National Firefighter Registry

OMB Control No. 0920-NEW

Type: New

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Date: 10-23-2020

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Part B. Collections of Information Employing Statistical Methods

# B.1. Respondent Universe and Sampling Methods

The NFR will be a surveillance system of adult (> 18 years of age) U.S. firefighters designed to evaluate cancer rates and occupational risk factors in the current U.S. firefighting workforce. There are over 1.1 million firefighters currently serving in the United States (NFPA, 2018). The goal of this project is to achieve a total NFR sample (i.e., General NFR Sample) of > 200,000 respondents 5 years after beginning enrollment that is diverse demographically (gender, race, ethnicity, etc.), geographically, and by firefighting specialization (fire investigation, wildland firefighting, etc.) and type of firefighter (career, volunteer, paid-on call, etc.). There will be no exclusion or inclusion criteria based on cancer or health status. There will be two components of the comprehensive General NFR Sample: a subsample comprised of a **Targeted Cohort** for assessing cancer incidence; and a more-inclusive **Open Cohort** for evaluating current trends in, or prevalence of, firefighter cancer risk factors.

*Sampling Design*

The Targeted Cohort will provide a diverse population at risk required for assessing cancer incidence and a method for ensuring adequate samples sizes of women, minorities, and volunteers, as mandated by the Firefighter Cancer Registry Act of 2018 (Act). The Targeted Cohort will be a prospective cohort of currently active firefighters recruited from two sampling frames: 1) fire department rosters, and 2) rosters from states that require regular recertification or documented training of all practicing firefighters in that state. Only a handful of states require recertification of all firefighters; any of these states able to share rosters with the NFR will likely be eligible for inclusion in the Targeted Cohort. But because there are roughly 25,000 fire departments in the U.S., spread across all states and territories, a strategy has been developed for identifying departments to participate in the Targeted Cohort (Attachment 3).

Targeted career and volunteer departments in the Targeted Cohort will be selected in two sampling phases. Phase 1 will include identification of and recruitment from departments with high numbers of female, minority, and volunteer firefighters. Phase 2 will utilize a random design stratified by the nine US Census divisions to select a geographically diverse sample of career and volunteer departments in order to maximize generalizability.

We used estimates for a hypothetical cancer incidence analysis informed by results of a previous NIOSH study (Daniels, et al. 2014) to estimate minimum sample sizes of participating firefighters necessary for the Targeted Cohort (See B.2.). Assuming roughly 50% participation at each department, we estimate that we would need approximately 135 departments to participate in the Targeted Cohort to achieve these minimum sample sizes. However, if one or more states contribute their certification database rosters, we can reach the sample size benchmarks with fewer individual departments. Therefore, the number of departments is subject to change. Nonetheless, department participation is critical for accessing incident records for a majority of those in the Targeted Cohort. We will strive for larger sample sizes than these benchmarks to the extent possible, as larger sample sizes will allow us to examine more granular subgroups of workers and more specific cancer sites with greater statistical power.

The Open Cohort will involve a non-probability sampling design and include all firefighters that voluntarily complete enrollment through the secure web portal not otherwise recruited for the Targeted Cohort. All adult members of the U.S. fire service, regardless of subspecialty, including active, former, and retired members, who have ever been an active firefighter will be eligible to join the NFR through this method. Some departments with high participation from the Open Cohort (e.g., >70% of the department’s fire personnel) may be added to the Targeted Cohort.

*Sample Considerations*

The Targeted Cohort will provide a sample of firefighters for assessing cancer incidence rates and ensuring high participation from subgroups mandated by the Act. This enrollment group will be important for several reasons, including: 1) this approach will limit selection/participation bias with specific eligibility criteria and a sampling design; 2) quality exposure information can be obtained from department records; 3) the design provides a defined population at risk for calculating cancer incidence rates; and, 4) department workforce information allows for the assessment of NFR response characteristics and potential biases of the Open Cohort. However, this enrollment method will be relatively cost and labor intensive.

On the other hand, enrolling large numbers of NFR respondents through the Open Cohort will be relatively quick and cost-effective. Further, because of the broad eligibility criteria for the Open Cohort, this approach will provide the opportunity for any fire service members to participate in the NFR, including subgroups/subspecialties not recruited through the Targeted Cohort (e.g., wildland firefighters). However, because of the non-probability sampling design, some firefighters may be more likely to register than others based on characteristics such as cancer status (i.e., selection/participation bias). Therefore, the Open Cohort may limit the ability of investigators to make statistical inferences related to cancer rates from this sample.

*Sample Size Calculation*

NFR data will be evaluated by NIOSH staff and external researchers for various potential analytic objectives, including but not limited to descriptive and hypothesis-generating investigations of cancer risk factors, exposure-response analyses, and comparisons of cancer risk and risk factors between subgroups of firefighters as well as external/general populations. Data analysis objectives and plans may change and evolve over time as the cohort grows and surveillance needs develop. However, a primary goal is to monitor trends in cancer incidence among firefighters (e.g., incidence rates), as specified in the mandate. A sample size calculation was used to determine the minimum baseline sample sizes in the Targeted Cohort (i.e., number of currently active firefighters) necessary to detect elevated cancer incidence rates for select subgroups of interest.

The sample size calculations were based on attaining 80% power from a Poisson regression with 30 years of follow-up, comparing the observed cancer rate of the cohort to the U.S. population cancer rate with an α = 0.05 level of significance. It was further assumed that the cohort would grow by 2.5% per year as was calculated from the Daniels et al. (2014) study data. Population death rates and cancer incidence rates were obtained from CDC Wonder and the average of the most recent 5 years (2012-2017 for mortality and 2011-2016 for incidence) was used and assumed to remain constant into the future. Using this information, an initial targeted cohort of 5,000 firefighters is needed to observe a standardized incidence ratio (SIR) of 1.09 for all cancer sites among a general sample of firefighters; a similar number of non-white firefighters (i.e., 6,500) is needed to observe an SIR 1.09 for all cancer sites among a sample of only non-white firefighters; and 1,000 female firefighters are needed to observe an SIR of 1.45 for breast cancer among a sample of only female firefighters. The SIRs for these calculations were obtained from the Daniels et al. (2014) study.

These sample sizes were used to determine the minimum number of departments to recruit for the Targeted Cohort. More specifically, mean reported counts of firefighters from a recent National Fire Protection Association (NFPA) census of U.S. fire departments were used to estimate current workforce sizes. Under an assumption of 50% participation rate, we estimate that the proposed fire department sampling strategy will contribute a baseline sample of roughly 26,000 firefighters, including approximately 1,000 women, 6,500 non-white firefighters, and 5,000 volunteers, that will grow to roughly 56,000 after 30 years of follow-up by 2050 (assuming an annual growth rate of 2.5%). The number of necessary fire departments could change based on observed participation rates and participation from state firefighter certification databases, which would greatly increase the sample size and potentially reduce the number of individual departments necessary to recruit for the fire department sampling strategy (Attachment 3).

# B.2. Procedures for the Collection of Information

*Collection of Information*

The primary objectives of the NFR are to: 1) Collect self-reported information from firefighters on employment/workplace characteristics, exposures, demographics, lifestyle factors, co-morbidities, and other confounders related to cancer; 2) Obtain records from fire departments/agencies to track trends and patterns of exposure as it relates to cancer in firefighters; 3) Monitor cancer in firefighters by linking with health information databases (e.g., population-based cancer registries and the National Death Index (NDI)) to assess cancer incidence and mortality.

Firefighters will be recruited by disseminating informational, promotional, and recruitment materials directly and through stakeholders, membership organizations, social media, and trade literature (Attachment 4). Individual enrollment into the NFR, for firefighters both in the Targeted and Open Cohorts, will involve providing consent in addition to self-reported exposure, demographic, health, and lifestyle information in a secure, online web portal.

To enroll as part of the Open Cohort, an individual firefighter will make an account through login.gov, provide consent (Attachment 3a), and complete the user profile and questionnaire (Attachment 3b, 3c) in the web portal. The process for enrolling individuals in the Targeted Cohort will first require selected departments or states to provide NIOSH with an active employment roster for recruitment purposes. NIOSH will then contact individuals to invite them to enroll. Contacted firefighters will either consent and enroll through the web portal, or they will be unresponsive or choose not to consent. In the latter case, NIOSH will not use any of the individuals’ information and they will not be included in the NFR. NIOSH will also request incident and employment records from departments participating in the Targeted Cohort. This process will be repeated for the Targeted Cohort every few years to obtain updated incident records and to actively recruit new firefighters since the last date records and rosters were shared. Nevertheless, enrollment will be open and available for firefighters on a continuous basis regardless of enrollment cohort.

*Enrollment Web Portal*

NIOSH is developing a secure web portal that allows any firefighter in the nation to self-register. The web portal will meet all requirements of the Federal Information Security Management Act of 2002 (FISMA). Firefighters will access the web portal through the dedicated NFR website (<https://www.cdc.gov/niosh/firefighters/registry.html>). This website will include frequently asked questions (FAQs) and other important background information about the NFR. After reviewing the NFR website, firefighters interested in enrolling in the registry will click the “REGISTER” icon. This will take them to the secure web portal, which will have multi-factor authentication (MFA) (see Data Security section for more details).

To complete enrollment in the NFR, the firefighters will need to first complete the informed consent document (Attachment 3a), then the user profile (Attachment 4b), and then the enrollment questionnaire (Attachment 4c). Icons for each of these documents will be included on their profile page or dashboard. If firefighters have questions that are not included or fully answered in the FAQs, they can call the NIOSH investigators at the phone number provided on the informed consent document. The questionnaire is expected to take less than 30 minutes to complete.

Once the questionnaire has been completed and submitted, all responses will be uploaded to a secure server and the firefighter respondent will no longer be able to access the questionnaire responses. Clicking the “back” icon will not pull up the responses. However, the profile page or dashboard will include the profile data that was entered (see Attachment 4b). All this information can be viewed and edited from the dashboard, but only after the respondent successfully logs in using MFA.

*Data Sharing*

The Firefighter Cancer Registry Act of 2018 recommends CDC/NIOSH make data available to the public. As such, NFR data will be accessible to external researchers through a Research Data Center (RDC). All requests for individual-level NFR data files must be made through a proposal to the RDC. The proposal will be reviewed by the RDC, CDC/NIOSH, and any state/population-based cancer registry (if applicable) outlined in the proposal. If approved by all parties, the appropriate data files will be provided to the researcher via the RDC for analysis. All direct identifiers (e.g., name, social security number) will be removed but indirect identifiers (e.g., sex, age, race/ethnicity) can be provided at the individual level for analysis. Some data on indirect identifiers or other characteristics may be redacted to minimize the possibility of identifying participants; for example, where indirect identifiers taken together could narrow the list of possible individuals to a small group of people with those characteristics. External researchers will only be permitted to remove summary data tables from the RDC, which RDC staff will review before releasing to the external researchers to ensure that participants cannot be indirectly identified.

# B.3. Methods to Maximize Response Rates and Deal with No Response

We will maximize participation through working with stakeholders from local, state, national, and federal organizations including representatives from academic institutions, other federal agencies, fire and emergency response organizations, firefighter unions, fire departments, and cancer registry experts.

A realistic estimate for response rate is unknown because self-reported information from firefighters for cancer surveillance has not previously been collected on a national level; additionally, we expect response rates to vary drastically by subgroups of firefighters (for example, career vs volunteer firefighters). However, two projects (the World Trade Center Health Registry and preliminary results from the Career Firefighter Health Study) provide response estimates for health-focused interviews and surveys of regional firefighters of ~70% and ~30%, respectively. Hence, we expect a response rate that is less than 80%.

NIOSH will have the ability to identify potential biases affecting the NFR sample by comparing the demographics and characteristics of NFR respondents to those of the U.S. firefighter workforce that are provided by external sources, such as NFPA, USFA, and the U.S. Bureau of Labor Statistics. Likewise, internal comparisons of NFR subsamples will identify strengths and limitations of pooling data, stratified analyses, sensitivity analyses, and controlling for select covariates. Additionally, with roster information available from fire departments and states selected in the Targeted Cohort serving as denominator estimates, NIOSH will be able to evaluate estimates of response and non-response.

# B.4. Test of Procedures or Methods to be Undertaken

The project team will request all information for the NFR electronically. The enrollment questionnaire and informed consent document will be made available to all interested respondents via a designated, secure web portal. Additionally, the respondents will have the option to print a copy of the informed consent document for their records. The questionnaire has been reviewed by subject matter experts who understand the importance of, and are mindful to, burden reduction for respondents. The subject matter experts have assisted with prioritization of information requested in the enrollment questionnaire to ensure that the vital information is being captured without any additional burden.

The NFR enrollment questionnaire has been reviewed by a survey methodologist to ensure quality and proper organization of questions. Additionally, several members of the U.S. Fire Service have reviewed and piloted the enrollment questionnaire for time burden, subject accuracy, and content organization. Skip patterns based on respondent selections are built into the questionnaire to minimize the burden of unnecessary questioning of respondents. Finally, we will have preprogrammed dropdown menus for capturing information such as place of employment and various demographics.

# B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The individuals listed in Table 1 and Table 2 have been consulted on the statistical design and/or will be responsible for the collection and analysis of information

**Table 1.** Personnel Consulted on Statistical Design

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Title** | **Affiliation** | **Phone** | **Email** |
| *FEDERAL AGENCY* |
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| Elizabeth Whelan | Branch Chief | NIOSH | *(513)841-4437* | Eaw0@cdc.gov |
| Andrea Wilkinson, MS | Health Scientist | NIOSH | *(513)458-7155* | Olq2@cdc.gov |

**Table 2.** Personnel Responsible for Collection and Analysis of Information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Title** | **Affiliation** | **Phone** | **Email** |
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| Miriam Siegel, DrPH | Lead Epidemiologist | NIOSH | *(513)841-4517* | Wrm9@cdc.gov |
| William Wepsala, MPA | Health Communications Specialist | NIOSH | *(513)841-4574* | Pqz3@cdc.gov |
| Andrea Wilkinson, MS | Health Scientist | NIOSH | *(513)458-7155* | Olq2@cdc.gov |

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