FORM APPROVED
OMB No. 0920-0215
Exp. Date 03/31/2023

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. 12/201

NATIONAL DEATH INDEX

National Center for Health Statistics

3311 Toledo Road, Room 5292
Hyattsville, Maryland 20782
301-458-4444
ndi@cdc.gov

NDI APPLICATION FORM INSTRUCTIONS

1. **Confidentiality Agreements Signatures-** To expedite the review of your application, you may submit your draft application form before you obtain all the required signatures on the Confidentiality Agreement and/or **Supplemental Confidentiality Agreement** pages and IRB determination letter. (Unsigned forms must at least have the name, title, and the organization of the person that will be signing, and IRB application must be submitted.)
2. A separate NDI application form must be submitted for each study or project.
3. **New Applications--** and amendments (changes to the original application) are reviewed by a group of NDI advisors. Your application is considered **complete** when your final **signed** version and your study's IRB determination letter is received by a group of NDI staff. Once your application is complete, it is sent to the advisors. Once your application is sent to the advisors for review, please allow two to three weeks for the application to be reviewed.
   (Please note: applications not completed 6 months from the original date of submission will be deleted).
4. If additional NDI repeated searches are needed, send an email with your approved NDI application number to ndi@cdc.gov to request that your application in the NDI Portal be unlocked for you to do the following:
   1. Verify that there are no changes to the application that has been approved.
   2. If required, update and upload the most recent IRB determination letter.
   3. If required, update the Data Disposition expiration date.
   4. Once all is verified, please submit your application.
   5. You will receive an email, that will include all documents needed to complete a search.
5. If you need to change the existing PI, please notify the NDI staff immediately and we will:
   1. Provide instructions on how to create an account.
   2. Once the PI creates his/her account, the NDI staff will reassign the NDI application to the new PI.
6. Please call at 301-458-4444 or e-mail us at ndi@cdc.gov, if you have questions.

Note: definition of "**IDENTIFYING or IDENTIFIABLE death record information**" — Any information on death certificates, other paper documents, or in computer files which by itself, or if linked with other records, would permit the identification of one or more individuals or establishments; for example, name(s), Social Security number, exact dates, addresses, and death certificate number. Even with the removal of direct identifiers and linkable study subject identification numbers, there is still a special concern that some combinations of the remaining variables could potentially be used to identify an individual. For example, a combination of date of birth, date of death, and/or cause of death is considered identifiable.

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 (must match 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?

List the names of all OTHER organizations providing funding for this project and indicate the type of support provided (i.e., grant, contract, cooperative agreement, interagency agreement, or other [specify]). NOTE: Except for a FEDERAL GRANT, each sponsor must complete and sign an NDI Supplemental Confidentiality Agreement at the end of this application. If a FEDERAL GRANT, enter FEDERAL GRANT "Name of Organization" and provide FULL Grant Number in "Type of Funding Support"

Names of Organization(s)	Type of Funding Support

4. Data sources

List all organizations (including your own) that have collected (or will be collecting) data on the study subjects. Under each organization listed, describe the types of data collected. If any of the **external** organizations listed will be receiving **IDENTIFYING or IDENTIFIABLE death record information**, they must also be listed in item 5 below.

5. Will INTERNAL or EXTERNAL parties (other than the NDI applicant) be receiving IDENTIFYING or IDENTIFIABLE death record information?

List the names of all parties (organizations or outside consultants) that will obtain **IDENTIFYING or IDENTIFIABLE death record information** or data derivatives from NDI. Parties employed by INTERNAL organization must complete and sign the Confidentiality Agreement. Parties in EXTERNAL organizations must complete and sign the NDI Supplemental Confidentiality Agreement.

Important: *Under each organization (or consultant) listed below, specify that 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. Parties employed by your organization must complete and sign the Confidentiality Agreement. Parties in other organizations must complete and sign an NDI Supplemental Confidentiality Agreement.*

*** If no other parties are listed, only the applicant will be obtaining **IDENTIFYING or IDENTIFIABLE death record information** or data derivatives from NDI.

Organization Information		
Name:		
Organization Name:		
Phone:	**Ext:**	
Email:	**Admin. Relationship:**	**Data Type:**
Organization's role and what project activities will be performed:		

6. Summary of study protocol or project activities

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

6a. Will the information obtained via NDI be included in a registry or any other type of study with long-term use or an indefinite end date?

What type of study is this? (e.g., disease registry, longitudinal cohort study, cross-sectional study, case-control study)

6b. Are you getting causes of death?

All applicants must complete item 6.c. If your application involves a Registry and Long-term Use and Indefinite End Date Study, be sure also to include the following information in item 6c. below: (1) the date the registry was founded, (2) the purpose of the registry, (3) the eligibility criteria for including person in the registry, and (4) describe the internal and external release of the NDI data. Registry and Long-term Use and Indefinite End Date Study should also refer to **Attachment B** for additional information to be included in this application.

6c. Purpose of study or project

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.

7. Death record follow-back investigations

7a. Does this study or project plan to perform "death record follow-back" investigations? ("Follow-back investigations" means that **once NDI identifies that certain study subjects are deceased,** your staff plans to collect additional information on those subjects by going **BACK** to individuals or establishments that are mentioned in the subjects' actual death certificates.) NOTE: Follow-up refers to contacting the next-of-kin or health providers based on information already contained in researchers' file.

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

7b. If yes, what type of respondents will be contacted? Check all that apply.

-

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 IRB review is REQUIRED for all NDI applications (please ensure that NDI applicant's name is referenced in the IRB letter). If this study or project involves death record follow-back investigations as described in item 7, a special letter from the IRB is REQUIRED (as explained in Attachment C).

8a. IRB approval status:

8b. Include a copy of the IRB review and provide the following:

Institution issuing the IRB:

IRB's Multiple Project Assurance (MPA) number or Federal wide Assurance (FWA) number:

(NOTE: If death record follow-back investigation will be performed as described in item 7, an explanation of why your organization does not require an IRB approval for such a study or project is not acceptable. 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 approved IRB in another organization.)

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

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

(1) Submit records of study subjects for the NDI file search(es):

Organization Name	Site Indicator

(2) Receive the results of the NDI search directly:

Organization Name	Site Indicator

Based on the results of the NDI file search(es), will copies of death certificates be requested from state vital statistics offices?

(3) Request copies of death certificates from the state vital statistics offices:

9b. 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, and stand-alone desktop use only. 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 (see: https://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.140-2.pdf and https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf).

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. Please include text indicating the number of persons who will have access to the backup files containing IDENTIFYING OR IDENTIFIABLE death record information.

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**.*

10. Completion of study or project

10a. Is the study or project ongoing or open-ended?

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. Will study subjects be notified of study results?

If yes, how will the subjects be notified?

""

11. Data disposition 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.

Except for data stored in registries, or other approved long-term studies, all identifying or identifiable data received from NDI must be removed from all research records at the conclusion of the study or within 5 years after receipt of the NDI data – regardless of the data set in which the data are kept. This means that all identifiers or potentially identifiable data elements associated with cause-of-death codes must be removed from all analysis files unless there is no way to identify an individual decedent. This also means that any linked files (with crosswalks) must be destroyed. **As long as there are no identifiers or linkage variables remaining in the analytic or public-use file(s), cause(s) of death codes may remain in such file(s).** (Note: Death certificates obtained directly from state offices may have to be shredded in less than 5 years depending on each state's requirements.)

1. Based on the above requirements, when do you plan to dispose of all **IDENTIFYING or IDENTIFIABLE death record information** obtained from NDI? Give the proposed month and year of destruction, or enter UNKNOWN if this is an open-ended or ongoing study that has no specific disposition plan at this time.

2. Only complete item 2a. 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 why the data need to be retained beyond this 5-year period.

   ""

   b. Within 5 years of submitting your NDI application, you are responsible for either (1) requesting an extension or (2) certifying the NDI data have been returned to NCHS or destroyed (see **Attachment A**). The extension request or certification of data disposal must be submitted to NDI staff within 5 years – no later than the month and year stated in the box below.

National Death Index Confidentiality Agreement

Study or Project Title:

The undersigned hereby agrees to the following terms and conditions associated with this National Death Index (NDI) Application and to the use of the information obtained from: (1) the NDI, (2) state death records, and (3) death record follow-back investigations:

A. Except for persons or organizations specified in the approved NDI Application Form, no data will be published or released in identifiable form to any party. **ALL REQUESTS FOR IDENTIFIABLE DATA OBTAINED VIA THE NDI WILL BE REFERRED IMMEDIATELY TO NDI STAFF.** In accordance with Section 308(d) of the Public Health Service Act, such identifiable data will specifically not be provided in response to a direct order from an official of any government agency, the Administration, or Congress, nor in response to an order from a court of justice.

B. The identifying information will be used ONLY for statistical purposes in medical and health studies.

C. The identifying information will not be used as a basis for legal, administrative, or other actions that may directly affect those particular individuals or establishments as a result of their specific identification in this project.

D. The identifying information will be used only for the study or project proposed and the purpose described in the approved NDI Application Form. Use of the information for a research project other than the one described in the application form will not be undertaken until after a separate NDI Application Form for that project has been submitted to and approved by the NDI.

E. The National Center for Health Statistics (NCHS) obtains death record information via contracts with the state vital statistics offices. These contracts contain specific restrictions on the use of the information by the NDI and by the NDI Plus service (which gives NDI users cause-of-death codes). By providing NCHS with these assurances, I understand that I am also providing the same assurances to the State Vital Statistics Offices. Violation of the terms and conditions of this Agreement may subject the organization/researcher to immediate abrogation of the Agreement by NCHS, the required return of all NDI data and related materials, and denial of future use of the NDI. Violation of the terms of the Agreement may also be a violation of federal criminal law under 18 U.S.C. Section 1001. In the event of unauthorized disclosure of identifiable information from NDI data, NCHS will pursue all legal remedies. Violations of the terms of the Agreement are also subject to state legal remedies.

F. The original version of the NDI data must be retained at a single location and no copy or extract of identifiable information may be made available to anyone except those persons identified in the NDI Application and those who have signed the NDI confidentiality agreements. The NDI data may not be re-released to others except as specified in item 5 of the NDI Application.

G. Access to identifiable NDI data maintained in computer memory must be controlled by password protection. Servers housing NDI data must be protected by a firewall and must not be directly accessible from the Internet. All persons must have completed required computer security training required by their institution. All printouts, diskettes, personal computers with data on hard disks, or other physical products containing identifiable information derived from the NDI must be kept in locked cabinets, file drawers, or other secure locations when not in use. Security procedures must be in place to ensure that identifiable NDI data cannot be used or taken by unauthorized individuals. Printouts, tabulations, reports, and other materials must be edited for any possible disclosures of NDI identifiable data before making the information available to anyone other than the persons identified in this Agreement.

H. Except for data stored in registries, or other approved long-term studies, all identifying or identifiable data received from NDI must be removed from all research records at the conclusion of the study or within 5 years after receipt of the NDI data—regardless of the data set in which the data are kept. This means that all identifiers or potentially identifiable data elements associated with cause-of-death codes must be removed from all analysis files unless there is no way to identify an individual decedent. This also means that any linked files (with crosswalks) must be destroyed. As long as there are no identifiers or linkage variables remaining in the analytic or public-use file(s), cause(s) of death codes may remain in such file(s). Files including backup and derived files with NDI identifying or identifiable data must be both deleted and overwritten to prevent recovery of the data. The requirements above also apply to all data derived from NDI data. Note: Death certificates obtained directly from state offices may have to be shredded in less than 5 years depending on each state's requirements. See Attachment A.

I. The organization/researcher agrees to report any confirmed or suspected losses, including theft and unauthorized disclosure/ access, of personally identifiable information (PII) from the NCHS data file(s) to the CDC Computer Security Incident Response Team's (CSIRT) 24x7 Emergency Number (1–866–655–2245) within 1 hour. After notifying CSIRT, the organization/researcher will notify Steven Schwartz (1–301–458–4210) of the NCHS Division of Vital Statistics with the incident number issued by CDC CSIRT. The organization/researcher will not communicate PII details via email.

NDI Confidentiality Agreement (continued)

J. Authorized NDI staff or agents may, upon request, be granted access to _____ facilities, where confidential NDI data are kept or used, for the purpose of inspecting the data security arrangements.

K. I understand that while state vital statistics offices may receive copies of this application, states may require additional information and/or assurances before responding to separate requests for copies of death certificates or for death record information directly from such states. Some states may not be able to honor certain requests because of the proposed uses of the state data. Furthermore, once data from a particular state are received from them, I understand that users of the data are subject to that state's laws and regulations relating to disclosure of information on individuals or establishments.

L. I have reviewed this NDI Application. All the statements made in this application and in any confidentiality assurances related to this application are true, complete, and correct to the best of my knowledge and belief. My signature below indicates my agreement to comply with the stated statutorily based requirements with the knowledge that deliberately making a false statement in any matter within the jurisdiction of any department or agency of the federal government violates 18 USC 1001 and is punishable by a fine of up to $10,000 or up to 5 years in prison.

The Data Steward for this project is: _____ Title: _____
Name

Organization: _____

Work phone number: _____ E-mail address: _____

As Data Steward, I affirm that I will act as the custodian of the NDI files and will be responsible for the observance of conditions of use.
I will notify the NDI Director, Dr. Lillian Ingster (1–301–458–4286; lingster@cdc.gov):

a. when access to the NDI data is no longer needed (see Attachment A);
b. if a change in site access is contemplated;
c. of the intent to modify the project's purpose; or
d. if these responsibilities are to be transferred.

Signature of Data Steward: _____ Date: _____

SIGNATURE of *Principal Investigator or Project Director:*

_____ _____
Signature Date

_____
Name (type or print)

_____
Title

_____
Organization

_____
E-mail

***SIGNATURE** of *official authorized to execute agreements (last person to sign and date)*

_____ _____
Signature Date

_____
Name (type or print)

_____
Title

_____
Organization

_____
E-mail

* NOTE: The "official authorized to execute agreements" will vary among organizations. Whenever possible, the NDI prefers that this official be someone at a higher level of authority than the principal investigator or other persons responsible for the study or project; for example, a university official authorized to sign grant proposals, a company vice president, or a government division or bureau director. By signing this agreement as the *authorized official,* you are declaring that you have the authority to make the above assurances on behalf of the university, company, agency, or other organization and to bind the organization to the terms of this agreement and you take responsibility for the confidentiality assurances of all organizations or individuals who are participating in this study.

For those individuals planning to sign digitally, please keep in mind that not all types of electronic signatures are acceptable. For further information, see Attachment D.

National Death Index (NDI) Supplemental Confidentiality Agreement

A separate Supplemental Confidentiality Agreement must be completed and signed by each ***EXTERNAL*** organization (funding or participating in this study) as listed in ***5*** of the NDI Application Form. The Supplemental Confidentiality Agreement(s) must then be submitted as an attachment to the Application Form. THIS REQUIREMENT IS WAIVED ONLY FOR A FEDERAL GRANT, AND THEN ONLY WHEN THE NDI APPLICANT (GRANTEE) CAN GIVE ASSURANCES THAT THE IDENTIFYING INFORMATION OBTAINED DIRECTLY OR INDIRECTLY FROM THE NDI WILL UNDER NO CIRCUMSTANCES BE PROVIDED TO THE GRANTOR.

Name and title of Principal Investigator, Project Director, Project Officer, or other responsible official:

Organization name and complete mailing address:

Phone Number: *E-mail :*

1. Will this organization (or individual) receive any of the identifying or identifiable death record information obtained from the NDI, state death records, and/or death record follow-back investigations? (By "definition of "IDENTIFYING or IDENTIFIABLE death record information"—Any information on death certificates, other paper documents, or in computer files that by itself, or if linked with other records, would permit the identification of one or more individuals or establishments; for example, name(s), Social Security number, exact dates, addresses, and death certificate number. Even with the removal of direct identifiers and linkable study subject identification numbers, there is still a special concern that some combinations of the remaining variables could potentially be used to identify an individual. For example, a combination of date of birth, date of death, and/or cause of death is considered identifiable.

   ☐ Yes ○ No ○ Maybe

2. Does this organization (or individual) have any contractual or other rights to the identifying information referred to above?

   ☐ Yes ○ No ○ Maybe

If you answered "No" to both questions 1 and 2, skip questions 3 and 4 and just provide the two requested signatures below. If you answered "Yes" or "Maybe" to either questions 1 or 2, please complete questions 3 and 4 and provide three signatures.

National Death Index (NDI) Supplemental Confidentiality Agreement (continued)

3. In the box below, describe how your organization will store and maintain the confidentiality of the identifying or identifiable death record information obtained from (1) the NDI, (2) state death records, and (3) death record follow-back investigations. Definition of "IDENTIFYING or IDENTIFIABLE death record information"—Any information on death certificates, other paper documents, or in computer files that by itself, or if linked with other records, would permit the identification of one or more individuals or establishments; for example, name(s), Social Security number, exact dates, addresses, and death certificate number. Even with the removal of direct identifiers and linkable study subject identification numbers, there is still a special concern that some combinations of the remaining variables could potentially be used to identify an individual. For example, a combination of date of birth, date of death, and/or cause of death is considered identifiable.

   Describe the following controls that would be used to maintain the confidentiality of the NDI data:

   - **Physical controls—**limiting access to data such as 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, and standalone desktop use only.
   - **Administrative controls—**how frequently files will be backed up, where backup files will be stored, methods in place to ensure least privilege access, methods for ensuring NDI identifying information is not co-mingled with administrative records not part of this project, how use of NDI data will be monitored to prevent its use for purposes other than those approved for this project, how personnel using the system will be trained and made aware of their responsibilities for protecting the NDI information, methods for keeping track of who has access to the data, and methods for ensuring return or destruction of data.

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 NDI data

4. How and when will your organization dispose of identifying or identifiable death record data? If your organization has no plans to dispose of some or all of the identifying or identifiable death record data, please explain why.

National Death Index Confidentiality Agreement

Study or Project Title:

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B. The identifying information will be used ONLY for statistical purposes in medical and health studies.

C. The identifying information will not be used as a basis for legal, administrative, or other actions that may directly affect those particular individuals or establishments as a result of their specific identification in this project.

D. The identifying information will be used only for the study or project proposed and the purpose described in the approved NDI Application Form. Use of the information for a research project other than the one described in the application form will not be undertaken until after a separate NDI Application Form for that project has been submitted to and approved by the NDI.

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H. Except for data stored in registries, or other approved long-term studies, all identifying or identifiable data received from NDI must be removed from all research records at the conclusion of the study or within 5 years after receipt of the NDI data—regardless of the data set in which the data are kept. This means that all identifiers or potentially identifiable data elements associated with cause-of-death codes must be removed from all analysis files unless there is no way to identify an individual decedent. This also means that any linked files (with crosswalks) must be destroyed. As long as there are no identifiers or linkage variables remaining in the analytic or public-use file(s), cause(s) of death codes may remain in such file(s). Files including backup and derived files with NDI identifying or identifiable data must be both deleted and overwritten to prevent recovery of the data. The requirements above also apply to all data derived from NDI data. Note: Death certificates obtained directly from state offices may have to be shredded in less than 5 years depending on each state's requirements. See Attachment A.

I. The organization/researcher agrees to report any confirmed or suspected losses, including theft and unauthorized disclosure/ access, of personally identifiable information (PII) from the NCHS data file(s) to the CDC Computer Security Incident Response Team's (CSIRT) 24x7 Emergency Number (1–866–655–2245) within 1 hour. After notifying CSIRT, the organization/researcher will notify Steven Schwartz (1–301–458–4210) of the NCHS Division of Vital Statistics with the incident number issued by CDC CSIRT. The organization/researcher will not communicate PII details via email.

NDI Confidentiality Supplemental Agreement (continued)

J. Authorized NDI staff or agents may, upon request, be granted access to _____ facilities, where confidential NDI data are kept or used, for the purpose of inspecting the data security arrangements.

K. I understand that while State Vital Statistics Offices may receive copies of this application, states may require additional information and/or assurances before responding to requests for copies of death certificates or for death record information. Some states may not be able to honor certain requests because of the proposed uses of the state data. Furthermore, after data from a particular state are received, I understand that users of the data are subject to that state's laws and regulations relating to disclosure of information on individuals or establishments.

L. I have reviewed this NDI Application. All the statements made in this application and in any confidentiality assurances related to this application are true, complete, and correct to the best of my knowledge and belief. My signature below indicates my agreement to comply with the stated statutorily based requirements with the knowledge that deliberately making a false statement in any matter within the jurisdiction of any department or agency of the federal government violates 18 USC 1001 and is punishable by a fine of up to $10,000 or up to 5 years in prison.

The Data Steward for this project is: _____ Title: _____
Name

Organization: _____

Work phone number: _____ E-mail address: _____

As Data Steward, I affirm that I will act as the custodian of the NDI files and will be responsible for the observance of conditions of use.
I will notify the NDI Director, Dr. Lillian Ingster (1–301–458–4286; lingster@cdc.gov):

a. when access to the NDI data is no longer needed (see Attachment A);
b. if a change in site access is contemplated;
c. of the intent to modify the project's purpose; or
d. if these responsibilities are to be transferred.

Signature of Data Steward: _____ Date: _____

SIGNATURE of *Principal Investigator or Project Director:*

Signature _____ Date _____

Name (type or print) _____

Title _____

Organization _____

E-mail _____

***SIGNATURE** of *official authorized to execute agreements (last person to sign and date)*

Signature _____ Date _____

Name (type or print) _____

Title _____

Organization _____

E-mail _____

* NOTE: The "official authorized to execute agreements" will vary among organizations. Whenever possible, the NDI prefers that this official be someone at a higher level of authority than the principal investigator or other persons responsible for the study or project; for example, a university official authorized to sign grant proposals, a company vice president, or a government division or bureau director. By signing this agreement as the *authorized official,* you are declaring that you have the authority to make the above assurances on behalf of the university, company, agency, or other organization and to bind the organization to the terms of this agreement and you take responsibility for the confidentiality assurances of all organizations or individuals who are participating in this study.

For those individuals planning to sign digitally, please keep in mind that not all types of electronic signatures are acceptable. For further information, see Attachment D.

Attachment A

National Death Index (NDI) Data Disposition Form

Use the multipurpose form on the next page to notify the NDI program of one of the following events:

- When you have disposed of ALL the identifying or identifiable death record information obtained from the NDI.
- If your initial NDI Application was submitted more than 5 years ago and you are now submitting an NDI Repeat Request Form (and have never completed this form).
- To request an extension for the retention of your identifying or identifiable death record information beyond 5 years from when your initial NDI Application was submitted.
- If you have already been approved for a 1 to 5 year extension, to request another extension beyond your previously approved extension period.

Some State Vital Statistics Offices have expressed concern about indefinite retention of "identifying or identifiable death record data" that could be used in the future by other persons for other purposes.

Definition of "IDENTIFYING or IDENTIFIABLE death record information"—Any information on death certificates, other paper documents, or in computer files that by itself, or if linked with other records, would permit the identification of one or more individuals or establishments; for example, name(s), Social Security number, exact dates, addresses, and death certificate number. Even with the removal of direct identifiers and linkable study subject identification numbers, there is still a special concern that some combinations of the remaining variables could potentially be used to identify an individual. For example, a combination of date of birth, date of death, and/or cause of death is considered identifiable.

Except for data stored in registries, or other approved long-term studies, all identifying or identifiable data received from NDI must be removed from all research records at the conclusion of the study or within 5 years after receipt of the NDI data—regardless of the data set in which the data are kept. This means that all identifiers or potentially identifiable data elements associated with cause-of-death codes must be removed from all analysis files unless there is no way to identify an individual decedent. This also means that any linked files (with crosswalks) must be destroyed. As long as there are no identifiers or linkage variables remaining in the analytic or public-use file(s), cause(s) of death codes may remain in such file(s). Files including backup and derived files with NDI identifying or identifiable data must be both deleted and overwritten to prevent recovery of the data. The requirements above also apply to all data derived from NDI data.

Please note: Death certificates obtained directly from state offices may have to be shredded in less than 5 years depending on each state's requirements.

NDI Data Disposition Form (continued)

National Death Index

Date request approved:

NDI Application number:

Title of study or project:

Principal Investigator or Project Director:

Title:

Organization:

Mailing address:

Phone number:

E-mail:

1. As the Data Custodian for the above listed study/project, I affirm that all electronic and paper files containing identifiable NDI data have been destroyed on: (If not destroyed, put NA and answer items 3–5 below.)
2. I also affirm that all derivative and back-up copies have been destroyed on: (If not destroyed yet, put NA and answer items 3–5 below.)
3. When will the identifiable death record information be destroyed? (State UNKNOWN if this is an open-ended or ongoing study that has no specific disposition plan at this time.)
4. If the answer to item 3 is: (1) unknown, (2) more than 5 years after you submitted your NDI Application Form, or (3) more than 5 years after you last requested an extension for the retention of your data, please provide a strong justification for why the data need to be retained beyond the 5-year period.
5. If it has been more than 5 years since your initial NDI Application (or since your last request for an extension), are you requesting an extension for the retention of identifiable NDI data? ◯ Yes ◯ No
6. If your extension is approved, you are responsible for submitting this form when your data have been destroyed OR within 5 years from now but no later than the date you indicate in the box to the right.

Data Steward (print name and title)	Signature	Date
Principal Investigator or Project Director (print name and title)	Signature	Date

Email form to: ndi@cdc.gov

Registries and Long-term Use and Indefinite End Date Studies: Additional Information Required for NDI Application Form

In addition to the information requested of all NDI applicants, the NDI Application Form must also include the following information in item 6 of the Application:

1. Provide brief descriptions of examples of specific studies that are now being performed or planned. After describing such studies, the applicant should state the following: Should there be any significant deviations from such studies, we fully understand that an amended NDI Application must first be submitted to and approved by NCHS."

   (The purpose of the above requirements is to provide evidence that the organization in fact will be using the registry mortality database solely for "statistical purposes in medical and health studies.")

2. If the applicant indicates that no death record follow-back investigations will be implemented, the applicant must make the following statement:

   "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 the NCHS Director.

3. Provide a specific statement that all hard-copy death record information obtained via the NDI, including copies of death certificates, will be flagged and stored separately from any administrative records or from 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.

Attachment C

National Death Index (NDI) Requirements for Approval by an Institutional Review Board (IRB) for the Protection of Human Subjects

General NDI Requirements for IRB Approvals:

1. The IRB determination needs to be made by (a) an institution that has a Multiple Project Assurance (MPA) or a Federal Wide Assurance (FWA) approved by the Department of Health and Human Services (DHHS) or (b) by an independent IRB registered with DHHS.

2. If the NDI applicant's institution has an IRB (or its equivalent) that is not approved by DHHS, the applicant must submit additional documentation describing the IRB and listing how its membership is constituted.

3. All applicants must submit a current IRB determination letter (official federal medical and health surveillance projects are exempt).

4. The review and approval by an IRB must occur before the approval of the NDI Application.

Specific NDI Requirements for Studies Involving Death Record Follow-back Investigations:

1. The applicant must obtain a letter from the IRB indicating specifically that the study's death record follow-back methodology has been reviewed and approved and that the review of the study also included an assessment of any potential emotional harm and undue respondent burden that may be caused by the proposed follow-back activities. (Of concern are any contacts made to next-of-kin, physicians, hospitals, or other establishments based on information appearing on death certificates obtained via use of the NDI.)

2. The letter must include language similar to the following statement (but tailored specifically to the study that was reviewed):

   "We have reviewed this study in conjunction with your application to use the NDI. We are satisfied that the procedure to be used to obtain additional information on deceased study subjects (from next-of-kin, physicians, hospitals, and/or others) provides appropriate protection to the respondents with respect to minimizing respondent burden, maintaining confidentiality, protecting their privacy, and avoiding or minimizing any emotional or other harm that may affect the respondent. Our review included an assessment of all existing and/or proposed contact letters, telephone techniques, questionnaires, and consent forms used in the death record follow-back investigations. These were all deemed to be satisfactory."

3. If the applicant is unable to obtain such a letter from the IRB, the study's IRB approval document must include attachments that clearly show that the IRB's review included the death record follow-back methodology.

Rationale:

It is understood that most studies using the NDI do not involve diagnostic, therapeutic, or any other forms of physical contacts with human subjects and consequently do not receive or need to receive IRB approvals based on requirements set forth by their own institution or by the regulations for the protection of human subjects from DHHS. On the other hand, NCHS and many State Vital Statistics Offices are concerned about the invasion of privacy, potential emotional harm, and undue respondent burden that can result (from contacts made to next-of-kin, physicians, hospitals, and others) as part of death record follow-back investigations that are felt to be essential components of some studies. Because of this concern, an IRB should review the follow-back methodology to be used in such studies, including review of all contact letters and/or telephone techniques, questionnaires, and consent forms (for release of medical records), as well as procedures for ensuring that the information obtained remains confidential. Therefore, IRB approvals have been made a prerequisite for NDI approvals for studies involving death record follow-back investigations.

NDI applicants or IRB committees requiring additional information on the above requirements should contact NDI staff at 1–301–458–4444.

CDC accepts digital signatures from any federal agency that employs a PIV or CAC card under the “interoperability requirement” of HSPD-12, as long as revocation information is available from that PIV or CAC card at the time we receive the form.

For persons who do not have a U.S. government-issued PIV or CAC card, CDC currently has no way of verifying that the signatures are authentic. As technology changes, this may become an option in the future.