Policy on Access to Public Health Datasets for Individuals or Entities Outside of Public Health Agencies

Purpose

This policy describes the permissible uses of non-publicly available public health data for research by organizations and individuals who are not a part of a public health agency. Individually identifiable information and Protected health information (PHI), are protected from disclosure under applicable federal and state privacy laws, including the Government Health Care Information Act (GHCIA), other Montana statutes under Title 50 of the Montana Code Annotated (MCA), the Health Insurance Portability and Accountability Act (HIPAA), and regulations promulgated thereunder (such as the HIPAA Privacy Rule). In the event one or more federal or state privacy laws applies, the most restrictive protective requirement shall control.

Scope

This policy only applies to data requests from agencies, organizations, or individuals that are NOT state, county, or tribal public health agencies but are engaged in research that requires the use of non-publicly available surveillance data collected and managed by the Public Health and Safety Division (PHSD). These surveillance systems include:

- Vital Statistics
  - Death certificate
  - Fetal death certificate
  - Birth certificate
  - Marriage
- Montana Central Tumor Registry (MCTR)
- Montana Infectious Disease Information System (MIDIS)
- Syndromic Surveillance (ESSENCE)
- Montana Immunization Information System (imMTrax)
- Emergency Medical Services (EMS) data
- Montana Trauma Registry (MTR)
- Montana Violent Death Reporting System (MT-VDRS)
- State Unintentional Drug Overdose Reporting System (SUDORS)
- Behavioral Risk Factor Surveillance System (BRFSS)

This policy does not apply to data released by the PHSD during the course of normal operations and with the purpose of disease control and prevention. Requests may be for de-identified, limited, or identified case-level data based on dataset availability (See Table 1 and Appendix B).

Exclusions:

1) Some programs in PHSD have established agreements, contractual, or legal obligations to supply data containing PHI or detailed reports based on PHI to other programs in PHSD, HIPAA Covered Entities, or other third parties as specified by Montana Code 50-16-603. Those relationships are not covered by this policy.

2) Public health activities that are being conducted by State of Montana employees outside of DPHHS or non-public health employees within DPHHS who are working on a public health project are not covered by this policy. Those data access requests will be covered by employee data access procedures and applicable federal and state privacy laws.

3) Some of the data managed by PHSD are not available for release by DPHHS. This includes case-level data on induced abortions (MCA 50-20-110), and divorces (MCA 50-15-122).

4) Medical Record or Report Requests: Requests for a specific EMS patient care report and trauma registry record will be referred to the agency or facility that provided the patient's care because EMSTS only contains partial information from the original medical record or report. Individual records requests (while still not a full medical record) may be granted from other data systems such as MCTR or imMTrax but this request process is not the appropriate avenue for those requests. Those seeking individual records for personal use should contact the desired data system directly. Copies of birth and death certificates can be requested from the Office of Vital Records.

5) Individuals or organizations who are requesting publicly available data should follow the Public Information Request Process administered by the Montana Department of Administration and will not be considered under this policy.

Permissible Uses of Data

Data requests will only be approved if all the following requirements are met:

- Disclosure of the dataset is permitted under applicable federal and state privacy laws
- The dataset meets project needs and adheres to the minimum necessary data standard
- Adequate procedures for data use, storage, and destruction are in place to safeguard against unauthorized disclosures
- Requester is qualified to perform proposed data analysis and has demonstrated adequate knowledge of the effects of bias that are subject to occur during the processes of data collection, classification and coding, and statistical analysis for the requested data source.

The minimum necessary data standard dictates that the least amount of information needed to accomplish the project goals will be released. Additionally, the data being requested must not violate the legal requirements for confidentiality of the data. Many different laws apply to PHSD surveillance data so the standard for what can be released may differ by data source. Please refer to Appendix B for a summary of what laws apply to each data source included in this policy. The following table provides a summary of what is available for release based on the Government Health Care Information Act (GHCIA) as it generally provides that the most restrictive privacy standard applicable to many of the included data sources.

Table 1: Availability of Released Dataset Based on the GHCIA

Does GHCIA apply to the PHSD data source?	De-identified Dataset	Limited Dataset	Identified Dataset
Yes	Available with • Data use agreement	Available with • Authorization of release from every individual included in the data and • IRB approval or exemption • Data use agreement	Available with • Authorization of release from every individual included in the data and • IRB approval or exemption • Data use agreement
No	Available with • Data use agreement	Available with: • IRB approval or exemption • Data use agreement	Available with • Authorization of release from every individual included in the data OR Waiver or alteration of authorization† from an IRB or privacy board • IRB approval or exemption • Data use agreement

† a detailed explanation of criteria for waiver or alteration of authorization is available in the definitions section of this policy.

Data requests for commercial or other non-public health purposes will be considered based on available time and resources to prepare the data and will be subject to fees as described in Montana Code Annotated 2-6-1006. There may also be additional fees for vital records as outlined by the Office of Vital Records Fee Schedule.

De-identification Standard

The Department has designated itself a hybrid entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under this Hybrid Designation Statement, much of PHSD is a covered entity for purposes of HIPAA. As such, PHSD adheres to the HIPAA De-identification standard which outlines two methods to de-identify data, Expert Determination or Safe Harbor. See Appendix A for which data elements cannot be included for Safe Harbor de-identification. Expert Determination of de-identification will be made on a case-by-case basis.

Definitions

Health Information is defined under regulations implementing the Health Insurance Portability and Accountability Act as "any information, including genetic information, whether oral or recorded in any form or medium that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individuals." 45 CFR 160.103.

Protected Health Information is any individually identifiable health information (as defined above) that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. It does not include individually identifiable health information in education records covered by the Family Education Rights and Privacy Act, in records described at 20 U.S.C. 1232g(a)(4)(B)(iv), in employment records held by a covered entity in its role as an employer, and regarding a person who has been deceased for more than 50 years.

The HIPAA Privacy Rule (set forth under 45 CFR Part 160 and Subparts A and E of Part 164) generally requires appropriate safeguards to protect the privacy of health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization.

The Expert Determination Method is a process of de-identifying PHI as described under 45 CFR 164.514(b).

The Safe Harbor Method is a process of de-identifying PHI by removing identifiers described under 45 CFR 164.514(b). These identifiers include: name, social security

number, file or medical record numbers, geographic subdivisions smaller than a state, and all elements of dates except year that apply to an individual (e.g., birth date) or to treatment events, telephone number, fax number, electronic mail addresses, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, device identifiers and serial numbers, URLs, IP address, biometric identifiers including finger and voice prints, full face photos, and any other unique identifying number.

Minimum Necessary (see 45 CFR 164.502(b) and 45 CFR 164.514(d)). The minimum necessary standard requires covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate access to and disclosure of protected health information.

Research is defined under 45 CFR 164.501 as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

Institutional Review Board (IRB) is a committee that performs ethical reviews of proposed research, especially but not limited to research involving human subjects. IRBs must have a Federal wide Assurance from the Office for Human Research Protections in order to review research proposals involving human subjects. PHSD does not have an internal IRB to review proposed research. Data requesters must find an IRB to review their research before requesting limited or identified data from PHSD.

De-Identified data set: a compilation of record-level data that have been de-identified by either the Expert Determination Method or the Safe Harbor Method (being absent all 18 data elements defined as identifying by HIPAA, see Appendix A).

Limited data set: a compilation of record-level data that may include some of the 18 data elements defined as identifying by HIPAA but does not include any directly identifiable data. See Appendix A.

Identified data set: a compilation of record-level data that may include all of the 18 data elements defined as identifying by HIPAA, see Appendix A.

Waiver or Alteration of Authorization: To use and/or disclose Protected Health Information (PHI) for research purposes, the HIPAA Privacy Rule in general requires that researchers obtain signed authorization from the individual. An IRB can grant a Waiver of HIPAA Authorization to permit use and/or disclosure of PHI for research purposes, without obtaining authorization. An IRB may also approve an alteration of the

requirements of written HIPAA Authorization provided the research meets the criteria for waiver or alteration which include:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

- an adequate plan to protect the identifiers from improper use and disclosure;
- an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
- adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

2. The research could not practicably be conducted without the waiver or alteration; and

3. The research could not practicably be conducted without access to and use of the protected health information.

Definition taken from the U.S. Department of Health and Human Services Research Guidance.

Appendix A: Availability of Data Elements by Type of Data Set

Data Elements	De-Identified*	Limited	Identified
Names	No	No	Yes
Street Addresses	No	No	Yes
City	No	Yes	Yes
Zip Code (full)	No	Yes	Yes
Zip Code (first 3 digits)	Yes^	Yes	Yes
Telephone numbers	No	No	Yes
Fax Numbers	No	No	Yes
Email addresses	No	No	Yes
Social Security Numbers	No	No	Yes
Medical Record Numbers	No	No	Yes
Name of hospital, EMS agency, or other healthcare provider	No	No	Yes
Free text or Narrative fields **without** name or other directly identifying information	No	Yes	Yes
Free text or Narrative fields **with** name or other directly identifying information	No	No	Yes
Health plan beneficiary numbers	No	No	Yes
Account numbers	No	No	Yes
Certificate license numbers	No	No	Yes
Vehicle Identifiers, including license plates	No	No	Yes
Device serial numbers	No	No	Yes
URLs	No	No	Yes
IP Address Numbers	No	No	Yes
Biometric identifiers	No	No	Yes
Full face photos	No	No	Yes
Full dates of: Admission, Discharge, Service, Death, or Birth	No	Yes	Yes
Year of: Admission, Discharge, Service, Death, or Birth	Yes	Yes	Yes
Age in years	Yes**	Yes	Yes
Age in months, days, or hours	No	Yes	Yes

Source: https://www.hhs.gov/hipaa/for-professionals/special-topics/de-identification/index.html

*De-identified according to the Safe Harbor Method described in HIPPA.

^The geographic unit formed by combining all zip codes with the same three initial digits must contain more than 20,000 people or areas with less than 20,000 must be coded 000

** Ages 90 or older must be grouped together.

Appendix B: Laws Governing PHSD Surveillance Data Available for Release

Covered by HIPAA	Covered by GHIA	Data System	Other Montana Code Annotated statute governing release
No	No	Death Certificates	Mont. Code Ann. § 50-15-121(4) A certified copy or other copy of a death certificate must be issued upon request of any person. Mont. Code Ann. § 50-15-122(2) The execution of a research agreement that protects the confidentiality of the information provided to a researcher in response to a written request is required for disclosure of information that may identify a person or institution named in a vital record or report. This agreement must be made in compliance with this chapter or rules adopted to implement this chapter. Each agreement must prohibit the release by the researcher of any information that might identify a person or institution, other than releases that may be provided for in the agreement.
No	No	Birth / Fetal Death Certificates	Mont. Code Ann. § 50-15-121(6) This section may not be construed to permit disclosure of confidential information contained in a birth certificate for medical or health use or of information for statistical purposes only contained in a certificate of marriage or report of dissolution of marriage unless disclosure is specifically authorized by law for statistical or research purposes or unless ordered by a court. Mont. Code Ann. § 50-15-122(5) Immediately upon the filing of a record with the department, the fact that a birth or death has occurred may be released to the public without restriction. Notwithstanding the restrictions provided in 50-15-121, complete birth records may be released to the public 30 years after the date of birth. The department shall adopt rules that provide for the continued safekeeping of the records. Mont. Code Ann. § 50-15-122(2) (see above)

No	No	Marriage	Mont. Code Ann. § 50-20-122 (5) (b) Upon the filing of a record of marriage with the clerk of the district court, information that may be released to the public without restriction is specifically limited to: (i) the names of the parties, the age of the parties, and their place of birth; (ii) the date and place of the marriage; (iii) the names and addresses of the parents of the parties; (iv) the name of the officiant; and (v) the type of ceremony. (c) Any other information contained in a marriage license application that is not authorized to be disclosed under subsection (5)(b) is considered confidential and is subject to the disclosure limitations and penalties provided in 50-15-114. (d) Notwithstanding the restrictions provided in 50-15-121 and this section, the information contained in a marriage license and marriage certificate may be released to the public 30 years after the date of the marriage.
Yes	No	MCTR	Mont. Code Ann. § 50-15-704 Confidentiality. Information received by the department pursuant to this part may not be released unless: (1) it is in statistical, nonidentifiable form; (2) the provisions of Title 50, chapter 16, part 6, are satisfied; (3) the release or transfer is to a person or organization that is qualified to perform data processing or data analysis and that has safeguards against unauthorized disclosure of that information; (4) the release or transfer is to a central tumor registry of another state and is of information concerning a person who is residing in that state; or (5) the release is to a health care practitioner or health care facility that is providing or has provided medical services to a person who has or has had a reportable tumor. *Although the tumor registry law is located in the same chapter as vital statistics, it has its own confidentiality requirements (listed above) that control over the general vital statistics statutes under 50-15-121 and 50-15-122
Yes	Yes	MIDIS	
Yes	Yes	imMTrax	
Yes	Yes	EMS data	
Yes	Yes	MT-VDRS	
Yes	Yes	SUDORS	
Yes	Yes	ESSENCE	

Yes	Yes	Montana Trauma Registry	Mont. Code Ann. § 50-6-415 (1) Data in a health care facility's hospital trauma register and reports developed from that data pertaining to quality of trauma care may be given by the facility only to: (a) the facility's peer review committee; (b) the regional trauma care advisory committee of the region in which the facility is located; (c) the trauma care committee; or (d) the department. (2) Data in the state trauma register and hospital trauma registers is not subject to discovery in a civil action and may not be introduced into evidence in a judicial or administrative proceeding. (3) Data and reports concerning peer review, quality improvement, or the quality of the trauma care provided by a health care facility or a health care provider that are produced by a regional trauma care advisory committee or the trauma care committee or provided by a health care facility to a regional trauma care advisory committee or the trauma care committee, as well as the proceedings of those committees concerning peer review and quality improvement, are not subject to discovery in a civil action and may not be introduced into evidence in a judicial or administrative proceeding. (4) A statistical report on trauma and trauma care developed by the department that does not identify specific health care facilities, health care providers, or patients is not confidential and is considered public information. (5) A statistical report developed by a health care facility from information in its hospital trauma register that does not pertain to peer review or quality improvement is not confidential and is considered public information. (6) Information in a department record or report that is used to evaluate and improve the quality of emergency medical service and trauma care by a health care facility or emergency medical service is not subject to discovery and may not be introduced in evidence in a judicial or administrative proceeding. (7) Information in a department record or report that is used to determine whether a health care facility will be designated or lose its designation as a trauma care facility is not confidential and is considered public information.
Yes	Yes	BRFSS	The Government Health Care Information Act (Mont. Code Ann. §§ 50-16-601, et seq.) only applies to the extent the data includes readily identifiable information on respondents