FORM APPROVED
OMB No. 0920-0215
Approval Expires 11/30/2007

MENT B

NATIONAL DEATH INDEX

APPLICATION FORM

ll us on (301) 458-4444 BEFORE
tempting to complete this form.

ment of Health and Human Services
Centers for Disease Control and Prevention
National Center for Health Statistics
CDC/NCHS-6205-1
(Rev. 04/2007)

NDI APPLICATION FORM INSTRUCTIONS

1. Use of the NDI is restricted to statistical purposes in medical and health research. The NDI may not be used as a basis for legal, administrative, or other actions which may directly affect particular individuals or establishments as a result of their specific identification in a given study or project. ***If you are in doubt as to whether your application will be approved, please phone us.***

2. ***Confidentiality Agreement signatures*** – To expedite the review of your application, you ***may*** e-mail your completed application form before you obtain all the required signatures on the ***Confidentiality Agreement*** and/or ***Supplemental Confidentiality Agreement*** pages. (Unsigned forms must at least have the name, title, and the organization of the person that will be signing.) Once we receive your application form, we will send you your assigned NDI application number. Use your NDI number when mailing us your original, signed forms or any additional documentation.

3. ***IMPORTANT --*** The electronic version of the NDI Application Form contains boxes for all your responses. Please note that your responses need not be limited to the space provided in each box. ***The boxes will expand to accommodate your responses. Never use the TAB key. Save your file often.***

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

5. ***New applications*** -- All new NDI applications are reviewed by a group of NDI advisors. Please allow 2 months for your application to be approved. Do not submit your records for an NDI search until after you have been notified that your application has been approved and you receive an NDI Transmittal Form to accompany your diskette or CD-ROM.

6. ***Repeat requests*** -- You can usually make future submissions for the ***same*** study or project without having to submit a new NDI application form. All future requests should be made using a one-page form entitled *Request for a Repeat NDI File Search.* (You will receive this form along with the results of each search.) If nothing in your initial, approved application has changed, you will be notified in about 2 weeks that your repeat request has been approved.

7. Please call or e-mail us if you have questions. Mail or e-mail your NDI application form to:

NATIONAL DEATH INDEX
National Center for Health Statistics
3311 Toledo Road, Room 7318
Hyattsville, Maryland 20782
301-458-4444
ndi@cdc.gov

The collection of the information requested in this application form is authorized by Section 306 of the Public Health Service Act (42 U.S.C. 242k). The principal purpose of the information requested in this form is to approve requests for the use of the National Death Index (NDI) based on a determination of (1) whether the proposed uses of the NDI conform with the criteria agreed upon between the National Center for Health Statistics and the state vital statistics offices and (2) whether the NDI user will be able to submit data on persons in his or her study in a manner which meets NCHS technical specifications. The form is also used to obtain assurances from the NDI user that the information obtained from NCHS will be kept confidential and will only be used for the study or project proposed by the user. Copies of the completed application form will be sent to the advisers for the NDI program and the state vital statistics offices. A completed application form must be submitted to NCHS in order for individuals or organizations to receive the NDI services. Provision of the requested information is voluntary; however, failure to supply all information may delay or prevent action on your application. The following information on each approved NDI user will be made available to the public: the project director's name, organization and address and the title of the study or project. The remainder of the information provided in the application form will be kept confidential. Voluntary disclosure of information, after being informed of the routine uses and disclosures described above, is an acknowledgment of consent to such uses and disclosures.

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 FORM

1. Title of Study or Project

2. Individual and Organization Requesting Use of the NDI

Principal Investigator or Project Director:
Title:
Organization:

Complete mailing (include street address, room number, city, state, and zip code)

Phone no.: Fax no.: E-mail:

Who should be contacted if more information is needed?:

Phone no.: Fax no.: E-mail:

Name(s)	Organization(s)	Phone number(s)

3. Co-Principal Investigators (if any): If there are no Co-PI's, type "None". (Co-PI's employed by the above organization must countersign the Confidentiality Agreement at the end of this application form. Co-PI's in other organizations must complete and sign the Supplemental Confidentiality Agreement.)

4. Type of NDI Search Requested

		Estimated number of records to be submitted
***Routine* NDI file search <u>only</u>**	May include **KNOWN** decedents for a *routine* search	
NDI *Plus* coded causes of death	Status of study subjects **UNKNOWN**	
NDI *Plus* coded causes of death	A separate file of **KNOWN** decedents	

5. External Funding Sources (If none, type “Internal funding only.”)

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, 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 form.)**

Names of Organization(s)	Type of Funding Support

6. Data sources

List all organizations (including your own) which 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 7** below.

7. EXTERNAL organizations (other than the NDI applicant's organization) receiving IDENTIFYING or IDENTIFIABLE death record information. (If there are no such external parties, type "None.")

(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.)

List the names of all EXTERNAL parties (organizations or outside consultants) who will obtain identifying or identifiable death record information from the NDI, from state vital statistics offices and/or from death record followback investigations. Include ***administrative relationships*** such as consultants, outside nosologists, contractors, subcontractors, sponsoring or participating agencies or organizations, and other major divisions or departments in your organization. If applicable, REPEAT some or all of the organizations listed in Items 5 and 6 above. **(Note: Each organization listed in item 7 must complete and sign a Supplemental Confidentiality Agreement at the end of this application form.)**

IMPORTANT: Under each organization (or consultant) listed below, specify that organization's role and what project activities will be performed. Also specify (1) what identifying or identifiable information 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.

Names of Organizations or Individuals*	**Administrative Relationship (consultant, contractor, etc.)**

*NOTE: A ***"National Death Index Supplemental Confidentiality Agreement"*** (see end of application form) must be completed by, or on behalf of, ***each*** organization (or individual) listed in ***items 5*** and ***7*** above and must be signed by responsible officials of that organization. This requirement is waived only for a FEDERAL GRANT listed in item 5 and then only when the NDI applicant gives assurances that identifying information obtained directly or indirectly from the NDI will not be provided to the granting agency.

8. 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 the NDI data will be used. Do not limit your responses to the space provided. The boxes will expand if more space is needed. (You should not attach your complete study protocol or a detailed description of your project.)

8.a. Registries -- It is understood that some users of the NDI are only indirectly involved in research or statistical activities, such as preparing and maintaining data files for disease or non-disease registries (e.g., cancer registries or occupational exposure registries).

Will the information obtained via the NDI be included in a disease or non-disease registry? ☐ Yes ☐ No

*All applicants must complete items **8.b** and **8.c**. If your application involves a registry, be sure also to include the following information in item **8.b.** 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 A** at the end of this application form for additional information to be included in item **8.c**. below.*

8.b. 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.

8.c. Study protocol or project activities -- Summarize the study protocol or project activities. Conclude your summary by describing how data obtained from the NDI, state death certificates, and death record "followback" investigations will be used. More information about death record followback investigations is requested in item **9**. (NOTE: ***Registries*** should also refer to ***Attachment A*** at the end of this application form for additional information to be included in the response to item **8.c.**)

9. Death Record Followback Investigations

9.a. Will this study or project require "followback" investigations to obtain additional information from individuals or establishments mentioned on death records?

☐ Yes ☐ No

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

☐ Decedent's next-of-kin

☐ Physicians

☐ Hospitals

☐ Other individuals or establishments mentioned on death record

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

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

9.e. Methods to be used in conducting followback investigations, including how EACH type of contact will be made:

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

(as defined by the U.S. Department of Health and Human Services in the Code of Federal Regulations, Title 45, Part 46):

Evidence of a current Institutional Review Board (IRB) approval is REQUIRED for all NDI applications. However, if this study or project involves death record "followback" investigations as described in item 9 above, a special letter from the IRB is REQUIRED (as explained in *Attachment B* at the end of the application form).

10.a. Has this study or project been reviewed and approved by an IRB? ☐ Yes ☐ No

10.b. If Yes, attach a copy of the IRB approval and provide the following:

Name of the IRB:

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

Date of the IRB's approval:

10.c. ***If the study or project DOES NOT have an IRB approval, please indicate the reason and attach a notice from an IRB indicating that the study is EXEMPT.*** [NOTE: If death record "followback" investigations will be performed as described in item 9 above, 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 Institutional Review Board (which 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.]

11. Obtaining State Death Certificates

11.a. Based on the results of the NDI file search(es), will copies of death certificates be requested from state vital statistics offices? ☐ Yes ☐ No

11.b. If you plan to request death certificates, what specific items of death certificate information do you expect to use in your analyses and/or to verify questionable matches?

12. Maintaining the Confidentiality of Identifying (or Identifiable) Information

12.a. Name the organization(s), including your own, which will:

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

(2) receive directly the results of the search:

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

12.b. 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 followback investigations. (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.)

[NOTE: Be specific about how both hard copy and computer records will be stored and protected by your organization. ***For example,*** *what precautions will be taken to ensure that copies of death certificates and other identifying information obtained via the NDI will only be used for the study or project described in this application? Will the identifying information be kept separate from your organizations medical, personnel, or other types of* ***administrative records*** *which may be accessible for purposes other than described in this application? Will separate computer files be used to segregate identifying information from other analytical data maintained on your study subjects? How will access to identifying information be restricted?]*

13. 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.

[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 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) 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 linkage variables remaining in the analytic or public-use file(s), cause(s) of death codes may remain in such file(s).**

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

MM/YYYY

2. Only complete items 2.a. and 2.b. 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 Form.

a. Please provide a strong justification of why the data need to be retained beyond this 5-year period.

b. It is to be understood that ***within 5 years of submitting your NDI Application Form*** you are responsible for (1) letting NDI staff know why the data are still needed and (2) requesting an extension for the retention of identifiable NDI data. This request is to be submitted to NDI staff within 5 years – no later than the month and year you state in the box below.

MM/YYYY

14. Completion of Study or Project

14.a. Indicate the scheduled termination date for the study, or whether the study is on going or open-ended.

14.b. In what form and to whom will the results of your study or activities be released?

14.c. Will study subjects be notified of study results? Yes ☐ No

If yes, how will the subjects be notified? ☐

15. Other Uses of the Data

15.a. Will any of the identifying information (obtained from the NDI, from the state vital statistics offices, and/or from death record followback investigations) be used as a basis for ***legal, administrative, or other actions*** which may directly affect particular individuals or establishments as a result of their specific identification in this project?

☐ Yes ☐ No ☐ Maybe

If *Yes* or *Maybe*, please explain:

15.b. Will the identifying information (obtained from the NDI, from the state vital statistics offices, and/or from death recordfollowback investigations) be used either directly or indirectly for any study or project other than the one described in "Summary of Study Protocol or Project Activities"? (See item 8 above.)

☐ Yes ☐ No ☐ Maybe

If *Yes* or *Maybe*, briefly describe the other purpose(s) for which the data will be used. (NOTE: A separate application form must be submitted for each study or project which will be using identifying information obtained via the NDI.)

16. Types of Data To Be Submitted to NCHS

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

☐ First and last name and month and year of birth

☐ First and last name and Social Security Number

☐ Social Security Number, month, day and year of birth, and sex

16.b. Which of the following NDI data set items will you be able to provide for the records you submit? You are encouraged to provide as many of these data items as possible. This will maximize the number of true matches that are generated and will assist you in assessing the quality of the matches that occur.

	On approximately what percent of your records?
1. First name	☐ %
2. Middle name	☐ %
3. Last name	☐ %
4. Father's surname	☐ %
5. Social Security Number (SSN)	☐ %
6. Month of birth	☐ %
7. Day of birth	☐ %
8. Year of birth	☐ %
9. Sex	☐ %
10. Race	☐ %
11. Marital status	☐ %
12. State of residence[1]	☐ %
13. State of birth	☐ %
14. Age at death (if known)[2]	☐ %
15. State of death[2]	☐ %
16. Date or year of death[2]	☐ %
17. Date or year of last contact[3]	☐ %

[1] This item refers to the *last known* state of residence. The item is useful in assessing the matching results.

[2] For users submitting records for KNOWN decedents, these items are useful in assessing the matching results.

[3] For users submitting records for subjects whose vital status is UNKNOWN and for whom different years of death need to be searched, providing the date or year of last contact is useful in assessing the matching results.

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) from State death records, and (3) from death record followback investigations:

A. Except for persons or organizations specified in the approved NDI application form, no data will be published or released in any form to any party if a particular individual or establishment is identifiable. **ALL REQUESTS FOR IDENTIFIABLE DATA OBTAINED VIA THE NDI WILL BE REFERRED IMMEDIATELY TO NCHS.** 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 research.

C. The identifying information will not be used as a basis for *legal, administrative, or other actions* which 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 National Center for Health Statistics.

E. 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 of this agreement may result in my and/or my organization's being denied (1) future use of the NDI and/or (2) copies of death certificates or other identifying death record information from the state vital statistics offices.

F. 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, once 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.

G. 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.

**** 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, 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.

SIGNATURE of *principal investigator, project director, project officer, or other responsible official.*

Signature Date

Date

Name (Please type or print)

Title

***SIGNATURE** of *"official authorized to execute agreements".*

Signature

Date

Name (Please type or print)

Title

NATIONAL DEATH INDEX SUPPLEMENTAL CONFIDENTIALITY AGREEMENT

A separate Supplemental Confidentiality Agreement must be completed and signed by each ***EXTERNAL*** organization or consultant funding or participating in this study, as listed in ***items 5 and 7*** of the NDI Application Form. Co-principal investigators listed in ***item 3*** and employed in ***external*** organizations must also sign this Supplemental Confidentiality Agreement. 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 person responsible for project activities:

Organization name and complete mailing address:

Telephone 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 "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.)

☐ 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

3. If YES or MAYBE to either questions 1 or 2, describe below how your organization will store and maintain the confidentiality of the identifying or identifiable information obtained from (1) the NDI, (2) state death records, and (3) death record follow back investigations. How and when will your organization dispose of each of these types of identifying information? If your organization has no plans to dispose of some or all of the identifying or identifiable information, please explain why.

NOTE: Be specific about how <u>both</u> hard copy and computer records will be stored and protected by the organization (or individual) specified above. For example, what precautions will be taken to ensure that copies of death certificates and other identifiable information obtained via the NDI will only be used for the study or project described in this application? Will the identifiable information be kept separate from your organization's medical records or other types of administrative records which may be accessible for purposes other than described in this application? Will separate computer files be used to segregate identifiable information from other data on the study subjects? How will access to identifiable information be restricted? **(Box below will expand if you need more space.)**

For your information, some state vital statistics offices have expressed concern about the indefinite retention of death certificates which could be used inadvertently in the future by other persons for other purposes. If you feel that the death certificates and other identifiable information must be retained indefinitely, please provide a strong justification here and indicate what precautions will be taken to ensure that the information is not used inadvertently in the future for other purposes. Please note, however, that when you request certificates from the individual state offices, you will have to conform with each state's data release policies or negotiate special arrangements.

National Death Index Supplemental Confidentiality Agreement (continued)

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) from State death records, and (3) from death record followback investigations:

A. Except for persons or organizations specified in the approved NDI application form, no data will be published or released in any form to any party if a particular individual or establishment is identifiable. **ALL REQUESTS FOR IDENTIFIABLE DATA OBTAINED VIA THE NDI WILL BE REFERRED IMMEDIATELY TO NCHS.** 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 research.

C. The identifying information will not be used as a basis for *legal, administrative, or other actions* which 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 National Center for Health Statistics.

E. 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 of this agreement may result in my and/or my organization's being denied (1) future use of the NDI and/or (2) copies of death certificates or other identifying death record information from the state vital statistics offices.

F. 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, once 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.

G. 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.

**** 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, 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.

SIGNATURE of *principal investigator, project director, project officer, or other responsible official.*	***SIGNATURE** of *"official authorized to execute agreements".*
Signature Date	**Signature**
Date	Date
Name (Please type or print)	Name (Please type or print)
Title	Title

February 7, 2007 **ATTACHMENT A**

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.

February 7, 2007 **Attachment B**

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.