

IMPACT OF THE HIPAA PRIVACY RULE IN THE HMO RESEARCH NETWORK

*A Sub-study for the Institute of Medicine Committee on
Health Research and the Privacy of Health Information: the HIPAA Privacy Rule*

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BACKGROUND

The Health Insurance Portability and Accountability Act (HIPAA) contains provisions for protecting the privacy of health information, and includes the HIPAA Privacy Rule, which specifies how individually identifiable health information may be used. Health-related research was consequently affected by the HIPAA Privacy Rule, since personally-identifiable information is often necessary to address numerous research questions. Quantifying this effect has taken on increased urgency, since a chorus of anecdotes and small studies have suggested that the HIPAA Privacy Rule and its procedural requirements have hampered research without meaningfully protecting the privacy of health information.

The Institute of Medicine (IOM) commissioned a series of studies to examine the impact of the HIPAA Privacy Rule on health research. The Cancer Research Network, which is a multi-site collaboration involving members of the HMO Research Network (HMORN) was identified as one of the study settings in which to examine the effects of HIPAA. The HMORN is a consortium of over 250 scientists who work in 15 research centers that are all based in health care delivery systems. All 15 sites, therefore, are part of covered entities. This study afforded an opportunity to both assess the interpretation of the HIPAA Privacy Rule at different institutions, and examine the impact of this Rule on multi-site studies.

In 2007, under the leadership of Sarah Greene at the Group Health Center for Health Studies, three data collection efforts were undertaken to systematically examine the effect of the HIPAA Privacy Rule in the HMO Research Network.

- Web-based survey of investigators in the Cancer Research Network
- Follow-up telephone survey for investigators who report having a study affected by the HIPAA Privacy Rule Regulations
- Mailed survey of IRB Administrators at the 15 HMORN sites

METHODS

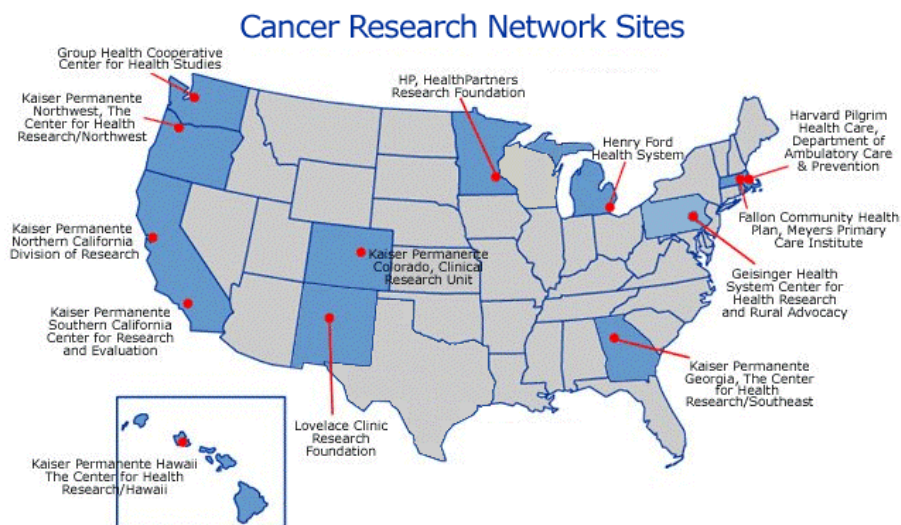
The Group Health Human Subjects Review Committee approved all three data collection components, as did the Institutional Review Board (IRB) of the Institute of Medicine. Final data collection instruments are provided in a binder of study materials sent with this report.

A) Web-based survey of investigators

Investigators from each of the Cancer Research Network sites were identified using publicly available web sites of each research center. Sites participating in the Cancer Research

Network sites are shown in Figure 1 below. Public sites were used to preempt the need to get IRB approval from every site to contact their investigators.

Figure 1.



We designed a survey in consultation with members of the IOM Committee. The survey was designed to be administered via web, and contained questions about the investigator's personal experience with the HIPAA Privacy Rule on one of his/her own studies, including changes to the study that were attributable to the HIPAA research provisions, and the effect of these alterations on study time, design and costs. We also asked general questions of all respondents (i.e., not just those directly affected by the HIPAA Privacy Rule) about attitudes toward HIPAA and use of the research-related provisions (e.g., waivers of authorization, limited data sets, etc.). Finally, respondents were invited to provide contact information in order to share their experiences via a follow-up interview.

Survey invitations were sent via email, and each invitee received a unique URL taking him/her to the survey. Once a respondent completed the survey, they were unable to reuse that URL, preventing completion of multiple surveys. Up to three invitations (initial + 2 reminder emails) were sent to prospective respondents.

Survey data were stored in the web server, then downloaded into SAS (version 9.0, Cary NC) for analysis. We report frequencies and simple descriptive statistics for these data.

B) Follow-up interviews

Telephone follow-up interviews were conducted using a semi-structured interview guide. The guide ensured systematic collection of key study details, but also enabled the respondent to tell their own individual stories about how the HIPAA Privacy Rule affected their project. The interview guides confirmed details about data collection, data sources, aspects of the protocol that were affected, and for studies with participant contact, the investigators estimation of whether the HIPAA-related requirements affected recruitment or elicited other reactions from investigators. All respondents were asked whether compliance with HIPAA Privacy Rule requirements added to the cost of their research project, and how this experience may influence their future research.

Interviews were recorded upon explicit permission from the respondents. At least two members of the study team were present for each interview to assist with note-taking and ensuring that all relevant information was captured. The principal investigator reviewed the qualitative data for common themes as well as unique issues, and rated responses as positive, negative or neutral.

C) IRB Administrator Surveys

A 6-page survey was developed in close consultation with representatives from the IOM Committee, to assess the perspectives of IRB members about the HIPAA Privacy Rule at their site. The survey included items in the following general tracks:

- how the IRB interacted with the privacy office at their health plan
- sample scenarios about HIPAA-related incidents to gauge each IRB's reaction
- attitudinal items about the impact of the Privacy Rule
- extent to which local sites had developed policies or procedures to address the regulations
- training related needs

We used the publicly-available web sites of each HMORN research center to identify the IRB administrators by name, where possible. If no name was available, surveys were addressed generically to "IRB administrator." The mailing protocol entailed sending the survey with a cover letter and \$5 gift card via overnight express mail (Federal Express), with both a standard business reply envelope and overnight mail return envelope. These two options were provided for the respondent's convenience, in case s/he did not have an on-site Federal Express drop box. A second mailing (identical except for no gift card) was sent to all participants about 10 business days after the first mailing. The surveys were separated from their mailing envelopes immediately upon receipt, effectively anonymizing them. A participant ID number was assigned at the point of data entry. All data were hand-entered into a Microsoft Access™ database and verified by a second member of the study team. The SAS System (version 9.0, Cary NC) was used for data tabulation and analysis.

RESULTS

A) Investigators Survey

A total of 235 investigators received invitations to participate in the web-based survey. Of these, 26 of the email invitations bounced, and 2 actively refused to participate. Ultimately 89 people responded to the survey—the remaining 118 never responded after the three invitations sent per protocol. The completion rate among those invitees with valid addresses was 43%. Overwhelmingly, these were doctoral-level scientists, and 72% had been in research for 10 or more years.

Nearly three-fourths of respondents, (73.9%) reported having a study affected by the HIPAA Privacy Rule and of these, 61% had been affected more than once. The study timeline was negatively affected more than half the time (54.5%). About 1/3 of the time, the investigator identified the need to modify the study because of HIPAA Privacy Rule requirements, and about one-third of the time, the Institutional Review Board made this determination. There were an array of different modifications required due to the HIPAA Privacy Rule, from the planned method of identifying participants (28.8%), restrictions on the kind of identifiers that could be collected (28.8%), and requirements to include additional consent and/or authorization language (59.4%). Delays due to HIPAA ranging from one month to more than three months were reported by one-third of the study respondents.

We sought to quantify the added time and effort required to address the changes to the study that were related to the HIPAA Privacy Rule. Participants reported a median of two additional

IRB iterations and a median of 20 additional person hours, and 20% reported four or more iterations were required. Twelve percent reported that 100 or more personnel hours were needed to address HIPAA-related changes.

In addition to collecting information about directly-affected studies, we asked respondents for their general viewpoints on the impact of the HIPAA Privacy Rule. Table 1 shows the breakdown of responses to this series of questions. Notably, while respondents overwhelmingly agree that the HIPAA Privacy Rule has strengthened patient privacy, over 60% are still reporting difficulty working with the regulations, nearly five years after the April 2003 implementation date. More troubling is the fact that 65% indicated that they somewhat or strongly agreed that they are hesitant to pursue new study ideas due to the HIPAA regulations. Also, a non-trivial proportion of respondents (22%) felt that their IRB did not balance the triad of concerns of the institution, the patients, and the researchers.

Table 1. Investigators' General Viewpoints on the HIPAA Privacy Rule

QUESTION \ RESPONSE	Strongly disagree	Disagree somewhat	No opinion	Agree somewhat	Strongly agree
The HIPAA Privacy Rule has strengthened patient privacy provisions.	6.0%	8.4%	10.8%	59.0%	15.7%
There are study ideas that I have considered pursuing, but am hesitant to do so because of the HIPAA regulations.	10.8%	18.1%	6.0%	41.0%	24.1%
I have found it easy to work within the new HIPAA regulations.	24.1%	36.1%	18.1%	20.5%	1.2%
My IRB's interpretation of HIPAA balances the concerns of the institution, the patients and our researchers.	6.0%	15.7%	15.7%	45.8%	16.9%

Another series of questions pertained to the effect of the HIPAA Privacy Rule in the context of multi-site studies. Nearly four-fifths (78%) reported participating in a multi-site study since the Privacy Rule was implemented, and 54% indicated that different IRBs raised different concerns related to HIPAA. Moreover, 45% of these respondents said that these differing concerns led to protocol variability from site to site, and in two instances participating sites dropped out of the study as a result of the HIPAA-related issues.

We asked investigators whether their IRBs' interpretation of the HIPAA Privacy Rule had changed since 2003, and approximately 40% said that it had, however, we did not probe to assess the extent of these changes, or whether the investigators felt the interpretation had a positive or negative effect on the research.

The HIPAA Privacy Rule introduced several new types of research-related provisions for acquiring and protecting data, including the use of so-called limited data sets, and criteria for waiver of HIPAA authorization. We sought to assess investigators use of these provisions as some are more facilitative toward research than others. Over 83% had used limited data sets with a data use agreement in place, and 76% had incorporated the HIPAA Authorization waiver directly into a study consent form (as opposed to using a standalone form). This suggests that researchers have become very facile with the research provisions necessitated by HIPAA. Finally, we asked about the extent to which accessing de-identified data had posed a problem, and 42% replied this was an occasional problem, and 13% indicated this was "routinely difficult." We provided space in the survey for respondents to share their open-ended remarks, whether about their own experience with the HIPAA Privacy Rule, this project itself, or comments on

specific ways that HIPAA has added to or detracted from research, and the balance of patient privacy and research considerations. Many respondents offered balanced perspectives about HIPAA, commenting on the positive effects on patient privacy, but also the burdensome paperwork and delays that results. A sample of respondents' verbatim remarks are provided below as embodiments of the tension between the importance of HIPAA's protective effects and challenges it poses for researchers. The full battery of comments is provided in the Appendix.

Table 2. Sample of Investigators' Verbatim Comments from Web-based Survey

<p>As organizations become increasingly concerned about HIPAA violations, some forms of research are becoming significantly more difficult to conduct. For example, interviewing individuals outside our research facilities and recording those interviews on digital recorders is becoming problematic (no differentiation is being made between laptop computers that can carry data for millions of people and a voice recorder that includes data from one or two individuals at a time). This makes it difficult to collect real-world data in settings (e.g., homes, care settings) that are critical to our understanding of chronic disease management, death and dying and interactions and processes of care delivery. I'm very supportive of protecting patient privacy and I believe HIPAA has been positive in that it has sensitized researchers to privacy concerns. At the same time, it seems that organizations are so concerned about HIPAA violations that they aren't adequately assessing the true differences in risks associated with different methods of data collection and storage. As these methods are increasingly limited, our ability to conduct research outside our laboratories/offices will become more and more difficult and our work less and less relevant.</p>
<p>The HIPAA rules, while well-meaning, have substantially complicated research, added to expense and complexity, and precluded some types of important research. This includes difficulty in using specimens collected for other purposes (even when minimal risk to the patient), difficulty in creating collaborations (because of concerns about HIPAA violations) and even in some states the incorporation of HIPAA-like standards into other institutions, that markedly impacts research. In some states, for example, the VA is no longer routinely sharing information with the cancer registries, creating havoc with interpretation of cancer rates (did rates go down, or is it only because we don't have the VA data?). The issue of patient privacy is important, but the provisions should mainly be geared towards the non-research environment to efficiently permit the continued enhancement of the public's health.</p>
<p>...as an analyst and researcher working with PIs of multi-site study, I have certainly felt the impact of HIPAA. One thing I would like to mention is an analysis I tried to conduct tagging on to an already established dataset from a multi-site study within the CRN. The analysis never got off the ground because the PI (at another site) did not want to take the time to contact other sites to see if they would be willing to set up DUA's and share data. Nor did she want to take the time to make a limited dataset that could be shared. Basically the only way this analysis could have happened was to have it be done at the original data collection site. This didn't work because my time was funded to do the analyses myself and not to pay someone else (who had no time anyway) to do them. I think the issues of patient privacy are extremely important. But the amount of time that it now takes to set up all of the HIPAA provisions in collaborative studies is almost prohibitive. It costs more (in terms of PI and PM time), making straightforward data-only studies inefficient and complicated.</p>
<p>HIPAA has added a definite burden to research, which I think the public would not be happy about if they knew about this side effect. All of the informed consents, which were already daunting, have been made more so, and less understandable, placing more burden on the subject and more costs to the project. It has become better over time, but overall it has greatly added to the cost and time for research. For example, for one study it has become extremely difficult to obtain follow-up data on subjects in a cancer screening study, even though they have signed informed consents for release of records. Hospitals seem to use HIPAA [sic] as a convenient excuse to say no.</p>
<p>The main problem on the research studies in which I have encountered HIPAA related issues seems to have stemmed from the inexperience of the IRBs reviewing the studies and due to this inexperience to err on the side of patient privacy and not to balance patient privacy and research considerations. As a result, the burden on our study participants has been substantially increased through the requirement of extensive consent forms for simple surveys or focus groups which has in turn resulted in an increased number of refusals to participate in the study.</p>
<p>HIPAA was enacted to promote patient privacy and avoid misuse of patient identifiers by commercial entities. One unintended consequence of the HIPAA rules, as they have been implemented, is that they have made drug safety studies much more difficult to conduct for us. In this way, HIPAA functions, ironically, to the advantage of the pharmaceutical industry, which would often prefer not to know about safety problems. This unintended consequence of HIPAA has perhaps also occurred to the disadvantage of the patients that HIPAA was supposed to</p>

protect.

B) Investigator Follow-up Interviews

Nineteen respondents to the web survey opted-in to complete follow-up interviews. However, two were deemed ineligible, having never served as the Principal Investigator of a study affected by HIPAA. Three others opted out when they were contacted about scheduling the interviews, and two could not be reached after four weeks of both email and phone attempts by the research interviewer. We therefore completed 12 interviews. Among the 12 respondents, four told us about their experiences with a study involving primary data collection, and the other eight respondents described their experiences on automated data-only studies.

Although the resulting sample of participants who completed interviews is far smaller than we had anticipated, the interviews still yielded many informative insights and several examples that quantify how the HIPAA Privacy Rule affected research budgets and timelines.

Among the respondents who described primary data collection studies, all four reported that they were obliged to augment the consent and authorization procedures (some studies were initiated before HIPAA took effect). All four also felt that the HIPAA authorization language definitely had an adverse effect on recruitment, describing how patients were “confused” and “frustrated,” that the long forms were “very off-putting.” The study costs and timeline were also affected detrimentally. In one case, for a set of linked studies, compliance with new HIPAA procedures incurred about 1,000-2,000 additional hours and \$100,000-200,000 in unanticipated costs. Another project reported one additional year to address HIPAA constraints, leaving no funds in the budget for analysis and reporting. One investigator spoke of the added and unexpected cost of having to translate the lengthier consent materials (six pages with HIPAA information) into Spanish. In this same study, the investigator had originally been permitted to use medical records to identify candidate study subjects, only to have the IRB revoke this invoking HIPAA (ultimately, the investigator renegotiated the ability to view the records). Another commented that HIPAA is “irrelevant for work done under purview of an IRB” reflecting that if researchers are approved under the Common Rule, there was no marginal improvements to patient protections gained through the HIPAA Privacy Rule regulations. Some participants also noted the challenge of various IRBs interpreting HIPAA differently.

Among the eight respondents who characterized their experience on their data-only projects, most of the challenges they described were onerous, but not insurmountable. However, in two cases, IRBs stipulated that the investigators could not acquire the data as originally intended, impinging on the ability to conduct certain kinds of analyses. For example, in a biosurveillance study designed to identify and predict abnormal events, rather than looking at anomalous diagnoses at an individual level as planned, the study team could only assess diagnoses at the level of age-by-gender for patterns. In every case, the interviewees cited significant additional resources (personnel time, unanticipated mailings, buying more secured equipment) needed to comply with the HIPAA-related requirements. There were no consistent processes with respect to Data Use Agreements (DUAs). Most investigators (5 out of 8) indicated that they would still repeat a similar study if the opportunity arose, but would do so armed with knowledge of how to anticipate data needs and other processes, and budget accordingly. The respondents were mixed in their reports of their institution’s responses to HIPAA. Three felt that the IRB has “a better handle on it,” “more straightforward guidelines,” and improved training. However, one noted that their IRB is stringent about requiring DUAs and confidentiality agreements even using

deidentified data. Another pointed out the still-problematic distinction between research studies and quality improvement work with regard to the “hoops to jump through” by being situated in the research department. Finally, when asked for any other comments, we received four uniformly negative responses, three balanced responses, and one wholly positive response. These comments are presented in Table 3.

Table 3. Comments from Follow-up Interviews among Investigators Who Worked on Data-Only Studies

Definitely feels that HIPAA has affected recruitment; studies cost-effectiveness of behavioral interventions and is tracking recruitment costs. Targeted sampling is harder; more refusals because participants are turned off by HIPAA packets
Feels that IRB and compliance office are comparatively conservative in their interpretation compared w/other sites; offered example of a 4-site health information exchange demonstration project in which other sites don't harbor same HIPAA-related concerns. Their state has mandatory limits on liability which seems to assuage HIPAA-driven fears; whereas [respondent's] organization is headquartered in another state, which seems to have resulted in a more conservative take on HIPAA. Also, though we've all learned how to adapt, not sure how much HIPAA has added to patient security or confidentiality--benefits do not seem to outweigh the measures undertaken.
Doing research in Pharmacoepidemiology on rare adverse events (<50) is much more difficult now. Prohibiting research on rare outcomes is a step in the wrong direction. [Respondent] feels generating questions from existing research is hampered - too many hoops to jump through in order to link data back once de-identified. Not worth the hassle & that's too bad for research.
HIPAA has "yet to prove itself useful." "Not enough bang for the buck."
It's labor intensive but in general HIPAA regulations are at appropriate levels of coverage - not overly burdensome.
The guidelines that programmers follow for de-identification have gone a little too far. In general [respondent] feels good about the additional protection for pts.
When study funders get nervous about the EpicCare data being used, [respondent] tells them about the [HMO's] enrollment consent clause which authorizes the use of their medical data for research. The [HMO's] IRB requires there to be a research hypothesis and non-disclosure plan, and requires that PHI not be shared with other sites. [HMO's] IRB HIPAA jargon drives [respondent] nuts (de-identified vs. limited data sets, etc). On plus side, recent training put out a one page reference sheet which [respondent] finds helpful. Feels an investigator's approach to HIPAA may affect the outcome of how difficult it is to work within. If they are not willing to commit w/IRB at all stages they may make it more difficult on themselves later.
[Respondent's] institute is incredibly supportive of research as a whole and they have a benevolent perspective when it comes to HIPAA

C. IRB Administrators Survey

We received responses from 11 of 15 sites for a final response rate of 73%. The IRB varied widely in both staff size and research volume, with a median staff of 3.5 and median volume of 90 initial applications reviewed in 2007.

We sought to understand the relationship and responsibilities between the research center and its parent health plan with respect to compliance with the research-related provisions of the Privacy Rule, use of PHI, training and other guidelines. Typically, responsibility for HIPAA compliance as it related to research was a shared function between the IRB and another official,

such as a designated compliance manager, the named Institutional Official, or the Privacy Office. Eight sites had a stand-alone Privacy Officer or Privacy Board as part of the research center. Oversight of the research use of PHI also varied; some research centers handled this internally, some reported shared responsibility between the health plan and research center, and three reported that this was solely overseen by the health plan's Privacy Office.

Respondents were presented with four hypothetical scenarios involving privacy breaches which were designed to assess the consistency of their reactions. In general, respondents were consistently indicated that the breaches would be reported to their Privacy Office, with occasional respondents reporting additional measures, such as reporting the incident to the HHS Office of Civil Rights, reporting to OHRP, or suspending/terminating the study. In response to the scenario, "Researcher sent a limited data set to a collaborator without a signed data use agreement in place," one of the 11 respondents indicated that they would do nothing, as this did not constitute a privacy breach, whereas the other 10 did feel that this was a breach that warranted notifying the Privacy Office and possibly other measures.

Table 4 shows the varied responses we received to a series of opinion questions about the HIPAA Privacy Rule. Some of these questions (noted by asterisk [*] below) were identical to those asked of investigators.

Table 4. IRB Administrators' Viewpoints Related to the HIPAA Privacy Rule

Question	Response				
	Strongly Agree	Agree Somewhat	No Opinion	Disagree Somewhat	Strongly Disagree
The HIPAA Privacy Rule has made it more difficult to conduct research	18.2%	45.4%	9.1%	18.2%	9.1%
Our health plan's interpretation of the HIPAA Privacy Rule has adversely affected the research climate at our Center.	9.1%	27.3%	--	27.3%	36.4%
* The HIPAA Privacy Rule has strengthened patient privacy provisions.	27.3%	63.6%	--	--	9.1%
* Our research center's interpretation of the HIPAA Privacy Rule balances the concerns of the institution, the patients and our researchers.	27.2%	54.6	9.1%	9.1%	--
* I have found it easy to work within the HIPAA privacy regulations.	18.2%	27.3%	18.2%	27.3%	9.1%
It is appropriate for individual research centers to use their own discretion to interpret and implement the HIPAA Privacy Rule as it relates to research.	--	27.3%	9.1%	18.2%	45.4%
I think the federal government needs to give more guidance to IRBs about interpreting and implementing HIPAA Privacy Rule research provisions	18.2%	54.6%	--	36.4%	--
Study participants are unduly burdened by the complexity of HIPAA authorization forms	--	54.6%	--	36.4%	9.1%

It is worth noting that of the three questions in common between the investigators' and IRB administrators survey, IRB administrators generally viewed the HIPAA Privacy Rule's effect on the research climate more positively, although both groups were similar in their viewpoints about the Privacy Rule's ability to better protect patient privacy. Figures 2-4 compare the perspectives of each group.

Figure 2. Investigators' and IRBs' Views on whether the HIPAA Privacy Rule has Strengthened Patient Privacy

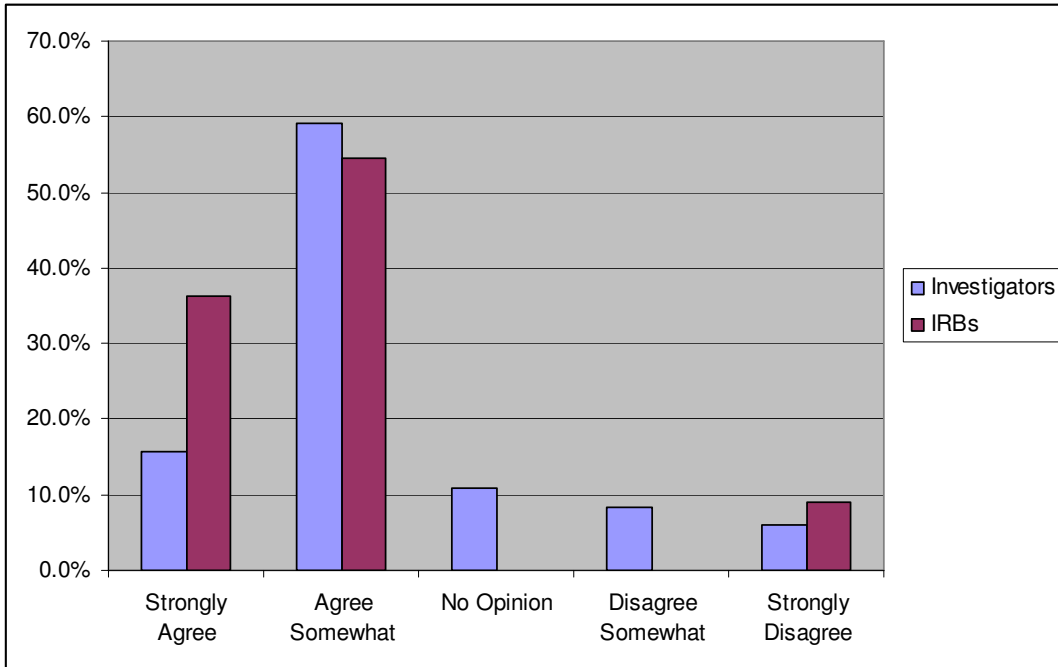


Figure 3. Investigators' and IRBs' Views on whether Interpretation of HIPAA Balances concerns of Institution, Patients, Researchers

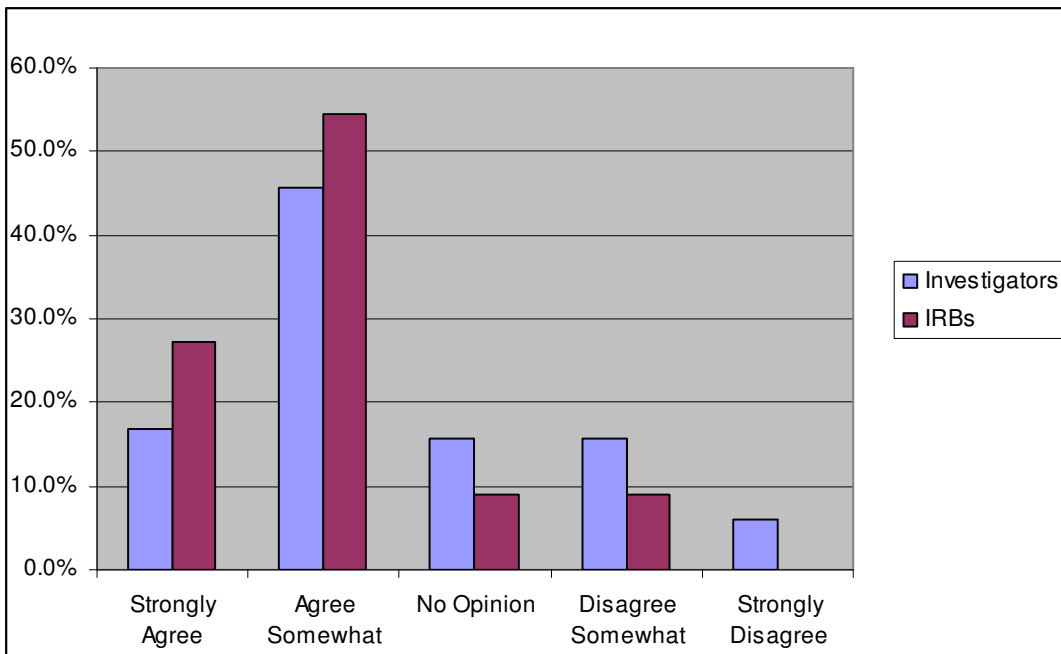
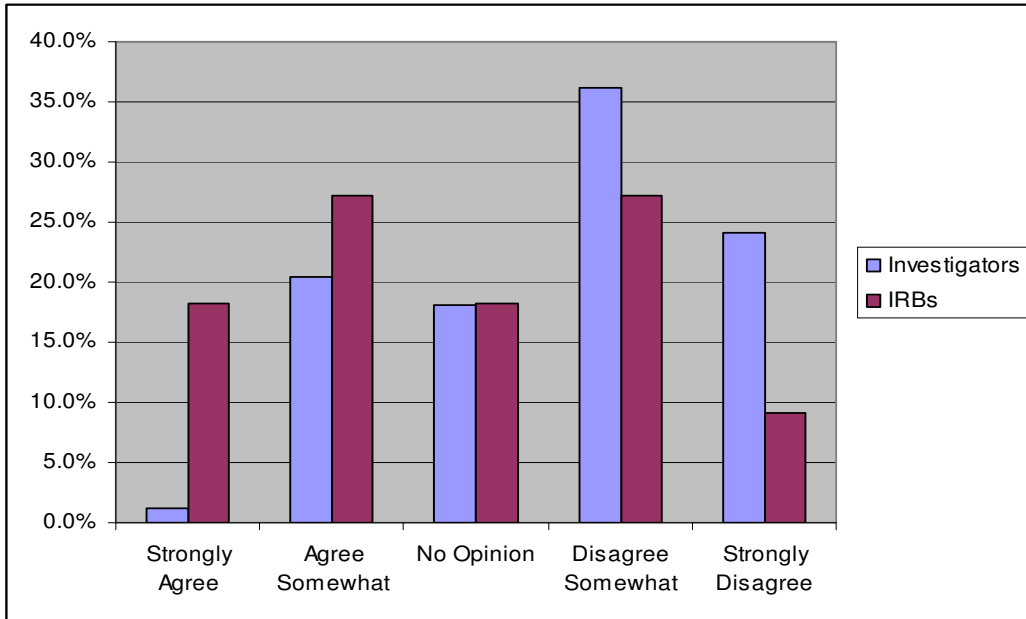
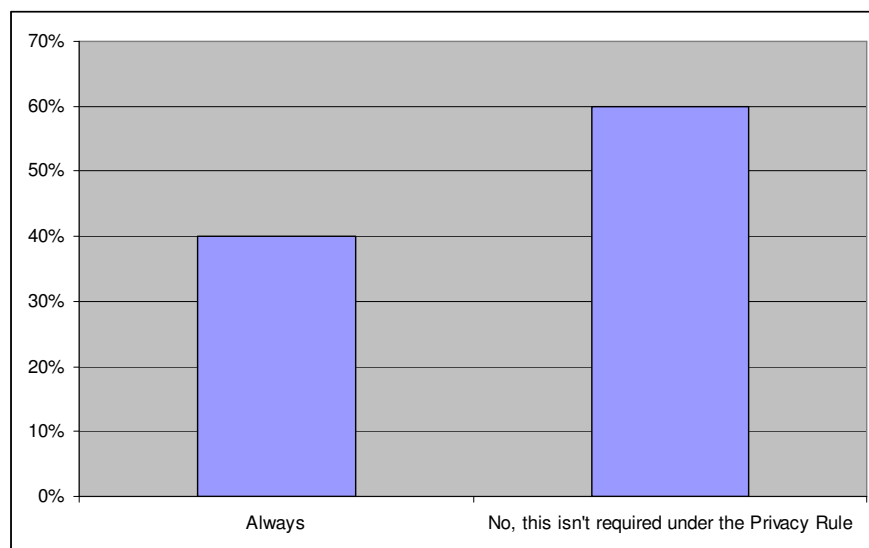


Figure 4. Investigators' and IRBs' Views on Ease of Working with HIPAA Regulations



We asked about procedures and resources that research centers (IRBs or other groups within their center) may have developed to address HIPAA Privacy Rule requirements. All sites have standard templates for HIPAA Authorization, waivers of authorization, and Data Use Agreements, and 10 of 11 have standard Privacy Rule training in place for their researchers. Most (64%) have established physical methods for safeguarding paper records, and an equal proportion have defined technological procedures for protecting electronic PHI. Ten sites have disclosure tracking procedures in place for researchers. IRBs were less knowledgeable about whether there were individuals who could assist with proper de-identification of data according to “the statistical method,” with only 4 of 11 sites indicating that this was complete/in progress. Four other sites were not sure. An important area of variability was the requirement around Business Associate Agreements, as shown in Figure 5.

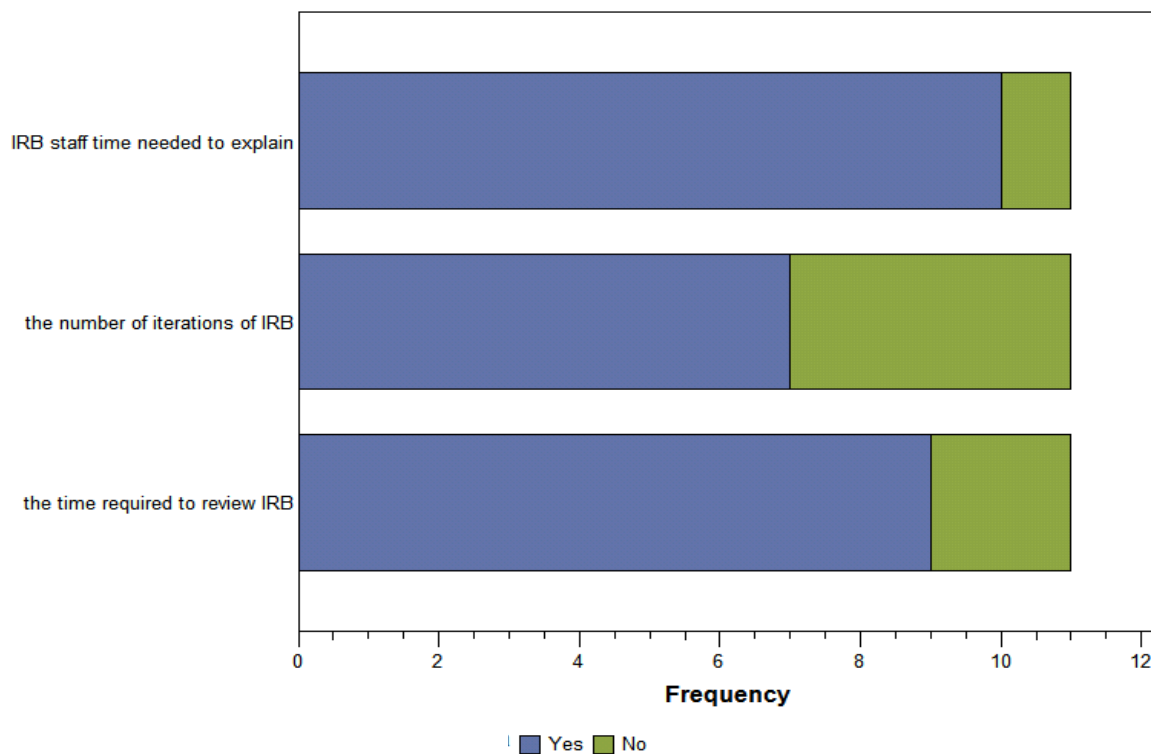
Figure 5. Requirements pertaining to Business Associate Agreements & Release of PHI



Note: One person skipped this item

The final set of questions asked about education, training and impact of the HIPAA Privacy Rule on the IRB itself. At all sites, both the IRB staff and members of the IRB received training on the HIPAA Privacy Rule, and for 9 of 11, the training covered both HIPAA in research and HIPAA provisions that relate to covered entities more generally. For multi-site studies, 4 of 11 IRBs require proof of HIPAA-related training for all participating investigators, including those at other sites, even though this is not stipulated by the HIPAA legislation itself. Overwhelmingly, the IRBs are feeling the impact of HIPAA in their work volume, as shown in Figure 6, below.

Figure 6. How the HIPAA Privacy Rule has Added to the Workload of HMORN IRBs



As with the investigators survey, IRB administrators were also offered the opportunity to provide open-ended feedback or offer ideas about whether there are specific kinds of clarifications or guidance from the DHHS Office of Civil Rights that would be beneficial. Since only a few people elected to provide open-ended comments, we are presenting the comments in their entirety in Tables 5a and 5b below.

Table 5a. IRBs' Desired Clarification or Guidance from the Office of Civil Rights

<ul style="list-style-type: none"> • Sample Authorization language written at an 8th grade level that our attorneys will accept.
<ul style="list-style-type: none"> • HIPAA status for case study publications. • Further clarification on waivers & HIPAA agreements.
<ul style="list-style-type: none"> • Clarify transactions & code standards. • More guidance on compliance & enforcement. • Educational materials on the difference between the security and privacy rule.
<ul style="list-style-type: none"> • One well-organized, comprehensive document for guidance.
<ul style="list-style-type: none"> • How to reconcile differences between Privacy Rule and Human Subjects regs, i.e., preparatory to research access, PHI v. individually identifiable information. • Release of info to registries.

Table 5b. IRBs' Additional Comments on the Impact of the HIPAA Privacy Rule on the IRB or Research Center

<ul style="list-style-type: none"> I think researchers are more cautious about accessing PHI, and that is a good thing. I think the waiver criteria are overboard - too narrow. I don't think most people care who every person is who will see their coded info and exactly why. When people give consent for research, they expect scientists, collaborators will use their PHI for the project.
<ul style="list-style-type: none"> Negative - Patients often do not understand the privacy rule. Positive - It strengthens compliance in data use & Business Agreements & contracts to protect PHI.
<ul style="list-style-type: none"> This has created an enormous amount of work with very limited improvement in safeguarding research subjects.
<ul style="list-style-type: none"> Was very difficult at first. We seem to have worked out what we can/cannot do.
<ul style="list-style-type: none"> NIH Privacy Rule info for researchers has been a good resource.

DISCUSSION

Both researchers and IRBs feel that the HIPAA Privacy Rule regulations were conceptually well-intended. However, operationalizing the regulations was incompletely considered, especially when different kinds of research are parsed more finely. Many researchers cited the “unintended consequences” of the HIPAA Privacy Rule, including the fact that researchers are rethinking whether or not to undertake certain studies, and clinicians and students may be discouraged from research careers in view of the complex regulatory burden. Furthermore, one researcher pointed out the irony that the HIPAA Privacy Rule makes drug safety studies more difficult to conduct, to the detriment of the public that HIPAA is intended to protect.

Our study has limitations that must be considered. First, retrospective recall about a topic that has excited as much controversy as the HIPAA Privacy Rule must be interpreted with a modicum of caution. We do believe that researchers, when serving as study participants, understand the importance of providing answers that are appropriately balanced and accurate, which we hope mitigates this limitation. Also, our response rate was modest among investigators, and may reflect that only more motivated or “affected” respondents were apt to complete the survey. Our survey of researchers was implemented shortly after a similar survey by a group of epidemiology societies, of which many of our would-be respondents are also members. Some may have thought that they had already completed the survey, or may have simply experienced “survey fatigue.”

The IRB administrators survey garnered a much higher response rate (73%), although we only had a small number of sites in our total sample. Still, this is the first study that we are aware of that has surveyed Institutional Review Boards for their views on the impact of the HIPAA Privacy Regulations on research at their site as well as the impact on the research enterprise more broadly. Our survey of IRB administrators revealed true differences, both in how HIPAA Privacy Rule was implemented from site to site and in its interpretation, among places that are otherwise fairly homogeneous for their placement within covered entities.

Similar to the recently published study by Ness¹, researchers have reported difficulty working with the HIPAA Privacy Rule regulations and reported additional study costs were incurred in

¹ Ness RB. Influence of the HIPAA Privacy Rule on Health Research. JAMA. 2007 Nov 14;298(18):2164-70.

the form of additional personnel time and unanticipated IRB iterations addressing HIPAA's research-related provisions. Another finding that is congruent with the Ness study is the substantial variability reported among the respondents who had taken part in multi-site research since the implementation of the HIPAA Privacy Rule. Nearly 70% of our respondents indicated that different IRBs raised different HIPAA-related concerns, and among these instances, nearly half reported resulting protocol variability from site to site. This is a cause for concern, as it is a potential threat to the integrity of the research from the standpoint of differential protections of subjects from site to site, as well as the potential for introducing higher proportions of non-response bias as sites that may have more onerous HIPAA-related requirements.

If there is a silver lining, it is that researchers and IRBs at these sites are becoming more facile at dealing with this complex regulation. However, the downside is that time spent dealing with these regulatory requirements is time and energy subtracted from the research itself. In extreme cases, HIPAA Privacy Rule has thwarted new research from going forward, and even provoked a handful of investigators to get out of a particular type of research. If this is a microcosm of the rest of the research community, this is a unfortunate unintended consequence of otherwise well-meaning legislation.

APPENDIX

Investigators Open-ended Feedback from Web Survey

Verbatim Comment Text from Investigators Survey on Impact of HIPAA Privacy Rule

1. HIPAA interpretation has changed since 2003. In general, HIPAA is manageable. At times, however, I think things can be more confusing for research subjects because of HIPAA. For example, when you are enrolling subjects and can't tell spouses information over the phone.
2. I believe that adding the HIPAA risk language to consent forms confuses potential participants and reduces their willingness to consent. It seems extraneous to the "regular" consent form text, and is much harsher in tone. Meeting HIPAA requirements for data transfer has also raised the administrative costs of conducting research, by delaying project timelines until IRB approvals are obtained and by requiring additional staff time to monitor and respond to HIPAA-related IRB requirements.
3. I see three major problems. 1) Data collected for feasibility studies can not be published - it has to be re-run following IRB approval. This is problematic for two reasons: a) the risk of a breach in confidentiality is exactly the same for running the feasibility analysis as it is after IRB approval; a) it is unethical because it is a waste of research dollars to re-run the analysis or collect the same information again. 2) It discourages clinician research. For example, the extra time it takes to conduct a simple case review will lead to less research. 3) It discourages job shadowing. Students who are interested in investigating potential careers in health science are having a very difficult time job shadowing. Many hospital and clinic have stopped allowing students to shadow. These problems could be addressed by having researchers, students and clinicians undergo annual HIPAA training that will cover all subsequent minimal risk research and training.
4. HIPAA has added a definite burden to research, which I think the public would not be happy about if they knew about this side effect. All of the informed consents, which were already daunting, have been made more so, and less understandable, placing more burden on the subject and more costs to the project. It has become better over time, but overall it has greatly added to the cost and time for research. For example, for one study it has become extremely difficult to obtain follow-up data on subjects in a cancer screening study, even though they have signed informed consents for release of records. Hospitals seem to use HIPAA as a convenient excuse to say no.
5. I believe you are conflating the IRB with the HIPAA panel. While many institutions may choose to make the same group serve in both capacities, this is not required.
6. The onerous level of additional regulations has made it so difficult to conduct research that I doubt that practicing physicians will be able to conduct research for much longer. I have moved from research to administration and quality improvement to avoid having to lead IRB governed research. I'm not sure I wouldn't have made this change on my own, but HIPAA combined with the new funding environment has pushed me there faster.
7. HIPAA was enacted for a noble reason, but as is usual with regulatory mechanisms for enforcing noble laws, little thought was given to unintended consequences of regulators developing rigid mechanisms and attitudes. At best, it requires much more time and effort to initiate and conduct really low risk health services research. At worst, potentially worthwhile projects don't happen.
8. Initial implementation of HIPAA appeared to cause delays/concern in study approval/implementation which do not appear quite as cumbersome now. However, more thoughtful consideration of HIPAA-related issues at the time of data collection is generally necessary during protocol development. In addition, I have found that the limited datasets analyzed for research projects do sometimes make addressing reviewer comments (on manuscripts submitted for publication) more difficult (if specific data necessary to address comments is not available in the limited datasets).

9. As organizations become increasingly concerned about HIPAA violations, some forms of research are becoming significantly more difficult to conduct. For example, interviewing individuals outside our research facilities and recording those interviews on digital recorders is becoming problematic (no differentiation is being made between laptop computers that can carry data for millions of people and a voice recorder that includes data from one or two individuals at a time). This makes it difficult to collect real-world data in settings (e.g., homes, care settings) that are critical to our understanding of chronic disease management, death and dying, and interactions and processes of care delivery. I'm very supportive of protecting patient privacy and I believe HIPAA has been positive in that it has sensitized researchers to privacy concerns. At the same time, it seems that organizations are so concerned about HIPAA violations that they aren't adequately assessing the true differences in risks associated with different methods of data collection and storage. As these methods are increasingly limited, our ability to conduct research outside our laboratories/offices will become more and more difficult and our work less and less relevant.
10. The amount of time my project team and I spend on paperwork related to HIPAA has become a real burden. It has not made me want to stop working on multisite collaborative projects, but I am much more hesitant and cautious when entering into new collaborations because I know that so much time will need to be committed to securing all of the needed approvals and putting additional layers of data security in place. I think this law has cut into the time I am able to spend thinking about science, and I often wonder if it really has done much of anything to truly protect health information. I also recently completed a similar survey through the Society for Epidemiologic Research.
11. I think if compliance officers and IRBs take to heart the opportunities and need to do research that preclude an individual-by-individual consent to view medical data (low risk with high potential yield or the burdens far outweigh the risk and benefits), HIPAA is good for both the patient and the research that needs and should be done. I have also run into many, many discussions of doom and gloom, where we are consenting individuals and thus, without concern (for those consenting) regarding the use of data. There continues to be a negative cloud over research regarding HIPAA, occasionally in places that are not necessary. Having said that, there is very much a slowing of the process at a minimum due to HIPAA, which translates into research undone or delayed. Some studies have been delayed as much as 7 months trying to get all parties to be on the same page.
12. HIPAA has been quite positive in emphasizing patient privacy protection(s) and reinforcing procedures to ensure them. It has been negative in adding ambiguity and confusion to the research process.
13. I think the biggest concern is the rules deter certain research from being developed. The loss is greater than the patient protection benefit.
14. While HIPAA has increased the time required to complete paperwork for IRB applications, at our institution research administration and the IRB has taken a fair balance between protection of data from unwarranted disclosure and the requirements of specific research projects.
15. I found, especially at the onset of HIPAA, that though HIPAA itself may have not required a change in other institutions practices in releasing information that HIPAA was used as an excuse to not comply to requests. For example, though HIPAA does not cover health information of decedents, release of decedent information was also much harder to accomplish after HIPAA. Additionally, health systems responded to the threat of HIPAA in ways that made work less efficient for researchers.

16. HIPAA has definitely complicated research. The front end work is more. I do feel good about the level of privacy protection it provides.
17. I can't think of a specific tangible benefit to patients related to HIPAA, although I can imagine some that might occur in theory. There are clearly negatives, as reflected in specific survey responses - longer and more confusing consent forms, practical difficulties in contacting patients for studies, more paperwork requirements involved in sharing data files among organizations involved in multi-site studies.....
18. The HIPAA rules, while well-meaning, have substantially complicated research, added to expense and complexity, and precluded some types of important research. This includes difficulty in using specimens collected for other purposes (even when minimal risk to the patient), difficulty in creating collaborations (because of concerns about HIPAA violations) and even in some states the incorporation of HIPAA-like standards into other institutions, that markedly impacts research. In some states, for example, the VA is no longer routinely sharing information with the cancer registries, creating havoc with interpretation of cancer rates (did rates go down, or is it only because we don't have the VA data?). The issue of patient privacy is important, but the provisions should mainly be geared towards the non-research environment to efficiently permit the continued enhancement of the public's health.
19. The impact of HIPAA cannot be disentangled from OPHR requirements. They intersect and often bump into one another. In research, we seek hard evidence of cause and effect before making decisions. Comprehensive electronic medical records on entire populations now permit us to learn more precisely and inexpensively than ever before how prevention and treatment affect the occurrence of morbid and mortal events they are designed to prevent. They also allow us to assess the relation of care costs to outcomes. The availability of such records which can teach us how to provide better and less expensive care is now an issue central to public health. Yes, we do need proper safeguards, and HIPAA supplies many of these appropriately. But the bureaucracy around it and the costs of that bureaucracy are exploding. A question central to public health is this: How can we protect privacy appropriately at REASONABLE COST and with REASONABLE EFFORT? Right now, we are not protecting the public health aspects. We have arbitrary and capricious IRBs well known to researchers who carefully submit protocols to those IRBs most likely to approve them. We need fewer "local standards" and more attention to protecting the public's need to use health care experience to improve health care quality and outcomes.
20. The main problem on the research studies in which I have encountered HIPAA related issues seems to have stemmed from the inexperience of the IRBs reviewing the studies and due to this inexperience to err on the side of patient privacy and not to balance patient privacy and research considerations. As a result, the burden on our study participants has been substantially increased through the requirement of extensive consent forms for simple surveys or focus groups which has in turn resulted in an increased number of refusals to participate in the study.
21. HIPAA was enacted to promote patient privacy and avoid misuse of patient identifiers by commercial entities. One unintended consequence of the HIPAA rules, as they have been implemented, is that they have made drug safety studies much more difficult to conduct for us. In this way, HIPAA functions, ironically, to the advantage of the pharmaceutical industry, which would often prefer not to know about safety problems. This unintended consequence of HIPAA has perhaps also occurred to the disadvantage of the patients that HIPAA was supposed to protect.

22. The biggest issue I believe is the additional cost of studies as a result of the additional work to be HIPAA compliant (deidentifying data, reviewing HIPAA privacy authorization with potential research subjects, additional time with IRB/Privacy Board related to expanded information that is required for IRB applications).
23. HIPPA [sic] is not my biggest problem. Bush is a problem. NIH leadership is a problem. Declining educational achievements of staff is a problem. Sexism in the workplace is a problem. HIPPA [sic]? Pretty trivial.
24. The type of research I do (survey and secondary data analyses within my health plan) do not seem to be adversely affected by HIPAA. However the multicenter study that I am participating in (TRIAD), has been somewhat slowed by HIPAA regulations. However I don't think the impact has been unwarranted or detrimental to the study.
25. I'm not sure what questions you asked solely of PI's (who answered yes to the first question). I have not served as PI, but as an analyst and researcher working with PIs of multi-site study, I have certainly felt the impact of HIPAA. One thing I would like to mention is an analysis I tried to conduct tagging on to an already established dataset from a multi-site study within the CRN. The analysis never got off the ground because the PI (at another site) did not want to take the time to contact other sites to see if they would be willing to set up DUA's and share data. Nor did she want to take the time to make a limited dataset that could be shared. Basically the only way this analysis could have happened was to have it be done at the original data collection site. This didn't work because my time was funded to do the analyses myself and not to pay someone else (who had no time anyway) to do them. I think the issues of patient privacy are extremely important. But the amount of time that it now takes to set up all of the HIPAA provisions in collaborative studies is almost prohibitive. It costs more (in terms of PI and PM time), making straightforward data-only studies inefficient and complicated.