

Supporting Statement A for Request for Clearance:

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

Revision

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## ATTACHMENTS TO SUPPORTING STATEMENT FOR OMB CLEARANCE REQUEST

- A – Authorizing Legislation
- B - National Death Index Application Form
- C - Request for a Repeat NDI File Search
- D - NDI User Data Transmittal Form
- E1 - 60-Day Federal Register Notice
- E2 – Federal Register Comments
- F - National Death Index Advisers
- G – 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 research.
- 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 revision request for a three-year clearance to update the three administrative forms used in the operation of the National Death Index (NDI) program (OMB Number 0920-0215, exp. October 31, 2016). For one of the three forms, the estimated burden per response will increase and the estimated number of responses will increase. This results in an increase in total estimated burden hours for the NDI.

The forms to be reviewed for this clearance request are presented as Attachments B through D.

## **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 research. The NDI contains identifying information on all U.S. decedents since 1979 and is compiled from electronic data submitted to NCHS by the state vital statistics 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 states in which the deaths occurred and the related death certificate numbers. The NDI user may then apply to the respective states 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 avoid 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 Form (Attachment B) is provided to all investigators who express an interest in the NDI. 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 C-D) 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 2016 the NDI has obtained over 86 million death records from the state vital statistics offices, covering deaths from 1979 through 2015. The death records are obtained via a contract with each state 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 state of death, date of death, death certificate number and the causes of death (as reported on the state'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 1982-2016. 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.

The forms being proposed for this revision will be used solely for the administration of the NDI program. The three forms are submitted by NDI users (investigators) when applying for use of the NDI and then when actually using the service. (Attachment B through D).

The National Death Index Application Form (Attachment B) is the first form. Changes have been made to this form to 1) further clarify the meaning of identifying or identifiable death record information, 2) request more detailed information about the physical, technical, and administrative controls to be used to maintain confidentiality of the NDI data, 3) expand the terms of the confidentiality agreements, 4) add a subform to be employed by the NDI users to notify the NDI program of the data's disposition, and 5) incorporate editorial changes designed to clarify the item directions. This application form is completed by organizations and agencies who are conducting health and medical research 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 F). The advisers review the applications by mail approximately every three to four weeks. The NDI program receives approximately 100 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 state 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 form is the Request for a Repeat NDI File Search (Attachment C). Changes to this form include 1) the replacement of an item requesting a fax number with a phone number, 2) the transition of a question to an instruction regarding the requirement that Institutional Review Board approval documentation must accompany the form, and 3) the addition of an item regarding resulting publications.

The third form is the User Data Transmittal Form (Attachment D). Editorial changes have been made to this form to capture current options for data transfer and service payment. Information provided on this form is intended to clearly identify the user and to provide NCHS data processing staff with information needed to process the user's data. The form permits users to request that their NDI output be sent to them via Secure File Transfer Protocol (sFTP) or CD-ROM. The form is also used to show the total cost of the NDI services and how payment will be made.

### **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 B) 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 to death records on file in the state 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**

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 B) to initiate use of the NDI for a particular study. The other NDI forms (Attachments C-D) 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 was published in the *Federal Register* on July 21, 2016 (Vol. 81, No. 140, pp. 47395-96). See a copy of the notice in Attachment E1. CDC received two non-substantive comments (E2), neither with contact information, so replies could not be sent.
- 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 in April 2015. 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 F. Please note that the four advisers employed by state health departments (Richard Genovese, Elizabeth Saadi, Derek Pate, and Jane Purtill) 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 state death record information and that such information is used only for the purposes described in the states' contracts with NCHS. NCHS is bound to maintain the confidentiality of the identifying death record information it obtains from the state 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 state 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 state office. Each contract contains provisions restricting the use of the NDI to "statistical purposes in medical and health research and prohibiting use of the NDI as a basis for legal, administrative, or other actions, which may directly affect particular individuals or establishments."

An assurance of confidentiality will be on each NDI form:

"We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m). In addition, NCHS complies with the Cybersecurity Enhancement Act of 2015. This law requires the Federal government to protect its information by using computer security programs to identify cybersecurity risks against federal computer networks."

The Cybersecurity Act of 2015 permits monitoring information systems for the purpose of protecting a network from hacking, denial of service attacks and other security vulnerabilities.<sup>1</sup> The software used for monitoring may scan information that is transiting, stored on, or processed by the system. If the information triggers a cyber threat indicator, the information may be

intercepted and reviewed for cyber threats. The Cybersecurity Act specifies that the cyber threat indicator or defensive measure taken to remove the threat may be shared with others only after any information not directly related to a cybersecurity threat has been removed, including removal of personal information of a specific individual or information that identifies a specific individual. Monitoring under the Cybersecurity Act may be done by a system owner or another entity the system owner allows to monitor its network and operate defensive measures on its behalf.

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1 “Monitor” means “to acquire, identify, or scan, or to possess, information that is stored on, processed by, or transiting an information system”; “information system” means “a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination or disposition of information”; “cyber threat indicator” means “information that is necessary to describe or identify security vulnerabilities of an information system, enable the exploitation of a security vulnerability, or unauthorized remote access or use of an information system”.

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 State’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 state death records are:

- Race
- Marital status
- State of birth
- State 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 state 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 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 G).

**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	100	1	4.5	450
Researcher	Repeat Request Form	70	1	18/60	21
Researcher	Transmittal Form	120	1	18/60	36
<b>Total</b>					<b>507</b>

**B. Estimates of Annualized Costs 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 2015) was \$38.78 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 cost to respondents is estimated at \$19,661.45.

**Total Annual Cost Burden**

Type of forms	Total Burden (in hours)	Avg. Hourly Wage Rate	Total Respondent Costs
All forms	507	\$38.78	\$19,661.46

**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 Revision request includes changes to all 3 forms and an increase in the total estimated annualized burden, from 182 hours to 507 hours (+325 hours). Changes are itemized below.

### **A. National Death Index Application Form (Attachment B)**

- a. We project increased use of the NDI over the next 3 years. The annualized number of respondents will increase from 50 to 100.
- b. Changes have been made to the content of the form to 1) further clarify the meaning of identifying or identifiable death record information, 2) request more detailed information about the physical, technical, and administrative controls to be used to maintain confidentiality of the NDI data, 3) expand the terms of the confidentiality agreements, 4) add a subform to be employed by the NDI users to notify the NDI program of the data's disposition, and 5) incorporate editorial changes designed to clarify the item directions.
- c. The estimated burden per response will increase from 2.5 hours to 4.5 hours. The revised estimate reflects changes to content summarized above, and the additional time needed to complete the application for submitters who represent multi-site entities.

### **B. Request for a Repeat NDI File Search (Attachment C)**

- a. There are no changes to the estimated burden per response or the number of respondents.
- b. Minor editorial changes to this form include 1) the replacement of an item requesting a fax number with a phone number, 2) the transition of a question to an instruction regarding the requirement that Institutional Review Board approval documentation must accompany the form, and 3) the addition of an item regarding resulting publications.

### **C. NDI User Data Transmittal Form (Attachment D)**

- a. There are no changes to the estimated burden per response or the number of respondents.
- b. Minor editorial changes have been made to this form to capture current options for data transfer and service payment.

## **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.