



## Guidance: Decedent Research (updated February 23, 2021)

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## History & Overview

Federal human research protection regulations govern the use of *living* humans or identifiable data about *living* humans in research. However, as State of California regulations protect health information of the *deceased* and *death* data files, University of California policy requires campus IRBs to review research involving death data files and medical records under certain circumstances.

This guidance explains when IRB review is required for research involving decedent medical records and death data files.

## California Death Data Files

California law requires IRB approval for any research using individually identifiable information from death data files held by the State Registrar, local registrars, and county recorders (i.e., state issued death certificates and indices). This law is more restrictive than federal human research protection regulations.

UCLA researchers wishing to obtain state death data files containing personal identifying information should:

- Submit an application to the UCLA OHRPP/IRB for review and
- Obtain approval from the California Department of Public Health Vital Statistics Advisory Committee (VSAC) and the California Health and Human Services Agency's Committee for the Protection of Human Subjects (CPHS).

**IMPORTANT NOTE:** Research analysis of individually identifiable information from California death data files requires UCLA IRB approval *prior* to UCLA investigators' access to and/or provision of the data.

## CDC National Death Index (NDI)

The [CDC National Death Index \(NDI\)](#) is a database of all the deaths in the United States. NDI is available to investigators solely for statistical purposes in public health and medical studies. In order to obtain this information, an application must be submitted to NDI and you must provide an IRB approval letter. Follow the instructions above in order to obtain IRB approval from UCLA.

## Decedent Medical Records

The health information of deceased individuals is protected under federal and state regulations. Whether review by the UCLA IRB is required is determined by whether the research will involve access to the protected health information (PHI) associated with the data.

**Records with no PHI:** If the decedent study will not have direct access to PHI, IRB review and approval is not required because the deceased individuals cannot be identified.

**Example:** Researchers receive only de-identified data from medical records. In this case, although the information comes from the medical record, the research team does not have access to the PHI in the medical record. Therefore, no OHRPP/IRB review or approval is required.

**NOTE:** While IRB approval is not required, please contact the [UCLA Office of Compliance Services](#) for a determination that HIPAA authorization is not required according to the criteria in 45 CFR 164.512.

**Records with PHI:** Decedent research that will involve direct access to UCLA medical records or PHI, even if identifiers will not be recorded, must be submitted for IRB review and approval.

**Example:** Researchers plan to review UCLA medical records of deceased individuals to verify biological specimen data. Even if PHI will not be recorded, the investigators will need to obtain IRB review and approval.

## Privacy Board Requirements for Decedent Research

The HIPAA Privacy Rule protects the individually identifiable health information about a decedent for 50 years following the date of death of the individual. During the 50-year period of protection, the personal representative of the decedent (i.e., the person under applicable law with authority to act on behalf of the decedent or the decedent's estate) has the ability to exercise the rights under the Privacy Rule with regard to the decedent's health information, such as authorizing certain uses and disclosures of, and gaining access to, the information.

Privacy Board Requirements for Decedent Research			
Access to or Use of UCLA Medical Records	Use of PHI from State Death Data Files	HIPAA Authorization	IRB Review
NO	NO	None	None
NO	YES	None	Expedited
YES	Either YES or NO	Waiver	Expedited

HIPAA Authorization is not required for research on decedent's information provided that the covered entity obtains from the researcher:

- a) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;
- b) Documentation, at the request of the covered entity, of the death of such individuals; and
- c) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

Researchers planning to use decedent health information from outside UCLA/UC should follow the requirements of the institution(s) holding those records.

## References and Regulations

[California Health & Safety Code Section 102175-102249](#)

UCLA-OHRPP guidance: [Determining When Use of Data and Specimens Requires IRB Review](#)

UCLA OHRPP guidance: [HIPAA](#)

[CDC National Death Index](#)

HHS Standards for Privacy of Individually Identifiable Health Information - [Section 164.512](#)

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Change history:

02/23/2021: Added information re: CDC NDI, HIPAA authorization not required, and updated links.