National Death Index

March 19, 2024

Criteria for Approving National Death Index Applications

The following information presents the current guidelines for approving National Death Index (NDI) applications. These criteria have evolved based on recommendations from NDI advisers. The advisers will continue revising these criteria, as needed, to address new issues or accommodate unique situations identified in future NDI applications.

1. Use of NDI for statistical purposes only

a. NDI data may only be used for public health and medical studies, provided that no actions are taken that may directly affect people or establishments.

b. NDI data may not be used for genealogical, legal, administrative, or commercial purposes or to generate profit.

2. Scientific merit of a study

Approval of an application is not based on the scientific merit of the study. The responsibility of NDI is to ensure that the NDI data are appropriately used and safeguarded. Note that the standard encryption requirement for sensitive federal information, like NDI data, is FIPS-140-2 in accordance with NIST 800-53.

3. Final disposition of identifiable data

"IDENTIFYING or IDENTIFIABLE death record information" is defined as any information on death certificates, other paper documents, or in computer files which by itself, or if linked with other records, would identify one or more people 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, some combinations of the remaining variables could potentially be used to identify a person. For example, a combination of date of birth, date of death, and cause of death is considered identifiable. No figure, including totals, will be less than 10 in tabulations for sub-national geographic areas, regardless of number of years combined. No data on an identifiable case will be derivable through subtraction or other calculation from the combination of tables in any presentation or publication. No data will permit disclosure when used in combination with other known data.

a. All applicants, except for data stored in registries or other approved long-term studies, must indicate the month and year ALL of the NDI identifiable data (including the data derivatives) received from the NDI will be destroyed and submit the Data Disposition Form (Attachment A).

b. If an applicant has no plans to destroy the NDI identifiable death record information within 5 years after submitting the NDI application, they must provide a strong justification for the need to retain the data beyond 5 years.

4. Approval by an Institutional Review Board for the protection of human subjects:

a. Evidence of a current Institutional Review Board (IRB) review is REQUIRED for all NDI applications, except official federal medical and health surveillance projects.

b. **For surveillance projects, applicants must submit a letter from an authorized institutional official stating that the project meets the definition of a public health surveillance activity excluded from the definition of research in the January 19, 2017, final Common Rule (45 CFR 46.102(l)(2)).**

c. If an applicant's study or project does not require IRB approval, the applicant must submit documentation from an IRB stating this.

d. 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 federal wide assurance from the U.S. Department of Health and Human Services (HHS). Approval from an independent IRB registered with HHS is also acceptable. If the IRB (or its equivalent) does not have HHS approval, the applicant must submit additional documentation describing the IRB (or its equivalent) and listing how its membership is created.

e. For an NDI application involving death record follow-back investigations, the applicant must obtain an approval document or a separate letter from the IRB (or its equivalent) specifying that the study's death record follow-back methodology has been reviewed and approved, and that 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 obtained from NDI.) 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 NDI. We are satisfied that the procedure to be used to obtain additional information on deceased study subjects (from next-of-kin, physicians, hospitals, 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 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."

It is understood that most studies using 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 from their own institution or by the regulations for the protection of human subjects from HHS. However, the National Center for Health Statistics (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 considered 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 telephone techniques, questionnaires, and consent forms (for release of medical records), as well as procedures for ensuring that the information obtained remains confidential. Consequently, IRB approvals are required for NDI approvals for studies involving death record follow-back investigations.

5. Use of identifiable data by a third party

a. If the applicant indicates that another organization will be receiving identifying NDI data, 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:
   - what IDENTIFYING or IDENTIFIABLE death record information will be received.
   - what form it will be received in (for example, computer files).
   - how the information will "flow" from one organization to another. The Supplemental Confidentiality Agreement must indicate how applicants will store and maintain the confidentiality of the identifying information (item 3) and how such information will be destroyed (item 4).

b. Except for National Institutes of Health (NIH) grant awardees who must provide the copy of their Notice of Award, each funding source must complete, sign, and upload an NDI Supplemental Confidentiality Agreement.

   The Notice of Award from NIH must contain specific language about the NDI data, otherwise the Supplemental Confidentiality Agreement must be completed.

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

6. Registries

A "registry" is defined as a roster of people whose data will be used for medical and health studies without any defined hypotheses to be examined. Registries usually use a standardized methodology, are subject to informal and sometimes formal controls, and may rely on other methods for follow-up for a majority of the roster. Such registries require special consideration.

Note that registries do not require a separate NDI application for each study; however, the NDI application must be updated as new studies are conducted. Multiple uses of NDI information obtained from NCHS 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. Long-term study or surveillance

Some organizations conduct mortality surveillance or long-term studies on other types of cohorts such as industrial workers, population samples, and members of particular families, and the death record information on those people may be used for multiple epidemiologic studies. These organizations 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; however,

the NDI application must be updated as new studies are conducted.

Multiple uses of NDI information obtained from NCHS 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 study finds it necessary to release identifiable death record information to an external organization, the applicant must first submit an amended NDI application, including a Supplemental Confidentiality Agreement completed by the external organization. The amended application must be approved by NDI advisers before the identifiable data are released. If these guidelines are not followed, future NDI applications may be denied.

8. Repeated searches (excluding reruns) of NDI data

a. Repeated searches (excluding reruns) of NDI data must be approved by NDI staff before additional searches can occur, to ensure that no significant changes have occurred since the initial application was approved. Examples of significant changes include a new principal investigator, funding source, another internal or external party receiving identifiable data, or adding follow-back investigation.

b. Nonsignificant changes typically include adding cohort members, activity that is a direct extension of ongoing work, activity that only involves further follow-up of cohort members, or new research within the bounds of the overall research objective(s) described in the initial approved NDI application.

c. Whenever additional repeated searches of the NDI data are needed, PI must send an email to ndi@cdc.gov for the application to be unlocked. The PI must verify within the NDI Portal that no significant changes have occurred, and if so, revise and submit appropriate documentation. All applicants must upload the most current IRB approval letter.

9. Required signatures

The **NDI Confidentiality Agreement** or **Supplemental Confidentiality Agreement** must be signed. The "official authorized to execute agreements" is the person 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 commit the organization to the terms of this agreement. Additionally, you take responsibility for the confidentiality assurances of all organizations or people who are participating in this study.

The Centers for Disease Control and Prevention (CDC) accepts digital signatures from any federal or state agency that uses 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 when the form is submitted. For people without a U.S. federal or state government-issued PIV or CAC card, CDC currently cannot verify that the signatures are authentic. As technology changes, this may become an option in the future.

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 Director (or their designated representative) may grant final approval

to each NDI application. The Director will usually act based on the recommendations of the NDI advisers and staff, however, retains the right to make the final decision.

b. Repeated searches of NDI data—See item 8 of this document.

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 and documents.

d. Deferral—Approval of an application will be deferred if one or more advisers have significant doubts or concerns about whether the application satisfies the NDI approval criteria. The applicant must submit a revised application form that addresses these concerns. The revisions must be sent to all advisers. Before a deferred application may be approved, the advisers with concerns must review the revised application and indicate their satisfaction 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 Division of Vital Statistics director for final approval.

Confidentiality

Data provided to the National Center for Health Statistics by the state vital statistics offices

The National Center for Health Statistics (NCHS) is required by law to maintain the confidentiality of identifying information it collects on people or establishments. This includes identifying information on decedents obtained under contracts with state vital statistics offices for use in the National Death Index (NDI). Data that identifies particular people 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) 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 (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 people or establishments, unless consented to in writing by the contractor; no information obtained under this contract regarding an identified person 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.

National Death Index Data Disposition Form-Attachment A

NDI application number: Date:

Title of study or project:

Principal Investigator or Project Director:

Title:

Organization:

Mailing address:

Phone number: E-mail:

1. I affirm that all electronic and paper files containing identifiable NDI data have been destroyed on:

2. I also affirm that all derivative and back-up copies have been destroyed on:

Data Steward (print name and title) Signature Date

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