Informed Consent for Research and Authorization under the Health Insurance Portability and Accountability Act Privacy Rule: An Integrated Approach

David Shalowitz, AB, and David Wendler, PhD

Researchers have found that implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is having a negative impact on clinical research. This impact traces, in part, to many research institutions complying with HIPAA by adding lengthy, complex language to their research consent documents. The addition of extensive language burdens institutional review boards and may undermine participants’ understanding of the research in which they take part. Comparative analysis reveals, however, that the addition of lengthy text often is unnecessary.

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA), calling for standards to protect individuals’ health information (1). In response, the Department of Health and Human Services issued the Privacy Rule, which established national standards to protect such information (2). The Privacy Rule covers “protected” health information, that is, health information that is “individually identifiable,” including health information that contains 1 or more of 18 identifiers, such as names or Social Security numbers. With few exceptions, the Privacy Rule requires “covered entities” and their workforces to obtain individuals’ signed authorization to use or disclose their protected health information for research purposes. Covered entities include health care providers that electronically transmit health information for insurance and billing purposes, suggesting that the Privacy Rule probably applies to most institutions that conduct clinical research.

Research institutions and institutional review boards often comply with the Privacy Rule by adding large amounts of text to research consent forms, burdening institutional review boards and possibly confusing research participants. Fortunately, covered entities may eliminate redundant language between authorization and consent forms (3) and, thus, may avoid these potential problems. In fact, consent forms that satisfy the regulations for clinical research (45 CFR §46 and 21 CFR §50 and §56) (4, 5) need only minimal additional text to also satisfy the authorization requirements under the Privacy Rule.

The “ADDITIVE” Approach

Except where prohibited by state law (6), the Privacy Rule allows combining of authorizations to use or disclose protected health information with research consent forms. When Privacy Rule authorizations are thus combined with research consent forms, approval of the combined form, including approval of the authorization language, falls to the relevant institutional review board. Many institutional review boards and institutions comply with the Privacy Rule by adding all the language required for authorization to research consent forms. This approach yields long and complicated forms.

In a recent survey of 100 top medical centers and 11 independent institutional review boards, researchers discovered that the authorization language used to satisfy the Privacy Rule has a median length of 744 words and is written at a median 12th-grade reading level (7). This wording is well above the eighth-grade reading level mandated by many institutional review boards (8) and the literacy level of most U.S. citizens (9). This complex language also seems inconsistent with the Privacy Rule’s requirement that authorizations be written in “plain language.” In another survey of investigators and institutional review board personnel, researchers found that the addition of extensive language to satisfy the Privacy Rule’s authorization requirements often confuses research participants, burdens the informed consent process, and undermines recruitment (10).

Increased complexity of research consent forms is worrisome given data showing that, even without additional privacy language, many participants cannot understand crucial aspects about the research in which they participate (11–15). Three extra pages of text, often written in complex language, may well increase participants’ confusion and distract them from more important information, such as the risks of participation and their right to withdraw.

Clinical investigators who work for covered entities can avoid the Privacy Rule’s authorization requirements by...
removing personal identifiers from health information or obtaining a waiver of authorization. Yet a decision to remove identifiers can diminish the value of research studies. Removal of dates of birth or places of residence can make it impossible to conduct important epidemiologic studies or medical records research (16). Removal of identifiers also may prevent investigators from following up on unexpected findings (17). Furthermore, the Privacy Rule allows a waiver of authorization only when, among other things, it is not “practicable” to conduct the research without a waiver. Because investigators often are able to obtain individuals’ authorization at the time of consent, most studies probably will not satisfy this requirement. Hence, they must obtain Privacy Rule authorization.

Comparing the Privacy Rule and the Federal Regulations

The Privacy Rule’s 9 requirements for authorization (Table) can be divided into 3 groups: 1) items duplicated in the federal regulations for human subjects research; 2) items similar to a requirement in the federal regulations; and 3) items not included in the federal regulations.

Privacy Rule Requirements Duplicated in the Federal Regulations

The federal regulations and the Privacy Rule require that information given to participants be understandable and that participants provide their signature. The Privacy Rule requires that signatures be dated and that a copy of the signed authorization be provided to the participant. Although these requirements are not explicit in the federal regulations, it is common practice to date signatures and provide participants with copies of their signed consent forms. The Privacy Rule also mandates that individuals be informed of any consequences of a failure to provide authorization, including whether any treatment or payment is conditioned on their authorization. The federal regulations similarly require participants to be informed that their “refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled” (4).

Privacy Rule Requirements Similar to a Requirement in the Federal Regulations

The Privacy Rule mandates that researchers inform individuals of what protected health information is being collected and the purpose of the collection. These requirements are similar to the federal regulations’ requirement that researchers describe the procedures and purposes of the research to participants. The Privacy Rule also mandates that researchers inform individuals that the research team may redisclose their health information and that information disclosed to others may not be protected by the Privacy Rule. In comparison, the federal regulations require that researchers inform participants of the extent to

| HIPAA Authorization Requirements (Reference) | Federal Research Consent Requirements (Reference) | Checklist of Needed Modifications† |
|---------------------------------------------|-------------------------------------------------|----------------------------------|
| Duplicate requirements                      |                                                 |                                   |
| Signature of individual and date (18)       | Signature of subject (19)                       | None†                            |
| Whether treatment, payment, enrollment, or  | Statement that refusal to participate will involve | None                            |
| eligibility are conditioned on authorization, and  | no penalty or loss of benefits to which the subject is otherwise entitled (21) |                                  |
| any consequences of failure to sign authorization |                                               |                                  |
| Authorization must be written in plain language (22) | Information needs to be understandable to the subject (23) | None                            |
| Similar requirements                        |                                                 |                                   |
| Description of protected health information to be used or disclosed (24) | Description of procedures (25) | Description of procedures should describe the health information to be collected |
| Purpose of the use or disclosure of protected health information (26) | Description of purpose of procedures (25) | Description of purpose of procedures should explain why health information is being collected |
| Statement that information may be redisclosed and may not be protected by the Privacy Rule once it is redisclosed (27) | Statement of extent to which confidentiality will be maintained (21) | Statement of confidentiality should explain that federal regulations may not protect health information after redisclosure |
| Statement of right to revoke authorization in writing; how to revoke it; and exceptions, if any (28) | Statement explaining that participation is voluntary, information on how to withdraw, and the consequences of doing so (21) | Statement of voluntariness should explain that participants may withdraw and, if choosing to do so, should notify the investigator in writing |
| Distinct requirements                       |                                                 |                                   |
| Persons authorized to use or disclose information and those to whom the information will be disclosed (29) | None | Describe those who will use the health information (e.g., “the research team”) |
| Expiration date or event for authorization or statement that authorization does not expire (30) | None | Explain how long the health information will be kept (may be kept indefinitely) |

* HIPAA = Health Insurance Portability and Accountability Act.
† Checklist describes the modifications needed to ensure that consent forms that satisfy the U.S. federal regulations for human subjects research also comply with the HIPAA Privacy Rule’s authorization requirements.
‡ Although not explicitly mandated by federal research consent requirements, it is common practice to ask participants to date their signatures.
which their confidentiality will be maintained. The Privacy Rule states that researchers must inform participants of their right to revoke their authorization in writing, how to revoke it, and any exceptions to this right. This requirement is similar to the federal regulations’ requirement that researchers inform participants that participation is voluntary and inform them how to withdraw.

Privacy Rule Requirements Not Found in the Federal Regulations

The Privacy Rule requires that individuals be informed of the persons authorized to access their protected health information and the persons to whom the information will be disclosed. The Privacy Rule also requires that individuals be told when, if ever, researchers will no longer be authorized to use their protected health information.

AN INTEGRATED APPROACH TO COMBINING INFORMED CONSENT AND AUTHORIZATION

The present comparison reveals substantial overlap between the Privacy Rule’s authorization requirements and the federal requirements for informed consent. This finding suggests that consent forms that satisfy the federal regulations need add only minimal additional text to comply with the Privacy Rule’s authorization requirements. This integrated approach is consistent with the Department of Health and Human Services’ statement that covered entities may eliminate redundant language between authorizations and consent forms (3).

To implement this integrated approach, descriptions of the research procedures in combined forms should include what information is being collected, who is authorized to collect it, and the reasons for the collection. For example, to describe a study’s screening procedures, the consent form might state that “members of the research team will conduct tests of your heart to determine whether you are eligible to participate in this study.” The combined form should also state whether this information will be retained, used, or disclosed after the study is completed.

Second, when stating that research participation is voluntary, as required by the federal regulations, the combined form should explicitly mention the option to withdraw. The Privacy Rule allows investigators to use participants’ protected health information until their authorization expires. Hence, combined forms should recommend that participants withdraw in writing. Third, when explaining confidentiality protections, researchers should state on the combined form that the regulations may not protect individuals’ health information after its disclosure. Finally, the Privacy Rule gives participants the right to access their protected health information. Hence, studies that require withholding certain information from participants, for instance, whether they are receiving drug or placebo, should state this on the combined form. These additions (Table) provide a checklist that investigators and institutional review boards can use to assess adherence to the Privacy Rule’s authorization requirements.

CONCLUSION

Institutions and institutional review boards often comply with the Privacy Rule’s authorization requirements by adding complex and lengthy text to research consent forms. Yet, the addition of extensive language is likely to confuse research participants already struggling to understand complicated research protocols. Fortunately, the Privacy Rule’s authorization requirements and the federal requirements for informed consent overlap substantially. Consent forms that satisfy the federal regulations for human subjects research need only minimal additional text to also satisfy the Privacy Rule’s authorization requirements. Limiting the amount of text added to consent forms through this integrated approach has the potential to increase research participants’ understanding of their privacy rights without sacrificing comprehension of their research participation. This integrated approach also may relieve institutional review boards of the burdens of reviewing complex and lengthy boilerplate authorization language in consent forms.

From the NIH Clinical Center, Bethesda, Maryland.

Acknowledgments: The authors thank John Barton, Lindsay Hampson, and Mary McCabe for their helpful comments on earlier versions of this manuscript.

Potential Financial Conflicts of Interest: Employment: D. Shalowitz (National Institutes of Health), D. Wendler (National Institutes of Health).

Requests for Single Reprints: David Wendler, PhD, Department of Clinical Bioethics, NIH Clinical Center, Building 10, Room 1C118, Bethesda, MD 20892; e-mail, dwendler@nih.gov.

Current author addresses are available at www.annals.org.

References

1. Health Insurance Portability and Accountability Act of 1996. Accessed at www.hhs.gov/ocr/hipaa/ on 1 March 2006.
2. U.S. Department of Health and Human Services. Standards for Privacy of Individually Identifiable Health Information; Final Rule. Code of Federal Regulations, Title 45, Parts 160 and 164. Accessed at http://hhs.gov/ocr/combinedreg-text.pdf on 1 September 2005.
3. Clinical Research and the HIPAA Privacy Rule—Frequently Asked Questions and Answers. Accessed at http://privacyruleandresearch.nih.gov/faq.asp#17 on 1 March 2006.
4. Office for Human Research Protections. Code of Federal Regulations. Title 45, Part 46. Protection of human subjects. Accessed at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm on 2 September 2005.
5. U.S. Food and Drug Administration. Protection of Human Subjects. Accessed at www.accessdata.fda.gov/scripts/cder/cfdocs/cfDR/CFRSearch.cfm on 1 March 2006.
6. Health Care Research Under HIPAA Rules. Sacramento, CA: California Office of HIPAA Implementation; 2004.
7. Breese P, Burman W, Rietmeijer C, Lezotte D. The Health Insurance Portability and Accountability Act and the informed consent process [Letter]. Ann
8. Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med. 2003;348:721-6. [PMID: 12594317]

9. Communicating with patients who have limited literacy skills. Report of the National Work Group on Literacy and Health. J Fam Pract. 1998;46:168-76. [PMID: 9487325]

10. Ehringhaus SH. AAMC project to document the effects of HIPAA on research. Presented at Associate General Counsel Association of American Medical Colleges SACHRP Meeting, Boston, Massachusetts, 30 March 2004. Accessed at http://aamc.org/advocacy/library/research/testimony/2004/033004.pdf on 1 September 2005.

11. Bergler JH, Pennington AC, Metcalfe M, Freis ED. Informed consent: how much does the patient understand? Clin Pharmacol Ther. 1980;27:435-40. [PMID: 6987027]

12. Harth SC, Thong YH. Parental perceptions and attitudes about informed consent in clinical research involving children. Soc Sci Med. 1995;41:1647-51. [PMID: 8746864]

13. Lynöe N, Sandlund M, Dahlgqvist G, Jacobsson L. Informed consent: study of quality of information given to participants in a clinical trial. BMJ. 1991;303:610-3. [PMID: 1932901]

14. Howard JM, DeMets D. How informed is informed consent? The BHAT experience. Control Clin Trials. 1981;2:287-303. [PMID: 6120794]

15. Riecken HW, Ravich R. Informed consent to biomedical research in Veterans Administration Hospitals. JAMA. 1982;248:344-8. [PMID: 7045344]

16. O’Herrin JK, Fost N, Kudsk KA. Health Insurance Portability Accountability Act (HIPAA) regulations: effect on medical record research. Ann Surg. 2004;239:772-6; discussion 776-8. [PMID: 15166956]

17. Hedenfalk I, Duggan D, Chen Y, Radmacher M, Bitner M, Simon R, et al. Gene-expression profiles in hereditary breast cancer. N Engl J Med. 2001;344:539-48. [PMID: 11207349]

18. 45 CFR §164.508(c)(vi)

19. 45 CFR §46.117(a)

20. 45 CFR §164.508(c)(vii)

21. 45 CFR §46.116(a)5

22. 45 CFR §164.508(c)3

23. 45 CFR §46.116

24. 45 CFR §164.508(c)(i)

25. 45 CFR §46.116(a)1

26. 45 CFR §164.508(c)(v)

27. 45 CFR §164.508(c)(ii)

28. 45 CFR §164.508(c)(ii)

29. 45 CFR §164.508(c)(iii), (iii)

30. 45 CFR §164.508(c)(i)
Current Author Addresses: Mr. Shalowitz and Dr. Wendler: Department of Clinical Bioethics, NIH Clinical Center, Building 10, Room 1C118, Bethesda, MD 20892.