



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 period 1982 through February 2007. 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 research, in improving the mortality and natality statistics system of the registration areas, or in other research by Federal and state agencies which 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 which are included in all state NDI contracts for the procurement of death record information.)
- b. An application will be disapproved if it proposes to use any of the identifying information (on NDI products or on state death certificates) for administrative, legal or other non-statistical purposes which 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 non-statistical 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 non-statistical purposes (in addition to the proposed statistical purpose), NCHS staff will request a revised application which eliminates non-statistical uses of the NDI. (Whenever possible, NCHS staff will request such a 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 data bases for medical and scientific research. 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 (in order to generate hypotheses or to 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: By “*identifying or identifiable death record information*” we mean any information on death certificates, other paper documents, or in computer files which by themselves, or if linked with other records, would permit the identification of one or more individuals or establishments. Furthermore, by identifiable data we mean name(s), Social Security Numbers, exact dates, addresses, death certificate numbers as well as variables that in combination could identify an individual.

- a. All applicants must address the final disposition of death record information received from the NDI, including copies of death certificates, the NDI CD, 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 13 of 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 13 of the Application Form) why the identifiable death record information needs to be maintained beyond 5 years or indefinitely.
- d. **Except for bonifide 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 4) 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:
 - 1) Confirm that all identifiable NDI information have been destroyed – and the destruction dates.
 - 2) Specify when existing identifiable information will be destroyed.
 - 3) Provide a renewed justification of why the identifiable data needs to be maintained beyond 5 more 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. An applicant must obtain and submit an IRB approval before the NDI Application form will be granted final approval.
- 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 must be current (within the past 12 months)
- d. At the discretion of an applicant's IRB (or its equivalent), an expedited IRB review and approval will be considered acceptable for NDI approval.
- e. 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.
- f. 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 on the second page of Attachment 3. 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.
- g. Because of the time generally required to obtain an IRB approval, NDI staff may send an NDI application to the advisers as conditionally approved pending receipt by NDI staff of the applicant's IRB approval. As long as the advisers have no other concerns about the application, NDI staff may arrange for the application to be approved as soon as the IRB approval is received by NDI Staff. (Exception: For studies involving death record follow-back investigations, the advisers must be provided with all pending IRB documents and must recommend approval before the NDI application can be changed from "conditional" to "approved" status.)

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. The third party must indicate (1) how they will store and maintain the confidentiality of the identifying information and (2) how such information will be disposed.
- 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 arrangements), 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 disposed.
- c. An NDI Supplemental Confidentiality Agreement is not required for a study which is supported by a Federal grant, except in those rare instances where the granting agency will receive identifying information from the grantee.

6. Disease Registries:

By “disease registry” is meant a roster of persons diagnosed and/or treated for a particular disease and maintained for the purpose of morbidity and/or mortality surveillance without any specific 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.

Applicants who propose to submit a roster of names deriving from such a registry should specify the date the registry was founded, the purpose of the registry, the eligibility criteria for including persons in the registry, the provisions for internal and external approval of the registries quality and methods (including human subject considerations), and the dates of the last documented internal and/or external reviews.

It is understood that applications from disease registries, especially from the most ubiquitous type of disease registries, cancer registries, have special problems. Several of the practices discouraged by the NDI are considered standard practice for cancer registries and are even counted as positive elements in the institutional approval process. These include (1) the practice of maintaining a hard copy of the death certificate as part of the registry record, (2) informing other bona fide tumor registries of the fact of death, and (3) the use of the knowledge of survival for research studies initiated subsequent to the NDI request without reapplication.

Furthermore, registries will not be required to submit 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 2). 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 research, (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.

It is understood that a disease registry may have occasion to release identifiable, record-level death information to approved researchers according to the registry’s data release policies. A registry must annually provide NDI staff with a list of such data releases. The list must contain the name of each researcher’s organization, the title of the study, and the study’s purpose or objectives.

7. General Consideration for Non-Disease Cohorts and Ongoing Studies:

Most NDI applicants are required to submit separate applications for specific studies. However, some organizations conduct mortality surveillance studies on “non disease” 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 exposure or other non-disease “registries” which 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 2).

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 research (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 non-disease registry (or 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.

8. Repeated Use of the NDI:

- a. Once 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.
- 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 a one-page 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 has 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 amended applications, the amendments must be sent to the advisers for review and approval.

9. Required Signatures:

The **NDI Confidentiality Agreement** in each *NDI Application Form* and in each *NDI Repeat Request Form* must be signed by the study's project director or principal investigator, or by a higher official in the organization. The Supplemental Confidentiality Agreement must have similar signatures for any external organization(s). These NDI forms must also be signed by an "official authorized to execute agreements" who represents the organization in policy, fiscal or legal matters.

NDI staff may send these documents to the NDI advisers unsigned with a recommendation that the applications be conditionally approved pending receipt by NDI staff of the signed documents. As long as the advisers have no other concerns with the application, NDI staff may arrange for the application to be approved as soon as the required signatures are received.

10. Types of NDI Approvals (General Definitions):

- a. **Approval** — An application will be approved only if it satisfies the above criteria. Only the NCHS Director (or his designated representative) may grant final approval to each NDI application. The Director will normally act based on the recommendations of the NDI advisers and NCHS staff; however, the Director retains the right to disagree or to settle conflicting recommendations.
- b. **Repeat Approval** — See item 8.
- c. **Conditional Approval** — An application will receive a conditional approval pending receipt by NDI staff of (1) all required signed forms, (2) the applicant's IRB approval, or (3) if one or more advisers recommend that the applicant submit minor clarifications to certain sections of the application form. In such instances those advisers do not have to review the relevant documents unless NCHS staff feels that the revisions (or signatures) do not satisfy the recommendations of those advisers.
- 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 which 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. Once 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 non-statistical 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 NCHS 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, 306,307, or 309 may be used for any purpose other than the purpose for which it was supplied unless authorized by guidelines in effect under section 306(l)(2) or under regulations of the Secretary; and (1) in the case of information obtained in the course of health statistical or epidemiological 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....

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. In the case of the NDI, the *purpose* for which the death record information is supplied is clearly specified in the contracts between NCHS and the State offices. Each contract contains the following provisions:

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:

The information obtained under this contract will only be used to identify State death records for statistical purposes in medical and health research, in improving the mortality and natality statistics system of the registration areas, or in other research by Federal and State agencies which 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 which 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.

**DISEASE AND NON-DISEASE REGISTRIES:
ADDITIONAL INFORMATION REQUIRED FOR THE NDI APPLICATION FORM**

In addition to the information requested of all NDI applicants, the NDI Application Form submitted for both disease and non-disease registries must also include the following information in item **8.c** of the Application:

1. Provide brief descriptions of examples of specific studies which 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 data base solely for "statistical purposes in medical and health research.")

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. Furthermore, before follow-back investigations are initiated, it is understood that we will also obtain approvals from the states from which death records had been obtained.”

3. 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 approval be granted by (a) an institution which has a Multiple Project Assurances (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 institutional review board (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. An "expedited" IRB review and approval is acceptable if performed by an institution having an MPA and if the research meets the conditions for "expedited" IRB review described in 45 CFR 46.110(a) or (b).
4. 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.
5. The review and approval by an IRB must occur prior to 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 which 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 which 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) provide 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 promulgated by the DHHS (45 CFR 46). On the other hand, 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 which 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 insuring 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. We are hopeful that IRB committees will be both supportive and responsive to this requirement, even though reviews of such studies are neither customary nor required for other purposes and may even be "exempt" as defined by the DHHS regulations at 45 CFR 46.101(b)

NDI APPLICANTS AND IRB COMMITTEES REQUIRING ADDITIONAL INFORMATION ON THE ABOVE REQUIREMENTS SHOULD CONTACT THE NDI STAFF ON 301-458-4444.

NATIONAL DEATH INDEX (NDI) DATA DISPOSITION FORM



Use the multi-purpose 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 prior to April 1, 2007 and you are now submitting a Repeat NDI Request (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 information*” 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 which by itself, or if linked with other records, would permit the identification of one or more individuals or establishments. Furthermore, by identifying or identifiable data we mean such items as 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.]

Except for data stored in bona fide registries, all identifying or identifiable data received from the NDI must be removed from all research records at the conclusion of the study or within 5 years after receipt submission of your initial NDI Application Form -- 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) are to be destroyed. (Note: Death certificates obtained directly from state offices may have to be shredded in less than 5 years depending on each state’s requirements.)

While the NDI staff recognizes that some research studies can remain active for several years, each study is viewed to have a limited duration. At the completion of the study ALL identifying or identifiable information that came from the NDI match must be destroyed, regardless of storage medium, unless no possible link could be made to an individual. **Note: As long as there are no identifiers or linking variables remaining in the analytic or public-use file(s), cause(s) of death codes may remain in such file(s).**

NATIONAL DEATH INDEX DATA DISPOSITION FORM



Date of initial NDI Application

NDI Application Number

Title of study
or project:

Principal investigator
or project director:
Title:

Organization:
Mailing address:

Phone:

E-mail:

1. When was the identifiable death record information destroyed?
(If not destroyed yet, put NA and answer items 2 – 5 below.)

2. 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.)

3. If the answer to item 2 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.

4. 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

5. 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.

Signature of Principal Investigator or Project Director

Date

Mail form to: National Death Index, NCHS, 3311 Toledo Road, Room 7318, Hyattsville, MD 20782