

Supporting Statement A for Request for Clearance:

Application Form and Related Forms for the  
Operation of the National Death Index

Reinstatement with Change  
OMB No.0920-0215

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Contact Information:

Lillian Ingster, Ph.D.  
Director, National Death Index  
Division of Vital Statistics  
National Center for Health Statistics  
3311 Toledo Road, Cubicle 5277  
Hyattsville, Maryland 20782  
Phone: 301-458-4286  
Email: LXI0@cdc.gov

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Table of Contents

A.

Justification.....	3
1. Circumstances Making the Collection of Information Necessary.....	4
2. Purpose and Use of the Information Collection.....	4
3. Use of Improved Information Technology and Burden Reduction.....	5
4. Efforts to Identify Duplication and Use of Similar Information.....	5
5. Impact on Small Businesses or Other Small Entities.....	5
6. Consequences of Collecting the Information Less Frequently.....	5
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	6
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	6
9. Explanation of Any Payment or Gifts to Respondents.....	6
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents. 6	
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	8
12. Estimates of Annualized Burden Hours and Costs.....	9
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers...	9
14. Annualized Cost to the Federal Government.....	10
15. Explanation for Program Changes or Adjustments.....	10
16. Plans for Tabulation and Publication and Project Time Schedule.....	10
17. Reason(s) Display of OMB Expiration is Inappropriate.....	10
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	10

## ATTACHMENTS TO SUPPORTING STATEMENT FOR OMB CLEARANCE REQUEST

- A – Authorizing Legislation
- B - 60-Day Federal Register Notice
- C1 - National Death Index Application Form (Paper Version Copy)
- C2- National Death Index Application Form (Electronic Version)
- D - Request for a Repeat NDI File Search
- E1 - NDI User Data Transmittal Form
- E2 - NDI User Data Early Release Transmittal Form
- F1 – Fee Worksheet
- F2 – Early Release Fee Worksheet
- G - National Death Index Advisers
- H – NCHS ERB letter

### **Supporting Statement A for Request for Clearance: Application Form and Related Forms for the Operation of the National Death Index**

- Goal of the project: The National Death Index (NDI) and the services it provides allows NCHS to collect mortality data, to support epidemiological research and to furnish mortality information.
- Intended use of the resulting data: The NDI is a central, computerized index of death record information designed to assist in the mortality ascertainment activities of investigators conducting prospective and retrospective studies in health and medical projects and studies.
- Methods to be used to collect: Investigators submit these forms to apply for the use of the NDI and then when actually using the service.
- The subpopulation to be studied: The National Death Index contains all deaths in the United States since 1979.
- How data will be analyzed: The collection of information is for administrative purposes and does not employ any statistical methods.

This is a reinstatement with change request for a three-year clearance to use of the administrative forms (the application form, repeat request form, and transmittal form) and the fee worksheets utilized in the operation of the National Death Index (NDI) program (OMB No. 0920-0215, Exp. Date December 31, 2019), while also making allowances for an early release component. These forms/worksheets are submitted by NDI users when applying for use of the NDI and when actually using the service. In addition, this request includes the introduction of electronic versions that will ultimately replace the paper documents, one of which (the application form) will include a minor reduction in the number of data collection items made possible through the elimination of redundancy necessary within the paper version. Overall, the estimated annual numbers of application, repeat request and transmittal forms are anticipated to increase, with the overall annual estimated burden increasing from 457 to 787 hours.

## **A. Justification**

### **1. Circumstances Making the of Collection Information Necessary**

The National Death Index (NDI) and the services it provides are authorized under 42 USC 242k (Section 306 of the Public Health Service Act) which mandates that NCHS collect mortality data and which permits NCHS to support epidemiological research and to furnish mortality information (see Attachment A).

The NDI is a central, computerized index of death record information designed to assist in the mortality ascertainment activities of investigators conducting prospective and retrospective studies in health and medical projects and studies. The NDI contains identifying information on all U.S. decedents since 1979 and is compiled from electronic data submitted to NCHS by vital statistics jurisdiction (states and territories) offices via contractual agreements.

Investigators use the NDI to determine whether persons in their studies may have died. If so, the NDI user is provided with the corresponding dates of death, names of jurisdictions in which the deaths occurred and the related death certificate numbers. The NDI user may then apply to the respective jurisdictions to procure copies of the death certificates from their vital statistics offices in order to obtain other information such as cause of death. NDI users can reduce the need for procuring copies of certificates if they opt for the NDI Plus service, which provides users with the cause of death information in coded form.

The NDI Application Forms (Paper and Electronic Version, Attachments C1 and C2, respectively) are provided/ made available to all investigators who express an interest in the NDI. The content in the two versions are nearly identical, except the electronic version allows for the elimination of some redundancy necessary on the paper version. While the Application Form is completed and submitted only by those investigators who actually decide to apply for use of the NDI services, the remaining forms (Attachments D-F2) are sent to the investigators after their Application Forms are approved. Additional information on the NDI can be found at its website <http://www.cdc.gov/nchs/ndi.htm>.

### **2. Purpose and Use of Information Collection**

The National Death Index (NDI) contains all deaths in the United States since 1979. As of 2019 the NDI has obtained over 98 million death records from the jurisdiction vital statistics offices, covering deaths from 1979 through 2019. The death records are obtained via a contract with each jurisdiction vital statistics office. The purpose of the NDI is to assist health researchers in determining whether their study subjects have died and if so provides the researchers with the jurisdiction of death, date of death, death certificate number and the causes of death (as reported on the jurisdiction's death certificates). The encrypted death records are maintained in the SQL server data management system. The NDI has served over 3,000 researchers over the period 1982-2019. The research studies or projects varied greatly and included: clinical trials, disease registries, occupational health studies, non-disease or population registries, and effectiveness of specific therapies for different diseases.

Historically, before a particular calendar year of deaths can be made available for NDI searches, the National Center for Health Statistics must receive, process, and edit death records from ALL 50 state vital statistics offices plus New York City, Washington D.C., Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa and Northern Marianas. This is a very time-consuming process that often results in delays in the creation of the final NDI file for a particular year, typically 10 or more months after the end of that calendar year. Over earlier years NDI users and staff expressed their frustrations with such delays. Consequently, the NDI initiated a new effort to make preliminary NDI files available for earlier searches. This effort was begun in 2018 and known as the Early Release Program.

The forms being proposed for this reinstatement with change will be used solely for the administration of the NDI program. The forms are submitted by NDI users (investigators) when applying for use of the NDI and then when using the service (Attachment C1 through F2).

The National Death Index Application Form (Attachments C1 and C2) is the first administrative form. This application form (available in a paper and electronic version) is completed by organizations and agencies who are conducting health and medical projects and studies and who would like to be approved for use of the NDI. NDI applications are reviewed by NCHS staff and advisers to the NDI program (Attachment G). The advisers review the applications by email approximately every three to four weeks. The NDI program receives approximately 130 new applications each year.

The application form is used by NCHS staff and advisers to determine (1) whether each proposed use of the NDI conforms with the criteria agreed upon between NCHS and the jurisdiction vital statistics offices; (2) how the applicant and any other participating organization(s) will maintain the confidentiality of the identifying death record information; and (3) whether the NDI applicant will be able to submit data on persons in the study in a manner which meets NCHS technical specifications.

The second administrative form is the Request for a Repeat NDI File Search (Attachment D) used for subsequent requests. Since the content is the same, there aren't separate paper and electronic version.

The third administrative form is the User Data Transmittal Form (Attachment E1), which will now also offer an early release version (Attachment E2). Information provided on these otherwise identical forms is intended to clearly identify the user and to provide NCHS data processing staff with information needed to process the user's data. The forms permit users to request that their NDI output be sent to them via Secure File Transfer Protocol (sFTP) or CD-ROM. These forms are also used to show the total cost of the NDI services (calculated using fee worksheets F1 and F2) and how payment will be made.

Charges for the investigator requested records are calculated based on the number of years to be searched, the number of subjects within each search year, the vital status (known or unknown) of the subjects, and the provision of cause of death information. To be consistent with the user transmittal form, there is a regular Fee Worksheet (Attachment F1) and an Early Release Fee Worksheet (Attachment F2).

### **3. Use of Improved Information**

#### **Technology and Burden Reduction**

Respondent burden in this collection is held to a minimum. There are no technical or legal obstacles to burden reduction and improved information technology would not reduce burden; however, an electronic version of the NDI Application Form (Attachment C) can be downloaded from the NDI website <http://www.cdc.gov/nchs/ndi.htm>.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

The NDI is the only central computerized index of death records containing cause(s) of death on file in the jurisdiction vital statistics offices. Consequently, the NDI Application Form and related administrative forms used by health investigators to obtain use of the NDI service are unique to this program. Information obtained from NDI applicants pertains only to use of the NDI. Similar information is not available from other sources.

#### **5. Impact on Small Businesses or Other Small Entities**

There are no specific or ongoing reporting or recordkeeping requirements for small business. The type of administrative information collected by the NDI forms applies equally to large and small organizations. Use of the NDI is not affected by an organization's size. Questions on the forms have been held to the absolute minimum required for the intended use of the information.

#### **6. Consequences of Collecting the Information Less Frequently**

An NDI applicant must only submit one NDI Application Form (Attachment C1 or C2) to initiate use of the NDI for a particular study. The other NDI forms (Attachments D-F2) come into play each time the NDI applicant wishes to submit data for a search of the NDI. About 40% of the NDI users only make one data submission. The remaining 60% of the users will submit

data every one, two or three years as more years of deaths are added to the NDI file. These short forms are used primarily to ensure that there have been no significant changes in the initial NDI application and to identify the user's records.

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

The project is in full compliance with all the guidelines in 5 CFR 1320.5.

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

- A.** A 60-day Federal Register Notice (Attachment B1) was published in the *Federal Register* on October 9, 2019 (Vol. 84, No. 196, pp. 54147-54148) as a revision. CDC received one non-substantive comment (Attachment B2). Due to processing delays and the expiration of 0920-0215, this information collection request is being submitted as a reinstatement with change.
  
- B.** Advisers to the NDI program meet periodically to review the NDI's operations and its procedures for reviewing and approving NDI applications. The last meeting of the advisers was on April 27, 2017. They were satisfied with the availability of the requested information, the frequency of collection, the clarity of the instructions and the items of information being requested. A list of the NDI advisers, their telephone numbers, and the organizations they represent is presented in Attachment G. Please note that the ten advisers employed by jurisdiction health departments (Marie A. Bailey, Jeff Duncan, Neeti Sethi, Mark Gildemaster, Kelly Nicole Troillet, Monique E. Wilson, Heidi Lengdorfer, Kathy Hutchinson, Kari Metzger and Derek Pate) who also represent the National Association for Public Health Statistics and Information Systems.

## **9. Explanation of Any Payment or Gift to Respondents**

There are no payments or gifts to respondents.

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

This submission has been reviewed for Privacy Act applicability and it has been determined that the Privacy Act applies under Systems of Record Notice 09-20-0166: Vital Statistics for Births, Deaths, Fetal Deaths, Marriages and Divorces Occurring in the United States During Each Year.

The NDI Application Form and the other related NDI forms are used to ensure that NCHS maintains the confidentiality of the jurisdiction death record information and that such information is used only for the purposes described in the jurisdictions' contracts with NCHS. Additionally, the NDI forms are used to obtain assurances from the NDI user that the information obtained from NCHS will be kept confidential and will only be used for the study or

project proposed by the user. NCHS is bound to maintain the confidentiality of the identifying death record information it obtains from the jurisdiction vital statistics offices. This is required under Section 308(d) of the Public Health Service Act (42 USC 242k) which states that "no information may be used for any purpose other than the purpose for which it was supplied..." Consequently, release by NCHS of data on decedents contained in the NDI file is restricted under Section 308(d) by the purpose for which the information was supplied to NCHS by the jurisdiction vital statistics office. In the case of the NDI, the purpose for which the death record information is supplied is clearly specified in the contracts between NCHS and each jurisdiction office. Each contract contains provisions restricting the use of the NDI to "statistical purposes in medical and health projects and studies and prohibiting use of the NDI as a basis for legal, administrative, or other actions, which may directly affect particular individuals or establishments."

A notice of privacy will be on each NDI form:

"CDC will keep the information you provide on the NDI application and forms private and secure to the extent permitted by law."

The application forms are all scanned and stored to a secure SharePoint drive as researchers often apply several times for data.

#### Items of Information Collected from the Jurisdiction's Death Certificates

In order to assist health researchers to determine if their subjects have died, a computer match must be performed using the following items of identifying information as part of the matching criteria:

- First name, last name, and middle initial
- Father's surname (especially for females)
- Social Security Number
- Date of birth
- Sex

Other data items obtained from the jurisdiction death records are:

- Race
- Marital status
- Jurisdiction of birth
- Jurisdiction of death
- Death certificate number
- Date of death
- Causes of death

Information in Identifiable Form (IIF) – Data Submitted on the Researcher's Study Subjects



For the NDI to be able to serve the health research community, it is essential that the NDI maintain the above data elements, most of which are Protected Health Information (PHI). To use the NDI a researcher must complete a detailed application describing his/her study and how confidentiality will be maintained. The application form must be accompanied by the researchers Institutional Review Board approval for the study that is being performed. Once the NDI Advisers review and recommend approval of the application, the researcher is able to submit records of study subjects who have been lost to follow up (or who have died) in order to find out their subjects dates and causes of death. The researcher is encouraged to provide as many of the following IIF data elements as possible in order to maximize the NDI's matching effectiveness:

- First name, last name, and middle initial
- Father's surname (especially for females)
- Social Security Number
- Date of Birth, and Sex

The other NDI data items like race, marital status and jurisdiction of birth should also be provided by the researcher to assist him/her in assessing the match results and confirming which possible matches are in fact true matches.

#### Administrative Information Collected from Health Researchers (about themselves)

When health researchers submit their requests for use of NDI services, they must complete several administrative forms at various points in the NDI process. The following administrative forms are required: NDI Application Form, NDI Transmittal Form, and for subsequent updates the NDI Repeat Request Form. Each of these forms requires the researcher to submit the following identifying information about themselves:

- Name and address of Principal Investigator, Co-Investigator, and Sponsors
- Name of organization
- Assigned NDI number
- Name and phone number of the person to contact for more information about the application or about the data submitted to the NDI by the researcher
- Name and address of person that will receive the NDI results via FedEx

The administrative forms also collect information about each researcher's study:

- Summary of the study protocol
- Name of study sponsor(s)
- How data confidentiality will be maintained
- Documentation of a current IRB approval
- The number of study subjects' records to be submitted for an NDI match
- The years of death to be searched
- When identifiable data obtained from the NDI will be disposed
- Signed NDI Confidentiality Agreements

All of these data items have been collected and approved in previous Paperwork Reduction Act (PRA) submissions.

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

None of the forms request information of a sensitive nature. Furthermore, because the NDI does not involve information on human subjects, it has been determined that the NDI does not require IRB approval (See Attachment H).

## 12. Estimate of Annualized Burden Hours and Cost

### A. Estimates of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Researcher	Application Form - Paper	10	1	3	30
Researcher	Application Form - electronic	120	1	2.5	300
Researcher	Repeat Request Form – Paper/Electronic	140	1	18/60	42
Researcher	Transmittal Form- Paper/Electronic	300	3	18/60	270
Researcher	Early Transmittal Form- Paper/Electronic	100	3	18/60	90
Researcher	Fee Worksheet	216	1	15/60	54
Researcher	Early Release Fee Worksheet	44	1	2/60	1
Total					787

### B. Estimates of Annualized Burden Cost to Respondents

The three administrative forms are completed by health researchers in government, universities, and private industry in order to apply for NDI services and to submit records of study subjects for computer matching against the NDI file.

The mean hourly earnings of "social scientists and related workers" (as of May 2018) was \$41.22 based on the U.S. Bureau of Labor Statistics National Occupational Employment and Wage Estimates. The BLS website for this information is: [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)

The total burden cost is estimated at \$32,459.

Total Annual Cost Burden

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Burden Cost
Researcher	Application Form - Paper	10	1	3	\$41.22	\$1,237
Researcher	Application Form - electronic	120	1	2.5	\$41.22	\$12,366
Researcher	Repeat Request Form – Paper/Electronic	140	1	18/60	\$41.22	\$1,731
Researcher	Transmittal Form- Paper/Electronic	300	3	18/60	\$41.22	\$11,129
Researcher	Early Transmittal Form- Paper/Electronic	100	3	18/60	\$41.22	\$3,710
Researcher	Fee Worksheet	216	1	15/60	\$41.22	\$2,226
Researcher	Early Release Fee Worksheet	44	1	2/60	\$41.22	\$60
						\$32,459

**13. Estimates of Other Total Annual Cost Burden to Respondent or Record Keepers**

There is no respondent cost burden associated with capital or maintenance costs.

**14. Annualized Cost to the Government**

The average annual cost associated with the three administrative NDI forms is estimated to be \$133,000 per year. This cost includes the development of the electronic forms plus NCHS staff costs of about \$130,000 per year to process the forms.

#### **15. Explanation for Program Changes or Adjustments**

This reinstatement with change request is submitted to continue the use of the three administrative forms (the application form, repeat request form, and transmittal form) utilized in the operation of the National Death Index (NDI) program. In addition, this request includes the introduction of electronic versions that will ultimately replace the three paper documents, one of which (the administrative form) will include a minor reduction in the number of data collection items. The total estimated annual burden hours are 787. This represents an increase of 330 hours from 457 in the most recent approval, due primarily to the expected increase in application, repeat request and transmittal forms.

#### **16. Plans for Tabulation and Publication and Project Time Schedule**

Not applicable. The NDI is an ongoing service with none of the information collected via the forms being intended for statistical use. The forms are used for administrative purposes in operating the program.

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

The display of the OMB expiration date is not inappropriate.

#### **18. Exceptions to Certification for Paperwork Reduction Act Submission**

There are no exceptions to the certification.