SUPPORTING STATEMENT OF THE REQUEST FOR OMB REVIEW AND APPROVAL OF THE

Registration of Individuals Displaced by the Hurricanes Katrina and Rita (Pilot Project)

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Section A: Justification

A.1. Circumstances Making the Collection of Information Necessary

Background

This is a new Information Collection Request. This data collection is authorized by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The legislative mandate and laws are found in Appendix A.

In the aftermath of Hurricanes Katrina and Rita, which struck the Gulf Coast in 2005, some 375,000 persons occupied temporary housing units supplied by the Federal Emergency Management Agency (FEMA). FEMA deployed over 143,000 travel trailers, park homes, and mobile homes as temporary housing for persons displaced by the hurricanes. Persons living in these units may have been exposed to levels of formaldehyde sufficient to arouse concern about the health impact.

Everyone is exposed to small amounts of formaldehyde. At room temperature, formaldehyde is a colorless, flammable gas that has a distinct, pungent smell. Household sources of formaldehyde exposure include fiberglass, carpets, permanent press fabrics, paper products, and some household cleaners as well as manufactured wood products found in new housing including mobile homes. The most common route of exposure to formaldehyde is inhalation, which is likely to cause nose, skin, and eye irritation (burning, itchy, tearing, and sore throat) in children as well as in adults. It is possible that people with asthma may be more sensitive to the effects of inhaled formaldehyde.

High levels of exposure may be associated with the risk of cancer in humans. In 2006, the International Agency for Research on Cancer (IARC) listed formaldehyde as one of the (currently 105) substances categorically considered to be "carcinogenic to humans." The Department of Health and Human Services (DHHS) has also determined that formaldehyde may reasonably be considered a carcinogen.

Between December 21, 2007 and January 23, 2008, CDC's National Center for Environmental Health (NCEH) sampled indoor air in 519 travel trailers and manufactured homes. Stratified sampling included all of the major types and brands of temporary accommodations provided by FEMA. These were, in order of increasing size, (1) travel trailers, (2) park homes, and (3) mobile homes. In many trailers and mobile homes formaldehyde levels were higher than usual in indoor air in most homes in the United States. Average levels of formaldehyde in all travel trailers and mobile homes were about 77 parts per billion (ppb). Formaldehyde levels varied by type of unit, but all types tested had some elevated levels. At levels found in some trailers and mobile homes, formaldehyde exposure could affect health. Travel trailers had significantly higher average formaldehyde levels than mobile homes. NCEH also found that temperature, humidity, trailer type and brand, keeping windows open, and mold affected formaldehyde levels.

ATSDR entered into an Interagency Agreement (IAA) with FEMA to design and implement a pilot registry of persons housed in FEMA supplied temporary housing units following

Hurricanes Katrina and Rita. The pilot registry will be comprised of contact information, demographics, health status, and details of documented exposure for persons who resided in the THUs, and who, as a result of exposure to formaldehyde, may have been exposed to health risks while residing in those units. The pilot registry project will be conducted in three phases: development of the initial pilot, pilot implementation, and evaluation of the pilot registry. If the pilot registry is successful, ATSDR will utilize the results of the pilot implementation to develop the final scope for implementation of the full registry. Final implementation and management of the registry beyond the pilot project is not funded under this current IAA. Should the pilot indicate that a full registry is feasible, we will submit a separate request for approval of data collection for a full registry.

The exact number of people who resided in each unit is not available. An approximate estimate of the number of affected people has been made based on data from the Census on household sizes in Louisiana and Mississippi. In the Year 2000 Census, the average size of a household in Louisiana was 2.62 persons. The size of the average household in Mississippi was almost identical: 2.63 persons. Multiplying 143,000 by 2.62 yields an estimated 374,660 (or approximately 375,000) persons who potentially had significant exposure to indoor air in FEMA-supplied temporary housing.

After this project received IRB approval, and while the information collection request was under review, we became aware of a study of children affected by Hurricane Katrina that was being planned by our sister agency CDC/NCEH. These two studies have different purposes and designs, and are not duplicative. The CDC/NCEH study intends to conduct cluster sampling of children who have remained in the area they lived before the hurricane to facilitate access to medical records. The purpose of the NCEH study is to assess health problems among children affected by the hurricane. The purpose of the study described in this package is to assess the feasibility of locating, contacting, and obtaining information from people who lived in FEMA supplied temporary housing units following Hurricanes Katrina and Rita. We are especially interested in the feasibility of locating and contacting people who no longer live in the same place they lived before the hurricanes. Collecting limited self-reported health information is part of this study but there will be no verification of that information and no review of medical records.

Privacy Impact Assessment (PIA)
Overview of the Data Collection System

A computer-assisted telephone interview (CATI) system based on a paper questionnaire will be created. The CATI system will be used during all interviews to collect data for this pilot registry. The CATI data collection instrument will be composed of two parts. The first part will consist of screening questions to determine eligibility for enrollment (Appendix E). The second part—the main questionnaire (Appendix F) contains contact information of the registrant and other household members, demographics, and health status questions—focusing on respiratory and mental health outcomes (for more detailed information see B2).

The data will be collected by RTI International, a contractor, and maintained in-house. Access to the data will be closely controlled and restricted to authorized users (staff working on the registry only) with valid accounts and passwords only. One of the linked tables within the database will

hold all unique person identifiers, demographics, employer, occupation, and relevant occupational history. At the conclusion of the project, all data will be transferred from RTI to ATSDR via encrypted secure FTP site.

How long this information is retained depends on whether a full registry is implemented. If a full registry is formed, the information collected as part of the pilot will be included in that registry and will be retained until the registry is terminated. The data in the registry will be retained at ATSDR for at least ten years after the release or publication of the last report of data from the pilot or as required by federal regulations.

The registry's principal investigator will enforce data security policies and procedures. These policies and procedures will apply to such things as controlling data access (through restriction to authorized users with valid accounts and passwords) and procedures for deletion or purging of registrants who opt not to participate in the registry after the enrollment phase.

All personnel dealing with registrants' personal identifiable information will be required to sign a confidentiality agreement that will specify penalties for unauthorized use or release of data from the registry.

Items of Information to be Collected

A pre-registration dataset will be created before enrollment. This dataset, provided by FEMA, will be populated with contact information of the study population—Temporary Housing Unit (THU). The following information will be collected from individuals or, if already available through the FEMA dataset, will be verified by the individuals:

- Name
- Date of Birth
- Sex
- Social Security number (full number provided by FEMA, last 5 digits provided by registrants for verification)
- Race/ethnicity
- Mailing Address
- Phone Numbers
- Marital Status
- Employment Status/Occupation
- Income
- Education
- Self-reported health information
- Health Insurance status
- E-mail Address

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

No website will be directed at children under 13 years of age. The website is intended to be used by adults. The website is designed to provide information about the pilot registry.

A.2. Purpose and Use of the Information Collection

Privacy Impact Assessment Information

ATSDR proposes to conduct a pilot test of the registry as requested by FEMA (See A.1.). The proposed pilot registry has two goals.

Primary Goal: Test the feasibility and cost of contacting and enrolling members in a registry by collecting phone interview data.

Secondary Goal: Test the difference in prevalence rates of health conditions compared to national surveys (i.e., NHANES and NHIS).

This pilot registry will consist of 5,000 completed interviews of people who occupied FEMA supplied THUs after hurricanes Katrina and Rita. The 5,000 completed interviews will be obtained from a proportional sample (Appendix H) drawn across the affected states having FEMA supplied temporary housing units. The outreach plan for encouraging participation is outlined in Appendix J. Appendices K through O describe the materials that will be used as part of the outreach to potential participants. The pilot registry will contain data on eligible registrants such as contact information, demographics, self-reported health conditions, and details of time spent living in the THUs. The data collected in the pilot registry and the evaluation of the pilot registry will be used to determine the feasibility and estimate the costs of developing and populating a more complete registry of people affected by Hurricanes Katrina and Rita. In addition, comparisons of prevalence rates of health outcomes obtained through the pilot registry with estimates from national surveys will help determine the utility of conducting a full registry. For example, if no health outcomes are present in excess, there may be no need for a full registry.

Potential participants will be sent a letter introducing the pilot registry (Appendix D) and will be contacted by telephone for the survey. The data collection instruments consist of a screening tool (Appendix E) and the questionnaire instrument (Appendix F). The screener will be used to determine eligibility for enrollment. The questionnaire instrument will obtain the contact information of the participants and other household members along with demographic information and health status with a focus on respiratory outcomes and mental health. The screener and questionnaire will be administered using Computer-Assisted Telephone Interviewing (CATI) technology. CATI software has built-in branching logic, which will skip questions that are not applicable to enhance data accuracy (will avoid confusion as to which symptom the participant is to focus on and which time frame). In addition, RTI International will provide highly skilled and well-trained interviewers

Monitoring of interviewers will be conducted on 10% of all cases worked, which is industry standard. Both quality control supervisors, advisors to interviewers on the production floor, along with quality experts, monitors, will observe the work of interviewers, complete monitoring forms, and provide verbal feedback immediately after the monitoring session. Project staff will also conduct monitoring sessions to ensure that project protocols are being followed and provide

feedback as warranted. If necessary, interviewers will either be re-trained on specific project protocols or dismissed from the project.

Specific data collection activities will include identifying, locating, and contacting potential registrants. As potential registrants are contacted, their identity will be verified and information related to their potential exposure to formaldehyde and health status will be collected. Ultimately, a comprehensive registry (for which this pilot may be a prelude) would have its greatest impact on the registrants. A comprehensive registry would permit relatively unbiased selection of subjects for scientific study of their health concerns about the exposure to formaldehyde that they may have experienced during their period of residence in FEMA-supplied housing. In addition, because of the repeated contacts of the registry with the registrants as it tracks them over time, a registry would be a natural point of contact through which study results can be transmitted to the former occupants of FEMA-supplied housing for whom they may be relevant.

The pilot registry will provide information which will be useful in understanding the issues associated with implementing a registry years after the event among a population that has dispersed over a large geographic region and will contribute to an understanding of the amount of time and effort required to develop such a registry.

Should creating a comprehensive registry prove feasible, this pilot registry will provide a basis for budgeting and further planning. Non-cost-effective strategies for locating potential registry participants will be identified and eliminated from consideration for the comprehensive registry, as will collection of data for which the yield does not justify the effort. Activities for which there may be potential economies of scale (that is, less expensive on a per-person basis for larger numbers of people) will be identified for possible use in a larger comprehensive cohort.

The Katrina-Rita Pilot Registry is a system of records as defined by the Privacy Act, 5 USC 552a (e). The applicable system of records is 09-19-0001, “Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances”. Accordingly, ATSDR will adhere to the Privacy Act provisions concerning the protection of information collected on registrants. This responsibility for protection involves adopting policies and procedures for ATSDR employees involved in the design, development, operation, or maintenance of the registry, and establishing administrative, technical, and physical safeguards to ensure the security of the records.

The Privacy Act established the conditions for disclosure of individually identified data held by Federal agencies, such as the information within the registry database. ATSDR is generally prohibited from disclosing information kept in a registry except with the prior written consent of registrants.

Access to the data will be closely controlled and restricted to authorized users (staff working on the registry only) with valid accounts and passwords only. One of the linked tables within the database will hold all unique person identifiers, demographics, employer, occupation, and relevant occupational history.

The data security policies and procedures will be enforced by the registry’s principal investigator. These policies and procedures will apply to such things as controlling data access

(through restriction to authorized users with valid accounts and passwords) and procedures for deletion or purging of registrants who opt not to participate in the registry after the enrollment phase.

All personnel dealing with registrants' personal identifiable information will be required to sign a confidentiality agreement that will specify penalties for unauthorized use or release of data from the registry.

Procedures will be developed for legitimate uses of registry data that may contain either personal identifiers or data that might be used to track and identify a registrant. Specifically, an application procedure for permission to use registry data will be developed. Researchers, health promotion specialists, and others will have to submit statements specifying the needs related to their specific projects. IRB approval may be required for proposed research projects. In addition, a board to approve requests for data will be formed to consider if data releases are appropriate. There should be adequate representation of persons with all relevant specialized knowledge on this Data Use Board.

Users of registry data must abide by appropriately developed data security and confidentiality agreements. It is expected that approved research projects will supplement registry data with information that the researcher obtains separately (such as updated contact information, medical records, air quality data, and survey information). Registry staff and investigators must agree on the registry staff's ultimate use of such data. Moreover, appropriate metadata regarding such items as the uses of the data agreed to by subjects will have to be maintained on file.
If a researcher wishes to study a sample of registrants, registry staff will select a sample according to agreed-upon criteria.

Data sets with all personal identifiers removed can be made available to the public. Such data will be sufficiently de-identified to prevent re-identification of individual registrants.

The branch responsible for conducting the Katrina-Rita Pilot Registry is the same branch that received OMB approval to collect similar information for one previous and one current registry: The National Exposure Registry (OMB # 0023-0006) from 1989 to 2000 and the Tremolite Asbestos Registry (OMB # 0923-0039) since 2002. This branch has a history of conscientious management of personally identifiable information and the preparation of public use datasets.

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

The initial pilot registry data will be obtained via telephone using CATI. Telephone interviewing was chosen instead of face-to-face or Computer-Assisted Telephone Interviewing (CAPI) because respondents now live in many different areas therefore, CATI is more efficient and cost effective.

CATI software has built-in branching logic, which will skip questions that are not applicable to enhance data accuracy (will avoid confusion as to which symptom the participant is to focus on and which time frame). Computer-assisted interviewing speeds data collection and processing, increases the accuracy of results, reduces respondent-interviewer burden by reducing the time of

the interview, and enhances the researcher's ability to elicit appropriate information through detailed contingent questioning or branching systems. 100% of the data responses will be collected electronically.

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

Information already held by FEMA will be used to initiate the data collection process. The collection of duplicate information will be limited to those data elements necessary to verify the identity of people already in the FEMA datasets. However, not all people eligible for the registry are included in the FEMA datasets.

All pilot registry activities will be carried out with the knowledge and cooperation of the regional offices of other appropriate Federal government agencies (i.e. FEMA) and the appropriate state, county and city health and governmental officials. Therefore, any duplication of effort would have been noted.

Not all of the questionnaire data and specific information necessary to meet the purpose of the pilot registry have been previously collected. The data provided by FEMA is on only a subset of the target population (i.e. the primary householder) and lacks information about health status.

No similar data—that is, health information associated with residential formaldehyde exposures to a general population—exists.

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

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation of 5 CFR 1320.5.

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

A. A copy of the April 13, 2009, Federal Register Notice, Volume 74, Number 69, page 16874-16875 is enclosed (Appendix B). No public comments have been received.

B. Efforts to consult inside and outside the agency in reference to the formation of the pilot registry included multiple meeting of experts from state, local and federal entities along with experts and concerned individuals from the community and local organizations. In addition, a Katrina Registry Panel of experts was also convened.

Purpose: Initial in-person meeting with FEMA to discuss the feasibility of creating the Katrina Pilot Registry	
Location/Date: Washington, DC; May 5, 2008	
Attendees	**Contact Information**
Diane Donley – FEMA Office of the FEMA Chief Counsel	Federal Emergency Management Agency 500 C Street SW Washington, D.C. 20472 202-646-2500 office diane.donley@dhs.gov
Mike Greer – FEMA National Processing Service (via telephone)	Federal Emergency Management Agency 500 C Street SW Washington, D.C. 20472 202-646-2500 office michael.greer@dhs.gov
Mike Lapinski – FEMA Federal Coordinating Office	Federal Emergency Management Agency 500 C Street SW Washington, D.C. 20472 202-646-2500 office michael.lapinski@dhs.gov
Blair McDonald – FEMA Gulf Coast Recovery (via telephone)	Federal Emergency Management Agency 500 C Street SW Washington, D.C. 20472 202-646-2500 office blair.mcdonald@dhs.gov
Mark Millican – FEMA National Processing Service Center	Federal Emergency Management Agency Attn: Mark Millican 500 C St. SW Rm. 615 Washington, DC 20472 In care of: Anissa Stigall 202-212-1071 office mark.millican@dhs.gov
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Tammi Wisko – FEMA Gulf Coast Recovery Office	500 C Street SW Room 820 Gulf Coast Recovery Office Washington DC 20472 BlackBerry 972-358-8945 tammi.wisko@dhs.gov

Purpose: To discuss FEMA's National Emergency Management Information System (NEMIS) database	
Location/Date: Winchester, VA; May 19, 2008	
Attendees	**Contact Information**
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Purpose: To discuss FEMA's Federal Response and Recovery Automated Tracking System (FRRATS) database	
Location/Date: New Orleans, LA; June 19, 2008	
Attendees	**Contact Information**
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Katrina Registry Panel: New Orleans, LA -- November 13, 2008

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Josephine Malilay, PhD, MPH – NCEH	Epidemiologist, Associate Director for Science (Acting) Division of Environmental Hazards and Health Effects National Center for Environmental Health/CDC 4770 Buford Hwy., Mailstop F-58 Atlanta, GA 30341

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Tammi Wisko – FEMA	500 C Street SW Room 820 Gulf Coast Recovery Office Washington DC 20472 BlackBerry 972-358-8945 tammi.wisko@dhs.gov
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A.9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be made to respondents.

A.10. Assurance of Confidentiality Provided to Respondents

IRB Approval

An institutional review board (IRB) clearance is applicable to this data collection effort. The project was initially approved by the CDC IRB on June 29, 2009. The current protocol expiration date is June 25, 2012. An amendment of the protocol to address concerns of OMB was approved on October 21, 2011 (Appendix G).

Privacy Impact Assessment Information

A. This submission has been reviewed and it has been determined that the Privacy Act is applicable. The Katrina-Rita Pilot Registry is a system of records as defined by the Privacy Act, 5 USC 552a (e). The applicable system of records notice (SORN) is 09-19-0001, "Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances".

B. Accordingly, ATSDR will adhere to the Privacy Act provisions concerning the protection of information collected on registrants. This responsibility for protection involves adopting policies and procedures for ATSDR employees involved in the design, development, operation, or maintenance of the registry, and establishing administrative, technical, and physical safeguards to ensure the security of the records.

The system's Security Plan defines the process for handling security incidents. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the

Chief Information Security Officer (OCISO). Reports of suspicious security or adverse related events will be directed to NCEH/ATSDR's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to the US-CERT as appropriate.

The safeguards that are in place to minimize the possibly of unauthorized access, use, or dissemination of the information being collected are detailed in Appendix C.

C. Verbal informed consent will be obtained prior to administering the registry questionnaire. The interviewer will read the informed consent to the registrant or proxy and proceed with the questionnaire only if the respondent consents to participate. Respondents who agree to the interview will be mailed a copy of the consent form within six weeks of the interview.

All information that must be conveyed to the registrant must comply with the Privacy Act, 5 USC 522a (e), which requires informing the participant about the registry's principal purposes, the routine uses which might be made of the information, the authority for establishing a registry, whether disclosure of information by the registrant is mandatory or voluntary, and the effects on the registrant, if any exist, should he or she provide all or any part of the information solicited.

D. Registrants will be informed about the voluntary nature of their responses. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

The Privacy Act established the conditions for disclosure of individually identified data held by Federal agencies, such as the information within the registry database. ATSDR is generally prohibited from disclosing information kept on a registry except with the prior written consent of registrants. However, the Privacy Act specifies certain parties to whom data can be disclosed without the prior written consent of the registrant. The Privacy Act conditions of disclosure that are most likely to be invoked for the registry data include:

1. To ATSDR personnel who maintain the registry;

2. If required by the Freedom of Information Act (personal identifiers removed);

3. For a routine use, where routine use is defined as the use of a record for a purpose which is compatible with the purpose for which it was collected;

4. To a recipient who has provided advance written assurance that the information released will be used solely for statistical research or as a reporting record. ATSDR intends to require that anyone seeking registry data for research purposes submit a study protocol for review to the agency review panel that will in turn make recommendations to ATSDR. The final decision for release of data will rest with ATSDR.

5. To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon disclosure to the requestor, notification is transmitted to the last known address of the individual;

6. To Congress or the Comptroller General;

7. Pursuant to the order of a court of competent jurisdiction.

A.11. Justification of Sensitive Questions

No information will be collected regarding sexual behaviour and attitudes, religious beliefs, or illegal drug use. However, some of the questions can be considered sensitive by at least some of the population. The questions included are necessary for the successful completion of the study. Questions regarding smoking and alcohol consumption and race and ethnicity are included because they may be potential risk factors for the health outcomes of interest.

The last five digits of the registrant's Social Security number (SSN) will be requested. The last five digits of SSN will be necessary to verify that the registrant is the individual about whom FEMA provided data and to maintain contact with registrants to monitor their health status over time. The last five digits of SSN are important for locating registrants for the update interviews. This string serves as a unique identifier of an individual, whereas name and other identifiers can be replicated at a site, changed over time (for example, through marriage or divorce) or used inconsistently (for example, nicknames). The registrant's disclosure of the last five digits of SSN will be voluntary. The registrant will be informed that the disclosure will not affect any benefits that may be received and the information will not be shared with any other government or nongovernment agency.

Registrants will be asked to identify their race and ethnicity. These questions are important when making a determination of potential disease causation. Questions about race and ethnicity help scientists to identify and examine what relationship, if any, these variables may have on health or exposure status. Race and ethnicity are also important in addressing disparities in site selection, environmental justice, and in the data collected and in setting goals and policies for the agency.

A.12. Estimates of Annualized Burden Hour and Costs

Estimated Annualized Burden Hours

The two minute screening questionnaire will be administered to a total of 8,000 respondents. Annualized over a two year period, 4,000 temporary housing unit respondents will be screened each year (Table 12-A).

The 25 minute main questionnaire will be administered to a total of 5,000 respondents. Annualized over a two year period, 2,500 respondents will complete the main questionnaire each year (Table 12-A).

The burden-hour estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of the screening and/or main questionnaire information. The average burden per response was estimated by performing timing tests on the data collection instruments. A total of five test

interviews were completed in-house by registry staff. The total time needed to complete the screening questionnaire ranged from 30 seconds to 2.0 minutes with an average completion time of 1.5 minutes; the timing of the main questions ranged from 20 to 25 minutes with an average completion time of 23 minutes. The total burden hours per form/respondent, was estimated by multiplying the number of respondents by the number of responses per respondent by the burden per response.

The total estimated annualized burden hours are 1,176.

A.12-A ESTIMATED ANNUALIZED BURDEN HOURS					
Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Temporary housing unit occupant	Screening questionnaire	4,000	1	2/60	134
	Main questionnaire	2,500	1	25/60	1,042
Total					**1,176**

Annualized Cost to Respondents

The annualized cost to respondents for the administration of the two-minute screening questionnaire at an hourly rate of $18.51, is $2,480.00 for the temporary housing unit occupants; for administration of the 25 minute main questionnaire at the same hourly rate is $19,287.00 for the temporary housing unit occupants.

The total annualized costs to respondents are $21,767.00.

A.12-B ANNUALIZED COST TO RESPONDENTS[1]			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate[1]**	**Total Burden Costs**
Temporary housing unit occupants	**1,176**	$18.51	**$21,767.00**

[1]According to the U.S. Department of Labor, Bureau of Labor Statistics, the average hourly earnings (for production and non-supervisory workers on private nonfarm payrolls—seasonally adjusted) in the United States as of April 2009 was $18.51.

A.13. Estimates of Other Total Annualized Cost Burden to Respondents or Record keepers

There will be no respondent capital and maintenance costs for the Katrina-Rita Pilot Registry.

A.14. Annualized Cost to the Federal Government

The estimated annualized cost of the Katrina-Rita Pilot Registry to the Federal Government is $1,726,770.50.

A.14 ANNUALIZED (ESTIMATED) COST TO THE FEDERAL GOVERNMENT			
Year	**In-House Cost[1]**	**Contractor Cost[2]**	**Total Cost**
FY12	$332,180	$1,394,590.50	$1,726,770.50
FY13	$332,180	$1,394,590.50	$1,726,770.50
SUBTOTAL	$664,360	$2,789,181.00	$3,453,541.00
		ANNUALIZED TOTAL	**$1,726,770.50**

[1]FTEs, Travel, Meeting Support, CDC Overhead
[2] Contractor Support (Implementation Plan, Training, Outreach, Tracing, Data collection, Contractor Overhead)

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

Project time schedule. OMB approval requested for a two year period.

KATRINA REGISTRY – TIME SCHEDULE	
ACTIVITY	**TIME SCHEDULE**
Interviewer/Supervisor Training	2-3 months after OMB Approval
Letters of Introduction to Potential Eligible THU Occupants	3 month after OMB Approval
Data Collection	4-18 months after OMB Approval
Analysis	19-22 months after OMB Approval
Preliminary Study Results Mailed to Registrants	23-25 months after OMB Approval
Public Availability Session to Answer Questions about Study Results (on-site)	26 months after OMB Approval
Publication of Study Results	27-36 months after OMB Approval

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

Exemption from displaying the OMB expiration date is not being requested. Expiration date will be displayed.

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

There will be no exceptions to the certification.