



Dear Prospective Researcher:

Thank you for your interest in obtaining Maryland Pregnancy Risk Assessment Monitoring System (PRAMS) data from the Maryland Department of Health (MDH). Release of Maryland PRAMS data requires the approval of the Maryland PRAMS Principal Investigator and the Director of the Vital Statistics Administration (VSA). In addition, the MDH Institutional Review Board (IRB) reviews all proposed research projects that involve data collection in which there is a possible identifiable linkage to the subject. Review of proposals by PRAMS/VSA and the IRB are two separate processes, and **approval of a project by PRAMS/VSA is required prior to IRB review**. Please do not send any forms to the IRB unless PRAMS/VSA has approved your project.

To begin the Maryland PRAMS review process, completed copies of the Request for Confidential PRAMS Data form (Attachment 1) and the Agreement for the Release of Confidential PRAMS Data (Attachment 2) may be emailed to monique.wilson@maryland.gov.

The PRAMS/VSA review will be completed within 30 days. If PRAMS/VSA has approved the project, required materials should be submitted to the MDH IRB. Information on IRB requirements is available at <http://health.maryland.gov/oig/irb>.

Once the IRB has given approval for a project to proceed, the documents listed below should be submitted to VSA. Work on the project cannot begin until all items have been received.

- Copy of the MDH IRB approval letter.
- Confidentiality Statements (Attachment 3) signed by all individuals who will have access to confidential data.

Questions about the PRAMS/VSA review may be directed to Dr. Monique Wilson monique.wilson@maryland.gov. Questions about the IRB review may be directed to Ms. Gay Hutchen, IRB Administrator, at 410-767-8448 or gay.hutchen@maryland.gov.

Sincerely,

Laurie Kettinger, MS
Acting Principal Investigator
Maryland PRAMS

Monique Wilson, Dr.P.H.
Director
Vital Statistics Administration

Attachments:

Attachment 1: Request for Confidential PRAMS Data

Attachment 2: Agreement for the Release of Confidential PRAMS Data

Attachment 3: Confidentiality Statement



ATTACHMENT 1
REQUEST FOR CONFIDENTIAL PRAMS DATA

Name: _____

Title: _____

Organization Name: _____

Organization Address: _____

Phone: _____ Fax: _____

E-mail: _____

Date of request: _____

Name, phone number, and e-mail address of person to contact for further information (if different than above):

Year(s) for which data are requested:

Please provide the following information on additional sheets:

- Summary of the project for which data will be used
- Public health importance of the project for which data will be used
- Description of safeguards to protect the confidentiality of data and prevent unauthorized access
- Justification for each variable requested, including justification for level of data requested (if aggregate-level data meets the requester's need, individual-level data will not be released; if a variable can be categorized, continuous data will not be released unless the researcher can demonstrate that the study cannot be done without continuous data)



ATTACHMENT 2

AGREEMENT FOR RELEASE OF CONFIDENTIAL PRAMS DATA

Maryland Code Annotated, Health-General Section 4-101 defines a confidential record as any “record, report, statement, note or other information that . . . names or otherwise identifies any person.” The following information from vital records may be considered confidential:

- Names
 - Addresses or small geographic areas
 - Social security numbers
 - Certain dates
 - Facility names and codes
 - Rare conditions
 - Rare causes of death
 - Individual level data with or without identifiers
 - Aggregate data with small cell sizes if the data could permit the deduction of the identity of any person.
1. Release of single record PRAMS data requires the approval of the Principal Investigator of the PRAMS Program and the Director of the Vital Statistics Administration (VSA).
 2. Release of single record PRAMS data for research purposes requires approval of the Institutional Review Board (IRB) of the Maryland Department of Health (MDH).
 3. The researcher must demonstrate a need for each variable requested, and justification must be provided for the level of data requested. Data will be provided only at the level needed. If aggregate-level data meets the requestor’s need, individual-level data will not be released. If a variable can be categorized, continuous data will not be released unless the researcher can demonstrate that the study cannot be done without continuous data.
 4. The following must be provided to prior to release of any confidential data:
 - Documentation that the individual(s) gaining access to the data will maintain the confidentiality of the data, as evidenced by Confidentiality Statements signed by all individuals who will have access to confidential data
 - A description of safeguards to protect the confidentiality of the data and to prevent unauthorized access.
 - Written authorization from the Department’s Institutional Review Board that approval has been given for projects that will use certificates or vital statistics data for research purposes.
 5. Data and data files may only be shared with those individuals and entities who have been authorized in writing by PRAMS/VSA to have access to the data.



ATTACHMENT 2 (cont.)

6. Data may be used by the requestor for the stated purpose only and may not be used for any other purpose without written approval of PRAMS/VSA.
7. No attempt will be made to link PRAMS records with any other source of information.
8. No listing of information from individual records, **with or without identifiers**, may be released or published.
9. No data may be published or released in any form if a particular individual described in it is identifiable. Aggregate data with small cell sizes may not be published or released if the identity of any person could be deduced by the data.
10. If requested by PRAMS/VSA, users of vital statistics data must provide periodic updates of the findings and status of the analysis of data to PRAMS/VSA.
11. At the conclusion of the project, all data files must be returned to the Maryland PRAMS Program or destroyed. Confirmation of destruction should be sent to the Maryland PRAMS Program.

In acknowledgement of the foregoing description of the terms and conditions for the release and utilization of Maryland Vital Statistics data, I accept the terms and conditions of this agreement.

Name (please print): _____

Title: _____

Organization: _____

Telephone number: _____

Signature: _____

Date: _____



ATTACHMENT 3

CONFIDENTIALITY STATEMENT

I understand that I am working with confidential data obtained from the Maryland PRAMS

Program on a project entitled: _____

I understand that these data can only be used for this project only, and only for purposes approved by the PRAMS Program, the Vital Statistics Administration and the Institutional Review Board of the Maryland Department of Health.

I understand that I am responsible for protecting the confidentiality of information disclosed for use in this project. I understand that access to these data is limited to persons with written authorization from the PRAMS Program who have signed Confidentiality Statements. I agree that I will immediately report any known or suspected breaches to the Maryland PRAMS Program and the MDH Institutional Review Board.

Name (please print): _____

Title: _____

Organization: _____

Telephone number: _____

Signature: _____

Date: _____