PROCEDURE TO RELEASE DATA
from the
Rhode Island Childhood Lead Poisoning Prevention Program

The Goal of this document:

1. To ensure data requests are properly designed for efficient uses of available data
2. To ensure all data requests are appropriately processed and to prioritize limited resources to design completion timeframes
3. To capitalize on resources and prioritize requests
4. To encourage research that promotes the responsible use and dissemination of these data

The type of data requests.

Based on prior experience, the following are the types of data requests we receive are classified as "Non-Confidential" and "Confidential."

A. NON-CONFIDENTIAL DATA.

1. AGGREGATE DATA CURRENTLY AVAILABLE.

For aggregate screening data, prevalence charts and race/ethnicity rates, visit us on the Internet, at http://www.health.ri.gov/lead/. The data posted on the web site is public information and can be used in the format and in the context that it is provided.

Other examples of aggregate data currently available include:

a) Prevalence of elevated lead in RI (among tested children)
b) RI Blood lead summary report for 1998-2016
c) Incidence of elevated lead levels by city and town

2. OTHER AGGREGATE DATA.

For other aggregate data not available in the web site, contact the Lead Program's Manager. Depending on the type of request (complexity, availability, accuracy, resources schedule) and purpose of data, requests will be placed on a priority list and an estimate of the timeframe will be provided.

Examples of these type of requests:

a) Number of screened children in the city of Providence in fiscal year 1998, by age.
b) Number of inspections performed in last 3 years that have status "open."

In cases where subgroups on which data is requested are relatively small, even aggregate data requests may have to be treated as confidential data. See next pages for details.

3. RAW DATA.

Requests of raw data to be analyzed primarily outside of the Lead Program can be made, and will be considered under the following conditions:

- Requested data doesn't include confidential data. If it includes confidential data (e.g., last name, street address or other item that can identify individuals), see section B of this document.
- Purposes of the study/analysis/investigation are approved by the PROGRAM
- Data is currently collected and available on the database for a reasonable time period that allows study's goals to be achieved.
- Results and format of the analysis/investigation are presented to the PROGRAM for further discussions, modifications and acceptance prior to public release. In the absence of such acceptance, a disclaimer indicating the data came from HEALTH but analysis was done independent from the Rhode Island Department of Health must be included in the final documents containing data analysis results. (Example: "The authors acknowledge the assistance of the RI Department of Health in providing data used in this report. This assistance does not necessarily constitute an endorsement of the methods, opinions and conclusions in this report.")
- An agreement in terms of partnership and sharing resources to conduct data analysis exists or is made between the PROGRAM and the entity requesting data.

PROCESS TO RELEASE NON-CONFIDENTIAL DATA REQUESTS.

The process for data requests is as follows:

1. Fill out the data request form, and submit it to the Program's Data Manager.
2. A response will be provided in no more than 10 working days, unless of force majeure causes.
3. The request will be forwarded to the unit handling data and will be processed in the priority it is received.

B. CONFIDENTIAL DATA.

The identity of any person (or any group of facts that tends to lead to the identity of any person) whose blood test result is submitted to the Rhode Island Childhood Lead Poisoning Prevention Program is confidential and shall not be open to public inspection or dissemination. Such information shall not be available for disclosure, inspection or copying under the Freedom of Information Act or the State Records Act (?). All information for specific research purposes may be released in accordance with procedures established by the Program.

This section refers to data requests for purposes of epidemiological researchers and other studies, which require individually identifiable data. Examples of this type of request are:

a) Names of children living in the city of Pawtucket and found with elevated lead levels of Pb >9 μg/dl during years 1997 and 1998.
b) Addresses of lead poisoned children in a certain geographic location. Note that individually identifiable data may include data requests that don't request name or last name.

B.1. REQUEST OF CONFIDENTIAL DATA.

All requests by researchers for confidential data must be submitted in writing to the Lead Program's Epidemiologist and Program Managers. In order to consider a request, the researcher investigator must submit the following:

1. A completed "Data Request Form" (attached). Additional information, such as a **study protocol**, may be submitted along with the completed Data Request Form.
2. Methods for documenting compliance with 42 CFR 2a.4(a) through (j), 2a.6(a) and (b), 2a.7 (a) and (b)(1);
3. For additional space, include separate sheets, or request an electronic copy of the Data Request Form.

B.2. LEVELS OF REVIEW.

It is desirable that you contact us for **PRELIMINARY** discussions if you are planning a study or research project. This way, we can ensure that the available data will support the study design, and that data requests are appropriately formulated.

Independent from the PRELIMINARY review, once the request for confidential data has been received, the review conducted has two levels:

- Scientific Review at the Program Level
- Review by the Institutional Review Board ("IRB") for the Protection of Human Subjects

At the Program Level, the Epidemiologist in conjunction with the Lead Management Team will conduct the scientific review, after which a response will be given. After the scientific review is completed, researcher(s) must apply to the IRB and be approved before data will be released.

B.3. SCIENTIFIC REVIEW AT THE PROGRAM LEVEL.

All requests to conduct research and modifications to approved research proposals involving the use of data which includes patient identifying information shall be subject to a review to determine compliance with the following conditions:

a) the request for patient identifying information contains stated goals or objectives

b) the request documents the feasibility of the study design in achieving the stated goals and objectives
c) the request documents the need for the requested data to achieve the stated goals and objectives
d) the requested data can be provided within the time frame set forth in the request
e) the request documents that the researcher has qualifications relevant to the type of research being conducted
f) the research will not duplicate other research already underway using the same data when both require the contact of a patient involved in the previously approved concurrent research, and
g) other such conditions relevant to the need for the patient identifying information and the patient's confidentiality rights because the Department will only release the patient identifying information that is necessary for research

Once the scientific review has been completed, the Program will issue a formal letter no later than 30 days after the receipt of the proposal, with recommendations that indicate either:

- Acceptance
- Acceptance with modifications
- Non-acceptance

If a communications is issued with "Acceptance," the process will continue to the second level of review, or IRB review (see section B.4).

Non-accepted requests may be revised and resubmitted, in which case the process will go back to step specified in item B.2. Reasons for non-acceptance include, but are not limited to, the following:

- security measures are unsatisfactory in the opinion of the Program,
- data requested is unavailable or unreliable in the opinion of the Program,
- the stated purpose does not meet the Program's mission statement,
- the Program is unable to provide the data in the requested format,
- the applicant is not an accredited or licensed research institution, a government agency, university research center or private research firm, or,
- the information can not be provided by the requested date.

B.4. THE IRB REVIEW.

For information on the IRB process, timeframes and others, see the IRB protocol available at http://www.health.ri.gov/topics/irb.php or contact the Rhode Island Department of Health, Margaret Gradie at (401) 222-5952 or Margaret.gradie@health.ri.gov

B.5. ACCEPTANCE TO RELEASE CONFIDENTIAL DATA.

The Program will enter into information agreements for all approved research requests that have also been approved by the IRB. These agreements shall specify the information that is being released and how it can be used in accordance with the standards in the Scientific Review section. In addition, the researcher shall include an assurance that:

a) use of data is restricted to the specifications of the protocol,
b) any and all data which may lead to the identify of any patient, research subject, physician, other person, or hospital is strictly privileged and confidential and the researcher agrees to keep all such data strictly confidential at all times,
c) all officers, agents and employees will keep all such data strictly confidential. The researcher will communicate the requirements of this section to all officers, agents and employees, will discipline all persons who may violate the requirements of this section, and will notify the Program in writing within 48 hours after any violation of this section, including full details of the violation and corrective actions to be taken,

d) all data provided by the Program pursuant to the agreement may only be used for the purposes named in the agreement and that any other or additional use of the data may result in immediate termination of the agreement by the Department, and,
e) all data provided by the program pursuant to the agreement is the sole property of the Program and may not be copied or reproduced in any form or manner, except for research use by the researcher, and that all data, copies and reproduction of the data made for the researcher's internal use shall be returned to the Department upon termination of the agreement.

Any departures from the approved protocol must be submitted in writing and approved by the Program in accordance with subsections c) and d) of this Section prior to initiation. No identifying information may be released by a researcher to a third party.

*Note: The **Childhood Lead Poisoning Prevention Program** reserves the right to adjust, modify and/or update the present document at any time. Please contact us if you have questions about the information contained here.*

DEFINITIONS.

LEAD PROGRAM'S MANAGEMENT TEAM. A team of Lead Program authorities formed by:
- Environmental Health Toxicologist
- Epidemiologist/Program Evaluator
- Operations Manager
- Data Manager/IS designee
- Environmental Lead Program Manager

PROGRAM. Abbreviated form for purposes of this document that refers to the "Rhode Island Childhood Lead Poisoning Prevention Program" as a whole.

LESS. The name of the Lead Program's database, Lead Elimination Surveillance System.

AGGREGATE DATA. Data that makes it impossible to identify any patient, reporting entity or primary care giver. These data can be made available to the public pursuant to the Freedom of Information Act.

CONFIDENTIAL DATA. Data that can identify any patient, reporting entity or primary care giver, or clinical history, results of a test, etc. of a patient.

ATTACHMENTS

1. Data request form
2. Confidentiality of Health Care Information Act (copy)
3. Rhode Island Department of Health's IRB protocol

CONTACT

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Or visit our web site at http://www.health.ri.gov/lead/