

Continuation, Amendment, and Completion of Study Requirements

Investigators whose studies have been approved by the Department must maintain their approval in good standing. **Annual review is required for each study for as long as DHSS-provided data are held.**

[Annual Review](#)

[Amendment](#)

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REPORTING REQUIREMENTS

ANNUAL REVIEW

Approved applications/continuations for use of Missouri vital records and/or patient abstract system data are valid for **one year** at a time, regardless of the duration of the research project or study. For studies not requiring DHSS IRB annual review, a completed [Request for Review](#) and an [Agreement for Oversight](#) must be submitted to the Project Coordinator 20 calendar days prior to the current approval expiration date. 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). For studies requiring DHSS IRB annual review, a completed [Request for Review](#), [Agreement for Oversight](#), and an [IRB Form 2](#) must be submitted to the Project Coordinator 45 calendar days prior to the current approval expiration date. The Department will attempt to email a reminder notice to the Principal Investigator on file prior to the current approval expiration date; however, **it is the responsibility of the Principal Investigator to ensure that annual review materials are submitted whether or not a reminder is received.**

A study must be reviewed annually as long as the study is ongoing and DHSS-provided data are retained. Projects in the data analysis phase are considered ongoing. A [Request for Review](#) includes the following:

1. **PROJECT SUMMARY:** Provide a summary of all research activities that have occurred since the last approval was granted. Continuous progress is essential for continued department support and extension approval. If you have not made any progress, plans should be developed and reported addressing how you will overcome the barriers hindering progress, or continuation may be denied and Department support withdrawn.
2. **SUPPORTING DOCUMENTS** (when applicable): A current signed DHSS [IRB Form 2](#); a current copy of your sponsoring or affiliated institutional review board approval(s); an annual progress report (when applicable); copy of current Consent Form (when applicable); copy of Human Research Protection Training certificates, completed within the last 3 years for the PI and DHSS Co-PI; as well as copies of any presentations, reports, and/or articles not previously submitted for DHSS review.
3. **PROJECT MODIFICATION** (when applicable): A written description of proposed changes and copies of any proposed revisions to study protocols and forms, or any changes to the projected end date.
4. **STUDY PERSONNEL** (when applicable): Report any **new** staff assigned to the research project or study since the last approval was granted, who have access to DHSS-provided data. All new staff members must sign a [Confidentiality Pledge](#) **prior** to being granted access to DHSS data. It is the responsibility of the Principal Investigator to ensure that all staff are aware of and adhere to the confidentiality and security procedures.

AMENDMENTS

Any changes to a study protocol require the submission of an amendment request to the Project Coordinator. Proposed project changes must be reviewed and approved by the Department's Data Steward and IRB (when applicable) **before** being implemented. In the rare event that changes to the project must be made without the prior approval, in order to protect subject safety and welfare, the Project Coordinator must be notified as soon as

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possible after the changes have been made. Please use the [Request for Review](#) form and [IRB Form 2](#), when applicable, to submit amendments, with all required back-up documentation.

COMPLETED PROJECTS/DISPOSITION OF DATA

When projects are completed, investigators must submit the following documents:

1. A completed/signed, final [Request for Review](#) closing out the study.
2. Copies of reports, citations and/or articles developed from the research not previously submitted.
3. An original signed/notarized [Affidavit of Data Disposal](#).
4. A completed/signed, final [IRB Form 2](#) (when applicable).
5. A copy of the final project report (when applicable).

TERMINATION/FAILURE TO COMPLY

If the DHSS receives a credible report or evidence that unauthorized release of data or other breach of confidentiality has occurred, the Department will investigate whether such has occurred and whether the project should be suspended. Researchers are responsible for notifying any consumer whose confidential information the research team breaches. However, the researcher **MUST** also notify the DHSS if the researcher has a breach of confidentiality involving data that was provided to the researcher by DHSS.

The Department will require that all data and information provided by the DHSS to the principal investigator be destroyed if the DHSS determines one or more of the following have occurred:

- data have been released to unauthorized persons;
- the identity of a person, patient, physician, or provider has been revealed to a person not listed as research staff on the approved research protocol;
- data are being used in an unapproved manner.

Per 192.067(5), RSMo, “any department of health and senior services employee, public health authority or coinvestigator of a study who knowingly releases information which violates the provisions of this section shall be guilty of a class A misdemeanor and, upon conviction, shall be punished as provided by law.”

The attorney general shall have exclusive authority to bring an action to obtain actual damages for a willful and knowing violation of 407.1500(1), RSMo and may seek a civil penalty not to exceed one hundred fifty thousand dollars per breach of the security of the system or series of breaches of a similar nature that are discovered in a single investigation.

Failure to comply with the annual review or close out process could result in the immediate withdrawal of DHSS approval of the research study/project. In the event of DHSS withdraws approval, the Department will require that all data provided by the DHSS to the principal investigator be destroyed.

The Department reserves the right to deny the release of future DHSS data files to the Principal Investigator for other research studies for any breach of the terms of the protocol application, confidentiality requirements, and/or the failure to comply with the annual review or close out process.