

Supporting Statement for Request for Clearance:
NATIONAL DEATH INDEX

OMB No.0920-0215
(Expires 11/30/2007)

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Contact Information:

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This is a request for a revision and additional three-year extension. Three of the administrative forms used in the operation of the National Death Index (NDI) program which was fully implemented by the National Center for Health Statistics (NCHS) in the fall of 1981 have been slightly revised. The OMB Number for this data collection is 0920-0215 (exp. Nov. 30, 2007).

The forms to be reviewed for this clearance request are presented as Attachments B through D. There have been no substantive changes to any of the major forms since the last clearance; however, two obsolete forms have been deleted.

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 magnetic tapes 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 names of states in which the deaths occurred and the corresponding death certificate numbers. The NDI user then arranges to procure copies of death certificates from the state vital statistics offices in order to obtain such statistical information 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.

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."

The services provided by the NDI are authorized under 42 USC 243k (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. 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 forms being proposed for extension of OMB clearance have been used solely for the administration of the NDI program. The three forms are submitted by NDI users (health investigators) when applying for use of the NDI and then when actually using the service. (Attachment B through D) Two minor forms that had been in previous submissions are now obsolete and have been removed from use.

The National Death Index Application Form (Attachment B) is the first form. No changes have been made to this form. 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 G). The advisers review the applications by mail approximately every six weeks. The NDI program receives approximately 70 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 last three pages of the form are used to obtain assurances from the NDI applicant (and other organizations participating in or sponsoring the study) that the identifiable data obtained from the NDI will be used only for

"statistical purposes in medical and health research" and will be used only for the study or purpose proposed in the application form.

Furthermore, the assurances specify that identifiable data obtained via the NDI will not be released in any form which would identify a particular individual or establishment and will not be used as a basis for legal, administrative or other actions which may directly affect individuals or establishments identified as a result of the NDI.

The second form is the Request for a Repeat NDI File Search (Attachment C). No changes have been made to this form. At the beginning of the NDI program, users were instructed to submit updated application forms each time they wanted to conduct a subsequent NDI file search for additional years of death. Each resubmitted application would have to be reviewed by the NDI advisers. The advisers soon realized that, because of the increasing number of users, this requirement would be burdensome to the NCHS staff, the advisers, and NDI users. This very abbreviated application form for repeat requests (first approved by OMB in 1986) provides adequate assurances that there have been no significant changes in the study protocol and confidentiality provisions specified in the user's initial application form. Furthermore, NCHS staff has been able to expedite the approval of most "repeat" requests for file searches (within one week of receipt) without holding up such requests until the next review of NDI applications by the advisers.

The third form is the User Data Transmittal Form (Attachment D). No changes have been made to this form. This form is to accompany the diskettes or CD-ROMS submitted to NCHS by NDI users. 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 on diskette 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) was implemented in January 2003. It is a word document that 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 1320.6

The project is in full compliance with all the guidelines in 5 CFR 1320.6.

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

- A.** As required by 5 CFR 1320.8(d), the 60-day notice soliciting comments on this information collection appeared in the Federal Register on February 5, 2007. See a copy of the notice in Attachment E. No comments were received.

- 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 2006. 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, Robert Hayman and Alvin Onaka) 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. Assurances of Confidentiality Provided to Respondents

The administrative data collected on these forms is protected by the Privacy Act. Moreover, data provided on persons in the research study are statistical information and are covered under NCHS confidentiality provisions as described below.

An assurance of confidentiality is provided to all research subjects according to section 308(d) of the Public Health Service Act (42 USC 242m) which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form,..."

In addition, legislation covering confidentiality for the research subjects is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) which states:

“Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both.”

The NCHS Privacy Act Systems of Record Notice covering the NDI program appears in the Federal Register, Vol. 49, No. 187, September 25, 1984, pages 37695-37697, Notice No.09-20-0166 (formerly 09-37-0012) (see Attachment H).

11. 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 and was dropped from the NCHS continuing IRB review list in 1999 (See Attachment G).

12. Estimate of Annualized Burden Hours and Cost

A. Estimates of Annualized Burden Hours

Form Type	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours.)	Total Burden (in hours)
Application. Form	50	1	2.5	125
Repeat Appl. Form	70	1	18/60	21
Transmittal. Form	120	1	18/60	36
Total	240			182

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 "management, professional, and related personnel" (as of June 2006) was \$31.45 based on estimates of the U.S. Bureau of Labor Statistics as cited in the following publication: National Compensation Survey: Occupational Wages in the United States, 2006, U.S. Department of Labor, U.S. Bureau of Labor Statistics, June 2007 (Summary 07-03, Table 1, page 3.). The BLS website for this document is: <http://www.bls.gov/ncs/ocs/sp/ncbl0910.pdf>.

The total cost to respondents is estimated at \$5,724.

Total Annual Cost Burden

Type of forms	No. of respondents	No. of responses/ respondent	Avg. Burden/ Response (in hours)	Total Burden (in hours)	Avg. Hourly Wage Rate	Total Respondent Cost
All forms	120	2	45/60	182.0	\$31.45	\$5,724

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 \$5,000 per year. This cost includes the initial costs of designing and printing the forms plus the annual NCHS staff (GS – 9) cost of about \$4,000 per year to process the forms. These forms will continue to be used in the future with no foreseeable termination date.

15. Explanation for Program Changes or Adjustments

The total annual hours of reporting burden have decreased somewhat from the 227 hours currently in the inventory. The total decreased by 45 hours due to the elimination of two obsolete forms no longer used by the researchers .

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

We again request approval to not display the expiration date for OMB approval. These three National Death Index (NDI) forms are printed in large quantities whenever supplies run low. These forms are used on an ongoing basis to approve NDI applicants and to process their data requests. By not being required to display an expiration date, we would be able to make the most efficient use of stockpiled forms. We would also avoid confusion which arises among users who receive the forms prior to the expiration date but who do not actually apply until a year or two later. The main application form (Attachment B) is now available online. That document does show the current expiration date and will be updated when new approval is received .

18. Exceptions to Certification for Paperwork Reduction Act Submission

As described in A. 17, we again request approval to not display the expiration date for OMB approval. The main application form (Attachment B) is now available online. That document does show the current expiration date and will be updated when new approval is received .

B. Statistical Methods

The collection of information is for administrative purposes and does not employ any statistical methods. 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 computer files 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 names of states in which the deaths occurred and the corresponding death certificate numbers. The NDI user then arranges to procure copies of death certificates from the state vital statistics offices in order to obtain such statistical information as cause of death. NDI users can now 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.

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ATTACHMENTS TO SUPPORTING STATEMENT FOR OMB CLEARANCE REQUEST

A - Section 306 of the Public Health Service Act 42 USC 242k.

B - National Death Index Application Form

C - Request for a Repeat NDI File Search

D - NDI User Data Transmittal Form

E - 60-Day Federal Register Notice (February 5, 2007)

F - National Death Index Advisers

G – NCHS ERB letter

H – Systems of Record Notice