National Firefighter Registry

OMB Control No. 0920-NEW

Type: New

Supporting Statement Part A –

Justification

Program Official/Project Officer: Kenneth Fent, PhD, CIH
Title: Team Lead, Research Industrial Hygienist
Phone: 513-841-4569
Email: kif5@cdc.gov
Fax: 513-841-4486

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Part A. Justification

Goal of the study: The main goal of the National Firefighter Registry (NFR), according to the Firefighter Cancer Registry Act of 2018, is, "to develop and maintain…a voluntary registry of firefighters to collect relevant health and occupational information of such firefighters for purposes of determining cancer incidence."

Intended use of the resulting data: Results from the NFR will provide information for decision makers within the fire service and medical or public health community to devise and implement policies and procedures to lessen cancer risk and improve early detection of cancer among firefighters.

Methods to be used to collect: The NFR will utilize multiple recruitment methods (i.e., an Open Cohort and a Targeted Cohort) and obtain consent and self-reported information through a secure web portal. The information collected for the NFR will be linked with records from state cancer registries, the National Death Index (NDI), and other information databases to monitor cancer incidence and mortality.

Subpopulation to be studied: Active, former, and retired U.S. firefighters

How data will be analyzed: Statistical analyses will be conducted in order to answer various questions related to descriptive characteristics of the current U.S. firefighting workforce; how the risk of cancer and mortality (i.e., health outcomes) in firefighters compares to the general U.S. population; if cancer risk changes with increasing firefighter exposures or other risk factors; and how cancer risk and risk factors vary by subgroups of firefighters.

A.1. Circumstances Making the Collection of Information Necessary

This proposal is a new information collection request to complete work in accordance with the Firefighter Cancer Registry Act of 2018, which authorized funding of $2.5M per year for fiscal years 2020-2023. Three years of OMB approval are being requested.

The President of the United States signed the Firefighter Cancer Registry Act of 2018 in July 2018 (Attachment 1), authorizing the Secretary of Health and Human Services (HHS) to develop a voluntary registry to collect data on cancer incidence among firefighters [H.R. 931, Firefighter Cancer Registry Act of 2018]. On October 23, 2019, the Secretary of HHS delegated authority for the Registry to the Director of the National Institute for Occupational Safety and Health (NIOSH).

According to the Act, NIOSH is required to "improve data collection and data coordination activities related to the nationwide monitoring of the incidence of cancer among firefighters"

and “to collect, consolidate, and maintain, epidemiological information and analyses related to cancer incidence and trends among volunteer, paid-on-call and career firefighters” (Attachment 1 [Sec. 2 (b)]). NIOSH is authorized to collect individual cancer risk factors and occupational history; basic demographic information; status of the firefighter as either volunteer, paid-on-call, or career firefighter; total number of years of firefighting; approximate number or estimate of fire incidents; and other medical information and health history (Attachment 1 [Sec. 2 (c)]). NIOSH will collect this information to evaluate how the data relates to cancer risk among firefighters.

Few state cancer registries collect occupational information, and the occupational information collected by registries that do is often vague and incomplete (Freeman, et al. 2017). One study found that roughly half of career firefighters in Florida with a cancer diagnosis were missing an occupation classification in the cancer registry, and only 17% were classified as a firefighter in the cancer registry (McClure et al., 2019). The requested data collection will help bridge this gap by developing a secure/encrypted database, or registry, of U.S. firefighters, along with other information outlined above, that can be matched to state cancer and other population-based registries throughout the United States.

Data collection will occur through a secure web portal with multifactored authentication and will be open to all firefighters regardless of their health status, firefighting role or type of department, race, sex, or ethnicity (Attachment 3). It will also be open to both active and former firefighters. Participation is voluntary and will require informed consent (Attachment 3a).

Analyses of demographic subgroups in the fire service have been underpowered because study samples have consisted of predominantly white male populations. Because roughly 20% of career firefighters are non-white or racial/ethnic minorities, and approximately 8% of all firefighters are women, and select subspecialty groups of firefighters may be even more diverse (BLS, 2019; NFPA, 2018), findings are not necessarily generalizable to the entire workforce unless samples sufficiently represent these demographics. There will be two components of the National Firefighter Registry (NFR): a subsample comprised of a Targeted Cohort for assessing cancer incidence and involving focused enrollment of women, minorities, and volunteers; and a more-inclusive Open Cohort for describing cancer risk factors and other cross-sectional analyses (Attachment 3), which will also be used to recruit firefighters from a broad range of subspecialties (e.g., both structural and wildland firefighters, instructors, airport rescue personnel, etc.).

The goal is to enroll 200,000 firefighters in the NFR. The user profile (Attachment 3b) and enrollment questionnaire (Attachment 3c) are expected to take approximately 40 minutes to complete, which equates to a total of 44,443 burden hours and an estimated annualized total respondent cost of $1,059,966. The NFR will require a full-time staff of at least five NIOSH

employees (~$600,00 in personnel salary and benefits), along with travel, licensing, fees, and contracts, totaling approximately $2.5M per year through fiscal year 2023.

The 60-day Federal Register Notice was published on 04/27/2020 (Attachment 2) and is further discussed in Section A.8."

A.2. Purpose and Use of the Information Collection

The purpose of this information collection is for general purpose statistics to be gathered from a registry of U.S. firefighters with the intent to monitor cancer incidence and risk factors among the U.S. fire service. The information collected will be the basis for the NFR. With the goal of enrolling ≥ 200,000 firefighters within the first 5 years, NIOSH will have a large dataset of information that will be used to increase our understanding of firefighter exposures, work behaviors, cancer diagnoses, and other relevant risk factors.

Without this data collection, NIOSH will be unable to meet the requirements of The Firefighter Cancer Registry Act of 2018, specifically with respect to Sec. 2(b)(2) (Attachment 1), "To collect, consolidate, and maintain…epidemiological information and analyses related to cancer incidence and trends among firefighters." Currently, some population-based (i.e., state) cancer registries collect occupational information, but it is often vague and incomplete (Freeman, et al. 2017) because patient information related to work history is often not obtained in the healthcare setting. Among firefighters specifically, accurate occupational information can be especially spare in state cancer registries (McClure et al., 2019). This estimate would likely be much smaller for former or retired firefighters, or volunteers working a non-firefighting job, at the time of cancer diagnosis, since the extent of occupational information ascertained may relate only to current job. Therefore, there is not enough accurate information available from state cancer registries alone to produce comprehensive estimates of cancer burden and risk factors among the fire service nationally. The information being collected for the NFR will help bridge this gap and allow investigators to better understand how occupational risk factors (and other risk factors) relate to cancer in firefighters.

NFR information will be used in concert with other sources of information. The information collected for the NFR will be linked with records from state cancer registries, the National Death Index (NDI), and other information databases to monitor cancer incidence and mortality. The collected information will help answer questions related to descriptive characteristics of the current U.S. firefighting workforce, including how the risk of cancer and mortality (i.e., health outcomes) in firefighters compares to the general U.S. population; if cancer risk changes with increasing firefighter exposures, other risk factors or control measures; and how cancer risk and risk factors vary by subgroups of firefighters.

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. The goal is to achieve a total NFR sample (i.e., General NFR Sample) of close to 200,000 respondents 5 years after beginning 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 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 describing cancer risk factors and other cross-sectional analyses. Firefighters in both cohorts will complete the informed consent (Attachment 3a), user profile (Attachment 3b), and enrollment questionnaire (Attachment 3c) using a secure web portal. Anyone with internet access will be able to access the web portal, and it will minimize the burden on the firefighter by utilizing skip patterns and auto-populating fields according to previous responses (Attachment 3).

The intent of the NFR is to be generalizable to the U.S. Fire Service, however there may be potential biases that affect our results. NIOSH will 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 the National Fire Protection Association (NFPA), The United States Fire Administration (USFA), Bureau of Labor Statistics (BLS), and FireCARES (NFPA, 2015-2017). 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 selected in the Targeted Cohort serving as denominator estimates, NIOSH will be able to evaluate estimates of response and non-response. Cancer rates in firefighters will be compared to the U.S. general population (controlling for demographics and potential confounders). In addition, internal comparisons among firefighters will be utilized in the analysis because that is the most direct way to achieve partial control for the healthy worker effect and to explore exposure-response relationships.

A.3. Use of Improved Information Technology and Burden Reduction

It is the intent of the research team to request all information for the NFR electronically. The informed consent, user profile, and enrollment questionnaire will be made available to all interested respondents via a 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 (physicians, epidemiologists, survey methodologists and U.S. firefighters) have assisted with prioritization of information requested in the enrollment questionnaire to ensure that the vital information is being captured without any additional, unnecessary burden.

The web portal will meet all requirements of the Federal Information Security Management Act of 2002. Firefighters will access the web portal through the NFR website (www.cdc.gov/niosh/firefighters/registry.html). This website will include frequently asked questions (FAQs) and other important background information about the NFR (Attachment 4). After reviewing the NFR website, firefighters that are 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). After registering, the respondent will have the opportunity to complete the informed consent (Attachment 3a), user profile (Attachment 3b), and enrollment questionnaire (Attachment 3c) (in that order).

The NFR enrollment questionnaire has been reviewed by a survey methodologist to ensure quality and proper organization of questions. Skip patterns and auto-population of choices based on responses are built into the questionnaire to minimize the burden to the respondent. Additionally, we will have preprogrammed dropdown menus for capturing information such as place of employment and various demographics. We anticipate 100% electronic submission participation; at this time, we will not be offering alternative methods for enrolling in the NFR. We have chosen to use the web portal for enrollment to make the process convenient and uniform for all respondents.

A.4. Efforts to Identify Duplication and Use of Similar Information

The Firefighter Cancer Registry Act of 2018 (Attachment 1) was signed with the purpose of developing a voluntary registry to collect data on cancer incidence among firefighters. This Act was created because this type of information is not currently available for the U.S. firefighter population. Previous data collection is limited and did not include minority groups. The Firefighter Cancer Registry Act of 2018 stipulates the NFR be a voluntary registry of firefighters, so all participants are required to complete an informed consent form during registration. With this stipulation, there are no practical alternatives available to NIOSH to register firefighters. The NFR team has conducted literature reviews, database searches, and contacted state cancer registries to ensure that this information has not been previously recorded.

Some population-based (i.e., state) cancer registries collect occupational information, but it is often vague and incomplete (Freeman, et al. 2017) because patient information related to work history is often not obtained in the healthcare setting. Among firefighters specifically, one study found that roughly half of career firefighters in Florida with a cancer diagnosis were missing an occupation classification in the cancer registry, and only 17% were classified as a firefighter in the cancer registry (McClure et al., 2019). This estimate would likely be much smaller for former or retired firefighters, or volunteers working a non-firefighting job, at the time of cancer diagnosis, since the extent of occupational information ascertained may relate only to current job. Therefore, there is not enough accurate information available from state cancer registries alone to produce comprehensive estimates of cancer burden and risk factors among the fire service nationally. Additionally, the NFR's proposed method (Attachment 3) will allow for more extensive information to be obtained regarding work and exposure history, demographics, co-morbidities, lifestyle factors, and other covariates. This information will be linked with records from state cancer registries, NDI, and other information databases to monitor cancer diagnoses and mortality and improve our knowledge about cancer risks for U.S. firefighters, especially those linked to workplace exposures.

The information gathering of the proposed study is imperative to fulfill the federal mandate which provides clear instruction on the information and population on which to focus; no similar data is currently available to fulfil this task.

A.5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses. Firefighters will likely complete the registration process, user profile, and enrollment questionnaire while at their respective fire departments or outside of work.

A.6. Consequences of Collecting the Information Less Frequently

The respondents are only required to fill out the enrollment questionnaire (Attachment 3c) once. It is our intent to minimize the burden of respondents and therefore we are including the informed consent on the same web portal as the enrollment questionnaire. Respondents may opt to return to the web portal to update their personal information in their user profile, including full name, date of birth, mailing address, email address, mobile number, current or most recent fire department, work status, job title, and cancer status. We do not anticipate that respondents will update this information more than once per year.

In order to fulfil the charge given to NIOSH to "develop and maintain… a voluntary registry of firefighters to collect relevant health and occupational information of such firefighters for purposes of determining cancer incidence" we must, at a minimum, collect the requested information one time from each respondent.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on April 27, 2020, Vol. 85, No. 81, pp. 23360-23361 (Attachment 2). CDC did not receive public comments related to this notice.

B. The individuals listed below (Table A.8.1) were consulted to obtain their expert views on availability of data, clarity of instructions, recruitment tactics, and survey content. Additionally, the NFR will hold regular meetings with a federal advisory subcommittee who report to the NIOSH Board of Scientific Counselors. Details about these meetings can be found at https://www.cdc.gov/niosh/bsc/nfrs.

Table A.8.1. 2019 External Consultations

Name	Title	Affiliation	Phone	Email

OUTSIDE CONSULTANTS				
John Gulotta	Captain	Tucson Fire Department	*(520)837-7096*	John.Gulotta@tucsonaz.gov
Craig Haigh	Fire Chief	Hanover Park Fire Department	*(630)823-5801*	chaigh@hpil.org
Gavin Horn, Ph.D.	Research Engineer	Underwriters Laboratories Firefighter Safety Research Institute	*(217)265-6563*	gavin.horn@ul.org
Sara Jahnke, Ph.D.	Director & Senior Scientist	Center for Fire, Rescue &EMS Health Research	*(913)681-0300*	sara@hopehri.com
Lynne Pinkerton	Contractor	NIOSH	*(513)841-4344*	Lep5@cdc.gov
Matthew Tobia	Deputy Chief	Harrisonburg Fire Department	*(540)432-7703*	Matthew.Tobia@harrisonburgva.gov
Darin Wallentine	Deputy Chief	Tucson Fire Department	*(520)837-7103*	Darin.wallentine@tucsonaz.gov
ACADEMIC INSTITUTIONS				
Jefferey L. Burgess, MD, MS, MPH	Associate Dean for Research	University of Arizona	*(520)626-4918*	jburgess@email.arizona.edu
Alberto Caban-Martinez Ph.D., D.O., M.P.H.	Assistant Professor	University of Miami	*(305)243-4565*	acaban@med.miami.edu
Judith Graber, PhD, MS	Director, Epidemiology Concentration	Rutgers University	*(732)235-9700*	graber@eohsi.rutgers.edu
David J. Lee, Ph.D.	Professor	University of Miami	*(305)243-6980*	dlee@med.miami.edu
Erin Mehalic Burr, PhD	Section Manager	Oak Ridge Associated Universities	*(865)241-4249*	Erin.burr@orau.org

Table A.8.2 2019 Consultations with CDC/NIOSH

Name	**Title**	**Affiliation**	**Phone**	**Email**
Matthew Dahm	Environmental Health Specialist	NIOSH	*(513)458-7136*	Iwa6@cdc.gov
Robert (Doug) Daniels	Epidemiologist, Health Physicist	NIOSH	*(513)533-8329*	rtd2@cdc.gov
Lynda Douglas	Public Health Advisor	CDC, DDNID	*(770)488-1075*	LDouglas@cdc.gov
Thomas Hales, MD	Medical Officer	NIOSH	*(513)841-4583*	trh1@cdc.gov
Kevin Horton, DrPH, MSPH	Branch Chief, SRB	ATSDR	*(770)488-1555*	dhorton@cdc.gov
David Weissman, MD,	Director, RHD	NIOSH	*(304)285-5749*	dqw4@cdc.gov

The National Firefighter Registry published a 60-day request for information (RFI) on the Federal Register on March 28, 2019 (Docket No. CDC-2019-0022 NIOSH-326) (Document Number 2019-05971) (Attachment 5). The purpose was to seek input and advice from all interested stakeholders on proposed recruitment strategies, how to define "firefighter" for the purpose of creating the NFR, recruitment and enrollment approaches, advice for maximizing respondent participation, volunteer department records, strategies for recruiting women, minorities, and volunteers, preferred methods of communication with firefighters, and sampling strategy. Summary feedback is listed below.

RFI Summary Feedback:

Sampling Strategy: The majority of commenters recommend utilizing a combination of all three strategies outlined in the RFI (Attachment 5). Some commenters had concerns with one particular strategy (e.g., bias that would result from using only open enrollment), but in general, commenters were supportive of including all strategies.

Definition of Firefighter for the purpose of creating the NFR: The consensus definition for firefighter is a member of an organized fire department assigned fire suppression duties in the 50 states and U.S. territories. The definition of firefighter should include:

- Career, volunteer, part-time, seasonal, and paid-per-call personnel
- Fire police, firefighter-paramedics, advanced and basic emergency medical technician (EMT);
- Members of industrial fire brigades
- Airport rescue and firefighters; military (DOD) firefighters
- Fire investigators and fire department instructors
- Prison inmates serving on firefighting crews
- Federal, state, and local wildland firefighters
- Private firefighters
- Contract employees, and contract personnel working in direct support of the fire service, such as air tanker pilots and crewmembers.

Ways to maximize firefighter participation in the NFR, preferred methods for communicating with firefighters, and other recruitment and enrollment methods that CDC should consider: Most commenters felt a national multi-media campaign should be utilized to promote the NFR and maximize firefighter participation. The campaign should include communications through social media (Twitter, Facebook, Instagram, YouTube, etc.), training events, trade publications, conferences (such as FDIC), and local, state, and federal fire service organizations. Specifically, the National Volunteer Fire Council (NVFC) recommended having booths at fire service trade shows and other events that bring large groups of firefighters together. Other commenters discussed promoting through fire academies and fire schools.

A few commenters mentioned creating an email list for registrants and others who wish to receive information about research findings. Others mentioned working with organizations that

host firefighter training events to use those events as platforms from which to recruit personnel to participate in the Registry.

Commenters recommended addressing privacy concerns upfront. We need to answer questions about security and confidentiality as well as limit the burden (time) on both firefighters and fire departments. The actual process of registering must be as simple as possible.

Ways to maximize the participation of fire departments in efforts to recruit firefighters: Commenters recommended we work closely with fire service organizations like the International Association of Fire Fighters (IAFF), the International Association of Fire Chiefs (IAFC), etc. when reaching out to fire departments. Commenters also recommend finding a point of contact at each fire department, and they recommend reassuring fire departments that the point of this study is not to place blame on fire departments.

Strategies that can be used to recruit volunteer firefighters: Commenters recommend working with organizations like NVFC and training academies when reaching out to volunteer fire departments. In addition, we need to make sure we're flexible when working with volunteer organizations.

Strategies that can be used to solicit cooperation of fire departments for the purpose of recruiting women and minority firefighters: Several commenters recommend working through organizations like the IAFC's Women Chiefs Council to recruit women, as well as the Black Chief Officers Committee for minorities. One stakeholder mentioned making sure recruiting materials are diverse as well.

A.9. Explanation of Any Payment or Gift to Respondents

NIOSH will not offer payment or incentives in exchange for participation in the NFR.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The information in identifiable form (IIF) required for registration into the NFR has been limited to only that needed to confidently link an individual to state cancer registries and National Death Index (NDI). IIF collected from firefighters will include employee ID, social security number (SSN), full name, date of birth, sex, and contact information (i.e., email and mailing address, mobile phone number). The SSN will be the primary information used to match against state cancer registries and NDI. If respondents do not provide their full SSNs, they will alternatively be given the option to provide the last four digits of their SSN. NIOSH may use other identifying information (above) to match to state cancer registries.

The NIOSH Information Systems Security Officer (ISSO) reviewed this submission and determined that the Privacy Act does apply (Attachment 6). The applicable Privacy Act System

of Records Notice (SORN) is No. SORN 09-20-0136 “Epidemiologic Studies and Surveillance of Disease Problems” (retrievable by name and ID number).” The following IIF Categories apply to this information collection (Attachments 3b & 3c):”

- Name
- Date of birth
- SSN
- Mailing address
- Phone numbers
- Medical information
- Email address
- Military status
- Employment status

IIF data will be collected and maintained as followed:

- Respondents will only be able to enter their information or see previously entered responses after successfully logging in using multi-factor authentication (MFA). Security of user accounts will meet requirements outlined in NIST 800-63-2 levels of assurance (LOA).
- Once respondents submit their enrollment questionnaires (Attachment 3c), their responses are uploaded to an on-premise secure and encrypted IT database. Their responses are then cleared from the web portal and can no longer be accessed by them, with the exception of information collected as part of their user profile (Attachment 3b).
- User profile information can be edited, but only after successfully logging in using MFA. IIF fields will be masked on the Graphical User Interface because of the sensitivity of the data. For example, month and year of birth will be masked.
- Data will be encrypted at rest and in transit following controls listed in NIST Special Publication 800-53, SC-28. Multiple layers of encryption will be implemented on the database.
- Collected data (including questionnaire data, exposure data, and matched cancer data) will be stored by unique respondent ID. This unique respondent ID will be a universally unique identifier (UUID), assigned by the MFA program.
- Respondents’ IIF (e.g., name, SSN, etc.) will be shared with population-based (e.g., state) cancer registries and NDI in order to match cancer diagnoses and identify vital status and cause of death. However, population-based cancer registries and NDI will not keep respondents’ IIF provided to them for matching purposes. The data exchange must meet federal standard of encryption FIPS 140-2, Security Requirements for Cryptographic Modules, according to CSPO Standard for Portable Media and Mobile Device Security.
- IIF data will not be given to external researchers. However, external researchers may have access to indirectly identifiable data (e.g., sex, race, etc.) through a Research Data Center (RDC).
- The following individuals will have access to IIF data: NIOSH employees and on-site contractors operating on CDC network that have been approved for access by the NIOSH

NFR Project Officer. Restrictions on internal access and auditing of internal access will be implemented to meet the controls listed in NIST Special Publication 800-53 (as amended), Security and Privacy Controls for Federal Information Systems and Organizations.

- NIOSH will maintain the IIF data according to the NIOSH Records Control Schedule.
- NIOSH will keep all individual identifiable data confidential according to an Assurance of Confidentiality (Attachment 7). An Assurance of Confidentiality (AOC) is a formal confidentiality protection authorized under Section 308(d) of the Public Health Service Act. An AOC protects individuals and institutions involved in either research or non-research (e.g., surveillance), thereby protecting the data provided by respondents involved in both surveillance and research.
- All incidents involving a suspected or confirmed breach of IIF must be reported to OCISO according to the policy titled "OCISO/CDC Standard for Responding to Breaches of Personally Identifiable Information (PII)."
- Respondents will be notified of their privacy protections, including the Assurance of Confidentiality (Attachment 7), through the informed consent document (Attachment 3a) that is required to be signed before advancing to the enrollment questionnaire on the web portal.

Collected data (including questionnaire data, exposure data, and matched cancer data) will be stored by unique respondent ID. This unique respondent ID will be a universally unique identifier (UUID), assigned by login.gov. User accounts will be proofed at (LOA3), corresponding to NIST 800-63-2 levels of assurance (LOA). All collected data will be stored in a secure database that meets NIST 800-53, SC-28 PROTECTION OF INFORMATION AT REST standards. Multiple layers of encryption will be implemented on the database. IIF fields will be masked on the Graphical User Interface because of the sensitivity of the data. For example, month and year of birth will be masked.

Identifiable information provided to state cancer registries or the National Death Index will not be kept by those programs. Additionally, NIOSH is obtaining an Assurance of Confidentiality (AoC) for all IIF data collected from firefighters, fire departments, and other institutions (e.g., population-based cancer registries) (Attachment 7). All IIF will be kept confidential and, aside from NIOSH or other Federal employees assigned to the project, government contractors, visiting scientists, guest researchers, and fellows and trainees, no one will be allowed to see or have access to the information.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB approval is not required. The development and maintenance of the NFR has been deemed non-research (Attachment 8).

Participation in, and all questions included in the NFR enrollment process are voluntary. The respondents will be informed that their responses to all questions are voluntary. Questions 36-

39 on the NFR enrollment questionnaire (Attachment 3c) may be considered sensitive information due to the topic of alcohol consumption. The collection of this information is necessary as there is evidence to support alcohol consumption as a risk factor for certain cancers (https://www.cancer.gov/about-cancer/causes-prevention/risk/alcohol/alcohol-fact-sheet). The cancers that have been identified as a result of increased alcohol consumption are also of interest in regard to exposure of firefighters. It will be important for the NFR to have this self-reported information in the case of cancer diagnosis and tracking.

Questions 41-51may also be considered sensitive in nature due to the subject matter of health history and diagnoses. Again, instructions will include that participation in any or all parts of the NFR (including individual questions) are voluntary.

It is necessary for the NFR to request respondents' SSN in order to ensure proper identification of the respondent for matching with state cancer registries and the NDI. Cancer mortality from NDI cannot be accurately determined for all respondents without a full SSN (i.e., there will likely be false matches or missed matches). Similarly, when linking data with state cancer registries, using anything less than full SSN would lead to substantially decreased sensitivity and specificity.

The question that asks for SSN (user profile, Attachment 3b), specifically notes: (1) the statute authorizing NIOSH to solicit the SSN; (2) how the SSN will be used; and (3) that providing the SSN is voluntary.

A.12. Estimates of Annualized Burden Hours and Costs

A. The NFR enrollment questionnaire was pilot tested by thirteen individuals: eleven firefighters and two research scientists. The completion times for each respondent were recorded and averaged, along with the time that it would take for a thorough review of the informed consent process. Respondents to the NFR will be U.S. firefighters who will be asked to enroll one time. We anticipate the average respondent to spend approximately 40 minutes completing the entire enrollment process, including informed consent (Attachment 3a, 5 min), user profile (Attachment 3b, 5 min), and questionnaire (Attachment 3c, 30 min). With a goal of enrolling 200,000 firefighters (66,666 annually), we anticipate total annual burden hours related to the information collection to be approximately 44,443 The summary of this information is provided below in Table A.12.1. Table A.12.2 provides our estimate of the annualized burden costs, which was based on an average hourly wage for firefighters according to The Bureau of Labor Statistics (https://www.bls.gov/ooh/protective-service/firefighters.htm).

Table A.12.1 Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
U.S. Firefighters	Informed Consent	66,666	1	5/60	5,555

U.S. Firefighters	NFR User Profile (web-portal registration)	66,666	1	5/60	5,555
U.S. Firefighters	NFR Enrollment Questionnaire	66,666	1	30/60	33,333
Total					44,443

Table A.12.2 Estimated Annualized Burden Costs

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
U.S. Firefighters	Informed Consent	66,666	1	5/60	5,555	$23.85	$132,487
U.S. Firefighters	NFR User Profile (web-portal registration)	66,666	1	5/60	5,555	$23.85	$132,487
U.S. Firefighters	NFR Enrollment Questionnaire	66,666	1	30/60	33,333	$23.85	$794,992
Total		66,666	1	40/60	44,443	$23.85	$1,059,966

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital or maintenance costs incurred by respondents. There are also no costs or burden to respondents for record keeping.

A.14. Annualized Cost to the Federal Government

To carry out the charge given to NIOSH, Congress has authorized funding in the amount of $2,500,000 for each fiscal year from 2020-2023 (H.R. 931- The Firefighter Cancer Registry Act of 2018) (Attachment 1).

Annual NIOSH personnel and overhead costs are $700,000.

Additional expenses will be incurred by NIOSH in order to operate a successful surveillance program/registry.

- Contract staff will contribute to this program; epidemiology support ($50,000), data collection and coding support ($150,000)
- Contract to develop and maintain the web portal for user enrollment ($200,000)
- Contract to promote the NFR and assist in recruiting firefighters ($300,000)
- Contract and fees associated with linking firefighters' records to state cancer registries and the National Death Index ($200,000)
- Travel to fire departments and fire service conferences to present information and enroll firefighters in the registry ($40,000/year)
- Multi-factor authentication licensing and fees ($25,000)
- Customer relation management software and licensing ($15,000)

These costs, along with miscellaneous costs, will total approximately $2,500,000 per year.

A.15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The NFR team will conduct periodic statistical analyses on the data in the system.

Table A.16.1

Project Time Schedule	
Activity	Time Schedule
Surveillance Activity	Ongoing data collection beginning 1-2 months following OMB approval
Summary Reports	Every year after OMB approval
Yearly Evaluation	Every year after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

References

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