Continuation and Completion of Project Requirements for Local Public Health Agency Applicants

Annual review is required for each approved project for as long as DHSS-provided data are held.

Annual Review Amendment	<u>Completion</u>	Termination
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REPORTING REQUIREMENTS

ANNUAL REVIEW

Approved applications/continuations for use of Missouri vital records and/or patient abstract system data are only valid for **one year** at a time, regardless of the duration of the project. A completed <u>Request for Review</u> and an <u>Agreement for Oversight</u> must be submitted to the Project Coordinator at least 20 calendar days **prior** to the current approval expiration date. The <u>Agreement for Oversight</u> requires both the requestor's signature and the LPHA Administrator's signature (must be two different LPHA staff). A reminder notice should be e-mailed to the LPHA Requestor prior to the current approval expiration date; however, **it is the responsibility of the LPHA Requestor to ensure that annual review materials are submitted on time whether or not a reminder is received.**

All approved projects will be reviewed annually as long as the request is ongoing and DHSS-provided data are retained. An annual review includes the following:

- 1. SUMMARY: Provide an overview/summary of all project activities <u>since</u> the last approval was granted. If you have not used the data provided, plans should be developed and reported addressing how you will overcome the barriers hindering progress.
- 2. SUPPORTING DOCUMENTS (when applicable): Copies of any presentations, reports, and/or articles not previously submitted for DHSS review.
- **3. MODIFICATION** (when applicable): An explanation of any proposed changes to the protocol or changes to the projected end date. (LPHAs may retain up to 10 rolling years of data at a time.)
- 4. PERSONNEL (when applicable): Report any new staff assigned to the project <u>since</u> the last approval was granted, who have access to DHSS-provided data. All new staff members sign a <u>Confidentiality Pledge</u> **prior** to being granted access to the data. It is the responsibility of the LPHA Requestor to ensure that all staff, including contractors, are aware of and adhere to the confidentiality and security procedures.

AMENDMENTS

Any changes to a project or personnel require the submission of an amendment request to the Project Coordinator. Proposed project changes must be reviewed and approved by the Department **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 possible after the changes have been made. Please use the <u>Request for Review</u> form to submit any amendments.

PROJECT COMPLETION/DISPOSITION OF DATA

When requests are completed and DHSS-provided data is no longer needed, the LPHA Requestor must submit the following documents:

- 1. A completed/signed, final <u>Request for Review</u> closing out the project.
- 2. Copies of any reports, citations and/or articles developed from the data not previously submitted.
- 3. An original signed/notarized <u>Affidavit of Data Disposal</u>.
- 4. If a contractor has been provided DHSS data, the contractor must also complete an <u>Affidavit of</u> <u>Data Disposal</u> at the conclusion of the contract work.

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. LPHAs are responsible for notifying any consumer whose confidential information the LPHA or contractor staff breaches. The LPHA <u>must</u> also notify the DHSS if the LPHA or contractor staff have a breach of confidentiality involving DHSS data.

The Department will require that all DHSS data be destroyed if the Department 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 on the approved application;
- 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. In the event of DHSS withdraws approval, the Department will require that all DHSS data be destroyed.

The Department reserves the right to deny the release of future DHSS data files to the LPHA for any breach of the terms of the application, agreement for oversight, confidentiality pledge, and/or the failure to comply with the annual review or close out process.