

# **USER'S GUIDE FOR ACCESS TO PROTECTED DATA**

**PA Department of Health  
Bureau of Health Statistics and Registries**

Revised May 2021

## INTRODUCTION

The Bureau of Health Statistics & Registries oversees the release of protected data maintained in the Vital Events Registry, Cancer Registry, and Immunization Registry. The release of this data may only be done in accordance with the following requirements.

1. The release of vital statistics information is governed in Pennsylvania by the **Vital Statistics Act of 1953**. This Act does permit access to vital records data for the purpose of medical research; however, the Act states that any release of information is permitted only under the approval and strict supervision of the Department of Health. Government agencies may only be permitted access to identifiable data in pursuance of their official duties.
2. The release of cancer data is governed in Pennsylvania by Act 67 which amended Act 224, the **Cancer Control, Prevention, and Research Act of 1980**. This Act permits the Department of Health to allow access to data only for the purpose of specific research, and only under the approval and strict supervision of the Department of Health.
3. The release of vaccination data is protected data under the **Disease Prevention and Control Law**. This Law permits the Department of Health to allow access to data only for the purpose of specific research, and only under the approval and strict supervision of the Department of Health.

To assist in the processing of requests for protected data, the Department of Health requires the submittal of an **Application for Access to Protected Data**. This application form is designed to serve three purposes:

1. To provide the Department of Health with sufficient information to determine whether the proposed use of the information conforms to the Department's approval criteria.
2. To obtain assurances from the user that the confidentiality of the information obtained will be protected and that the data provided by the Department will be used only for the proposed study.
3. To provide the Department with an indication of whether the user will be able to submit data on persons in the proposed study in a manner which meets the Department's technical requirements for location of records.

All requests and inquiries should be directed to [RA-DHPROTECTEDDATA@pa.gov](mailto:RA-DHPROTECTEDDATA@pa.gov) or by phone to (717) 783-2548.

## DEFINITIONS

**CONFIDENTIALITY** is a status accorded to data indicating that it is sensitive and, therefore, needs to be protected and carefully controlled. Confidentiality is a short-hand term referring to how information once collected, will be treated. Confidential treatment means that no one outside the immediate data-collecting organization will have access to identifiable individual responses without thorough prior review and approval by the Pennsylvania Department of Health in accordance with existing legislation.

**IDENTIFIABLE DATA** refers to any information which could permit the identification of any individual. This is not only name and address, but also individual case record data where other demographic items such as age, sex, race, and place of residence could possibly be used to identify subjects.

**INDIVIDUAL** is a natural person, living or dead.

**INDIVIDUAL CASE-LEVEL DATA** are data about a single person as opposed to statistical aggregate data; for example, computer line listings are individual case-level data. Individual case-level data can be identifiable data.

**PROTECTED DATA** are data that are kept confidential because they are identifiable. The protected data maintained by the Bureau of Health Statistics & Registries includes certificates of births, deaths, and fetal deaths; cancer records; and patient vaccination records.

## PROCESS FOR REQUESTING ACCESS TO PROTECTED DATA

Researchers or government agencies interested in obtaining identifiable or individual case record data from the Pennsylvania Department of Health's Bureau of Health Statistics & Registries files should submit a completed **Application for Access to Protected Data** to:

Pa Department of Health  
Bureau of Health Statistics & Registries  
555 Walnut St., 6th Floor  
Harrisburg, PA 17101-1914

or by email to: [RA-DHPROTECTEDDATA@pa.gov](mailto:RA-DHPROTECTEDDATA@pa.gov)

If a National Death Index application has already been approved for the same study or if Pennsylvania's protected data are needed for inclusion in a Tumor Registry, the **Application for Access to Protected Data** may not need to be completed. If this is the case, please contact the Bureau at (717) 783-2548 for clarification.

## COMPLETION OF THE APPLICATION FORM

All answers to questions must be typed or printed. "NA" should be entered for those questions which are not applicable. Responses are to be as specific as possible. If additional space is required for some answers, a separate page(s) may be added, and each answer should be numbered.

If assistance is required in completing any part of the application, please contact (717) 783-2548 or [RA-DHPROTECTEDDATA@pa.gov](mailto:RA-DHPROTECTEDDATA@pa.gov).

## DATA AVAILABILITY

### 1. Vital Records Documents

The Bureau of Health Statistics & Registries maintains vital records documents from 1906 to the present. Noncertified copies of death records and fetal death records are available for approved studies. Only abstracted information from birth records is available for approved studies.

### 2. Vital Statistics Data

The Bureau of Health Statistics & Registries maintains vital statistics data from 1960 to the present. Data will be provided in a fixed length text file with appropriate record format.

### 3. Cancer Data

The Bureau of Health Statistics & Registries maintains cancer data back to 1985, which was the first full calendar year all hospitals in Pennsylvania reported cancer cases to the Department of Health. Data will be provided in the NAACCR formatted text file with appropriate record format.

**Please note that for cancer research studies, only invasive diagnoses cases will be released. Should the study also be requesting in situ cases, additional documentation supporting the need for this information must be provided in order to be considered for release.**

### 4. Vaccination Data

The Bureau of Health Statistics & Registries maintains vaccination data back to 1997. There is no state mandate that vaccination data be reported to the Bureau's Immunization Registry. Certain federal vaccine programs, such as the COVID-19 Vaccine Program, do require reporting to the Immunization Registry if the facility is receiving vaccine from CDC. Data for vaccinations administered in Philadelphia County is not available from the Bureau's Immunization Registry. Individuals seeking vaccination data for doses administered in Philadelphia should contact Philadelphia County and request data from PhilaVax, Philadelphia County's Immunization Registry.

## **GUIDELINES FOR FOLLOWBACK ACTIVITIES USING PENNSYLVANIA RECORDS**

The Department of Health's followback policies are listed here for your information. These policies must be followed if followback investigations (based on information provided by Pennsylvania records) are required to obtain additional information.

1. An Institutional Review Board (IRB) for the Protection of Human Subjects approval is required if a study or project involves any followback activities (to families, next-of-kin, or the study subject) based on information provided by Pennsylvania records. If the principal investigator does not have a professional affiliation with a university, hospital, or other institution with an IRB, application may be made to the Pennsylvania Department of Health's IRB for review of the study or project. Additional information concerning the Pennsylvania Department of Health's IRB may be obtained by calling (717) 783-2548.
2. Initial contact for investigations to families, next-of-kin, or surviving cancer patients must be by mail using your cover letter and informed consent form. No personal or telephone contacts may be made initially, if names and/or addresses are obtained from Pennsylvania records. A signed consent form must be received before a personal or telephone interview can be conducted. If a negative response is received from a potential respondent, further contact is not permitted.

**There must be an "opt in" and an "opt out" option** in the initial mailing. It is required to receive active consent to proceed, not passive. All mailings shall be completed using envelopes on which there is no information that states or implies the recipient's diagnosis (e.g., "Cancer Survivorship Study" cannot appear on the envelope). If you do not receive a response to the initial mailing within a reasonable amount of time, a second mailing may be completed. If you do not receive a response to the second mailing, within a reasonable amount of time, a telephone call is permitted only to inquire if the potential respondent has received the mailing (at this time, the researcher may ask the subject if he/she intends to participate).

If a second mailing to non-respondents of the first mailing is not done, there cannot be any telephone contact attempted to non-respondents of the first mailing. **The total number of contacts is limited to two mailings and a phone call. Please note that the PA Department of Health does NOT collect individual's phone numbers. Thus, this is not a data item that can be requested.**

3. Copies of the initial contact letter, consent forms, and any survey forms or questionnaires must be attached to the Application for Access to Protected Data and labeled appropriately. The following information is to be included in the initial contact letter and/or consent form:
  - a. The name and address of the principal investigator(s)
  - b. The name and telephone number of a person who can be called concerning any questions about the study

- c. A general description of the study including:
  - Purpose
  - Why the individual is included in the study
  - The nature of the questions that will be asked
  - The approximate length of interview and how the interview will be conducted, e.g., phone or in person
- d. A listing of any risks or benefits to the participant
- e. A description of any cost or payments involved
- f. An overview of the assurances of confidentiality
- g. A description of how the findings will be used
- h. A specific location for the individual to sign and indicate their **willingness or non-willingness** to participate in the study
- i. Inclusion of the Pennsylvania Cancer Registry Brochure (if applicable).

## **EMPLOYEE REGISTRIES**

In addition to the information required of all applicants, researchers requesting that Pennsylvania data be included in an employee registry must also complete an additional section in the Application for Access to Protected Data form.

This information is required to provide the Department with assurances that Pennsylvania records included in an employee registry will be used solely for statistical purposes in medical or health research.

All death record information (non-certified copies of death certificates, data files, etc.) obtained from the Department must be flagged as Pennsylvania records 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.

If an OSHA-regulated organization is requesting access to death record data, they may be asked to remove all identifiers or store the Pennsylvania death record data separately from the medical records in the unlikely event that records are requested by OSHA. This would eliminate a potential problem with maintaining the confidentiality of the Pennsylvania records.

The Bureau of Health Statistics & Registries must receive an abstract of the protocol for each specific study that will include Pennsylvania records from an employee registry prior to their use. Any specific study that involves followback activities must adhere to the [Guidelines for Followback Activities Using Pennsylvania Records](#) contained in this User's Guide.

## FEES

### 1. Individual Copies of Death and Fetal Death Records

Noncertified copies of the complete death or fetal death record can be obtained at the current fee of \$3.00/copy (for each certificate found). If actual dates of death are supplied by the requestor, the Division of Vital Records will search the year given as well as one year prior to and one year after the given year. If the date of the last contact or date last known alive is supplied by the requestor, the Division will search that year plus the next two succeeding years. For this reason, it is important that all dates be properly labeled when submitted. This three-year search is done free of charge. Additional searching can be provided, upon request, at the current searching fee of \$10.00/hour. Study subjects must be grouped alphabetically within the year of death.

### 2. Cancer Records

All cancer records are computer-generated. Therefore, the costs are listed below under computer charges.

### 3. Computer Charges

The standard charge for data is \$200 for the first year of data and \$100 for each additional year. These amounts will be charged for each separate data file for which data is produced. Exact charges will depend upon specific requirements of the study, and a cost estimate will be provided upon approval of the application.

Output is transmitted through a secure website.

### 4. Linking Charges

Charges for linking to cancer, vaccination or vital statistics data is \$200 for the first year matched and \$100 for each additional year of match requested. In addition, there is a charge of \$0.001 per record per year of match for vital statistics data and \$0.005 per record submitted for cancer data. All matching **must** be completed in the Bureau of Health Statistics & Registries

## PAYMENT

Please do not send payment in advance. The Bureau of Health Statistics & Registries will invoice after application review and approval. Full payment is required prior to release of data. If it is necessary to make any advance payment, please contact (717) 783-2548 or [RA-DHPROTECTEDDATA@pa.gov](mailto:RA-DHPROTECTEDDATA@pa.gov).

## Guidelines for Providing Files to be used for Linkages

Data items needed to produce accurate linkage results:

- Last name
- First name
- Date of birth (mm/dd/yyyy)
- Social Security Number (or at least the last 4 digits)

Additional data items used when available to resolve questionable matches:

- Address – street
- Address – city
- Address – state
- Address – zip code
- Last Name Prior to First Marriage (i.e., Maiden Name) or Birthing Parent’s Last Name Prior to First Marriage
- Cancer site/histology (for cancer linkages)

## RE-RELEASE OF PENNSYLVANIA PROTECTED DATA

A **Supplemental Assurances Form** must be completed by each organization and/or individual who will obtain identifiable information or individual case record data from Pennsylvania files. This includes consultants, outside nosologists, contractors, data processing vendors, subcontractors, and sponsoring or participating agencies or organizations. This form is found in the **Application for Access to Protected Data**.

Individually identifiable case-level data may not be released without prior written approval of the Pennsylvania Department of Health, Bureau of Health Statistics & Registries.

## PUBLICATION AND DISCLAIMER

If data extracted from Pennsylvania records are used in any publication, the following statement must be included in such publication or any other release of the data:

This data was were supplied by the Bureau of Health Statistics & Registries, Pennsylvania Department of Health, Harrisburg, Pennsylvania. The Pennsylvania Department of Health specifically disclaims responsibility for any analyses, interpretations, or conclusions.

A copy of any published materials or study results should be made available to the Pennsylvania Department of Health upon request.