

**(INSERT GOVT ENTITY)
STATEMENT OF WORK (SOW)**

A. GENERAL INFORMATION

1. Title of Project: Environmental Epidemiology Studies

2. Scope of Work: This Indefinite Delivery/Indefinite Quantity (IDIQ) contract will provide services to the (INSERT GOVT ENTITY), (INSERT GOVT ENTITY). The (INSERT GOVT ENTITY) intends, through this procurement, to increase the number of contractors and resources available to provide required services, to enhance the ability to produce various data and reports.

Over a 5-year period, the contractor(s) will provide a full range of integrated strategic, analytic and technical support services that (INSERT GOVT ENTITY) may need in order to design and implement optimal Environmental Health initiatives and ensure progress toward meeting requirements and goals. The intent is to acquire professional expertise in Environmental Health program areas to assist the (INSERT GOVT ENTITY) in initiatives such as: study design and data collection, auxiliary/support services, and data analyses and reporting. The selected contractor(s) shall have subject matter expertise and provide all resources necessary to perform the specific requirements as defined in the Task Orders.

Individual Task Orders will not be awarded that exceed \$2 million dollars or one year. Individual Task Orders will be awarded on a firm-fixed price basis. The Contracting Officer may waive the dollar limit and the period of performance ceilings for individual task orders. Solely the Contracting Officer, on a case-by-case basis, shall determine deviations from the dollar limitation and the period of performance ceilings.

3. Background: _____ is currently working to expand the public health and epidemiologic services available to the (INSERT GOVT ENTITY).

The goal of a public health approach is to improve health by focusing on the well-being of communities, _____ (INSERT GOVT ENTITY) health staff. Our mission unfolds through a commitment to:

- Making sound public policy part of everything we do
- Designing programs that prevent illness and promote healthy behaviors
- Understanding environmental factors that affect health
- Supporting vulnerable populations
- Coordinating Veterans Health Administration preparedness for responses to disasters and emergencies

As part of OPH, the _____
administers various programs related to environmental and occupational exposures of

U.S. Veterans during military service, including Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF), Gulf War, Vietnam, World War II and atomic Veterans activities. [REDACTED] also maintains several registries based on these exposures and manages the War-Related Injury and Illness Study Centers (WRIISC).

The [REDACTED] consists of two interrelated programs:

- The Environmental Programs evaluates research, recommends policy and develops educational and outreach materials for various environmental issues and health outcomes related to military service, including:
 - Agent Orange
 - Gulf War Veterans' Illnesses
 - Operations Enduring Freedom and Iraqi Freedom Hazardous Exposures
 - Burn Pits
 - Ionizing and Non-Ionizing Radiation
 - Toxic Embedded Fragments
 - Depleted Uranium
 - Cold and Heat Injuries (Thermal Injuries)
 - Project 112/Project SHAD
 - Mustard Gas
 - Occupational and Environmental Hazards
 - Noise, Vibration and Other Physical Exposure

- The Epidemiology Programs conducts surveillance and studies on Veterans' health and health care. Findings from these studies help health professionals and policymakers, including (INSERT GOVT ENTITY) and Congress, improve health care practices and policies for Veterans. Findings from Epidemiology Program research studies help health professionals and policymakers, including (INSERT GOVT ENTITY) and Congress, improve health care practices and policies for Veterans. Epidemiology Program activities include:
 - Blasts Exposures
 - Post Traumatic Stress Disorder
 - Traumatic Brain Injury
 - OEF/OIF Veteran Studies
 - Complementary and Alternative Medicine
 - Bipolar Disorder
 - Gulf War, Vietnam and Unique Veteran Studies

4. Performance Period: The period of performance for this IDIQ is five years, beginning on the date of award, with annual reviews by the Contracting Officer.

5. Type of Contract: Indefinite Delivery/Indefinite Quantity with Firm Fixed Price task orders placed against the contract.

6. Place of Performance: TBD

7. Services to be Provided:

The services contemplated under this contract include study design and data collection, auxiliary/support services, data analyses and reporting, and all that may be necessary to complete a particular project. An individual task order may require services in only one of these activities or a combination of the activities. All requirements, tasks and deliverables apply to contractors and all subcontractors awarded under this contract and all task orders.

All task orders will require the following three items:

Item 1: Project Plan and Procedures

The contractor will develop a detailed initial project plan and will designate personnel to work under this contract and task orders. The project plan will include all of the following elements:

Procedures to be employed in the training of supervisors and staff.

- Quality control measures to ensure that all aspects of contract work are
- accurate. The database(s) to be used for the project.
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Item 2: Quality Assurance

The contractor will develop a quality control plan that covers all aspects of the work to be performed under this contract. The quality control plan will include the following: The contractor will have a management system that identifies potential problems early,

- ensures high-quality data and adherence to schedules, controls project costs, and maintains close communication with the (INSERT GOVT ENTITY). Project operations will include frequent conversations concerning progress and challenges, meetings to discuss and resolve problems, and regular reporting between the contractor and the (INSERT GOVT ENTITY).

The contractor will provide staff training as required for the project. This training will

- include study procedures, problem identification, and protection of the rights of human subjects. All people who will collect or handle data must have a certificate in human subjects research protection and Health Insurance Portability and Accountability Act (HIPAA) training, obtained before beginning work on this study and renewed once each year.

The (INSERT GOVT ENTITY) COTR, together with other (INSERT GOVT ENTITY)

- staff, will make announced and unannounced visits to monitor contractor operations on-site.

Item 3: Submit a Confidentiality Plan and Data Security Procedures

The contractor will ensure the highest degree of security to protect personal and confidential data of Veterans from intentional or unintentional release, loss, or destruction.

Prior to receipt of any data files from the (INSERT GOVT ENTITY), the contractor will

- submit a confidentiality plan and data security procedures for approval by the (INSERT GOVT ENTITY) COTR and revise it per the (INSERT GOVT ENTITY)

accordance with (INSERT GOVT ENTITY) and [REDACTED] including the following:
(INSERT GOVT ENTITY) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- COTR instructions. Data will be transferred, retained, utilized, and destroyed in All individuals working on the project must sign Data Use Agreements indicating that they understand their scope of effort and responsibilities for non-disclosure. Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and (INSERT GOVT ENTITY) Directives and Handbooks as (INSERT GOVT ENTITY) and (INSERT GOVT ENTITY) personnel regarding information and information system security.
- Every effort must be made to avoid inadvertent breaches of confidentiality. For example, Veterans names or other personal identifiers should only appear on page one of mailed letters.
- The contractor will use a Secure Socket Layer (SSL) connection or equivalent technology approved by the (INSERT GOVT ENTITY) COTR to provide a secure direct connection between the (INSERT GOVT ENTITY)'s designated office and the electronic database of responses. The purpose of the secure connection between the client ((INSERT GOVT ENTITY)) and a server (contractor) is to permit (INSERT GOVT ENTITY) to access the databases and download them, without risking a breach of privacy. The contractor will monitor data transmission for anomalous traffic behavior(s), and will immediately (within 24 hours) report to the (INSERT GOVT ENTITY) COTR any unauthorized access, including release of personally identifiable data, in writing.

B. SPECIFIC TASKS AND DELIVERABLES

Task 1: Study Design and Data Collection - These studies propose technical designs (measurements and comparisons) to be used in evaluating a health issue, and test those designs by collecting appropriate data. Data collection studies may require that contractors identify and apply the appropriate data collection methodologies (survey mode – web, phone, mail; medical records review) and research designs for various purposes at the local, regional and national levels. In addition contractors may be required to construct and field test/validate a survey instrument, compile written survey protocols, train interviewers as necessary, prepare OMB clearance packages for submittal, perform extensive survey related tasks and perform the appropriate survey follow up. Additionally, these studies may require the ability to access databases from appropriate sources and construct databases.

These studies may also include identifying problems in and improving the quality of evaluations and evaluation systems. They may include activities such as researching and piloting new methods of collecting data to improve timeliness and reliability; developing new methods of data collecting such as electronic methods of transmission; working with other organizations to coordinate data collections; and improving the

quality and utility of program data collections. Minor Information Technology requirements may be called for under this task such as encoding a survey into electronic format for use of laptop computers by survey personnel in conducting the survey.

Deliverable 1: Obtain necessary IRB and OMB Approvals

The contractor will prepare and submit any forms necessary to obtain IRB and OMB approvals for the study.

Deliverable 2: Develop Contact Information/ Locate Addresses

- The contractor will create a database to store and track contact information and addresses.
- For surveys to Veterans, the contractor will be expected to update address files supplied by the (INSERT GOVT ENTITY) COTR. The contractor will use other proprietary databases (e.g., National Change of Address, Credit Bureau, etc.) and use other techniques to update address and telephone number information. The contractor will make a major effort to determine the correct addresses of Veterans whose mailed materials are returned due to incorrect addresses. The (INSERT GOVT ENTITY) COTR will try to assist with this process by using (INSERT GOVT ENTITY) records to the extent that this is permitted.
- For mortality studies involving mailings to next of kin, the contractor will identify and locate next of kin of deceased Veterans using Accurant, other major credit bureau records, or other appropriate means. The contractor will make a major effort to determine the correct addresses and the (INSERT GOVT ENTITY) COTR will try to assist by using (INSERT GOVT ENTITY) records to the extent that it is permitted.
- For both mail surveys and mortality studies, the contractor will report to the (INSERT GOVT ENTITY) COTR all incorrect address information and the extent to which they have succeeded in locating the correct address. The contractor will compute error rates for addresses by source of address information (e.g. Department of Defense, Internal Revenue Service, and (INSERT GOVT ENTITY)). The contractor will create an electronic database consisting of the name, each address, phone number and any other available contact information for each member of the target population. Each address provided to the contractor will be included, together with a variable denoting whether the individual address was “good” or “not delivered.” The contractor should have a set list of potential mailing addresses from a variety of sources to use if any mailing packet is returned to sender. The (INSERT GOVT ENTITY) COTR may request additional efforts.

Deliverable 3: Conduct a Pilot Study

(INSERT GOVT ENTITY) will provide the contractor with a pilot study sample. The contractor will conduct a pilot study to evaluate possible barriers to participation in all phases of the study (e.g. survey, CATI, medical records review, in-person measurement study) and modifications to overcome these barriers. The contractor will implement the approved protocol in order to identify modifications that are needed for the study. This pilot study may include any of the following activities to be conducted by the contractor:

For a mailing effort:

- Assess the extent to which incorrect addresses are present.
- Compare error rates for addresses by source of address (e.g. Department of Defense, Internal Revenue Service, (INSERT GOVT ENTITY), etc).
- Evaluate methods for correctly locating Veterans whose initial addresses prove to be inaccurate and suggest modifications as appropriate.

For a survey:

- Evaluate if survey instructions and questions are clear for respondents.
- Investigate whether respondents are directly answering the questions that they are asked and that there are not unanticipated responses.
- Explore whether survey questions flow logically, as well as with regard to skip patterns in the online survey.
- Determine whether the time to complete the survey falls within the expected time frame.
- Refine the questionnaire structure and content changes with the concurrence of (INSERT GOVT ENTITY) as needed.
- Provide the (INSERT GOVT ENTITY) COTR with original versions of all mail questionnaires (scanned into a document scanner) and corresponding databases for comparison

The contractor will submit findings from the pilot study to the (INSERT GOVT ENTITY) for review along with any recommendations for changes. The recommended changes will be incorporated into the main study only with the written approval of the (INSERT GOVT ENTITY).

Deliverable 4: Data Management

The contractor will develop and implement a data management system to track the status of any participants selected for a study at any time and at any point in the address search, mail or online questionnaire, telephone questionnaire, or medical record retrieval (INSERT GOVT ENTITY) process. The data management system also will include (when applicable):

- An automated method for data entry and data editing, including computer programs for range edits, logic edits, and checks for skip patterns inherent in a questionnaire
- A method for systematic documentation of all edit specifications and all corrections made during the editing process
- A system of computer programs that provide quality control checks to ensure the accuracy of data after the editing process is complete

Deliverable 5: Data Entry

5.1: Scanning and Editing of Questionnaires

Paper questionnaires will be scanned into both a data collection scanner (to record responses) and document scanner (to capture a PDF image of the

questionnaire) when received by the contractor. The contractor will propose a method of editing questionnaires based on cost-effectiveness, speed, accuracy, and consistency of edits to the same question. The contractor will choose to do pre-data-scanning edits of the questionnaire, post-data-scanning edits of the questionnaire, or a combination of both. If the questionnaire is reviewed prior to data scanning, the contractor will make any necessary changes that may hamper accurate data collection (for example, remove stray marks).

Advanced data collection scanning technologies will allow checking for errors after data scanning to increase efficiency and accuracy. A high (> 98%) confidence level may need to be assigned so that the image of an answer corresponds to a unique character that the computer is programmed to recognize. All marks that cannot be identified at the specified confidence level will be assessed by a staff member and entered manually into a database. The questionnaire may also contain some open-ended questions which the contractor will manually enter into a database. Any forms which are unreadable by the data collection scanner will be corrected and entered manually into a database.

A PDF image of each questionnaire will be created using a document scanner. These PDFs will be provided to the (INSERT GOVT ENTITY) COTR at intervals decided upon by the (INSERT GOVT ENTITY) COTR. The contractor will keep files of all PDFs through the end of the project.

5.2: Coding of Open-Ended Questions in a Survey and Entry of Text Responses

A coding manual for open-ended questions will be developed and approved by (INSERT GOVT ENTITY). (INSERT GOVT ENTITY) prefers that the coders try to combine similar answers into a single code rather than having multiple codes for responses that mean the same thing. For example, a Veteran may refer to a blast or refer to an explosion, but both of these answers represent the same concept and should be combined in a single code.

Monitoring and feedback mechanisms will be implemented for coders to ensure that coding practices are consistent. The coding procedures and manual will be included in the methodology report.

Text entries which are not coded will be double-entered into a database for accuracy.

5.3: Stuck-Together Pages

The contractor will look for evidence of stuck-together pages that precluded full responses and will contact respondents to request responses to questions included on stuck-together pages. This will be done by telephoning the respondent and asking those questions. If the Veteran cannot be reached by telephone a photocopy of the pages in question, together with another copy of

the consent form and a personalized note, will be mailed.

5.4: Scanner Capability and Settings

Data collection scanning should be performed on an advanced technology scanner (such as INSIGHT™ OMR Scanner) with an accuracy rating of nearly 100%. The data collection scanner should be calibrated and tested periodically throughout the scanning process to ensure accurate alignment, threshold levels, and mark reliability. The threshold validity for a valid mark should be at level five. If the scanner reads two valid marks where only one is allowed, the mark with the higher level will be selected as the valid answer as long as the read levels for the two marks are at least two levels apart. If the competing read levels are either the same or only one level apart, the item will be left blank but flagged in the output file.

5.5: Quality Control for Paper Questionnaires

Data recorded using the data collection scanner and manually entered data will be subjected to periodic random checks by visually inspecting the questionnaires and comparing them to the databases. The contractor will compare an initial set number of mail questionnaires to the data recorded by scanning and provide an inspection of additional randomly selected mail questionnaires and compare them with the results of scanning and compute an error rate. Results from this comparison will be reported to (INSERT GOVT ENTITY). The contractor will prepare a brief report for the (INSERT GOVT ENTITY) COTR that indicates whether any inconsistencies have been detected and whether any changes need to be made in the procedures for recording mail questionnaire data. The contractor will make modifications to scanning procedures and equipment as appropriate, under the guidance of the (INSERT GOVT ENTITY) if error rates are unacceptably high according to the (INSERT GOVT ENTITY) COTR. Error rates will be computed by counting each omission or incorrect entry as one error. (INSERT GOVT ENTITY) requests that error rates be no higher than 0.1%.

5.6: Quality Control for Online Questionnaires

Quality control measures are necessary to ensure that responses to the online questionnaire are recorded correctly. The contractor will develop appropriate measures, including comparison of a set number of online questionnaires submitted during the beginning of data collection to electronic data files that capture the online responses and report the results of this comparison to the (INSERT GOVT ENTITY). The contractor will prepare a brief report for the (INSERT GOVT ENTITY) COTR that indicates whether any inconsistencies have been detected and whether any changes need to be made in the procedures for recording online data.

5.7: Format of Data Entry and Reporting

The contractor will combine data from all questionnaire modes (mail questionnaire, online questionnaire, telephone questionnaire) into a database. The database will include a variable indicating which survey mode was used.

All questionnaires received via mail are required to be date-stamped. Similarly, online questionnaires must indicate the date submitted and telephone questionnaires must indicate the date completed. A separate variable will be created to denote date of receipt.

The contractor will create a SAS program generating frequencies for select variables. Frequency counts of these select variables will be output at a frequency determined by the (INSERT GOVT ENTITY) COTR and checked by the contractor to detect any inconsistencies in totals or potential systematic problems. The contractor will provide the (INSERT GOVT ENTITY) COTR with the output from frequencies, including missing data and out-of-range answers. Missing data, out-of-range responses, and inconsistent responses will be used by the contractor to detect and correct potential problems.

5.8: Late-Arriving Questionnaires

Mail and online questionnaires are sometimes submitted after the vast majority of surveys have been returned and databases have been created. To maximize the participation rate, the contractor will continue to scan mail questionnaires and enter data up through the end of the contract. Similarly, late online questionnaires will be incorporated into databases up through the end of the contract. The contractor will be flexible in accommodating any telephone questionnaires that are scheduled after the planned time period. The final database will include late submissions.

Deliverable 6: Data Delivery

All Contractors and subcontractors shall be subject to the same Federal laws, regulations, standards and (INSERT GOVT ENTITY) policies as (INSERT GOVT ENTITY), and (INSERT GOVT ENTITY) personnel, regarding information and information system security. Contractors and subcontractors shall follow policies and procedures outlined in (INSERT GOVT ENTITY) Directive 6500, *Information Security Program* and its handbooks to ensure appropriate security controls are in place. Furthermore, Contractors and subcontractors are to adhere to all requirements established in (INSERT GOVT ENTITY) Handbook 6500.6, Contract Security, dated March 12, 2010.

6.1: Communicating with the (INSERT GOVT ENTITY)

The contractor will provide an accounting of the results of each mailing wave with a frequency agreed upon by (INSERT GOVT ENTITY). The accounting will include the original number mailed, the number returned undelivered with a new address, the number returned undelivered with no address, and the number re-mailed. In addition, the contractor will maintain a log that is updated during the work week at a frequency to be determined by the (INSERT GOVT ENTITY) COTR, indicating which participants have completed the questionnaire online.

6.2: Storage and Access to Data

Questionnaires, consent forms and medical records will be scanned into a document scanner as they arrive to create a PDF of each document. Participant responses from the completed mail and online questionnaires will be entered into separate, dated electronic databases at a frequency to be determined by the (INSERT GOVT ENTITY) COTR and the (INSERT GOVT ENTITY) COTR will be notified when complete. The (INSERT GOVT ENTITY) shall have electronic access to all databases. A cumulative file of all respondent records will be created and maintained by the contractor. There will be no comingling of (INSERT GOVT ENTITY) information on disk drives with non-(INSERT GOVT ENTITY) information.

6.3: Backing Up Data (INSERT GOVT ENTITY) will maintain the master database. However, the contractor will maintain an archive of all completed databases for the duration of the project. The contractor will have a secure backup system in a different building to protect against loss or destruction of data files; backup must occur at a frequency to be determined by the (INSERT GOVT ENTITY) COTR. There will be no comingling of backed-up data with other non-(INSERT GOVT ENTITY) backed-up data.

6.4: Handing Over Data to the (INSERT GOVT ENTITY) COTR Upon Completion of Project

All files must be given to the (INSERT GOVT ENTITY) COTR when the work order is complete, or disposed of in accordance with instructions from the (INSERT GOVT ENTITY), and the contractor will not keep any copies of the final products. The contractor will submit a signed letter indicating that it does not retain any of the final electronic or paper data records of completed responses and must agree to an onsite inspection by the (INSERT GOVT ENTITY) COTR to ensure that no electronic or paper data records remain.

6.5: Ensuring that Scanned Images of Questionnaires are Complete and Accurate

As noted in the next item, the paper questionnaires eventually may be destroyed. Thus, it is critical that the contractor develop a method of assuring that the scanned images (PDFs) of the questionnaires are complete and accurate (no missing or illegible pages). This method will need to be explained to and approved by the (INSERT GOVT ENTITY).

6.6: Destruction Plan

The contractor will develop a destruction plan and allocate resources for destruction of paper copies of returned questionnaires or other paper materials, and media sources, depending on instructions from the (INSERT GOVT ENTITY) COTR. (INSERT GOVT ENTITY) anticipates that scanned images (PDFs) of all returned questionnaires will be stored electronically and given to the (INSERT GOVT ENTITY), which may mean that paper copies are not needed after the project closeout date. Destruction must not be carried out until the (INSERT

GOVT ENTITY) COTR approves of such action. Alternately, the (INSERT GOVT ENTITY) COTR may decide that the contractor needs to transfer the paper questionnaires into the (INSERT GOVT ENTITY)'s safekeeping. The contractor needs to have resources for paper instrument and media sources transfer within the destruction plan budget and staffing.

Task 2: Auxiliary/Support Services - The contractor(s) will provide auxiliary and support services for various needs.

Deliverable 7: Design and Print Mail Materials

7.1: Design proofs

For survey studies, the contractor will prepare for approval by (INSERT GOVT ENTITY) COTR all contact materials used for data collection. Survey contact materials may include the following: personalized introductory letter, information sheet, opt-out postcard, consent form with second copy for Veteran's records, follow-up letter, questionnaire booklet, letter to health care providers, outer envelope with "return to sender" request, self-addressed stamped return envelope, and thank you/reminder postcard.(INSERT GOVT ENTITY) will provide the language for all survey contact materials and the contractor will print them and/or post them on the Web. The contractor will check the quality of the print, paper used, web design, and general appearance of all contact materials to ensure that they meet the specifications/standards outlined by the (INSERT GOVT ENTITY). Proofs should be treated as proprietary information.

7.2: Questionnaires

Questionnaires must follow principles of good design for imaging. The mail questionnaires will be formatted for scanning into a data collection scanner (such as INSIGHT™ OMR Scanner) after completion. Requirements for good design include:

- Providing squares with a faint X inside the square so that respondents can mark X's for answers instead of traditional bubbles.
- Providing answer squares that are at least 1/8" by 1/8".
- Leaving space between answer squares similar to space within squares.
- Using adequate space for open-ended questions.
- Using symbols to help respondents know when to answer questions or leave them blank.
- Placing instructions right before a question rather than after a question or at the beginning of the questionnaire.
- Using question numbers for both mail and online surveys.

(INSERT GOVT ENTITY) has final say in the questionnaire format to be used. Veterans will be given an individual study identification number which will be printed on the first page of the questionnaire as well as somewhere in the body of the questionnaire. The questionnaires should be printed separately for each mailing wave to allow for wording changes to the text if necessary and to indicate

subsequent mailings.

7.3: Postcards

Personalized thank you/reminder postcards will be manufactured using both sides of postcard-weight paper. One side will be printed with the recipient's name and address.

7.4: Envelopes

The contractor will provide outgoing envelopes, printed with return address and the appropriate mailing postage for address corrections for all mailings. The contractor will also provide additional envelopes as needed for Veterans with incorrect addresses. Envelopes will be marked to indicate "return to sender, do not forward" or the equivalent phrase in use by the U.S. Postal Service at the time of the mailing. Additionally, the contractor will provide return envelopes, printed with return address and the appropriate postage, to be included in the questionnaire package. Based on the expected response rate, the contractor will provide additional envelopes for the additional mailing waves.

Deliverable 8: Assemble, Address, and Mail Materials

Materials for all questionnaire packages should be assembled and folded in such a way that respondents remove all materials together at once from the envelope to avoid the problem of one or more components being left in the original mailing envelope.

The contractor will create a database for tracking mailings. After sending introductory letters and after each subsequent mailing, the contractor will ascertain which addresses have returned as incorrect addresses and attempt to update the addresses. The (INSERT GOVT ENTITY) COTR may assist with this process by using information from (INSERT GOVT ENTITY) records, if permissible. For those envelopes returned by the U.S. Postal Service (USPS) marked as "forwarding order expired" (or similar), the contractor will contact the specific USPS in the ZIP code by letter using (INSERT GOVT ENTITY) letterhead to request the address on file with the USPS. The contractor will follow up by re-mailing the introductory letter or questionnaire packet to the new address. Vigorous efforts need to be made to obtain correct addresses. There should be flexibility in scheduling mailings to allow for unforeseen circumstances that may arise.

The contractor will handle address corrections immediately as new addresses are provided on returned envelopes. Documents should be re-mailed within specified period of time after receipt to be determined by the (INSERT GOVT ENTITY) COTR rather than being held for a later mass mailing.

The contractor will mail thank you/reminder postcards to all study participants after questionnaire mailings. Subsequent questionnaire packages for those who did not respond to the initial or subsequent mailings or for those who request a replacement package will be sent. Subsequent questionnaire mailings will be marked so that the respondent is aware that these are repeat mailings.

Deliverable 9: Design and Maintain a Web Site and Online Questionnaire

Survey study participants will have the option of answering the questionnaire online. The contractor will develop and maintain an electronic version of the survey instrument. The contractor is responsible for securing a domain name, hosting the site, programming, creating, and managing the online questionnaire. The secure Web site must be built within a password-protected firewall to ensure participant confidentiality. Maintenance of the online questionnaire will include procedures to identify duplicate responses, aggregate data collected online with data collected from mailed responses, and allow (INSERT GOVT ENTITY) to identify respondents who completed the online questionnaire.

The secure Web site needs to be 508 compliant so that a visually impaired or colorblind Veteran is able to complete the questionnaire online. The Web site must include a toll-free telephone number, prominently displayed, so Veterans can seek technical assistance with the online survey or notify the contractor of any problems with the Web site.

Each potential participant will be assigned a unique username and password for the online version of the questionnaire. An informed consent page will be created with a clickable button to consent as a prerequisite to participation. Participants will be able to log out in the middle of the survey and then log in again at a later time to complete the survey. The online questionnaire will be designed with skip patterns to reduce the burden on the respondents. Participants will have the option to print their answers at home for their own personal records.

The contractor will design a mechanism to ensure that mail and online questionnaires by the same participant are not computed as two submitted surveys. If a mail and online questionnaire are submitted by the same participant, then they will be identified as duplicates in the database. The contractor will make a judgment as to which survey is most complete, but will report results from both surveys to the (INSERT GOVT ENTITY) COTR (being careful not to count the responses twice). When duplicate responses occur, the contractor must not mix and match responses from the multiple surveys. Instead, one survey per person will be included in the final database. For the final dataset, the most complete survey among the duplicates will be included and the definition of "most complete" will be determined by the (INSERT GOVT ENTITY) in conjunction with the contractor.

Specifications for online questionnaires--Principles of good internet survey design must be incorporated. These include:

- An encouraging welcome screen that explains the importance of participation, ease of response, and explains how to get to the next page
- Presenting each question in a format similar to the paper questionnaire and making it easy to read
- Considering the effects of different download methods, dial-up versus high-speed Internet users, different screen configurations, operating systems,

browsers, and screen displays so that the visual appearance of online questions is similar despite these differences

- Pilot testing the online survey on different types of browsers and equipment and download speeds (or a simulation of these different types) to identify modifications that are needed
- Being very careful about the use of color, which can result in problems in navigation and readability
- Numbering each question
- Providing respondents with a sense of how far they have progressed in completing their online survey so as to motivate them to finish
- Giving simple specific instructions on how to take each step at the point where it is needed (do not assume that all respondents are experienced with drop-down menus, etc.)
- Minimize drop-down boxes and identify each drop-down box with an instruction that says something like “click here”
- Respondents MUST be permitted to skip questions before being allowed to proceed to the next question to preserve the rights of respondents to not answer any question for any reason
- Allowing respondents to go back and change or remove their answers if they so choose before they finally submit the survey
- Providing clear skip instructions
- Keeping potential answer choices on the same screen

The (INSERT GOVT ENTITY) COTR will review and approve questionnaire design proofs, including the online questionnaire, prior to printing or implementation of the electronic instrument. Proofs should be treated as proprietary information.

Deliverable 10: Telephone Interview Using CATI (Computer-Assisted Telephone Interview) System

For a medical records review, the contractor will create a telephone script to obtain consent for release and location of medical records. (INSERT GOVT ENTITY) shall review the telephone script prior to implementation of telephone interviews. The contractor will program the telephone interview script for computer assisted telephone interview (CATI) application.

For a survey study, the contractor will develop a CATI questionnaire based on the paper questionnaire. This CATI script and questionnaire will be provided to the (INSERT GOVT ENTITY) COTR for approval.

The contractor will create a file of Veterans who did not respond to the online or mail questionnaire. Using this file, the (INSERT GOVT ENTITY) COTR shall provide the contractor with the identities of a sample of non-respondents for the contractor to interview using the CATI script. The contractor is responsible for locating telephone numbers for these individuals. The (INSERT GOVT ENTITY) COTR shall help provide telephone numbers, but the contractor also will need to use other sources. If the initial

telephone numbers are incorrect, then additional telephone numbers must be sought.

The (INSERT GOVT ENTITY) expects that multiple callbacks will be necessary. Calls must be made during days, evenings, and weekends to maximize the chances of reaching Veterans successfully. The interviewer should stop leaving voice messages after three voice messages have been left requesting the Veteran to call back without any response. If Veterans clearly refuse to participate, their wishes must be respected. A toll-free number will be established by the contractor so that Veterans can return phone calls. Telephone interviewers need to ask the Veteran if they are reaching them on a cell phone and offer the toll-free number at which Veterans can call them back. Veterans will be given the option to break the questionnaire into shorter segments or reschedule the interview, in order to minimize the inconvenience to the Veteran. Requests from the non-respondents regarding convenient times for interviews will be granted.

There will be a set participation rate goal for telephone questionnaires, defined by the (INSERT GOVT ENTITY) COTR. If the contractor is unable to reach this goal, the (INSERT GOVT ENTITY) COTR has the option of supplying additional names of non-respondent Veterans.

Interviewers will understand the nature and purpose of the study and be able to answer questions commonly asked by respondents about the project. Interviewers will be prepared to handle reactions of emotional distress by participants by having a (INSERT GOVT ENTITY) mental health 1-800 hotline number on-hand. Supervisors will monitor a percentage of interviews set by the (INSERT GOVT ENTITY) COTR, to ensure quality control. The contractor will plan for encountering special technical problems and solutions, including addressing the needs of hearing-impaired Veterans.

Deliverable 11: Medical Records Retrieval and Coding

The contractor will track the progress of medical records retrieval using the Excel database. The contractor will make as many follow-up contacts with providers as necessary by mail, phone, or FAX. The measure for successfully obtaining copies of relevant medical records from providers is 65% or higher of targeted records.

Deliverable 12: Data Security Procedures

Consent forms and medical records will be scanned into a document scanner as they arrive to create a PDF of each document. If a CATI is used, participant responses will be entered into separate, dated electronic databases at a frequency to be determined by the (INSERT GOVT ENTITY) COTR and the (INSERT GOVT ENTITY) COTR should be notified when complete. A cumulative file of all respondent records should be created and maintained by the contractor.

Deliverable 13: In-Person Measurement Study

The contractor will develop a detailed study plan for the in-person measurement to include sampling of participants, methods to obtain informed consent, data collection,

and quality assurance/control procedures. The contractor will develop a sampling plan for participants to ensure that they represent the target population of interest. Veterans who are chosen and agree to an in-person measurement (blood pressure reading, venipuncture, spirometry, anthropomorphic measurements, etc) study will be sent a consent form to complete and send back, a second consent form to keep, and additional information regarding the measurement study.

The contractor will develop a detailed Standard Operating Procedure (SOP) for the collection of in-person measurements. The SOP will explicitly define the object to be measured, the data to be collected that define the measurement, the timing of the data collection, and any synthesis of data for the measurement (if applicable). The contractor will pilot test their SOP on a sample of Veterans and modify the procedure based on this sub-sample.

The contractor will also prepare a detailed description of the examiner's general requirement and qualifications and training specific to this task. Consistent training of personnel is essential in order to minimize between-rater variability.

The contractor will send a trained medical professional with appropriate measurement devices to the data collection site ((INSERT GOVT ENTITY), (INSERT GOVT ENTITY), (INSERT GOVT ENTITY), etc).

The contractor will develop a quality assurance plan which includes assessing the reliability and validity of their data collection at a minimum of three times during the data collection effort. The contractor will prepare a brief report to the COTR with appropriate measures including Kappa statistic, coefficient of variation, intra-class correlation coefficient, and other measures.

Deliverable 14: Follow up Contacts with Veterans and Health Care Providers

Contractor shall make as many as 10 follow-up contacts with Veterans and health care providers, by mail, email, phone, or FAX to obtain interviews, written informed consent forms, medical records, or in-person measurements.

Deliverable 15: Veteran Technical Assistance

The contractor will provide toll-free telephone and email technical support. Professional staff will be trained to promptly answer questions and complete telephone questionnaires if requested by Veterans. The toll-free number(s) must be posted prominently where the Veteran may see them (e.g. on a Web site, the first page of a mail questionnaire, or personalized letter included in a mailing.) This number also will be given to Veterans if they are contacted for telephone questionnaires or medical record requests. The technical support staffing level must be adjusted to adequately meet the call and email demands throughout the data collection by closely monitoring the contact volume and times. Contact reasons will be recorded for evaluation of possible reporting of data collection-related problems and to identify respondent concerns, and these will be provided to the (INSERT GOVT ENTITY) COTR during the

data collection at a frequency to be determined by the (INSERT GOVT ENTITY) COTR.

For an online questionnaire, adequate and secure computer resources will be provided to handle volume to avoid any Internet connection interruptions and ensure timely completion of the data collection. The quality control procedures will include regular monitoring of online questionnaire submissions to identify any Internet browser issues and ways to ensure that consistent practices are employed for data integration.

The contractor will also set up a project email account to answer respondent questions as well for use for communicating with Veterans who prefer email contact. All email inquiries will receive a response no later than the next business day. Email inquiries will be recorded and provided to the (INSERT GOVT ENTITY) COTR during the data collection at a frequency to be determined by the (INSERT GOVT ENTITY) COTR.

Deliverable 16: Payment of Incentives and Additional Incentive for Veterans to Maximize Participation

In order to maximize the survey response rate and timely completion of data collection, the contractor will develop a plan for an effective ADDITIONAL monetary or non-monetary incentive for Veterans in the event that response rates are lower than desirable. An incentive plan will be presented to the (INSERT GOVT ENTITY) COTR for discussion and approval.

Incentive procedures will comprise part of the mailing of an initial or subsequent questionnaire package and possibly a telephone questionnaire, so decisions will be made on whether to use incentives after results from an initial or subsequent wave questionnaire package mailing(s) are apparent. The incentive plan also may need to be activated in the event that response rates to requests for medical records are unacceptably low, as determined by (INSERT GOVT ENTITY).

The contractor will budget for the expense of preparing an incentive plan and also will include a budget item for the actual incentive. The contractor will follow Government regulations when developing a plan for an incentive.

Task 3: Data Analyses and Reporting - The contractor shall be able to complete both simple and complex analyses of data, and develop a variety of reports based on the findings.

Deliverable 17: Analyses of Data The contractor will use statistical analysis software packages, particularly Statistical Analysis System (SAS), and other technical skills may be required. The contractor will conduct tasks which vary from the straightforward to the complex (for example, analysis of datasets using SAS and SUDAAN). These tasks may involve short deadlines. Analyses may include cross-tabulations, calculations, reliability and validity, sample selection, power analyses, trends, projections, estimates, calculations of sample sizes, and the preparation of narrative materials, graphs, charts, overheads and PowerPoint presentations suitable for clearance and distribution.

Deliverable 18: Provide Monthly Progress Reports

The contractor will provide the COTR with monthly progress reports detailing the progress of the study, continuing throughout the life of the contract.

Deliverable 19: Methodology Report

Within a time frame to be determined by the (INSERT GOVT ENTITY) COTR, the contractor will submit an outline for the methodology report for (INSERT GOVT ENTITY) COTR approval. The contractor will then submit a draft methodology report for the (INSERT GOVT ENTITY) COTR to review that describes the entire study process. This report will include information such as:

- All sources used for locating the Veterans and an indication of the usefulness of each source
- All survey and/or research procedures (mail/online/CATI data collection, editing, data processing, debriefing summaries)
- Results of quality control efforts for each of the survey operations
- Possible biases or errors arising from each stage of the survey
- Questionnaire design and implementation, including interviewer training, participant location, and data collection
- Data preparation and implementation (data keying, coding, cleaning, editing, and imputation).

The final report will be submitted after the (INSERT GOVT ENTITY) COTR approval of the draft report. The data file will not be finalized until discrepancies between the draft methodology report and the electronic databases are resolved.

Deliverable 20: Final Data Analyses Report

The contractor will develop a data analysis report which presents the results of the study with a detailed description of the data analyses used to generate all study results. This report will include details of the exploratory data analyses to include univariable and bivariable statistics, exploration of missing data (including potential correlates of missing data), and more. The report will also include a description of all multivariable methods including reason for model choice, model development (evaluation of confounders, mediators, etc), and model diagnostics. The report will include a detailed description of all other statistical procedures, to include correction for measurement error, missing data, and confounding.

Deliverable 21: Post-Stratification Weighting Analysis Plan

The contractor will develop a post-stratification analysis plan for data collection efforts which employ a sampling strategy (e.g. cluster sampling, stratified sampling, matched sampling, oversampling). The plan will include an evaluation of the sampling errors induced by the design and non-sampling errors such as non-response and undercoverage. The analysis plan will include procedures for generating sampling weights, appropriate estimation of the variance for all statistics, and adjustment for non-

response. The contractor may be asked to develop a plan or to generate all of the weights and an analytic dataset depending on the complexity of the study.

Deliverable 22: Manuscript Collaboration

The contractor will collaborate with (INSERT GOVT ENTITY) on all steps of the manuscript process including conducting background research, creating tables, writing, editing, submitting a completed, (INSERT GOVT ENTITY)-approved manuscript to peer-reviewed scientific journals, and corresponding with journal editors.

C. GENERAL REQUIREMENTS

1. For every task, the contractor will identify in writing all the necessary tasks and subtasks (if any), associated costs by task, and together with associated sub-milestone dates. The contractor's subtask structure will be reflected in the technical proposal and detailed project management plan (PMP).
2. All written deliverables will be phrased in layperson language. Statistical and other technical terminology will not be used without providing a glossary of terms.
3. In advance of publication, and where a written milestone deliverable is required in draft form, (INSERT GOVT ENTITY) will complete their review of the draft deliverable within 10 calendar days from date of receipt. The contractor will have 10 calendar days to deliver the final deliverable from date of receipt of the Government's comments. The contractor's committee will brief (INSERT GOVT ENTITY) on their findings and recommendations at least one week in advance of publication.

D. QUANTITIES OF SUPPLIES AND SERVICES

This contract is worth no less than \$1,000,000 and not more than \$25,000,000. The realistic expectation for this IDIQ contract vehicle is that the Government will expend \$1,000,000 - \$4,000,000 annually on an unidentified number of task orders. The Government is not required to order a minimum number of task orders from any contractor nor a minimum annual dollar value of services from any contractor. However, the Government is required to order a minimum of \$200,000 from each contractor during the life of the IDIQ. The Government expects to contract with 3-5 vendors.

E. INSPECTION AND ACCEPTANCE CRITERIA

Final inspection and acceptance of all work performed, reports and deliverables will occur at the place of delivery by the COTR. Final approval and acceptance of documentation required herein shall be by letter of approval and acceptance by COTR. The Contractor shall not construe any letter of acknowledgment of receipt material as a waiver of review, or as an acknowledgment that the material is in conformance with this SOW.

The Government will monitor performance and review deliverables utilizing solicited and unsolicited feedback.

F. CHANGES TO STATEMENT OF WORK

Any changes to this SOW shall be authorized and approved only through written correspondence from the CO. Costs incurred by the contractor through the actions of parties other than the CO shall be borne by the contractor.

G. GOVERNMENT RESPONSIBILITIES

The government shall assure that the contractor has access to VBA reference material, program documentation and the VBA SharePoint site as appropriate.

H. KEY PERSONNEL

The Contractor shall be responsible for managing and overseeing the activities of all Contractor personnel, as well as subcontractor efforts used in performance of this effort. The Contractor's management responsibilities shall include all activities necessary to ensure the accomplishment of timely and effective support, performed in accordance with the requirements contained in the statement of work.

The Contracting Officer may notify the Contractor and request immediate removal of any personnel assigned to the task order by the Contractor that are deemed to have a conflict of interest with the government or if the performance is deemed to be unsatisfactory. The reason for removal will be documented and replacement personnel shall be identified within three business days of the notification. Employment and staffing difficulties shall not be justification for failure to meet established schedules.

1. Key Personnel: Certain skilled experienced professional and/or technical personnel are essential for accomplishing the work to be performed. These individuals are defined as "Key Personnel" and are those persons whose resumes were submitted and marked by the vendor as "Key Personnel". Substitutions shall only be accepted if in compliance with "Substitution of Key Personnel" provision identified below.

<u>Name</u>	<u>Title</u>
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2. Substitution of Key Personnel: All Contractor requests for approval of substitutions hereunder shall be submitted in writing to the COTR and the Contracting Officer at least thirty (30) calendar days in advance of the effective date, whenever possible, and shall provide a detailed explanation of the circumstances necessitating the proposed substitution, a complete resume for the proposed substitute, and any other information requested by the Contracting Officer necessary to approve or disapprove the proposed substitution. New personnel shall not commence work until all necessary security

requirements, as defined in Section J, have been fulfilled and resumes provided and accepted. The COTR and the Contracting Officer will evaluate such requests and promptly notify the Contractor of approval or disapproval in writing.

I. PERSONNEL QUALIFICATIONS:

- a. Successful contractor shall have personnel with a proven track record of providing medical monitoring programs for high risk occupational groups, as well as designing and providing web and other communications activities.
- b. Personnel must be experienced in enrollment of workers, performance of work history interviews and review of exam reports and *Results Letters*.
- c. The Contractor shall document that the qualifications of the professional, technical and administrative staff proposed are adequate for full performance of tasks. Curriculum Vitae (CVs) or detailed bios are provided for each proposed staff member.
- d. The Contractor shall identify the key roles and specific responsibilities for each key role of the professional, technical and administrative staff proposed.
- e. The Contractor shall demonstrate the appropriate mix and balance of education, academic excellence, training and experience of proposed team members.
- f. The Contractor shall ensure that proposed program managers and senior level professionals are qualified, and available for consultation with (INSERT GOVT ENTITY) from 8 am EST to 6 pm PST.
- g. Project Manager: Must have 5 to 10 years experience in managing similar programs for high risk occupations.
- h. IT manager: Must have as a minimum, 5 years experience in development of software for similar systems.
- i. Technical Director: Must have a minimum of 5 years experience in occupational high risk management. Dr, PhD or M.P.H. in occupational environmental health or related field is highly desirable. Must have expertise in managing similar governmental projects, and proven leadership in occupational medicine advancements for web-based electronic health IT.
- j. Communications Director: Must have a minimum of 5 years experience in communications planning and implementation, including proven track record in web communications.

J. SECURITY – PRIVACY REQUIREMENTS

General - All Contractors and Contractor personnel shall be subject to the same Federal

laws, regulations, standards and (INSERT GOVT ENTITY) policies as (INSERT GOVT ENTITY), and (INSERT GOVT ENTITY) personnel, regarding information and information system security. Contractors shall follow policies and procedures outlined in (INSERT GOVT ENTITY) Directive 6500, *Information Security Program* and its handbooks to ensure appropriate security controls are in place. Furthermore, Contractors are to adhere to all requirements established in (INSERT GOVT ENTITY) Handbook 6500.6, Contract Security, dated March 12, 2010.

See Appendix 1: Security & Privacy Requirements for additional language. **POINT OF**

CONTACT: For questions, contact [REDACTED]

Schedule of Deliverables	
Deliverable	Description
Task 1: Study Design and Data Collection	
Deliverable 1	Obtain necessary IRB and OMB approval
Deliverable 2	Develop Contact Information/Locate Addresses
Deliverable 3	Conduct a Pilot Study
Deliverable 4	Data Management
Deliverable 5	Data Entry
Deliverable 6	Data Delivery
Task 2: Auxiliary/Support Services	
Deliverable 7	Design and Print Mail Materials
Deliverable 8	Assemble, Address, and Mail Materials
Deliverable 9	Design and Maintain a Web Site and Online Questionnaire
Deliverable 10	Telephone Interview Using CATI (Computer-Assisted Telephone Interview) System
Deliverable 11	Medical Records Retrieval and Coding
Deliverable 12	Data Security Procedures
Deliverable 13	In-Person Measurement Study
Deliverable 14	Follow-up Contacts with Veterans and Health Care Providers
Deliverable 15	Veteran Technical Assistance
Deliverable 16	Payment of Incentives and Additional Incentive for Veterans to Maximize Participation

Task 3: Data Analyses and Reporting		
Deliverable 17	Analyses of Data	
Deliverable 18	Provide Monthly Progress Reports	
Deliverable 19	Methodology Report	
Deliverable 20	Final Data Analyses Report	
Deliverable 21	Post-Stratification Weighting Analysis Plan	
Deliverable 22	Manuscript Collaboration	