

The HIPAA Privacy Rule: Lacks Patient Benefit, Impedes Research Growth

Mindy J. Steinberg, MPH,
and Elaine R. Rubin, PhD

Revising the HIPAA Privacy Rule is imperative to sustain the research enterprise.



Association of Academic Health Centers®
Leading institutions that serve society

The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), a regulation designed to protect the privacy of health information, continues to have a negative impact on the nation's research enterprise, according to the latest survey of academic health center research administrators and principal investigators by the Association of Academic Health Centers (AAHC). Since the 2003 implementation of the Privacy Rule (45 CFR 160, 164), studies have shown that it has imposed barriers to research at academic health centers, the nation's major research institutions, thus slowing the pace of research, increasing the costs, and significantly hindering participation of individuals in important research studies.^{1,2,3}

Research was not intended to be governed by the HIPAA Privacy Rule, but neither was it exempted from the regulation. However, the new constructs and restrictions on information mandated by the Rule have had untold consequences for the conduct of research and the advance of science and discovery in the United States. Despite repeated efforts by the research community to highlight the negative consequences of the HIPAA Privacy Rule, policymakers have made little attempt to address the Rule and consider options to remedy the situation. With the U.S. facing critical socioeconomic challenges, including an aging population and the desire for new treatments and cures for disease and illness, it is essential that policymakers reexamine the HIPAA Privacy Rule.

The AAHC called for changes to the HIPAA Privacy Rule and recommended options to address these critical research issues based on evidence from a limited number of focus groups conducted with researchers throughout the country in 2007.⁴ This year, to broaden its information base, the AAHC developed a questionnaire that was administered online to 102 members of the AAHC's executive leadership group of Vice

“Research was not intended to be governed by the HIPAA Privacy Rule, but neither was it exempted from the regulation.”

Presidents for Research as well as other senior leaders (e.g., legal counsel and chief compliance officers) who are members of the Vice Presidents for Research Workgroup on HIPAA. The vice presidents for research were also asked to forward the survey to 2-4 principal investigators at their institution in the interest of including the perspective of researchers along with that of senior research administrators.

The five section, 46-question survey addressed the impact of the HIPAA Privacy Rule on:

- The scope, pace, and cost of research at the institution and for the nation as a whole;
- Research administration and processes;
- Multi-site research;
- Research using specific data sources; and
- Subject recruitment.

54 respondents from 27 different institutions completed the survey, and an additional 12 others began the survey but did not complete it. The study once again confirmed that the HIPAA Privacy Rule has created problems that are ongoing, expanding, and increasingly threatening to the nation’s health and economic well-being.

THE HIPAA PRIVACY RULE AND OTHER RESEARCH RULES

Research throughout the U.S. has long been governed by regulations to ensure ethical conduct and protection of the rights and welfare of individuals who participate in research studies. Patient privacy and the confidentiality of patient information, the most basic tenets of research, are ensured within institutional systems established for the review, oversight, and approval of research studies. With the advent of new information technology and the growing reliance on the electronic transfer of information by health care institutions in the late 1990s, public concerns increased over the threats such technology posed to individual privacy as it related to sensitive

health information. As a result, Congress included a mandate in HIPAA, passed in 1996, that the privacy of health information be dealt with immediately. The HIPAA Privacy Rule was the result of that mandate and for the first time codified requirements for the protection of health information. The Rule was implemented in 2003.

Prior to the implementation of the HIPAA Privacy Rule, the primary regulations regarding human subject research were the Common Rule (45 CFR 46) and human subject protection regulations (21 CFR 50) of the Food and Drug Administration (FDA). Within the Common Rule are requirements to ensure that institutions and researchers protect the safety and privacy of human research subjects, including the protection of patient information. The Common Rule requires that all research on human subjects, funded or conducted by a federal agency that has adopted the Rule, be approved by an institutional review board (IRB), and that all human subjects give informed consent prior to participation in a research study.⁵ The Common Rule has been adopted by 17 federal agencies, including the Department of Health and Human Services and the Department of Defense. The Rule also applies to the Central Intelligence Agency (by Executive Order 12333), and the Social Security Administration (by P.L. 103-296).⁶ Research funded or conducted by any other agency is not subject to the Rule. However, the prevailing practice of academic health centers is to require all research conducted at their institution to comply with the Common Rule regardless of funding source.

FDA regulations regarding human subject protection are virtually identical to the Common Rule, but specifically govern research being conducted for approval of any drug or device subject to FDA regulation.

The HIPAA Privacy Rule added a new dimension to research protections by strictly defining what constituted protected health information (PHI) and what defined certain institutions, or covered entities, that held such information. PHI is defined in the HIPAA Privacy Rule as information that is transmitted electronically, maintained in electronic media, or

transmitted or maintained in any other form or medium,⁷ which identifies (or could be used to identify) an individual. In order to be considered PHI, this information must also be held by a covered entity, which is defined in the Privacy Rule as a health care provider that conducts certain transactions in electronic form, a health care clearinghouse, or a health plan. Furthermore, the HIPAA Privacy Rule places restrictions on how covered entities use and share PHI. It was recognized soon after the HIPAA Privacy Rule was proposed that it posed substantial problems for the conduct of research because researchers needed access to medical records or other data that was now designated as PHI and subject to the restrictions placed upon the entities holding such information. These limit-setting barriers have the potential to cause serious problems for the research enterprise as a whole.

AAHC FINDINGS

General Impact of the HIPAA Privacy Rule

The growing elderly population, the challenging economy, the regulatory environment, and the increasing demands for new treatments and cures for disease and illness require a reexamination of the impact of the HIPAA Privacy Rule, not only on the institutions and research personnel sustaining the nation's research enterprise, but also on the patients who participate in research studies.

The survey contained five questions about the scope, pace, and cost of research and one question about the privacy protection afforded to research participants by the HIPAA Privacy Rule. In each question, respondents were asked to characterize the impact of HIPAA on a scale from strongly negative to strongly positive.

The AAHC findings show that:

- 59.1% of respondents characterized the impact of the Privacy Rule on the scope of research at their institution as negative or strongly negative while only 7.5% said the impact was positive or strongly positive.
- 63.6% said the pace of research at their institution was impacted negatively or strongly negatively by the Rule.

- 1.5% said the impact was strongly positive. No respondents characterized the impact as positive.
- 68.2% said the impact on the pace of research in the nation as a whole was negative or strongly negative.
- 3% characterized the impact as positive. No respondents said the impact was strongly positive.
- 70.8% of respondents characterized the impact on the costs of research as negative or strongly negative.
- 1.5% said the impact was positive and no respondents said the impact was strongly positive.
- 66.7% of respondents said that the Rule had no impact (neutral) on their institution's ability to secure research funding.
- 27.2% characterized the impact as negative or strongly negative and 3% said the impact was positive or strongly positive.
- 42.4% of respondents said that the Rule had no effect on privacy protection for research participants.
- 48.5% said the impact was positive or strongly positive and 9.1% said the impact was negative or strongly negative.

In short, the majority of survey respondents believe the HIPAA Privacy Rule had a significant negative impact on the scope, pace, and costs of research. The greatest concern was expressed about the negative impact on the costs of research. Respondents also indicated they were aware of research studies that were stopped or never pursued because of Privacy Rule related problems. The negative perceptions of research leaders are especially significant.

The HIPAA Privacy Rule imposes another limitation on America's ability to fulfill the promises of new science. A lack of interest in scientific careers, and decreased federal funding of research when coupled with the HIPAA Privacy Rule, create a burdened and troubled environment for the future.⁸

"The greatest concern was expressed about the negative impact on the costs of research."

Research Administration and Processes

The HIPAA Privacy Rule added many new procedures to institutional, administrative, and compliance functions that regulate a research study from its inception to its conclusion. Questions in this section of the survey address the nature and scope of the impact on research administration, administrative processes, and institutional resources. This section included questions on general infrastructure, institutional review boards, researcher time, and understanding of the HIPAA Privacy Rule.

There were six questions about the research administration and administrative processes related to the Privacy Rule. Respondents were asked about officials with designated responsibilities for HIPAA and research, hybrid entities (an institution that performs both covered and non-covered functions and has chosen to designate the health care components of the institution as the covered entity and the other components as not subject to HIPAA), and HIPAA's disclosure requirements, which permit research participants to request information about the release/sharing of their PHI. All six questions required yes or no answers.

The AAHC findings show that:

- 81.3% of respondents reported their institution had a designated official to assist researchers with Privacy Rule issues.
- 57.1% of survey respondents said their institution is a hybrid entity.
- Of those respondents with declared hybrid entities, 70% said the majority of researchers at the institution are employees of the covered entity portion.
- 17.2% of respondents said their institution had received requests from a patient

(or patients) for an accounting of research-related disclosures;

- 26.6% said they had not received any such requests; and
- 56.3% were not sure whether requests had been received.
- 63.9% of respondents said additional expenditures were required to ensure compliance readiness for disclosure requests.
 - 57.1% said additional staff was required, and 40.7% said a change in organizational structure was required.

The designation of an institutional official with responsibilities for assisting researchers with HIPAA problems is one indication of the far-reaching impact of the HIPAA Privacy Rule on institutional programs and functions. The significant number of institutions with an individual appointed to these tasks is just one example of the impact the Privacy Rule has had on the infrastructure of academic health centers.

Problems may arise when researchers who are employees of the non-covered entity portion of a hybrid entity need to access PHI for research purposes. While the Privacy Rule allows a great deal of latitude to covered entities when it comes to sharing PHI among personnel within that entity, the same does not hold true for sharing such information with researchers or health care professionals who are not employed by that entity. Almost 60% of respondents were at hybrid entities, and 70% of those respondents said the majority of the researchers at their institutions are employed by the covered entity. Thus, in addition to the hundreds of researchers at institutions that were not covered entities, a significant number of researchers at the hybrid entities would not be able to access critical information for research purposes.

The HIPAA Privacy Rule gives every patient the right to request a record of certain instances in which the institution shared (or disclosed) his or her PHI with another institution for the six years prior to the request. This requirement, referred to as "accounting for disclosures," was intended to increase transparency of information sharing and thus heighten public trust in institutions and systems that handle medical information.

"...in addition to the hundreds of researchers at institutions that were not covered entities, a significant number of researchers at the hybrid entities would not be able to access critical information for research purposes"

“The significant number of institutions with an individual appointed to these tasks is just one example of the impact the Privacy Rule has had on the infrastructure of academic health centers.”

To comply with this accounting for disclosures requirement, institutions must maintain large quantities of detailed information on every patient and research participant and have it readily and easily accessible to fulfill requests at any time.

Survey findings show that increased expenditures and staff, as well as changes in organizational structure, are required to maintain this information even though it appears that very few patients are requesting accountings of disclosures. These findings are particularly troublesome in a time of fiscal constraint when institutions must be sure that resources are allocated and used in the most effective fashion and applied to the conduct of essential research.

Institutional Review Boards

Within research universities, institutional review boards (IRBs) are the arbiter of what research can and cannot be conducted. IRBs are responsible for evaluating each proposed research protocol to assess if it adequately protects the health, safety, and privacy of human research participants and ensuring that the study will be conducted in an ethical manner. No human subject research can be conducted at an academic health center without the approval of an IRB. Since the implementation of the Privacy Rule in 2003, many institutions have had their IRBs take on additional responsibilities for the HIPAA Privacy Rule; others have established separate privacy boards to comply with the regulation. Given the centrality of the IRB to the research enterprise at institutions throughout the nation, the AAHC wanted to determine the impact of the Privacy Rule on IRB processes and whether IRBs were negatively affected in any way.

There were six questions about the impact of the HIPAA Privacy Rule on IRBs and the IRB process. The questions focused on the IRB’s responsibility for HIPAA, IRB workload, IRB staffing and faculty participation, and HIPAA

authorization and informed consent processes. Four of the questions required yes or no answers. The other two questions asked respondents to characterize the impact of the Privacy Rule on a scale from strongly negative to strongly positive.

The AAHC findings show that:

- 76.6% of survey respondents said their institution’s IRB had assumed additional responsibilities to address the Privacy Rule, including approving waivers of HIPAA authorizations.
- 62.3% of those respondents characterized the impact of these additional responsibilities on the IRB members and staff as negative or strongly negative. 20.8% said there was no impact on the IRB and 11.3% said the impact was positive or strongly positive.
- 31.3% said their institutions had hired additional IRB staff to assist with the added workload.
 - 51.6% of respondents said their institution had not hired additional staff and 17.2% were not sure.
- 32.8% characterized the impact of the Privacy Rule on faculty participation in IRBs as negative or strongly negative.
 - 57.8% of respondents said the Rule had no impact and only 3.2% said the impact was positive or strongly positive.
- 54% of respondents said their institution used a stand-alone HIPAA authorization to comply with the Privacy Rule.
- 67.2% of respondents said their institution had integrated the HIPAA authorization into the traditional informed consent documents.

For decades, the Common Rule has required that all research participants must give their informed consent before participating in a research study. The HIPAA Privacy Rule added the requirement that all human research participants sign an authorization document allowing the researcher to use their PHI for the specific study in which they were enrolling. Just as there is a process that allows an IRB to waive the need for informed consent when a study poses minimal risk to the research participant, so too HIPAA permits the IRB—or a privacy board—to grant waivers of authorizations to researchers when a researcher can show that

a study poses minimal risk to the participant's privacy. With this waiver, a researcher is permitted to use a participant's PHI without having to obtain an authorization from each study participant.

When IRBs assume the added responsibility for waivers of HIPAA authorizations, they automatically increase their workload. More than 75% of survey respondents said their institutions chose not to establish a new Privacy Board but rather had the IRB take on the responsibility for approving waivers of HIPAA Authorizations. The majority of those respondents felt the impact of those added responsibilities was negative. When IRBs accept responsibilities for Privacy Rule processes, time must be allotted at each IRB meeting for members to deal with HIPAA issues, which by necessity increases the IRB process. Of note, more than 50% said their institution had not brought on additional staff to assist with these added responsibilities.

The HIPAA Privacy Rule permits institutions to incorporate authorizations, which allow researchers to use a research participant's PHI, into informed consent documents. The informed consent document is signed by a research participant prior to enrolling in a study. It was assumed that a combined form would ease the administrative burden on institutions and thus facilitate the implementation of the Privacy Rule. In fact, it was widely assumed that the combined form would be more universally accepted and easily instituted than a stand-alone HIPAA authorization in addition to the usual informed consent document. Unfortunately, the outcome was not as envisioned.

Despite the intent to simplify, the addition of the HIPAA authorization made informed consent documents more complex and much longer. The incorporation of the HIPAA authorization into informed consent documents has been so unsuccessful in easing the burden that some institutions consider the two options as interchangeable. More than 20% of the survey respondents indicated that both a stand-alone HIPAA Authorization and an incorporated informed consent/HIPAA authorization were being used at their institutions.

Researcher Time

The public expectation is that researchers conduct research and that their time is dedicated to patient care, including discussing and explaining treatment options and the risks and benefits of treatment to research participants. Such conversations are necessary and vital in the physician-patient relationship. These encounters ensure that patients are sufficiently educated about their treatment options and have the necessary knowledge to give their informed consent in a research study.

There were two questions about the impact of the Privacy Rule on the time a researcher can spend on the conduct of research, including time spent with patients. For both questions, respondents were asked to characterize the impact of the Privacy Rule on a scale from strongly negative to strongly positive.

The AAHC findings show that:

- 57.9% of survey respondents said the HIPAA Privacy Rule had a negative or strongly negative impact on the time a researcher can spend conducting research.
 - 35.9% said the Rule had no impact at all on researcher time and only 6.2% said the Rule had a positive or strongly positive impact.
- 48.5% said the Rule had a negative or strongly negative impact on the time a researcher can spend with research participants explaining treatment.
 - 34.4% said it had no impact at all and 17.1% said it had a positive or strongly positive impact.

Understanding of the HIPAA Privacy Rule

Since its implementation, researchers have asserted that the HIPAA Privacy Rule was poorly constructed and lacked clarity on key issues. In addition, guidance from HHS on the Rule has been contradictory over the years. The AAHC survey wanted to determine whether misunderstandings

“Despite the intent to simplify, the addition of the HIPAA authorization made informed consent documents more complex and much longer.”

“Since its implementation, researchers have asserted that the HIPAA Privacy Rule was poorly constructed and lacked clarity on key issues.”

still persist five years after implementation, and whether the confusion is more pronounced among certain groups of stakeholders.

There were six questions about the understanding of the Privacy Rule by staff, researchers, and research participants. Respondents were asked about staff understanding of the HIPAA Privacy Rule as well as the processes necessary for a researcher to obtain a waiver of authorization from an IRB or Privacy Board. Respondents were also asked about their perceptions related to the level of understanding of the average researcher with regard to authorization waivers. The average research participant’s understanding of HIPAA authorization documents was also explored. Respondents were asked to rate the understanding of each stakeholder group on a scale from extremely poor to excellent.

The AAHC findings show that:

- 66.6% of survey respondents rated staff understanding of the HIPAA Privacy Rule regulations and guidance documents average or better (31.7% average, 23.8% above average, 11.1% excellent).
- 68.2% rated staff understanding of the process for granting waivers of authorization average or better (44.4% average, 17.5% above average, 6.3% excellent).
- 81.2% of respondents rated the average researcher’s understanding of the process for obtaining waivers of authorization as average or worse (32.8% average, 37.5% below average, 10.9% extremely poor).
- 82.7% of respondents rated the average research participant’s understanding of the language in HIPAA authorization documents as average or worse (35.9% average, 35.9% below average, 10.9% extremely poor).
- 75.1% of respondents rated the average research participant’s understanding of HIPAA authorization documents in medically invasive trials as average or

worse (31.3% average, 31.3% below average, 12.5% extremely poor).

- 78.1% rated the average research participant’s understanding as average or worse in minimal risk studies (32.8% average, 37.5% below average, 7.8% extremely poor).

The high ratings for staff understanding of the Privacy Rule are not entirely clear and may be related to intensive training or testing on the subject. The average or below ratings for the researchers are also understandable given the amount of time researchers must devote to the actual conduct of research. It is possible that confusion and misinterpretation of the Rule’s requirements, as well as the administrative burden that accompanies the Rule, may deter many top researchers from pursuing important scientific inquiry. Similarly, a low level of understanding among research participants could distract their attention away from adequate comprehension of the treatments and procedures included in the research protocol, and thus compromise the integrity of informed consent.

Multi-Site Research

The new paradigm of research, encouraged by the advent of NIH Clinical and Translational Science Awards (CTSAs), is multi-disciplinary, multi-site, and often conducted in collaboration with community partners. Such collaborative research involves the transfer and sharing of PHI between researchers and institutions. Because of the Privacy Rule’s restrictions on the transfer of information, the AAHC wanted to examine the impact of the Rule on multi-site research.

The survey contained four questions about: 1) the impact of the Privacy Rule on multi-site research; 2) participation of community partners in research; 3) multi-disciplinary research; and 4) the IRB approval process for multi-site research. The first three questions asked survey respondents to characterize the impact of the HIPAA Privacy Rule on a scale from strongly negative to strongly positive. The fourth question required a yes or no answer.

The AAHC findings show that:

- 42.2% of survey respondents rated the impact of the HIPAA Privacy Rule on the

participation of community partners in research as negative or strongly negative, while 35.9% said that there was no impact at all and 4.7% said the impact was positive. No survey respondents said that the impact was strongly positive.

- 47.6% said the impact of the Rule on multi-state or multi-site research was negative or strongly negative and 34.9% said there was no impact at all.
- 68.8% said the impact of the Rule on accessing identifiable information for multidisciplinary research was negative or strongly negative. Only 17.2% of respondents said there was no impact at all.
- 41.9% of respondents said that their institution requires multiple IRB approvals for multi-site research.
 - 40.3% said that it depended on the specifics of the study.

The Privacy Rule has the potential to pose a significant barrier to multi-site research, given the multiple restrictions it places on covered entities releasing PHI to other institutions. Community partners have been reluctant to participate in this research in the face of added administrative hurdles and complications, some of which arise from misinterpretation and lack of clarity in the Rule.

Neither HIPAA nor the Common Rule requires multiple approvals in the case of multi-site research. As long as one institution's IRB approves the protocol, the requirements for compliance have been met. However, a lack of clarity in the Privacy Rule, along with its guidance and a fear of liability, have resulted in more than 40% of survey respondents reporting that their institutions do require multiple approvals for multi-site research. Multiple IRB or Privacy Board approvals can radically slow down the research process and could discourage researchers or community partners from participating in multi-site research.

“The Privacy Rule has the potential to pose a significant barrier to such research given the multiple restrictions it places on covered entities releasing PHI to other institutions.”

Specific Data Sources

Certain types of research require that researchers perform retrospective analyses of populations and disease factors necessitating access to medical records and tissue samples (both considered PHI under the HIPAA Privacy Rule) sometimes months or years after the original consent was given and the patient received treatment. Researchers have called attention for some time to the specific sources of data to which they have difficulties accessing because of stipulations of the HIPAA Privacy Rule. Those data sources are stored tissues, genetic datasets, cancer (and other) patient registries, and data warehouses and medical records. The AAHC wanted to confirm whether access to this data is still hindered due to HIPAA Privacy Rule requirements.

The survey contained eight questions about the impact of the HIPAA Privacy Rule on research requiring access to one of the aforementioned data sources and on the number of studies affected. Survey respondents were asked to characterize the impact on each data source on a scale from strongly negative to strongly positive. Survey respondents were asked to answer the questions about the number of studies affected on a scale of none to all.

The AAHC findings show that:

- 53.2% of survey respondents characterized the impact of the HIPAA Privacy Rule on research requiring access to stored tissues as negative or strongly negative.
 - 24.2% said there was no impact at all and 9.7% said the impact was positive or strongly positive.
- 57.5% said that the Rule affected at least some of the studies requiring access to stored tissue (42.6% said some were affected, 13% said most were affected, and 1.9% said all were affected).
- 59% of survey respondents rated the impact of the Rule on research that requires access to data warehouses or medical records as negative or strongly negative.
 - 19.7% of respondents said the Rule had no impact at all and 8.2% said the impact was positive or strongly positive.

- 55.8% said that the Rule affected at least some of the studies requiring access to data warehouses or medical records (36.5% said some were affected, 13.5% said most were affected, and 5.8% said all were affected).
- 44.1% characterized the impact of the Rule on research requiring access to genetic datasets as negative or strongly negative.
 - 28.8% said there was no impact at all and 6.8% said the impact was positive or strongly positive.
- 42.2% said at least some of the studies requiring access to genetic datasets were affected (28.8% said some were affected, 9.6% said most were affected, and 3.8% said all were affected).
- 47.5% of respondents rated the impact of the Rule on research requiring access to cancer patient registries (or other patient registries) as negative or strongly negative.
 - 29.5% said there was no impact at all and 4.9% said the impact is positive or strongly positive.
- 44% said at least some of the studies requiring access to patient registries were affected (32% said some were affected, 10% said most were affected, and 2% said all were affected).

Prior to the implementation of the HIPAA Privacy Rule, the informed consent process under the Common Rule allowed research participants to consent to having their medical records and/or tissue samples stored and used later by other researchers and/or for later research studies, thus permitting researchers to do retrospective analyses using these important data sources. Under the Rule, research participants may authorize their PHI (e.g. medical records and tissue samples) to be stored. However, in order for researchers to use that stored information in research, they must seek a separate authorization from each individual providing the researcher the right to use the PHI in a new study. According to the survey respondents, the HIPAA Privacy Rule and its new added restraints have had a negative impact on this important research.

“The HIPAA Privacy Rule has made it more difficult, time-intensive, and costly to recruit research participants.”

Subject Recruitment

The HIPAA Privacy Rule has made it more difficult, time-intensive, and costly to recruit research participants. The AAHC wanted to determine whether the Rule was continuing to hamper patient recruitment.

The survey contained seven questions about the impact of the Privacy Rule on patient recruitment, the average personnel time required, costs of recruiting research participants, patient participation in research studies, and the diversity of patients consenting to participate in research. Two of the questions required a yes or no answer. The other five questions asked respondents to characterize the impact of the Rule on a scale from strongly negative to strongly positive.

The AAHC findings show that:

- 45.3% of survey respondents characterized the overall impact of the HIPAA Privacy Rule on research subject recruitment as negative or strongly negative.
 - 43.4% said HIPAA had no impact at all and only 3.8% said the impact was positive or strongly positive.
- 48.1% rated the impact of the Rule on the cost of recruiting research participants as negative or strongly negative.
 - 40.7% said there was no impact at all and 3.7% said the impact was positive. No respondents said the impact was strongly positive.
- 61.1% of respondents said that the Rule had a negative or strongly negative impact on the average personnel time spent recruiting research participants.
 - 27.8% said the Rule had no impact at all on personnel time and 3.7% said it had a positive impact. No respondents said the impact was strongly positive.
- 42.6% said the Rule had no impact on patient participation in research studies.

- 37.1% said there was a negative or strongly negative impact and 9.3% said the impact was positive or strongly positive.
- 47.2% said the Rule had no impact on the diversity of patients consenting to participate.
 - 32% said there was a negative or strongly negative impact and 3.8% said there was a positive or strongly positive impact.

The HIPAA Privacy Rule mandates that researchers and research staff complete complex and often duplicative administrative procedures before they may begin to contact potential research participants. Research personnel must also spend significant amounts of time explaining the HIPAA Authorization forms. This is in addition to the time spent explaining informed consent documents. Many researchers contend that only a well-educated and highly literate population could understand the complex and esoteric language of HIPAA authorization documents, resulting in denied access to research studies for a large segment of the population. Often people are very intimidated by the amount of paperwork, have difficulty trying to understand the complex maze of HIPAA terms and conditions, and thus are not able to focus on the issues related to the medical treatment. This negative impact on participant recruitment and the diversity of research participants has fundamentally changed the conduct of research. With a less diverse participant pool, the scientific credibility of research is at risk for the future.

CONCLUSION

The HIPAA Privacy Rule has now been fully implemented for five years and the problems observed at implementation remain today. Researchers still overwhelmingly believe that the HIPAA Privacy Rule has had a negative impact on the scope, pace, and cost of research.

The Privacy Rule creates obstructions most significantly in research requiring access to stored tissues, genetic datasets, patient registries, and data warehouses and medical records. These types of information are often crucial in conducting population-based research, which is often at the cutting edge of genomics and studies investigating

the causes of life-threatening illnesses like cancer and heart disease. For the results of population-based research to be robust and scientifically credible, access to medical records or information from thousands of patients is required. The Privacy Rule has rendered obtaining this type of data an arduous and often insurmountable task.

The consequences of the HIPAA Privacy Rule have not only significantly slowed the pace of scientific discovery in this country, but also threatened the nation's ability to compete in a global economy. Institutions are increasing expenditures to pay for additional staff to be compliant with the Privacy Rule. In addition, as the time necessary for research studies to be approved and conducted has lengthened, the cost of research has substantially increased.

In the face of economic crisis and rapidly diminishing funding for research at academic health centers, increased research costs created by the Privacy Rule will only continue to reduce the number and quality of studies in the United States. Given the significance of research to the United States' economy, there are justifiable concerns from the research community that overly burdensome regulations that do not benefit the patient might threaten an enterprise critical to the nation's future. This is particularly evident in the negative impact of the Privacy Rule on multidisciplinary, multi-site research projects that have been recommended and encouraged by the government.

The problems with the HIPAA Privacy Rule are extensive and are likely to be even broader than the survey suggests. Furthermore, there is no clear evidence that the Rule is achieving its intended purpose in the research arena. Given the longstanding history of the Common Rule in research, it would be most expedient and effective to exempt research from the HIPAA Privacy Rule and to defer to the Common Rule. The Common Rule — an essential safeguard that has worked successfully — has been responsible for ensuring

“Researchers still overwhelmingly believe that the HIPAA Privacy Rule has had a negative impact on the scope, pace, and cost of research.”

“The problems with the HIPAA Privacy Rule are extensive and are likely even broader than the survey suggests.”

the protection of research participants’ safety and privacy for more than 30 years.

The negative impact of the HIPAA Privacy Rule on research ultimately translates into negative consequences for patients, with more terminally ill patients missing out on the opportunity to participate in clinical trials that have the potential to save their lives. To remedy this threat to research and the American people, revision of the HIPAA Privacy Rule is imperative.

The AAHC recommends that research be exempt from the HIPAA Privacy Rule and that it be solely governed by the Common Rule. Furthermore, the AAHC recommends a revision of the Common Rule to incorporate more explicit standards for the privacy of health information and to augment the protections of the Common Rule to accommodate new technologies and guard against new threats to patient safety and privacy.

References:

- ¹ Wolf MS, Bennett CL. Local perspective of the impact of the HIPAA privacy rule on research. *Cancer* 2006;106:474-9.
- ² Armstrong D, Kline-Rogers E, Jani SM, Goldman EG, Fang J, Mukherjee D, et. al. Potential impact of the HIPAA privacy rule on data collection in a registry of patients with acute coronary syndrome. *Arch Intern Med* 2005;165:1125-1129.
- ³ Ness RB. Influence of the HIPAA privacy rule on health research. *JAMA* 2007;298(18):2164-2170.
- ⁴ Association of Academic Health Centers. HIPAA Creating Barriers to Research and Discovery. Washington: 2008.
- ⁵ 45 CFR 46 [online]. 2005 Jun 23[cited 2008 Jun 26]; Available from: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.
- ⁶ Williams ED. Federal protection for human research subjects: an analysis of the Common Rule and its interactions with FDA regulations and the HIPAA Privacy Rule (Order Code RL32909). Congressional Research Service, The Library of Congress: 2005.
- ⁷ U.S. Department of Health and Human Services, Office for Civil Rights. HIPAA Administrative Simplification Regulation Text (45 CFR Parts 160, 162, and 164). Unofficial version, as amended through February 16, 2006.
- ⁸ National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. Rising above the gathering storm: energizing and employing America for a brighter economic future. The National Academies Press, Washington DC: 2007.



Association of Academic Health Centers[®]
Leading institutions that serve society

VISION

To advance health and well-being
through the vigorous leadership of
academic health centers.

MISSION

To mobilize and enhance the strengths
and resources of the academic health
center enterprise in health professions
education, patient care, and research.

1400 Sixteenth Street, NW, Suite 720
Washington, DC 20036
202.265.9600
202.265.7514 fax
www.aahcdc.org

For more information, contact:

Mindy Steinberg, MPH, Program Associate, msteinberg@aaahcdc.org

Elaine Rubin, PhD, Vice President for Policy and Program, erubin@aaahcdc.org

© 2009 by the Association of Academic Health Centers