

Section B. Collections of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

Frame Development Overview

The Feasibility Study aims to enroll a total of 500 children, including 250 exposed children who resided in FEMA-provided Temporary Housing Units (THUs) and 250 unexposed children who did not reside in FEMA-provided THUs.

We will use FEMA data files (i.e., National Emergency Management System and FEMA Response & Recovery Tracking System) to select the exposed sample. These FEMA data files provide the most reliable list of individuals who requested assistance from FEMA as a result of the Hurricanes Katrina and Rita. The data files were updated regularly and contain supplementary information that will be useful in locating the sample individuals.

We employed two general strategies for analyzing the quality of the FEMA data files as a sampling frame—we examined the process in which the information was collected and for internal consistency. We worked closely with the group that standardized and reconciled the data from the FEMA data files that was used to build the master FEMA data file, which represents our final sample frame. From this group, we learned that the system used to collect the information was conducted in a systematic manner. We received similar confirmation from other FEMA offices in the Gulf Coast area regarding the thorough information collection process. As an additional step, we compared several field office lists with the master data file and found virtually no missing cases in the master FEMA data file. We concluded that the FEMA data files had a high level of accuracy and completeness.

We also checked the quality of the frame by employing a bootstrapping technique; specifically, we reviewed the data in the master data file for internal inconsistencies and other types of error. We found few data problems such as missing data and duplicates. All addresses, except for a few, were complete and locatable (GIS coordinates were identified). Overall, the occurrence of missing data was estimated to be 0.001%. Any duplicates in the master FEMA data file will be eliminated prior to sampling for the exposed population. We found the master data file to represent a well-constructed and well-maintained list of exposed household addresses. Within this sampling frame, the exposed sample in the Feasibility Study will be drawn from two states: Louisiana and Mississippi.

To identify the unexposed sample we will use a US Postal Service computerized delivery sequence file (address lists with names added) as the sample frame. The unexposed sample will also be drawn from Louisiana and Mississippi, from the same Census Block Groups of the exposed participants. Address lists as sample frames are increasingly being used in the survey research community, often to replace traditional random digit dialing and cell phone lists. The US Postal Service computerized address lists have been shown to offer nearly complete coverage, accurate address information, and in many cases, useful information for contacting the sampled households.

Sample Size and Statistical Power

During the Feasibility Study, we expect to enroll 500 participants at Baseline and retain 450 participants at the 6-month Follow-up (assuming 10% attrition). The sample size for the Feasibility Study was recommended by CDC in the Request for Proposals (RFP) to be able to assess general qualitative trends on specific subgroups to help inform the design of the Full Study. The sample size determination was not based on the ability to assess statistically significant differences between groups or to test

hypotheses; rather, the sample size needed to be sufficient to test a variety of operational issues by subgroups within each objective (e.g., children with asthma, families involved in litigation, primary language, etc.). Also it was important that the Feasibility Study attempt to find and enroll a large enough sample size for us to be able to examine, for example, participation rates within various subgroups in order to assess the potential for selection bias (e.g., exposed and unexposed status [250 in each group], involvement in litigation, etc.). Similarly, the ability to locate medical records is particularly important for the subset of children with a reported health condition, which is expected to be about 15% of the total. Last, we are also interested in looking at the variability in the biological and environmental measurements over time and we will need a sample size that is large enough to capture normal/temporal variability, especially for contaminants that do not have prior data. This is described in more detail in Section B.2 and **Exhibit 9**.

Based on information obtained from the CHATS Community Advisory Panel (CAP) and Technical Advisory Panel (TAP), it is believed that the type and duration of exposures to FEMA-provided THUs might differ according to whether the THUs were located on group sites (primarily families that were renters at the time of the Hurricanes) or on private property (primarily families that were home owners at the time of the Hurricanes). Thus, we plan to use a stratified sample of exposed participants from the master FEMA data files that will include 125 children who resided in THUs on group sites and 125 children who resided in THUs on private property. **Exhibit 8** shows the sample sizes expected for the exposed and unexposed samples, stratified by THU location. The unexposed sample will be selected from areas in which the exposed participants are currently living, thus the unexposed sample will not be stratified by private property or group site.

The response rates used to calculate the required sample size of 500 to be drawn from the sampling frames represent RTI's best estimates of success at locating the households, screening them, determining eligibility, and then following participants for various time periods. These rates are based on extensive and numerous surveys in the past, coupled with local information on the likely conditions for this particular survey. Specifically, given the information learned from our local partners, the nature of the study that utilizes a personal mode of interview and interaction, and the target audience, we anticipate that our estimated location rate of 65–75%, a screening rate of 85%, an eligibility rate of 28%, an acceptance rate of 80%, and a 90% retention rate at 6 months, to be achievable. These rates were generated based on similar face-to-face surveys conducted previously. Accordingly, 3455 households need to be drawn from the sampling frame in order to locate 2628 households that could be screened for eligibility. Additional information regarding maximizing response rates is provided in Section B.3.

Exhibit 8. Feasibility Study Sample Size for Exposed and Unexposed

	Exposed - Private Property	Exposed - Group Site	Unexposed	Total*
	No.	No.	No.	
Sample Size	875	938	1640	3455
Locate	657	657	1314	2628
Screen	558	558	1116	2232
Eligible	157	157	314	628
Baseline	125	125	250	500
6-month Follow-Up	112	113	225	450

*Numbers do not sum due to rounding

B.2 Procedures for the Collection of Information

Statistical Method for Stratification and Sample Selection

The target population for the Feasibility Study is children who currently reside in designated geographic areas and who meet all of the following eligibility criteria:

1. aged 15 years old or less as of June 1, 2011 and were born before December 31, 2007
2. reside in a household with at least one parent/guardian who is aged 18 years or older
3. reside in a household in which the parent/guardian speaks English, Spanish, or Vietnamese
4. currently live in Louisiana or Mississippi
5. either resided in the storm affected areas at the time of Hurricanes Katrina or Rita, or were born after the Hurricanes, but have subsequently resided in the storm-affected areas
6. either never resided in a FEMA-provided THU *in utero* (e.g., pregnant mother must not have lived in a THU) or after birth (unexposed); or resided for at least 2 months in a FEMA-provided THU (exposed). Children born after the Hurricanes, but whose mother had resided in a FEMA-provided THU while pregnant, will also be included as exposed.

Using the master FEMA data files, the exposed population will be divided into two groups—private and group THUs—for sampling in the Feasibility Study. The exposed sample will be limited to six parishes in Louisiana (Orleans, Jefferson, St. Bernard, East Baton Rouge, Livingston, and St. Helena) and three counties in Mississippi (Harrison, Jackson, and George). These areas were selected to represent a range of urban and rural areas and to capture the general geographic dispersion of the target population. All selected areas also represent a relatively high proportion of target population households to help increase our efficiency of screening for the Feasibility Study. These areas will be treated as strata, thereby enabling us to incorporate the Feasibility Study participants into the Full Study, should that become a reality. The target sample for each group (private and group THU) will be allocated to the strata in proportion to the number of exposed population households in each stratum. As much as possible, we will maintain equal selection probabilities, and therefore weights, across the strata. Addresses in these designated geographic areas identified for the exposed population will be selected using stratified probability sampling, where each address will have the same probability of selection. From each selected eligible address, the number of eligible children in the household will be enumerated and one child in each household will be randomly selected to participate.

The unexposed population will be selected from a current address-based sampling frame—the US Postal Service Delivery Sequence File—in the same Census Block Groups as the exposed population sample. We believe that it is important to identify unexposed populations that are similar to the exposed populations. An optimal match between the exposed and unexposed populations would occur if both populations came from the same residential areas before Hurricanes Katrina and Rita. This tension between drawing an efficient sample and having a good control group complicates the sample design and requires a compromise between these two objectives. We will therefore select the unexposed sample in areas in which the exposed sample members currently reside.

The matching of exposed and unexposed households will be limited to geographical proximity at the neighborhood level. While a 1:1 match will not be attempted, we anticipate that the samples will be similar not only with respect to geographical distribution but also in many basic demographic and socioeconomic characteristics such as age, gender, household composition, and general socioeconomic status. While it is true that within any Census Block Group the two households (exposed and unexposed) could be different, we anticipate that—on average across all Census Block Groups—the two samples will have similar distribution patterns. Furthermore, this approach will not only reduce field

costs by enabling interviewers to visit both exposed and unexposed sample households in the same areas, but will also help inform us on the feasibility of using this approach for the Full Study.

Similar to the procedure utilized for the exposed population, the addresses in the designated geographic areas for the unexposed population will be selected using probability sampling. Each address in the designated geographic areas will have the same probability of selection. For each eligible address selected, the number of eligible children in the household will be enumerated and one participating child in each household will be selected at random.

For both the exposed and unexposed samples, a main and reserve sample will be created. All sampling and subsampling for the main and reserve samples will be random so the probabilities of selection are known. A list of households will be drawn from the main sample and provided to the field staff. In the event we find a greater number of ineligible or refusal households on that list than anticipated, we will provide more addresses from the main sample; if that turns out to be insufficient, we will release addresses from the reserve sample.

Estimation Procedure

An objective of the Feasibility Study will be to test the weighting procedure and to identify the extent of outlier weights, as part of the study's operational testing, to assist in the design of the Full Study. To do so, weights will be calculated to adjust for unequal probabilities of selection. Calculation of the final weight consists of three component weights: (1) base weight to adjust for unequal probabilities of selection, both by design and unintentional; (2) nonresponse adjustment to account for variable nonresponse; and (3) post-stratification to calibrate the sample distributions to known population distributions. The final weight will be the product of the three component weights. If the Full Study is exercised, these weights can be used to estimate population proportions and means where the population of interest is the sampling frame. The second weight adjustment component mentioned above will provide information about nonresponse bias, that is, the extent to which our sample distributions differ from known population distributions. The information will help inform future efforts, nonresponse bias reduction, and effective adjustment procedures.

Degree of Accuracy Needed for the Purpose Described in the Justification

The data generated from the Feasibility Study will be used primarily to assess operational issues. Due to the complexity of the proposed Full Study, a large array of study processes need to be assessed during the Feasibility Study to ensure that unbiased and high quality data are collected during the Full Study. In addition, the results of the Feasibility Study will be used to assist in streamlining the field assessments in the Full Study so the burden to the participant and cost to the government, which would include more than 3,000 participants with seven visits each, are minimized.

Analyses will be conducted to address the following broad areas: locating, enrolling, and retaining study participants; locating medical records; evaluating the ranges and effectiveness of biomarkers to assess exposures (described in Section A.1 and **Exhibit 2**); and assessing nonparticipation bias, information bias in the self-reported Health Assessments, and the quality of data. These analyses will take into account a number of participant and residential characteristics that may affect various operational issues. These characteristics include: exposure status, language spoken by the participant, age of child, current residential ownership status, awareness of prior reports and litigation of health concerns, and specialty of medical provider. **Exhibit 9** provides examples of the types of analyses that will be performed using the Feasibility Study data and estimates of the sample sizes that will be available for analyses, given a baseline sample size of 500 participants.

The study size at Baseline was chosen so reasonably precise estimates of the variables of interest could be made for analyses of subgroups shown in **Exhibit 9**, even when we are faced with small sample sizes. For example, to address the objective to locate medical records it is estimated that—among children with reported adverse health outcomes (estimated to be 15% of 500 or n=75)—a 25% medical record abstraction rate would have a confidence interval of 19–33%.

Exhibit 9. Examples of Feasibility Study Analyses to Assess Operational Issues

Operational Issue	Variable of Interest (Data Source)	Analytic Process	Group (Estimated Sample Size)
<i>Locating, Enrolling, and Retaining Study Participants</i>			
Efficacy of tracing approach (exposed sample)	Locate Rate (Batch, Interactive and Field Tracing using electronic database searches, e.g., Acxiom, Internet white and yellow pages)	Estimate rates for different tracing approaches	All (1813*); Private trailer site (875); Group trailer site (938); LA (1179); MS (634) *We expect to trace 875+938=1813 exposed households (<i>Exhibit 8</i>)
Effectiveness of outreach campaigns	Percent aware of study (Question regarding awareness of study in Eligibility Screener)	Estimate percentage by subgroup	Urban (400*); Rural (100*); Hispanic (70); Vietnamese (15); Foreign-language speakers (50); LA (320); MS (180); Refusals (125) *This question will be asked to the 500 participants who agree to participate in the Feasibility Study
Enrollment	Percent enrolled in Baseline Session 1	Estimate percentage by subgroup	All (500); Hispanic (70*); Vietnamese (15*); Foreign-language speakers (50*); LA (320*); MS (180*); Property owner (200*); Renter (300*) *Estimates are based on distribution found in master FEMA data file.
Participation at 6 months	Percent retained at 6-month Follow-up, Session 1	Estimate percentage by subgroup	All (450); Hispanic (63); Vietnamese (13); Foreign-language speakers (45); LA (288); MS (162); Property owner (180); Renter (270)

Operational Issue	Variable of Interest (Data Source)	Analytic Process	Group (Estimated Sample Size)
Nonparticipant bias	Age of Child, Litigation participation, Study awareness, Foreign-language speakers (Eligibility Screener), Trailer site (master FEMA data file)	Descriptive statistics by responder status	Enrollees (500); Refusals (128*); Exposed Enrollees (250); Exposed Refusals (64*) *Refusals represent the difference between the total number of eligible participants (628, <i>Exhibit 8</i>) and the number enrolled (500). We anticipate a refusal rate of 20% (or an 80% acceptance rate).
<i>Locating medical records</i>			
Medical record abstraction consent	Percent agreeing to medical chart abstraction (Session 1 of Baseline and 6-month Follow-up Assessments)	Estimate percentage by subgroup	All requested (125*); With reported health outcome (75*); Children <12 yrs (350); Children ≥12 yrs (150); Without health insurance (100) *Medical record abstraction will be conducted on approximately 30% of children, which includes all children with self-reported asthma or other targeted health outcomes (estimated to be 15% of 500, or 75, and another 50 children who are randomly chosen) (Section A.1., Overview of the Data Collection System)
Ability to provide name of physician	Name agreement (Baseline Session 1 interview; chart abstraction database)	Estimate percentage by subgroup	All (375*); with reported health outcome (225) *We will ask each participant who agrees to medical chart abstraction to provide 3 physician names: 3x125=375.
Provider participation rate	Percent of providers participating (chart abstraction database)	Estimate percentage by subgroup	All (375); LA (225); MS (150); General practitioner (175); Specialists (200); Clinic (200); Private practice (175)
Medical records destroyed	Percent of charts not located (chart abstraction database)	Estimate percentage by subgroup	All (375); LA (225); MS (150)

Operational Issue	Variable of Interest (Data Source)	Analytic Process	Group (Estimated Sample Size)
Over- and under-reporting of health outcomes	Diagnosis and age of onset reported by family and in medical charts (Baseline Session 1 interview; chart abstraction database)	Estimate agreement by subgroup	All (125*); with self-reported health outcome (75); with no self-reported health outcome (50) *Total number of medical records to be abstracted (please see "Medical record abstraction consent" above)
<i>Environmental data collection: participation and data quality</i>			
Environmental monitoring participation rate	Percent participating in Session 1 of Baseline and 6-month Follow-up	Estimate percentage by subgroup and assessment period	All (Baseline: 500, Follow-up: 450); Private trailer site (125, 112); Group trailer site (125, 113); Urban (400,360); Rural (100,90); Property owner (200, 180); Renter (300, 270)
Environmental data quality	Analyte mass, concentration (mass per unit volume), or loading (mass per unit area) (Laboratory data base)	Percent of samples complete, accurate, precise; percent of samples above detection limit	All (440* personal samplers, 160* fixed platform (i.e., indoor and outdoor), dust 500); Urban (350 personal samplers, 130 fixed platforms, 400 dust); Rural (90 personal samplers, 30 fixed platforms, 100 dust) *Estimated number of eligible participants who will wear the personal sampler, aged ≥7 years. "Fixed platforms" will be installed in the homes of the 60 participants who are too young to wear the personal sampler (<7 yrs) plus 100 additional participants who are wearing the personal sampler. This subgroup of 100 represents the group that will be examined in the next row "Exposure misclassification".

Operational Issue	Variable of Interest (Data Source)	Analytic Process	Group (Estimated Sample Size)
Exposure misclassification	Quintile assignment of environmental data (personal, indoor, outdoor, dust from Baseline and 6-month Follow-up Assessments); Quintile assignment of exposure (e.g., children with highest contaminant level measurements or children with highest biomarker level) (monitor, biomarker data from Baseline and 6-month Follow-up Assessments)	Quintile agreement between environmental and biomarker by subgroup; quintile agreement between exposure measured by different platforms	All (100*); Urban (75); Rural (25) *a subgroup of 100 participants will have both environmental and biomarker measurements conducted.
Distribution of exposures to environmental pollutants	Contaminant level distribution by environmental sample platform (e.g., personal, indoor, outdoor, dust) (Baseline Assessment)	Descriptive statistics by subgroup	All (440* personal sampler, 160 fixed platform, 500 dust); Urban (350 personal sampler, 130 fixed platforms, 400 dust); Rural (90 personal sampler, 30 fixed platforms, 100 dust) *Estimated number of eligible participants who will wear the personal sampler, aged ≥ 7 years
Seasonal variability of exposures	Contaminant levels from environmental samplers (e.g., personal, indoor, outdoor, dust) (Baseline and 6-month Assessments)	Variability of paired differences (intra-household, intra-individual); Difference in means between assessment periods	All (396 personal sampler, 144 fixed platform, 450 dust); Urban (315 personal sampler, 117 fixed platforms, 360 dust); Rural (81 personal sampler, 27 fixed platforms, 90 dust)
<i>Biomarker data collection: participation, ability to assess exposures, and data quality</i>			
Biospecimen participation rate	Percent participating (Session 2 in Baseline and 6-month Follow-up Assessments)	Estimate percentage by subgroup and wave	All (Baseline: 500, Follow-up: 450); Children <5 (30, 27); Children ≥ 5 (470, 423)
Biospecimen shipping/storage	Loss percentage	Estimate percent loss during shipment or percent with poor quality after storage	All (~4000)

Operational Issue	Variable of Interest (Data Source)	Analytic Process	Group (Estimated Sample Size)
Biomarker data quality	Biomarker levels by medium (urine, blood) (Laboratory data base)	Percent of samples complete, accurate, precise; percent of samples above detection limit	All (500 urine, 470* blood) *Blood will not be drawn on participants <5 years; all participants will provide urine samples.
Biomarker distribution	Biomarker levels by medium (urine and blood) at Baseline Assessment (Laboratory data base)	Descriptive statistics by subgroup	All (500 urine, 470 blood); Urban (400 urine, 380 blood); Rural (100 urine, 90 blood)
Seasonal variability of biomarkers	Biomarker levels by medium at Baseline and 6-months (Laboratory data base)	Variability of paired differences (intra-household, intra-individual); Difference in means between assessment periods	All (450* urine, 423* blood); Urban (360 urine, 342 blood); Rural (90 urine, 81 blood) *Assuming 10% attrition at the 6-month Follow up.
Environmental sample or biomarker association with health outcome	Environmental, biomarker, and current and past health data (Baseline Assessment; Laboratory data base)	Pearson correlations, multivariate analysis	All (500 urine, 470 blood, 440 personal sampler, 160 fixed platform, 500 dust)
<i>Other operational issues to assess residential recall, sample selection, and field operations</i>			
Agreement of trailer residence	Type and location of trailer, Length of residence (master FEMA data file, Baseline Session 1 interview)	Chi-square, quintile agreement	Exposed (250)
Multiple trailer exposures	Percent of exposed who lived in more than one trailer (master FEMA data file, Baseline Session 1 interview)	Estimate percentage by subgroup	Exposed (250); Private trailer site(125); Group trailer site(125); LA (170); MS(80)
Potential for exposed: unexposed frequency matching	Age of child, gender, race/ethnicity, Property owner vs. renter, Health Insurance status (Baseline Session 1 interview)	Estimate descriptive statistics by subgroup	Exposed (250); Unexposed (250)

Operational Issue	Variable of Interest (Data Source)	Analytic Process	Group (Estimated Sample Size)
Field administration errors	Questionnaire administration errors, errors in deployment of environmental samplers, Health Assessment errors, shipment errors (Case Management System)	Counts: Field interviewer (18 conducting 52 visits); Nurses (6 conducting 150 visits)	N/A
Effectiveness of results communication to participants	Question regarding results in telephone inquiries to participants; number of undelivered letters of individual results (<i>Attachment X</i>).	Counts: Phone inquiries; undelivered letters	N/A

Unusual Problems Requiring Specialized Sampling Procedures

The major challenge is the need to identify unexposed populations that are similar to the exposed populations and that can serve as controls. For reasons of field efficiency and budgetary considerations, it will be necessary to cluster the exposed sample with respect to their current place of residence. An optimal match between the exposed and unexposed populations would occur if both populations came from the same pre-Katrina residential clusters. This tension between drawing an efficient sample and having a good control group complicates the sample design and requires a compromise between these two objectives. We will select the unexposed sample in areas in which the exposed sample members currently reside. This will result in a good match between the two samples, especially with respect to residence, and will reduce field costs by enabling interviewers to visit both exposed and unexposed sample households in the same areas.

Use of Periodic (less frequent than annual) Data Collection Cycles to Reduce Burden

In order to conduct the Feasibility Study within the two-year contract period, both the Baseline and Follow-up Assessments are conducted within a 12-month period, with the Follow-up Assessment occurring 6 months after the Baseline Assessment. The 6-month Follow-up Assessment will assist in evaluating the feasibility of retaining participants over time as well as allow the investigators to assess the potential for seasonality bias and changes in health for each participant over time.

Data Collection Procedures

Households with potential participants will be notified with an introductory letter (*Attachment H*) and a brochure (*Attachment I*) describing the study. A field interviewer (FI) will go to the home and conduct a brief screening interview with an adult at least 18 years of age, using a secure handheld computer (*Attachment K*). 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.

The Feasibility Study includes 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. During Session 1 of the Baseline Assessment, the FI will administer the health and

environmental exposure questionnaire using a laptop, perform a visual home inventory, set up the exposure assessment equipment in the house, explain the time and activity diary procedure, and instruct the parent on the use of a cell phone-sized personal air monitoring device (MicroPEM™) that children aged 7 years and older will wear for one week. During Session 2 of the Baseline Assessment, the FI will return to the home with a registered nurse (RN). The FI will administer the exposure questionnaire, record all information gathered from the exposure assessment equipment, enter data from the time and activity diary, and collect GPS information. The RN will conduct the Health Assessment on 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 procedures for the 6-month Follow-up Assessment are the same as for the Baseline Assessment except that blood will not be collected during Session 2.

Medical record abstraction (**Attachment S4**) will be conducted on approximately 30% of the children, which includes all children with self-reported asthma or other targeted health outcomes, such as dermal irritation, eczema, and increased allergic responses, 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.

Further details of all data collection procedures are provided in **Attachment J**. All questionnaires for the Baseline Sessions 1 and 2 are provided in **Attachments L and M**, and for the Follow-up Sessions 1 and 2 in **Attachments N and O**. **Attachments P – Y** is described in **Attachment J**.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Our ability to gain and retain respondent cooperation is critical to the success of the Feasibility Study Baseline and Follow-up endeavors. As mentioned previously, we invested considerable effort in establishing realistic levels of response. Based on our previous experience with face-to-face personal interviews from a list frame (both the USPS and FEMA data bases are examples of high quality list frames), we believe that it is reasonable to achieve relatively high levels of participation. However, the field strategy will need to be well-planned and tailored to the target population. In an effort to minimize non-response and maximize the ability to obtain 80% response rates and 90% retention levels at 6-month Follow-up we will:

- Establish a CAP to provide insight into the study-related concerns of target neighborhoods across the study area and build awareness.
- Utilize advanced community outreach to raise awareness about the project and to encourage participation.
- Mail a lead letter along with supporting materials from recognized leaders and organizers within the local community and a high-quality study brochure (**Attachment I**) to potential participants in advance of making contact to inform them of the study.
- Make recruitment materials and all consent/assent/permission forms available in English, Spanish, and Vietnamese in order to reach a large proportion of non-English-speaking households. These materials will be made available in Vietnamese because, during Hurricane Katrina, the Vietnamese community (approximately 20,000 or 1.5% of the New Orleans population) was heavily concentrated in sections of East New Orleans that were impacted by the flooding.
- All interview scripts and questionnaires have also been translated into Spanish and will be administered to Spanish-speaking participants in Spanish. We will have trained Vietnamese interpreters available to administer the interview scripts and questionnaires to Vietnamese-speaking participants in Vietnamese. Because the overall Vietnamese population in the Gulf

Coast was estimated to be 0.33% based on the 2005–2007 American Community Survey, we are not translating the interview materials into Vietnamese for the Feasibility Study. We will re-evaluate the need to translate interview materials into Vietnamese for the Full Study based on Feasibility Study results.

- Hire field interviewers and registered nurses who are members of the community.
- Ensure that participation is as easy and non-burdensome as possible.
- Provide focused training to field interviewers and nurses on the issues surrounding decisions to participate in the interview, clinical exams, environmental exposure collections and blood draw.
- Offer tokens of appreciation to both the parents and children during each session of participation based on the activity and burden involved.
- Employ proven refusal conversion methods.
- Deploy a multi-strategy tracking approach of batch, field, interactive and mail-outs to capitalize on recent contacts with study participants and maximize retention.

B.4 Tests of Procedures of Methods to be Undertaken

We plan to thoroughly test the CAPI instruments and all supporting systems prior to data collection. We will also test the environmental protocol, clinical protocols, and questionnaires with fewer than 10 respondents for each component.

B.5 Individuals Consulted on Feasibility Study Objectives - Statistical Aspects and Collecting or Analyzing Data on Feasibility and Health/Exposure

Exhibit 10 shows the individuals who were consulted on the statistical aspects of the design, as well as the agency and contractor staff who will collect and/or analyze the data from the Feasibility Study. Also provided is the CDC project officer who will receive and approve contract deliverables.

Exhibit 10. Individuals Consulted on Statistical Aspects of the Design and Personnel who will Collect and Analyze Data or Receive Contract Deliverables

Name	Organization	Title and Role	Telephone/Email
Mr. Gary Teague	CDC	Project Officer	(770) 488-3460 gteague@cdc.gov
Dr. Fuyuen Yip	CDC	Technical monitor; will analyze the data	(770) 488-3719 fyip@cdc.gov
Dr. Tegan Boehmer	CDC	Technical monitor; will analyze the data	(770) 488-3741 tboehmer@cdc.gov
Dr. Diane Wagener	RTI –Contractor	Project Director; designed study and data collection operations	(919) 485-5628 dwagener@rti.org
Ms. Lisa Thalji	RTI – Contractor	Deputy Project Director; designed data collection operations	(312) 456-5245 thalji@rti.org
Dr. Karol Krotki	RTI – Contractor	Director, Sample Design and Statistics; sample design and implementation; will analyze the data	(202) 728-2485 kkrotki@rti.org
Ms. Marjorie Hinsdale-Shouse	RTI – Contractor	Director, Participant Recruitment and Data Collection; oversees all recruitment and data collection operations	(919) 541-7368 mhs@rti.org

Name	Organization	Title and Role	Telephone/Email
Dr. Laura Strange	RTI – Contractor	Assistant Director, Clinical Data Collection; oversees clinical data collection	(770) 986-5052 lstrange@rti.org
Dr. Jonathan Thornburg	RTI – Contractor	Assistant Director, Environmental Exposure Assessments; oversees environmental exposure data collection	(919) 541-5971 jwt@rti.org
Dr. Ralph Delfino	University of California, Irvine	Vice Chair, Research and Graduate Studies, Epidemiology School of Medicine; will advise study on use of PEM and asthma data	(949) 824-1767 rdelfino@uci.edu
Dr. W. Dana Flanders	Emory University School of Public Health	Professor, Departments of Epidemiology and Biostatistics and Bioinformatics; will provide consultation on data analysis	(404) 727-8716 wflande@sph.emory.edu
Dr. David Olsen	CDC	Biostatistician; will provide consultation on data analysis	(770) 488-3724 Dolsen@cdc.gov
Dr. Shahed Iqbal	CDC	Senior Service Fellow; will analyze the data	(770) 488-0787 SIqbal@cdc.gov