



**COUNTY OF EL DORADO, CALIFORNIA
BOARD OF SUPERVISORS POLICY**

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BACKGROUND:

The Health Insurance Portability and Accountability Act (“HIPAA”) supplements Federal and State laws which specifies how human research can be conducted. This policy specifies how El Dorado County may use or disclose confidential information about individuals for research purposes as permitted by 45 CFR §164.508(b)(3)(i) and 45 CFR §164.512(i).

Note: HIPAA will not supercede any contrary State law that imposes more stringent privacy protections.

POLICY:

1. Research

Research refers to a systematic investigation including research development, testing, and evaluation [45 CFR § 164.501]. This policy supplements other federal or state laws such as the Common Rule [45 CFR Part 46] that may govern research protocol. The Common Rule (regulations requiring an Institutional Review Board (“IRB”) and approval of research studies using human subjects with federal funding) must be followed to the extent it governs El Dorado County.

- a. El Dorado County may use or disclose protected health information (“PHI”) for research purposes when:
 - i. A valid authorization is signed by an individual,
 - ii. A waiver of authorization has been approved by an Institutional Review Board (“IRB”) or by a Privacy Board,
 - iii. A review of PHI is conducted preparatory to research, subject to limitations,
 - iv. Research is conducted solely on decedent’s information, subject to limitations,
 - v. A limited data set agreement is approved {45 CFR § 164.514(e)},
 - vi. PHI is de-identified [45 CFR § 164.514(e)], or
 - vii. It is required by law [45 CFR §164.512(a)].
- b. El Dorado County may also conduct public health studies, studies that are required by law, and studies or analyses related to its health care operations.
- c. PHI disclosed for research purposes is subject to an accounting of disclosures.



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2. Individual Research Authorization

- a. El Dorado County may use and disclose protected health information for research purposes with a signed authorization from an individual.
 - i. The authorization must meet all the requirements as described in the policy “Use and Disclosure of Protected Health Information”.
 - ii. If the research includes treatment, the provider may condition the provision of research related treatment on the provision an authorization is obtained for use and disclosure for such research.

3. Authorization Waiver

- a. El Dorado County may use or disclose PHI for research without an authorization regardless of the source of funding, provided the covered entity obtains prior to using or disclosing PHI, documentation of an authorization waiver or alteration approved by either:
 - i. An Institutional Review Board established in accordance with federal regulations [45 CFR Part 46]; or
 - ii. A privacy board that:
 - A. Includes members with diverse backgrounds and the appropriate professional competency, necessary to review the effect of research protocols on an individual’s privacy rights and related interests.
 - B. Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person affiliated with any of these entities [45 CFR § 164.512 (i)1)(i)].
- b. The IRB or privacy board waiver approval must document the following:
 - i. The name of the board and the date of the approval.
 - ii. A statement that the IRB or privacy board has determined the alteration or waiver, in whole or in part, authorizes the use or disclosure of PHI, and involves minimal risk to the privacy of individuals with the following measures:
 - A. An adequate plan to protect the identifiers from improper use and disclosure;



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B. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;

C. An adequate written assurance the PHI will not be reused or disclosed to any other person or entity, except as, required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

iii. The research would not be feasible without the waiver of alteration; and

iv. The research would not be feasible without access to and use of PHI.

c. A brief description of the PHI deemed to be necessary by the IRB or privacy board to be used or disclosed.

d. A statement that the alteration or waiver of authorization has been reviewed and approved under normal or expedited procedures according to 45 CFR § 164.512 (i)(2)(iv).

e. The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

4. Research Preparation [45 CFR § 164.512(i)(1)(ii)]

In developing a research protocol or in preparation for research, a researcher may request access to individual confidential information. El Dorado County must determine if such use or disclosure is permitted by state or federal laws without patient authorization or approval from an IRB or privacy board. If access is granted, the researcher will provide written representation that:

a. The PHI is to prepare a research protocol or for similar purposes preparatory to research,

b. No PHI is to be removed from the covered entity by the researcher in the course of the study, and

c. The researcher agrees not to use or further disclose the information other than as provided in the written agreement, and to maintain appropriate safeguards to prevent the use or disclosure of the information.

5. Research with Decedent's PHI [45 CFR § (i)(1)(iii)]

In developing a research protocol or in preparation for research, a researcher may request access to confidential information of decedents. El Dorado County must determine if such use or disclosure is permitted by state or federal laws without a personal representative's authorization or approval from an



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IRB or privacy board. There may be instances where it would be inappropriate to disclose sensitive medical information. If access is granted, the researcher will provide written representation:

- a. The PHI is for research of decedents;
- b. If requested, documentation of the death of the decedent;
- c. The PHI is necessary for research purposes;
- d. The researcher agrees not to use or further disclose the information other than as provided in the written agreement, and to maintain appropriate safeguards to prevent the use or disclosure of the information.

6. Limited Data Set [45 CFR § 164.514(e)]

El Dorado County may use or disclose a limited data set if the covered entity enters into a data use agreement with the limited data set recipient as specified in the “De-identified Protected Health Information, Limited Data Sets, and Data Use Agreements Policy”.

7. De-identified PHI [45 CFR § 164.514]

El Dorado County may use PHI when certain identifiers are blocked or deleted as defined in the “De-identified Protected Health Information, Limited Data Sets, and Data Use Agreement Policy”.

8. Required by Law [45 CFR § 164.512(a)]

Use or disclosure of PHI is permitted when required by law.

9. Research and Accounting of Disclosures [45 CFR § 164.528 (b)(4)]

- a. If a research study consists of 50 or more individuals, the information provided in the accounting of disclosures may include:
 - i. The name of the protocol or research study;
 - ii. A description and purpose of the research activity;
 - iii. A brief description of the type of PHI that was disclosed;
 - iv. The date or period of time during which such disclosure occurred, or may have occurred, including the date of the last such disclosure during the accounting period;



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- v. The name, address, and telephone number of the entity that sponsored the research and the researcher to whom the information was disclosed;
 - vi. A statement that the PHI of the individual may or may not have been disclosed for particular protocol or other research activity.
- b. If it is reasonably likely that the PHI of the individual was disclosed for a research protocol or activity, El Dorado County will, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

Primary Department: Privacy Compliance Office

References: 45 CFR § 160 - 164