Children's Health after the Storms (CHATS) Study

Paperwork Reduction Act Submission Supporting Statement

February 22, 2012

Prepared for

Centers for Disease Control and Prevention
National Center for Environmental Health
Division of Environmental Hazards and Health Effects

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Section A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), Division of Environmental Hazards and Health Effects (EHHE) is requesting a 3-year Office of Management and Budget (OMB) clearance to conduct the Feasibility Phase of a longitudinal health study to assess the potential adverse health effects of environmental exposures to Federal Emergency Management Agency (FEMA)-provided Temporary Housing Units (THUs) among children who had resided in areas affected by Hurricanes Katrina and Rita (i.e., storm-affected area). The data collection authority for this study is Section 301 of the Public Health Service Act (42 USC 241) (***Attachment A***).

Background

On August 29, 2005, Hurricane Katrina made landfall on the Gulf Coast between New Orleans, Louisiana and Mobile, Alabama as a Category 3 storm. Soon after, Hurricane Rita made landfall on September 24, 2005 between Sabine Pass, Texas and Johnsons Bayou, Louisiana as a Category 3 storm. Families were evacuated from the United States Gulf Coast and returned later to severely damaged housing. FEMA provided disaster-related housing along the US Gulf Coast beginning in October 2005. At that time, FEMA typically addressed disaster-related housing requirements with a combination of THUs including travel trailers, mobile homes, and park models. Temporary housing units have been used principally for short-term housing needs and were placed on either private sites while a homeowner's permanent residence was being repaired or in group configurations to primarily support displaced renters.

In the spring of 2006, several physicians along the US Gulf Coast observed an increased reporting of upper respiratory illnesses among children who lived in FEMA-provided THUs following Hurricanes Katrina and Rita. Residents of FEMA-provided THUs expressed concerns about formaldehyde levels in their units and possible adverse health effects. To date, the CDC has conducted two investigations to begin evaluating these reports and concerns. The ICR number for these CDC projects conducted as Epi-AIDS is 0920-0008, "Emergency Epidemic Investigations". First, CDC conducted a case-series investigation in Hancock County, Mississippi to assess the overall occurrence of respiratory diseases in children between August 2004 and August 2007. Second, CDC measured formaldehyde concentrations in a sample of 519 occupied FEMA-provided THUs in Louisiana and Mississippi. Epi-Aids, by their nature, are rapid responses to address specific goals. After these two investigations, there was continued concern regarding the potential long-term health effects of various indoor exposures among children who resided in FEMA-provided THUs, who represent a vulnerable population in areas affected by Hurricanes Katrina and Rita. Based on these concerns, FEMA asked CDC to assess the health risk to people who lived in the THUs for extended periods.

On July 03, 2008, CDC, Department of Health and Human Services (DHHS) posted a Request for Information (RFI) to FEDBIZOPS seeking recommendations on a range of issues as it developed an acquisition strategy for a longitudinal cohort study to identify potential health effects of various indoor exposures from FEMA-provided THUs among children who had resided in areas affected by Hurricanes Katrina and Rita. Based upon the analysis of the responses received, CDC determined that the best approach for the cohort study was a "centralized approach" with a prime contractor assuming full responsibility for the study.

On May 8, 2009, CDC released a Request for Proposals (RFP) to design and conduct a longitudinal health study to assess the potential health effects of environmental exposures to FEMA-provided THUs among children who had resided in areas affected by Hurricanes Katrina and Rita. The study will be conducted in two phases: a two-year base period (Feasibility Study Phase) and an optional six-year period (Full

Study Phase). In the RFP, CDC specified that the Feasibility Study include development and assessment of study materials and data collection procedures, including the collection of Baseline and follow-up health and environmental exposure data on approximately 500 children. CDC will use the results of the Feasibility Study to determine whether or not conducting the Full Study is practical. The criteria that will be used to assist CDC in making this determination include: (1) availability of a sufficiently large cohort of exposed and unexposed participants (i.e., ability to locate, enroll, and retain study participants); (2) ability to locate medical records; and (3) availability of adequate funding. If the Full Study is exercised, the contractor will be able to revise the Full Study protocol based on information obtained during the Feasibility Study. Additionally, the 500 participants from the Feasibility Study will be enrolled as part of the Full Study cohort and will continue to be followed prospectively.

On August 31, 2010, RTI was awarded a contract to conduct the two-year Feasibility Study. The Full Study Phase will be conducted by RTI if CDC determines that the study is feasible. Please note that materials provided in the attachments refer to the study as "Children's Health after the Storms" or by the acronym "CHATS."

Privacy Impact Assessment

Overview of the Data Collection System

NOTE: As is CDC's usual procedure, Privacy Impact Assessment (PIA) information is being provided within the Supporting Statement Sections A1, A2, and A10. However, for this ICR it is being included for OMB informational purposes only. Because of the sensitive nature of the information being collected, a full Privacy Impact Assessment (PIA) was submitted to the NCEH Office of Information Systems for transmission to the CDC Chief Information Security Office as part of the National Institute of Standards and Technology (NIST) Certification and Accreditation process. Final approval from CDC's Chief of Information Security was received via email on December 8, 2011.

The primary objective of the Full Study is to determine if there is an association between prior occupancy[1] in FEMA-provided THUs[2] and adverse health effects among children who had resided in storm-affected areas at the time of Hurricanes Katrina or Rita. Three types of adverse health effects will be assessed in the Full Study: (1) short-term symptoms or diagnostic conditions that have since resolved, (2) long-term effects that are still present, and (3) increased sensitivity to current exposures. To accomplish this, the study will obtain retrospective and prospective information on exposure and health. Specifically, information on the residential, exposure, and medical history of the child through interviews with parents and medical record abstraction will be collected to assist us in characterizing short-term symptoms or diagnostic conditions that have since resolved. To assess the current health status and the development of any increased sensitivity to current exposures, information on the child through a physical assessment and measurement of current and ongoing exposures to specific contaminants through (a) tests on biospecimens, (b) air and dust monitoring of the house and neighborhood, and (c) personal exposure measurements using a portable air sampler (MicroPEM™) will be conducted over multiple follow-up assessments.

The Feasibility Study data collection system includes all of the measurements and procedures that are proposed for the Full Study. The Feasibility Study will include a Baseline and 6-month Follow-up Assessment, each of which is comprised of two home visits by field staff, referred to as Session 1 and Session 2 that will occur approximately one week apart. Prior to beginning the Baseline Assessment, a field interviewer (FI) will go to the home of potential participants and conduct a brief eligibility screening

[1] "Prior occupancy" refers to the period after September 2005.

[2] A FEMA-provided THU refers to a THU that was provided to a resident whose home was impacted as a result of Hurricane Katrina or Rita.

interview with an adult at least 18 years of age using a secure handheld computer. If the household has an eligible child, the FI will speak with the adult parent/guardian about the study and ask for consent to participate.

During Session 1 of the Baseline Assessment, the FI will administer the health and environmental exposure questionnaire, perform a visual home inventory, set up the exposure assessment equipment, explain the time and activity diary procedure, and instruct the parent on the use of a cell phone-sized personal air monitoring device (MicroPEM^{TM}) that children aged 7 years and older will wear for one week. During Session 2 of the Baseline Assessment, a registered nurse (RN) will accompany the FI to administer the Health Assessment to the child, which includes measuring the height and weight of the child, assessing the child for dermal rashes, conducting respiratory assessments, and obtaining biospecimens (blood and urine). The FI will administer the exposure questionnaire, record all information gathered from the exposure assessment equipment, enter data from the time and activity diary directly into the laptop, and collect GPS information. The procedures for the 6-month Follow-up Assessment are the same as the Baseline except that blood will not be collected during Session 2.

In addition, medical record abstraction will be conducted on approximately 30% of the children, which includes all children with self-reported asthma or other targeted health outcomes and a random sample (n= 50) of the other children. Health care providers will be identified by the parent/guardian. Abstraction will be conducted only with those providers for whom the parent/guardian provides consent for the study to contact.

All questionnaire data will be collected using computer-assisted interviewing (CAI) technologies - either via laptop or handheld device - with the following two exceptions: (1) the time and activity diary will be recorded on paper by the respondent and data will be entered into a laptop by the FI; and (2) medical records abstraction will be collected on paper and then data will be entered into a computer program.

Wherever possible, questions included in the data collection tools represent questions from validated or cognitively tested questionnaires (e.g., International Study of Asthma and Allergies in Childhood [ISAAC], Behavioral Risk Factor Surveillance System [BRFSS]) and exposure assessment surveys that have been used in similar national-scale studies (e.g., National Children's Study).

Data will be collected by: (1) FIs hired by the contractor, RTI International; (2) RNs hired by two subcontractors, Louisiana State University (LSU) and Coastal Family Health Center; and (3) medical records abstractors hired by Aten Solutions Inc. Biospecimens (urine and blood) will be collected by the RNs and shipped directly to the LSU laboratories for analysis. Environmental specimens will be collected by FIs and shipped directly to RTI laboratories for analysis.

De-identified data, including questionnaire and specimen analysis results, will be maintained at CDC for up to 20 years. Personally identifying information will be retained by the contractor for 10 years after the end of the funded period of the Study.

Items of Information to be Collected

Information in Identifiable Form (IIF) will be collected to facilitate the personal contact with participants required to conduct the study. However, none of the IIF will be provided to CDC as part of the deliverable data, per the contract specifications. The IIF include: name of the parents/guardians and child, residential address, email address, social security numbers of the parents/guardians and child, names of persons who can assist in providing new contact information if the participant moves, and, for a subset of participants, medical records information. Other indirectly identifiable demographic data, such as age, race, ethnicity, and birth date of the child, will also be obtained and will be provided to CDC. (See A.10 for a description of how the data will be de-identified.)

The sources of information, data collection method, and type of data that will be obtained during the Feasibility Study are shown in ***Exhibit 1***. A more detailed description regarding the selection of health and environmental data that will be collected is also summarized below and in ***Exhibit 2***.

Exhibit 1. Source of Information, Data Collection Method and Type of Data Collected

Source of Information	Data Collection Method	Type of Data
Home	Screening questionnaire with adult in household	- Whether the family members had resided in FEMA THUs and, if so, how long - Roster of children ≤15 years old using first and last initials
	Questionnaires on health and environmental exposure of child	- Demographic data and residential history since 2005 - Medical history of health outcomes and health care utilization - Stress and quality of life - Daily activities - Symptom history and frequency, and management among children with asthma, rhinitis, or eczema - Occupational and residential history - Family history of selected health outcomes - Smoking in the home and car - Hurricane-related home damage - Household activities (e.g., use of household cleaners, combustion-related activities, and activities that can affect air flow) - Time and Activity Diary
	Physical assessment of child by Registered Nurse	- Height and weight - Dermal and respiratory symptoms - Pulmonary function test - Exhaled nitric oxide - Urine sample will be collected for creatinine, metabolites of contaminants, and cotinine - Among children aged 5 years and older, blood will be collected for complete blood count (CBC) and IgE (total and specific to local allergens)
	MicroPEM™ (personal air sampler) worn by child ≥7 years old	- Personal exposures to specific contaminants (e.g., particulate matter)
	Visual inventory of home by Field Interviewer	- Combustion sources - Carpeting - Visible inspection for mold, mildew, dust, and construction - Layout and room sizes
	Dust samples in home	- Allergens, molds, and endotoxins
	Air monitors in home	- Household exposures to specific contaminants (e.g., particulate matter) - Temperature and relative humidity - Air exchange rate
Physician office or clinic	Medical Record abstraction	- History and treatment of specific health outcomes

Source of Information	Data Collection Method	Type of Data
Local US EPA site	Ambient air monitoring	- Outdoor exposures to specific contaminants

Selection of Health and Environmental Data to be Collected and Rationale for 6-month Follow-up

Specific contaminants were identified for inclusion in the assessments based on prior studies. Specifically, the contaminants selected for CHATS represent the predominant chemical contaminants that have been found to be unique or more prevalent in THUs in comparison to other types of housing: formaldehyde, volatile organic compounds (VOCs: aliphatics, aromatics, terpenes), and plasticizers (including phthalates). The health outcomes described in the literature that are most commonly associated with these contaminant exposures include: respiratory symptoms, asthma, dermal irritation, eczema, ocular irritation, increased allergic responses, and cancers. There are well-characterized exposures associated with these health outcomes including exposures to particulate matter (PM), environmental tobacco smoke, nitrogen dioxide (NO_2), allergens, molds (e.g., β-glucans), endotoxins, hydrogen sulfide (H_2S), and ozone; accordingly, these exposures were also included in the suite of contaminants to be monitored in addition to THU-specific contaminants. In the Full Study, we will assess the occurrence of these health outcomes and their association to the various contaminants based on data collected from the series of follow-up visits. Because the onset of some of these health outcomes can vary depending on the child's age and because exposures to specific contaminants (e.g., allergens, molds) can also vary by season and activity patterns, we had proposed a six-year longitudinal Full Study so that information on the children can be collected over several years to more clearly and comprehensively assess the potential impacts of these exposures on health.

During the Feasibility Study, several methods of exposure assessment will be evaluated to determine the most effective approaches to be applied in the Full Study. ***Exhibit 2*** lists these assessment methods (physical and biological) and the contaminants that will be measured. There are aspects of each method that can affect its utility; for example, personal air samplers can have compliance issues, air monitors on fixed platforms in the homes represents the child's exposure in one environmental location, and the analysis of urine metabolites to assess a child's dose to a specific contaminant often represents recent and acute changes in dose. However, a comprehensive study comparing these contaminant exposures and assessment methods in the Gulf Coast area—where the environment is still changing as a result of extensive rebuilding and where strong seasonal differences can exist—has not been conducted, especially among children. ***Exhibit 2*** also lists the various comparisons that we will make between the methods. The choice of method for the Full Study will be based on factors including compliance, equipment reliability, sensitivity to peak exposures, misclassification bias (e.g., consistency in assignment to quintiles of exposure), and consistency in test-retest variability. Depending on the findings from the Feasibility Study, a reduced set of assessment methods will be used in the Full study.

Exhibit 2. Environmental Assessment Methods, Contaminants Assessed, and Comparisons Conducted during Feasibility Study

Assessment Method	Contaminants assessed	Comparisons Conducted in Feasibility Study to inform Full Study
MicroPEM (deployed as personal, indoor, and outdoor platforms)	Particulate matter mass, environmental tobacco smoke (ETS), allergens, β-glucans, endotoxins	- Compare personal sampler with indoor and outdoor platforms - Compare allergens with blood specific IgE and allergens in dust sample - Compare β-glucans and endotoxins with dust sample - Compare ETS with urine cotinine concentrations
Passive badges (deployed as personal, indoor, and outdoor platforms)	VOCs, aldehydes, NO_2, H_2S	- Compare contaminants collected from personal sampler with indoor and outdoor platforms - Compare VOCs and aldehydes with VOCs measured in urine
Dust	Allergens, β-glucans, endotoxins, phthlates	- Compare allergens, β-glucans, and endotoxins with those collected by the MicroPEM - Compare phthalates in dust with phthalates measured in urine
Urine	VOCs, aldehydes, phthalates, cotinine	- Compare urine VOCs and cotinine with MicroPEM measurements - Compare VOCs and aldehydes with passive badges - Compare phthalates in urine with phthalate concentration in dust
Blood	CBC, Total/specific IgE	- Compare blood specific IgE and allergens to allergens collected by MicroPEM

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The study will maintain a website with public information about the study including information regarding frequently asked questions as well as information targeted specifically for study participants (***Attachment C1 and C2***). None of the information will be directed at children less than 13 years of age. Cookies will not be used by this website. The website will contain a secure portion that is accessible by project staff only. The information contained in the secure portion will include minutes, reports, and meeting materials. No confidential information about participants will be maintained on any part of the website.

A.2 Purpose and Use of Information Collection

The primary purpose of this study is to determine if there is an association between prior occupancy in FEMA-provided THUs and adverse health effects among children who had resided in storm-affected areas at the time of Hurricanes Katrina or Rita. This study is in support of the NCEH mission to plan, direct, and coordinate a national program to maintain and improve the health of the American people by promoting a healthy environment and by preventing premature death and avoidable illness and disability caused by non-infectious, non-occupational environmental and related factors. Within NCEH, EHHE has the mission to investigate the relation between human health and the environment.

The data collected during the Feasibility Study will be used by CDC to determine whether or not a Full Study is practical and will be exercised. The objectives of the Feasibility Study are to:

1. Assess feasibility of locating, enrolling, and retaining study participants;
2. Assess feasibility of locating medical records; and
3. Evaluate operational issues of proposed data collection methods (e.g., data quality, selection bias, information bias, health, and exposure assessment methodology).

No data currently exist to address these issues. The data collected during the Feasibility Study will be used to inform the design of the Full Study.

Failure to collect this information will limit the ability of CDC to evaluate and understand the anecdotal reports of adverse health impacts as a result of living in FEMA-provided THUs after Hurricanes Katrina and Rita.

This Feasibility Study will not be repeated. Results from the Feasibility Study will be published in a final report.

Privacy Impact Assessment

The information obtained by this study is being collected to generate scientifically valid data on the potential health impacts of residing in the THUs. IIF is being collected for four purposes:

- Identifying individuals and families who resided in the THUs and who may be eligible to participate in the study
- Obtaining medical records as consented to by the parent/guardian
- Tracking participants over the course of the longitudinal study
- Providing individual results and findings to the participants

Names and social security numbers will be shared with electronic database vendors solely for the purpose of obtaining information relevant to tracing and tracking potential study participants. We are not collecting SSN to create a new database that did not already exist; NCEH has the FEMA database which contains SSNs and these existing SSNs will be used for tracing the exposed cohort. The purpose of the study will not be revealed to the vendors. RTI has Data Use Agreements in place with the electronic database vendors to ensure the protection and security of the data. The Data Use Agreement requires all vendors to adhere to all security and confidentiality requirements set forth by RTI. It specifies the requirements for secure handling of data and is in accordance with Privacy Act principles. There are reasonable technical, administrative, and physical safeguards, and adequate procedures in place to deal with an “information security event” or “security breach.” In addition, specific mention is made of encrypting data transmitted via the internet.

IIF will remain at RTI and will not be forwarded to CDC. Only RTI will maintain the link between the participants' names and study ID numbers. The IIF data maintained at RTI will be destroyed in accordance with CDC records control schedules. (See A.10 for a description of how the data will be de-identified.)

The data collected by this study could be considered sensitive in light of ongoing litigation. Specifically, information on residential and medical history could be of interest to those participants already involved in litigation or considering that action. To protect the privacy of this information, all electronic infrastructure was certified and accredited and CDC received an Authority to Operate in accordance with NIST special publication 800-37 (*Guide for the Security Certification and Accreditation of Federal Information* Systems) on December 8, 2011. In addition, to prevent compelled release of identifiable information, the study applied for a Certificate of Confidentiality with the CDC's Office of Scientific Integrity under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) and received approval on October 14, 2011.

A.3 Use of Improved Information Technology and Burden Reduction

The screening questionnaire will be conducted using computer-assisted interviewing using a hand-held device. The health and environmental exposure questionnaires will be conducted with a laptop using computer-assisted personal interviewing (CAPI) technology in which an interviewer reads questions and records respondents' answers directly within a computer-controlled questionnaire. The CAPI technology minimizes the burden placed on respondents and improves the quality of collected data. This methodology facilitates the use of more complex routing in the questionnaire. The computer is programmed to implement skip patterns and auto-fill words specifically based on answers previously provided by the respondent. This will reduce interview time and errors made by interviewers due to faulty implementation of skip instructions on a traditional paper and pencil instrument. Another improvement relates to the consistency of data. The computer is programmed to identify inconsistent responses and attempt to resolve them through respondent prompts. This reduces the need for most manual and machine editing, saving both time and money. Respondent-resolved inconsistencies result in data that are more accurate than those resolved using editing rules.

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

CDC made efforts to identify duplication in two ways: (1) by conducting a thorough literature search on the health effects associated with environmental exposures to temporary housing and other similar housing types; and (2) discussing the research question with subject matter experts from federal government agencies and academic institutions. In the literature search, CDC found that there were very few published articles that examined the association between residence in temporary housing, trailers, or other similar housing, and respiratory health outcomes—especially among children. The subject matter experts whom CDC consulted confirmed that a comprehensive evaluation of potential adverse health effects among children from environmental exposures to FEMA-provided THUs after Hurricanes Katrina and Rita would be a novel and innovative approach to filling this knowledge gap.

Within CDC, the only other effort to collect information on persons who resided in FEMA-provided THUs after Hurricanes Katrina and Rita is a pilot registry project being conducted by the Agency for Toxic Substances and Disease Registry (ATSDR). The goal of the ATSDR pilot registry is to determine whether it is possible and reasonable to conduct a full scale registry of people who lived in FEMA-provided THUs. The ATSDR pilot registry is currently under OMB review, thus the methodology of the pilot registry is subject to change.

CDC staff from the two programs had spoken on numerous occasions to discuss ways to minimize duplication between the two projects. There are important differences between the objectives and

methodologies of the two projects. First, the NCEH study is specifically focused on the health of children whereas the ATSDR pilot registry project is not. Second, the NCEH study is an epidemiologic cohort study that will compare the health status of children who were exposed to FEMA-provided THUs to children who were not exposed to THUs. In contrast, the ATSDR pilot registry will only collect information from persons who were exposed to THUs. Third, the NCEH study involves in-home data collection efforts, including a physical assessment of current health status, collection of biospecimens, and environmental exposure measurements. In contrast, the ATSDR registry will collect self-reported information via telephone interviews only. These key differences in the methodologies necessitate distinct sampling and data collection approaches. For example, to minimize field (travel and time) costs for the in-home data collection efforts, the NCEH study will apply a clustered sampling design to target specific geographic areas in Louisiana and Mississippi during the Feasibility Study.

Because both projects are being conducted by the same contractor, RTI has taken additional measures to avoid potential contact of the same households. RTI will use a "permanent random number" approach to minimize any potential overlap between the two study samples. Each household in the frame will be assigned a permanent random number and the file will be sorted in ascending order with respect to the permanent random number. The NCEH study will sample the necessary number of records starting with the smallest permanent random number at the beginning of the list. The ATSDR pilot registry sample will sample the necessary number of records in the reverse direction, starting with the largest permanent random number at the end of the list.

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 post-event study to evaluate whether short- and long-term health effects have resulted from living in FEMA-provided THUs. At this point in time, almost all of the Gulf Coast residents have moved out of the THUs. Hence, if the data are not collected at this point in time, the ability to locate the residents will become increasingly difficult. Further, the ability to meaningfully evaluate the health status of children, especially of young children, exposed to these environments will be diminished.

This study is a one-time only study. The study involves multiple visits because the impact of exposures to allergens and molds varies substantially over seasons and because the risk of some health outcomes, such as asthma, varies as the child becomes older. There are no legal obstacles to reduce the burden.

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

There are no special circumstances. The data collection complies with the guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the FRN and Efforts to Consult Outside of the Agency

Comments in Response to FRN

A 60-day Federal Registry Notice was published in the *Federal Registry* on November 16, 2010, Vol. 75, No. 220, pp. 70006-70007 (***Attachment B1***). A letter from the American Academy of Pediatrics (AAP) was received on January 7, 2011 and a response was prepared by NCEH Division of Environmental Hazards and Health Effects (EHHE) (***Attachment B2***). The AAP suggested that the study investigate the health impact of mold exposure in addition to formaldehyde and that additional information about cancer and collection of medical records be considered. On January 20, 2011, EHHE sent a letter responding to these concerns. In the letter EHHE provided information about the plans for mold assessment and

medical records assessment. EHHE agreed to add questions that capture history of cancer diagnosis, cancer type, and date of diagnosis to the Baseline and 6-month Follow-up questionnaires (***Attachments L and N***).

Efforts to Consult Outside of Agency

In 2008, TKC Integration Services convened an external expert panel to review results from completed and ongoing CDC and FEMA studies and to provide expert guidance for the design and development of future studies, including the children's longitudinal cohort study. The expert panel consisted of representatives from academia, a national laboratory, and a medical and research center. Members of the expert panel included: Michael Apte, Scientist, Environmental Energy Technologies Division, Lawrence Berkeley National Laboratory; Tom Burke, Associate Dean for Public Health Practice and Training and Professor, Johns Hopkins University; Luke Naeher, Associate Professor, University of Georgia; Leslie Staner, Professor of Epidemiology and Director of the Division of Epidemiology and Biostatistics, University of Illinois at Chicago; David Tinkelman, Department of Pediatrics and VP of Health Initiatives, National Jewish Medical and Research Center. A report with their recommendations was provided to CDC.

Additionally, the following groups from within CDC were consulted to obtain their views on the availability of data, the clarity of instructions, disclosure, and the data elements to be recorded and reported: NCEH Division of Environmental Hazards and Health Effects, NCEH Division of Laboratory Science, ATSDR Division of Health Sciences, and National Institute of Occupational Safety and Health (NIOSH) Division of Applied Research and Technology.

A.9 Explanation of Any Payments or Gifts to Respondents

We propose to provide a token of appreciation to respondents for their participation in the Feasibility Study. Depending upon the age of the child and level of participation, the token of appreciation can vary from $75—$135 per household for the Baseline Assessment and from $125—$135 per household for the 6-month Follow-up Assessment. To encourage full participation, incremental tokens of appreciation, based on activity and burden, will be provided for each completed activity. For each child participant <8 years old, a token of appreciation will be provided in the form of an activity or coloring book. Among child participants aged 8–12 years old, a cash token of appreciation will be received by the parent on behalf of their child. Child participants aged 13–17 years old will receive a cash token of appreciation of $30 directly for wearing the PEM. Parents of children aged 7–12 will receive a token of appreciation of $20 for providing assistance to their child wearing the PEM.

Based on published scientific research, RTI's experience in similar studies, and recommendations from the study's Technical Advisory Panel (TAP) described below, cash, rather than non-monetary incentives, has been proposed as the token of appreciation for this study.

A large body of empirical survey research literature has been devoted to examining the role of incentives in survey outcomes and how incentives influence participation decisions. Meta-analyses have shown that cash is typically more effective than non-cash incentives for both pre-paid and promised incentives (Church, 1993; Singer et.al., 1999, Singer, 2008), even when controlling for the value of the incentives.

A 2005 study (Herget, et al.) conducted by RTI to investigate the effects of different types of incentives showed a significant difference in the response rate based on incentive type among a population of school-aged children. Using the field test of the Education Longitudinal Study of 2002, the authors implemented an incentive experiment to examine student response rates under a variety of incentive conditions including cash ($25), gift cards ($25), and non-monetary incentives (key chain). The response

rate among participants offered cash (95.26%) was significantly higher than the response rate for respondents offered gift cards (85.53%) or non-monetary gifts (86.83%). For the full scale study, all respondents were offered a cash incentive unless the school restricted the use of cash incentives. For the full scale study, the response rates remained higher for the cash incentive students (91.96%) than for the gift card incentive students (88.52%). In fact, the gift card incentive provided no significant increase in response rate over a group of students that received no incentive.

RTI has also implemented cash incentives with success for adolescents 12–17 years old in the National Survey of Drug Use and Health. The two studies described above have been approved by OMB and the RTI IRB.

In addition, several members of the TAP recommended that, based on their experience, the use of cash over gift cards was preferred because low-income study participants might have difficulty accessing a specific type of store because of travel costs and limited transportation access.

The proposed cash amounts for this study are based on cash amounts provided for other similar studies conducted among children and adolescents that involve longitudinal data collection and biological and environmental sample collection. Recent experiences for surveys with a similar respondent burden provide additional support for the cash amount proposed for the Feasibility Study. RTI has used similar structures to achieve at least 80% interview response rates in multiple studies. For example, in Wave IV of the National Longitudinal Study of Adolescent Health (N=19,962) that was completed in 2008/2009, the initial incentive for the 1.5 hour CAPI survey with 30-minutes of biospecimens and anthropometric measures was $100, but was increased to $160 for the last few months of data collection. Evidence from the survey research literature also suggests that increasing the amount of the incentive for future visits in longitudinal studies may also have a positive effect on response rates (Groves et al., 1998).

Tokens of appreciation will be provided separately for the Baseline and 6-month Follow-up Assessment. The activities for parents/guardians and children and the token of appreciation associated with those activities for the Baseline and 6-month Follow-up Assessments are listed in ***Exhibit 3***. If the participant does not complete the entire study, they will be given a token of appreciation for each of the activities that they complete. The parent/guardian of the participating child will sign a Cash Receipt Form (***Attachment D***) to acknowledge receipt of the token of appreciation. Participants will also benefit from receiving written feedback of results on clinically relevant tests.

Exhibit 3. Baseline and 6-month Follow-up Activities and Associated Tokens of Appreciation

Activity	Participant Type	Session	Baseline Token of Appreciation ($)	Follow-up Token of Appreciation ($)
Session 1 surveys and environmental sample deployment	Parent	1	40	40
Session 2 surveys and environmental sample collection, physical assessment of child, and blood/urine samples	Parent/child	2	65	65
Assisting child with personal exposure monitoring compliance	Parent of children 7-12 yrs	2	20	20
Personal exposure monitor (PEM)	Child (13-17 yrs) Child (8-12 yrs) Child (7 yrs)*	2	30 10 Coloring/	30 10 Coloring/

Activity	Participant Type	Session	Baseline Token of Appreciation ($)	Follow-up Token of Appreciation ($)
			activity book	activity book
Total amount possible per household			135	135

*Only children ≥7 years will be eligible to wear the personal exposure monitor.

A.10 Assurance of Confidentiality Provided to Respondents

All interviewers will be trained on techniques for maximizing respondents' privacy during questionnaire administration. This training will include: (1) the need to conduct the interview in a private setting to minimize distractions, allow for the participant to feel comfortable in responding to the interview questions, and allow for the interview to proceed as efficiently as possible; (2) strategies to deal with disruptions (e.g., pausing the interview if someone tries to listen in or passes near during the interview); and (3) procedures to follow if a sufficiently private or comfortable setting for the subject is not possible (e.g., offering to reschedule the interview at a better time, offering to complete the interview at a neutral site away from the residence).

Privacy of all records pertaining to individuals in the study will be carefully protected in the following ways. During data collection, names of individuals will be used solely for purposes of locating study participants and conducting the household visit. Personal identifiers will not be retained on any data record used for analysis. On all working draft and final analysis data files, participants will be identified only by a study ID number. Identifying information will be maintained in a separate, secure data file. The RTI Project Director and the RTI Task Director for Data Management will be responsible for maintaining data security. All data files that are transmitted to CDC will not contain any information that permits identification of individual respondents. If sample sizes in any category are sufficiently small to permit possible identification of individual respondents, data that would identify the members of the category or the category identifier itself will be suppressed. Further, data in reports will be presented only in such a way that prevents identification of individual respondents. In addition, to protect the investigators and institutes from being compelled to release information that could be used to identify participants, the study applied for a Certificate of Confidentiality from CDC's Office of Scientific Integrity under Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) and received approval on October 14, 2011.

IRB Approval

On March 23, 2011, the RTI Institutional Review Board (IRB) indicated their initial approval of the protocol (***Attachment E1***). The study obtained a Certificate of Confidentiality to provide the strongest protections against compelled disclosure of data, to help ensure high participation rates and the accuracy of respondent reports. The CDC IRB conducted an expedited review and granted a site restricted approval of the protocol on July 29, 2011 (***Attachment E2***). The LSU IRB approved the study protocol on August 22, 2011 (***Attachment E3***). The CDC IRB subsequently lifted the LSU site restriction via an E-mail correspondence dated August 23, 2011 (***Attachment E4***). An amendment addressing the CDC IRB changes was approved by the RTI IRB on August 11, 2011 (***Attachment E5***).

Privacy Impact Assessment Information

A. Privacy Act

The NCEH Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is applicable. Personally identifying information will be collected. The contractor, RTI, in holding the personally identifying information and the list linking participant names to the study ID numbers, will maintain a system of records under Privacy Act system notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

B. How Information is Secured

Concern for privacy and protection of respondents' rights will play a central part in the implementation of the study. Strict procedures will be followed for protecting the privacy of information gathered from the participants and for obtaining informed consent from the participants.

The procedures that will be implemented to secure respondent data and identifying information are listed below.

- The privacy and data security measures that will be used on this study were fully described to the RTI, CDC, and LSU IRBs as part of the IRB approval process.
- The privacy protections offered to research participants are described in the informed consent forms that participants will be required to sign (***Attachment F***).
- All study staff members (including field interviewers and nurses) will receive Human Subjects Protection Awareness training (if not already obtained). This training will promote awareness of the human subjects' protection offered by the research design, ethical issues and concerns, and regulations and assurances by which RTI's human subjects' research is governed.
- Each RTI staff member or subcontractor involved in any phase of handling personal information will be required to sign a legally binding privacy agreement *(**Attachment G**)* pledging that the data they collect or work with will not be disclosed to anyone not assigned to the project. The privacy agreement reinforces privacy requirements of the study and states that any procedural violation that jeopardizes a respondent's privacy will be grounds for immediate termination and possible legal action.
- Access to data will be restricted to RTI staff members on a need to know basis and who have signed privacy agreements.
- Field interviewers and/or nurses will not be allowed to interview or process data for subjects who they know personally.

We consider the secure collection and maintenance of the collected data of utmost importance. The laptop systems that our interviewers will use to collect data and the data storage systems will be designed and developed with maximum attention to data security. System security features will include:

- User ID and Password authentication required to access all systems.
- Interview files, once completed, will be automatically locked.
- Collected interview data will be encrypted and electronically transmitted to RTI daily via secured data transmission.
- Subscription to virus-protection services from McAfee VirusScan with automated update of virus signature files on all computers.

- Maintenance of all servers in RTI's environmentally-controlled Computer Center. Fire protection is provided by a halon system and all servers have an Uninterruptable Power Supply (UPS).
- Daily incremental backups of all data files, with full backups created weekly.
- Laptops used for field data collection will be ID and Password protected, and successfully-transmitted data will be automatically removed from the laptop hard drive after receipt of data is confirmed at RTI. Deletion will occur during the next data transmission.
- Hardcopy forms (e.g., consent forms) will be retained in secure storage facilities in Research Triangle Park, NC. Field interviewers will be trained to maintain hardcopy documents in a secure, private location while the study materials are in their possession. The hardcopy documents will be transmitted to RTI via express mail, using tracking numbers to document the transmittal.
- Paper permission and consent forms will only include the name and signature of the parent/guardian. Child assent paper forms will also only include the name and signature of the child. All permission, consent, and assent forms will be sent to RTI for receipt, and stored in locked file cabinets in a secured facility.
- The paper medical records abstraction form will contain a tear off cover that includes the name, address, and phone number of the provider, the name of the child and the study ID. The abstraction form itself will only include the study ID. After the medical records abstractor has completed the on-site medical records abstraction, he/she will tear off the cover page with the provider contact information and the child's name, and send the completed abstraction form that only contains the study ID to RTI for processing. RTI will receipt the form, and data enter it into a computer program. The form will be stored in locked file cabinets in a secured facility.
- Personally identifying information will be retained by the contractor for 10 years after the end of the funded period of the Study.

C. Obtaining Respondent Consent

The study incorporates several procedures to ensure that respondent's rights are protected. The lead letter and project brochure specify the purpose of the research, the topics covered in the interview, and the voluntary nature of participation.

Four different consent forms will be used: (1) Consent for Parent/Guardian and Child Permission for Participation; (2) Child/Youth Assent for children 12 to 15 years of age; (3) Child Assent for children 8 to 11 years of age; and (4) Child Assent for children 7 years of age and younger. The difference in the Child Assent forms for children 8 to 11 years of age and children 12 to 15 years of age is the reading and comprehension level. Both forms will require a written signature from the child. The Child Assent form for children 7 years of age and younger will not require a signature. Consent forms are provided in ***Attachment F.*** A Certificate of Confidentiality was approved on October 14, 2011; accordingly, the consent language reflects what is preferred by the CDC Confidentiality Lead.

Field interviewers will administer informed consent during Session 1 of both the Baseline and Follow-up Assessments. If the parent/guardian who signed the consent form during Session 1 of the Baseline or Follow-up Assessment is not present during Session 2, then informed consent will be obtained from the parent/guardian who is present during Session 2. Further, FIs and nurses will be trained to ensure that the parent and child respondents fully understand the content of the consent forms. First, the parent

respondent will be given a copy of the Consent for Parent/Guardian and Child Permission to read. The parent respondent will be asked to read over the form. After the parent respondent has read the form, the interviewer will summarize the key points following a script programmed in the computer (***Attachment F***). After reading the script, the interviewer will ask the parent respondent if he/she has any questions. Interviewers will address any questions the parent respondent has, and then ask the parent respondent to sign the consent form. Interviewers will be trained to observe the respondent for signs of difficulty in understanding the content of the consent. For example, if the respondent asks an unusually large number of questions, the interviewer may switch from reading the script and instead read the entire consent form. For children 11 years of age and younger, the interviewer will read the assent form to the child and then summarize the key points following a script programmed in the computer. For children 12 to 15 years of age, the interviewer will follow the same procedures as the parent/guardian consent, i.e., ask the child to read the assent form and then summarize the key points.

To address other questions or concerns of the respondents, the consent forms also provide the names and toll-free numbers of the RTI Project Director and the IRBs of RTI and LSU. Respondents who appear to understand the content of the form will be asked to sign and print their name in the space provided at the end of the form. Each respondent will be given a copy of the consent form for their records, and the original will be returned to RTI.

To assure validity of the interview information, we will also conduct a brief verification interview by telephone with approximately 10 percent of the respondents. Telephone interviewers from RTI's Call Center will read a brief verbal consent statement over the phone prior to the verification interview. After obtaining verbal consent, the interviewer will confirm the respondent's participation and ask questions to confirm the interview protocol was properly followed. For participants who do not have a telephone or who the interviewers are otherwise unable to contact by phone, a mail verification letter will be sent along with the series of verification questions.

D. Information about Voluntary Nature of the Study

Respondents will be informed of the voluntary nature of their responses. The consent form contains the Privacy Act advisement elements: (1) purpose; (2) the intended uses of the data; (3) with whom identifiable data will be shared; (4) the legal authority for data collection; and (5) that there will be no untoward effect for not responding. The information collected will become part of a system of records in accordance with the Privacy Act of 1974.

A.11 Justification for Sensitive Questions

Information collected during the study that respondents might consider to be sensitive includes questions that ask about Social Security Number (SSN), the child's psychological well-being and medical conditions, socioeconomic status (race and ethnicity, household income), and participation in any litigation related to the FEMA-provided THUs, as well as data obtained from medical records abstraction.

Additional measures to ensure proper notification for collecting SSN will be followed. Respondents will be told about the authority for collecting the SSN and that the SSN is needed to maintain contact with the parent/guardian to monitor their child's health status over time. The SSN is important for locating parents/guardians for the 6-month Follow-up data collection effort. Specifically, we will be using existing SSNs in the FEMA database to locate participants; we will not be creating a new database of SSNs. SSN is a unique identifier of an individual, whereas name and other identifiers can be replicated, changed over time (e.g., through marriage or divorce), or used inconsistently (e.g., nicknames). The full SSN will be most effective in our tracking efforts, and batch vendors and interactive databases require the full SSN. Safeguards were considered in the contract planning stage to protect the privacy of

participants. If SSN were not used, we would need to rely on alternate approaches that would likely be more costly and labor intensive. Further, this project underwent a full Privacy Impact Assessment under the Certification and Accreditation Process, and stringent safeguarding measures are in place to protect the SSNs. The confirmation or updating of the parent/guardian's SSN will be voluntary. The parent/guardian will be informed that the disclosure of SSN is voluntary and will not affect any benefits that may be received and the information will not be shared with any other government or nongovernment agencies.

Questions about the psychological well-being and medical conditions the child may have, and medical records abstraction to identify health conditions or concerns, are critical to understanding the short- and long-term health effects of exposure to FEMA-provided THUs on children's health. Medical records abstraction will be used to confirm parent-reported diagnosis for his/her child, medications, and the dates of onset of medical conditions. These records will be particularly important for evaluating short-term health effects that occurred prior to the initiation of the study.

Questions about race, ethnicity, and income help scientists identify and examine what relationship, if any, these variables may have on health or exposure status. Race, ethnicity, and income are also important in addressing any disparities in environmental justice, in the data collected, and in setting goals and policies for the agency.

During the past several years, a number of litigations have been brought about in the aftermath of Hurricanes Katrina and Rita, including litigations regarding the health of children resulting from living in the FEMA-provided THUs. These litigations have received broad media attention. The purpose of asking the question during the Feasibility Study regarding knowledge and participation in litigation is to determine whether this influences the willingness of the person to participate in the Study. If it is determined that this knowledge has a strong influence on participation, the study would try to determine whether the information obtained through data collection was biased. CDC would then carefully evaluate the feasibility of conducting a Full Study.

Safeguards have been incorporated into the study design to ensure the private collection and safeguarding of data on sensitive issues/information. As a part of the interview process and upon introduction, the interviewer informs the respondent about why the information is necessary, indicates who sponsors the survey, requests consent to conduct an interview, and explains the procedures which assure confidentiality. Respondents will be also informed that participation is voluntary and they may refuse to answer any of the questions.

Written consent and signed HIPAA authorization forms will also be obtained from the child's parent/guardian. These will be shared with the health care provider when the abstractors access the records at the health care provider sites. Relevant HIPAA requirements, such as confidentiality, will be addressed in accessing patient records.

A.12 Estimates of Annualized Burden of Hours and Costs

Estimates of Annualized Burden of Hours

There are four components of information collection that contribute to participant burden: (1) eligibility screening; (2) Baseline Assessment; (3) 6-month Follow-up Assessment; and (4) verification interviews. The burden for the Baseline and 6-month Follow-up Assessments is divided by Session 1 and Session 2 and provided separately for the parent/guardian and the child.

Where possible in the burden table (***Exhibit 4***), the Form Name (e.g., "Eligibility Screener") is used. However, because each session of the Baseline and 6-month Follow-up Assessments is comprised of

multiple different data collection instruments, in which the FI switches between interviewing the parent/guardian and the child, we believe it is clearer and more logical to combine forms into modules (i.e., "Parent Module" and "Child Module") for each session (***Attachments L-O***). ***Exhibit 4*** shows the total burden for each form or module administered during the four components of information collection described above. The respondent burden is also summarized in ***Exhibit 4***; the total burden is annualized over a 3-year OMB approval period.

The number of participants involved in each of the components of the information collection varies. We expect to conduct the eligibility screener among 2,236 households (annualized to the 3-year requested OMB approval period, or 745 households) in order to identify a total of 500 eligible respondents (annualized to 167 parents and children aged 3–15 years) who agree to participate and complete the Baseline Session 1 and Session 2 visits. Using an estimate of 10% attrition of the sample between Baseline and 6-month Follow-up, we anticipate that a total of 450 participants (annualized to 150 parents and children aged 3–15 years) will complete the 6-month Follow-up Session 1 and Session 2 visits. The verification interviews will be completed among a predetermined proportion or subsample of respondents (proportion shown in ***Exhibit 4***); for example, a 10% subsample of respondents, or 75 household members when annualized to the 3-year OMB approval period, will be selected for the Verification Questionnaire Eligibility Screener.

Exhibit 4 includes the estimated average time for each form or module based on timed trials conducted by RTI. The average time for the Baseline Assessment (Session 1 and Session 2 combined) is 2 hours and 45 minutes, which is split between the child and the parent/caregiver. However, the time for the Baseline Assessment is expected to range from 2 hours and 15 minutes to 3 hours and 15 minutes depending upon several factors (e.g., the number of activities or procedures performed, the number of health conditions the child has, the level of detail provided by the parent/guardian). The average time for the 6-month Follow-up Assessment (Session 1 and Session 2 combined) is 1 hour and 55 minutes, which is split between the child and the parent/caregiver. The time for the 6-month Follow-up Assessment is expected to range from 1 hour and 25 minutes to 2 hours and 25 minutes.

Exhibit 4. Estimates of Annualized Burden Hours

Respondent	Form Name or Module	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden* (in hours)
Household member 18 years or older	Eligibility Screener	745	1	10/60	124
Children ages 3-15	Baseline: Session 1 (Child Modules)	167	1	15/60	42
Parents of children ages 3-15	Baseline: Session 1 (Parent Modules)	167	1	1	167
Children ages 3-15	Baseline: Session 2 (Child Modules)	167	1	1	167
Parents of children ages 3-15	Baseline: Session 2 (Parent Modules)	167	1	30/60	84
Children ages 3-15	6-month Follow-up: Session 1 (Child Modules)	150	1	7/60	18
Parents of children ages 3-15	6-month Follow-up: Session 1 (Parent Modules)	150	1	40/60	100
Children ages 3-15	6-month Follow-up:	150	1	37/60	93

Respondent	Form Name or Module	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden* (in hours)
	Session 2 (Child Modules)				
Parents of children ages 3-15	6-month Follow-up: Session 2 (Parent Modules)	150	1	30/60	75
Household member 18 years or older	Verification Questionnaire for Eligibility Screener (10% subsample)	75	1	2/60	3
Household member 18 yrs or older	Verification Questionnaire for Baseline and 6-month Follow-up Visits (9% subsample)	29	1	5/60	2
Household member 18 yrs or older	Mail Verification Form for Baseline and 6-month Follow-up Visits (1% subsample)	3	1	5/60	0.25
				Total Annualized Burden	875

*Burden values were rounded up or down, as appropriate.

Estimated Annualized Costs

Using the Department of Labor's average hourly wage for the 2 states along the Gulf Coast (i.e., $22.00 for New Orleans, LA and $17.99 for Mississippi), which is an average of $20.00, the total annualized respondent costs is $16,648 for the adult participants. The hourly wage for the child respondents is assumed to be $0.00.

The costs are summarized below in ***Exhibit 5***. Similar to ***Exhibit 4***, the total respondent costs are annualized over a 3-year OMB approval period.

Exhibit 5. Estimates of Annualized Respondent Costs

Respondent	Form Name or Module	Total Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
Household member 18 years or older	Eligibility Screener	124	$20	$2480
Children ages 3-15	Baseline Session 1 (Child Modules)	42	$0*	$0
Parents of children ages 3-15	Baseline Session 1(Parent Modules)	167	$20	$ 3340
Children ages 3-15	Baseline Session 2 (Child Modules)	167	$0	$0
Parents of children ages 3-15	Baseline Session 2 (Parent Modules)	84	$20	$1680
Children ages 3-15	6-month Follow-up: Session 1 (Child Modules)	18	$0	$0
Parents of children ages 3-15	6-month Follow-up: Session 1 (Parent Modules)	100	$20	$2000
Children ages 3-15	6-month Follow-up: Session 2 (Child Modules)	93	$0	$0
Parents of children ages 3-15	6-month Follow-up: Session 2 (Parent Modules)	75	$20	$1500
Household member 18 years	Verification Questionnaire for Eligibility	3	$20	$60

Respondent	Form Name or Module	Total Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
or older	Screener (10% subsample)			
Household member 18 years or older	Verification Questionnaire for Baseline and 6-month Follow-up Visits (9% subsample)	2	$20	$40
Household member 18 years or older	Mail Verification Form for Baseline and 6-month Follow-up Visits (1% subsample)	0.3	$20	$6
			Total Annualized Costs	$11,106

*Assume that wages for child respondents will be $0.00

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There is no capital, startup, operational, or maintenance costs to respondents.

A.14 Annualized Cost to the Government

The average annualized cost of the study over the 3-year OMB approval period duration is $3,929,333 (***Exhibit 6***).The total cost was obtained by combining the contractual cost and the cost of federal employees.

Exhibit 6. Estimates of Annualized Cost to the Federal Government

Item	Total Cost	Annualized Cost (based on 3 years)
Contractor	$11,018,001	$3,672,667
Federal Salaries (personnel costs of federal employees involved in planning and analysis) based on five staff members, ranging from 10–30% effort	$255,000	$85,000
Travel for site visits	$30,000	$10,000
Contractor, Survey Statistician	$100,000	$33,333
Subtotal Federal	$385,000	$128,333
Total Contractor and Federal	$11,788,001	$3,929,333

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

Statistical Analysis Plan

Analyses will be conducted to address the three Feasibility Study objectives: (1) assess feasibility of enrolling, locating, and retaining study participants; (2) assess feasibility of locating medical records; and (3) evaluate operational issues of the proposed data collection methods which include: ranges and effectiveness of biomarkers for assessing exposures, nonparticipation bias, and quality of data. Examples of the types of analyses that will be performed using the Feasibility Study data to address the objectives are listed in Section B.2, ***Exhibit 9.*** Results of the Objective 1 and 2 analyses will assist CDC in making the determination if the Full Study Phase is feasible. Results of the Objective 3 analyses will be used to inform the design of the Full Study. All proposed analyses will be conducted by CDC. Findings from the Feasibility Study will be summarized in a report.

Project Schedule

This request is for a 3-year OMB clearance covering the Feasibility Study Phase. See ***Exhibit 7*** below for a summary of the project schedule.

Exhibit 7. Project Schedule

Activity	Time Schedule
Conduct screening and subject recruitment	1 – 9 months after OMB approval
Mail lead letters to participants on an ongoing basis	1 –24 months after OMB approval
Conduct health and environmental data collection	1 – 24 months after OMB approval
Laboratory analyses	1 – 24 months after OMB approval
Data analysis	6 – 36 months after OMB approval
Summary report	20 – 36 months after completion of data collection

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

This submission does not request such approval. The OMB expiration date will appear on all documents prepared for data collection use.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to this certification.

References

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