Factors Influencing Children's Potential Exposures to Indoor Contaminants

(The Green Housing Study Add-on)

March 3, 2016

Supporting Statement **A**

Justification

OMB Control No. 0920-NEW

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- Goal of the study: The U.S. Environmental Protection Agency (EPA) is funding this add-on research study to the existing Green Housing Study (GHS) (OMB Control No. 0920-0906, expiration date 10/31/2017) which will be conducted in New Orleans. The primary objectives are two-fold: 1) to contribute to EPA's interest in evaluating questionnaire-derived exposure estimates against those derived from measurements; and 2) to understand whether there is sufficient value in adopting alternative measurement methods for the GHS at future sites.
- Intended use of the resulting data: Data will be used to assess personal, housing, and community factors influencing children's potential exposures to indoor contaminants living within the same home environment. Results from the Add-on Study will inform the ongoing Green Housing Study methods and could significantly decrease the burden hours for study participants in future study sites.
- Methods to be used to collect data: Data collection methods include: 1) questionnaires regarding time-activity patterns of their children to be administered to mothers/primary caregivers; 2) accelerometers and GPS to aid in the assessment of time-activity patterns and locations of the children; 3) air, soil, dust samples, and product inventory from the respondent's home; and 4) biological (urine, hand wipes, socks), duplicate diet, and surface samples from respondents' eligible children.
- The population to be studied: Children with asthma (7-12 years) and one younger sibling (between 4-12 years) from the same household.
- How data will be analyzed: The analysis includes the following: 1) descriptive statistics to characterize environmental exposures; 2) regression models and tests to examine associations between different types of environmental exposures; and 3) exposure and dose model evaluation.

JUSTIFICATION

The Centers for Disease Control and Prevention (CDC) requests a new three-year approval for an information collection request (ICR) titled "Factors Influencing Children's Potential Exposures to Indoor Contaminants" (hereafter, the "Add-on Study"). This ICR is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Appendix A**). The 60-day Federal Register Notice was published on 05/06/2015 (**Appendix B**), and is further discussed in Section A8. The CDC's Institutional Review Board (IRB) approved research protocol is provided in **Appendix C**.

A.1. Circumstances Making the Collection of Information Necessary

This research study is an add-on to the OMB-approved CDC Green Housing Study (GHS) (0920-0906, expiration 10/31/2017). The Green Housing Study began in 2011 as a collaboration between CDC and the U.S. Department of Housing and Urban Development (HUD) to gain a better understanding of the extent to which green-built, low-income housing reduces exposures to allergens and toxic substances when compared to standard low-income housing. The study was designed to investigate if changes in such exposures are associated with changes in asthma morbidity among children.

The GHS involves a design in which data are collected from 64 housing units (and households) in each of 13 cities. Half of the 64 homes in each city will be "green" and the other half will be "non-green". The green housing low-income apartments are defined as those using: 1) integrated pest management (IPM) to decrease the use of pesticides; and 2) low volatile organic compound (VOC) products in the renovation. Non-green apartments are those that are not undergoing any renovation. The GHS is designed such that

data from across all 13 sites will be aggregated in order to have sufficient power to draw the types of conclusions discussed above. To date, data have been collected from two sites–Boston and Cincinnati. CDC is adding a third site, New Orleans. In New Orleans, the main protocol will be identical to that which was already approved (and the burden accounted for in 0920-0906). However, with funding from the U.S. Environmental Protection Agency (EPA), CDC wishes to conduct additional data collection in New Orleans. This information collection request is only for the additional data collection in New Orleans.

The additional data collection is consistent with CDC's health protection research agenda, which calls for research to identify major environmental causes of disease and disability and related risk factors. This study directly supports several of the United States (U.S.) Health and Human Services' (HHS) Healthy People 2020 objectives (available at http://healthypeople.gov/2020/topicsobjectives2020/default.aspx). This study also supports EPA's mission to protect public health and safeguard the environment. The EPA Office of Research and Development's (ORD) Sustainable and Healthy Communities (SHC) Research Program is designed to help decision makers implement environmental management in ways that increase sustainable benefits, such as reducing or eliminating indoor exposures to pollutants from building materials, insecticides, or chemicals found in consumer products. Research conducted in the Enhancing Children's Health project in the SHC program develops the information and methods that decision makers need to assess how the natural and built environments affect children's health and well-being.

The Add-on Study is being conducted by CDC and EPA in partnership with HUD and Tulane University and will be implemented by integrating it into the regularly-scheduled activities of the GHS. The Add-on Study will provide an opportunity to gather information on chemical exposures and children's interactions with their environments, and will provide an impetus to evaluate sample collection methods, and novel approaches to capture information that may significantly decrease the burden hours for study participants in future GHS sites.

The Add-on Study has two overall objectives (refer to **Appendix C** for details):

1) Contribute to EPA's interest in evaluating questionnaire-derived exposure estimates against those derived from measurements. For example, assessing the factors affecting children's exposures to chemical ingredients from consumer products found in their everyday environment will support the data and modeling needs of the exposure components of EPA's national research programs. One method of accomplishing this includes using socks worn by children and hand wipes from the same children for analysis of consumer products. These measurements will be compared with biomarkers in the children's urine samples. Other methods used in the multimedia measurement assessment include duplicate diet (i.e., a duplicate set of food and drink consumed by the child during a 24-hour period), global positioning system (GPS) and accelerometer devices, passive and active air sampling of the home, and biological samples from the children (i.e., nail clippings, feces, blood, and urine). A detailed discussion of multimedia comparisons is in **Section A10.**

2) Test whether there is sufficient value in adopting alternative methods for the GHS (across the remaining 10 sites). Value would be determined by the extent to which alternative methods reduce burden, increase specificity, and otherwise provide additional or improved data for helping researchers better understand the potential impact of environmental exposures on asthma outcomes in children. Specific sampling approaches being tested for future inclusion in the GHS are: a comprehensive time-activity questionnaire, GPS and accelerometer use to improve time-activity assessment and potentially supplant the use of paper questionnaires, nail clippings as a long-term measure of exposure to potentially replace the need for the invasive measure of blood collection, electrostatic dust wipes as an integrated measure of exposure, hand wipes of children to assess dermal exposure, and sock measurements as a

measure of exposure directly related to the home environment. The four acceptance criteria for inclusion in future GHS sites is discussed in **Supporting Statement B Section B5**.

A.2. Purpose and Use of Information Collection

This information collection request leverages the opportunity to gather additional multimedia measurements and comprehensive time-activity and location information on index children actively participating in the GHS and a sibling. By recruiting a single sibling of each index child participating in the GHS, we will gain insight into within-family variability in children's exposures when multiple children have the potential to be exposed to the same chemicals contained in consumer products found in their environment. To the extent practicable, we will try to recruit siblings who are newborns to age 3 years because there is a dearth of information about exposure patterns in this age group, and thus environmental exposure assessment for this age group has not been well-studied. Within this Add-on Study, children are asked to provide biological samples and the mother/caregiver is to provide duplicate diets for enrolled children. A complete matched set of the following four samples is necessary for mass-balance estimation (described in **Appendix C**): 1) feces; 2) duplicate diet, 3) blood; and 4) nails. Although the information collected is focused on children, the respondents to the questionnaires **(Appendices D2 and D3)** are the mother/primary caregivers of the children. Children will not answer questionnaires.

Listed below are justifications for the data collection. We also describe the practical utility of the expected results to federal government agencies.

1. Time-activity and location information: In the GHS, we only asked a brief questionnaire about where the children were during the days and nights when we conducted air sampling in their homes. In contrast, the Add-on Study will use a more detailed questionnaire about the children's time-activity and location patterns (in 30-minute increments) so that we can understand activities that might have preceded the biomarker collection and could affect multimedia comparisons. The goal is to determine if a waistband-mounted accelerometer-based activity monitor and a GPS can supplant the use of a questionnaire at future GHS sites, since the accelerometer and GPS are considered minimally burdensome when compared to the time involved with completing a questionnaire.
2. Multimedia measurements: The Add-on Study could provide a complementary set of measurements (compared to those currently in the main GHS). The goal is to determine if measures such as nail clippings can be used to assess exposures to indoor contaminants instead of a blood sample. Details of each type of measurement are listed in **Section A10 (Tables 4 & 5)**.

This ICR is supported by the EPA which has committed funds for the GHS to CDC via interagency agreement #DW-75-95845001-0. This commitment also leverages personnel and laboratory resources from CDC.

There are several strengths to using the GHS as a setting for conducting research of EPA interest regarding relationships between multimedia measurements and time-activity patterns: 1) the participation of a cohort of children and their siblings who share similar exposures to environmental agents in the home; 2) a longitudinal design; 3) the opportunity to collect multimedia measurement information for consumer product active ingredients. By collaborating on this study, EPA can wisely use its limited resources to collect non-chemical stressor information.

We acknowledge limitations to this protocol for achieving results that are generalizable to all children. Because the sampling protocol for the GHS uses a convenience sample, there is no reason to expect the sample for the Add-on Study to be reflective of the biological, socio-cultural, and environmental

characteristics of children in the U.S. population as a whole. In other words, the Add-on Study is also a convenience sample. Another limitation is the sample size, which is fixed and dependent on CDC's grantee's ability to recruit and retain participants throughout the time period of the study. The final sample size may be lower if there are no eligible siblings in the household; this will influence the amount of data available for statistical analyses and generalizability. Many analyses such as correlations between environmental measurements and biomarkers assume independence of children; however, the siblings will not be independent from their siblings that are participants in the GHS. This design will allow us to explore the variability in biomarkers within the same home environment. In other words, the siblings living in the same home might have biomarkers that are influenced by other factors such as those that might be revealed by collection of comprehensive time-activity and location information.

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

We are testing whether implementing a novel approach to collect data in the form of wearable GPS data logging instruments and accelerometers aids in the assessment of time-activity patterns and location information. At each scheduled home visit, activity and location data will be collected from both the index child and the sibling using minimally burdensome technologies, namely a waistband-mounted accelerometer-based activity monitor (Actical™; Philips Respironics, Bend, Oregon) and a GPS Data Logger (model BT-Q1000XT; Qstarz International, Taipei, Taiwan). Field study technicians will prepare the devices for data collection and instruct participants on placement and use of the devices.

Information from the mothers/caregivers will be collected by in-person interview via paper form (**Appendices D2 and D3**). For the paper forms, the respondents have minimal burden in providing their responses because they do not have to read questions or write answers; the data collectors record all of their verbal responses. The data collectors will enter the survey data into an electronic database which enables electronic transmission of data to CDC's Add-on Study researchers. We chose paper forms for most of the data collection because it is the least expensive data collection method compared with transcribing answers from voice recorders or paying for laptop/notepad computers.

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

We conducted a thorough literature search on exposure pathways for children in the home environment. The results of the extensive literature search and citations used are found in **Appendix C.** Although there have been a variety of studies that have collected multi-pathway exposure assessments, additional information, particularly about children, is still needed to increase our understanding of exposure sources and optimal monitoring approaches.

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

The collection of this information does not directly impact small businesses or small entities.

A.6. Consequences of Collecting the Information Less Frequently

Some of the environmental and biospecimen data are collected repeatedly for several reasons: 1) to address seasonal variation in measurements; 2) to obtain better estimates of average exposure; and 3) to minimize recall bias. To improve exposure modeling, the four-visit-sampling scheme is the minimum number of visits required to obtain valid estimates. The primary technical obstacle to reducing the burden is the necessity of obtaining valid estimates of exposure. It is important to collect data for each of the four seasons in order to adjust for expected seasonal variations in certain data.

There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A notice was published in the *Federal Register* on 05/06/2015, Vol. 80, No. 87, pages 26055-6 (**Appendix B**). No public comments were received.

B. During the design phase of this Add-on Study, investigators from CDC's National Center of Environmental Health (NCEH) and EPA/ORD reviewed published literature on children's exposure pathways. Activities included consultation with researchers from HUD, other CDC center, and academic institutions. EPA's research protocol was externally peer-reviewed by subject matter experts. We also discussed availability of data and frequency of collection of the questionnaires with the subject matter experts listed in Table 1.

Table 1. Experts consulted regarding study design and frequency of data collection

Name	Title	Affiliation	Contact information	Year of Consultation
Peter Ashley, DrPH	Director, Policy and Standards Division	U.S. Dept. of Housing and Urban Development	Peter.J.Ashley@hud.gov Phone: 202-402-7595	2013
Gary Adamkiewicz, PhD	Research Scientist	Harvard School of Public Health	GADAMKIE@hsph.harvard.edu Phone: 617-384-8852	2013
Tiina Reponen, PhD	Professor	University of Cincinnati	Reponeta@ucmail.uc.edu Phone: 513-558-0571	2013
Pat Ryan, PhD	Assistant Professor	University of Cincinnati	patrick.ryan@cchmc.org Phone: 513-803-4704	2013

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

Tokens of appreciation are given as part of the GHS; the amount is $50 for each home visit (i.e., GHS: $50 per visit times 4 visits equals $200). If a household participates in both the GHS and the Add-on Study, they will receive an additional $50 per home visit in order to acknowledge the substantial increase in burden placed on the household (i.e., Add-on Study: $50 per visit times 4 visits equals $200). An additional one-time token of appreciation of $25 will be given if, at the designated home visit, all four of the following samples can be collected from a single child (the sibling): 1) duplicate diet; 2) feces; 3) nail clippings; and 4) blood.

As such, the total amount available to each household for participating in the Add-on Study is $225. These amounts are generally comparable with other environmental exposure assessment studies as described in Table 2, and the incremental $50/home visit plus a one-time incentive of $25 for the set of four samples (i.e., duplicate diet, feces, nail clippings, blood) needed for the mass-balance equation is commensurate with two previously-approved ICRs:

Biomonitoring of Great Lakes Populations Program (OMB Control No. 0923-0044, expiration date 10/31/2015)
Biomonitoring of Great Lakes Populations Program II (OMB Control No. 0923-0052, expiration date 4/30/2017)

Table 2. Burden, Incentive, and Response Rates in Federal Studies with Multiple Data Collection Formats

Study Name/Agency	Year	Study description	Respondent burden	Incentive	Response rate
Third National Health and Nutrition Examination Survey (NHANES III)/ CDC NCHS	1988-1994	NHANES is designed to collect information about the health and diet of people in the United States to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States.	In-person interview, medical examination	$230 (plus exam results)	Interview=82 % Exam=73%
National Human Exposure Assessment Survey (NHEXAS) Region 5/ EPA	1995-1997	A population-based pilot study of the exposure to metals, pesticides, volatile organic compounds, and other toxic chemicals of ~500 people in 3 US regions.	Questionnaires, video-taped observations, duplicate diet samples, collection of blood and urine, measurements of air quality and soil and dust in and around the home	$195	Questionnaire = 71.5% Visit 1 = 80% Visit 2 = 56.8% Visit 3 = 47.8%
Minnesota Children's Pesticide Exposure Study (MNCPES)/ EPA	1997	Study of multi-pathway and multi-pesticide exposures in children. The primary objective was to characterize children's exposure to selected pesticides through a combination of questionnaires, personal exposure measurements and monitoring of biological samples, environmental samples, and	4-day duplicate diet samples, 6-days of personal air monitoring, keeping time and activity diaries, blood, urine and hair collections, videotaping.	$195 (children given age-appropriate gifts and parents offered videotapes of their children)	Telephone Screening = 67.5%

		children's activity patterns.			
School Health Initiative: Environment, Learning, Disease Study (SHIELD)/ EPA	1999	School-based investigation of children's environmental health in economically disadvantaged urban neighborhoods of Minneapolis.	Health questionnaires, 48-hour VOC sampling, blood draw, vacuum sampling in home, urine collections, school records review	$140 (children given age-appropriate gifts)	Recruitment= 56.7% (interviews/ data collections ranged from 76-88%)
Biologic Specimen-based Study of Dietary Measurement Error/ NCI	1999	This study assessed dietary measurement error by comparing energy and protein intakes from two self-reported dietary data collection instruments (the NCI Diet History Questionnaire and the in-person 24-hour dietary recall interview) with two biomarkers (doubly labeled water and urinary nitrogen excretion)	Three clinic visits. Dietary History Questionnaire, 24-hour dietary recall, height/weight measurements, physical activity questionnaires, urine collection, Doubly-labeled water dose, 24-hour urine collection	$200	Telephone recruitment=79% Visit=100% (5 and 2 hours)

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the CDC Information Collection Review Office which determined that the Privacy Act does apply. The applicable Privacy Act System of Records Notice (SORN) is SORN No. 09-20-0136 “Epidemiologic Studies and Surveillance of Disease Problems” (records retrievable by name and ID number).

In addition, the NCEH Information Systems Security Officer (ISSO) reviewed this protocol and approved the system for GPS collection and data transfer.

A.10.1. Privacy Impact Assessment Information

1. An overview of the data collection system

Data collection will be integrated into the regularly-scheduled home visits of the GHS. Participants will be enrolled on a rolling basis over a period of three years. More details of the study design are provided in the protocol (**Appendix C**).

The target sample size for the Add-on Study is 32 green homes and 32 non-green homes. Participants in each family will include the index child with a doctor diagnosis of asthma; a younger sibling of the index child living in the same household, and the mother/caregiver.

Sixty-four younger siblings (only one sibling per household) will be the maximum number enrolled as part of the Add-on Study. Siblings do not participate in the main GHS; they only participate in the Add-on Study. However, the index child in the GHS is also invited to participate in the Add-on Study. The mother/primary caregiver of each child participant will respond to the questionnaires (**Appendices D2 and D3**). Environmental and biological samples, GPS and accelerometer measurements, and questionnaire responses will be collected from residents by field technicians at each of the four home visits. No additional home visits are required.

An overview of data collected in the Add-on Study is presented in Tables 3 and 4. A flow chart of recruitment and sample collection is shown in **Appendix E**.

Table 3. Information collection summary for the Add-on Study

Information Type	Index Child (Age 7–12 years)	Sibling (newborn to 12 years)	Mother/ Caregiver	Purpose
Questionnaire about Sibling of Index Child			✓	This questionnaire collects information about the location and activity of the sibling in 30-minute increments and will be used in assessment of time-activity patterns that might influence the biomarker measurements obtained from the sibling. In addition, the questionnaire assesses the diet of the child and behaviors in the home which could also influence the biomarker measurements. Therefore, the questionnaire data will improve our interpretation of biomarker relationships with environmental measurements in the home.
Questionnaire about Index Child			✓	This questionnaire is identical to the questionnaire about the sibling, but it is for the index child.
Household Inventory			✓	This questionnaire assesses home characteristics which were not captured in the main GHS. These home characteristics could also influence the biomarker and environmental measurements.
Accelerometer and GPS information	✓	✓		The accelerometer worn by the children assesses physical activity of the child. The GPS device can assess location of the child and will used in conjunction with the accelerometer to provide data for a computational algorithm which calculates time spent indoors, outdoors, and in travel (in vehicles)

*The questionnaires will be administered to the mother/caregiver as described in the protocol (**Appendix C**).

Table 4. Multimedia sample collection for the Add-on Study:

Sample	Residence	Index Child (Age 7–12 years)	Sibling (Age newborn to 12 years)	Purpose
Indoor air (active, passive, personal)	✓	✓	✓	Air samples will be analyzed for volatile organic compounds (VOCs) and semi-volatile organic compounds (SVOCs) in the home. These may include chemicals from off-gassing of building materials, furnishings, cleaning products, pesticides, consumer products, and others.
House dust[a] (Technician and participant collected vacuum samples)	✓			Dust samples will be analyzed for pesticides, metals, and consumer products such as those found in shampoos, detergents, lotions, and toothpaste.
Electrostatic dust collection	✓			The dust will be analyzed for mold.
Surface wipe	✓			Dust from wipes will be analyzed for SVOCs in the home. These include chemicals from pesticides, consumer product active ingredients, and others.
Soil	✓			Soil will be analyzed for pesticides and metals
Hand wipe		✓	✓	Dust from the wipes will be analyzed for SVOCs on the children's hands which might be indicative of exposures in the home or locations beyond the home environment. These may include chemicals from pesticides, consumer product active ingredients, and metals.
Socks		✓	✓	Dust from the socks will be analyzed for SVOCs which might be indicative of exposures from residential floors. These may include chemicals from pesticides and consumer product active ingredients.
Urine (collected in traditional urine cups as part of the GHS)		✓[b]		This sample might be indicative of relatively short-term exposures from the home or locations beyond the home environment. The portion of the urine used for the Add-on study will be analyzed for consumer products such as those found in shampoos, detergents, lotions, and

				toothpaste. (traditional)
Urine (collected in special acid-washed, metals-free urine bottles)			✓	This sample might be indicative of relatively short-term exposures from the home or locations beyond the home environment. The urine will be analyzed for pesticide metabolites, metals, and consumer products such as those found in shampoos, detergents, lotions, and toothpaste.
Duplicate diet[c]			✓	This represents food and drink that is consumed by the child over a 24 hour period. This represents ingestion of potential chemicals which might be indicative of exposures in the home or locations beyond the home environment. The duplicate diet will be analyzed for pesticide metabolites, metals, and consumer products such as those found in shampoos, detergents, lotions, and toothpaste.
Blood[c]			✓	This sample might be indicative of relatively short-term exposures in the home or locations beyond the home environment. The blood will be analyzed for pesticide metabolites, metals, and consumer product active ingredients.
Nail clippings[c]			✓	This sample might be indicative of relatively long-term exposures in the home or locations beyond the home environment. The nail clippings will be analyzed for metals.
Feces[c]			✓	This sample might be indicative of relatively short-term exposures in the home or locations beyond the home environment. The feces will be analyzed for metals.

[a] Add-on Study samples in addition to GHS samples already being collected for allergens and fungi.
[b] Aliquot from index child's GHS biological samples.
[c] These four samples from the sibling must be matched for estimation of mass-balance equations.

2. A description of the information to be collected

The following information in identifiable form (IIF) will be collected and sent to CDC and EPA staff involved in the Add-on Study: birthdate of the sibling and the index children, biological specimens (urine, blood, nail clippings and feces) and GPS location (latitude and longitude coordinates). Although names, phone numbers and addresses are collected by the local study site staff for scheduling home visits and providing consent, these data are not shared with federal government researchers; however, these records will be protected by the awardee to the same extent as required for the federal government, and is reviewed and approved by the NCEH ISSO.

Tulane University field technicians will conduct the data collection for both the main GHS and the Add-on Study. Once the field technicians collect the data, they send information to CDC's Add-on Study staff.

The CDC staff then forward this information to EPA. Figures 1 and 2 show the relevant data flow for the accelerometer/GPS data and questionnaire data, respectively.

Figure 1. Diagram of data flow: accelerometer and GPS data

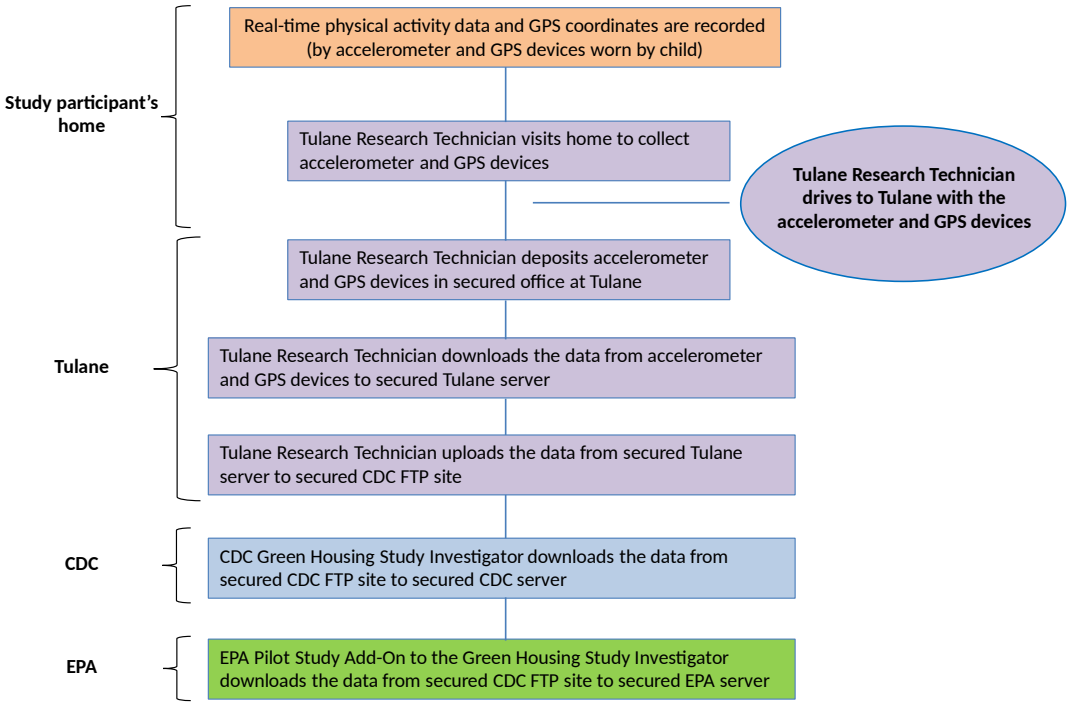
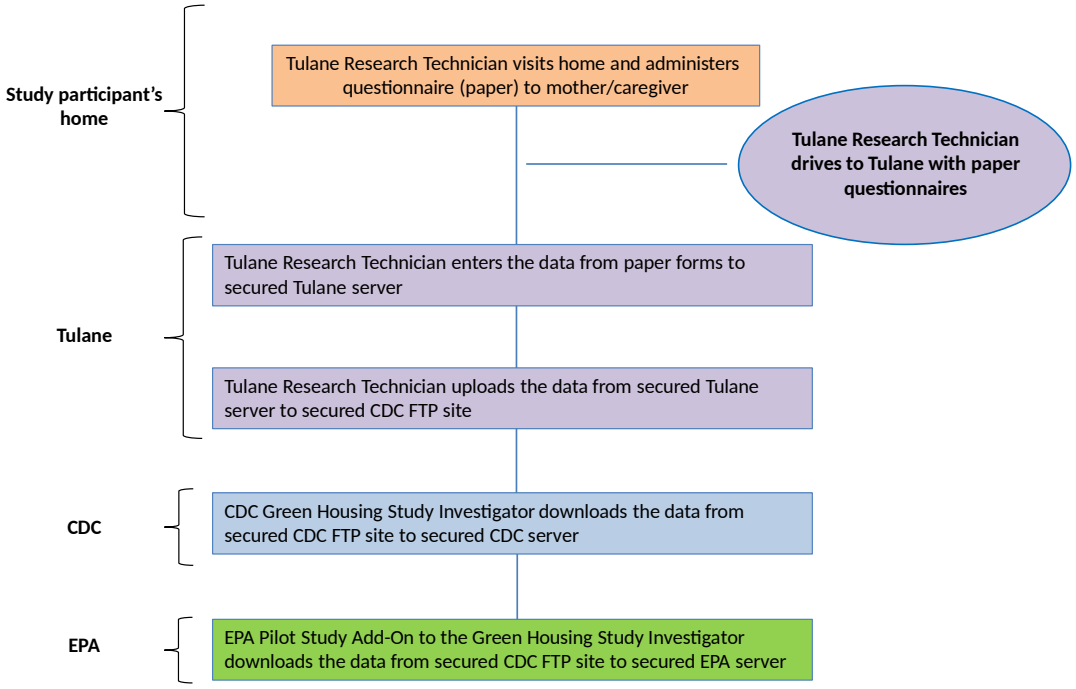


Figure 2 shows the data flow for the questionnaires (**Appendices D2 and D3**). The questionnaires will query the respondent on location, transportation, activity, diet, and consumer products use that might affect the children's environmental exposures and will be used by the field staff to record home observations

Figure 2. Diagram of data flow: questionnaire data



All paper copies of consent/assent forms (**Appendices F and G**) and questionnaires (**Appendices D2 and D3**) are scanned into electronic files. The paper copies will be stored securely at the study site's research institution for 5 years beyond the last peer-reviewed publication of the results. At that time, paper copies will be shredded and recycled. The electronic files are shared with CDC, and CDC will keep them in accordance with approved record control schedules. The electronic files contain data only identified by study ID number. The data collectors will have the link to names and address. GHS investigators will continue to take steps to reduce the amount of individually-identifiable data maintained at CDC and EPA.

3. A description of how the information will be shared and for what purpose

The Add-on Study will comply with the requirements of the "CDC Plan for Increasing Access to Scientific Publications and Digital Scientific Data Generated with CDC Funding" issued January, 2015. This plan complies with OMB Memo M-13-13, issued in May 2013."

4. The impact the proposed collection will have on the respondent's privacy

If there is a breach of confidentiality for any of the above IIF, some effect on the respondent's privacy could occur. However, the CDC, EPA, and Tulane Add-on Study investigators have taken steps to reduce the amount of IIF maintained at their respective locations. Survey data will be safeguarded to protect privacy in the field and in the office; paper surveys will be kept in a locked location, computer files will be password protected, and access will be limited to study personnel.

5. Whether individuals are informed that providing the information is voluntary or mandatory

During the consent process, CDC-trained interviewers explain to the residents that participation in the study is voluntary and they may withdraw at any time without negative consequences. The interviewers explain that the intended use of the data is to study environmental exposures in the home, that information

will be shared among GHS and Add-on Study researchers, and that the legal authority for the data collection is through the Public Health Service Act. Respondents will be informed of the potential risks and benefits of their participation and their privacy will be protected to the full extent allowed by the law. Respondents will be informed that no penalties will occur if they do not wish to respond to the information collection as a whole or to any specific questions.

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

The opportunity to consent to participate in the Add-on Study is discussed in the protocol (**Appendix C**: section labeled as Recruitment and Eligibility Criteria). Copies of the consent/assent forms are provided to the study participants **(Appendices F and G**). Data collectors are required to have human subjects training in accordance with their institution's IRB and/or the CDC's IRB. A component of human subjects training addresses data security measures.

7. How the information will be secured

The GHS and Add-on Study staff will make every effort to keep collected data secure by a variety of methods. The data from the paper questionnaires will be entered into a password-protected database and a unique Study ID is assigned as a key identifier for all study forms. The electronic files will contain data only identified by study ID number. All paper copies of questionnaires (**Appendices D2 and D3**) and consent/assent forms (**Appendices F and G**) will be scanned into electronic files. The paper copies will be stored securely at the study site's research institution for 5 years beyond the last peer-reviewed publication of the results. At that time, paper copies will be shredded and recycled.

Based on the overarching GHS protocol, the environmental and biological samples and measurements for the Add-on Study will only be identified by study ID. Field data collectors maintain their paper files in locked cabinets and their electronic files are stored on secured servers with password protection. Encrypted data files are sent electronically to GHS/Add-on Study investigators at CDC. Data are stored on highly-secured CDC servers in Atlanta, GA. The servers are housed in a secure computer room complete with climate control, emergency power, and an uninterruptible power supply (UPS). Daily back-ups and integrated security are implemented through the CDC computer services infrastructure. All data access is password-protected, and all network communications use encryption. All servers and PCs that are part of the CDC infrastructure are protected by both host-based firewalls and software in order to prevent the undetected installation of "spyware." At CDC, only GHS/Add-on Study investigators are given access to read the encrypted data files.

In addition, the EPA staff involved with the Add-on Study will maintain all study records in accordance with applicable policies and procedures necessary for Federal Information Security Management Act (FISMA) compliance. Paper records sent to EPA will be stored in locked offices or locked file cabinets. Electronic records will only be stored on IT systems that are protected by EPA's firewall and security systems. All electronic records will be backed-up on secure servers. The EPA Add-on Study staff will store personal identifying information in encrypted format on secure servers. Only EPA Add-on Study researchers working directly with the personal identifying information will be provided with the encryption keys.

Biological specimens will be temporarily stored in secured Tulane University freezers until they can be shipped to secured freezers at CDC and EPA. The environmental and biological samples and measurements are only identified by study ID and will not carry any identifying information. All study samples will be stored securely for 5 years beyond the last peer-reviewed publication of the results.

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

The applicable System of Records Notice (SORN) under the Privacy Act is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. While names are not sent to CDC, the data collectors have the capability of maintaining the link between name and study ID number; therefore, the Privacy Act does apply.

9. IRB approval

This study was initially approved by CDC's IRB (Protocol No. 5587.0) on December 19, 2014 and renewed under the auspices of the GHS on February 26, 2016. The CDC IRB approval is attached (**Appendix H**).

A.11. Justification for Sensitive Questions

Questions about activities are considered sensitive by some people. We have tried to avoid asking questions that might be emotionally upsetting. We also acknowledge that the analysis of biospecimens and environmental samples can reveal information that some people would consider sensitive. Since this is an exploratory study, we are collecting many types of data simply to determine their importance for future studies. In this way, we hope to minimize collecting data that may be considered sensitive in the future. Participants may decline responding to any question and participating in any particular data collection component.

A.12. Estimates of Annualized Burden Hours and Costs

The incremental burden on participants, over and above their participation in the standard GHS protocol covered in OMB 0920-0906, is listed in Table 5. The Add-on Study site has 64 households which will be enrolled on a rolling basis over a period of three years. Therefore, rounding to whole numbers, on average 22 mothers/primary caregiver respondents will be enrolled each year. All environmental exposure information about children will be provided by their mothers/primary caregivers (i.e., no children will fill out questionnaires). For the purposes of assessing potential burden, we are using the maximum number and time burden of mothers/primary caregivers as respondents for the instructions and recording of information (Attachment D1), biospecimen collection, environmental sample preparation and collection, and the questionnaires for any siblings and index children who volunteer their time and information in the study (Attachments D2 and D3). The household inventory (Attachment D4), although assessed at each of the four home visits, includes gateway questions to initiate skip patterns to reduce time burden where the inventory has not changed since the previous visit. The total annualized burden for all activities is 440 hours.

Table 5. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Mothers/Primary caregivers of enrolled children	Participant Instruction and Record Book	22	4	30/60	44
	Biospecimen Collection from Children	22	4	40/60	59
	Preparation and	22	4	180/60	264

	Collection of Data Other than Biospecimens				
	Questionnaire about Sibling of Index Child	22	4	20/60	29
	Questionnaire about Index Child	22	4	20/60	29
	Household Inventory	22	4	10/60	15
				Total	440

For the annualized burden cost in Table 6, we assume earning potential for participants in our study (low-income mothers/primary caregivers living in multifamily, urban housing) is minimum wage. Effective from July 24, 2009 to the present, the Federal minimum wage remains $7.25 per hour (http://www.dol.gov/whd/minimumwage.htm).

Table 6. Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)	Total Burden (hours)	Hourly Wage Rate	Total Respondent Costs
Mothers/ Primary caregivers of enrolled children	Participant Instruction and Record Book	22	4	30/60	44	$7.25	$319.00
	Biospecimen collection from their children	22	4	40/60	59	$7.25	$427.75
	Preparation and collection of data other than biospecimens	22	4	180/60	264	$7.25	$1914.00
	Questionnaire about Sibling of Index Child	22	4	20/60	29	$7.25	$210.25
	Questionnaire about Index child	22	4	20/60	29	$7.25	$210.25
	Household Inventory	22	4	10/60	15	$7.25	$108.75
						Total	$3190.00

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

There is no anticipated cost burden to respondents resulting from the collection of information, except the costs associated with the respondents' time. Respondents are not required to incur: a) capital or start-up costs; or b) operation, maintenance and purchase of services costs. The mother/primary caregiver respondents are asked to keep records of factors that could affect time-activity patterns of their participating children (**Appendix D1**). The record book is only for the period of time during the home visits and then would be given to the field technician at the end of each home visit.

A.14. Annualized Cost to the Government

The Add-on Study is conducted by EPA, CDC and the cooperative agreement awardee. The estimated cost for CDC personnel, study coordination, laboratory analysis, data analysis and oversight of the awardees' work is $1,429,000 over 3-years. Table 7 shows the annualized costs.

Table 7. Annualized Cost Estimate of Proposed Study

Category	Annual Costs (dollars)
CDC, including	Total = $231,000
- three staff (GS-13) at 75% effort	$225,000
- travel for site visits	$6,000
Cooperative agreement awardee, including all staff, travel, interviewing, supplies, sample collection, laboratory analyses, data analysis, and reporting.	$200,000
Laboratory analysis	$45,333
Total costs	$476,333

A.15. Explanation for Program Changes or Adjustments

There are no burden and program changes. This is a new collection.

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

CDC and/or EPA will prepare at least two peer-reviewed journal articles of exposure assessment. CDC will also provide technical information and recommendations to various housing programs based on the findings of this study.

The research program will be conducted over 3 years. Table 8 shows the projected schedule of accomplishments and milestones for the study.

Table 8. Project Time Schedule

Activity	Months after OMB approval

Train study staff from each site to collect environmental, survey, and clinical data	2 months prior to approval
Data collection	1-36
Subcontract with laboratories to assay environmental samples and biomarkers collected during the study.	2
Summary of laboratory results from subcontracted institutions	6, 12, 24, 36
Summary of survey results from study sites	6, 12, 24, 36
Conduct statistical analysis	6, 12, 18, 24, 30, 36
Submit articles for peer review in journals	12, 24, 36

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

Display of the OMB expiration date is appropriate.

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

There are no exceptions to the certification.