Supporting Statement A

GuLF STUDY:

Gulf Long-Term Follow-Up Study

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This is being submitted as a Revision.
Yellow highlights indicate changes since the last submission in 2010.

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36. IRB Approval—Biomedical Exam Reimbursement 07-19-2013

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 . 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 related to 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 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.

Recruitment and baseline data collection began in late February, 2011 and concluded in May, 2013, resulting in the enrollment of 32,762 participants into the cohort. Of the 32,762 enrolled into the Full Cohort, 20,000 have been selected to participate in telephone follow-up as part of the Active Follow-up Sub-cohort, made up of those who completed a Baseline Home Visit Exam and a random sample of those who did not. A total of 6,000 cohort members from the Gulf States have been selected to participate in the Biomedical Surveillance Sub-cohort Clinical Exam. The purpose of this request is: 1) to seek reinstatement of our current OMB clearance to allow us to continue collecting updated contact information for the Full Cohort and conducting biennial follow-up telephone interviews with the Active Follow-up Sub-cohort; and 2) to seek approval for a revision to allow for additional data collection. Specifically, we seek approval for adding a mental health module to the telephone interview. The mental health module will be repeated several times over a two-year period with a subset of the Active Follow-up Sub-cohort. We also seek approval for the data collection plan for the clinical examination for the Biomedical Surveillance Sub-cohort that was described in our initial application. These follow-up activities are essential to retaining the cohort and collecting data to address the main study hypotheses about the long-term health impacts of the oil spill.

Previously approved follow-up activities began as the baseline enrollment phase ended in May of 2013. Between January, 2012 and September, 2013, we carried out a mail and email campaign to collect updated contact information from participants in the Full Cohort (see Attachments 8 and 9). The materials sent to participants encouraged them to confirm or update their contact information via a secure

application on the study website or by calling the study hotline. We plan to continue using these methods to request updates annually.

The first follow-up telephone interview began in March 2013, approximately 2 years after the start of enrollment, and is currently underway. The follow-up interview questionnaire was based largely on questions that were included in the baseline telephone enrollment questionnaire, and we intend to administer the same follow-up questionnaire at each biennial interview (see Attachment 4 for a table showing carry-over of questions from the baseline questionnaire to the follow-up questionnaire). We will attempt to complete follow-up interviews with about 20,000 participants in the Active Surveillance Follow-up Sub-cohort. We expect 16,000 (~80%) to complete the first follow-up telephone interview, and 15,000 (~75%) to complete the second follow-up telephone interview. We will target all participants for each follow-up interview, so participants who do not complete the first follow-up interview are not precluded from completing the second one. Participation rates may be lower if efforts to trace hard-to-reach participants are not as successful as we anticipate or rates could be higher if tracing and outreach efforts work better than expected.

The supplemental mental health module (Attachment 6) will be used to assess mental health trajectories among those affected by the oil spill and utilization of mental health services in the Gulf region. The module was developed in collaboration with Sharon Larsen and other senior staff from the Substance Abuse and Mental Health Services Administration under an Interagency Agreement. We plan to invite ~4,600 participants in the Active Follow-up Sub-cohort who completed the baseline home visit to complete the module four times over a two-year period. In order to enrich the sample for participants initially showing signs of mental distress, we will select all participants with one or more "poor" scores on mental health scales (N~3600) at the baseline home visit and a random sample (N~1,000) of the remaining Active Follow-up Sub-cohort. This sample size accounts for anticipated difficulties contacting participants and expected attrition over time and will allow us to complete four prospective assessments with at least 2,000 participants. The module will be administered at the time of the first follow-up telephone interview, as a stand-alone administration at 6 and 12 months later, and as part of the second

follow-up interview approximately 24 months later. The brief mental health module includes standardized scales that were used in the baseline telephone interview and home exams as well as additional questions and scales designed to enhance our assessment of disaster-related stress and resilience.

We plan to invite ~ 6,000 participants in the Biomedical Surveillance Sub-cohort to take part in a comprehensive research-based clinical examination between February, 2014 and July, 2015. The clinical examination provides an opportunity to carry out more comprehensive clinical testing and mental health evaluations than could be completed during the baseline home visit. We anticipate that 4,000 cohort members will complete the examination (67% response rate). The clinical examinations will be performed under the direction of health professionals from the University of South Alabama and the Louisiana State University Health Sciences Center. The four-hour clinical examinations will allow for a much more in-depth assessment of pulmonary, neurological, and mental health outcomes that may be associated with the Deepwater Horizon oil spill exposures and experiences. Specifically, the examinations are designed to more thoroughly address the following questions:

1. Are worker exposures to constituents of oil, dispersants, and oil & dispersant mixtures associated with adverse effects on respiratory and neurological function?
2. Are worker exposures or experiences related to the DWH oil spill resulting in measurable and sustained psychological or mental health related outcomes?
3. Are there biomarkers of potentially adverse biologic effects associated with oil spill-related 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 to stress due to 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 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 associated with the Deepwater Horizon disaster; and to create a resource for additional collaborative research on focused hypotheses or subgroups. Over 100,000 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 to stress due to widespread economic and lifestyle disruption. The purpose of collecting data on stress-related factors 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. The proposed new data collection enhances our efforts in this area.

Exposures range from negligible to potentially significant; however, potential long-term human health consequences are largely unknown due to insufficient research in this area. Our cohort was recruited from across job/exposure groups of primarily English, Spanish, or Vietnamese speaking adults who performed oil-spill clean-up-related work ("exposed") and similar persons who did not ("unexposed" controls). Exposures to specific chemicals are being estimated using detailed job-exposure matrices developed from data from exposure monitoring performed by different agencies and organizations during the crisis, information obtained by interview, and the available scientific literature. We are investigating

acute health effects among all cohort members via structured self-report during the enrollment interview, and via clinical measures and biological samples from Active Follow-up Cohort members. 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. (Instruments and supporting materials for baseline data collection activities are not included in this submission, since baseline data collection has been completed.)

The type and amount of information we collected at baseline and will collect at subsequent intervals fulfill many scientific and clinical needs. Many of the exposures and modifying factors 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, lifestyle and occupational factors, *before* the onset of disease.

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, was used for the initial eligibility questionnaire (administered to all respondents) and enrollment questionnaire (administered to all enrolled participants), and will be used for the biennial follow-up questionnaire (administered to the Active Follow-up Sub-cohort). 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.

Follow-up data collection activities were initiated as baseline enrollment and data collection efforts were winding down. We completed the first annual request for contact information updates (via mailing participants a request to visit the GuLF STUDY web site or call the study hotline to update their contact information) prior to initiating the first follow-up telephone interview in May, 2013. This request for updates and others in the future will help us maintain relationships with participants and mitigate loss to follow-up over time. The first follow-up telephone interview is currently underway with the Active Follow-up Sub-cohort (N~20,000) to characterize changes in health, lifestyle, and other experiences since baseline. The information collected in the biennial follow-up telephone interviews will help us better understand persistent and late health effects of the oil spill. The proposed mental health add-on module will allow us to prospectively follow a subgroup of participants to more thoroughly characterize ongoing mental health issues, utilization of mental health services, and relationships between mental and physical health. The clinical examinations that are currently planned for February 2013 will allow us to complete more detailed neurobehavioral evaluations, pulmonary function testing, and mental health questionnaires than we could in the home setting, and it will build on reports from other smaller, shorter-term studies that have suggested the potential for these adverse outcomes among clean-up workers.

Data collection for the biennial follow-up of the Active Follow-up Sub-cohort is carried out using computer assisted telephone interviewing. Prior to the interview, participants are sent an invitation letter (Attachment 2) encouraging them to complete the follow-up questionnaire. The follow-up interview (Attachment 3) takes approximately 30 minutes to complete. The mental health questionnaire (Attachment 6) will be administered at the time of the first follow-up questionnaire, and again at 6, 12, and 24 months later. Participants selected for this effort have been held for later calling while this instrument was being developed and reviewed to minimize the need for second calls to participants who would otherwise have already completed their follow-up telephone interview. The mental health questionnaire module takes approximately 15 minutes to administer. We will request updated contact information from all participants annually, either as a stand-alone effort or as part of the follow-up telephone interviews. During stand-alone efforts, participants will receive emails and/or letters

encouraging them to update their contact information using a secure section of the study website or by contacting the study hotline.

Participants in the Biomedical Surveillance sub-cohort will receive an invitation letter (Attachment 10) and will be contact by phone (Attachment 11) several days later to schedule their visit. Once the visit is scheduled, a confirmation letter (Attachment 12) will be sent about 4 to 5 days in advance of the scheduled visit along with preparatory materials, which include a one-page summary of key information in the consent form (Attachment 13), a list of answers to frequently asked questions (Attachment 14), pre-visit instructions (Attachment 15) and directions to the clinical site. The components of the clinical examination are shown in Table 1. The examination is expected to take about 4.0 hours to complete, and participants will be compensated for their time and travel costs. Data collected during the clinical examination will be recorded in the Clinic Exam Questionnaire (Attachment 27) and the Mental Health Questionnaire (Attachment 28) modules of the electronic data collection system. At the end of the examination, participants will be provided a report (Attachments 17-22) of clinical findings.

Table 1. Clinical Visit Overview

Activity	**Time**	**Notes**
Visit Scheduling	N/A	• Initiation mailing • Scheduling calls • Pre-visit procedural eligibility assessment • Confirmation letter and visit preparation materials mailed
Arrival and Greeting	5 min.	• Greetings and introduction to study staff
Informed Consent	10 min.	• Review and obtain informed consent
Anthropometric Measures	10 min.	• Height, Weight, Waist and Hip Circumference
Physiological Measures	5 min.	• Resting Blood Pressure and Heart Rate

Activity	Time	Notes
Biological Specimen Collection	15 min.	• Hair, Blood, Toenail Clippings*, Saliva, and Urine Collection • Finger stick for Hemoglobin A1c • Provide training and materials for serial saliva samples (for a subset)
Clinic Visit Questionnaire	15 min.	• Clinic Visit Questionnaire
Neurobehavioral Tests	50 min.	• Symbol-Digit • Finger Tapping • Simple Reaction Test • Continuous Performance • Trailmaking • Digit Span • Match to Sample • Progressive Ratio
Peripheral Nervous System Tests	25 min.	• Standing Balance • Standing Steadiness • Vibrotactile Threshold Testing • Visual Acuity • Visual Contrast Sensitivity • Handgrip Strength • Walking Speed • Long Distance Walk (400m)
eNO and EBC	15 min.	• Exhaled Nitric Oxide • Exhaled Breath Condensate (for a subset)
Pulmonary Function Testing	30 min.	• Pre/post-bronchodilator spirometry
Mental Health Assessment	40 min.	• Questionnaire administration and referral, if needed
Biological Specimen Processing	N/A	• Process, aliquot, label, and temporarily store specimens

Activity	Time	Notes
Report of Findings	10 min.	• Handout provided with clinically relevant findings and recommendations for seeking additional care, if indicated • Referral provided, if needed
Check-Out and Remuneration	5 min.	• Remuneration
Clean-up and Specimen Shipping	N/A	• Samples packed and shipped in batches by clinical staff
Total time	**~4 hrs.**	

A Privacy Impact Assessment (PIA) was approved by the Department of Health and Human Services in 2012. A PIA is designed to identify and protect employee and public citizens' personally identifiable information (PII) and it ensures that the government has considered necessary safeguards for the PII passing through or being collected, maintained, or disseminated in the GuLF STUDY IT systems. The name of the IT system for this project is the "NIH NIEHS GuLF Worker Study System (GWSS)" (Attachment 30).

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 on 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. The Protocol (Attachment 1) contains the full list of references reviewed. Several smaller scale studies have or are focusing on mental health or resiliency among specific subsets of the population affected by the Deepwater Horizon oil spill disaster. None of these studies targets clean-up workers whose exposures were different. The NIEHS in partnership with several other NIH agencies has funded oil-spill related consortium research grants to

Universities and community partners. None of these studies is directed at workers and none is as large or comprehensive in nature as the GuLF STUDY. The studies largely investigate mental health and resiliency, seafood consumption and toxicology, and adverse effects on women, children, and pregnancies. 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, biennial questionnaires will take ~30 minutes, and the supplemental mental health module will take ~15 minutes at each administration. The clinical examination will take about 4 hours to complete. 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 November 7, 2013 on pages 66945-66946.

No comments were received.

Efforts to Consult Outside the Agency:

The GuLF STUDY is an NIEHS intramural study designed to allow for trans-NIH and extramural collaboration. A GuLF STUDY Scientific Advisory Board was established as a subcommittee of the NIEHS Board of Scientific Counselors to provide additional oversight. This Board includes one or more members of the Board of Scientific Counselors, other 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 was established. The Institute of Medicine convened a panel to review the initial study plans. Prior to obtaining approval by the NIEHS Institutional Review Board, the study also underwent blinded external peer review coordinated by the then Acting Clinical Director, NIEHS. 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 provided input and review during study development and was invited to provide written peer-review of the initial study proposal. 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. In addition to the continuing efforts with public health and community group representatives, we have conducted 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).

We have worked 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 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

The remuneration provided during the follow-up phase is consistent with what was provided at baseline. The remuneration plan reflects the feedback received from scientific, community, institutional and ethical advisory boards – all of which strongly advised that some remuneration be provided. We also took into account the norms for disaster-related and other research being conducted in the affected communities.

As with participants who completed the home visit during the baseline phase, participants who complete the Follow-up Telephone Questionnaire will be entered into a drawing for a $500 gift card. One drawing will be held after every 500th participant completes the interview. The odds of winning are about 1 in 500. Early responders who complete the Follow-up Telephone Questionnaire within three weeks of the release of their invitational mailing will be entered in an additional drawing for a $500 gift card. One drawing will be held after every 500th early responder completes the interview. The odds of winning are about 1 in 500. There is no cost associated with entering the drawings or accepting the gift cards.

Participants selected to complete the mental health add-on module will receive a $10 gift card for their additional time and effort following each interview ($10 per interview; $40 total). This amount is consistent with remuneration offered during the baseline phase for other add-on modules, such as the Ammonia Release Survey Module ($20) and Quality Assurance/Quality Control biospecimen collection during the baseline home visit ($10).

The Biomedical Surveillance Sub-cohort will be an intensively evaluated subgroup nested within the Active Follow-up Sub-cohort. It was sampled from across the categories of job/potential exposure and from controls, with oversampling of workers with the highest potential exposures. This sub-cohort will undergo the same follow-up procedures as the rest of the Active Follow-up Sub-cohort, but will additionally participate in multiple follow-up visits involving health assessments, neurological testing, and collection of repeat biological and environmental samples.

During the baseline phase, participants received remuneration of $50 for the 2-hour baseline home visit. For the 4-hour Biomedical Surveillance Clinical Examination, participants will receive $100 for their time and effort, remuneration that is proportionate to that for the baseline home visit considering the duration (4 rather than 2 hours) and location (clinic rather than participant's home) of visits. Participants will also receive reimbursement for travel costs based on the table below. Reimbursement for lodging and meals will be provided, if needed, to participants who travel long distances (e.g., 100 miles), and whose scheduled appointment would otherwise require very early morning or late evening travel.

Travel Reimbursement for Clinic Visits

Approximate Distance from the Clinic	Amount
≤ 30 miles	$25
31 miles – 60 miles	$50
≥ 61 miles	$75

The subset of participants who complete the saliva collection and return their samples will receive an additional $20. This amount is consistent with the range of remuneration offered during the baseline data collection for additional, add-on data collection modules (e.g., $20 for the Ammonia Release Survey module, $30 for wearing a personal air monitoring device).

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 Records, published December 29, 1993**.**
- All study personnel are required to complete on-line training in the protection of human research subjects. The investigators and study staff 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 is stored securely. All study datasets, laboratory specimens, and administrative forms are identified by a code number in order to maintain participant confidentiality. All records that contain names or other personal identifiers are stored separately from study records identified by code number. All databases are 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 are stored in a separate, locked file in an area with limited access.
- A Federal Certificate of Confidentiality (Attachment 29) has been obtained for this study. The Certificate expires on 02/15/2021. 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 are 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. IRB approvals (Attachments 31-36) for the follow-up activities and Biomedical Surveillance Clinical Examination have been obtained.
- Informed consent forms spell out the steps taken to protect privacy. Similar information is provided verbally at the time of enrollment. Informed consent will separately be obtained for the clinic visits and include similar information about privacy protection and confidentiality.
- 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 other clinical research 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.
- For the clinic visits conducted for the Biomedical Surveillance Sub-cohort, study computers with whole-disk encryption will be issued to the clinical sites, as required by the security plan in effect for the GuLF STUDY. A clinical data management and scheduling system will be utilized to standardize data collection and centralize the storage of study data. The system will be accessible only to project team members at the coordinating center and clinical sites, via an encrypted, secure connection to GuLF STUDY central servers (VPN or Secure-Socket-Layer). Thus, no project data will be archived on remote computers for long-term storage. Study data recorded on the neurobehavioral and PFT computers will be uploaded weekly and stored in a secured,

password protected database at the study coordinating center. The system has user access rights designed to ensure site personnel have access only to participants assigned to their site, and cannot see data collected elsewhere. Any ancillary data collected using 3rd party software (e.g., pulmonary function data) will not contain personally identifying information when possible. Study computers will be returned to the central office at the closure of clinical data collection efforts.

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. During administration of the supplemental mental health questionnaire and the Biomedical Clinical Exam mental health questionnaire, our research staff will follow protocols and procedures developed for administration of the baseline questionnaire to respond to signs of mental health distress. These procedures include job aides to help identify signs of distress, protocols for escalating difficult cases to study managers, and a database for making referral to the national suicide hotlines and local mental health resources.

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 Federal Certificate of Confidentiality (Attachment 29) has been obtained for this study. The Certificate expires on 02/15/2021.

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

- *Frequency of Response:* Participation will include annual contact information update (0.25 hr; Active and Passive Follow-up Sub-cohorts), biennial follow-up telephone interviews (0.5 hr; Active Follow-up Sub-cohort only), mental health questionnaire (0.25 hr. for each of 4 administrations; subset of Active Follow-up Sub-cohort), and biennial clinic visits (4 hr; Biomedical Surveillance Sub-cohort) for 10 years or more.
- *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.
- *Estimated Number of Respondents:* Active Surveillance Follow-up Sub-cohort (N~20,000); Passive Surveillance Follow-up Sub-cohort (N~13,000); subset of the Active Surveillance Sub-cohort receiving mental health questionnaire (N~4,600); and Biomedical Surveillance Sub-cohort (N~4,000).
- *Estimated Number of Responses per Respondent:* See table below.
- *Average Burden Hours per Respondent:* 0.68.
- *Estimated Total Burden Hours Requested:* 65,172 (over 3 years).
- *Average Annual Burden Hours Requested:* 21,724.
- *Annualized Cost to Respondents:* $13.60 (assuming $20 hourly wage X 0.68 hour).

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

The estimated burden for the next three years, and the annualized burden, is shown in the following table:

Form/Activity	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Burden Hour (for 3 years)	Annualized Burden Hour
Annual Recontact Questionnaire	Cleanup & non-Cleanup Workers	32,762	3	15/60	24,572	8,191
Supplemental Mental Health Telephone Questionnaire	Cleanup & non-Cleanup Workers	4,600	4	15/60	4,600	1,533

Form/Activity	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Burden Hour (for 3 years)	Annualized Burden Hour
Follow-up Telephone Questionnaire	Cleanup & non-Cleanup Workers	20,000	2	30/60	20,000	6,667
Clinical Exam	Cleanup & non-Cleanup Workers	4,000	1	240/60	16,000	5,333
	Total				65,172	21,724

*****The clinical examination components are shown in Table 1.

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 total projected cost to the federal government to complete years 3-5 of the GuLF STUDY is $17,516,221. This averages to $5,838,740 annually. The estimated costs for years 3-5 are shown below.

	Year 3	Year 4	Year 5	Total
Contractor Costs				
Cohort Maintenance	$1,710,704	$2,822,982	$2,770,628	$7,304,314
Biomedical Surveillance Clinical Exams	$1,023,976	$4,857,943	N/A	$5,881,919
Follow-up Telephone Interviews	$546,200	N/A	$546,077	$1,092,277
Supplemental Mental Health Questionnaire	N/A	$237,711	N/A	$237,711
Subtotal	**$3,280,880**	**$7,918,636**	**$3,316,705**	**$14,516,221**
NIEHS Costs				
Travel				
Gulf site visits and community meetings	$12,000	$15,000	$13,000	$40,000
Scientific meetings	$5,200	$5,500	$5,500	$16,200
Conferences, workshops, other meetings	$2,800	$3,000	$3,000	$8,800
IT				
Employee IT devices	$5,000	$5,000	$5,000	$15,000
Personnel				
Epidemiology and Biostatistics	$634,106	$650,000	$675,000	$1,959,106
Office of the Director	$80,205	$75,000	$75,000	$230,205
Other costs				
Consultants	$25,000	$20,000	$10,000	$55,000
Sample and data analysis	$235,689	$226,500	$213,500	$675,689
Subtotal	**$1,000,000**	**$1,000,000**	**$1,000,000**	**$3,000,000**
Total Cost to the Federal Government	**$4,280,880**	**$8,918,636**	**$4,316,705**	**$17,516,221**

A.15. Explanation for Program Changes or Adjustments

This revision and continuation is a program change due to agency discretion and represents the estimated burden for the first three years of the follow-up phase of the GuLF STUDY.

The primary objectives of the GuLF STUDY continue to be the assessment of a wide range of potential short- and long-term human health effects associated with clean-up and disposal activities surrounding the Deepwater Horizon oil spill in the Gulf of Mexico.

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		•	•	•	•	•	•	•														
Newsletter & Annual Contact Update											•	•	•	•	•	•	•	•	•	•	•	•
Active Sub-cohort Follow-up												•	•	•	•			•	•	•	•	
Biomedical Surveillance Sub-Cohort Follow-up															•	•	•	•	•	•	•	

Given the very limited health effects research conducted to date on oil spill clean-up workers, the GuLF STUDY is designed 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.