

Dear Prospective Researcher:

Thank you for your interest in obtaining confidential vital statistics information from the Vital Statistics Administration (VSA) of the Maryland Department of Health (MDH). Release of confidential birth, death, fetal death, marriage or divorce data requires the approval of the VSA. In addition, the MDH Institutional Review Board (IRB) reviews all proposed birth, marriage and divorce research projects that involve data collection in which there is an identifiable linkage to the subject, as well as projects requesting next of kin information from death records. Review of proposals by VSA and the IRB are two separate processes, and **approval of a project by VSA is required prior to IRB review**. Please **do not send any forms to the IRB** unless VSA has approved your project.

To begin the VSA review process, completed copies of the <u>Request for Confidential Vital Statistics Data</u> form (Attachment 1) and the <u>Agreement for the Release of Confidential Vital Statistics Data</u> (Attachment 2) should be sent to VSA using one of the following methods:

E-mail: <u>monique.wilson@maryland.gov</u>

Fax: 410-358-4750

Mail: Maryland Department of Health Vital Statistics Administration 4201 Patterson Avenue, 5<sup>th</sup> Floor Baltimore, Maryland 21215

The VSA review will be completed within 30 days of receipt of the request, and the Principal Investigator (PI) will be notified in writing of VSA's decision regarding release of data for the project. If VSA has approved the project, required materials for all projects requesting birth, marriage or divorce data, as well as next of kin information from death records, should be submitted to the IRB. **IRB approval is <u>not</u> required for projects requesting death data unless next of kin information is requested.** Information on IRB requirements is available at <u>https://health.maryland.gov/oig/irb/Pages/IRB.aspx</u>.

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

- > Copy of the MDH IRB approval letter (if required).
- Confidentiality Statement(s) (Attachment 3) signed by <u>all individuals</u> who will have access to confidential data.
- Payment of \$10 per birth or death certificate or \$12 per fetal death certificate if the request is for a known quantity of paper copies of certificates. For requests that involve an unknown number of paper certificates, or that involve preparation of electronic data files or other VSA services, an estimate of costs will be sent to the PI for approval before work begins. Checks should be sent to the address above to the <u>Attention of Dr. Monique Wilson</u> and made payable to the **State of Maryland**.

Questions about the VSA review may be directed to Dr. Monique Wilson, Assistant Director, at 410-764-3875 or monique.wilson@maryland.gov.

Questions about the IRB review may be directed to Ms. Gay Hutchen, IRB Administrator, at 410-767-8448 or <u>gay.hutchen@maryland.gov</u>.

Sincerely, Lee Hurt, Dr.P.H. Director, Vital Statistics Administration

## **Attachments**

Attachment 1: Request for Confidential Vital Statistics Data Attachment 2: Agreement for the Release of Confidential Vital Statistics Data Attachment 3: Confidentiality Statement



## **REQUEST FOR CONFIDENTIAL VITAL STATISTICS DATA**

Requestor's Informa	ation
Name:	
Title:	
Organization:	
Address:	
Phone: E	-mail:
Fax: D	Date of Request:
Signature:	
Name, phone number, and e-mail address of person to con than above):	
Type(s) of data requested: (Check all that apply)         Birth       Death         Fetal death	Marriage Divorce
Format of data requested: (Check all that apply)	
Certificates Electronic data files Othe	r (Specify):
Area(s) of Maryland for which data are requested:	
Year(s) for which data are requested	
<ul> <li>Please provide the following information on additional sheets:</li> <li>Summary of the project for which data will be used</li> <li>Public health importance of the project for which data will be used</li> </ul>	ed

- > Description of the vital statistics data (including a listing of each data item) being requested
- Justification for each variable requested, including justification for level of data requested (if aggregate-level data meet 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)
- > Description of safeguards to protect the confidentiality of data and prevent unauthorized access



## Agreement for the Release of Confidential Vital Statistics 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 confidential birth, death, fetal death, marriage and divorce data requires the approval of the Director of the Vital Statistics Administration (VSA) or his/her designee.
- 2. Release of confidential birth, marriage and divorce data for research purposes requires approval of the Institutional Review Board (IRB) of the Maryland Department of Health (MDH). Release of next of kin information from death records will also require the approval of the IRB.
- 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 meet 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 VSA 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. Certificates and data files may only be shared with those individuals and entities who have been authorized in writing by VSA to have access to the data. 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 VSA.

- 6. If a researcher seeks to make contact with an individual or institution named on a certificate or data file, initial contact with that individual or institution must be made by VSA. No contact of any kind is to be made with an individual or institution named on a certificate or data file unless the individual or institution named on a certificate or data file unless the individual or institution named on the certificate or data file agrees in writing to be contacted by the researcher.
- 7. No contacts of any kind are to be made with any individual or institution named on a certificate or data file without the written permission of the MDH IRB. Information obtained from certificates or data files cannot be used for any type of follow-up, including institutional follow-up, without the express permission of the MDH IRB.
- 8. No attempt will be made to link vital records with any other source of information without written authorization from VSA.
- 9. No listing of information from individual records, with or without identifiers, may be released or published.
- 10. 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.
- 11. No birth certificate information may be released if it is to be used for commercial solicitation or private gain.
- 12. The following fees are charged by VSA:
  - > There is a fee of \$10 per record to search for a copy of a birth or death certificate.
  - There is a fee of \$12 per record to search for a copy of a fetal death, marriage or divorce certificate.
  - There is no charge for the first two hours of data analyst time spent on a request. After the first two hours, the fee for data preparation is \$75 per hour.
  - > There may be additional charges for clerical time, supplies, postage, and photocopy expenses.
- 13. An estimate of charges for VSA services will be prepared before work begins on a request. Work on the request cannot begin until these charges have been accepted in writing by the Principal Investigator.
- 14. If requested by VSA, users of vital statistics data must provide periodic updates of the findings and status of the analysis of data to VSA.
- 15. The requestor of the data is expected to give VSA a copy of any publication or release of findings which makes reference to the data at least 48 hours before publication or release of findings.
- 16. The Department must be acknowledged as the source of data in publications or other release of the data resulting from the disclosed data. The following disclaimer must be included:

"Certain data were provided by the Vital Statistics Administration, Maryland Department of Health, Baltimore, Maryland. The Department of disclaims responsibility for any analyses, interpretations or conclusions."

- 17. At the conclusion of the project, all copies of certificates and/or data files must be returned to VSA or destroyed.
- 18. Any unauthorized use or release of Vital Statistics information is subject to prosecution to the fullest extent of the law.

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:	
Address:	
Telephone number:	
Signature:	
Date:	



## **Confidentiality Statement**

I understand that I am working with confidential data obtained from Maryland vital records on a project entitled:

I understand that these data can only be used for this project only, and only for purposes approved by both 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 Vital Statistics Administration who have signed Confidentiality Statements. I understand that the confidentiality of these data is protected by law and unauthorized use or disclosure is subject to legal penalties. I agree that I will immediately report any known or suspected breaches to the Vital Statistics Administration and the Maryland Department of Health Institutional Review Board.

Name (please print):
Title:
Organization:
Address:
Telephone number:
Signature:
Date: