RESEARCH USE

Statutes, Rules and Regulations Pertaining to Vital Records Data

Missouri state statutes (193.045, 193.245, & 193.255) and the Code of State Regulations (19 CSR 10-10.090 Access to Vital Records) allow for the release of record-level vital records data by the Missouri Department of Health and Senior Services. The statutes listed above only apply to vital events occurring within Missouri's borders. The records of vital events that occur to Missouri residents in other states are the property of the state where the events take place.

Under section 610.035, RSMo, the department is prohibited from disclosing any Social Security number of a living person unless such disclosure is permitted by federal law, federal regulation or state law. Section 208.120, RSMo prohibits the department from disclosing any information obtained by them in the discharge of their official duties relative to the identity of applicants for or recipients of benefits or the contents of any records (e.g., Medicaid, Food Stamps). Public assistance information can be provided on de-identified records only.

45 C.F.R. Part 160 and Part 164. Vital Records requestors for research purposes will only be provided access to the minimum information necessary to achieve their specific research requests. Requestors are prohibited from disclosing any information that would identify a person and are also prohibited from the re-release of the data provided.

Statutes, Rules and Regulations Pertaining to Patient Abstract System Data

Missouri state statutes (192.067, 192.665, & 192.667) and the Code of State Regulations (19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers) allow for the release of Patient Abstract System (PAS) data by the Missouri Department of Health and Senior Services. The Department and other public health authorities are authorized to utilize PAS information for epidemiologic studies and for surveillance. The statutes listed above apply to Missouri residents only.

Application Procedures

To request record-level data (whether identified or de-identified) for research, a principal investigator must submit a completed *Application for Missouri Vital Records or Patient Abstract System Data for Research Purposes*. The application requires detailed information about the study protocol, justification for all data elements requested (each data element must be related to the hypotheses), and measures to ensure the confidentiality and security of the data. All information must be clear, consistent and specific. General descriptions do not allow accurate assessment of the value of the study or the need for the data items. Release of data from vital records and/or the Patient Abstract System by the Missouri Department of Health and Senior Services is granted to an agency/institution for the sole purpose of the research project described in the protocol application. The applicant will be required to complete and submit an *Agreement for Oversight*. The Agreement for Oversight requires both the requestor's signature and the Agency/Institutional Official's signature with the authority to bind the agency into the agreement (must be two different staff). All persons that will have access to the data must be listed in the application and will be required to sign *Confidentiality Pledge* **prior** to being granted access to the study data.

It is the principal investigator's responsibility to design a valid study that would make a contribution to public health, and it is not the department's role to help refine a faulty study or a poorly described study until it meets generally acceptable scientific standards. Protocols of this nature will be rejected and further processing of such applications will be discontinued. An application will be immediately rejected if it is determined that 1) it does not clearly describe a well-designed research or epidemiologic study, 2) the data will be used for commercial or marketing purposes, or private gain, 3) being a co-investigator would overburden the department, or 4) there is reason to believe that confidentiality of the data would be jeopardized by its release.

Researchers interested in obtaining DHSS data should first familiarize themselves with the data sets prior to designing their studies (see Data and Surveillance Systems). Only those data elements related to the hypotheses and

necessary for the study should be requested. The principal investigator will be notified of any discrepancy between the list of data elements requested in the research protocol and those determined by DHSS staff to be needed. Vital Records and Patient Abstract Data custodian contact information may be found under the Contact Us link.

PLEASE NOTE:
All research proposals involving Patient Abstract System files/data are also reviewed by an independent Data Release Advisory Committee (DRAC). If the study involves identifiable record-level data for living subjects; linkage with another data set; or contact with family, next-of-kin, or acquaintances, proposals will also be submitted to the Department of Health & Senior Services (DHSS), Institutional Review Board (IRB) for review before study approval determination can be made by the appropriate data steward(s).

The following forms must also be completed for DHSS IRB review and approval (when applicable):

Abstract of Protocol
IRB Form 1 'Request for Review of Research Protocol'
Protocol Template
Checklist for Submission of Research/Study Protocols

If a study does not involve DRAC and/or DHSS IRB review, we suggest submitting a completed application at least **two to three months prior** to when data will be needed. Studies involving DRAC and/or DHSS IRB review generally require a longer review period, so we suggest submitting the completed application and IRB packet at least **four to five months prior** to when data will be needed. *Protocol applications are reviewed on an 'as time permits' basis between other priority projects. The complexity of the requested data sets and the number of priority projects may impact the response time.* Please plan accordingly.

Regardless of the duration of the study, approval is only for one year at a time. Annual review is required for each study for as long as Department data are held.

Review Process

A primary reviewer is assigned to each application to conduct a preliminary review and to correspond with the applicant if the information provided is unclear or incomplete. If insufficient documentation is presented to determine approval, additional information will be requested to clarify the application. The primary reviewer will be reviewing issues such as the purpose of the request, ensuring the research design demonstrates adequate scientific rigor, the appropriateness of requested data to answering proposed research questions, ensuring provisions for maintaining confidentiality and security protections are adequate, and the availability of department resources to fill the request.

Once the primary reviewer completes the review, a recommendation is provided to either the State Registrar and/or PAS Authority or their designee, as needed, to approve or deny the application. Applications requiring DRAC and/or DHSS IRB review will then be distributed to the appropriate members for review/approval. You will be notified in writing of the final decision by the DHSS IRB Chair and the Project Coordinator. If your protocol application is approved, you will receive a *Scope of Work (Project Estimate/Quote)* outlining the requested files for your review/approval. Once the signed *Scope of Work* has been received back, the records/files will be prepared on the basis of your research application in accordance with Missouri statutes, rules and regulations. If your request is denied, you will be notified of the reasons within 60 days of the denial.

Approval Criteria

Studies and/or research projects must meet the following specific standards and criteria:

- be scientifically valid and statistically sound;
- contribute to public health practice;
- not use Department resources unreasonably and unnecessarily;
- be conducted ethically and with integrity;
- be in compliance with state and federal statutes and regulations, including confidentiality provisions;
- be reviewed by the Department Institutional Review Board when required; and
- be consistent with Department policy.

Fee Schedule

In an effort to recover the service cost incurred for staff time and other expenses involved in data delivery, the Section of Epidemiology for Public Health Practices will access fees for their data and services based on the posted *Fee Schedule*. Fees are assessed for preparation of data based on programming time and materials. Pre-payment is required before data files will be released.

Application Submissions

All applicants must complete, sign, date, and submit the *application*, *Agreement for Oversight*, *Confidentiality Pledge(s)*, and appropriate DHSS IRB forms when applicable. If data files are requested, a completed *Data Element Checklist* is also required for **each** data set being requested.

Completed packets should be mailed to the Project Coordinator at the address listed below. Electronic submission of applications with all applicable signatures is acceptable. **When scanning, please scan in black and white only**. Please do not scan black and white documents in color (default) due to size limitations.

Section of Epidemiology for Public Health Practices
Missouri Department of Health and Senior Services
Attn: Project Coordinator
Physical: 920 Wildwood Drive (65109)
Mailing: PO Box 570 (65102-0570)
Jefferson City, MO

Email: Dawn.Parker@health.mo.gov