

## What's New in GCP? HIPAA Changes Respond to Research Concerns

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The Department of Health and Human Services (HHS) tackled concerns researchers have had with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in proposed revisions to the regulations prompted by the Health Information Technology for Economic and Clinical Health (HITECH) Act.

"The big ticket was the HITECH provisions dealing with business associates and the Security Rule," Christina Heide, with the HHS Office for Civil Rights, told the Secretary's Advisory Committee on Human Research Protections (SACHRP) July 21, adding the revisions "did address some research issues."

### Change Allows 'Compound Authorization'

The key change was allowing "compound authorization," in which a researcher can obtain HIPAA authorization for a research project that includes a clinical trial and the collection of specimens and/or information for future research, such as material for a specimen bank.

"This limitation on certain compound authorizations was intended to help ensure that individuals understand that they may decline the activity described in the unconditioned authorization yet still receive treatment or other benefits or services by agreeing to the conditioned authorization," the department's explanation of the proposed rules said.

"The impact of these authorization requirements and limitations can be seen during clinical trials that are associated with a corollary research activity," the agency said. "We believe that the proposed provision would reduce burden on the research community by eliminating the need for multiple forms for research studies involving both a clinical trial and a related research repository or study."

Presently, 45 C.F.R §164.508(b)(3)(iii) prevents covered entities from obtaining a single authorization for the use or disclosure of protected health information for a research study that includes both treatment as part of a clinical trial and tissue banking of specimens (and associated protected health information) collected, since a research-related treatment authorization generally is conditioned and a tissue banking authorization generally is not conditioned. "Various groups, including researchers and professional organizations, have expressed concern at this lack of integration," HHS said, noting both SACHRP in 2004 and an Institute of Medicine panel in 2009 recommended combined authorizations for clinical trials and biospecimen storage.

"Research-related treatment offered through a clinical trial is nearly always conditioned upon signing the informed consent to participate in the trial and the authorization to use or disclose the individual's protected health information for the trial. Thus, covered entities must obtain separate authorizations from research participants for a clinical trial that also collects specimens with associated protected health information for a central repository," the agency said. "For clinical research trials that may have thousands of participants, documenting and storing twice as many authorizations is a major concern. There is also a

concern that multiple forms may be confusing for research subjects," the HHS explanation said.

### **HHS Cites HIPAA Effect on Recruitment**

The department noted reports of trial recruitment being slowed "because the multiplicity of forms for research studies dissuades individuals from participating in research. We have also heard that redundant information provided by two authorization forms (one for the clinical study and another for related research) diverts an individual's attention from other content that describes how and why the personal health information may be used."

The department noted that although seeking an institutional review board (IRB) or privacy board waiver of the authorization requirement is an option, they are "less likely to approve a request for a waiver of authorization for a foreseeable use or disclosure of protected health information to create and maintain or contribute to a central tissue or information repository if the covered entity is planning to seek informed consent from the individual for this purpose. Accordingly, the waiver provisions generally do not resolve concerns expressed by the research community," HHS said.

The department agreed that combined research authorizations "would streamline the process for obtaining an individual's authorization for research and would make the documentation responsibilities of these covered entities more manageable. Such a modification would also result in an authorization that would be simpler and, therefore, more meaningful to the individual."

The proposed regulation allows for the combination of conditioned and unconditioned authorizations for research, "provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities."

The notice added that "while the proposed modifications do not alter the core elements or required statements integral to a valid authorization, covered entities would have some flexibility with respect to how they met the authorization requirements."

The notice said covered entities could aid an individual's understanding of a compound authorization by describing the unconditioned research activity on a separate page of the compound authorization. They also could cross reference relevant sections of the compound authorization to minimize the potential for redundant language. There also could be a separate check box for the unconditioned research activity to signify whether an individual has opted in to the unconditioned research activity, while maintaining one signature line for the authorization.

Or the compound authorization could have a "distinct signature line for the unconditioned authorization to signal that the individual is authorizing optional research that will not affect research-related treatment."

### **How to Differentiate Research Activities**

HHS wants to know if there are other ways to clearly differentiate to the individual the conditioned and unconditioned research activities on the compound authorization.

The proposed regulations also examined the question of authorizing future research use or disclosure.

HHS has interpreted the Privacy Rule to require that authorizations for research be study specific and that an authorization must include a description of each purpose of the requested use or disclosure. "In part, the department's interpretation was based on a

concern that patients could lack necessary information in the authorization to make an informed decision about the future research, due to a lack of information about the future research at the time the authorization was obtained.”

HHS added that not all uses and disclosures of protected health information for future research would require a covered entity to re-contact the individual to obtain another authorization through a waiver of authorization from an IRB or privacy board or the use or disclosure of a limited data set.

“The department has heard concerns from covered entities and researchers that the department’s interpretation encumbers secondary research and limits an individual’s ability to agree to the use or disclosure of their protected health information for future research without having to be re-contacted to sign multiple authorization forms.”

In addition, the interpretation “appeared to diverge from the current practice under the Common Rule with respect to the ability of a researcher to seek subjects’ consent to future research, so long as the future research uses are described in sufficient detail to allow an informed consent,” the notice said. HHS again noted that SACHRP and the IOM panel “have urged the department to allow the HIPAA authorization to permit future research use and disclosure of protected health information or, at a minimum, for the department to modify its interpretation to allow the authorization to encompass certain future use and disclosure of protected health information for research, provided certain parameters are met.”

HHS is considering whether to modify its interpretation to:

- permit an authorization for uses and disclosures of protected health information for future research purposes to the extent that such purposes are adequately described in the authorization and such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research;
- permit an authorization for future research only to the extent the description of the future research included certain elements or statements specified by the Privacy Rule, and if so, what should those elements would be; or
- permit an authorization for uses and disclosures of protected health information for future research purposes as a general rule but require certain disclosure statements on the authorization in cases where the future research may encompass certain types of sensitive research activities, such as research involving genetic analyses or mental health, that may alter an individual’s willingness to participate in the research.

HHS wants comments on the options and their effect on the conduct of research and patient understanding of authorizations.

“Any modification in this area would not alter an individual’s right to revoke the authorization for the use or disclosure of protected health information for future research at any time, and the authorization would have to include a description of how the individual may do so,” the department added. “We request comment on how a revocation would operate with respect to future downstream research studies.”

The notice added that any change in the interpretation in the final regulations “will be closely coordinated with the HHS Office for Human Research Protections (OHRP) and the FDA to ensure the Privacy Rule policies are appropriately harmonized” with 45 C.F.R. Part 46 and 21 C.F.R. Part 50.

### **To Find Out More**

The proposed regulations are available at  
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/nprmHITECH.pdf>.

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