

**JUSTIFICATION TEMPLATE**  
**Airborne Hazards and Open Burn Pit Registry Self-Assessment Questionnaire**

**B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

Public Law 112-260 requires the Department of Veterans Affairs (VA) to “establish and maintain” a registry to “ascertain and monitor the health effects” of potential exposures in eligible individuals. Because of self-selection bias, the registry is unlikely, to provide “reliable” data generalizable to the population of all eligible individuals. The overarching goal of VA’s analysis and reporting of self-assessment data is to improve VA’s understanding of Veteran health and VA programs related to environmental hazards encountered during deployment to contingency operations. VA will provide periodic adhoc reports to quantify and monitor the health of Veterans who self-report that they may have been exposed to open burn pit emissions, or other airborne hazards, such as elevated levels of particulate matter in the ambient air during their service. These results may help improve VA programs related to health care and help develop hypotheses for follow-on research.

- 1. Provide a numerical estimate of the potential respondent universe and describe any sampling or other respondent selection method to be used. Data on the number of entities (e.g., households or persons) in the universe and the corresponding sample are to be provided in tabular format for the universe as a whole and for each strata. Indicate expected response rates. If this has been conducted previously include actual response rates achieved.**

Potential respondents include all members of the Armed Forces (Army, Navy, Air Force, Marine, Coast Guard, Active National Guard, and Reserve) who deployed in support of a contingency operation in the Southwest Asia theatre of operations (approximately 700,000) on or after August 2, 1990 or Afghanistan or Djibouti on or after September 11, 2001 (approximately 2.4 million). There is no sampling plan. All members of the Armed Forces who meet the above criteria are eligible per Public Law 112-260.

Statistical methodology for stratification and sample selection: There is no statistical sample selection involved in this collection. All individuals who meet eligibility criteria in VA records derived from Department of Defense (DoD) sources (e.g. VA Defense Information Repository (VADIR)) are eligible to complete the self-assessment questionnaire. Data from optional in-person medical evaluations and other Veterans Health Administration (VHA) clinical data will be linked to the individuals’ responses on the self-assessment questionnaire in accordance with the appropriate VHA Systems of Record Notices. Refer to 173VA005OP2 VA Mobile Application Environment (MAE) –VA, 172VA10P2 VHA Corporate Data Warehouse-VA, and 24VA10P2 Patient Medical Record –VA).

Estimation procedure: Based on past experience with other VA Special Environmental Health Registries required by law (e.g. Agent Orange, Gulf War), approximately 11% of the eligible population may participate over a ten year period.

Degree of accuracy needed: Participation is voluntary. VA cannot control participation. We will use the data generated by this study to generate hypotheses about exposure response relationships rather than test such hypotheses. Subsequent studies would be needed to test any hypotheses.

## **2. Describe the procedures for the collection of information:**

VA has incorporated the launch of the Airborne Hazards and Open Burn Pit Registry into a broader strategy related to the long-term health effects of airborne hazards such as burn pits and to provide appropriate follow-up medical care for active-duty Veterans and Servicemembers. This communications plan relies heavily on the use of intermediaries to promote awareness of and participation in the Airborne Hazards and Open Burn Pit Registry. Using this strategy, Post-Deployment Health will build relationships with established Veteran points-of-contact (e.g., public affairs officers, Operation Enduring Freedom (OEF)/ Operation Iraqi Freedom (OIF)/Operation New Dawn (OND) Program Managers, Women Veterans Call Center, Veterans Service Organizations, Environmental Health Clinicians/Coordinators) and provide them with resources to promote the registry.

When the registry is ready to launch, VA may notify Veterans through various means including a news release, social media, VHA and Office of Public Health Web sites, and Environmental Health Coordinators and OEF/OIF/OND Program Managers interacting directly with Veterans. In addition to being informed about the registry launch, Veterans will be directed to: (1) talk to their primary care provider or Patient Aligned Care Team (PACT) to schedule an appointment for a medical evaluation if they are already enrolled in VA health care, (2) contact an Environmental Health Coordinator at the nearest VAMC if not already enrolled in VA health care, or (3) discuss any concerns or health issues with their health care provider if a Servicemember. Veterans can find the nearest Environmental Health Coordinator by visiting the following link: <http://www.publichealth.va.gov/exposures/coordinators.asp>.

## **3. Describe methods to maximize response rate and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield “reliable” data that can be generalized to the universe studied.**

To maximize registry participation, VA will utilize multiple modes of communication to inform eligible Veterans of the benefits of participation (as required in Public law 12-260). Existing registries that require in-person evaluations for participation have an average cumulative response rate of 11%.

Data from a previous large scale population based health survey of OEF/OIF Veterans indicated the prevalence of self-reported exposures to airborne hazards to be anywhere from 38-91%, depending on the particular exposure. So while VHA can estimate the total number of potentially eligible Veterans, there is no way to determine the range of exposures which will be reported in Veterans who choose to participate in the registry, making it difficult to determine response bias as a function of exposure. However, based on DoD records of Servicemembers, we may be able to examine whether there are patterns with respect to demographic characteristics, length of service, or location of service, which could be surrogates of exposure.

Recent VA reports suggest that Veterans and Servicemembers from OEF/OIF/OND and the Gulf War rely on using the internet as an information source. In order to maximize potential registry participation among Veterans and Servicemembers, VA is developing a web-based system to enable eligible individuals to enroll in the registry by completing an online self-assessment questionnaire. In person medical evaluations, in addition to the web based questionnaire, will be provided if Veterans request them.

VA plans to communicate information about the registry to Veterans, Servicemembers, and stakeholders regarding how to sign-up, how long the questionnaire will take to complete, and the benefits of registering through various modes of communication. VA plans to use social media sites such as Facebook and Twitter to advertise the registry. VA will also post information about the registry on its websites. VA expects that by using social media sites, websites, and postcard/fact sheets to inform Veterans about the value of participating in the registry, participation in the registry will be maximized. VA will additionally distribute postcards and fact sheets containing important information about the registry and how to participate at VA Medical Centers. In addition, VA will publicize information about the registry through VA news releases.

Improving participation in the registry also involves coordinating with key stakeholders, such as Veterans Service Organizations (VSOs). This will enable VSOs to provide information directly to Veterans through their normal channels of communication. Since the law was enacted, VA's Office of Public Health (OPH) has informed VSOs of its progress in meeting the requirements of Public Law 112-260. OPH will continue to work closely with VSOs before and after the registry is launched to ensure Veterans and Servicemembers continue to receive accurate and helpful information.

**4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions of 10 or more individuals.**

No testing of the instrument employed to collect self-reported data will be done in more than 10 individuals. The legislative mandate to establish the registry within 12 months of enactment of Public Law 112-260 requires VA to leverage existing survey questions to the maximum extent possible (e.g. the National Health Interview Study (NHIS) for health conditions and symptoms) and use expert consensus for the development of questions where existing questions are insufficient to meet the goals of the registry (e.g. environmental exposures unique to military service in contingency operations). By law, VA will contract with an independent scientific organization upon approval of this information collection to provide recommendations within the two-year statutory requirements of Public Law 112-260, on how to improve the registry program, to include improving the questionnaire as necessary. A review of the registry data will help guide these improvements which may require a PRA review.

VA performed extensive one-on-one software usability testing with eight Veterans to improve the web application user interface. VA will perform additional technical testing of the web system in a production environment upon OMB approval of this information collection to ensure system functionality under varying system loads.

**5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.**

Expert statistical consultation was provided by staff within the VHA Office of Public Health, Post-Deployment Health Group, POC Dr. Erin Dursa (202) 461-1020. The data will be collected and analyzed by the VHA Office of Public Health, Post-Deployment Health Group, POC Dr. Paul Ciminera, (202) 461-1020.