

RESEARCH UNDER THE AMENDED HIPAA PRIVACY RULE

On January 25, 2013, the Department of Health and Human Services published a final rule modifying the HIPAA Privacy, Security, Enforcement and Breach Notification Rules in accordance with the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act (hereafter the “Final Rule”). This Final Rule and Preamble made several changes relating to research that were intended to simplify HIPAA research requirements, and harmonize the HIPAA research requirements with those contained in the Common Rule. Summarized below are the key research provisions of the Final Rule. The chart describes how these changes impact concerns previously raised by patients and researchers about the impact of the HIPAA Privacy Rule on research.

Compound Authorizations

The Final Rule simplifies the consent process for research activities by allowing covered entities to combine conditioned and unconditioned authorizations, as long as the authorization (1) clearly distinguishes between the conditioned and unconditioned research components, and (2) provides a clear opportunity for individuals to opt-in to the unconditioned component. *Prior to the issuance of the Final Rule, if a covered entity was engaged in a clinical trial that was associated with corollary research activities (e.g. – biospecimen banking), the covered entity was required to obtain separate authorizations for the clinical trial participation (conditioned authorization) and participation in the corollary activity (unconditioned authorization).*

Future Authorizations

The Privacy Rule requires authorizations to use and disclose protected health information (PHI) to describe the “purpose” of the requested use and disclosure. *Previously, the Department of Health and Human Services (HHS) has interpreted this as requiring study-specific descriptions of the purpose, which meant a prohibition on authorization for use or disclosure of PHI for future, unspecified research.* In the Preamble to the Final Rule, HHS announced it would no longer require research authorizations to describe a study-specific research purpose. Instead, authorizations may address the use and disclosure for future research purposes provided the purposes are described adequately such that it would be reasonable for the patient to expect that his or her PHI could be used or disclosed for such future research.

Sale of PHI

The Final Rule generally prohibits the sale of PHI without an authorization, but includes a research exception, whereby PHI may be disclosed for research purposes without an authorization, provided that the only remuneration is a reasonable, cost-based fee to cover the costs or preparation and transmittal of the information.

C-Change: Patients' and Researchers' Concerns Re: Privacy Rule Prior to Revision	Impact of Final Rule on Concerns
<p>Deters patients from participating in research</p> <ul style="list-style-type: none"> • Requires a complicated and lengthy consent process • Delays and deters patient enrollment and access to new treatments • Makes care process more unpredictable and confusing 	<p>Permitting compound authorizations should:</p> <ul style="list-style-type: none"> • Allow for a simpler consent process • Result in fewer patients being deterred from study participation by lengthy enrollment processes • Decrease confusion caused by multiple authorization forms
<p>Fosters research findings with limited relevance to patients</p> <ul style="list-style-type: none"> • Results in decreased enrollment/participation of some types of participants • Narrows the population for which treatments are proven effective, and results in perpetuating health disparities 	<p>Permitting compound authorizations should:</p> <ul style="list-style-type: none"> • Streamline the authorization process, which will ideally decrease self-selection bias and contribute to more representative research populations • Increase availability of data on participants from all populations <p>Allowing authorizations for future research should:</p> <ul style="list-style-type: none"> • Increase availability of data on participants from all populations
<p>Hampers personalized medicine research dependent on biospecimens and stored clinical data</p> <ul style="list-style-type: none"> • Wastes investments in accumulated research data for future purposes • Limits accumulation of large clinical databases to support stronger conclusions or study rare conditions or population sub-sets • Adds to the cost of care • Limits the impact patients can have on future research 	<p>Permitting compound authorizations should:</p> <ul style="list-style-type: none"> • Encourage researchers to combine research activities such as biospecimen banking with clinical trials • Facilitate participation in biospecimen banking by patients who would be deterred by multiple authorization requirements • Increase availability of stored clinical data and banked biospecimens <p>Allowing future research authorizations should:</p> <ul style="list-style-type: none"> • Enhance researchers' ability to work with existing research data • Enable research participants to have a larger impact on future research
<p>Increases the time and expense of clinical trial development</p> <ul style="list-style-type: none"> • Increases time of discovery • Increases cost of research • Delays access to approved treatments • Delays comparative effectiveness research 	<p>Permitting compound authorizations should:</p> <ul style="list-style-type: none"> • Streamline the consent process and decrease enrollment time • Decrease costs associated with obtaining and storing multiple authorizations <p>Allowing future research authorizations should:</p> <ul style="list-style-type: none"> • Enhance efficiency by enabling researchers to work with existing research data
<p>Fosters rejection or abandonment of clinical studies</p> <ul style="list-style-type: none"> • Contributes to higher rate of abandoned studies • Raises ethical concerns with continuity of patient treatment • Erodes patient trust • Limits treatment choices 	<p>Permitting compound authorizations should:</p> <ul style="list-style-type: none"> • Streamline the consent process, thereby minimizing abandonment of clinical studies as a result of problems enrolling sufficient numbers of participants • Enhance patient trust through a more transparent, single form.
<p>Increases time and cost of large, multi-site studies</p> <ul style="list-style-type: none"> • Limits accumulation of large databases to support stronger conclusions or study rare conditions or population sub-sets • Leads to migration of research to other nations with more hospitable regulatory climates • Limits treatment options to participate in clinical trials, particularly in community hospital settings • Leads to treatments designed for less diverse populations 	<p>Permitting compound authorizations should:</p> <ul style="list-style-type: none"> • Decrease costs associated with obtaining and storing multiple authorizations. <p>Allowing future research authorizations should:</p> <ul style="list-style-type: none"> • Lower costs associated with obtaining authorizations from patients whose data was accumulated in past studies <p>Limits on the sale of PHI should:</p> <ul style="list-style-type: none"> • Lower costs of research studies