DHCF Data Request Institutional Review Board Approval and Privacy Board Guidance

If you are requesting personal health information (PHI) from DHCF for use on a proposed project, please be advised that DHCF has specific processes in place to safeguard the use of Medicaid beneficiaries' data.

The following information will be required by the agency before completing a data use agreement (DUA) with any external party. Requestors should anticipate and plan an appropriate timeline to complete all required elements of DHCF's standard DUA, including the need to demonstrate compliance with Institutional Review Board (IRB) or Privacy Board reviews, as relevant.

HIPAA Background

Without individual authorization, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Rule limits DHCF's use or disclosure of protected health information (PHI) for treatment, payment and healthcare operations (TPO) purposes only.

The use or disclosure of PHI for purposes *other than* TPO requires your organization to either:

1) obtain authorization from the individual or
2) provide DHCF documentation that a waiver was approved by an IRB. A waiver is a determination the organization has obtained from the IRB, whereby IRB has changed or waived informed consent requirement for obtaining authorization to use or disclose PHI.

An IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. A Privacy Board is a review body that may be established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. Where these boards coexist, the Privacy Rule requires approval of a waiver or an alteration of authorization by only one of them.

In some circumstances, IRB's and Privacy Boards are the same entity.

Privacy Requirements: Documentation Checklist

To demonstrate that your organization has met HIPAA privacy requirements, DHCF requires partners to obtain the following documentation from an IRB or Privacy Board and submit with your data request:

1. **IRB identification and date of action.** Please provide a statement identifying the IRB has reviewed your study, including the date your waiver was approved.
2. **Waiver criteria.** Please provide a statement from IRB indicating the waiver satisfies the following criteria:

    A. The use or disclosure of PHI involves minimal risk to the privacy of individuals based on the following:

i. An adequate plan to protect the identifiers from improper use and disclosure
ii. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and,
iii. Adequate written assurances that the PHI will not be re-used or disclosed except as required by law, for authorized oversight of the research study, or for other research as permitted under the HIPAA Privacy Rule.

B. The research could not practicably be conducted without the waiver; and,
C. The research could not practicably be conducted without access to and use of the protected health information.

3. **Requested protected health information needed.** Please provide a brief description of the protected health information that the IRB determined to be necessary.
4. **IRB review and approval procedures**. Please provide a statement confirming what procedures were used to review and approve the waiver.
5. **IRB required signature.** The documentation approved by IRB must be signed by the chair or designee.