

APPENDIX D

User Authorization Forms

User Authorization

Instructions for Completion of Confidentiality Statements Required to Become an Authorized User of CEDR Data

I. General Instructions

The attached confidentiality statements must be completed and returned to the Department of Energy (DOE) at the following address before CEDR data relating to DOE Worker Health and Mortality Studies can be released:

Barbara G. Brooks
CEDR Program Manager
Office of Epidemiologic Studies, EH-62/27CC
U.S. Department of Energy
11901 Germantown Road
Germantown, MD 20874

The blank forms may be reproduced by xeroxing; however, original signatures are required on completed forms. The completed forms should be mailed to DOE and cannot be faxed.

The first confidentiality statement assures DOE that the data will be used in a manner which ensures the protection of individual privacy and in compliance with DOE regulations. The additional three forms are required by the States of Alabama, Pennsylvania, and Rhode Island. Upon receipt of the completed statements, the Office of Health at DOE will retain the DOE statements and will forward the others to the appropriate state officials. The review of these statements should take place in a very short time. Written approval is needed from the State of Pennsylvania; a signed release from Pennsylvania will be sent to you and to DOE. Within two weeks after the date of your approval by Pennsylvania, DOE will review the completed confidentiality statements and will notify you when your application is approved. At that time you may contact personnel at Lawrence Berkeley National Laboratory (LBNL) to establish your account.

II. Specific Instructions for Each Statement

DOE Confidentiality Statements (Forms 1 and 2)

There are two types of statements: The first is for a "Primary User" who is defined as the person to whom a CEDR account number is given and who is the actual recipient of the data from the CEDR personnel at LBL. It is self-explanatory and should be completed by those who wish to establish their own CEDR account.

The second statement is for "Secondary Users" who are defined to be those with whom a primary user may share CEDR data. Secondary users do not interact directly with LBL and the CEDR information system and do not need their own CEDR account. The statement should be completed by those wanting access to CEDR data through the primary user's account.

Pennsylvania's Individual Case Record Release Form

Each prospective CEDR user must complete this self-explanatory form and return it to DOE. Some questions are already completed, in accordance with Pennsylvania's instructions. Note that a brief, two- or three-sentence paragraph describing the study protocol is required in Part II. CEDR staff will submit the completed form to the Pennsylvania Department of Health for written approval.

Alabama's Confidentiality Statement for CEDR Users

Each prospective CEDR user must complete this self-explanatory form and return it to DOE. CEDR staff will submit it to the Alabama Department of Public Health before authorizing release of CEDR data.

Rhode Island's Research Assurance Form

Each prospective CEDR user must complete this form and return it to DOE. Note that a brief, two- or three-sentence paragraph describing the study protocol is required in Part II. CEDR staff will submit it to the Rhode Island Department of Health before authorizing release of CEDR data.

Most of the questions and terms are self-explanatory. However, Item 5 (b) means that computer tapes or other electronic media containing data originating from Rhode Island's vital records should be completely erased or returned to DOE. In Item 7, please note that the data should be returned to DOE.

**U.S. DEPARTMENT OF ENERGY COMPREHENSIVE EPIDEMIOLOGIC DATA RESOURCE (CEDR)
Confidentiality Statement for Data Providers**

I agree to the following conditions which are necessary to ensure the protection of individual privacy and to comply with certain regulations and agreements.

1. I understand that the Department of Energy (DOE) releases CEDR data for statistical purposes only. Therefore, I will not link data from CEDR with any other sources of information that leads to the identification of an individual having records in CEDR. I accept responsibility for any misuse of the data provided to me and agree to hold DOE harmless for such misuse.
2. As a CEDR Data Provider, I will limit my use of CEDR data files to activities pertaining to the files submitted to CEDR. If I wish to use data in other CEDR files, which I did not submit, I will complete the DOE confidentiality forms, and forms for approval by the states of Alabama, Pennsylvania, and Rhode Island.
3. I agree to assure that data files and documentation I submit to CEDR will be consistent with CEDR's Guidelines for Data Providers (<http://cedr.lbl.gov/strucdoc/coverpage.html>).

User Signature (written and printed) _____ Date _____

Print Name _____

Organization, Address, Phone No. _____

Email address _____

DOE Reviewing Official _____ Date _____

U.S. DEPARTMENT OF ENERGY COMPREHENSIVE EPIDEMIOLOGIC DATA RESOURCE
Confidentiality Statement for Secondary Users

In order to become an authorized user of data in CEDR, I agree to the following conditions which are necessary to ensure the protection of individual privacy and to comply with certain regulations and agreements.

1. I understand that the Department of Energy (DOE) releases CEDR data for statistical purposes only. Therefore, I will not link data from CEDR with any other sources of information that leads to the identification of an individual having records in CEDR. I accept responsibility for any misuse of the data provided to me and agree to hold the Department of Energy harmless for such misuse.
2. I will not disclose CEDR data to any other parties, either by allowing them to see the data, giving them copies of the data, or by any other means.
3. I agree that if a publication results from the analysis of CEDR data, the primary author will provide a copy of the analysis files, along with structured documentation, to CEDR when the study is prepared for presentation or is accepted for publication. I understand that all analysis files will be made available to other CEDR users.
4. I agree to acknowledge the use of CEDR data in any resulting publications or presentations and agree to include a disclaimer statement that the protocol and results of my study were not reviewed by DOE and that conclusions do not necessarily reflect those of the U.S. Government or DOE.

User Signature (written and printed) _____

_____ Date _____

Organization, Address, Phone No. _____

Email address _____

Description of Statistical Use of the Data _____

DOE Reviewing Official _____ Date _____

CONFIDENTIALITY STATEMENT FOR USERS OF ALABAMA DEATH CERTIFICATE DATA FROM CEDR

I, the undersigned, hereby agree to the following terms and conditions related to the use of information obtained from Alabama death certificates contained in the Department of Energy Comprehensive Epidemiologic Data Resource (CEDR) data base:

1. All identifiable data obtained from Alabama death certificates contained in the CEDR data base will be used only for scientific research and statistical purposes. No data will be published or released in any form if a particular individual or establishment supplying the information or described in it is identifiable. Furthermore, the identifiable 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.
2. No data from Alabama death certificates contained in CEDR will be linked to computer files or other sources of information that might lead to identification of individuals or establishments.
3. No data from Alabama death certificates contained in CEDR will be used to compile lists of individuals or establishments for commercial purposes.
4. Information obtained from Alabama death certificates from the CEDR data base will not be disclosed to any parties other than those working directly on the specific project for which CEDR data is being used and for which a CEDR Confidentiality Statement for Primary Users has been signed. In no way will Alabama death certificate data be disclosed to anyone else.

THIS CONFIDENTIALITY STATEMENT MUST BE SIGNED BY THE PRIMARY USER.

Signature _____ Date _____

Typed Name _____

Title _____

Organization _____

Address _____

Name of Study _____

DOE Approval _____ Date _____

PENNSYLVANIA DEPARTMENT OF HEALTH APPLICATION FOR ACCESS TO PROTECTED DATA
Individual Case Record Release Form

I. Original Study Title/Applicant Information:

Study Title: CEDR File

Applicant: U.S. Department of Energy/Bonnie Richter/Barbara Brooks

Application Number and Approval Date: 1 C 1382 8/21/91

II. Information to be Released:

Organization Name (that is requesting the data): _____

Study Title: _____

Data to be Released: _____

Please attach a Summary Study Protocol.

III. Applicant Assurances (to be completed by the organization that will receive the data):

The undersigned hereby agrees that use of the individual case record data obtained from Pennsylvania death records will not be undertaken for any purposes other than the above stated study to the extent approved separately in writing by the Department.

Name: _____

Title: _____

Address: _____

Telephone Number: _____

Signature: _____ Date: _____

RESEARCH ASSURANCES FORM

Division of Vital Records, R.I. Department of Health

1. The purpose of this research study is (please summarize in space below or attach additional sheets if necessary):

2. I acknowledge that access to information contained in vital records furnished by the Division of Vital Records is granted solely upon the condition that I agree to utilize said information in the manner and upon the terms set forth in this Research Assurances Form. Specifically, I agree to comply with the following conditions:
 - a) That the information will be used solely for the purpose stated above;
 - b) That no communication shall be made with individuals named or listed on vital records, or with family members, or with informants (individual or institutional), unless approval in writing has been obtained from the Director of Health or his designee;
 - c) That no information from vital records shall be published or disseminated in a form that might permit identification of individuals named or listed in vital records;
 - d) That no statement shall be made indicating or suggesting that interpretations drawn from vital statistics are those of the Department of Health or of the state of Rhode Island; and
 - e) That the confidentiality of all information obtained from vital records will be maintained as required by Chapter 5-37.3-4 of the General Laws of Rhode Island and by all federal and state laws and regulations related to confidentiality of such information, and by requirements specified by the Institutional Review Board of the Department for the protection of human subjects.

3. I understand that the Rhode Island Department of Health reserves the right to final determination of access to confidential information it provides for research purposes, and may terminate access at any time.

4. I understand that I cannot use any information provided under this agreement for any commercial purpose, as defined in Section 38-2-6 of the General Laws of Rhode Island.

5. I agree that all information provided under this agreement, when disposed of, will be handled as follows:
- a) Paper records will be shredded or burned; and
 - b) Computer tapes will be completely erased or returned to the Division of Vital Records. Computer diskettes will be returned to the Division of Vital Records.
6. I accept responsibility for any misuse of the information provided and agree to hold Rhode Island Department of Health harmless for such misuse.
7. Should I fail to comply with the terms and conditions of this Research Assurances Form, access to information on vital records will be terminated immediately, and all data will be returned to the Division of Vital Records. I understand that unauthorized disclosure of information from confidential records may be punishable, upon conviction, by a fine and/or imprisonment or both, and/or civil penalties as prescribed by law.

(Signature) _____

(Title) _____

(Organization) _____

(Date) _____

Approved by: _____
(Signature of State Registrar)