**For BHSR Use Only**

**APPLICATION FOR ACCESS**

**TO PROTECTED DATA**

**PA Department of Health**

**Bureau of Health Statistics and Registries**

Revised May 2021

**Please read *USER’S GUIDE FOR ACCESS TO PROTECTED DATA*****before completing this application.**

1. **ORGANIZATION OR INDIVIDUAL REQUESTING ACCESS**

Project Director: Click or tap here to enter text.

Title: Click or tap here to enter text.

Organization: Click or tap here to enter text.

Street Address: Click or tap here to enter text.

City, State, Zip Code: Click or tap here to enter text.

Telephone: Click or tap here to enter text.

E-Mail Address: Click or tap here to enter text.

**Other persons who should be contacted if more information is needed:**

* + 1. Name: Click or tap here to enter text.

Telephone: Click or tap here to enter text.

E-Mail Address: Click or tap here to enter text.

Address (if different than above): Click or tap here to enter text.

* + 1. Name: Click or tap here to enter text.

Telephone: Click or tap here to enter text.

E-Mail Address: Click or tap here to enter text.

Address (if different than above): Click or tap here to enter text.

Name and address of sponsor(s) or funding organization(s) for this project: Click or tap here to enter text.

1. **TITLE OF STUDY OR PROJECT:** Click or tap here to enter text.
2. **TYPE OF DATA REQUESTED:**

 [ ]  Aggregated Data

 [ ]  De-Identified Case-Level Data

 [ ]  Identified Case-Level Data

1. **OTHER ORGANIZATIONS PARTICIPATING IN THIS STUDY OR PROJECT**

List the names of organizations and/or individuals who will obtain identifiable information or individual case level data from Pennsylvania files and describe their roles in this study. Include consultants, outside nosologists, contractors, data processing vendors, subcontractors, and sponsoring or participating agencies or organizations. **A** [**Supplemental Assurances Form**](#SupplementalAssurancesForm) **must be completed by EACH organization (or individual) listed below and must be signed by responsible officials of that organization.**  The completed forms must be submitted as an attachment(s) to this application form.

Click or tap here to enter text.

1. **INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS**

Has this research project been reviewed and approved by an Institutional Review Board (IRB) for the Protection of Human Subjects? (**An IRB approval is mandatory if this study or project requires the receipt of personal identifiers from Pennsylvania records**.)

 [ ]  YES: List the name of the review board and date of approval below and **attach a copy** **of the approval to this application**.

 Name of Review Board: Click or tap here to enter text.

[ ]  NO: Indicate reason: Click or tap here to enter text.

1. **SUMMARY OF STUDY PROTOCOL OR PROJECT ACTIVITIES**

 You may append a copy of your complete study protocol (or selected sections) to this application; however, the abstract that you provide in response to these questions should be self-contained so that it can serve as a complete and accurate description of the project though separate from any appended document.

It is understood that some requestors might only be indirectly involved in research or statistical activities (e.g., preparing and maintaining data files to be used in the research efforts of other organizations) or for government agency projects. If any of these situations apply, you should first describe your own activities and then indicate how the identifiable data released to you will be provided to and used by other organizations.

IN RESPONDING TO THE FOLLOWING QUESTIONS, BE AS CLEAR AND AS SUCCINCT AS POSSIBLE USING THE SPACE AVAILABLE. If you require additional space for answers, insert a separate page(s) and number each answer.

* + 1. **Describe the health or medical problem addressed by your study or activities.**

Click or tap here to enter text.

* + 1. **List the primary study or project objectives. Include a description of the hypotheses to be tested.**

Click or tap here to enter text.

* + 1. **Summarize the project’s data collection methods, indicating specific followback procedures, if they apply.**

Click or tap here to enter text.

* + 1. **Summarize the project’s analysis, indicating how the data will be used.**

Click or tap here to enter text.

* + 1. **Describe any data files that will be linked with the data provided and specify the source of these data files.**

Click or tap here to enter text.

* + 1. **In what form and to whom will the results of your study or activities be released?**

Click or tap here to enter text.

1. **EMPLOYEE REGISTRY DESCRIPTION**

The Employee Registry Description section should be completed **only if** you are planning to include Pennsylvania records in an Employee Registry.

The following information is required to provide the Department of Health with assurances that Pennsylvania records included in an Employee Registry shall be used solely for statistical purposes in medical or health research.

* + 1. **What is the date that the Registry was founded?**

Click or tap here to enter text.

* + 1. **What is the purpose of the Registry?**

Click or tap here to enter text.

* + 1. **What are the eligibility criteria for including persons in the Registry?**

Click or tap here to enter text.

* + 1. **Will the records be flagged to identify them as Pennsylvania records?**

 [ ]  YES [ ]  NO

* + 1. **Will the records be stored separately from administrative records?**

 [ ]  YES [ ]  NO

* + 1. **Is your organization OSHA regulated?**

 [ ]  YES [ ]  NO

If yes, can you guarantee that Pennsylvania death records will not be released to OSHA?

 [ ]  YES [ ]  NO

* + 1. **List below each study which uses records from the Employee Registry. All current studies should be included as well as anticipated studies.**

Click or tap here to enter text.

Summary Protocol:

A summary protocol for each study listed above must be attached to this application form. The summary should include the following information.

1. Title of Study.
2. Description of the health or medical problem addressed by your study.
3. List of the primary study objectives and a description of the hypotheses to be tested.
4. Summary of the project’s data collection methods, indicating specific followback procedures, if they apply. Refer to the User’s Guide for the guidelines which must be followed when using Pennsylvania records for followback activities.
5. Summary of the project’s analysis and how the data will be used.
6. Description of any data files that will be linked with the data provided and the sources of these data files.
7. The form in which the results of the study will be released. Copies of any reports that are published externally should be forwarded to the Bureau of Health Statistics and Registries.

If the complete protocol is sent in lieu of this summary, the sections from the protocol which contain the above requested information should be highlighted.

If Pennsylvania records are released for inclusion in your Employee Registry, summary protocols of any future studies (which are not included in this application) must be forwarded to the Bureau of Health Statistics and Registries for written approval prior to using any Pennsylvania records in the study.

Any changes to study protocols, particularly with respect to followback and additional uses of the data, must be submitted to the Bureau of Health Statistics & Registries.

1. **RECORDS AND/OR IDENTIFIABLE DATA REQUIRED**
	* 1. **Identify the records you will require for the needs of this project.**

|  |  |  |
| --- | --- | --- |
|  | **Data (Text) Files** | **Paper Copies** |
| **Death Files** |[ ] [ ]
| **Birth Files** |[ ]  Not Available |
| **Cancer Files** |[ ]  Not Available |
| **Vaccination Files** |[ ]  Not Available |

**If other data sets are needed, please specify:**

Click or tap here to enter text.

* + 1. **List the data variables that you need. Social Security Number is not releasable:**

Click or tap here to enter text.

* + 1. **List the data years you require for this project (i.e., 2007 or 2002-2005, etc.):**

Click or tap here to enter text.

* + 1. **If data file linkage is required, identify and briefly describe your data files that will be linked with the Department of Health’s records, the source of this data, and the data items on which the match may be completed.**

Click or tap here to enter text.

* + 1. **If the project requires data linkage, the PA Department of Health requires that the linkage be conducted by Department of Health employees. If linkage is required, tell us how many records there are, and how often will the linkages take place (annually, quarterly).**

Click or tap here to enter text.

* + 1. **In what form and to whom will the results of your study or activities be released?**

Click or tap here to enter text.

* + 1. **How many future requests do you expect to make?**

Click or tap here to enter text.

* + 1. **Complete the questions below only if you are requesting review of records or copies of records.**

**How many names do you expect to submit to the Department?**

 Click or tap here to enter text.

**Is year of birth, death, cancer diagnosis, or vaccination known for each name?**

 [ ]  YES [ ]  NO

**If yes, please specify range of years involved:**

Click or tap here to enter text.

**How many future searches do you expect to request?**

 Click or tap here to enter text.

**Name the organization(s), including your own, which will be requesting review of records or copies of records (itemize your responses if more than one organization will be involved).**

 Click or tap here to enter text.

1. **MAINTAINING THE CONFIDENTIALITY AND SECURITY OF IDENTIFIABLE DATA**
	* 1. **How will you maintain the confidentiality and security of identifiable data obtained from Department of Health records? (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-level data where other demographic items such as age, sex, race, and place of residence could possibly be used to identify subjects.)**

Click or tap here to enter text.

* + 1. **Disposition of identifiable data: (NOTE: The Pennsylvania Department of Health requires that paper records or electronic data files be destroyed at the end of the study, or as soon after the end of the study as possible. This includes case-level data with or without personal identifiers.)**

**How long will you store copies of records or other identifiable data?**

Click or tap here to enter text.

**How will you dispose of copies of records or other identifiable data?**

Click or tap here to enter text.

* + 1. **Approximate date of study completion:**

Click or tap here to enter text.

* + 1. **Will you require followback investigations based on information provided by Pennsylvania records to obtain additional information from any of the following: Study subjects, decedent’s next-of-kin, physicians, hospitals, and/or other individuals or facilities mentioned in the record.**

 [ ]  YES [ ]  NO

**If YES, briefly describe the following:**

**Types of followback respondents to be contacted. (If the answer to this question includes families, next-of-kin, or the study subject, please answer the following questions 2 and 3.)**

Click or tap here to enter text.

**Information to be obtained from respondents. (A copy of the survey form or questionnaire must also be attached and labeled appropriately).**

Click or tap here to enter text.

**Methods to be used in conducting such investigations. (A copy of consent form and initial contact letter to be mailed to followback individual must also be attached and labeled appropriately.)**

Click or tap here to enter text.

* + 1. **Will any of the identifiable case-level data obtained from the records and/or followback investigations be used as a basis for legal, administrative, or other actions which may directly affect particular individuals as a result of their specific identification in this project?**

 [ ]  YES [ ]  NO

**If YES, please explain.**

Click or tap here to enter text.

* + 1. **Will the identifiable case-level data obtained from the records or followback investigations be used either directly or indirectly for any project or purpose other than the one described in Part V?**

 [ ]  YES [ ]  NO

**If YES, briefly describe the other research project(s) or purpose(s) for which the data will be used. A separate application form must be submitted for each project which will be using protected data obtained from Pennsylvania Department of Health records.**

Click or tap here to enter text.

1. **APPLICANT ASSURANCES**

The undersigned hereby agrees to the following terms and conditions related to this application and to the use of information obtained from the Pennsylvania Department of Health.

* + 1. Any identifiable case-level data obtained following written approval from the Department of Health shall be used only for the study proposed and the purposes described in the [Summary of Study Protocol or Project Activities](#SummaryofStudyProtocol) and in the [Employee Registry Description](#EmployeeRegistry). Use of the information for a project or purpose other than that described in Sections F and G shall not be undertaken unless a separate application form for the subsequent project has been submitted to, and approved by, the Pennsylvania Department of Health.
		2. No individually identifiable case-level data shall be released without prior written approval by the Pennsylvania Department of Health. Paper records and electronic data files containing Pennsylvania case-level data will be destroyed upon completion of the study, or as soon as possible thereafter.
		3. 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 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.

* + 1. I have thoroughly reviewed the contents of the User’s Guide for Access to Protected Data dated May 2021, which are incorporated herein by reference, and I shall adhere to the guidelines set forth therein.
		2. I agree to pay in full the invoice provided to me for services rendered by the Bureau of Health Statistics & Registries in reference to the study proposed in the [Summary of Study Protocol or Project Activities](#SummaryofStudyProtocol).
		3. All statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

Click or tap here to enter text.

**Project Director’s Name**

Click or tap here to enter text.

**Project Director’s Title**

Click or tap here to enter text.

**Organization**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click or tap here to enter text.

**Signature Date**

**ATTACHMENT**

**SUPPLEMENTAL ASSURANCES FORM**

A separate Supplemental Assurances Form must be completed and signed by **EACH** [**organization**](#OrganizationsParticipating) **listed on page 3** of the application form as participating in this study. The Supplemental Assurances Form(s) must then be submitted as an attachment to the application form.

**Name:** Click or tap here to enter text.

**Title:** Click or tap here to enter text.

**Organization:** Click or tap here to enter text.

**Street Address:** Click or tap here to enter text.

**City, State, Zip Code:** Click or tap here to enter text.

**Telephone:** Click or tap here to enter text.

**E-Mail Address:** Click or tap here to enter text.

1. **How will you maintain the confidentiality and security of identifiable data obtained from the Department of Health records? (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.)**

Click or tap here to enter text.

1. **Disposition of identifiable data. (NOTE: The Pennsylvania Department of Health requires that paper records or electronic data files be destroyed at the end of the study, or as soon after the end of the study as possible. This includes case-level data files with or without personal identifiers.)**

**How long will you store copies of records or other identifiable data?**

Click or tap here to enter text.

**How will you dispose of copies of records or other identifiable data?**

Click or tap here to enter text.

**If there are no plans to dispose of some or all of the identifiable data, please explain why.**

Click or tap here to enter text.

1. **Approximate date of study completion:**

Click or tap here to enter text.

1. **Will you require followback investigations to obtain additional information from decedent’s next-of-kin, study subjects, physicians, hospitals, and/or other individuals or facilities mentioned on the records?**

 [ ]  YES [ ]  NO

**If YES, briefly describe the following:**

**Types of followback respondents to be contacted.**

Click or tap here to enter text.

**If the answer to question 1. includes families, next-of-kin, or the study subject, please answer the following two questions:**

**Information to be obtained from respondents. (A copy of the survey form or questionnaire must also be attached and labeled appropriately.)**

Click or tap here to enter text.

**Methods to be used in conducting such investigations. (A copy of consent form and initial contact letter to be mailed to followback individual must also be attached and labeled appropriately.)**

Click or tap here to enter text.

1. **Will any of the identifiable data obtained from the records and/or followback investigations be used as a basis for legal, administrative, or other actions which may directly affect particular individuals as a result of their specific identification in this project?**

 [ ]  YES [ ]  NO

**If YES, please explain.**

Click or tap here to enter text.

1. **Will the identifiable data obtained from the records or followback investigations be used either directly or indirectly for any project or purpose other than the one described in Part V of the Application for Access to Protected Data?**

 [ ]  YES [ ]  NO

**If YES, briefly describe the other research project(s) or purpose(s) for which the data will be used. A separate application form must be submitted for each project which will be using protected data obtained from the Pennsylvania Department of Health.**

Click or tap here to enter text.

**APPLICANT ASSURANCES**

The undersigned hereby agrees to the following terms and conditions related to this application and to the use of information obtained from the Pennsylvania Department of Health.

1. The identifiable data obtained following written approval from the Department of Health shall be used only for the study proposed and the purposes described in the [Summary of Study Protocol or Project Activities](#SummaryofStudyProtocol) and in the [Employee Registry Description](#EmployeeRegistry). Use of the information for a project or purpose other than that described in Sections F and G shall not be undertaken unless a separate application form for the subsequent project has been submitted to, and approved by, the Pennsylvania Department of Health.
2. No individually identifiable data shall be released without prior written approval by the Pennsylvania Department of Health. Paper records and electronic data files containing Pennsylvania case-level data from vital statistics or cancer files will be destroyed upon completion of the study, or as soon as possible thereafter.
3. 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:

These data 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.

1. I have thoroughly reviewed the contents of the User’s Guide for Access to Protected Data dated May 2021, which are incorporated herein by reference, and I shall adhere to the guidelines set forth therein.
2. I agree to pay in full the invoice provided to me for services rendered by the Bureau of Health Statistics & Registries in reference to the study proposed in the [Summary of Study Protocol or Project Activities](#SupplementalAssurancesForm).
3. All statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

Click or tap here to enter text.

**Project Director’s Name**

Click or tap here to enter text.

**Project Director’s Title**

Click or tap here to enter text.

**Organization**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click or tap here to enter text.

**Signature Date**