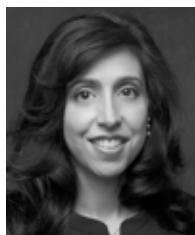


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Certain Barriers to Research Removed by HHS



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On Jan. 25, 2013, the U.S. Department of Health and Human Services (“HHS”) published the long-awaited final omnibus rule (the “Final Rule”) in the *Federal Register*¹ that makes sweeping changes to the Privacy and Security Rules² established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The effective date of the Final Rule is March 26, 2013.

The overall purpose of the new regulations is to enhance privacy protections and security safeguards for individuals’ health information.³ While the Final Rule

¹ 78 Fed. Reg. 5566 (Jan. 25, 2013).

² The Privacy Rule is located at 45 C.F.R. Part 160 and Subparts A and E of Part 164 and the Security Rule is located at 45 C.F.R. Part 160 and Subparts A and C of Part 164.

³ These new regulations are meant to enhance the standards of privacy protection and security safeguards for consumer health data and are based on statutory changes under the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, and the Genetic Information Nondiscrimination Act of 2008 (GINA), which clarifies that genetic information is protected under the HIPAA Privacy Rule and prohibits most health plans from using or disclosing genetic information for underwriting purposes and also prohibits employers from utilizing genetic information to discriminate against a person, such as by using such information to make an employment decision.

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affects many aspects of privacy protections, this article discusses its impact on research.

Research-Related Provisions of the Final Rule

There are three ways that the Final Rule affects research, all of which better facilitate the conduct of research. Below is a summary of each change in the law affecting research, followed by a more in-depth discussion of each such change.

A. Compound Authorizations. To an individual who is thinking about participating in a clinical trial, multiple consent forms can be daunting and confusing and may impede participation in the trial. The Final Rule amends the Privacy Rule to allow for a single authorization that combines both a “conditioned authorization” and an “unconditioned authorization,” which previously had to be presented to the study subject in separate consent forms. This change will reduce the number of forms with which a study subject is confronted before participating in a trial. In order for a single authorization to be valid, however, such single authorization must (i) clearly differentiate between the conditioned and unconditioned research components and (ii) clearly allow the individual the option to opt in to the unconditioned research activities.

B. Authorizations Allow for Use or Disclosure of Protected Health Information for Future Research. The two main bodies of law governing consents in research, HIPAA and the Common Rule,⁴ diverged regarding the required level of specificity in a consent form with respect to the purpose for which health information could be used in future, unspecified research. As a result, this area became confusing and, at times, unworkable. Many hours of negotiation, discussion, and drafting were spent grappling with the parameters of the valid use and disclosure of health information for future, unspecified research. Moreover, this disparity created the need to find past research participants and obtain authorization for the new research, leading to delays and/or termination of a research project where those past participants were difficult to find or could not be found.

⁴ Published in 1991, the Federal Policy for the Protection of Human Subjects, also known as the “Common Rule,” is codified in separate regulations by 15 federal departments and agencies. The HHS regulations, 45 C.F.R. Part 46, include requirements for an informed consent at 45 C.F.R. §§ 46.116 and 46.117.

In the Final Rule, HHS modified its interpretation of one of the core elements of a HIPAA authorization. As a result, the “purpose” for which a use or disclosure may be given by an individual for future research no longer must be study-specific. Rather, in order to meet the requirements of Section 164.508(c)(1)(iv),⁵ an authorization for future research purposes must adequately describe the purposes such that it would be reasonable for the individual to expect that his or her protected health information⁶ could be used or disclosed for such research purposes. HHS also clarified that an authorization for future research allows for the consent to use or disclose health information not in existence at the time of the consent (e.g., “Your future medical records at [Hospital]”), further broadening the reach of allowable future, unspecified research.

C. Researcher as a Business Associate. A business associate is generally an individual or entity that performs certain services or functions on behalf of a covered entity.⁷ A business associate has direct statutory obligations regarding the protection of health information and, therefore, also runs the risk of statutory penalties for the violation of any such obligations. A researcher may be discouraged from pursuing a specific research project if he or she believes such research activity would create a business associate relationship and thereby create potential liability for the researcher.

In the Final Rule, HHS clarified that a researcher is not a business associate by virtue of conducting research activity for a covered entity nor is an external or independent Institutional Review Board (“IRB”) a business associate of a covered entity by virtue of conducting research review, approval, and/or continuing oversight functions. Instead, a researcher or IRB would be considered a business associate if such individual or entity were to conduct any of the activities or functions described in the definition of “business associate.” Since research activities are not so described, the conduct of such research activities will not create a business associate relationship.

The Final Rule Amends Regulations With Respect to Compound Authorizations

As stated above, prior to the Final Rule, an individual interested in participating in a clinical trial was faced with multiple consent forms, which could lead to confusion and/or a decision not to participate in the trial.

⁵ The citations to regulations throughout this article are to Title 45 of the Code of Federal Regulations, if not otherwise specified.

⁶ Protected health information is any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (3) identifies an individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. (See 45 C.F.R. § 160.103).

⁷ See 45 C.F.R. § 160.103. A “covered entity” is a health plan, a health care clearinghouse, or a health care provider that transmits any health information in electronic form in connection with a transaction covered by the Privacy Rule. (Also see 45 C.F.R. § 160.103).

In order to streamline the process and ameliorate these concerns, the Final Rule amends Sections 164.508(b)(3)(i) and (iii) to allow a covered entity to combine conditioned and unconditioned authorizations for research, provided that the single authorization:

1. Clearly differentiates between the conditioned and unconditioned research components; and
2. Clearly allows the individual the option to opt in to the unconditioned research activities.

Conditioned Versus Unconditioned Authorizations. To understand this rule one must understand what is meant by a “conditioned authorization” and an “unconditioned authorization.” For these purposes a conditioned authorization is one that conditions treatment, payment, enrollment in a health plan, or eligibility for benefits on the individual giving the authorization to use or disclose such individual’s information.⁸ An unconditioned authorization is one that does not condition the treatment, payment, enrollment in a health plan, or eligibility for benefits on an individual giving the authorization to use or disclose such individual’s information.⁹

Permitted Use of Conditioned Authorization in Research. Covered entities generally are prohibited from utilizing a conditioned authorization, except in very limited circumstances.¹⁰ One of those limited circumstances is in the context of research. A covered entity may utilize a conditioned authorization in the provision of research-related treatment.¹¹ In other words, a covered entity may utilize a conditioned authorization and condition the provision of research-related treatment on the individual study participant giving an authorization for the use or disclosure of his or her protected health information for such research.¹²

Limitation on Combining Conditioned and Unconditioned Authorization. As a general rule, an authorization for the use or disclosure of protected health information may not be combined with any other document to create a compound authorization. One enumerated exception to this general rule is research.¹³

Application of this General Limitation Prior to the Final Rule. Before the issuance of the Final Rule, an authorization for the use or disclosure of protected health information for a research study could be combined with any other type of written permission for the same research study, such as an informed consent as required by the Common Rule and any other authorization (excluding the compounding of a conditioned authorization and an unconditioned authorization into a single authorization), for the use or disclosure of protected health information for research or a consent to participate in such research.¹⁴ Therefore, prior to the Final Rule, while a covered entity could condition the provision of research-related treatment on an individual giving his or her authorization for the use or disclosure of protected health information for such research (i.e., a conditioned authorization), such authorization could not be combined with an unconditioned authorization.

⁸ 78 Fed. Reg. 5566, at 5609.

⁹ *Id.*

¹⁰ 45 C.F.R. § 164.508(b)(4).

¹¹ 45 C.F.R. § 164.508(b)(4)(i).

¹² *Id.*

¹³ 45 C.F.R. § 164.508(b)(3).

¹⁴ 45 C.F.R. §§ 164.508(b)(3)(i) and 164.508(b)(4)(i).

The underlying intention of this prohibition was to ensure that individuals understood that they may decline the activity described in the unconditioned authorization and still receive treatment, or other benefits or services, by agreeing to the conditioned authorization.

For example, if a research study includes the delivery of research-related treatments and also banking of tissue samples in a biorepository for future research, the researcher can condition the delivery of research-related treatment to the individual on the individual giving an authorization to use or disclose his or her protected health information for the research study. However, the researcher may not condition the delivery of research-related treatment (or any other treatment, payment, enrollment in a health plan, or eligibility for benefits) to the individual on the individual giving an authorization to use or disclose his or her protected health information (i.e., the tissue sample) as part of the biobanking component. In order to conduct such a research study, under regulations prior to the Final Rule, a researcher would have to obtain one authorization for the research-related treatments (a conditioned authorization) and a separate authorization for the biobanking (an unconditioned authorization). These two could not be combined into a single authorization.

Application of the General Limitation After the Final Rule. The Final Rule now allows a covered entity to combine conditioned and unconditioned authorizations for research, provided that the single authorization clearly differentiates between the conditioned and unconditioned research components and it clearly allows the individual the option to opt in to the unconditioned research activities (i.e., thus preserving the original public policy behind the previous prohibition against combining an unconditioned authorization with a conditioned authorization).¹⁵

Psychotherapy Notes and Combined Authorizations. Psychotherapy notes are considered sensitive information and have added protections. An authorization for the use or disclosure of psychotherapy notes may only be combined with another authorization for the use or disclosure of psychotherapy notes.¹⁶ It should be noted that a covered entity may never condition the treatment on the receipt of an individual's authorization to use or disclose his or her psychotherapy notes, as the use of psychotherapy notes is not one of the exceptions to the general rule that a covered entity may not use a conditioned authorization.¹⁷ Therefore, any authorization for the use or disclosure of psychotherapy notes must be an unconditioned authorization and can only be combined with another unconditioned authorization for the use or disclosure of psychotherapy notes.

The Final Rule Allows Flexibility With Regard to Compliance

The Final Rule provides covered entities, institutions, and IRBs with flexibility to determine the best approach for clearly differentiating the conditioned and unconditioned research activities in a single authorization and giving research participants the option to opt in to the

¹⁵ 45 C.F.R. §§ 164.508(b)(3)(i) and (iii), as amended by the Final Rule.

¹⁶ 45 C.F.R. § 164.508(b)(3)(ii).

¹⁷ 45 C.F.R. §§ 164.508(b)(3)(iii) and (b)(4).

unconditioned research activity. Some approaches for distinguishing between conditioned and unconditioned research activities that were found acceptable to HHS in the preamble to the Final Rule include:¹⁸

1. Using a combined consent/authorization form for the conditioned research activity (e.g., clinical trial research) and the unconditioned research activity (e.g., optional tissue banking component), with a check box for the individual to have the choice to opt in to the unconditioned research activity, with one signature;

2. Using a combined consent/authorization form for the conditioned research activity (e.g., clinical trial research) and the unconditioned research activity (e.g., optional tissue banking component), with one signature for the clinical trial and another signature to indicate the individual agrees to the unconditioned research activity; and

3. Using a combined consent/authorization form for the conditioned research activity (e.g., clinical trial research) and the unconditioned research activity (e.g., optional tissue banking component), with a check box for the individual to have the choice to opt in to the unconditioned research activity, with one signature, with detailed information about the unconditioned research activity (e.g., optional tissue banking component) presented in a separate brochure or information sheet that is referenced directly in the consent/authorization form that is incorporated by reference into the authorization/consent form such that it is considered to be part of the form even if not physically attached to the form.¹⁹

The Final Rule Changes the Authorization for Future Research Use or Disclosure

An individual must give a written informed consent to participate in order to be a study subject in a clinical trial. Such informed consent must meet the requirements of the Common Rule.²⁰ In addition, the study subject must authorize the use of his or her protected health information through an authorization that meets the requirements of the Privacy Rule under HIPAA.²¹ It should be noted that study subject data may be used without a subject's written authorization in limited circumstances.²²

¹⁸ 78 Fed. Reg. 5566, at 5610.

¹⁹ It should be noted that HHS stated that if the brochure or information sheet includes any of the required elements of the authorization (or informed consent), and authorization/consent has not been altered by an IRB, then the brochure or information sheet must be made available to potential research participants before they are asked to sign the authorization/consent document (unless the authorization form itself includes the required elements). See 78 Fed. Reg. 5566, at 5611.

²⁰ The HHS regulations that contain the Common Rule are located at 45 C.F.R. Part 46. The specific informed consent requirements are found at 45 C.F.R. §§ 46.116 and 46.117.

²¹ The core elements of a HIPAA authorization are found at 45 C.F.R. § 164.508(c)(i).

²² Study subject data may be disclosed for research purposes, including future research, without an authorization from a study subject, if (i) a waiver of study subject's authorization for use or disclosure of his or her information is approved by an IRB or a Privacy Board, pursuant to 45 C.F.R. § 164.512(i)(1)(i); (ii) the use or disclosure is preparatory to re-

The Privacy Rule requires that the authorization describe a purpose for the requested use or disclosure.²³ Prior to the Final Rule, HHS interpreted this in the context of future research to mean that the authorization must be study-specific.²⁴ In part, HHS's interpretation was based on the concern that patients could lack necessary information to make an informed decision about future research.²⁵

HHS's requirement that the authorization be study-specific diverged with accepted practice under the Common Rule. Under the Common Rule, a study subject's consent to the use of his or data in future trials is valid so long as the future uses are described in sufficient detail to allow an informed consent.²⁶ In other words, there is no need to be study-specific in order to comply with the Common Rule's requirements.

To comply with both the Common Rule and the HIPAA authorization requirements as previously interpreted by HHS, institutions attempted to limit the use or disclosure of protected health information, including protected health information stored (or attached to tissue stored) in a repository, to purposes related to the study specifically described in the consents.

HHS Modifies Its Interpretation to Move Away From Requiring Study-Specific Language. HHS stated that it received comments from covered entities and researchers that its interpretation encumbered secondary research and limited individuals' ability to agree to the use or disclosure of their protected health information for future research.²⁷ In the preamble to the Final Rule, HHS announced a modification of its interpretation of the "purpose" provision of Section 164.508 (c)(iv) for an authorization to be valid. HHS stated that the "purposes" requirement will be met (for all HIPAA authorizations, including but not limited to those for future research), if the authorization:

"adequately describes such purposes 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 research purposes."²⁸

This is a much more flexible standard and will allow researchers, covered entities, and IRBs to more easily comply with both the Common Rule and the HIPAA authorization requirements.

Sensitive Information. HHS stated that the authorization could include specific statements with respect to sensitive research (e.g., genetic analyses or mental health research) to the extent such research is contemplated. HHS, however, also stated that it did not prescribe specific statements with respect to such sensitive research. Rather, it defers to covered entities, research-

ers, and IRBs to determine what adequately describes future research purposes depending on the circumstances, as what is considered "sensitive information" changes over time.²⁹

HHS Clarifies How Much Information Can Be Used or Disclosed in Future Research. Section 164.508(c)(1)(i) requires that a valid authorization contain a description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion. HHS clarified that in order to meet this requirement in the context of future research, covered entities have flexibility to describe the information to be used or disclosed for future research, so long as it is reasonable from such a description to believe that the individual would expect the information to be used or disclosed for the future research.³⁰

HHS then clarified that such language may include information that is not in existence at the time the consent is given, stating that the description of the protected health information to be used for the future research may include information collected beyond the time of the original study. Therefore, for example, the description of information to be collected may reference "your future medical records [at Hospital]" or "your future medical records, [relating to diseases/conditions]."³¹

HHS Clarifies to Whom Information May Be Disclosed for Future Research. Section 164.508(c)(1)(ii) states that a valid HIPAA authorization must contain the name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure. HHS clarified that covered entities and researchers have flexibility in the manner in which they describe the recipients of the protected health information for future research, so long as it is reasonable from such description to believe that the individual would expect his or her protected health information to be shared with such persons for the future research.³²

HHS Clarifies the Expiration of Authorizations for Future Research. Section 164.508(c)(1)(v) requires that a valid HIPAA authorization state an expiration date or expiration event that relates to the individual for the purpose of the use or disclosure. That section continues by saying that the statement "end of the research study," "none," or similar language is sufficient if the authorization is for the use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository. HHS clarified that its interpretation of this requirement has not changed.³³

HHS Clarifies its Position with Regard to Oral Revocation of Authorization. Section 164.508(b)(5) requires that a revocation of an authorization by an individual be in writing. HHS clarified that while this provision requires that a revocation of an authorization be in writing, uses and disclosures by the covered entity and researchers pursuant to such authorization are permissive and not required. Therefore, a covered entity and researchers may simply stop using or disclosing the

search pursuant to 45 C.F.R. § 164.512(i)(1)(ii); or (iii) the use or disclosure is under a limited data set pursuant to 45 C.F.R. § 164.514 (e). In addition, covered entities and researchers may use study subject data without authorization where such data are de-identified pursuant to 45 C.F.R. § 164.514(b)(1) and (2).

²³ 45 C.F.R. § 164.508(c)(1)(iv).

²⁴ See 67 Fed. Reg. 53,182, at 53,226, Aug. 14, 2002.

²⁵ 78 Fed. Reg. 5566, at 5611.

²⁶ See, for example, Appendix D of the letter from the Secretary's Advisory Committee on Human Research Protections to the Secretary of HHS, dated Sept. 27, 2004, found at <http://www.hhs.gov/ohrp/sachrp/appendixd.html>.

²⁷ 78 Fed. Reg. 5566, at 5612.

²⁸ 78 Fed. Reg. 5566, at 5612.

²⁹ *Id.*

³⁰ 78 Fed. Reg. 5566, at 5613.

³¹ *Id.*

³² *Id.*

³³ *Id.*

protected health information pursuant to an oral request by an individual to do so.³⁴

The Final Rule Clarifies When a Researcher May Be a Business Associate

When an individual or entity becomes a business associate to a covered entity, many statutory obligations with respect to the privacy and security of protected health information are triggered, as well as the potential for statutory penalties for violations of such obligations.

HHS confirmed that neither an individual who conducts research nor an external or independent IRB that conducts research review, approval, and/or continuing oversight functions is considered a business associate by virtue of conducting such research activities, even if the covered entity has hired the researcher or the IRB to perform such research activities.

A researcher or an external IRB could be deemed a business associate, however, if (i) such person or entity is conducting a function or activity regulated by the HIPAA rules on behalf of a covered entity (e.g., health care operations, or providing one of the services listed in the definition of “business associate”), and (ii) in the performance of such duties the person or entity has access to protected health information.

Therefore, for example, if a researcher performs the function of creating a de-identified or limited data set

on behalf of the covered entity, that researcher is performing a function that falls within the definition of a health care operation being performed on behalf of the covered entity and would be considered a business associate.

Similarly, if such researcher creates, receives, maintains, or transmits protected health information as part of a function or activity of the covered entity regulated by HIPAA, including data analysis, processing administration, quality assurance, certain patient safety activities, data aggregation, or other services listed in the definition of “business associate” in Section 160.103, such researcher would be a business associate.³⁵

Practical Impact on Conduct of Research

The Final Rule’s changes with respect to research activities should encourage participation in clinical trials and facilitate the consent process. It eliminates the need for multiple forms for certain research studies by permitting compound authorizations and removes the need to find past research participants and obtain new authorizations for new research uses of their protected health information by allowing individuals to authorize future research uses and disclosures at the time of initial enrollment. Moreover, it clarifies that researchers and IRBs are not business associates by virtue of conducting research activities. Organizations involved in research should carefully consider with whom and how research data are being shared and update their policies, practices, and authorization forms accordingly.

³⁴ *Id.*

³⁵ See also, http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/239.html.

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