Policy and Procedure for Requesting Access to Public Use Maryland State Unintentional Drug Overdose Reporting System (SUDORS) Data Files

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The Maryland State Unintentional Drug Overdose Reporting System (SUDORS) is a systematic surveillance system for capturing detail about the circumstances of accidental and undetermined intent overdose fatality and is currently collected as a project under the Overdose Data to Action (OD2A) grant. Summary SUDORS data is available through a federal online portal at https://www.cdc.gov/overdose-prevention/data-research/facts-stats/sudors-dashboard-fatal-overdose-data.html as well as through data products and reports prepared by Maryland which are available on the Maryland SUDORS webpage at https://health.maryland.gov/phpa/OEHFP/Injury/Pages/sudors.aspx. You may also contact the SUDORS project manager at Georgette.Lavetsky@maryland.org; the OD2A surveillance coordinator at charles.howsare@maryland.gov, or the OD2A program manager at Marie.Stratton@maryland.gov for information about available data.

Requests for a public-use version of the Maryland SUDORS data file for independent analysis by data requesters require approval by the SUDORS data managers and by the Strategic Data Initiative (SDI) Team https://health.maryland.gov/iac/Pages/sdi.aspx. This document describes the process and timeline for making requests for data files and includes all required forms.

Maryland SUDORS data files are available by calendar year and by six-month period (January – June and July – December) beginning with July 2017. Please note the 2017 and 2018 data files only include data for opioid-detected fatal overdose as collected under the Enhanced State Opioid Overdose Surveillance (ESOOS) grant, while data from 2019 and later years include data for all fatal overdose deaths and are not limited to opioid-detected overdose per requirements of the OD2A grant. Please also note that there is approximately a six month lag time between date of death and completion of data abstraction. Data for abstracted cases are collected by CDC on a semi-annual basis. Upon submission of data to the CDC, data undergo a thorough quality control procedure which takes several additional months. Therefore, data for deaths occurring between January 1, 2025 and June 30, 2025 are expected to become available during the spring of 2026, and data for deaths occurring between July 1, 2025 and December 31, 2025 are expected to become available during the fall of 2026, and so on.

Due to the sensitive nature of the data, and the data suppression requirements set forth by the Centers for Disease Control and Prevention (CDC), requesters will generally be provided a public use version of the raw data file which includes only the variables specifically requested and approved. Public use data files will generally not include personally identifying information (PII) such as name, date of birth, death certificate number, medical examiner number, census tract and block, and so forth unless specifically requested and approved. For more information, please refer to the list of SUDORS variables. Additional detail about variables collected is available upon request.

Key steps:

1. Data file requests will be acknowledged upon receipt of the completed data file request and data use agreement.

2. Data file requests will then undergo an internal review process by the Maryland SUDORS program. Additional information may be required to clarify a data file request.

3. *Provisional approval* by the SUDORS program is typically provided within four weeks of request. This does not constitute final approval of the project; however, it does acknowledge the SUDORS' program's support of the project and willingness to submit the project to Maryland's Strategic Data Initiative (SDI) Team for final review and approval.

4. All requests for data files are reviewed by Maryland's SDI Team. . Timelines and requirements for SDI review are set forth by the SDI review body. For more information about SDI, please visit https://health.maryland.gov/iac/Pages/sdi.aspx.

5. **Only after SDI approval is granted will the request be considered fully approved**, at which time the agreement will be signed by the SUDORS program and a copy of the signed agreement will be sent back to the requester along with a copy of the SDI approval letter. At that time, the SUDORS program will begin preparing the requested data file. The time required to produce the data file will vary by size of the request and by programmatic capacity.

Use the form below to submit a data file request and to sign a data use agreement (DUA). Both are required at the time of request and are pre-requisites for review.

Please note: All fields are required. Failure to provide requested information, including copies of IRB approvals, as appropriate, will result in delays. If additional space is needed, please attach additional sheets.

Maryland State Unintentional Drug Overdose Reporting System (SUDORS)

Data File Request Form

Requester contact information:
Last name:
First name:
Organizational affiliation:
Phone number:
Email address:

Description of need for data:

Q1: Identify the periods for which data are requested.
*Select one time period option for each year of interest. Please note that 2017 and 2018 include opioid-detected deaths only.**

2017:*		☐Jul/Dec	
2018:*	☐Jan/Jun	☐Jul/Dec	☐Complete year
2019:	☐Jan/Jun	☐Jul/Dec	☐Complete year
2020:	☐Jan/Jun	☐Jul/Dec	☐Complete year
2021:	☐Jan/Jun	☐Jul/Dec	☐Complete year
2022:	☐Jan/Jun	☐Jul/Dec	☐Complete year
2023:	☐Jan/Jun	☐Jul/Dec	☐Complete year
2024:	☐Jan/Jun	☐Jul/Dec	☐Complete year

Q2: Describe the purpose for which data are requested and the analyses that will be conducted, including the need for the public use data file. If this may be considered research, include a description of the proposed study design. In addition to a project overview, please describe your need to link SUDORS data to other data, if applicable. Include your anticipated project timeline and a description of any anticipated reports and publications.

Q3: List the variables you would like included in the data set and explain the importance of the variables to your analysis. No explanation is required for requesting demographic variables. Single explanations for groups of variables is acceptable in some circumstances (e.g. reason for requesting toxicology findings which include multiple variables requires one explanation). If you are requesting access to personally identifying information (PII) such as medical examiner record number, census block and tract, etc., please clearly state this and provide a detailed justification of the need for PII.

Q4: Describe the primary applicant's qualifications to perform proposed analyses. Include any prior experience analyzing large and complex data files. Include names and qualifications of all additional individuals participating in this project who will be granted access to the data file.

Q5: Identify the public health benefit of the proposed analysis for prevention and response efforts, including any benefit to the State of Maryland.

Q6: If a requester's project may be considered research, the requester is required to submit an approval or exemption letter from the Maryland Department of Health Institutional Review Board (IRB) in addition to an approval or exemption letter from their own IRB, if applicable. If the requester does not believe their proposed analysis could be considered research, a full explanation of the reasons why must be provided below.	
Project considered research? (Check "Yes" or "No" below and complete the section)	
☐ **Yes**	☐ **No**
Select one for MDH: ☐ MDH IRB decision received *(Attach copy of IRB approval/exemption)* ☐ MDH IRB decision pending **Select one for Requester's agency:** ☐ Requester's IRB decision received *(Attach copy of IRB approval/exemption)* ☐ Requester's IRB decision pending ☐ Requester is part of MDH	**Explain:** _____ _____ _____ _____ _____ _____

THE ADDITIONAL QUESTIONS BELOW ARE REQUIRED FOR SDI REVIEW AND THEREFORE MUST BE COMPLETED WITH THIS SUBMISSION

Q7: Will the Data Partner share this MDH data with a subvendor(s), including third-party IT providers?	
☐ Yes: List all subvendors that may access, store, use, or view MDH Data in relation to this agreement. Provide a brief description of their role.* **Please note that you must provide a copy of a Risk Assessment Report for each subvendor, and that Risk Assessment Report must be 1) A HITRUST Certification, SOC 2 Report, CSET Report, or other independent 3rd party evaluation; 2) On the subvendor's systems and environments–General reports on Google Cloud, AWS, Azure will not count; and 3) Within the last year.* _____ _____ _____ _____ _____	☐ No (go to Q8)

Q8: Risk Assessment: Please select one of the options below.
☐ SOC-2 Report* ☐ Risk Assessment Report* ☐ HITRUST CERTIFICATION* ☐ Free Evaluation (CSET Tool)* ☐ Report is in Progress* ☐ Not applicable because the Data Partner is an MDH Unit, Government Entity (state(s), local, or federal), certified EHR or EMR, and/or Accredited University ☐ Not applicable because only aggregate data is being shared ☐ Not applicable because MDH Data is not stored on another party's system **Submit a copy of your risk assessment with this application. Applications without a risk assessment will not be reviewed. If a report is in progress, please provide an estimated completion date.*

Q9: Where will the Data Partner (i.e. the requester) store the data? i.e. Where is the MDH Data going? Select ALL that apply.		
☐ Data Partner's System ☐ Email ☐ Google Drive ☐ MDH Platform ☐ State of MD Platform	☐ Microsoft OneDrive ☐ Cloud System ☐ Data Center ☐ Database ☐ Fax	☐ Flash Drive ☐ EHR or EMR ☐ Laptop ☐ Hard Copies ☐ MD THINK

Q10: Will MDH Data on the Data Partner (i.e. the requester)'s system stay inside the US at all times?	
☐ Yes *(go to Q11)*	☐ No: Explain: _____ _____ _____ _____ _____

Q11: Are all employees of the Data Partner (i.e. the requester) accessing MDH Data physicall located inside the US?	
☐ Yes *(go to Q12)*	☐ No: Explain: _____ _____ _____ _____ _____

Q12: Are all employees of the other party/vendor (i.e. requester) with access to PHI/PII MDH provided HIPAA training? Explain.	
☐ Yes: Explain: _____ _____ _____ _____ _____ _____	☐ No: Explain: _____ _____ _____ _____ _____ _____

Maryland State Unintentional Drug Overdose Reporting System (SUDORS)

Data Use Agreement

This agreement establishes the terms and conditions under which the data requester and other analysts stated in this application can acquire and use the Maryland State Unintentional Drug Overdose Reporting System (SUDORS) data set.

1. The data requester agrees to only use the data set for the purposes described in this application.
2. The data requester agrees to only share, publish, or otherwise release any findings or conclusions derived from analysis of the SUDORS data set through the specific reports and publications described in the recipient's application **and** with prior review and comment from the Maryland SUDORS program prior to release of data.
3. The data requester has the qualifications necessary to analyze large and complex public health data sets. The data requester agrees to consult the Maryland SUDORS program with any data use or analysis questions.
4. The data requester agrees to work collaboratively with the Maryland SUDORS program to understand and adhere to SUDORS data analysis and data suppression requirements, which prohibit any sharing or publication of data about populations and population sub-groups with fewer than 11 decedents represented in the data file.
5. The data requester has obtained Institutional Review Board (IRB) approval or exemption for research involving deceased subjects from the Maryland Department of Health (MDH) IRB and any additional affiliated IRBs as applicable.
6. The Maryland SUDORS program will request SDI approval for this project on behalf of the requester.
7. The data requester agrees to use appropriate administrative, physical, and technical safeguards to prevent use or disclosure of the data set other than as provided for by this agreement.
8. The data requester agrees to only share the data set with the analyst(s) named in this application. If additional analysts will be added to the project, the data requester agrees to notify the SUDORS Program in writing within 5 days. The data requester agrees not to release data to any other third party without prior written approval from the Maryland SUDORS program.
9. The data requester agrees to include the following disclaimer on any reports or publications, if applicable: *This publication utilizes data provided by the Maryland Department of Health, Maryland State Unintentional Drug Overdose Reporting System (SUDORS); collected under guidance of the Centers for Disease Control and Prevention under cooperative agreement number [INSERT COOPERATIVE AGREEMENT NUMBER(S) HERE]; and analyzed by [INSERT NAME OR ORGANIZATION HERE]. Its contents are solely the responsibility of the author(s) and do not necessarily represent the official views of the Maryland Department of Health or the Centers for Disease Control and Prevention.*

10. The data requester agrees to notify the Maryland SUDORS Program immediately upon having reason to know or suspect that a data breach, unauthorized data use, or confidentiality violation has occurred.
11. This data use agreement remains in effect for one calendar year from the approval date, after which time it will expire unless renewed by the Maryland SUDORS program.
12. All data shall remain the property of the Maryland Department of Health, and the data requester agrees to return the data set to the Maryland SUDORS program or destroy the data set upon termination of this agreement or the end of the project.

The requester's signature below constitutes agreement with the requirements listed above in reference to use of the requested Maryland SUDORS data, as applicable. It does **not** constitute a completed agreement with the SUDORS program for release of the data, which requires both programmatic and SDI review and approval.

Signature of data requester Date

*Section to be completed by the SUDORS program after an SDI decision has been reached. The signature below constitutes approval of the request by both the Maryland SDI program and the SUDORS program. Agreement is not executed until **all** parties sign off.*

The data requester has obtained SDI approval for this project. The SDI approval number is #_____ and approval letter is dated ___/___/_____.

Signature of SUDORS Program Manager Date