

Research Under The Newly Amended Privacy Rule:
Implications For C-Change Research Project Activities

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 table below shows both changes that arguably advance the C-Change research agenda, as well as the remaining C-Change issues (Cons) that the agency did not address.

| Pros | Cons |
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| <p><u>Compound Authorizations</u> 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. <i>Prior to the issuance of the Final Rule, if a covered entities 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).</i></p> | <p><u>Authorization Requirements Still Confusing For Patients.</u> The bureaucratic requirements for a valid compound authorization are cumbersome and because of variations from one IRB to the next, can lead to very low participation rates due to confusion about the multiple different requests and what they mean.</p> <p>Big question of whether hospitals and academic medical centers will actually implement these new changes in a way that will facilitate maximum utility of clinical trial data. If they do not, we would still be reaping less than the full scientific and patient benefit from investments in clinical trials, making it longer and more expensive to find effective treatments and cures.</p> |
| <p><u>Future Authorizations</u> The Privacy Rule requires authorizations to use and disclose protected health information (PHI) to describe the “purpose” of the requested use and disclosure. <i>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.</i> 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.</p> | <p><u>Future Research Authorizations Require Opt In</u> In addition to the language concerns above, this is still a requirement to obtain patient opt in for future analyses of data where the patient’s identity is protected, rather than a patient choice to opt out of data research. Too many declines may result in data sets that are less robust than what is needed for epidemiological and outcomes research.</p> |

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| <p><u>Sale of PHI</u> 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.</p> | <p>Has not previously been an issue; explicit clarification may be useful in light of HITECH's enhanced prohibitions regarding sale of information.</p> |
| | <p><u>De-Identification</u> No change to existing standard; HHS still lags behind FDA and FTC in recognizing better ways to use de-identification methods that facilitate data activities important to the public while protecting individual privacy.</p> |
| | <p><u>Pre-Emption of State Laws</u> Not addressed in new regulation; not within agency discretion. Requires federal legislation.</p> |