Supporting Statement A

GuLF Study:

Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers

(NIH/NIEHS)

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TABLE OF CONTENTS

LIST OF ATTACHMENTS & APPENDICES

Attachment 1:	Protocol (FINAL post-IRB review 12/21/2010)	
Attachment 1 SUPP:	Appendix A:	Scientific References
Attachment 1 SUPP:	Appendix B:	Schedule of Procedures/Evaluations
Attachment 1 SUPP:	Appendix C:	Lab Processing Flow Sheet / Template for Specimen Collection
Attachment 2:	Appendix D:	Informed Consent Form
Attachment 3:	Appendix E:	Informed Consent Quick Reference Guide
Attachment 4:	Appendix F:	Lead Letter
Attachment 5:	Appendix G:	Brochure
Attachment 6:	Appendix H:	Frequently Asked Questions
Attachment 7:	Appendix I:	Enrollment Questionnaire
Attachment 8:	Appendix J:	Baseline Questionnaire
Attachment 9:	Appendix K:	Oil Spill Work History Form
Attachment 10:	Appendix L:	Report to Participants (In-Home)
Attachment 11:	Appendix M:	Participant Blood Pressure Report (In-Home)
Attachment 12:	Appendix N:	Report to Participant – Referral Guide — Mobile County AL
Attachment 13:	Appendix O:	Physician Notification Letter
Attachment 14:	Appendix P:	Report to Participant – Normal Values (Mailed Follow-up)
Attachment 15:	Appendix Q:	Report to Participant – Abnormal Values (Mailed Follow-up)
Attachment 16:	DELETED	
Attachment 17:	Appendix R:	Active Follow-up Sub-cohort Pre-visit Appointment Cover Letter
Attachment 18:	Appendix S:	Active Follow-up Sub-cohort Home Visit Instructions
Attachment 19:	Appendix T:	Active Follow-up Sub-cohort Home Visit Instructions for Urine Collection
Attachment 20:	Appendix U:	Available Environmental Monitoring Data
Attachment 21:	Appendix V:	Participant Remuneration Receipt Form
Attachment 22:	Questionnaire Sources	

Materials translated into Spanish and Vietnamese will be submitted to OMB as a non-substantive change at a later date.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The National Institute of Environmental Health Sciences (NIEHS) is responsible for conducting research on chemical, physical, and biological factors in the environment that affect human health. The **GuLF Study**, with its focus on potential short- and long-term health effects associated with oil spill clean-up activities and exposures surrounding the Deepwater Horizon disaster, is supported by the mandate of NIEHS as defined by US Code Title 42, Chapter 6A, Subchapter III, Part A, Section 281, as amended by the Health Research Extension Act of 1985, which is "the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly."

There has been little research on the long-term health effects from oil spills despite the fact that between 1970 and 2009, there were 356 spills of more than 700 tons from oil tankers, with approximately 38 of these spills affecting coastal populations [International Tanker Owners Pollution Federation Limited (ITOPF) 2009, Aguilera, et al. 2010]. The Deepwater Horizon disaster, with its release of approximately 5 million barrels (~680,000 tons) of crude oil into the Gulf of Mexico, is far larger than any of these tanker spills. Given the magnitude of this spill and the scope of the potential exposures – at least 55,000 workers involved in clean-up efforts and countless residents of the affected areas – study of the human health effects of this spill is urgently needed to monitor Gulf clean-up workers and to understand the adverse consequences of oil spills in general.

This research effort is designed to investigate potential short- and long-term health effects among workers engaged in clean-up activities surrounding the Deepwater Horizon oil spill. Given the very limited health effects research conducted to date on oil spill clean-up workers, the GuLF Study is designed not to study a few narrow *a priori* hypotheses, but rather to allow the investigation of a wide range of potential adverse health effects, including physical, psychological, and biological effects. The long-term goal of this study is not only to identify adverse health outcomes related to clean-up activities

among the Deepwater Horizon responders, but also to assemble information that can be used for prevention and intervention of adverse health outcomes in any future similar disasters.

The over-arching hypotheses of this study are:

1. Exposure to constituents of oil, dispersants, and oil-dispersant mixtures, and to spill-related stress by workers engaged in clean-up of the Deepwater Horizon oil spill are associated with adverse health effects, particularly respiratory, neurological, hematologic, and psychological or mental health.
2. There are exposure-response relationships between the above exposures and health effects.
3. Biomarkers of potentially adverse biologic effects are associated with the above exposures.

A.2. Purpose and Use of the Information

Information collected in this study will be used to further scientific understanding of the short- and long-term health effects associated with oil spill clean-up activities and exposures to a range of known and suspected toxins in crude oil, burning oil, and dispersants, to excessive heat, and possibly to stress due to widespread economic and lifestyle disruption. Epidemiologists and biostatisticians at NIEHS and their collaborators at other institutions will be responsible for testing the hypotheses of interest and disseminating results through the scientific literature. Results will be published in medical and epidemiologic journals as well as basic science journals when appropriate. Results will be presented at scientific meetings and to other interested groups. Given the very limited health effects research conducted to date on oil spill clean-up workers, the GuLF Study is designed not to study a few narrow *a priori* hypotheses, but rather to allow the investigation of a wide range of potential adverse health effects, including physical, psychological, and biological effects. The long-term goal of this study is not only to identify adverse health outcomes related to clean-up activities among the Deepwater Horizon responders, but also to assemble information that can be used for prevention and intervention of adverse health outcomes in any future similar disasters.

The purpose of the GuLF Study is to investigate potential short- and long-term health effects associated with oil spill clean-up activities and exposures surrounding the Deepwater Horizon disaster; and to create a resource for additional collaborative research on focused hypotheses or subgroups. Over 55,000 persons participating in oil-spill clean-up activities have been exposed to a range of known and suspected toxins in crude oil, burning oil, and dispersants, to excessive heat, and possibly to stress due to widespread economic and lifestyle disruption. The purposes for collecting data on stress exposures of oil-spill workers is to explore how stress may affect health outcomes and biomarkers for health outcomes. Additionally, we have an opportunity to contribute information to the topic of mental health aspects of the oil spill environmental disaster although we recognize that because this is a secondary aim of the study, we have not designed a definitive study of the impact of the spill on mental health.

Exposures range from negligible to potentially significant, however, potential long-term human health consequences are largely unknown due to insufficient research in this area. A cohort of 55,000 participants will be recruited from across job/exposure groups of primarily English, Spanish, or Vietnamese speaking adults (accommodations for other languages developed as appropriate) who performed oil-spill clean-up-related work ("exposed") and similar persons who did not ("unexposed" controls), and followed in either an *Active Follow-up Sub-Cohort* (N~24,000) or a *Passive Follow-up Sub-Cohort* (N~31,000). Exposures will be estimated using detailed job-exposure matrices developed from data from monitoring performed by different agencies and organizations during the crisis, information obtained by interview, and the available scientific literature. We will investigate acute health effects among all cohort members via self-report from the enrollment interview, and via clinical measures and biological samples from Active Follow-up Cohort members only. All cohort members will be followed for development of a range of health outcomes through record linkage (e.g., cancer, mortality) and possibly through linkage with routinely collected health surveillance data (collected by health departments and the CDC) or with electronic medical records. Recruitment of subjects should begin in early 2011, with telephone interviews and the baseline home visits conducted within 24 months.

[A *Biomedical Surveillance Sub-cohort* (N~5,000) will be nested within the Active Follow-up Cohort, and will participate in clinical assessment after an initial home visit, including pulmonary function testing, neurological testing, and collection of additional biological and environmental samples. Periodic follow-up of the Biomedical Surveillance Sub-cohort will include clinical evaluations (e.g., spirometry, neurological testing) and collection and analysis of additional biospecimens (e.g., immunologic parameters, liver function, renal function, DNA damage). Clinical protocols for the Biomedical Surveillance Sub-cohort will be developed and carried out in collaboration with local university partners identified through a request for proposals (RFP). **Clinical Exemption will be sought separately for the Biomedical Surveillance sub-cohort.]**

The type and amount of information we will collect at baseline and at subsequent intervals fulfill many scientific and clinical needs. Many of the exposures of interest, including endogenous hormone levels, micronutrients, and some environmental exposures, are measured most accurately in biological samples collected before the onset of disease or treatment and their associated symptoms and biological and lifestyle changes. The cohort design allows us to collect data on exposures, including biological exposure measures, diet and lifestyle, *before* the onset of disease. Instruments for baseline data collection activities are appended (Appendices I & J).

Brief self-administered forms will be used annually to update changes in contact information. Biennial updates will record changes in health, lifestyle, occupational and environmental exposures within the Active Follow-up sub-group (~24,000 participants).

Clinical exemption will be sought separately for more extensive testing and long-term follow-up of a small group (5000 of the Active sub-group) who will comprise a Biomedical Surveillance Sub-cohort.

A.3. Use of Information Technology and Burden Reduction

Computer Assisted Telephone Interview, or CATI, a special data collection approach designed to reduce the burden to respondents and improve quality control, will be used for the initial eligibility

questionnaire (administered to all respondents), enrollment questionnaire (administered to all enrolled participants), and biennial questionnaire (administered to Active sub-group). This technology allows several advantages over the traditional pencil and paper method. First, it requires less paper. Second, there is no "mail wait" to get the information from participants. Also, the telephone interview requires little reading for the participants, an important factor when a segment of the population has low educational level or poor eyesight. Last, data extraction is more efficient with the CATI system as compared to the keyed entry method because skip patterns are automated and response inconsistencies can be queried at the time of the interview. Web-based questionnaire options will be explored as needed to increase response rates.

Name, address, SSN, date of birth, and medical information will be collected. Personal identifiers will be stored encrypted and separately from all other data. PII will be used to address Update materials. A Privacy Impact Assessment will be completed for the information management system.

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

The information we will collect is not available from other sources. There has been little research of the long-term health effects from oil spills. The few studies that have evaluated the human health consequences of oil spills have primarily focused on acute physical effects and psychological sequelae. These studies have examined the *Exxon Valdez* (Alaska, 1989), *Braer* (Shetland Islands, UK, 1993), *Sea Empress* (Wales, UK, 1996), *Nakhodka* (Oki Islands, Japan, 1997), *Erika* (Brittany, France, 1999), *Prestige* (Galicia, Spain, 2002) and *Tasman Spirit* (Karachi, Pakistan, 2003) oil tanker spills. Most of these studies were cross-sectional and limited in breadth. Appendix A contains the full list of references reviewed. We are unaware of any duplication of this project with any other project now underway at other organizations.

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

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

Annual updates take ~15 minutes, and biennial questionnaires will be ~30 minutes. Annual contact is necessary to preserve reliability and completeness and will facilitate maintenance of the cohort and tracing of those who are lost to follow-up. Biennial contact cannot be done less frequently because the analysis relies on exposure and health-status changes over time, and ascertaining cases close to the time of diagnosis is important. A participant's recall diminishes greatly with time, and death may occur.

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

There are no special circumstances relating to the guidelines of 5 CFR 1320.5 and the project fully complies.

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

A 60-Day Federal Register Notice was published 7 October 2010 on pages 62132-3. One public comment suggested that since BP was supposed to pay for medical costs associated with the spill, that service records billed to BP should contain all information necessary for the study, and thus no survey is needed at the public's expense.

Agency Response: BP covered the medical costs of workers who required care while they are engaged in clean-up efforts. There are no provisions for BP coverage for short-term medical care needed when workers have completed their service. Thus focusing only on medical records will potentially seriously underestimate the extent of illness linked to the oil spill and will not assess any latency or persistence of effects. There is no systematic assessment of health care needs or disease incidence. Focusing only on those who sought care at the time they were working can lead to serious bias – either underestimating illnesses because workers may have been afraid of retribution or job loss if they reported a problem, or over-reporting because clinics provided free care during work and did not require the symptoms or conditions to be oil-spill related. BP is contributing to the cost of this research. They made $10M available to NIH via a gift for health research. About $6M will go toward this study. The door is

still open to other gifts from BP in future years. The DHHS is carefully tracking costs associated with health care research including the GuLF Study so that they will be in a position to seek reimbursement from BP from any funds made available in the future either voluntarily or as a result of governmental or legal actions.

The GuLF Study is an NIEHS intramural study designed to allow for trans-NIH and extramural collaboration. A GuLF Study Scientific Advisory Board will be established as a subcommittee of the NIEHS Board of Scientific Counselors to provide additional oversight. This Board will include one or more members of the Board of Scientific Counselors, scientific experts, community representatives and Federal agency representatives. A separate Community Advisory Board, consisting of representatives of key study populations in the affected states, also will be established. The Institute of Medicine has reviewed the initial study plans, and periodically will review progress and findings. An Interagency working group made up of representatives from each Federal Agency involved in some aspect of the oil spill response met in August 2010, and is expected to meet regularly to provide study oversight. In addition we have established contacts with community organizations, representative worker organizations, advocacy groups, and state and local governments to identify the primary health issues of concern locally and to discuss study implementation issues across the five state area. Further, we will identify Community Outreach Coordinators to organize and implement outreach activities in each of the Gulf States. In addition to the continuing efforts with public health and community group representatives, we have been conducting and will continue webinars, dockside chats, and phone and in-person briefings with key stakeholder groups and health departments. **These activities are itemized in detail in section 2.4 of the attached study protocol (Attachment 1).**

Potential participants will be identified via tremendous cooperation among organizations and agencies providing access to relevant worker databases: the NIOSH Voluntary Worker Roster, Petroleum Education Council (PEC; access provided by BP), and we will seek a similar agreement to obtain other known lists of individuals involved in clean-up activities (e.g., parish responder lists, BP contractor payroll, and lists of Federal workers and contractors deployed to, or otherwise engaged in, on-site clean-

up activities in, the Gulf, including the Coast Guard, OSHA, NIOSH, NOAA, EPA, Fish and Wildlife Service, US Geologic Survey, National Guard, etc.). We will work closely with academic and federal partners such as OSHA and NIOSH to convene a panel of experts to systematically work through exposure assessment issues and develop a scientifically sound method for assigning exposures to the study participants.

Advisory to the study principal and lead investigators in regular monthly meetings are the study team, all of whom will contribute to study oversight, and have the experience necessary to provide this oversight:

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

In addition to non-monetary incentives such as refrigerator magnets, chip clips, stationery, and pens, participants in the Active Follow-up Sub-cohort will receive remuneration for their time and effort in the form of pre-paid gift cards or phone cards. A monetary incentive will be offered to participants at the baseline home visit. Gift cards with a $50 value will be given to participants immediately upon completion. Participants will be asked to acknowledge their receipt of their gift card by completing a form (Appendix V), which will be returned by the HVA to the study office with other study materials. If the Participant also provided an additional Quality Control Sample for the study, they will be given an additional $10 gift card, receipt of which will also be acknowledged on this form.

Study Event	Active Follow-up Sub-cohort	Passively followed members of full cohort
Baseline Home Visit	$50	N/A
Duplicate Biospecimen Collection at Baseline Home Visit*	$10*	
Total in first year	$50 or $60*	N/A

Only for the n=300 randomly selected individuals participating in the QA/QC biospecimen collection.

A separate remuneration schedule will be developed for the more comprehensive activities of the Biomedical Surveillance Sub-cohort (separate clinical exemption will be sought for this sub-group).

Additional incentives for recruitment and participation such as drawings for prizes such as sporting event tickets, and recruitment events featuring food bank distributions, community health fairs, or other community events will be explored based on feedback from the community and assessment during the run-in phase of the study. We will confer with the appropriate scientific, community, institutional and ethical advisory boards to determine the appropriateness of these additional incentives.

A.10. Assurance of Confidentiality Provided to Respondents

Procedures to protect the confidentiality of the study population and the data collected include the following:

- The data constitute a system of records under the Privacy Act System (#09-25-0134; Federal Register Notice of System of Recordsm published December 29, 1993**.**
- All study personnel will be required to complete on-line training in the protection of human research subjects. The investigators and study staff will strictly maintain participant confidentiality to the extent permitted by law. This confidentiality will be extended to cover questionnaire data, clinical assessments, biological samples, and environmental samples.
- All study-related information will be stored securely. All study datasets, laboratory specimens, and administrative forms will be identified by a coded number in order to maintain participant confidentiality. All records that contain names or other personal identifiers will be stored

separately from study records identified by code number. All databases will be secured behind firewalls with password-protected access systems. Worksheets, lists, logbooks, appointment books, and any other documents that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access.

- A Federal Certificate of Confidentiality will be obtained for this study. The Certificate will help protect against disclosures of study-related information by Federal, State or local civil, criminal, administrative, legislative, or other proceedings, although it will not guarantee that data cannot be released. Participants will be informed about the certificate during the informed consent process.
- The proposal was initially reviewed by the Institutional Review Board of NIEHS on 11/09/2010 and approved after revisions in response to stipulations.
- Informed consent forms spells out the steps taken to protect privacy. Similar information is provided verbally at the time of enrollment.
- The GuLF Study will follow NIH policies on data sharing. We will be required to send de-identified datasets to an approved NIH repository such as DbGaP (where data from GWAS studies and studies like the Framingham Study are now stored) — http://www.ncbi.nlm.nih.gov/gap. Currently, investigators are required to sign confidentiality agreements and agree to use the data just for the purposes specified in their request. They must agree to not attempt to contact any individuals in a study. Security procedures and requirements can be found at — http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?document_name=dbgap_2b_security_procedures.pdf. An NIH committee reviews the request and assesses the qualifications of the requestor. The goal is to provide data to as many qualified individuals as possible while attempting to protect participants from disclosure of identity, and to allow for maximal and rapid use of a government funded resource. Open access to de-identified data is being driven by the NIH director. Traditional identifying information will not be shared. This includes name and address, complete date of birth, social security numbers, and GPS coordinates.

- The biological and environmental samples collected will be stored indefinitely in a secure building for future testing and may be disposed of at any time at the Investigator's discretion. Specimens are labeled with ID number only. Specimens shared with outside researchers— only with the approval of the IRB— will be assigned a new identification number; the code linking the new and the old identification number will be known only to the NIEHS contractor responsible for the GuLF Study field work. This new identification number will not be linked to any identifying information.
- Participants may elect to leave the study at any time. As explained in the Informed Consent documents, no new data will be collected from individuals who elect to drop out, but the data already provided will continue to be used in some analyses unless a written request to destroy data and specimens is received. Screening data on respondents who are found to be ineligible will not be retained.

A.11. Justification for Sensitive Questions

Exposures and health outcomes experienced by oil spill clean-up workers are likely to be complex. Sensitive questions such as personal and family history of illness and detailed medical history are critical to study hypotheses. For example, alcohol use, while part of a standard medical history, may be perceived by some to be too personal, but it must be accounted for in analyses exploring health outcomes. Some questions, such as about mental health or social support, may be perceived as especially sensitive, but the study seeks to understand effects that stress exposures during the clean-up work may have on health. The baseline questionnaire, administered to the Active Follow-up group, elicits information not included in the enrollment questionnaire, including more detailed information on residential and occupational history, personal and family medical history, alcohol and tobacco consumption, mental health and anxiety, and recent eating and drinking and use of medications.

Information is collected directly from participants. Participation is voluntary, and respondents can withdraw from the study at any time. Participants may refuse to answer specific individual questions,

including those they find to be too sensitive or personal. All information is kept confidential to the extent provided by law. At no time will any individualized genetic results be given out. A Certificate of Confidentiality will be sought for this study.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

Frequency of Response: Participation will include one enrollment telephone interview (0.65 hr); collection of biological and environmental samples, basic clinical measurements, and GPS coordinates (2.75 hr) from the Active Follow-up Cohort only; annual contact information update (0.25; Active and Passive) or biennial follow-up telephone or web interviews (0.5 hr; Active only) for 10 years or more. We also anticipate shorter eligibility screening times (~13.5 minutes) for ~31,000 ineligible respondents. *Affected Public:* Individuals or households. *Type of Respondents:* Workers involved in Deepwater Horizon disaster clean-up, and similar individuals not involved in clean-up effort. The annual reporting burden is as follows: *Estimated Number of Respondents:* Active Follow-up Cohort (N~24,000) and Passive Follow-up Cohort (N~31,000). *Estimated Number of Responses per Respondent:* See table below. *Average Burden Hours Per Response:* 0.60 hour; and *Estimated Total Burden Hours Requested:* 155,975 (over 3 years). The average annual burden hours requested is 51,992. The annualized cost to respondents is estimated at $12 (assuming $20 hourly wage X 0.60 hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ACTIVITY (3-yrs)	Estimated number of respondents	Estimated responses per respondent	Burden hours per response	Total Burden hours per respondent	Estimated total burden hours
Ineligible respondents	31,000	1	0.225	0.225	6,975
Enrollment interview (All)	55,000	1	0.65	0.65	35,750
Home Visit (Active)	24,000	1	2.75	2.75	66,000
Annual Contact Info Update (Passive)	31,000	3	0.25	0.75	23,250
Annual Contact Info Update (Active)	24,000	2	0.25	0.50	12,000
Biennial interview (Active)	24,000	1	0.50	0.50	12,000
Passive Cohort Total responses & hrs		4		1.40	
Active Cohort Total responses & hrs		5		4.40	
TOTAL responses & avg hrs per response		9		0.60	**155,975**
Average per year					51,992

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

There is no *other* total annual cost burden to respondents or recordkeepers.

A.14. Annualized Cost to the Federal Government

The estimated cost of contracting for the GuLF Study is $34million — this averages to $6.8million annually. The first two years are shown below:

Total Enrollment Years	**Year 1**	**Year 2**	
Task 1 - Project Leadership & Spt	**$885,976**	**$638,235**	**$1,524,211**
Task 2 - Community Outreach	**$424,711**	**$193,374**	**$618,085**
Task 3 - Develop Master Recruitment Database	**$113,223**	**$0**	**$113,223**
Task 4 - Data Management	**$1,150,274**	**$789,327**	**$1,939,602**
Task 5 - Recruitment & Enrollment	**$2,077,185**	**$0**	**$2,077,185**
SRA Labor (primarily for telephone interviewing)	$1,822,279	$0	$1,822,279
Participant Reimbursement	$0	$0	$0
Long Distance Charges	$92,029	$0	$92,029
Credit Bureau Searches	$92,862	$0	$92,862
Postage	$58,198	$0	$58,198
Printing	$11,798	$0	$11,798
Training Supplies	$1,466	$0	$1,466
Task 6 - Home Visits	**$2,629,442**	**$9,449,419**	**$12,078,861**
Labor			
Home Visit Labor	$1,077,463	$4,183,227	$5,260,690
Central Processing Lab Labor	$257,122	$998,270	$1,255,392
Regional Field Managers Labor	$214,772	$501,134	$715,906
Spirometry Trainer	$26,120	$101,412	$127,532
SRA Labor	$94,882	$95,349	$190,232
Home Visit Kit Preparation	$18,475	$71,728	$90,202
Equipment & Supplies			
Biospecimen & Enviro Sample Collection Supplies	$241,146	$936,246	$1,177,393
Home Visit Agent Durable Equipment	$89,377	$289,169	$378,546
HVA Expendable Supplies	$14,395	$46,573	$60,968
Laptops/cell phones for Regional Managers	$9,215	$26,131	$35,347
Other			
Incentives & Reimbursements	$236,535	$918,343	$1,154,878
Home Visit Travel	$218,094	$846,746	$1,064,840
Shipping	$82,767	$325,016	$407,783
Training costs/training travel	$35,052	$64,930	$99,981
Printing	$11,070	$42,981	$54,051
Postage for Mailing Results	$2,974	$11,545	$14,518
Printer/fax machines (for each Regional Manager)	$701	$2,721	$3,422
Task 7 - Lab Sample Processing, Shipping & Storage	**$490,674**	**$1,604,482**	**$2,095,156**
SRA Labor	$103,102	$103,621	$206,724
CPL Biospecimen Processing & Storage Supplies	$387,915	$1,506,072	$1,893,986
Task 8 - Statistical Support	**$50,596**	**$101,438**	**$152,033**
Grand Total of All Tasks	***$7,822,081***	***$12,776,275***	***$20,598,355***

- $21M is estimated for completing screening of all workers and home visits with the Active Follow-up sub-cohort, based on similar activities in other studies with home visits.
- Cost of 2 follow-up interviews (n=24k), 4 annual contact information updates and newsletters (n= 55,000) and 3 years of NDI and cancer registry linkages, data cleaning, documentation, posting, and analysis is estimated at $6M.
- 2 home visits for the Biomedical Surveillance sub-cohort — $5.5 M.
- Industrial Hygiene/exposure reconstruction $500,000 (includes hourly rates for consultants at 3 levels and travel time to Gulf for worker focus groups, site visit(s), and expert panel meeting(s)
- $1M Intramural costs for years 2-5 — contracts and Gulf travel for consultants, Staff Scientist, federal salary support, other support contract costs

A.15. Explanation for Program Changes or Adjustments

This is a new collection. There are no changes.

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

	Q3 2010	Q4 2010	Q1 2011	Q2	Q3	Q4	Q1 2012	Q2	Q3	Q4	Q1 2013	Q2	Q3	Q4	Q1 2014	Q2	Q3	Q4	Q1 2015	Q2	Q3	Q4
Study Design and Scientific Input	•	•																				
Community Outreach	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Study Start		•																				
Subject Recruitment		•	•	•	•	•	•	•														
Enrollment Questionnaires		•	•	•	•	•	•	•														
Home Visits		•	•	•	•	•	•	•														
Biomedical Surveillance Sub-Cohort Follow-up						•	•	•	•													
Newsletter Follow-up						•	•	•	•													
Year 2 Follow-up										•	•	•	•									
Newsletter Follow-up														•	•	•	•					
Year 4 Follow-up																		•	•	•	•	

Given the very limited health effects research conducted to date on oil spill clean-up workers, the GuLF Study is designed not around a particular *a priori* hypothesis, but rather to allow investigation of a wide range of potential adverse health effects, including physical, psychological, and biological effects. These include both short-term and long-term effects focused on, but not limited to, the following areas: respiratory, cardiovascular, hematologic, dermatologic, neurologic, cancer, reproductive, mental health, immunologic, hepatic, and renal. A priori outcomes of greatest interest based on previous studies are respiratory effects, neurological dysfunction, and genotoxic and hematologic effects.

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

None

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

There are no exceptions to certification for this submission.