



Data Request Procedure for Individuals or Entities Outside of Public Health Agencies

Scope

This process describes how individuals or entities outside of state, local, or tribal public health agencies may request non-publicly available data sets while protecting the confidentiality of those data in compliance with all state statutes and policies, federal laws, and pertinent agreements.

Procedure

1) Initial data request:

Agencies, organizations, or individuals who are not public health authorities or partner organizations engaged with public health authorities in a public health project must make a data request through the [Montana Department of Administration Public Information Request](#). Start a new request by selecting “Submit Public Records Request” and then select “New Request” on the left menu. Be sure to select HHS – Department of Public Health and Human Services as the state agency on the request form.

The appropriate PHSD data steward will review the request and determine the best way to meet the project need. In some instances, the data need can be met with aggregate statistics or publicly available data and there is no need to continue with the application process. However, if non-publicly available, case level data is needed, the data steward will initiate the rest of the request procedure.

2) Application:

The data steward will provide a blank PHSD Application for Case-level Public Health Data to be completed. The application must include:

- a. The name, affiliation of, and contact information for the person or entity requesting the data.
- b. The names of all individuals who will have access to the data, including employees, subordinates, and subcontractors of the applicant.
- c. A detailed description of the proposed study including main objective of the study and justification for why data elements are needed for the study.
- d. A list of all requested data elements. Note data stewards may question requested data elements and ask for additional justification if the study description doesn't support the need for particular elements



- e. A copy of the IRB approval or IRB determination of exemption must be attached, including the Federal wide Assurance number of the IRB and a copy of the study protocol as submitted to the IRB.
- f. A detailed description of the security measures the applicant will take to protect the data, including a description of final disposal of the data at the end of the project.
- g. Any dataset specific requirements

The completed application should be submitted back to the data steward of the requested dataset.

3) **Review:**

Applications will be first reviewed by the data steward for the requested dataset. This initial review will focus on application completeness and clarity of study design, justification for data need, and purpose (see [PHSD case level data request review tool](#)). If the data steward has any questions about the application, they will communicate with the requester until they have a complete understanding of the request. If the data steward determines that the proposed study is an appropriate use of the data, they will send the application to the Data Request Review Committee for review.

The Data Request Review Committee will consist of at least 3 data stewards or program managers and include at least one member from each of the following bureaus within PHSD: Communicable Disease Control and Prevention, Chronic Disease Prevention and Health Promotion, and Epidemiology and Scientific Support. The Internal Review Committee will have a monthly meeting time set aside for review of applications but will only meet if there is at least one application in need of review. Review by the committee will focus on ensuring all requirements for data sharing are met as outlined in the policy, [Access to Public Health Datasets for Individuals or Entities Outside of Public Health Agencies](#) and determine if a fee waiver is appropriate using the [PHSD case level data request review tool](#). If the application is denied, the committee must explain the reason for denial. The committee will communicate their decision to the data steward who will initiate a data use agreement for the requester or communicate the reason for denial as applicable.

All applications should have a final determination within one month of the application being submitted to the Data Request Review Committee.

4) **Data Use Agreement:**

The data steward will send the appropriate data use agreement (DUA) to the requester depending on whether the request was for de-identified, limited, or identified



data. The Primary Responsible Party must ensure that all individuals who will have access to the data are listed as an Authorized Party and accept responsibility for ensuring all Authorized Parties adhere to the terms of the DUA. If a requester wishes to modify the DUA before signing, the proposed changes must be reviewed by the Section Supervisor who supervises the requested data system and DPHHS legal counsel (if needed) before being agreed to. The DUA is considered complete once it has been signed by the Primary Responsible Party and the appropriate Section Supervisor. Approved studies must have a fully signed DUA before data can be released. If fees are required, the requestor must also pay fees as described in the public information request invoice prior to data release.

5) **Data Release:**

The data steward will prepare the requested dataset according to the application specifications and communicate with the requester to clarify any issues. Data and required documentation should be shared with the requester via a secure method, such as the [State of Montana File Transfer Site](#) as agreed upon by the requester and the data steward. The prepared datasets should be completed and sent within five working days of the DUA being completed and applicable fees being paid unless otherwise specified by the data steward according to estimated time to complete the request and other work obligations.

6) **Monitoring Active Data Use Agreements:**

Once the project is approved and data are released to the authorized parties, data stewards are responsible for monitoring all active data use agreements to ensure terms of the DUA are upheld. For this purpose, a log of all active DUAs within PHSD will be maintained by the Surveillance and Informatics Section within the Epidemiology and Scientific Support Bureau. All data stewards and section supervisors over affected data systems will have access to the log and will be responsible for monitoring DUAs that are for their data. The following questions should be evaluated at least annually.

a. Is the DUA valid and unexpired?

The primary responsible party will be notified 60 and 30 days in advance of the DUA expiration date.

If the project is continuing, they must:

- Upload an IRB letter renewal (if applicable)
- Verify or update the list of authorized users
- Sign a new DUA

If the project is ending, they must:



- Attest that data has been destroyed. It is best practice to destroy all identifiable data upon project completion; analytic files that do not contain direct identifiers can be retained for up to 3 years post project completion.
- Data steward closes the DUA and the project
- All records are archived and retained

If the primary responsible party does not respond to the requests for DUA renewal:

- Email stating that the DUA has lapsed and failure to respond will result in the responsible institution being contacted.

b. Is the list of authorized users accurate?

The electronic version of the project application must be updated to reflect new staff with access to the data. This will occur throughout the duration of the project. It is the responsibility of the primary responsible party to notify the data steward of any changes.

c. Have there been substantial* changes made to the project?

** change of institution, Primary Responsible Person, change to the project scope.*

A change of institution or primary responsible party can be handled by updating the DUA to note the changes and signing a new DUA if the data steward determines that the changes will not affect whether the project meets data sharing criteria. A change to the project scope, such as adding a new primary objective or extensively changing the analysis plan, will require a new application to be submitted and a new review by the Internal Review Committee. It is the responsibility of the primary responsible party to notify the data steward of any changes.

d. Have there been any data breaches or unintended disclosures?

Data breaches or unintended disclosures must be reported to the data steward in writing as soon as the primary responsible party becomes aware of a breach. Upon notification of a breach, the data steward should notify their section supervisor and the DPHHS privacy officer.