

SCHOOL OF PUBLIC HEALTH AND PREVENTIVE MEDICINE

GUIDELINES FOR ACCESS TO DATA COLLECTED BY THE VICTORIAN MAJOR TRAUMA REGISTRY (VSTORM)

Access to major trauma data collected and collated by VSTORM is guided by strict protocols and procedures to ensure that privacy and other ethical principles are maintained at all times. Provision of data to VSTORM, particularly since patient consent is not obtained from the outset, is subject to strict guidelines and the study protocol as submitted to all hospital, Department of Health (DH) and Monash University ethics committees. In particular, specific measures have been put in place to maintain the confidentiality of personal identifying information.

This document outlines the VSTORM Data Access policy. Access to data is subject to the approval of the DH.

FORMAL POLICY FOR DIRECT ACCESS TO, AND EXTRACTION OF, DATA FROM THE MAJOR TRAUMA REGISTRY

The following data access policy has been adopted:

1. Access to the data is subject to the Specific Access Guidelines given on the next page
2. Only VSTORM staff who report directly to the Head of VSTORM have direct access to the Major Trauma Registry data base;
3. All uses of the Major Trauma Registry, in whatever context, must receive prior approval from the Head of VSTORM and/or Department of Health, through the steering committee. In some instances, specific hospital ethics committee approval is also required.
4. Any material to be published using VSTORM data must be seen by the VSTORM steering committee before it is released for publication.
5. "Deidentified aggregate data will be provided to researchers under the 'Guidelines for Access to Data Collected by VSTORM'. Each research project requiring disclosure of data from the registry to third party researchers will need to seek ethics approval for their project and approval from the registry steering committee."
6. Only requests that meet Specific Access Guidelines 1 and 5 (see next page) will be provided free of charge, unless a large number of such requests are made. This will be reviewed from time-to-time. The provision of data for all other data requests (specific access guidelines 2-4) will be subject to a fee-for-service. Refer to the fee for provision of data document for an explanation of these.
7. All third party requests for access to VSTORM data must take appropriate timelines into account as these requests will need to be scheduled along with routine VSTORM tasks. As a general rule, requests for data under Specific Access Guidelines 1 and 5 will take 2-4 weeks to complete. Data cannot be supplied within 2 weeks of a request. All other requests must be first made to the Head, VSTORM who will circulate the request to the VSTORM steering committee members for out of session approval and data cannot be extracted until approval is given. Under exceptional circumstances, when data is required earlier, the Head of VSTORM and DH may convene a 'special meeting' to consider specific data requests. Once approval has been received, it will take 2-6 weeks to supply the data.

8. All data requests must be formally lodged via email to the Trauma Registry Data Manager (vstormdata@monash.edu)

VSTORM SPECIFIC ACCESS GUIDELINES

1. Where only summary data is requested and this is available from the quarterly reports (after formal acceptance of the report by the STC, which is usually 4 months after the end of the quarter), this information can be provided by VSTORM staff. Such provision of data would not require steering committee advice but VSTORM will require a formal request in writing and will keep a record of such requests. The steering committee will be given a summary record of such requests on a quarterly basis. A caveat and conditions of use statement will be provided with the data.
2. All requests for other aggregate data must be in writing to the Head of VSTORM. The Head of VSTORM will circulate the data request to the VSTORM steering committee members. A decision on whether to grant access to the data will be considered following advice from the steering committee. At no stage will data summaries that could identify hospitals or patients be provided. If a researcher requires data from a particular hospital or hospitals, a specific ethics application approval from the DH HREC will be required before data is able to be made available. This ethics approval should be made jointly with VSTORM. A caveat and conditions of use statement will be provided with the data.
3. No requests by third parties for direct access to unit records will be approved under any circumstances as this contravenes confidentiality and data access policies as required under the privacy legislation and ethics agreements. However, researchers may request VSTORM to undertake specific analyses of data. In all cases, the researchers would be provided with aggregate data only. Once again, a formal written request needs to be made to VSTORM for subsequent advice from the steering committee. If a researcher requires data from a particular hospital or hospitals, a specific ethics application approval from the DH HREC will be required before data is able to be made available. This ethics approval should be made jointly with VSTORM.
4. Deidentified aggregate data will be provided to researchers under the 'Guidelines for Access to Data Collected by VSTORM' Each research project requiring disclosure of data from the registry to third party researchers will need to seek ethics approval for their project and approval from the registry steering committee.
5. If a hospital or ambulance service makes a specific request for its own performance data, this should be provided by VSTORM. No data that could specifically identify a patient would be provided. All requests for this level data should be made in writing to the Head, VSTORM. Whilst such data requests would not require specific steering committee advice, VSTORM will notify the steering committee of such requests.