

# HIPAA Creating Barriers to Research and Discovery

Association of Academic Health Centers

## HIPAA Problems Widespread and Unresolved Since 2003



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Recent findings from the Executive Leadership Group of Vice Presidents for Research of the Association of Academic Health Centers (AAHC) reveal that the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) has serious and often detrimental effects on biomedical research. It is known that the U.S. is a global leader in biomedical discovery and that research conducted at academic health centers has led to new lifesaving discoveries and treatments for disease and chronic illness. What is often not recognized beyond the research community is the negative impact—often unintended—of the myriad regulations and mandates such as HIPAA. Ultimately, societal interests are at stake when unintended barriers hamper research processes and progress. The AAHC learned from focus groups around the U.S. that one regulation in particular, HIPAA, continues to hamper a wide array of health research activities, and corrective action is needed in order to advance biomedical research and science in the U.S.

Vice presidents for research from several academic health centers conducted focus groups with leading researchers and research administrators at their respective institutions to assess the impact of HIPAA on research activities. Focus group participants were asked to describe how HIPAA has affected different aspects and areas of research. Researchers identified major cross-cutting areas of negative impact, as well as particular categories of research that have suffered setbacks from HIPAA.

The cross-cutting concerns for researchers nationwide are: (1) ambiguity and misinterpretation of the rule; (2) administrative burden; and (3) recruitment of research participants. The specific areas of research particularly affected by HIPAA include: (1) access to stored tissue and genetic datasets; (2) data warehouses, Clinical and Translational Science Awards, and medical records; and (3) community research. Together, these

concerns show that HIPAA is no small obstacle; it threatens the social good by seriously restricting biomedical research and unnecessarily slowing the path toward life-saving discoveries.

## THE HIPAA PRIVACY RULE

Passed by Congress in 1996, HIPAA was designed to guard the protected health information of patients. A key part of HIPAA is the Privacy Rule, which gave patients new rights to access their medical records, restricted most disclosures of protected health information (PHI), and established new sanctions for improper use of PHI. While research was not a primary consideration of HIPAA, the impact and consequences of HIPAA on research have grown over the years, creating a web of confusion, misinterpretation, and obstacles that now threaten the research enterprise.

The Privacy Rule applies to a “covered entity,” which is a health plan, a health care clearinghouse, or a health care provider. Researchers are not themselves part of the covered entity, and HIPAA was not designed to effect health research.<sup>1</sup> However, researchers are affected by the rule if they receive their data from health care providers, which are covered by the rule.

## NEGATIVE IMPACT ACROSS THE RESEARCH ENTERPRISE

### Ambiguity and Misinterpretation Stalling Research

Focus groups revealed many HIPAA-related problems arising from the widespread confusion over the rule’s unclear language. Confusion over the meaning of HIPAA was found to be common among all players, from research participants to privacy boards to institutions and even states. Different institutions and states interpret and

implement HIPAA inconsistently, which makes multi-site and inter-state research more difficult, if not impossible.

In addition, among the multiple sets of regulations governing confidentiality and exchange of clinical research information (e.g., regulations from the Food and Drug Administration, National Institutes of Health, state genetic privacy laws), HIPAA overlaps with some regulations and conflicts with others.

Concern was raised over a lack of understanding of HIPAA and the fear of violating regulations that discourage community partners (e.g., hospitals) from joining or collaborating in research with academic health centers. One group commented:

After discussions with the community sites, it appears their reluctance to provide a waiver of authorization is based at least in part on their lack of understanding the HIPAA regulations as they pertain to research.

A recurring theme raised in focus groups was that fear of liability causes unnecessarily strict organizational decision-making, which seriously impedes research. Five years after HIPAA’s implementation, the lack of clarity and information still drives inappropriately strict construction of the rule. Some focus group members noted that:

Fear of regulatory punishment is driving IRB [Institutional Review Board]/Privacy Board, Privacy Officer and Organizational decision-making in clinical research...

Drawing attention away from patient care and the need to research future treatments, HIPAA is causing decision-makers to focus instead on deciphering unduly complex regulations and protecting institutions from liability.

### Administrative Burden Increases

All focus groups consistently reported the administrative burden created by HIPAA. Across the board, focus group members said that by generating additional paperwork and causing confusion and misinterpretation, HIPAA has imposed substantial and onerous demands on the time of research and administrative personnel.

Since HIPAA has been implemented, more time is required to (1) define what does and

does not constitute research; (2) complete additional forms and review documents; (3) track unauthorized disclosures of protected health information and requests for amendments; and, (4) de-identify data from research participants. HIPAA has also increased the amount of time that researchers must spend reviewing legal matters with research participants and decreased the time available for substantive discussions about risk, diagnosis, and clinical treatment issues. Likewise, HIPAA has increased the amount of time that researchers must spend discussing regulatory matters with community practitioners and staff, educating them about the regulation and addressing areas of inconsistency or confusion. One focus group noted:

The administrative burden is large... An enormous amount of time has been spent discussing the issues with community practices.

Another focus group summed it up:

All that HIPAA represents is the need for more forms, more review, more time and more personnel costs.

These impositions on the time and resources of the principal investigator and research team are “slowing research unnecessarily,” according to all groups, without providing benefit to research or the public.

Widespread misunderstandings of HIPAA have also raised the costs of conducting research. Institutions have had to hire additional staff to handle administrative tasks, assist investigators, and conduct training or provide clarification about the rule, all of which also drains funding for the research projects. One focus group noted:

The complexity of the regulations leads to the need for multiple authorization and consent documents, which is costly to investigators and Privacy Board/IRB staff.

Money and resources are also wasted or lost when a study, due to HIPAA complications, cannot conduct follow-up contacts. As noted by members of one group:

We are unable to locate a significant number of our patients, which limits the ability of the biobank to provide needed follow-up data to the researchers, therefore, wasting a lot of money on obtaining patients [whom] we cannot follow-up.

Focus groups were quick to point out that the additional demands of time and cost of implementing HIPAA are producing high levels of stress and are adversely affecting the researchers themselves. There was significant investigator and staff burnout with fewer faculty members willing to participate in clinical research, which further threatens to weaken the clinical research infrastructure not only for academic health centers but also for the nation.

## Research Participant Recruitment Hampered

The negative impact on participant recruitment was perceived to be one of the greatest threats that HIPAA poses to research. Researchers often have difficulty accessing patient records for initial review or making an initial contact with the patient. When the principal investigator is unable to review patient medical records to identify eligible patients, that task falls to employees of the health care provider’s office. However, those employees often lack the time to complete this additional work and are often unwilling or unable to assist.

Academic health center focus groups reported that investigators were unable to contact participants from past studies to assess their interest in new studies. Recruitment of participants for healthy control groups is hampered by time- and effort-intensive procedures, such as waivers or approval by the Institutional Review Board (IRB) for amendments, which slow research and limit patient numbers. One group noted:

We would like to recruit normal [healthy] controls for the biobank. To do this, we need to submit an amendment and get a waiver for authorization for screening and recruiting. This takes a lot of time and effort... The extensive efforts to expand our ability to recruit limit our patient numbers.

The delays caused by HIPAA authorization are “seemingly unnecessary requirements” for studies

**“The negative impact on participant recruitment was perceived to be one of the greatest threats that HIPAA poses to research.”**

such as surveys or telephone interviews, which do not involve any protected health information, and for which HIPAA authorization therefore seems irrelevant.

The confusing and legalistic terminology of HIPAA documents were perceived as undermining research participant recruitment by most of the focus groups. Since patients are easily overwhelmed by the length and complexity of HIPAA documents, especially during critical care situations, HIPAA appears to make potential participants less likely to agree to join studies. Furthermore, a substantial number of research participants have difficulty understanding the long legalistic forms. One focus group commented:

The families think HIPAA documents are too long and too much information for them to handle. There are reading problems... Interpretation and understanding of what is to happen [in the study] is often obscure at best.

Another focus group noted:

The complexity of language in and length of these documents is confusing to subjects and betrays the plain language rule. This is detrimental to the effectiveness of the consent process.

Paradoxically, it was pointed out that the excessive length of documentation may discourage potential participants from reading through the forms carefully before signing, thus undermining the entire notion of “informed consent.” It is generally agreed that HIPAA impedes the ability of participants to obtain clear, concise, intelligible information about the research study.

## KEY RESEARCH AREAS THREATENED

### Restricting Access to Stored Tissue & Genetic Datasets

Focus groups pointed out that HIPAA regulations have imposed additional difficulties for particular types of studies, including those involving stored tissue and genetic datasets.

“Differences between state genetic privacy acts also produce ambiguities about which state’s act applies”

### Removing the Patient from the Data

De-identified data has diminished value for genetic datasets. If research is to unravel the genetic causes of complex diseases, it is critical that researchers be able to access the identifiable aspects of genetic data. One focus group member noted:

The tissue alone is not as valuable as the data [pertaining to the signs and symptoms of the patient] associated with the tissue. HIPAA is problematic in this way.

### Back to the Future: Ongoing Concern

Several concerns involve the future use of data. Because HIPAA presents obstacles in locating patients for follow-up in the months or years after the study, biobanks lose the ability to obtain crucial follow-up data. Researchers may be unable to notify patients in a “duty to warn situation”, such as if an adverse mutation is found and a treatment becomes available.

Furthermore, researchers are not permitted to write a generic authorization for future use of data, even though it is difficult or even impossible to predict how genetic data might be used in the future.

Additional concerns and confusion involve data collected in the past, before HIPAA regulations were implemented. Research slides created prior to HIPAA implementation may not adhere with the rule. Likewise, databases in existence before April 2003, which are attractive for longitudinal studies, are problematic for researchers to use because of the HIPAA rule.

### Lack of Harmonization of Regulations

Tissue banks and genetic datasets are also affected by conflicts between state and/or federal regulation. For example, interstate genetic datasets may be required for analyses of larger populations, but are precluded by state laws. Differences between state genetic privacy acts also produce ambiguities about which state’s act applies depending on where the research is conducted, where material is stored, where patients live, or other variables. There is also concern about conflict with guidelines from the National Institutes of Health (NIH), given that new NIH guidelines dictate that datasets from NIH-funded studies should be widely available.

A number of specific administrative burdens affect this area of research too. These burdens include contracting with hospitals for access to tissues; paying for authorized staff time to generate de-identified data; and obtaining participant reauthorization in case of extension of research beyond the consented work or “duty to warn” situations with genetic research.

### **HIPAA Obstructs Data Warehouses, CTSAs, & Medical Records**

HIPAA also impacts data warehouses, Clinical and Translational Science Awards (CTSAs), and/or medical records. CTSAs present a dramatic new opportunity for interdisciplinary research at academic health centers nationwide, and the ability to move data among different sites is critical to such research. Problems with CTSAs reveal how HIPAA is holding back the pace of biomedical research.

In one institution, HIPAA regulations have stymied the institution’s efforts to create an integrated electronic medical records system, which is a mandate of the CTA. Another institution noted that collaboration in statewide CTA networks is hampered by institutional policies that preclude direct periodic follow-up with patients to define future medical conditions. Follow-up is only permitted if research participants, at the time of sampling, give consent to be contacted for future follow-up.

Focus groups noted that HIPAA regulations have generally hindered researchers’ ability to access electronic medical records, and therefore have generated burdensome requirements for printing, organizing, filing, and securing paper copies of records. Members of one focus group commented, “Ownership of data, patient records, and de-identifying data have all resulted in halting any development of a centralized mechanism for centralizing data.”

Many institutions also face difficulties in engaging different parties (such as university departments and the hospitals) in joint ventures due to HIPAA-related complications. Problems extend to statewide datasets and research as well.

Institutions noted a great impact on research in the minimal risk category (e.g., database

research) where extra documentation significantly slows research because (unlike interventional studies where authorization is obtained) waivers, business associate agreements and accounting for disclosures are the primary mechanisms for compliance with HIPAA for these studies.

### **Community Research in Danger**

Another troubling finding is that hospitals and community physicians are often reluctant to become engaged in research, largely due to HIPAA requirements. Much medical research involves collaboration with hospitals, community physicians, and other health providers outside the academic health center. However, since the implementation of HIPAA, many health care providers have been reluctant to become involved with clinical research. As one focus group summed up the problem:

Practitioners’ offices do not wish to participate in clinical research because of time issues and ... the burden of potential liability because of participation.

Such reluctance on the part of providers often stems from misinterpretation and confusion over the meaning of HIPAA. Many fear liability and punishment for potential privacy violations and misunderstand HIPAA regulations as they pertain to research, which can lead to overly cautious and unduly restrictive interpretation of the rule. Such unnecessarily and excessively strict interpretation has been impeding and significantly delaying research progress.

Policy barriers prevent institutions from collecting and analyzing data from regional and statewide groups working on the same chronic diseases. By causing duplication and inefficiency, these obstacles slow the progress of research.

### **HIPAA PROBLEMS WIDESPREAD AND UNRESOLVED**

Five years after HIPAA’s implementation, persistent problems are still creating impediments to valuable and important research. The AAHC’s findings provide new insight on HIPAA while affirming past observations about the impact of HIPAA on research, indicating that the problems that first

appeared after HIPAA's implementation in 2003 remain serious and widespread. An earlier survey of investigators, study coordinators, research administrators, and other research personnel at medical schools found that 72 percent of clinical research was negatively affected by HIPAA. Patient recruitment and data access were the functions reported to be the most affected at that time.<sup>2</sup>

Hearings at the Department of Health and Human Services in 2003 and 2004 revealed widespread concern over HIPAA's detrimental impact in increasing the time, effort, and cost of conducting research; hampering research participant recruitment; discouraging community research; and obstructing family history studies, retrospective chart review studies, and other types of research.<sup>3</sup>

Little changed by 2006, when the Institute of Medicine uncovered similar concerns, including administrative burden, variability in the Privacy Rule's implementation, barriers for family history studies and population-based studies, and adverse impact on research participant recruitment.<sup>4</sup>

Specific case studies demonstrating HIPAA's impact have appeared in peer-reviewed literature. In 2005, the University of Pittsburgh found that research participant recruitment in a study of pregnant women dropped dramatically after the HIPAA compliance date. When HIPAA introduced restrictions on the researchers' ability to identify potential participants, average weekly recruitment fell from 12.4 women per week to an average range of 2.4 to 5.7 women per week.<sup>5</sup> That same year, the University of Michigan showed that in a study of acute coronary syndrome patients, HIPAA caused consent rates to drop dramatically. Consent rates fell dramatically from 96.4% to 34.0% after HIPAA was implemented.<sup>6</sup>

The most recent evidence of HIPAA's negative impact on research came from a 2007 report by University of Pittsburgh researchers who surveyed more than 1500 epidemiologists in academia, government, industry, and other sectors, and found that 67.8% of respondents declared that HIPAA had made research "a great deal" more difficult.<sup>7</sup>

**"...the patient whom HIPAA is designed to protect does not appear to recognize, understand, or care about this complex law as it applies to research"**

## CONCLUSION

The HIPAA Privacy Rule has a negative impact on research by:

- Generating confusion and misinterpretations due to the rule's ambiguity
- Imposing a heavy administrative burden
- Hampering research participant recruitment

AAHC findings also identified how HIPAA harms certain areas and types of research, specifically:

- Access to stored tissue and genetic datasets
- Data warehouses, CTSAs, and medical records
- Community research

The significant burden that HIPAA imposes on research is not offset by any corresponding benefits, and HIPAA may, in fact, not offer any greater protection than current longstanding effective regulations in the research arenas. The privacy of research participants is already adequately guarded by the Common Rule, which is the Office for Human Research Protections' Federal Policy for the Protection of Human Subjects. Research participants are also protected, if necessary, by Certificates of Confidentiality issued by the NIH and other agencies of the Department of Health and Human Services.

In fact, HIPAA requirements actually undermine the notion of true "informed consent." It appears that as various documents, such as authorizations, opt-in/opt-out documents, and genetic consent forms grow longer and more confusing, the less likely research participants are to carefully read or comprehend such documents. Putting more paperwork before research participants is counterproductive if participants are less likely to understand what they are signing.

Finally, the patient whom HIPAA is designed to protect does not appear to recognize, understand, or care about this complex law as it applies to research. It seems that research

participants do not care to make requests for information about disclosures, as permitted by HIPAA. The HIPAA Privacy Rule gives patients and research participants the right to request and receive an accounting of disclosures of their protected health information if they had signed a HIPAA waiver of authorization. However, findings show that such requests are made exceedingly rarely. For example, one academic health center reported that between 2003 and 2007, the institution received only 23 requests for accounting of disclosures, and none were from research.

## Recommendations

In order to ensure that American science can flourish, there is a need to address HIPAA-related barriers that are impeding research. The AAHC recommends the following:

- The Department of Health and Human Services (DHHS) should revise the HIPAA Privacy Rule to allow it to defer to the Common Rule in matters of protecting the privacy of protected health information of research participants. Existing Common Rule guidelines already protect health information, and if an IRB believes that extra protection is warranted, it can require a Certificate of Confidentiality. Such revisions should be carried out through the DHHS Office of Civil Rights through their policy change mechanism.
- The Office for Human Research Protections (OHRP) should provide updated guidance to emphasize the importance of preserving the privacy of protected health information (PHI). OHRP guidance has the effect of federal rule for IRBs and this unequivocal guidance from them would ensure that the HIPAA deferral to the Common Rule would not sacrifice any increment of PHI protection.
- Congress should implement a national genetic privacy act (GPA) or include a GPA in a revision of HIPAA. Implementation of a national GPA could help resolve the current conflicts and confusion over differences in state genetic privacy acts and HIPAA, which are currently hampering tissue bank and genetic dataset research.

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