National Death Index

January 2021

Criteria to be Applied in Approving National Death Index Applications

Presented below are the approval criteria, or guidelines, currently being used to approve National Death Index (NDI) applications. These criteria have evolved based on recommendations made by the NDI advisers over the years. The advisers will continue revising these criteria as necessary to address new issues or accommodate unique situations identified in future NDI applications.

1. Use of NDI Solely for Statistical Purposes:

a. An application should clearly indicate that the NDI will solely be used "…to identify state death records for statistical purposes in medical and health studies, in improving the mortality and natality statistics system of the registration areas, or in other research by federal and state agencies that only requires disclosure of information on the probable fact of individual death." (Refer to Attachment 1 for the National Center for Health Statistics [NCHS] confidentiality requirements as well as the provisions that are included in all state NDI contracts for the procurement of death record information.)

b. An application will not be approved if it proposes to use any of the identifying information (on NDI products or on state death certificates) for administrative, legal, or other nonstatistical purposes that may directly affect those particular individuals or establishments as a result of their specific identification in the study. (It is understood, and generally accepted, that aggregate statistics could eventually be used for administrative, legal, or other nonstatistical purposes.)

c. If the response to a question leads the advisers to believe that any of the identifying information obtained from the NDI or from state death certificates may be used for administrative, legal, or other nonstatistical purposes (in addition to the proposed statistical purpose), NCHS staff will request a revised application that eliminates nonstatistical uses of the NDI. (Whenever possible, NCHS staff will request this revision before the application is even submitted to the advisers for review.)

d. The use of the term "statistics" subsumes various uses essential to the preparation of databases for medical and health studies. For example, registries of people with certain characteristics, or who have had certain experiences or exposure, or who have been diagnosed and/or treated for certain diseases have been widely established. The establishment of such registries for the purpose of instituting surveillance of morbidity and/or mortality (to generate hypotheses or identify risks or systematic inadequacies of treatment) constitutes a legitimate form of applied scientific activity. (See sections 6 and 7 below.)

2. Scientific Merit of a Study:

Approval of an application will not be contingent on the scientific merit of a study. Although the advisers may comment on the merit of a study, it is understood that the merit of the study is actually determined by the sponsoring agency and/or by the organization performing the study.

3. Final Disposition of Identifiable Data:

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.

a. All applicants must address the final disposition of death record information received from the NDI, including copies of death certificates, computer printouts, and all analytic files containing identifiable death record information.

b. Except for bona fide registries (see items 6 and 7 below), an applicant must indicate the month and year ALL of the identifiable data obtained from the NDI will be destroyed. (See the revised Data Disposition Plan in item 11 of the NDI Application Form.)

c. Any applicant who has no plans for the destruction of identifiable death record information within 5 years after the submission of his or her NDI Application must justify (in item 11 of the Application Form) why the identifiable death record information needs to be maintained beyond 5 years or indefinitely.

d. Except for bona fide registries, all new applicants and repeat NDI users shall be informed that they must submit an updated NDI Data Disposition Form no later than the disposition date noted in their initial NDI Application Form (or at least within 5 years of their application). This NDI Data Disposition Form (see Attachment A) is to be enclosed with both the NDI approval letters and the NDI results letters sent to all new and repeat NDI users. This document will enable users to:

- Confirm that all identifiable NDI information has been destroyed—and the destruction dates.
- Specify when existing identifiable information will be destroyed.
- Provide a renewed justification of why the identifiable data needs to be maintained beyond 5 years of receipt of the initial application or beyond a previously approved extension period.

4. **Approval by an Institutional Review Board (IRB) for the Protection of Human Subjects:**

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

   b. If an applicant's study or project does not require an IRB approval, the applicant must at least submit documentation from an IRB that the study or project is EXEMPT from the IRB approval requirements.

   c. The IRB approval may be granted by an IRB (or its equivalent) in the applicant's institution or by an IRB in another institution as long as the IRB has a Multiple Project Assurance (MPA) or a Federal Wide Assurance (FWA) from the U.S. Department of Health and Human Services (DHHS). An IRB approval from an independent IRB registered by DHHS is also acceptable. If the IRB (or its equivalent) does not have DHHS approval, the applicant must submit additional documentation describing the IRB (or its equivalent) and listing how its membership is constituted.

   d. For an NDI Application involving death record follow-back investigations, the IRB approval document or a separate letter from the IRB (or its equivalent) must address the potential harm that may be caused by follow-back investigations—and must reference the concerns described in the second page of Attachment C. If the applicant is unable to obtain such a letter from the IRB, the IRB approval document must have attachments that clearly show that the IRB's review included the death record follow-back methodology.

5. **Use of Identifiable Data by a Third Party:**

   a. If the applicant indicates that another organization will be receiving identifying NDI or state death record information, that organization must complete and submit an NDI Supplemental Confidentiality Agreement before NDI approval can be granted. Under each organization (or consultant) listed in item 5 of the NDI Application, 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. In their Supplemental Confidentiality Agreement, they must indicate (item 3) how they will store and maintain the confidentiality of the identifying information and (item 4) how such information will be destroyed.

   b. If the applicant's study is sponsored by a funding arrangement other than a federal grant (via a contract, interagency agreement, cooperative agreement, or other funding arrangement), the sponsoring organization must complete and submit an NDI Supplemental Confidentiality Agreement even if the sponsoring organization does not currently have any contractual or other rights to the identifying information collected by the applicant. The sponsoring organization must indicate (1) that it does not have any rights to (or any plans to obtain) the identifying information or (2) what it would do to protect the confidentiality of any identifying information it will or may obtain and how such information will be destroyed.

   c. All applicants regardless of funding source must complete the NDI Confidentiality Agreement.

6. Registries:

A “registry” is defined as a roster of persons whose data is to be used for medical and health studies without any defined hypotheses to be examined. Registries usually employ a standardized methodology, are subject to informal and sometimes formal controls, and may rely on other methods for follow-up of a majority of the roster. Such registries deserve special consideration. All applicants must complete item 6. If your application involves a registry, 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, and (3) the eligibility criteria for including persons in the registry. A registry should also refer to Attachment B at the end of this application form for additional information to be included in item 6c.

There are special exceptions for bona fide state disease registries. These include the following:

1) the practice of maintaining a hard copy of the death certificate as part of the registry record,
2) informing other bona fide state disease registries of the fact of death, and
3) the use of the knowledge of survival for studies initiated subsequent to the NDI request without reapplication.

Please note: Registries will not be required to submit a separate NDI Application for each study; however, they will be required to describe expected protocols and give specific, current, or future examples of studies (see Attachment B). Multiple uses of NDI information obtained from the National Center for Health Statistics are permitted provided that: (1) each study is solely for statistical purposes in medical or health studies, (2) adequate assurances are given that the confidentiality of the identifying death record information will be maintained, and (3) death record information will be kept separate from any administrative records.

7. General Consideration for Long-term Use and Indefinite End Date Studies

Most NDI applicants are required to submit separate applications for specific studies. However, some organizations conduct mortality surveillance studies on other types of cohorts such as industrial workers, population samples, and members of particular families, and the death record information on those individuals may be used for multiple epidemiologic studies. Such organizations, in essence, are maintaining records that may facilitate epidemiologic studies of groups with particular experiences. Such organizations will not be required to submit separate NDI Applications for each study, although they will be required to describe expected protocols and give specific, current, or future examples (see Attachment B).

Multiple uses of NDI information obtained from the National Center for Health Statistics are permitted provided that: (1) each study is solely for statistical purposes in medical or health studies, (2) adequate assurances are given that the confidentiality of the identifying death record information will be maintained, and (3) death record information will be kept separate from any administrative records.

When an approved long-term/ongoing study finds it necessary to release identifiable death record information to an external organization, the registry must first submit an amended

NDI Application, including an NDI Supplemental Confidentiality Agreement completed by the external organization. The amended application must be approved by the NDI advisers before the identifiable data are released. If those guidelines are not followed, future applications for the NDI may be denied.

8. Repeated Use of the NDI:

a. After an applicant is approved to use the NDI for a specific study or project, the approval is valid as long as there are no significant changes in the project described in the initial application. Examples include: project being supported by a new organization, new organization will be receiving identifiable information, adding follow-back investigation, changes in the provisions of maintaining the confidentiality of identifiable information.

b. Except as noted in 6 and 7 above, an approved applicant must submit a new NDI Application Form to use the NDI for a different study.

c. A new application usually will not be required if additional cohort members are being added, the activity is a direct extension of ongoing work, the activity only involves further follow-up of cohort members, and/or the new research effort still falls within the bounds of the overall research objective(s) described in the initially approved NDI Application. Should an NDI user inquire about how significant his or her proposed changes are, NDI staff will decide whether the user must submit a new application, an amended application, or just an *NDI Repeat Request Form*.

d. Whenever an approved applicant wants to submit records for a repeat search of the NDI file, the applicant need only complete and submit the form entitled *NDI Repeat Request Form*. This form requires the applicant to attach an updated or amended NDI Application Form only if any of the following have occurred since the submission of the last application form: (1) excluding any new **federal grants**, the project is supported by a new organization(s), (2) a new organization will be receiving identifying death record information, (3) confidentiality provisions have changed, (4) provisions for disposing of identifying death record information have changed, (5) identifying death record information will be used for legal, administrative, or other actions which could directly affect particular individuals or establishments, (6) the NDI will also be used for a different project, (7) there are changes in the project's research objectives, (8) the proposed death record follow-back investigations are continuing without a **current IRB** approval, (9) the proposed follow-back methodology has changed, or (10) follow-back investigations will be initiated.

e. *NDI Repeat Request Forms* are routinely approved by NDI staff; however, if they are accompanied by an amended application, the amended application must be approved by NDI staff or Advisers before data can be released.

9. Required Signatures:

The ***NDI Confidentiality Agreement*** and ***Supplemental Confidentiality Agreement*** in each *NDI Application Form* and in each *NDI Repeat Request Form* must be signed. There are specific requirements on how signatures are to be obtained for each one of these forms. Please contact NDI staff for guidance.

10. Types of NDI Approvals (general definitions):

a. Approval—An application will be approved only if it satisfies the above criteria. Only the Division of Vital Statistics (DVS) Director (or their designated representative) may grant final approval to each NDI Application. The DVS Director will normally act based on the recommendations of the NDI advisers and staff; however, the DVS Director retains the right to make the final decision.

b. Repeat Approval—See item 8.

c. Conditional Approval—An application will receive a conditional approval if one or more advisers recommend that the applicant submit minor clarifications to certain sections of the application form. In such instances, the advisers may choose to review the relevant documents or recommend that NDI staff simply verify receipt of necessary changes/ documents.

d. Deferral—Approval of an application will be deferred if one or more advisers have significant doubts or concerns as to whether the application satisfies the NDI approval criteria. The applicant must submit a revised application form that satisfies the concerns raised by those advisers. The revisions must be sent to all the advisers. Before a "deferred" application may be approved, the advisers that raised concerns must review the revised application and must indicate that they are satisfied with the revisions. Other advisers may also comment if they have new concerns or if they are not satisfied with the revisions. After the revisions are deemed to be satisfactory, the application is sent to the DVS Director for final approval.

e. Disapproval—An application will be recommended for disapproval if it does not satisfy the NDI approval criteria presented in this document. An application always will be disapproved if the applicant proposes to use the NDI for administrative, legal, or other nonstatistical purposes, or if the applicant is unable to provide satisfactory assurances that the confidentiality of the identifiable NDI and state data will be protected. If one or more advisers disapprove an application, then the concerns of those advisers must be shared with the other advisers. The application then must be evaluated again by all the advisers before it is sent to the DVS Director for final approval or disapproval.

Confidentiality

Data provided to NCHS by the State Vital Statistics Offices

NCHS is required by law to maintain the confidentiality of identifying information it collects on individuals or establishments. This includes identifying information on decedents obtained under contracts with the State Vital Statistics Offices for use in the NDI. Data permitting identification of particular individuals or establishments cannot be disclosed without the consent of the provider of the information. The Public Health Service Act (42 U.S.C. 242m) states in Section 308(d):

> No information obtained in the course of activities undertaken or supported under section 304, 305, 306, or 307 may be used for any purpose other than the purpose for which it was supplied unless authorized under regulations of the Secretary; and (1) in the case of information obtained in the course of health statistical activities under section 304 or 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, and (2) in the case of information obtained in the course of health services research, evaluations, or demonstrations under section 304 or 305, such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

Release by NCHS of any information on decedents contained in the NDI file is restricted under Section 308(d) above by the purpose for which the information was supplied to NCHS by the State Vital Statistics Offices. The following provisions apply:

> Pursuant to Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the Government (NCHS) assures the Contractor (the State Vital Statistics Office) that:
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> The information obtained under this contract will only be used to identify state death records for statistical purposes in medical and health studies, in improving the mortality and natality statistics system of the registration areas, or in other research by federal and state agencies that only requires disclosure of information on the probable fact of individual death; the information obtained under this contract will not be released for use as a basis for legal, administrative, or other actions that may directly affect particular individuals or establishments, unless consented to in writing by the contractor; and no information obtained under this contract regarding an identified individual or establishment will be released, except for information indicating the probable fact of death and identifying the appropriate state death certificate numbers, without the written consent of the contractor.

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.

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.