

August 6, 2020

To: Human Research Protection Program Directors

Subject: The Common Rule's exempt category 4(iii) and UC's Hybrid Entity status

Purpose

This guidance memo explains when it is appropriate to use the Common Rule's exempt category 4(iii) given UC's Hybrid Entity status.

Background

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") required the creation of regulations for the protection of health information. These regulations, commonly referred to as the "Privacy Rule", became effective in 2003 and are codified in 45 CFR [Part 160](#), and Subparts A and E of [Part 164](#). While the main impact of the Privacy Rule is on uses and disclosures of, and the provision of individual rights with respect to, health information obtained in the provision of clinical health care services, 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.

Definitions

- **Common Rule.** The Federal Policy for the Protection of Human Subjects as adopted by (and codified in the regulations of) multiple federal agencies. For the purposes of this guidance and related policy guidance or procedure documents, the Common Rule refers to Subpart A of Department of Health and Human Services (HHS) regulations at Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46, Subpart A).

- **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 CFR 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 CFR 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 CFR 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).
- **Transaction.** The transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions (45 CFR 60.103):
 1. Health care claims or equivalent encounter information.
 2. Health care payment and remittance advice.
 3. Coordination of benefits.
 4. Health care claim status.
 5. Enrollment and disenrollment in a health plan.
 6. Eligibility for a health plan.
 7. Health plan premium payments.
 8. Referral certification and authorization.
 9. First report of injury.
 10. Health claims attachments.
 11. Health care electronic funds transfers (EFT) and remittance advice
 12. Other transactions that the DHHS Secretary may prescribe by regulation.

Refer to the [UC HIPAA Glossary](#) and the [IS-3 policy](#) for other definitions.

Guidance

Common Rule Exempt 4(iii) Category

Effective January 21, 2019, the [Revised Common Rule](#) (“2018 Rule”) includes eight exempt categories, outlined at 45 CFR 46.104(d). Research activities in which the only involvement of human subjects falls within one or more of the categories outlined at Section 46.104(d) may qualify for exemption from review by the IRB.

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.

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 such cases, the IRB should conduct a limited review as described in §___.111(a)7 to ensure that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of the data. This review will lessen administrative burden for researchers and IRBs while providing commensurate protections for the subjects and their data.

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.

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