

The National Firefighter Registry for Cancer
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Request for Office of Management and Budget (OMB) Review and Approval
For a Federally Sponsored Data Collection

Revision

Part B

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The NFR is a surveillance system of adult (≥ 18 years of age) U.S. firefighters, or a database of occupational and health information on firefighters designed to evaluate cancer rates and occupational risk factors in the current U.S. firefighting workforce. The goal is to achieve an enrollment that is diverse demographically (gender, race, etc.), geographically, and by firefighting specialization (arson investigation, wildland firefighting, etc.) and type of firefighter (career, volunteer, paid-on call, etc.). There is no exclusion or inclusion criteria based on cancer or health status. There are 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.

The Targeted Cohort will provide the population at risk required for assessing cancer incidence by targeting a sample of firefighters from career and volunteer fire departments that are diverse by geographic, demographic, and occupational characteristics, and following their vital and cancer status prospectively. The Targeted Cohort will be a prospective cohort (continuous enrollment). Firefighters in the Targeted Cohort will be recruited from two sampling frames: selected departments and state firefighter certification registries. Eligible participants will be all current firefighters from selected departments or states with rosters of certified firefighters. These eligible fire personnel will be invited by NIOSH to participate in the NFR. Additionally, departments with high participation from the Open Cohort (e.g., $\geq 70\%$ of the department's fire personnel) may also be added to the Targeted Cohort, as described below in the *Open Cohort* section.

The Open Cohort involves a non-probability sampling design and includes all firefighters that complete enrollment through the secure web portal not otherwise recruited for the Targeted Cohort. All adult members of the U.S. fire service, including active, former, and retired members, who have ever been an active firefighter are eligible to join the NFR through this method. This includes former firefighters at fire departments selected for the Targeted Cohort. Additionally, the Open Cohort is designed to recruit large representation from sub-specialties of firefighting, such as wildland, instructors, fire investigators, and airport rescue. Participants are able to enroll on a continuous basis.

B2. Procedures for the Collection of Information

Targeted Cohort Sampling Strategy

Firefighters for the Targeted Cohort will be identified by a combination of stakeholder selection and random sampling. As instructed by the Act, this design will oversample for female, minority, and volunteer firefighters. Firefighters from both the Targeted and Open Cohorts will be recruited by disseminating informational and promotional materials directly and through stakeholders, membership organizations, social media, and trade literature.

The Targeted Cohort will be important for several reasons, including: 1) sampling for a representative cohort of firefighters to provide accurate estimates of cancer incidence, prevalence, and mortality, 2) obtaining quality exposure information supplied by employment and incident records, and 3) providing denominator estimates (i.e., department roster) for which to assess response characteristics and potential biases of the NFR sample.

Because of the non-probability sampling design of the Open Cohort, some firefighters may be more likely to register than others based on characteristics such as cancer status. Therefore, the Open Cohort may limit the ability of investigators to make statistical inferences from this sample because those who enroll in this manner may be different from the general population of firefighters. Nevertheless, NFR data from these participants will be helpful to NIOSH investigators for descriptive analyses and generating hypotheses. Further, this approach would provide the opportunity for any fire service members to participate in the NFR and for NIOSH investigators to have a relatively quick and cost-effective means for cross-sectional analysis of characteristics relevant to reducing cancer incidence in the U.S. fire service.

Participation is voluntary and firefighters who agree to participate complete an informed consent and enrollment questionnaire. The enrollment questionnaire obtains information about work and exposure history, demographics, co-morbidities, and lifestyle factors, as outlined in the Act. This information will be linked with data from federal vital records and state cancer registries to monitor cancer diagnoses and improve our knowledge about cancer risks for firefighters, especially those linked to workplace exposures.

Power/Sample Size Calculations

A sample size calculation was used to determine the minimum baseline sample sizes (i.e., number of currently active firefighters) necessary to detect elevated cancer 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 US population cancer rate with an $\alpha = 0.05$ 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 an SIR of 1.09 for all cancer sites, 6,500 non-white firefighters are needed to observe an SIR 1.09 for all cancer sites, and 1,000 women firefighters are needed to observe an SIR of 1.45 for breast cancer. 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 with the fire department sampling strategy. More specifically, mean reported counts of firefighters from a recent NFPA census of U.S. fire departments were used to estimate current workforce sizes. Under an assumption of 50% participation rate, it is estimated that the proposed fire department sampling strategy will contribute a baseline sample of roughly 26,000 firefighters,

including at least 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%).

With participation from fire departments selected in the fire department sampling strategy and multiple states, the Targeted Cohort could be used to evaluate even smaller measures of effect, more subgroups of firefighters, and rarer cancers.

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

To complete enrollment in the NFR, the firefighters need to first complete the informed consent document (Attachment 3a) and then the user profile (Attachment 3b) and then the enrollment questionnaire (Attachment 3c). Icons for each of these documents are included on their profile page or dashboard. If firefighters have questions that are not included or fully answered in the FAQs, they can email the NIOSH investigators at the email address provided on the informed consent document or call or email the designated help desk listed on the web portal.

After completing and electronically signing the informed consent document, firefighters are taken to a user profile page. This page serves to collect basic information from the firefighter that could change overtime and hence can be accessed and updated by the user. After completing the user profile questions, the firefighter has the option of completing the enrollment questionnaire. The questionnaire collects information on employment/workplace characteristics, exposure, demographics, lifestyle factors, co-morbidities, and other confounders.

The last question of the demographics section of the questionnaire asks for the participant’s last four digits of the Social Security Number (SSN). The questionnaire explains why the last four digits of the SSN is needed, “In the United States, each state has a cancer registry that collects and combines information on all cancer diagnoses from all hospitals in that state. Providing the last four digits of your social security number (SSN) will increase the likelihood of linking your profile and questionnaire information to any past or potentially future cancer diagnosis reported to a state. This information is necessary to meet the statutory requirements of the Firefighter Cancer Registry Act of 2018. You can choose to provide this information or not. As noted on the informed consent, all your private information will be encrypted, secured, and protected to the fullest extent allowed by law”.

An icon is provided next to the SSN question where firefighters can learn more information about why they are being asked for the last four digits of their SSN. If they click the icon, the firefighter is shown the following message:

“Why are we asking for this?

We need to track firefighters’ health over time to truly understand their cancer risks and improve their protections. Sharing the last four digits of your social security number will let us do this by linking your information to state cancer registries. With this information we can see any potential future cancer diagnosis without any further action from you. Each firefighter that shares this information will increase the accuracy of our findings, which could potentially lead to greater protections for all firefighters. Sharing the last four digits of your social security number will ensure your participation has the maximum impact.

We will protect your information to the fullest extent allowed by law. The National Firefighter Registry is covered by an Assurance of Confidentiality, which is the highest level of protection available for identifiable information. Under this formal protection, we are not allowed to share your identifiable information without your written permission.”

If firefighters are unable to complete the questionnaire in one sitting, they can log-off and return at a later date to complete it. If they did not complete registration after completing the informed consent, they receive a reminder email using the email address they provided during login and/or a text message using the mobile phone number they provided as part of the consenting process. If necessary, another reminder email or text message will be sent 7 days, 14 days, 28 days, 42 days, and 90 days later. If there is no response after 90 days, no further emails or text messages will be sent.

Once the questionnaire has been completed and submitted, all responses will be uploaded to a secure server and the firefighter participant 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 4c). All this information can be viewed and edited from the dashboard, but only after the participant successfully logs in using MFA.

B3. Methods to Maximize Response Rates and Deal with No Response

NIOSH is maximizing 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. NIOSH is also actively reaching out to fire leadership and union leadership (if applicable) at select fire departments as part of the targeted enrollment process and providing instruction and enrollment assistance to firefighters from these departments.

A realistic estimate for response rate is unknown because no similar studies have been done on a national level; additionally, response rates are expected to vary drastically by subgroups of firefighters (for example, career vs volunteer firefighters). A response rate that of less than 25% is expected for firefighters who hear about the NFR through open enrollment communications, and 70% or less for firefighters in the targeted enrollment population.

NIOSH will have the ability to identify potential biases affecting the NFR sample, such as response bias, by comparing the demographics and characteristics of NFR participants to those of the U.S. firefighter workforce that are provided by NFPA, USFA, and BLS, as well as comparing the Open Cohort and Targeted Cohort. Additionally, with roster information available from fire departments selected in the Targeted Cohort serving as denominator estimates, NIOSH will be able to evaluate characteristics of response and non-response.

B4. Tests of Procedures or Methods to be Undertaken

All information is currently requested electronically. The enrollment questionnaire and informed consent are available to all interested participants via the designated, secure web-portal. The questionnaire has been reviewed by subject matter experts who understand the importance of and are mindful to burden reduction of 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 reviewed and piloted the enrollment questionnaire for time burden, subject accuracy, and content organization. Prior to the national launch, 7 fire departments pilot tested the enrollment system for usability and technology testing. Skip patterns based on participant responses are built into the questionnaire to minimize the burden of unnecessary questioning of participants. Additionally, preprogrammed dropdown menus for capturing information such as place of employment and various demographics will be included.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Table 1. Personnel Consulted on Statistical Design

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