



National Death Index

**NATIONAL DEATH
INDEX APPLICATION**

*As you complete this form, please call 301-458-
4444
if you have any questions*



Centers for Disease
Control and Prevention
National Center for
Health Statistics

CDC/NCHS-6205-1

(Rev. 12/2016)

NATIONAL DEATH INDEX
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CDC estimates the average public reporting burden for this collection of information as 2.5 hours per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0215).

Assurance of confidentiality:

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 U.S.C. 242m(d)). Furthermore, NCHS complies with the Federal Cybersecurity Enhancement Act of 2018 (6 U.S.C. § 663) which protects Federal information systems from cybersecurity risks by screening their networks.

NDI APPLICATION FORM INSTRUCTIONS

1. For the preliminary review of the application, please submit the draft application along with prefilled, but unsigned NDI Data Use Agreement, NDI Supplemental Data Use Agreement, or both. Be sure to include the name, title, and organization for each individual who will be signing these agreements.

*Please hold off on obtain signatures until the preliminary review has been completed.

2. A separate NDI application must be submitted for each study or project.

3. New applications and amendments to already approved applications- all submissions are reviewed by a group of NDI advisors. For your application to be considered complete, please make sure to submit the final version of your application, signed NDI DUA agreement(s), IRB approval letter, and IRB protocol. Once all required documents are received, your application will be forwarded to the NDI advisory board for review. Once your application is submitted to the advisers, the review process typically takes about two to three weeks.

4. Repeated searches of NDI data - excluding reruns - must be approved by the NDI staff to ensure that no significant changes have occurred since the original application was approved. If you need to conduct a repeated search, you must send an email to ndi@cdc.gov to request your application be unlocked. The PI must confirm that no significant changes have occurred. If there are any changes, revisions must be made and submitted. Significant changes include a new principal investigator, changes in funding source, involvement of another internal or external party who will receive NDI identifiable data or adding the follow-back investigation

*Additionally, all applicants are required to upload the most current IRB approval letter.

5. If you have any questions, please feel free to call us at 301-458-4444 or send an email to ndi@cdc.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention
National Center for Health Statistics

Assigned NDI Application Number

NATIONAL DEATH INDEX APPLICATION

- 1. Title of study or project**
(same as on IRB letter)

- 2. Individual and organization requesting use of NDI**

Principal Investigator
or Project Director:
Title:
Organization:
Address:

Phone no.:

Ext:

E-mail:

3. External funding sources? Yes or No (Internal funding ONLY)

List of all organizations that are providing funding for this project, along with the type —such as grant, contract, cooperative agreement, interagency agreement, or other.

Note: Except for NIH Grant Awardees, each funding source must complete and sign the NDI Supplemental Data Use Agreement. If you are an NIH Grant Awardee, please provide a copy of your Notice of Award. Please note that the Notice of Award must contain specific language regarding the NDI identifiable data; if it does not, the Supplemental Data Use Agreement will need to be completed.

Names of Organization(s)	Type of Funding Support

4. Data sources:

List of all organizations—including yours—that have collected or will be collecting data on the study subjects. For each organization, please provide a description of the types of data being collected.

4a. Will the data be used from a previously approved study or registry?

Yes or No

4b. Each record which you submit will be searched against records in the NDI file ONLY if your record contains at least one of the following combinations of data items. Check all that apply:

Check box:

FIRST and LAST NAME and SOCIAL SECURITY NUMBER

FIRST and LAST NAME and MONTH and YEAR OF BIRTH

SOCIAL SECURITY NUMBER and DATE OF BIRTH and SEX

5. Is NDI death record information shared with anyone other than the NDI applicant?

Yes or No

List the names of all parties that will be receiving any NDI death record information. All parties employed by the INTERNAL organization are required to complete and sign the NDI Data Use Agreement. All parties employed by EXTERNAL organization must sign the NDI Supplemental Data Use Agreement.

Please note: All parties reporting directly to the PI or Co-PI do not need to be listed. If you have any doubt about who needs to be listed, please reach out to the NDI.

Organization Information		
Name:		
Organization Name:		
Site Indicator (ensure that is corresponds to the same organization in 9a):		
Phone:	Ext:	
Email:	Admin. Relationship:	Data Type:
Specify organization's role and what project will be performed. Also specify (1) what IDENTIFYING or IDENTIFIABLE death record information will be received, (2) in what form it will be received (e.g. death certificates or computer files), and (3) how the information will "flow" from one organization to another.		

Organization's role and what project activities will be performed:

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6. Summary of study protocol or project activities

In responding to the following questions, please provide sufficient details to describe your study or project and how data obtained via NDI will be used.

6a. Are you getting causes of death? Yes or No

If yes, please explain how the cause of death data received from the NDI will be used in this project.

6b. Will the information obtained via NDI be included in a registry or long-term study? Yes or No

6c. Purpose of study or project:

If your application involves a study, be sure to respond to the following:

Describe the health or medical problem(s) addressed by your study or project.

Include some background information to support why the study or project is being done. What are the primary objectives? If appropriate, include a description of hypotheses to be tested.

If your application involves a registry or long-term study, be sure to respond to the following:

- The date the project started.
- The objectives of the project.
- Outline both the inclusion and exclusion criteria.
- Provide list of studies currently being conducted or planned in the future.
- Explain the process for internal and external dissemination of identifiable NDI data.
Please note: Identifiable record-level NDI data may not be shared externally unless approved by the NDI. The only two permissible methods for releasing data without NDI approval are:

1. **Aggregate reports charts, tables or public use files:** When releasing statistical information, the recipient will make every effort to avoid inadvertent disclosure. Counts, rates, and percentages for sub-national geographic areas will be suppressed and not displayed in any manner if they are based on 1 to 9 observations in the numerator, denominator, or total, regardless of the number of years combined. This data suppression rule applies to all text, tables, and figures (including maps) contained in main and supplemental files. No data on an identifiable case should be derivable through subtraction or other calculations from the combination of tables in a given publication. Data should not permit disclosure when used in combination with other known data.
2. **Research Data Center or enclave** – Researcher may come to designated secured center or use VPN to view identifiable, restricted, and sensitive data, however, may only leave with aggregate data, tables, and charts. One of the criteria we insist on, for all of NCHS not just the NDI, is that no presentations or publications can include cell sizes under 10 in tabulations for sub-national geographic areas, regardless of number of years combined. That is considered potentially statistically identifiable. This stipulation must be included in your application. You must also describe the approval process through which an external user is granted access to view identifiable, restricted, and sensitive data.

*** 1,250 Word Maximum! *** Extra words will be truncated.

6d. I have read and acknowledge that: check box

- Should there be any significant deviations from such studies, we fully understand that an amended application must first be submitted to and approved.
- Should follow-back investigations become necessary, and involve death records obtained via the NDI, it is understood that first we must:
 - (1) submit an amended Application Form describing the follow-back investigations,
 - (2) obtain and submit an approval from an Institutional Review Board for the Protection of Human Subjects, and
 - (3) wait for the amended application to be reviewed by the NDI advisers and approved by Director of the NCHS Division of Vital Statistics.
- Any information obtained via the NDI will be flagged and stored separately from any administrative or statistical records that could be used in the future for purposes not described in the application. Computer records containing death record information obtained via the NDI shall also be flagged so that they will not be used in the future for purposes not described in the application.

7. Death record follow-back investigations:

"**Follow-back investigations**" refers to the process where, after NDI determines certain study subjects are deceased, your staff intends to gather more information by going back to individuals or establishments listed in those subjects' actual death certificates.

7a. Does this study or project plan to perform "death record follow-back" investigations?

Yes or No

If yes, refer to **Attachment C** for additional documentation needed.

7b. If yes, what type of respondents will be contacted?

7c. What information will be obtained from EACH type of respondent?

7d. Name the organization(s) or consultant(s) who will be contacting EACH type of respondent:

7e. Name the methods to be used in conducting follow-back investigations, including how EACH type of contact will be made.

8. Institutional Review Board (IRB) for the Protection of Human Subjects

(Defined by the U.S. Department of Health and Human Services in the [Code of Federal Regulations, Title 45, Part 46](#))

Evidence of a current Institutional Review Board (IRB) review is **REQUIRED** for all NDI public health and medical studies. For surveillance project, applicant must submit a letter from authorized institutional official stating that project meets the definition of a Public Health Surveillance activity excluded from the definition of research in January 19, 2017, final Common Rule, at 45 CFR 46.102(l)(2).

All others must ensure that:

1. NDI applicant's name is referenced in the IRB letter
2. IRB must review and approve the release of Personal Identifiable Information to NDI and address how the NDI identifiable data is being utilized.
3. If this study or project involves death record follow-back investigations as described in item 7, a special letter from the IRB is **REQUIRED**.
4. If central IRB is responsible for reviewing research protocols for multiple institutions or sites involved in a multi-site research study, a Reliance Agreement must be submitted.

IRB's name that approved the project:

IRB's Federal wide Assurance (FWA) number:

If you have questions about FWA, please visit: [Assurance Process Frequently Asked Questions \(FAQs\)](#) |

[HHS.gov](#) If you don't know your FWA number, please search under FWA tab at:

<https://ohrp.cit.nih.gov/search/search.aspx>

(**NOTE:** If your organization does not have an IRB [that has been approved by the Office for Human Research Protections, Department of Health and Human Services], you may have the study reviewed by an external, independent IRB, or by establishing a reliance agreement with another institution).

9. Maintaining the Confidentiality of IDENTIFYING or IDENTIFIABLE death record information:

9a. Name the organization(s), including your own, that will:

- a. Submit records of study subjects for the NDI file search(es):

Organization Name	Site Indicator

- b. Receive the results of the NDI search directly:

Organization Name	Site Indicator

9b. Check the box, if your organization will NOT receive **IDENTIFYING or IDENTIFIABLE death record information** (for additional information, please read the definition found below).

NOTE: *If multiple sites are involved in the above-mentioned study project, each site must describe its own controls that would be used to maintain the confidentiality of the **IDENTIFYING or IDENTIFIABLE death record information**.*

Describe the following controls that would be used to store and maintain the confidentiality of the **IDENTIFYING or IDENTIFIABLE death record information** at your organization:

Physical controls – building guards, identification badges, key cards, closed circuit TV, and locked offices.

Technical controls – user identification, passwords, firewalls, encryption, virtual private network, intrusion detection system. All non-federal applicants must store and access the NDI data on a secure server of the affiliated institution or organization. The NDI data cannot be directly accessible from the Internet. Only federal agencies are permitted to store and access NDI data on FedRAMP moderate approved cloud-based systems. The NDI data must stay behind the affiliated institutional or organization firewalls and must not be stored on portable devices or personal computers. Please be aware that the standard encryption requirement for sensitive federal information, like the NDI data, is FIPS-140-2 in accordance with NIST 800-53. NIST 800-53 is only intended for federal agencies. The parallel standard for non-federal entities is NIST 800-171.

Administrative controls – frequency of backing up files, where backup files will be stored, methods to ensure least privilege access, methods for ensuring IDENTIFYING or IDENTIFIABLE death record information is not co-mingled with administrative records not part of this project, how use will be monitored to prevent use for purposes not approved for this project, how personnel using the system will be trained and made aware of their responsibilities for protecting the IDENTIFYING or IDENTIFIABLE death record information, methods for monitoring who has access to the data, and methods for ensuring return or destruction of data.

10. Completion of study or project

10a. Is the study or project ongoing or open-ended? **Yes or No**

If "No", indicate the scheduled termination date for the study:

10b. In what form (e.g., aggregate, statistical, report, etc.) and to whom (e.g., peer-reviewed scientific journals, monographs) will the results of your study or activities be released? (NDI would appreciate a courtesy copy of any publications that may result from the use of NDI data.)

10c. I have read and acknowledge that:
Check Box

When releasing statistical information, the recipient will make every effort to avoid inadvertent disclosure. Counts, rates, and percentages for sub-national geographic areas will be suppressed and not displayed in any manner if they are based on 1 to 9 observations in the numerator, denominator, or total, regardless of the number of years combined. This data suppression rule applies to all text, tables, and figures (including maps) contained in main and supplemental files. No data on an identifiable case should be derivable through subtraction or other calculations from the combination of tables in a given publication. Data should not permit disclosure when used in combination with other known data.

10d. Will study subjects be notified of study results?

Yes or No

If yes, how will the subjects be notified?

11. Data destruction plan

Some state vital statistics offices have expressed concern about indefinite retention of **IDENTIFYING or IDENTIFIABLE death record information** that could be used in the future by other persons for other purposes. All applicants, except for data stored in registry or long-term study, must indicate the month and year ALL the NDI identifiable data (including the data derivatives) received from the NDI will be destroyed and submit Data Destruction Form (Attachment "A").

1. Based on the above requirements, when do you plan to destroy ALL the NDI identifiable data (including the data derivatives)? Give the proposed **month and year** of destruction or enter **UNKNOWN** or **99/9999** if this is an open-ended or ongoing study that has no specific destruction plan at this time. **NOTE:** The Data Destruction Form (Attachment "A") must be submitted to NDI staff no later than the month and year stated in item 11(1). A reminder will be sent 30 days prior.

2. Only complete item 2a. and 2b. if the above date is UNKNOWN or if the date is more than 5 years after the month and year that you submitted this NDI application.

a. Please provide a strong justification for retaining the data beyond 5-year period:

""

- b. Within 5 years of submitting your NDI application you are responsible for either (1) destroying ALL the NDI identifiable data (including the data derivatives) received from the NDI and submitting the Data Destruction Form (Attachment "A") or (2) requesting an extension. If requesting an extension, please reach out to the NDI staff at ndi@cdc.gov.

3. **END OF DOCUMENT**