ATTACHMENT J

Data Collection Protocol

A.1 Tracing Process

We will conduct tracing using several different methods including, and listed in the order in which they will be implemented: 1) Batch tracing, using the National Change of Address and telephone matching lookup; 2) Letter mail out and telephone follow-up; 3) Interactive database tracing; and 4) In-person field tracing. We will also search government lists, such as the Department of Motor Vehicle and Housing and Urban Development lists, to locate more recent addresses of these eligible families.

We will test the efficacy of these approaches to evaluate locate rates and determine the best combination of approaches to use in the Full Study to find potential participants. In addition, during the Feasibility Study, we will test the proposed Full Study tracing methods by attempting to locate 50 children in each of the four Full Study states from the FEMA databases.

A.2 Data Collection Process

The steps involved in the data collection process for the Feasibility Study are described below.

A.2.1 Communication and Public Involvement

Prior to the start of data collection in the field, efforts will be made to develop awareness about the study in the study areas, and to encourage residents to participate if their address is chosen during sampling. RTI will organize an outreach approach that will include partnerships with organizations serving communities in each of the two Feasibility states (Louisiana and Mississippi).

RTI will also partner with various local senior advisors and organizations that have experience in developing outreach programs in these states. These groups will provide access to the populations they serve through newsletters, public forums, and faith-based events.

A.2.2 Staffing and Training

For conducting fieldwork, RTI contracts with Headway Corporate Staffing Services to hire all Field Supervisors and Field Interviewers (FIs). Headway is an organization contracted by RTI to handle the project field staff payroll processing including expense reimbursement and tax withholding. Louisiana State University (LSU) and Coastal Family Health Centers (CFHC) will recruit and employ the Registered Nurses (RNs) using their established resources, including internet job postings, local newspapers, and professional publications. Aten Clinical Solutions, Inc. has the capacity to supplement these efforts to employ RNs, in addition to hiring and managing the medical records abstractors.

A 5-day FI Training Session and a 3-day RN Training Session will be held in-person in New Orleans, LA. In addition to the project-specific interviewer training, bilingual (English/Spanish) staff will receive a 4-hour training on the Spanish version of the instruments and materials, as well as any challenges to recruiting the Hispanic population for enrollment. The Vietnamese translators will receive a 2-hour training session on standardized translation practices.

The Record abstractors will hold certification as Certified Coding Assistants (CCA) from the American Health Information Management Association (AHIMA); additionally they will receive a three-day training prior to beginning work on the project.

A.2.3 Translation

Based on estimates from the 2005-2007 American Community Survey, 9% of the population in the Gulf Coast states speak Spanish, but English less than "very well," and 0.33% speak Vietnamese, but English less than "very well." Since Spanish is the first language for almost 10% of the study population, the English questionnaires and materials will be translated into Spanish. RTI language methodologists will work together to translate survey documents and ensure that the final Spanish translations accurately reflect the intent of the English version and are written in a manner that is appropriate for a native Spanish-speaker. For Vietnamese, the third most spoken language in the Gulf Coast, the respondent materials (e.g., introductory letter and study brochure) will be translated into Vietnamese to encourage participation and answer questions. Local translators will be hired to assist with administering the English questionnaire to sample members whose primarily language is Vietnamese. Based on Feasibility Study findings, we will recommend whether the questionnaires should be translated in Vietnamese for the Full Study.

A.2.4 Recruitment Materials

For potential sample members with confirmed addresses, FIs will mail materials to the household describing the study objectives in advance of their in-person visit or telephone call. The materials will include an introductory letter (***Attachment H***) and a brochure describing the study (***Attachment I***). FIs, RNs, and abstractors will be given a letter of authorization from RTI to collect data for this research study, which they can show to residents and offices to confirm their role on the project (***Attachments T1, T2 and T3***).

A.2.5 Screening and Recruitment

Within a 2-week period following the receipt of the recruitment materials, a locally hired FI will visit the home to introduce the study, collect screening data, and, if appropriate, discuss participation in the study. In areas where an in-person visit is not cost-efficient, FIs will contact the household first by telephone to introduce the study, and collect screening data over the telephone. If the household is eligible, the FI will make an appointment for an in-person visit to discuss participation. The FI will visit the address at times of the day or evening which maximizes the potential for contact with a resident.

The Eligibility Questionnaire, also referred to as the Screener, (***Attachment K****)* will be programmed for administration on a secure handheld screening device that will collect information from an adult in the residence. An FI will visit the home and ask to speak to an adult 18 years or older, preferably the head of the household. The FI will approach the house with the handheld device turned on but with the computer screen locked. If no adult is present, a "Sorry I Missed You Card" (***Attachment U***) with a note about when the FI plans to return will be left. If an adult is present, the FI will obtain verbal informed consent and complete the Screening questionnaire. Based on the responses, the handheld device will determine whether a child at the residence is eligible for the study (zero or one child may be selected from each household).

If no children are eligible, the FI will thank the respondent and no further follow-up is necessary. If a child at the residence is eligible to participate, the FI will ask to speak with the parent or guardian of the child. After obtaining written informed consent from the parent baseline activities may begin during the

same visit. The participant must be available for a second session the following week. Participants will be assigned to the exposed and unexposed cohorts based on their occupancy history.

If the parent or guardian declines participation, an additional five questions in the Screener will be asked only during the Feasibility Study to determine the reasons for refusal. In addition, the FI will note the neighborhood (not the specific address) of the nonresponder. Names of potential participants will be checked against the FEMA lists of individuals who received THUs.

The FIs will be instructed to make at least five attempts to contact an eligible screening respondent and complete the screening at each selected address. If the FI is unable to contact anyone at the home after repeated attempts, the FI's Field Supervisor may send an Unable to Contact (UTC) letter. The UTC letter re-iterates information contained in the lead letter and presents a request for the respondent to consider participating in the study (***Attachment V***).

If a potential respondent refuses to be screened, the FI is trained to accept the refusal in a positive manner, thereby avoiding the possibility of creating an adversarial relationship and precluding future opportunities for conversion. A refusal letter may then be sent by the Field Supervisor. Two refusal letters have been prepared to address the more common reasons for refusal, General Refusal (***Attachment W1***) and anti-government sentiment (***Attachment W2***). At least one additional in-person attempt will be made to enroll one of the residents at the sample address in the screening process. If there are no adult residents willing to participate in the screening interview, the case will be coded a "refusal".

A.2.6 Household Interview – Session 1 and Session 2

As noted above in the General Overview, we will collect health and environmental data from all study participants at the baseline and 6-month follow-up visit. Data collection activities will be conducted by trained FIs, RNs, and medical records abstractors. The FIs will enroll participants and obtain health history information and administer the environmental surveys; RNs will perform health assessments and collect biospecimens.

Session 1 (FI Administered)

Each baseline and follow-up visit will consist of two sessions in the home, 5 to 9 days apart. At the first session, using a laptop computer, the FI will administer the baseline or 6-month follow-up health questionnaire to the parent or guardian, set up the environmental assessment equipment, instruct the parent/child on how to complete the Time& Activity Diary and, if the child is old enough to wear the Personal Exposure Monitor (PEM), the FI will instruct the family regarding the use of the personal monitor. In addition, at the baseline visit and any subsequent visit after a participant has moved, the FI will perform a home visual inspection survey.

Session 2 (FI and RN Administered)

At the second session, the RN will accompany the FI to the home in order to collect health measurements from the child. After reviewing the data collected by the FI from the first session, the RN will perform a health assessment and collect biospecimens. The FI will interview the parent or guardian using an exposure questionnaire; collect the time-activity diary and data enter it into the laptop while at

the home; collect dust and GPS location; and retrieve the environmental assessment equipment deployed during session 1. In an estimated 5% of the cases, it may be difficult to perform the interviews with the knowledgeable adult or examine the child in the home due to difficulty scheduling or lack of appropriate space to conduct these activities. For these situations, one of four mobile health units available to the project will be used for these interviews and examination activities.

During the Feasibility Study only, the FI and RN will be asked to document observations at the end of the session regarding perceived burden for the participant and difficulties obtaining data, including household distractions, child's fear of examination and biospecimen collection, damage to samplers, etc. (***Attachments S***). Also, the time required to administer the various components will be noted. Data on the rate of acceptance of the mobile unit option and compliance will be noted, as well as the quality of examination results in the home and the mobile unit.

A.2.7 FI Health Survey Instruments and RN Clinical Instruments

The FI will collect information on self-reported diagnoses, symptoms, and stressors from the parent and the RN will perform a health assessment and collect blood and urine. Pulmonary function (spirometry) and exhaled nitric oxide will be conducted according to standards of the American Thoracic Society (ATS). During the Feasibility Study, both the FI and RN will document observations regarding perceived burden from the participant and difficulties obtaining data.

Baseline Questionnaire (FI Administered)

During session 1 of the baseline visit, the FI will administer a questionnaire (***Attachment L***) to the parent in order to collect demographic information, detailed residential history, medical history of the child, frequency of respiratory and dermal symptoms, health care utilization, other risk factors, daily activities of the child including school and physical activities, family characteristics, and family history of target adverse health conditions. In addition, the baseline questionnaire will obtain information on the extent of hurricane-related home damage to the residence at the time of the hurricanes, and awareness and participation in litigation regarding FEMA THUs. The questionnaire includes an unstructured invitation to share health concerns. These responses will guide revisions to the instruments as the longitudinal study progresses. The questionnaire will also collect contact information for up to two friends or family members of the parent/guardian (***Attachment S***).

Quality of Life Questionnaire (FI Administered)

During session 1 of baseline and follow-up visits, the FI will also administer the Pediatric Quality of Life Inventory (PedsQL) (***Attachment L and M***) to the parent. For children with a diagnosed history of asthma or symptoms consistent with asthma, the Pediatric Quality of Life Inventory Asthma Module will be used instead of the PedsQL.

Health Assessment (RN Administered)

During session 2 of baseline and follow-up visits, all selected children will receive a health assessment that consists of dermal and facial assessments consistent with the ISAAC protocol (***Attachment M***), and height (using a portable Charder stadiometer) and weight (using a SECA portable scale model 803W) measurements consistent with the American Academy of Pediatrics examination protocols. For children

with self-reported diagnosed asthma, the age specific National Asthma Education and Prevention Program (NAEPP) Asthma Severity Scale is also assessed (***Attachment M***). Facial inspection will identify characteristics of allergic reactions such as swollen, red eyes, "allergic shiners," the "allergic salute," and irritated skin around nose, potentially secondary to rhinitis. Dermal inspection will follow the performance and quality assurance standards established in the ISAAC with a focused assessment for evidence of flexural eczema on the legs, arms, ankles, face, and neck.

Pulmonary Function Tests - Spirometry and Fractional Exhaled Nitric Oxide (RN Administered)

This test (***Attachment M***) will be conducted on children 5 years of age and older according to standards of the American Thoracic Society (ATS) (Miller et al., 2005) during session 2 of baseline and follow-up visits. The Easy One Frontline Spirometer, which measures all standard pulmonary function parameters, is especially designed to allow for easier tidal breathing and consequently greater accuracy and has been used effectively in several studies of asthmatic children. The Aerocrine NIOX MINO, which is used to measure fractional exhaled nitric oxide, has been used effectively in a study of asthma children and provides reliable assessment of airway inflammation.

Follow-up Health Questionnaire (FI Administered)

During session 1 of follow-up visits, the FI will collect information from the parent on changes in family characteristics, socioeconomic status, residence characteristics, and medical history of the child since last visit, or litigation participation since the last visit.

A.2.8 FI Exposure Survey Instruments

The FIs will use the surveys below to collect information that characterizes the child's potential exposure to the various environmental contaminants of interest.

Home Inspection Survey (FI Administered)

During session 1 at the baseline visit and any subsequent visit after a participant has moved, the FI will collect information inside/outside of the home about relevant household characteristics (e.g., home layout, room sizes, heating and air conditioning systems), resident lifestyle (e.g., cooking, cleaning, and use of humidifiers), and other risk factors (such as recent construction and painting, carpet installation, visible mildew/mold, and dust) (***Attachment L***).

Exposure Survey (FI Administered)

During session 2 of each visit, the FI will collect information on personal activities that may have led to potential exposure to a pollutant (***Attachment M***). These scenarios include environmental tobacco smoke, travel in a vehicle, use of household cleaners, residence ventilation conditions, classes in school temporary buildings, etc.

Time & Activity Diary (Respondent Administered)

During session 1, the Time & Activity Diary will be left for the parent and/or child to complete during the 5 - 9 day period (***Attachment M***). During Session 2 of each visit, the FI will collect and enter data into the laptop as high-level documentation of the child's location and activities during the exposure monitoring period.

Environmental Assessment (FI Administered)

During sessions 1 and 2, the FI will use this form to record the start and stop times of the environmental exposure equipment he/she set up in the participant's home (***Attachment L and M***).

Neighborhood Source Survey (FI Administered)

During session 2 of each visit, the FI will collect information on contaminant sources in the neighborhood for study-related contaminants as well as other potentially important contaminants, such as nearby chemical plants, roads, farm land, or other point and non-point sources (***Attachment S***).

A.2.9 Environmental Exposure Assessments

For this study, we will use multiple methods to assess environmental contaminant exposures.

Air Sampling

Three methods for air sampling will be deployed. Children age 7 years and older will wear a small cell-phone sized device, the MicroPEM™ for 7 days to measure their inhalation exposure. For children less than 7 years of age, fixed-location monitoring (FLM) will be used either indoor or outdoor or both in the participant's home depending on the group in which the household was sampled. The MicroPEM™ and related monitoring equipment will be set up during the first session and retrieved at the second session five to seven days later, accommodating the participants schedule.

Dust Collection (FI Administered)

Dermal exposures will be assessed with residential dust sample. Indoor dust sampling will be performed using the Housing and Urban Development (HUD) 2004 method "Vacuum Dust Sample Collection Protocol for Allergens." This method uses an electric canister microvacuum equipped with an autoclaved HEPA filter sock to collect the vacuumed dust. Individual samples will be collected from the common living area, the child's bedroom, and kitchen. In the common room, a 1 m^2 area adjacent to a frequently used sofa or chair and 2 m^2 of upholstery of the selected furniture will be vacuumed for 5 minutes. Similarly, dust from the child's bedroom floor and bed (including bedding) will be collected. The third 5-minute vacuum sample is the perimeter of the kitchen floor, including the kitchen island if present. Socks will be placed into zip-lock bags for transport. Dust collection will be conducted at the second session.

CO_2 Measurement/Air Exchange Rate (FI Administered)

A subset of the homes will be also tested for real-time indoor air exchange rate during Session 2. The FI will spray CO_2 from a canister, in the room where the indoor samples were collected and record its concentration data over 20 minutes using a hand-held CO_2 monitor. The FI will then download the data from the monitor and upload to the secure database at the end of day.

SLAMS (State-Local Air Monitoring System)

Daily air samples will be collected at U.S. EPA outdoor monitoring sites in the state of Louisiana and Mississippi for one 6-month period. On the first day of sampling, the FI (or a responsible project staff member) will place a wire box with weather shield on a RTI-provided stake, place the air sampler in the wire box, turn on the equipment, remove the caps from the samplers, and record the time of

deployment. Each day the FI (or staff member) will return to the SLAMS site and replace the air samplers.

A.2.10 Biospecimen Collection

In addition to performing a health assessment, the RN will collect blood and urine biospecimens from each selected child during the baseline home visit and only urine during the follow-up visit, using age-specific collection methods.

Urine Sample Collection (RN Administered)

A urine specimen will be collected from all children at each session 2 visit for assessment of exposure to pthalates, VOCs, tobacco smoke (cotinine), and urinary creatinine (to permit normalization of pollutant measures across participants) (***Attachment M***).

Blood Sample Collection (RN Administered)

Blood will be collected at each session 2 visit, except the 6 month follow-up visit, among children age 5 years or older (***Attachment M***). At baseline, 4 mL blood will be collected for complete blood count (CBC) and IgE (total and specific IgE).

A.2.11 Medical Record Abstractions

Medical record abstraction will be performed on a selected number of subjects' medical records based on subject and provider consent. We estimate that 30% of children will be reported to have one of the THU signature adverse health outcomes. We will request consent to access medical records for these participants to validate guardian/child reported diagnoses. In addition, for the Feasibility Study only, we will randomly select 50 cases of the remaining children for medical record abstraction to evaluate the incidence of diagnostic underreporting. The same structured abstraction form will be used for medical records from all provider sources. We anticipate the parents of children with a health condition to nominate, on average, three providers per child per interview. The form (***Attachment S***) will include abstraction for: the provider, demographic data (to validate that the correct record has been abstracted), visit date, diagnoses (related to THU signature adverse health outcomes), prescribed medications, family history of related conditions, serum IgE and carboxyhemoglobin levels, allergen skin and lung function test results, hospitalizations or referrals to specialists, and notes associated with these visits that relate to the residential situation of the participant.

Once we receive permission from the parent and authorization for disclosure of health information, the abstraction process will begin with the best practice of mailing an advance package to the providers. Abstractions will be performed by visiting the provider's location in person or using electronic records where appropriate. Diagnoses identified will be coded according to ICD-9-CM (International Classification of Diseases, 9th Revision, and Clinical Modification) standards to complete the abstraction form. Aten Solutions, a small business with expertise in clinical research, will perform the abstraction.

A.2.12 Feedback to Participants

Because of the relevance of some of the assessments made in this study, every effort will be made to provide the participants with health-related results that may require follow-up with a provider or changes in their home environment. We do not plan to provide results for every test but only the ones

most relevant. At this time we anticipate sharing findings on: NO2, PM10, cotinine, CBC, and total IgE. Normal and abnormal test results for blood, urine, and air quality that have utility will be communicated to the parent/guardian by means of a letter through the US Postal Service. Included in the letter (***Attachments X1-8***) will be the results of the test or measure, interpretations of those results, and suggestions for possible referrals to health care providers or clinics (***Attachment Y***). For the air quality tests, the letter will also include the test results, interpretation of the results, and suggestions on how to improve air quality in their home if the findings indicate this result.

Additionally, during the course of the focused health assessment in the home, the nurse will limit her clinical functions to the data collection activities as described in the clinical field protocol. A record of the findings of the in-home health assessment (including weight, evidence skin allergies, spirometry results, and exhaled nitric oxide) will be provided to the parent at the end of the interview. Any measurements that are outside normal limits for which medical follow-up is recommended will be clearly identified in the documentation. General information about the assessments and the implications of elevated or abnormal readings will be part of the documentation left with the parent (***Attachments X1-8***). Parents with additional questions about any other health-related questions will be referred to the child's primary care provider/clinic. If the parent indicates that the child does not have a primary care provider, the nurse can offer a list of local doctors and clinics so that the parent may choose a provider for the child. The nurse will not make any recommendation for a specific medical practitioner from the list.

In rare cases, it is possible that the laboratory analyzing the blood or urine samples could encounter a value that exceeds the critical threshold, requiring immediate reporting to a medical professional. In such cases, the LSU Laboratory staff will contact the CHATS Lead Nurse by telephone to report the critical laboratory value. The Lead Nurse will contact the child's parent by phone and inform him/her of the critical nature of the laboratory value and the need to obtain immediate medical care. The Lead Nurse will contact the child's parent by phone between the hours of 8:00 am and 8:00 pm any day of the week and inform him/her of the critical nature of the laboratory value and the need to obtain immediate medical care. In addition, the parent will receive a letter via the US Postal Service, describing the need for urgent follow-up. Such notification activity occurs commonly in nursing practice and is within in the scope of professional practice.

To assure the highest quality and accuracy of this task, 100% manual quality control will be used to ensure that letters are error-free and are being sent to the correct family.

A.2.13 Quality Control Procedures

There are a number of quality control measures that will be implemented for this study, both during the screening and the interview.

Screening and Interview Verification

To assess the quality of the screening and interviewing procedures, we will validate a 10 percent random sample of screenings where no one is selected to participate, or where the FI indicates the sampled address is vacant, not the primary residence, or not a residential housing unit (***Attachment P***). We will also validate a 10 percent random sample of completed interviews (***Attachment Q***). In all of these

situations, the name and telephone number of the individual who provided the data will be recorded in the questionnaire for the case. Telephone interviewers will make calls to the telephone numbers provided and ask a brief set of questions to verify that the outcome reported by the FI is correct. For participants who do not have a telephone, we will mail a version of the verification questionnaire (***Attachment R***).

CARI and In-Person Verification

We will use computer- audio recorded interviews (CARI), a process developed by RTI, to authenticate and validate that an interview took place, and assure that instrument protocols were followed. This silent interviewer monitoring feature will be used on 10% of the completed interviews, and respondents will be informed that participating in CARI is voluntary. Consent for recording will be requested of the participant as part of the general informed consent procedures. If it is determined that additional verification of a case is needed due to concerns about CARI feedback or a high number of verification refusals, RTI will review the need for implementing in-person verification.

Medical Record Abstraction Verification

To ensure high quality data, 20% of the abstracted records (performed by Aten) will be re-abstracted by a separate group of abstractors also employed by Aten. Any emergent discrepancies will be adjudicated by a senior abstractor and booster trainings will be performed as necessary.

Field Observations

For quality control, RTI survey staff and trained graduate students from the local university partners will randomly attend home visits and record observations of the session. These observation sessions also will serve as educational opportunities for the students to learn survey and epidemiologic methods.

Other Quality Assurance Activities

Quality monitoring activities to evaluate and assure performance to established standards will be used throughout the study. In addition to those listed above, additional quality assurance protocols will include: data coding; field or laboratory audits; and data frequency reviews. These quality assurance steps generate performance metrics that help guide corrective and quality improvement actions.

A.2.14 RTI and LSU Laboratories

All environmental exposure samples will be shipped to and processed at the RTI lab. The RTI lab will receive samples from the FIs with sample study ID only. All biospecimen samples will be shipped to and processed at the LSU lab. The LSU lab will receive samples from the RNs with sample study ID only. Samples will be stored for the duration of the Feasibility Study only. RTI standard shipping and handling protocols for biospecimens and environmental samples will be used.

The laboratory analyses of the blood and urine, which will be conducted within a few days of the in-home collection, will test the following: hemoglobin levels, white blood cells, blood platelets, total IgE and specific IgEs (such as cockroach, dust mite, oak tree, and mold), and urinary creatinine. As noted earlier, results from the laboratory analyses will be provided to the parents within five months of the in-

home visit. Both normal and abnormal results will be reported in written form, mailed by US Postal Service.

The laboratory analyses of the environmental exposures, which will be conducted within a few weeks of the in-home visit, will test for the following:

Air

- PM_{10} (indoor, outdoor, personal)
- Aldehydes (formaldehyde, acetaldehyde)
- VOCs (indoor, outdoor, personal)
    - Including 1,3-butadiene, acrylonitrile*, vinyl chloride, 1,2-dichloroethane, BTEX
- NO_2 (indoor, outdoor, personal)
- H_2S
- Environmental tobacco smoke (ETS) (from PM filter)
- Air Exchange Rate

Dust (indoor)

- Mold (beta-1,3-glucans)
- Endotoxins
- Allergens
    - dust mites (Der p 1, Der f 1)
    - cat (Fel d 1)
    - dog (Can f 1)
    - mouse (Mus m 1)
    - cockroach (Bla g 2)

- Phthalates