May 8, 2024

To: CalHHS Committee for Protection of Human Subjects

From: CalHHS Legal

Re: CPHS Application of Federal Common Rule

Questions Presented

Does the federal common rule apply (or can it apply) to all Committee for Protection of Human Subjects (CPHS) review decisions? Or are there are some CPHS decisions that are limited to review under the state Information Practices Act (IPA)?

Short Answers

The federal common rule does not apply to all CPHS review decisions. CPHS is required to use the common rule only where it is asked to review a research project that the Health and Human Services Agency (CalHHS) is engaged in, that involves human subjects as defined in federal regulations, and that is not exempt. In some instances—as explored below—review under the IPA *and* the common rule will be required, and in other instances, review will only be required under the IPA. However, even if the IPA is the only required standard of review, CPHS has the discretion to apply other criteria while conducting its review on a case-by-case basis, which may include factors from the common rule. Should CPHS opt to adopt this approach, we recommend that CPHS promulgate regulations to establish when and how this discretion may be utilized to avoid the appearance of inconsistent or discriminatory use. Should CPHS adopt standards of general application concerning application of common rule or other factors, formal regulation promulgation is necessary.

I. Background

When CPHS was established in 1976, its role was limited to reviewing human subject research under the federal common rule that governs institutional review boards (IRBs), to ensure that the research was conducted ethically.[1] In 2006, the IPA was amended to require CPHS review and approval before personal information held by any state agency or department can be released for research purposes. These changes resulted in CPHS having two roles: (1) reviewing CalHHS departmental projects involving human subject research, governed by the federal common rule, and (2) reviewing all requests for state data for research, governed by the IPA.

[1] Letter from CPHS Chairs to the Secretary seeking approval of updated CPHS Policies and Procedures (July 6, 2023).

CPHS's policies and procedures document was updated in July 2023 to outline CPHS's structure and duties, including delineating when a project was limited to an IPA only review. But as made clear in recent CPHS meetings, questions remain as to (1) when each standard applies, and (2) if CPHS has the discretion to impose the stricter common rule even when the research is such that it would be governed by the IPA.

II. CPHS Policies and Procedures

The July 2023 CPHS policies and procedures, states that CPHS has jurisdiction as an IRB to review research projects that involve human subject contact. It states that for data-only projects, CPHS's review is "limited to" IPA review.

> *Data Only Projects: CPHS has jurisdiction to review all research projects that involve state data. The scope of CPHS' review **is limited to** the criteria listed in Civil Code section 1798.24(t).* [emphasis added]
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> *Human Subjects Projects: CPHS has jurisdiction as an IRB to review research projects conducted by or funded by (regardless of original source) the CalHHS and its 13 component departments (see below) that involve human subject contact. Jurisdiction also includes all research involving subjects for whom the CalHHS or its components have direct responsibility, such as patients in state hospitals. CPHS also has jurisdiction to choose to review projects as an IRB for other public entities, such as a public university, as well as entities that do not have their own IRB, such as a county. CPHS has authority to review projects as an IRB when the CPHS has a contract with another IRB authorizing the review consistent with the federal Common Rule.*
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> *Combined Human Subjects and Data Projects: CPHS has jurisdiction to review the portion of the project that involves state data **only using** the Civil Code criteria specified in section 1798.24(t) of the Civil Code and the portion of projects that involve human subject contact using the criteria in the federal Common Rule.* [emphasis added]

III. Communications between CPHS member and federal HHS pre-March 1 meeting

OHRP has been contacted by at least one CPHS member who was seeking clarification on the application of the common rule, and whether CPHS should apply the common rule to IPA-governed projects.

In response, OHRP expressed that it is not uncommon for review committees to apply different standards based on different types of research subjects, and stated that if the definition of human subject is not satisfied, no IRB review and approval will be needed and the common rule requirements do not apply. It does not appear that OHRP

provided formal guidance on discretionary use of the common rule when application of the rule is not required.[2]

V. Federal Common Rule

a. Relevant Regulations

The Common Rule is codified in 45 CFR 46 Subpart A: "Basic HHS Policy for Protection of Human Research Subjects."

45 CFR 46.101(a). "Except as detailed in § 46.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the policy applicable to such research. [...] Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy."

45 CFR 46.102(e)(1) defines "human subject" as "a living individual about whom an investigator (whether professional or student) conducting research:

> (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
>
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Under 45 CFR 46.101(a), the common rule requires IRB review only when the institution is *engaged* in research. If an institution is solely *releasing* information that falls under the "human subjects" definition, rather than *engaging* in that research, the releasing institution is not required to review and approve the research under the common rule.[3] In general, an institution is considered engaged in human subjects research when its employees or agents for the purposes of the research project obtain: "(1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research."[4]

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[2] See email correspondence between CPHS board member and OHRP dated November 12, 2023 through February 27, 2024.
[3] OHRP issued guidance in 2008 clarifying that the common rule applies when an institution is "*engaged* in non-exempt human subjects research that is conducted or supported by HHS[.]" (emphasis in original).
[4] See id. at Section III.

Notably, an institution operating a data center is not considered by OHRP to be engaged in human subjects research when assisting researchers, even if the services provided by the institution through the data center are not typically performed by the institution for non-research purposes.[5] The IRB of the institution *engaging* in non-exempt human subjects research is required to apply the common rule, rather than the IRB of institution operating the data center, who is not considered engaging in the research under OHRP guidance.[6]

b. CalHHS FWA

CalHHS has entered into a Federal-wide Assurance (FWA) for the Protection of Human Subjects (FWA00000681). All institutions engaged in non-exempt human subjects research conducted or supported by the federal government must submit an FWA to be approved by OHRP, committing under the FWA that it will comply with the common rule.[7]

While all institutions that submit an FWA are agreeing to comply with the common rule when the human subjects research they are engaging in is conducted or supported (*e.g.*, funded)[8] by a federal department or agency, it is optional for institutions to voluntarily agree to extend their compliance with the common rule beyond research conducted or supported by the federal government. CalHHS has agreed to this optional requirement, electing to apply the common rule to all of the human subjects research it engages in regardless of whether the source of support for the research came from a federal department/agency or elsewhere, unless the research is covered by a separate assurance.[9] OHRP has issued guidance that the terms of an FWA apply only when the institution (here, CalHHS) is "engaged" in the human subjects research,[10] as discussed above.

Because CalHHS has selected this optional requirement in its FWA, CPHS does not need to take into consideration the source of support for the research when determining whether the common rule applies to its review.

c. *Common rule application*

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[5] OHRP issued further guidance in 2011 to clarify the role of data centers.
[6] *Id.*, 45 CFR 46.101(a).
[7] See OHRP guidance re: FWAs.
[8] OHRP has clarified that "federally-supported" refers to the U.S. Government providing any funding or other support.
[9] See FWA00000681, Section 4(b).
[10] See OHRP guidance re: FWAs.

Taking into account the above, the following questions should be asked to determine if the common rule applies:

- Did the State *engage* in research?
- Does the research meet the definition of human subject at 45 CFR 46.102(e)(1)?
- Is the research conducted, supported by, or otherwise subject to regulation by any federal department or agency, or did the State agree via an FWA to utilize the common rule to all of the human subjects research it engages in? (for CalHHS, the answer is yes).

If the answer to all of the above questions is yes, then ask: does the activity meet the criteria for one or more of the regulatory exemptions at 45 CFR 46.104[11]? If the research does not qualify for an exemption, the common rule is the standard of review.

Examples:[12]

- The common rule **does** apply where CalHHS receives a grant award from federal HHS to conduct research, and the research involves conducting interviews and administering questionnaires.
- The common rule **does** apply where CalHHS funds its own research, and its employees obtain informed consent of human subjects for the research.
- The common rule **does** apply where CalHHS employees obtain identifiable information from a research institution, to be used for research CalHHS is conducting.
- The common rule **does not** apply where CalHHS releases to researchers at another institution identifiable private information or identifiable biological specimens.

VI. Information Practices Act

a. Relevant Statute

The Information Practices Act[13] provides limits on the collection, management, and dissemination of personal information by state agencies. Under Section 1798.24, an agency "shall not 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 in certain, enumerated ways. Under subsection (t)(1), personal information

[11] See 45 CFR 46.104.
[12] See OHRP guidance (2008). In each of these examples, it is assumed that the research is not exempt under 45 CFR 46.104.
[13] Cal. Civ. Code Section 1798 et seq.

may be disclosed "if the request for information is approved by the Committee for the Protection of Human Subjects (CPHS) for the California Health and Human Services Agency." CPHS's review under the IPA is generally focused on approving data privacy and security measures, such as ensuring that there are sufficient safeguards to protect personal information from security threats, and that the researcher provides a sufficient plan to protect the information from improper use and will destroy or return all information when it is no longer needed. [14] Subsection (t)(1) specifies that CPHS's approval "shall include" a review and determination that the criteria listed in the statute have been satisfied.

Subsection (t)(3) adds additional criteria for CPHS to review and approve, if the personal information in question is held in "agency databases." The subsection specifies that CPHS shall, "at a minimum," accomplish a list of review and approval criteria for the research project for the purpose of protecting personal information stored in agency databases, such as determining whether the information is needed to conduct the research, and permitting access to the information only to the extent necessary.

If a researcher requests the disclosure of personal information held by CalHHS, CPHS must apply the IPA standard of review to determine if the information may properly be disclosed. If the information being requested is held in a CalHHS database, CPHS must look at additional criteria before making that determination. It is possible for both the common rule and IPA to apply to certain requests.

VII. CDII Regulatory Authority

CDII has statutory authority to adopt regulations to implement Division 109 of the Health and Safety Code, which establishes CDII and its duties, including the administration of CPHS.[15] Before adopting regulations, the statute requires CDII to adopt certain standards, such as posting the proposed regulation online at least 45 days prior to adoption, and accepting public comment for at least 30 days.[16] CDII is exempt from certain requirements of the Administrative Procedure Act when adopting regulations, until June 30, 2024.[17]

VIII. Administrative Procedure Act

[14] See Section 1798.24(t)(1)(A)-(C); see also Section 1798.1 (declarations and findings regarding individuals' privacy rights).
[15] See Health and Safety Code sections 130205, 130210.
[16] Health & Safety Code section 130210.
[17] Id.

The Administrative Procedure Act (APA)[18] establishes formal rulemaking procedures and standards for state agencies in California. It provides for the public to meaningfully participate in the rulemaking process, by generally requiring a state agency to provide a 45-day public notice and written comment period, followed by a public hearing, before promulgating a regulation.[19] The APA also requires that documents and information on which the rulemaking action is based are available for review and inspection, and provides for review of proposed regulations by the Office of Administrative Law (OAL).[20]

With some exemptions, state agencies are required to follow the procedures laid out in the APA when adopting regulations. A regulation is defined in the APA as a "rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure."[21]

a. *Underground Regulations*

The California Code of Regulations defines "underground regulation" as "any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, including a rule governing a state agency procedure, that is a regulation … but has not been adopted as a regulation and filed with the Secretary of State pursuant to the APA and is not subject to an express statutory exemption from adoption pursuant to the APA."[22]

If a state agency enforces, or attempts to enforce, a guideline, rule or standard of general application without following the APA procedures when it is required to do so, the rule is considered an "underground regulation" and is legally unenforceable. Individuals can challenge alleged underground regulations by filing a petition with the OAL.[23]

VIII. Conclusions

Based on the authority explained above, if CPHS is asked to review a request for the disclosure of personal information by the State for a research project, it must comply with the IPA when conducting its review. If CPHS is asked to review a research project

[18] The APA is codified in Gov. Code section 11340, et seq.
[19] See Gov. Code section 11346.4.
[20] Gov. Code sections 11340.1, 11340.4.
[21] Gov. Code section 11342.600.
[22] 1 CCR Section 250(a)(1); see also Gov. Code section 11340.5.
[23] See https://oal.ca.gov/underground_regulations/

that CalHHS is engaged in, that involves human subjects per the regulatory definition and is not exempt, and the research involves the disclosure of personal information by the State, CPHS must use the common rule standards and the IPA to review the project.

If CPHS determines that the IPA standard of review applies, and that review under the common rule is not *required,* but CPHS would like to apply certain criteria from the common rule (or elsewhere) as well, it appears that CPHS may do so. The language of the IPA specifies that the IPA review "shall include" certain factors, but it does not state that those are the *only* factors that can be taken into consideration.[24] We recommend that any additional factors applied during IPA review, from the common rule or otherwise, be aligned with the purpose and intent of the IPA and consistent with CPHS's role under the IPA, which is focused on data privacy and security.

We further recommend that any application of additional criteria, on a discretionary basis, be based on the specific facts and circumstances of the individual project justifying the application of the additional criteria. If CPHS anticipates that it will choose to apply common rule or other additional criteria, we recommend that CPHS first promulgate regulations to establish how and when these factors will be applied, to avoid the appearance of CPHS utilizing additional criteria on an inconsistent or discriminatory basis.

Should the board wish to adopt any generally applicable policies, rules or standards concerning the application of additional factors such as the common rule, formal regulation promulgation is necessary.

[24] The "presumption of nonexclusive 'include'" holds that the word "include" does not ordinarily introduce an exhaustive list. *See United States v. Herrera*, 974 F.3d 1040, 1048 (9th Cir. 2020) (citing to Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 132 (2012)).