

Louisiana Childhood Lead Poisoning Prevention Program (LACLPPP)

**Genetic Diseases Program
Office of Public Health
Department of Health and Hospitals**

Data Request Application

The Louisiana Childhood Lead Poisoning Prevention Program (LACLPPP) Review Panel is charged with reviewing applications for use of LACLPPP data. Applications will be reviewed to ensure that the proposals are of scientific merit and that the applicant and proposed users will maintain the confidentiality of the data and the subjects. Where health research is involved, the Panel is charged with assuring that the study design selects subjects on a scientific basis and that the investigators or researchers are deemed qualified based on past research, employment, and education. In addition, the Panel assures that where appropriate, the approval of an institutional review board has been obtained and that the informed consent process and forms follow the guidelines outlined in the Louisiana Administrative Code (LAC) 48:V.11709 and Louisiana Statute (LSA-RS) 40.3.1.

Louisiana Childhood Lead Poisoning Prevention Program (LACLPPP) Data Request Application Procedure:

1. The applicant must complete and submit a LACLPPP Data Request Application along with supporting documents and a Confidentiality Statement to the LACLPPP Program Coordinator.
2. The Program Coordinator will review the application for completeness and forward it to members of LACLPPP Program Staff for review.
3. The Panel will review the application and recommend approval or disapproval based on criteria set forth in the Louisiana Administrative Code (LAC) 48:V.11709 and Louisiana Statute (LSA-RS) 40.3.1.
4. After the Panel reaches a decision, the application will be returned to the Program Coordinator, who will notify the applicant of approval or disapproval.
5. If the application is disapproved, the Panel will provide the applicant with an explanation and notify the applicant of their right to revise and resubmit the application or request a hearing before the Panel.
6. Records of Panel actions relative to the LACLPPP Data Request Application will be maintained as stated in the Confidentiality Statement.
7. All applicants must allow at least 2 weeks for a written response to their application.

LACLPPP Data Request Applications are required of all interested parties.

**Louisiana Childhood Lead Poisoning Prevention Program (LACLPPP)
Data Request Application**

Please complete and submit to the LACLPPP Program Coordinator at 1450 L & A Road – 2nd Floor, Metairie, LA 70001 or via fax at (504) 219-4452.

I. Applicant Information

Date: _____ **Contact Person:** _____

Organization: _____

Program: _____

Address: _____

Telephone: _____ **Fax:** _____ **Email:** _____

II. Statement of Purpose

For **aggregate data requests** please describe the health or medical problem addressed or administrative purpose served by use of data and refer to Attachment 1: _____

For **research/administrative use** attach study protocol, curriculum vitae of researchers, institutional review board approval, informed consent process and forms and refer to Attachment 1.

For submission of **journal articles for publications** please refer to Attachment 1.

For **abstracts and presentations** please refer to Attachment 1.

III. Definition of Records Requested

Year(s): _____ **Format Required:** Hard Copy Electronic
If electronic, please provide a layout labeled Layout 1.

For **record level data** without identifiers please provide variables: _____

For **aggregate data** please supply descriptions of the tables to be produced: _____

Additional Comments: _____

IV. Means of Protecting Confidential Records

Locked cabinet: _____ **Password:** _____ **Other** (please specify): _____

Method of record destruction upon study/administrative use completion: _____

V. Access to Confidential Records

Name(s) and classification(s) of person(s) to be authorized access to LACLPPP data.
Confidentiality statements signed by each person who will have access to electronic and/or hard copy records should be attached.

Name

Classification/Title

Telephone

VI. Statement of Research Assurances

The applicant states that data obtained from LACLPPP under this agreement will only be published in the aggregate and that no individual participants will be identified. The strictest procedures will be followed to protect the data from unwarranted disclosure and to protect the privacy of study subjects and their families. The applicant understands that hard copy records are not to be duplicated without prior approval and that electronic records containing identifiers are to be stored on one secure computer. A backup disk or data tape may be maintained in locked storage. The applicant further agrees that records will be used only for the stated purpose and that no identifying information will be released to other OPH programs, employees or non-OPH persons without the specific prior approval of the LACLPPP Review Panel.

VII. LACLPPP Review Panel Action

Please circle Approve or Disapprove

Signature: _____ Approve/Disapprove Date: _____

VIII. Reviewer Comments

Agreement for Accessing LACLPPP Data

All LACLPPP records are considered confidential in accordance with Louisiana Legislative Statutes (LSA-R.S.40.3.1). Confidential records shall be used only for statistical, scientific, and medical research purposes relating to the cause of condition of health. LACLPPP will release confidential information from these records for research or administrative purposes providing the following conditions are met.

The applicant agrees to the following conditions for accessing confidential LACLPPP information:

- Data will be used only as proposed. User will not make any copies of the data, and will not release, share or further distribute any data containing complete or partial individual records to anyone who has not co-signed the LACLPPP Confidentiality Statement. Data includes all indices and ratios derived from the data. Any person who intentionally discloses the content of LACLPPP confidential data to a third party, except those who have co-signed the Confidentiality Agreement, shall be subject to a civil penalty in an amount not less than one thousand dollars and not more than five thousand dollars plus court costs, paid by the person whose record was unlawfully disclosed (LSA-R.S. 40-.3.1).
- User will not divulge the identity of any individual or entities distinguished by the data. User will not contact any individuals or entities identified by the data. All follow-up studies involving contact with individuals or next-of-kin identified in certificates or confidential information are prohibited.
- User must acknowledge the data source in all published and unpublished written works and presentations resulting from the data. Citation should state “Louisiana Childhood Lead Poisoning Prevention Program, Louisiana Office of Public Health and the Center for Applied Environmental Public Health, Tulane University School of Public Health and Tropical Medicine.”
- A copy of the final results and any written work must to provided to LACLPPP before publication.
- After work with the data is completed, all copies of the data will be returned to LACLPPP or destroyed.
- The user agrees to indemnify, defend, and hold harmless The Office of Public Health (from damages, litigation, liability, and any expenses including legal fees) in the event of claims or losses.
- After one year, user forfeits claim to data and analyses if they have not produced and submitted a manuscript for publication.
- In the case where analyses result in cell sizes of less than five in either numerator or denominator, all numbers and rates will be replaced with a symbol (i.e., ***) in publications. Identifiable characteristics of individuals that result from analyses will not be used in any publications.
- All confidential information obtained from LACLPPP will not be used to deny current and/or future benefits or eligibility for services or care.
- Any release of the data derived from LACLPPP is to contain the following statement: “This data was supplied in part by the Louisiana Childhood Lead Poisoning Prevention Program of the Louisiana Department of Health and Hospitals, Office of Public Health, which disclaims responsibility for any analyses, interpretations, or conclusions.”

- One LACLPPP team member must be included as an author on any publication using data from LACLPPP.
- Violation of these conditions will automatically result in the voiding of this agreement and may result in the refusal of future research requests.
- All data must be stored in a secure location; and means of protecting confidential records must be provided.

Confidentiality Statement
LACLPPP Data Request Application

I, _____, certify that I have read the Louisiana Childhood Lead Poisoning Prevention Program (LACLPPP) agreement and confidentiality statement and state that identifying information obtained from LACLPPP under this assurance of confidentiality will be held in strictest confidence and will be protected against unwarranted disclosure. No data will be published or disclosed from which an individual participant can be identified except upon written authorization of the LACLPPP Review Panel. I understand that unauthorized disclosure may result in disciplinary action in accordance with departmental policies, Louisiana Statute (LAS-RS) 40:3:1 and Louisiana Administrative Code (LAC) 48:V.11709 as applicable.

Signature: _____

Date: _____

Name(please print): _____

Title: _____

Telephone number: _____

Attachment 1 – Statement of Purpose

I. Research and Administrative Use Submission of Journal Articles for Publications

Authorship includes all written, authored publications (journal articles, manuscripts, abstracts, presentations, reports, newsletters, fact sheets, etc.).

The user/investigator must provide proper credentials to use the data based on past research, employment, and education.

A. For all internal and external Office of Public Health applicants*:

All applicants must sign a Confidentiality Statement prior to publication. All manuscripts must be reviewed by LACLPPP prior to publication. This applies to all requests for record level data.

B. For all CDC LACLPPP Requesters, other CLPPP states, and external researchers endorsed by the CDC:

Louisiana has agreed to give approval to all CDC CLPPP requests for use of the data on a case-by -case basis. Any member of the CDC CLPPP team must submit a mini-proposal prior to publication. All CDC-authored manuscripts will not be submitted for publication or to a conference until LACLPPP has had an opportunity (at least two weeks) to review and provide comments. LACLPPP must provide approval prior to publication.

External Researchers endorsed by the CDC must sign the Agreement for Sharing Data with Non-CDC Researchers with the CDC and must forward a signed copy with all supporting documents prior to approval. All CLPPP applicants and external researchers must allow at least 2 weeks for a written response to their application. LACLPPP must provide approval prior to publication.

II. Review of Abstracts for Presentations

For all submissions for abstracts for presentations, all internal and external OPH applicants* must fill out a Louisiana Childhood Lead Poisoning Prevention Program (LACLPPP) Data Request Application. All applicants must sign a Confidentiality Statement prior to use of LACLPPP data. One week needs to be provided for review of the abstract or presentation by the LACLPPP.

CDC-authored abstracts will not be submitted for presentation until LACLPPP has had an opportunity to review and provide comments. LACLPPP must provide approval prior to the presentation. At least one week needs to be provided for review of the abstract for presentation.

III. Requests for Aggregate Data

All requests for aggregate data or use of aggregate data for reports, newsletters, fact sheets must be accompanied by the Louisiana Childhood Lead Poisoning Prevention Program (LACLPPP) Data Request Application.

* External researchers include all individuals or organizations not employed by the Office of Public Health. These include individuals or agencies under contract with the Office of Public Health and all other offices of Department of Health and Hospitals. External researchers do not include CDC CLPPP. CDC CLPPP members will be held responsible for all confidentiality and application arrangements.

**A state data release policy addressing external researcher requests should describe the following elements: 1) documentation for the proposed research; 2) a signed agreement from the researcher that protects the state against breaches of confidentiality and prevents any potential misuse of the data; 3) how the data will be given to the researcher; 4) how the state will monitor access given to external researchers; and 5) security procedures during the analysis and after the analysis has been completed.

Exceptions for release of data:

All confidential data shall be made available to the state health officer when necessary for the purpose of controlling nuisances dangerous to the public health, including but not limited to communicable, contagious, and infectious diseases (LSA-R.S.40.3.1B); or to other agencies or medical researchers when the confidential information is necessary to carry out the duties of the agency or researcher in the investigation, control, or surveillance of disease, as determined by the Office of Public Health (LSA-R.S.40.3.1C). Any disclosure to other agencies shall include only the information necessary for the stated purpose of the request, and shall be made only upon written agreement that the information will be kept confidential and not be further disclosed without written authorization by LACLPPP.