

MANAGEMENT MEMO

	NUMBER: MM 08-09
SUBJECT: REQUESTS FOR AND APPROVAL TO RELEASE PERSONAL INFORMATION FOR RESEARCH	DATE ISSUED: AUGUST 15, 2008 EXPIRES: UNTIL RESCINDED
REFERENCES: California Civil Code (CC) 1798.24(t) State Administrative Manual (SAM) sections 5300 through 5399 45 Code of Federal Regulations (C.F.R) 164.512(i) CalOHI Policy Memorandum 2003-28 – Exhibit 4: Chapter 17-Research	ISSUING AGENCY: Office of Information Security and Privacy Protection

Background and Purpose:

California state agencies often receive requests from academic researchers to use personal information about individuals held in governmental data bases. Such disclosures are specifically limited by California law as discussed below. The knowledge generated by these researchers can be of great value for informing the public and government about the impact of policies, programs, and treatment interventions. However, personal information about Californians, regardless of media type (such as electronic, paper, or verbal), must be guarded and protected from misuse, loss and theft. For example, in recent incidents state agencies have provided individuals' personal information to academic researchers, and that information was subsequently compromised by unauthorized electronic access and by theft of storage devices.

The purposes of this Management Memo are, (1) to emphasize the importance of adequately protecting personal information released for research purposes, and (2) to inform state agencies of recent changes in the Information Practices Act (IPA) that require all planned releases of personal information to the University of California (UC), or to a non-profit educational institution conducting scientific research, to be reviewed and approved by the Committee for the Protection of Human Subjects (CPHS) of the California Health and Human Services Agency (CHHSA). Pursuant to Civil Code (CC) Section 1798.24(t), the CPHS is the Institutional Review Board (IRB) of the CHHS.

Policy:

Subdivision (t) of CC section 1798.24 mandates a detailed protocol be followed before an agency may release any personal information for scientific research to UC or other non-profit educational institutions. Due to the specificity and intricacy of that law and in order to avoid misunderstanding or confusion, the relevant provisions of section 1798.24 are copied below:

CC section 1798.24: "No agency may disclose any personal information in a manner that would link the information disclosed to the individual to whom it pertains unless the information is disclosed"

CC section 1798.24(t):

"(1) To the University of California or a nonprofit educational institution conducting scientific research, provided the request for information is approved by the Committee for the Protection of Human Subjects (CPHS) for the California Health and Human Services Agency (CHHSA). The CPHS approval required under this subdivision shall include a review and determination that all the following criteria have been satisfied:

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Policy (Cont.):

(A) The researcher has provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

(B) The researcher has provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project, unless the researcher has demonstrated an ongoing need for the personal information for the research project and has provided a long-term plan sufficient to protect the confidentiality of that information.

(C) The researcher has provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project.

(2) The CPHS shall, at a minimum, accomplish all of the following as part of its review and approval of the research project for the purpose of protecting personal information held in agency databases:

(A) Determine whether the requested personal information is needed to conduct the research.

(B) Permit access to personal information only if it is needed for the research project.

(C) Permit access only to the minimum necessary personal information needed for the research project.

(D) Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.

(E) If feasible, and if cost, time, and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher to minimize the release of personal information.

(3) Reasonable costs to the agency associated with the agency's process of protecting personal information under the conditions of CPHS approval may be billed to the researcher, including, but not limited to, the agency's costs for conducting a portion of the data processing for the researcher, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes.

(4) The CPHS may enter into written agreements to enable other institutional review boards to provide the data security approvals required by this subdivision, provided the data security requirements set forth in this subdivision are satisfied... .”

Personal information is defined in the IPA as, “...any information that is maintained by an agency that identifies or describes an individual, including, but not limited to...medical or employment history. It includes statements made by, or attributed to, the individual.” [CC § 1798.3(a)]

CPHS, in general, will be guided by the principles related to information security and integrity as set forth in SAM sections 5300 through 5399. State agencies releasing identifiable data for research are still required to determine that such releases are permitted by other state and federal legal requirements. The

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Policy (Cont.): CPHS may require letters from departments stating this. See instructions on the CPHS website (see Contact Information below).

In addition, agencies that are covered entities under the Health Insurance Portability and Accountability Act (HIPAA) must also comply with HIPAA standards and requirements. The HIPAA standards and requirements for handling Personal Health Information (PHI) for research purposes are discussed in California Office of HIPAA Implementation's Policy Memorandum 2003-28 – Exhibit 4: Chapter 17 – Research. As an institutional review board constituted under 45 CFR Part 46, CPHS may grant waivers of patient authorization under HIPAA. See instructions on the CPHS website (see Contact Information below).

Roles and Responsibilities:

Before releasing personal information in any format or medium, Agency Secretaries and Department Directors will ensure that program staff are knowledgeable about, and in compliance with appropriate requirements of the:

- IPA regarding approval from the CPHS; and
- SAM Sections 5300 through 5399, including the requirement for data use agreements in Section 5310.

In addition, Agency Secretaries and Department Directors of State HIPAA covered-entities will also ensure that program staff are knowledgeable about and in compliance with requirements of HIPAA for handling PHI for research purposes.

Implementation, Next Steps, and Contact Information:

The Office of Information Security and Privacy Protection will ensure changes to SAM section 5320.5(2)(d) are forthcoming.

The CPHS maintains a website with detailed information about how researchers may apply for approval for the use of personal information held by state agencies (www.oshpd.ca.gov/boards/cphs). Questions may be directed to the Administrator of CPHS by calling 916-326-3660 or e-mailing cphs-mail@oshpd.ca.gov.

Original SAM Management Memo signed by Michael Saragosa (Undersecretary) for Rosario Marin, Secretary State and Consumer Services Agency

SIGNATURE:

Rosario Marin, Secretary
State and Consumer Services Agency
