Frequently Asked Question: California State Law Applicability for Separation of HIPAA Authorization for Research and Informed Consent Document
Date: May 9, 2022

The Office of Research and Development (ORD) and Office of General Counsel, Specialty Team Advising Research (OGC STAR), are providing the following guidance on the following query:

Question: Must VA separate the written IRB-approved consent and written HIPAA authorization for research language into separate documents, the latter of which required to be in at least 14-point font, for purposes of VA research conducted at VA sites in California?

Response: No. For this limited purpose, VA is not required to adhere to the California Confidentiality of Medical Information Act (CMIA; Cal. Civ. Code §§ 56 *et seq*.). The CMIA requires that an authorization for release of medical information be clearly separate from any other language present on the same page and executed by a signature which serves no other purpose than to execute the authorization. Additionally, this same California statute requires the written authorization language to be in a typeface no smaller than 14-point type.

As background to the above response, federal laws apply at VA facilities. Consequently, VA looks to federal law to determine whether there is a basis to apply state law. VA, as a federal department, adopted the Federal Policy for the Protection of Human Subjects, also referred to as the "Common Rule", in 38 C.F.R. Part 16. Within the Common Rule, 38 C.F.R. § 16.101(f) reads:

> *This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.*

This citation within the Common Rule provides a basis for VA to follow state laws that are otherwise applicable *and* provide additional protections for human subjects.[1] In the past, VA has interpreted implicated law and deferred to the CMIA by implementing a process that separated the written authorization from the IRB-approved informed consent form for research. VA has re-evaluated this policy.

Through this guidance to the VA community conducting research at VA sites (including in the state of California) and to related stakeholders, VA permits research with written authorization for the use and disclosure of protected health information (PHI), in accordance with the Health Information Portability and Accountability Act (HIPAA)[2], either via one or more signatures on a combined authorization and informed consent form[3] or via a standalone authorization form distinct from the informed consent document, in conformance with applicable VHA privacy requirements.[4] In addition, VA reinforces in this guidance that the written HIPAA authorization language for VA research at VA sites is not required to be in at least a size 14 font.

Implication: No action is required for ongoing VA research. For VA research initiated at VA sites upon or after this guidance, VA shall have the flexibility to obtain written authorization, as applicable, by the means and as described in the paragraph immediately above.

Please send questions regarding this guidance to VHACOORDREGULATORY@VA.GOV.

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[1] Note that 38 C.F.R. § 16.116(i) contains an express preemption clause related to informed consent requirements that does not alter the conclusions expressed herein, notwithstanding that an authorization may be embedded within an informed consent form, because the CMIA does not require *additional information* to be disclosed for *informed consent* to be legally effective.

[2] Rather than application of the Common Rule or the CMIA, HIPAA specifically governs authorization for the use and disclosure of PHI at government facilities, including in the context of research. Moreover, no provision within HIPAA requires application of the CMIA to an authorization obtained for VA research at VA sites because HIPAA is not "contrary" to the CMIA in this circumstance. *See* 45 C.F.R. § 160.202.

[3] This guidance in no way alters the requirements for various signatures necessary to document informed consent in any particular research study (e.g., person obtaining consent, legally authorized representative, witness, etc.).

[4] *See generally* VHA Directive 1200.05(2) (23)(a).