0-1 values) from an econometric model of the health states defined by the new HRQOL instrument. Specifically, the DCE-based health state values will be estimated statistically using conditional and mixed logit choice models based on each respondent's stated choice. A mixed logit model will be used for the final results, but since this is a computer-intensive routine, conditional logit is used in initial data analysis. Most DCE papers today continue to report both models although the mixed logit is preferred for several econometric properties.

The parameter estimates from the mixed logit model will be used to predict the utility of each health state on 0.0-1.0 scale. This procedure follows Brazier et al. (2002) and Ratcliffe et al. (2009). In these choice models, the respondent's choice is the dependent variable, and the amount of time traded off (TTO method) enters as an attribute, or independent variable. Other independent variables are indicators for each health-state domain and all levels within these domains, plus possible interactions (minus omitted categories for statistical identification). To convert to 0.0-1.0 scales, the time tradeoff is used as a numeraire, with preferences over other attributes relative to changes in the numeraire. The key tables for this manuscript will be Tables A.16-2 and A.16-7.

A second manuscript will report on the HRQOL burden of CM. This manuscript will use the health-state utilities from the prior manuscript and combine these with the actual health states (outcomes) reported by respondents for the current health, and retrospectively for ages 5-11 and 12-17. First, the TTO specification with the best fit from the model in the previous manuscript (Table A.16-7) will be used to provide the utility "weights" for each possible health state outcome. These utility weights are multiplied by the actual responses to generate a 0-1 health state utility value for each respondent. Next, the predicted health state utilities (Table A.16-5) are used as the dependent variables in a multivariate linear or random effects regression model. The key independent variables for this analysis are indicators for each type of abuse or any abuse (Table A.16-4) to identify history of CM, which will be derived from the recommended scoring algorithm for the CTQ-SF instrument (Bernstein et al., 2003). Abuse in any of the five types (physical abuse, sexual abuse, physical neglect, emotional neglect, and emotional abuse) is classified into one of four levels: no abuse, low, moderate, and severe. The CTQ-SF documentation recommends that either the low or moderate levels be used to screen abuse; we will follow this standard, while also considering severe and low cutoffs for CM in sensitivity analysis. Additionally, any respondent whose CTQ score reaches the "low" level for any type of abuse will be asked a follow-up question to identify the timing of abuse as approximately beginning in early childhood (before age 5), childhood (ages 5-11), or adolescence (ages 12-17). This will be an important control variable in other parts of the analysis so that we do not inadvertently attribute CM in adolescence to HRQOL impacts in childhood (Smith et al. 2004).

Other independent variables used are those shown in the descriptive tables A.16-2 and A.16-3. Together in a multivariate model, the coefficients corresponding to the abuse types (or any abuse vs. no abuse) will generate the marginal utility differences between CM victims and non-maltreated (Table A.16-6). As noted earlier, a sample of n=750 respondents ages 18-29 will be gathered separately from another sample of n=1100 respondents ages 18 and older. The “recalled” child and adolescent health states are expected to have greater salience for respondents ages 18-29 than for those ages 30 and older, so we have powered the difference in health states study to be estimable off of respondents who are ages 18-29 in both samples. (In exploratory analysis, we also expect to combine both the n=750 and n=1100 samples, based on the inverse of their selection probability and weighted back to obtain results representative of the Census distribution of persons ages 18+.) The key tables for this manuscript are Tables A.16-3 through A.16-6.

**Table A.16-2:** Descriptive Statistics, Overall Sample Means by Characteristic

| <b>Characteristic</b>                  | <b>Overall Sample Mean</b> |
|--|----------------------------|
| Age                                    |                            |
| Gender                                 |                            |
| White, non-Hispanic                    |                            |
| Black, non-Hispanic                    |                            |
| Multiple races, non-Hispanic           |                            |
| Hispanic ethnicity, any race           |                            |
| Other races, non-Hispanic              |                            |
| Income                                 |                            |
| Household size                         |                            |
| Married                                |                            |
| Never married                          |                            |
| Divorced or separated                  |                            |
| Widowed                                |                            |
| Unmarried, living with partner         |                            |
| Region                                 |                            |
| Education                              |                            |
| Any child maltreatment history         |                            |
| Child maltreatment began before age 12 |                            |
| Child maltreatment began ages 12-17    |                            |
| Physical abuse history                 |                            |
| Sexual abuse history                   |                            |
| Emotional abuse history                |                            |
| Physical neglect history               |                            |
| Emotional neglect history              |                            |

**Table A.16-3:** Descriptive Statistics, Sample Means by Abuse Type and Characteristic

| Characteristic               | Sample Means by Abuse Type |                |              |                 |                  |                   |                |
|------------------------------|----------------------------|----------------|--------------|-----------------|------------------|-------------------|----------------|
|                              | No Abuse                   | Physical Abuse | Sexual Abuse | Emotional Abuse | Physical Neglect | Emotional Neglect | Physical Abuse |
| Age                          |                            |                |              |                 |                  |                   |                |
| Gender                       |                            |                |              |                 |                  |                   |                |
| Black, non-Hispanic          |                            |                |              |                 |                  |                   |                |
| Multiple races, non-Hispanic |                            |                |              |                 |                  |                   |                |
| Hispanic ethnicity, any race |                            |                |              |                 |                  |                   |                |
| Other races, non-Hispanic    |                            |                |              |                 |                  |                   |                |
| Income                       |                            |                |              |                 |                  |                   |                |
| Household size               |                            |                |              |                 |                  |                   |                |
| Married                      |                            |                |              |                 |                  |                   |                |
| Never married                |                            |                |              |                 |                  |                   |                |
| Divorced or separated        |                            |                |              |                 |                  |                   |                |
| Widowed                      |                            |                |              |                 |                  |                   |                |
| Unmarried, live w/partner    |                            |                |              |                 |                  |                   |                |
| Region                       |                            |                |              |                 |                  |                   |                |
| Education                    |                            |                |              |                 |                  |                   |                |
| CM began ages 5-11           |                            |                |              |                 |                  |                   |                |
| CM began ages 12-17          |                            |                |              |                 |                  |                   |                |
| Physical abuse history       |                            |                |              |                 |                  |                   |                |
| Sexual abuse history         |                            |                |              |                 |                  |                   |                |
| Emotional abuse hist.        |                            |                |              |                 |                  |                   |                |
| Physical neglect hist.       |                            |                |              |                 |                  |                   |                |
| Emotional neglect hist.      |                            |                |              |                 |                  |                   |                |

**Table A.16-4:** The Prevalence and Inter-correlation between Types of Childhood Maltreatment among Respondents

| <b>Childhood Maltreatment Type</b> | <b>Correlations</b>           |                       |                     |                        |                         |                          |
|------------------------------------|-------------------------------|-----------------------|---------------------|------------------------|-------------------------|--------------------------|
|                                    | <b>Prevalence, Number (%)</b> | <b>Physical Abuse</b> | <b>Sexual Abuse</b> | <b>Emotional Abuse</b> | <b>Physical Neglect</b> | <b>Emotional Neglect</b> |
| Physical Abuse                     |                               |                       |                     |                        |                         |                          |
| Sexual Abuse                       |                               |                       |                     |                        |                         |                          |
| Emotional Abuse                    |                               |                       |                     |                        |                         |                          |
| Physical Neglect                   |                               |                       |                     |                        |                         |                          |
| Emotional Neglect                  |                               |                       |                     |                        |                         |                          |

**Table A.16-5:** Predicted Utilities, by Sample Populations among Respondents

| <b>Age Group (years)</b> | <b>No Childhood Maltreatment</b> | <b>Childhood Maltreatment</b> |
|--------------------------|----------------------------------|-------------------------------|
| 5-11 (recalled)          |                                  |                               |
| 12-17 (recalled)         |                                  |                               |
| 18-29                    |                                  |                               |
| 30-39                    |                                  |                               |
| 40-49                    |                                  |                               |
| 50-59                    |                                  |                               |
| 60-69                    |                                  |                               |
| ≥70                      |                                  |                               |
| <b>All ages</b>          |                                  |                               |

**Table A.16-6:** Marginal Utility Differences (95% Confidence Intervals) Between Childhood-Maltreatment and No-Childhood-Maltreatment Groups, by Age Group and Type of Maltreatment

| <b>Age Group, y</b> | <b>Any Childhood Maltreatment</b> | <b>Physical Abuse</b> | <b>Sexual Abuse</b> | <b>Emotional Abuse</b> | <b>Physical Neglect</b> | <b>Emotional Neglect</b> |
|---------------------|-----------------------------------|-----------------------|---------------------|------------------------|-------------------------|--------------------------|
| 5-11 (recalled)     |                                   |                       |                     |                        |                         |                          |
| 12-17 (recalled)    |                                   |                       |                     |                        |                         |                          |
| 18-29               |                                   |                       |                     |                        |                         |                          |
| 30-39               |                                   |                       |                     |                        |                         |                          |
| 40-49               |                                   |                       |                     |                        |                         |                          |
| 50-59               |                                   |                       |                     |                        |                         |                          |
| 60-69               |                                   |                       |                     |                        |                         |                          |
| ≥70                 |                                   |                       |                     |                        |                         |                          |
| All                 |                                   |                       |                     |                        |                         |                          |

**Table A.16-7:** Coefficients From Health-State Utility Model (TTO method)

|                            | <b>Conditional<br/>Logit<br/>Regression</b> | <b>95%<br/>Confidence<br/>Interval</b> | <b>Mixed Logit<br/>Regression</b> | <b>95%<br/>Confidence<br/>Interval</b> |
|----------------------------|---|--|-----------------------------------|--|
| HRQOL Domain<br>1: level 1 |   |  |                                   |  |
| ...                        |   |  |                                   |  |
| HRQOL Domain<br>8: level 4 |   |  |                                   |  |
| n =                        |   |  |                                   |  |
| Log-likelihood             |   |  |                                   |  |
| Pseudo R <sup>2</sup>      |   |  |                                   |  |

**A.17 Reasons Display of OMB Expiration Data is Inappropriate**

Display of OMB expiration is not inappropriate in this information collection.

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

There are no exceptions to the certification for this information collection.

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