

**Purpose:** This document provides additional information on why UCI does not use exempt category 4(iii).\*

## I. Background

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) required the creation of regulations for the protection of health information. The Privacy Rule also affects the use and disclosure of certain health information in connection with research. The law permits organizations like universities to identify themselves as “hybrid covered entities” consisting of defined covered and non-covered components; it also permits hybrid covered entities to exclude from their covered components certain non-covered functions, including research.

The University of California is a hybrid entity with a Single Health Care Component (SHCC) that performs multiple functions covered by HIPAA. [UC’s Administrative Policy on HIPAA](#) sets forth the portions of UC that are part of the Covered Component, and research is not a covered function under the HIPAA Privacy Rule. This means that UC’s employees and workforce members, when acting in their capacity as researchers, are not considered a part of the SHCC.

## II. Definitions

**Covered Entity:** A health plan, a health care clearinghouse, or a health care provider who transmits any Health Information in electronic form in connection with a transaction. [45 C.F.R. § 160.103.] Covered Entities are subject to HIPAA.

**Disclosure:** The release, transfer, provision of access to, or divulging in any manner of individual identifiable health information outside the Covered Entity that maintains such information. [45 C.F.R. § 160.103.]

**Hybrid Entity:** A single legal entity that is a Covered Entity whose business activities include both health care and non-health care functions. An entity must designate itself as a “hybrid entity” and identify its health care components that comprise the Covered Entity. (45 C.F.R. § 164.103.) UC has designated itself as a Hybrid Entity, identifying health care at its medical facilities as part of its healthcare component, yet excluding education and research from its healthcare component.

**Use:** The sharing, employment, application, utilization, examination, or analysis of individually identifiable health information within an entity that maintains such information. [45 CFR § 160.103]

## III. Exempt Research – Category 4(iii):

Exempt category 4(iii) lists the following as an exempt category: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- iii. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that **Use** is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care

operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); [emphasis added]

The exempt 4(iii) exemption does not apply to activities outside of the Covered Entity’s **Use** of the PHI. Research is not part of UC’s Covered Entity. This means that once PHI is **Disclosed** by the SHCC to the researcher under either a signed authorization or a waiver of authorization, any research use of the identifiable private information is no longer protected under the Privacy Rule, and further use or disclosure of this data would only be governed by the signed authorization or terms of the waiver of authorization. Therefore, under these circumstances, the exempt 4(iii) category cannot be utilized by UC.

#### **IV. Allowable Uses of the Exempt Category 4(iii)**

In some circumstances, IRBs may receive protocols that would be considered exempt under category 4(iii) but for the fact that UC is a Hybrid Entity. The University applies commensurate protections for research that is not subject to the Common Rule. Therefore, for protocols that are not funded or supported by a federal agency that has adopted the Common Rule, this exemption category may be used.

In addition, when UC serves as the IRB of Record for an institution that maintains research as part of the covered component, the exempt category 4(iii) may be applied for those particular protocols in which the research use of identifiable health information will be maintained at the other institution.

#### **V. Use of UCI**

**To avoid the need to continue to verify research type of funding for exemptions under 4iii, UCI has elected to not use exempt 4iii effective early Fall 2020.**