THE COSTS OF HIPAA:
TO PATIENTS, TO PROGRESS, AND TO THE NATION’S HEALTH

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About C-Change: The mission of C-Change is to eliminate cancer as a major public health problem at the earliest possible time by leveraging the expertise and resources of our members. A 501(c) 3 organization, C-Change is comprised of approximately 150 of the Nation's cancer leaders from the private, public, and non-profit sectors. These leaders collaborate on issues spanning the continuum of research, prevention, and care - that cannot be solved by one organization or even one sector alone.

Abstract
Recent studies including a 2009 Institute of Medicine report have highlighted how the HIPAA Privacy Rule fails to protect privacy and has created significant barriers to research. The purpose of this article is to outline the impact of the HIPAA Privacy Rule on patients and its cost to the research enterprise in terms of time, dollars, and lost opportunities. During this review, we found that HIPAA burdens the research process by deterring patients from participating in research, creating an enrollment bias and translating into research that is not applicable to all populations, perpetuating treatment disparities. Biospecimen data is difficult to re-use, limiting personalized medicine, which directly impacts cancer patients’ and their ability to quickly find a treatment that will benefit them and minimize side effects. The limited utility of de-identified data and perceived restrictions on data mining also limit other forms of research including comparative effectiveness research. Further, the protocols required to meet HIPAA privacy standards have subjected clinical trial enrollees to burdensome paperwork and added thousands of hours and hundreds of thousands of dollars to the time and costs of individual studies, taking limited resources away from clinical cancer research. In some trials, insufficient resources to manage these protocols have led to the abandonment of studies all together, undermining the trust that clinical researchers have worked to establish with clinical trial participants. We conclude that actions must be taken to exempt research from the HIPAA Privacy Rule to improve patient privacy protection and improve the economy and efficiency of lifesaving research.
I. INTRODUCTION

Millions of Americans are burdened by debilitating and often terminal disease, leading many patients and their families to tirelessly advocate for the discovery of new treatments to reduce suffering and death. Fortunately, the U.S. has long been a global leader in biomedical and clinical research, drug development, and disease prevention. However, burdensome and unnecessary federal legislation threatens the U.S. biomedical research enterprise and its efforts to reduce suffering and death. This report details the adverse effects of the Privacy Rule promulgated under the Health Insurance Portability and Accountability Act (HIPAA), which became operative in 2003. Although the main intent of the HIPAA Privacy Rule was to improve the privacy of personal health information data transmitted electronically, unintentional consequences have dramatically altered the landscape of health research and continue to negatively impact patients.

Appropriately, research is guided by many laws and regulations to ensure the safety, efficacy, and protection of patients and their health information. However, the HIPAA Privacy Rule makes medical research more inefficient and costly, causes delays in clinical trials and in some cases causes researchers to abandon planned studies or studies already underway. The Privacy Rule also impedes researchers from using genetics, molecular medicine and other “personalized medicine” tools to craft therapies uniquely beneficial for particular patients. This causes certain types of patients to be more likely to participate in clinical studies than others, thereby limiting the relevance of study findings. From a patient perspective, this means that HIPAA interferes with the ability to find better treatments for all patients, and as a result perpetuates health disparities. It also causes the patient experience to be more complicated and unpredictable, and in significant ways restricts the rights of patients to independently decide how they wish to participate in the research process. From a public health perspective, HIPAA creates barriers to the comparative effectiveness and epidemiologic research continually needed to improve medical care.

In addition, the Privacy Rule contributes to the regulatory burden that is one of the major reasons why clinical trials are moving off shore to other countries with more hospitable climates for research. The implications of this trend could be significant: limiting access to treatments that are relevant to the diverse population of the U.S.; reducing the economic benefits of conducting clinical trials in this country; and threatening the U.S. position as a global leader in science.

Consequently, the HIPAA Privacy Rule has drawn the attention of a wide range of scientists, clinical investigators, patient advocates, and the public. The Congressionally-chartered Institute of Medicine (IOM) was asked for an independent appraisal of the impact the Privacy Rule has on both patient privacy and the nation’s capacity for productive medical research. The IOM, the health arm of the National Academy of Sciences, is an independent, not-for-profit organization which serves as an advisor to the nation to improve health by providing unbiased, authoritative advice to decision makers and the public. In the IOM’s appraisal, which is detailed in its 2009 consensus report, the Institute concluded that the HIPAA Privacy Rule does not adequately protect patient privacy and instead significantly impedes research. (IOM, 2009a) Two prior IOM reports specifically cited barriers to research imposed by HIPAA in the context of biomarker-
based tools for cancer screening, diagnosis and treatment, and with patient authorization requirements to enable new research on previously collected samples. (IOM, 2006, IOM, 2007)

This report updates and builds on the IOM report by summarizing the impact of HIPAA on the health research process, and showing the subsequent impact on patients. It also provides a more in-depth illustration of the dollar, time, and opportunity costs HIPAA imposes on biomedical research. This is especially timely given the current period of severely restricted resources for such research.

II. HISTORICAL CONTEXT AND BACKGROUND

Although congress passed HIPAA in August of 1996 with the primary goal of improving the portability of health insurance for patients, it also recognized concerns about the privacy and security of the increasingly common use of electronic medical records. To address these concerns, the legislation directed the Secretary of The Department of Health and Human Services (HHS) to promulgate regulations to improve the privacy and security of personal health information. The final version of the HIPAA Privacy Rule was issued in 2002 by HHS, with most health care providers and health plans required to comply with the final version by April 14, 2003, and small health plans a year later. The HIPAA Security Rule was also adopted in 2003, with most health plans required to be in compliance by April 21, 2005, and smaller plans a year later.

A. Privacy Rule

The Privacy Rule restricts the use or disclosure of an individual’s Protected Health Information (PHI) unless authorized (given written permission) by the individual, or unless exempted by the Privacy Rule for public health efforts, such as law enforcement, product recalls, or judicial or administrative proceedings. No such exemption exists for research. (IOM, 2009a) Authorization to use or disclose PHI must specify in writing how, why, and to whom the health information can be used or disclosed. This additional requirement is distinct from, and in addition to, the traditional and well established informed consent for research. When patients sign the latter, they give consent to their participation in a specific clinical study, after they have been informed of the specific potential risks and benefits of that research. Some informed consents also give permission for future research uses of patients’ health information data or blood, tissue, or other biospecimens.

Although these specific consents for future research are provided in writing by the patients and authorize the use of data for future research, they are not considered specific enough to comply with the patient authorization requirements of the Privacy Rule. (IOM, 2009a) Consequently, information and biospecimens collected for one research study cannot be used in another study without authorization of the original participants in the first research study. This limits the impact patients can have on the progress of research on their health, and slows down the pace of discovery.

Responding to concerns that such an authorization requirement would impede biomedical research, the HHS modified its guidance in 2006 so that authorization for future research would not be required if a waiver of authorization was granted for a subsequent study by an Internal
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Review Board (IRB) or Privacy Board. The waiver could be provided once the board determined that the new research would pose minimum risk (undefined) to patient confidentiality and safety, and that the research could not practically be done without the waiver. But the Privacy Rule does not provide guidance as to what factors should be considered in determining whether those criteria are met. (IOM, 2009a) The lack of clear regulations and guidance place an undue burden on IRBs which are volunteer organizations whose primary function is assessing risk/benefit of trials to patients, not assessing privacy risks.

The onerous accounting of disclosures has interfered with research. Institutions are required to provide detailed records of any disclosures of personal health information made for research purposes. As a result, many hospitals and other healthcare facilities refuse to make personal health information available to researchers, according to case reports gathered for the Association of American Medical Colleges. (National Committee on Vital and Health Statistics, 2003)

One way to avoid breaches of patient privacy is to make personal health records anonymous. According to the Privacy Rule, researchers can use personal health information without authorization by individuals if they strip that information of anything that could be used to identify the individual, including the person’s name, social security information, date and place of birth, etc., and assure that the data will not be used or disclosed for purposes other than research. However, such “de-identified” or limited datasets can be of limited value as they often cannot be linked to data on the same individuals in other databases, such as hospitalization or death records, for which the person’s name or social security number is needed to retrieve the data. “Because datasets from multiple sources cannot be linked to generate a more complete record of a patient’s health history without a unique identifier, such datasets often are of minimal value to researchers and are not frequently used,” noted an IOM report. (IOM, 2009a)

B. The Security Rule
Recognizing that the security of data stored on computers can be breached, the HHS also promulgated the HIPAA Security Rule. The Security Rule only protects electronic personal health information, and requires covered entities that process such electronic records to maintain sufficient security measures to ensure confidentiality, integrity, and availability of the data. The Security Rule does not specify the technological approaches that covered entities should undertake to comply with the Security Rule, but rather sets the bar for data security standards, and encourages covered entities to use future technology as it develops. (IOM, 2009a)

C. Covered entities
Only certain offices, organizations and institutions called “covered entities” have to comply with the Privacy Rule and the Security Rule. These entities are individuals or organizations that electronically transmit health information, including private and federal health care providers and health plans, as well as some universities, or parts of universities, such as health centers, and their researchers. But these rules do not apply to all entities conducting biomedical research, including pharmaceutical companies and the contract research organizations they often employ to conduct their research, nor does it apply to research foundations, or student health services (if they do not bill for services). In addition, individual authorization is not required to disclose personal health information to public health authorities so they can monitor health threats and diseases, survey workplace safety, regulate products overseen by the Food and Drug
D. General criticisms

There have been several serious criticisms of HIPAA’s Privacy Rule related to its lack of specificity, clarity, and comprehensiveness.

1. Inconsistent and overly cautious interpretations limit research

As noted in an IOM report (IOM, 2009a), the Privacy Rule is so vaguely worded and conflicts with previous regulation, including HHS regulations for the protection of human subjects (the Common Rule), that it leads to difficulties and inconsistencies in interpretation, and overly cautious interpretations by IRBs and Privacy Boards. For example, the reporting of cancer cases to state registries does not require patient authorization or IRB waivers as this activity falls under public health activities that are exempt from such requirements. But after the Privacy Rule became effective, 17 hospitals in the San Francisco Bay area restricted the California state cancer registry’s access to such patient data, causing significant delays in the several studies that depended on the data until a court settlement restored access to cancer patient files and records. One of those studies aimed at assessing why African Americans in the Bay Area have a higher risk of lung cancer than other racial and ethnic groups was nearly abandoned due to two-year delays caused by misinterpretation of the Privacy Rule. (Russell, 2004)

Often medical information that can be captured from the biospecimens and personal medical health data of research subjects is useful even after those subjects have died. For example, genetic studies to determine which cancers are the most aggressive and thus need more aggressive therapy can be effectively done using the biospecimens and health records of research subjects years after they have died. The HIPAA Privacy Rule is silent on whether authorization is required from the personal representative or next of kin of deceased individuals to conduct research using their personal health information. As a result, some organizations interpret the Privacy Rule to require researchers to obtain authorization from next of kin or a waiver of authorization from an IRB or Privacy Board to access the personal health information of those research subjects who have died. (Ness, 2007)

By not being more specific, the HIPAA Privacy Rule has slowed down and made more costly biomedical research aimed at personalizing medicine.

2. Gaps in patient privacy protection

Despite its efforts to improve patient privacy, there are still notable gaps in HIPAA’s privacy protections. Not all institutions that gather personal health information are required to conform to the patient privacy protections HIPAA specifies, including pharmaceutical companies and the companies with whom they contract to conduct their research. These non-covered entities must comply with various inconsistent state laws regarding patient privacy and health data security. (See Table 1) In addition, paper medical records are not subject to HIPAA provisions unless the institution that keeps them bills electronically or otherwise transmits such information electronically. Despite the growing movement from paper to electronic medical records, many health records still exist only in paper form. Of note, the National Ambulatory Medical Care Survey conducted by the American Hospital Association in 2010 reported that only 25 percent of
physician offices and 15 percent of acute care hospitals were utilizing electronic medical records. (NAMCS, 2010)

Electronic medical records are not fully protected by HIPAA. Studies indicate that even after following the proper de-identification of data procedure specified by the Privacy Rule, individual health data can still be re-identified with a moderate degree of accuracy by using remaining data, and combining it with information in public databases. (Clause et al, 2004, Malin, 2001)

3. One-size-fits-all regulation
Another major criticism of the HIPAA Privacy Rule is that it does not distinguish between clinical research in which patients are given an experimental drug or procedure that could be potentially physically harmful, and research based on previously collected medical records and/or biospecimens whose potential harm would not produce risk of injury. As the IOM report on HIPAA noted, “There are fundamental differences between information-based research (e.g. using medical records or stored biological samples) and direct interventional human subjects research. Applying the same human subjects’ protections in these two different scenarios is neither appropriate nor justifiable.” (IOM, 2009a) Indeed, since the Privacy Rule, IRBs often do not correctly distinguish between clinical and health services research. The latter uses medical records to document the safety or effectiveness of various health services, many of which are not experimental or even interventional. In a post-HIPAA survey of health services researchers, 44 percent of the responders noted that IRBs did not correctly differentiate between clinical and health services research. (Helms, 2008)

Prior to the Privacy Rule, IRBs did not have to review health services research in the same detail, so their unfamiliarity with this type of research has made their reviews challenging. As one cancer researcher responding to a survey noted, “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.” (Greene, 2008)

The increasingly large work loads of IRBs due to the increasing complexity and number of regulations, including the new demands of the HIPAA Privacy Rule, have also increased the difficulty of both recruiting experienced IRB members and allowing them sufficient time for making knowledgeable decisions about human research projects. (IOM, 2002) The end result is that IRBs are increasingly denying approval for important studies that could suggest new ways to improve patient care without endangering patient privacy.

The cumulative effects of the HIPAA Security and Privacy rules create inconsistencies, gaps, and inflexibility in the protection of patient privacy. In addition, HIPAA has introduced various legal nuances and bureaucratic procedures that have made it more difficult for patients to participate in health research, thereby slowing down the speed of discovery for cancer, heart disease, diabetes and many other illnesses, and making that discovery process more costly. The difficulties the HIPAA Privacy Rule create in the biomedical research arena provide the basis for understanding the cost ramifications of HIPAA and will be explored more fully in the next section of this report.
III. HIPAA EFFECTS ON HEALTH RESEARCH

HIPAA impacts the research process and as a result has a direct impact on patients. HIPAA has hampered health research and patients’ ability to participate in such research mainly by its effects on the patient informed consent and authorization process, and the IRB review process. These effects include deterring patients from participating in research, fostering research findings with limited relevance to patients, hampering personalized medicine research dependent on biospecimens and stored clinical data, fostering rejection or abandonment of clinical studies, and hampering and increasing the time and cost of large, clinical studies.

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<th>Impact on the Research Process</th>
<th>Impact on Patients</th>
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<td>- More complicated and lengthy consent</td>
<td>- Delays and deters patient enrollment and access to new treatments</td>
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<td>- Makes care process more unpredictable and confusing</td>
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<td>- Decreased enrollment / Decreased participation of some types of patients</td>
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<td>- Wastes investments in accumulated research data for future purposes</td>
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<td>- Limits accumulation of large clinical databases to support stronger conclusions or study rare conditions or population sub-sets</td>
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<td>- Limits treatment options to participate in clinical trials, particularly in community hospital settings</td>
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A. Deters patients from participating in research

The additional authorization for use of personal health information for research lengthens consent forms and the research consent process. This burdens patients and makes them less inclined to participate in research. Further aggravating the problem is the fact that many research participants cannot understand the forms they are required to sign. (Nosowsky and Giordano, 2006) Researchers attending an IOM workshop on multi-center trials agreed that consent forms that can be as long as 30-35 pages post-HIPAA are too long for patients to read. (IOM, 2009b) One study found that the HIPAA authorization alone added an average of two pages to an informed consent form. (Breese, et al, 2004) This study found that the median reading level of HIPAA authorization forms from 125 academic medical centers was that of a freshman in college, and nearly all were above the 8th grade reading level, even though half of the U.S. adult
population reads at or below this level. (Breese, et al, 2004) Many Americans read at a 4<sup>th</sup> grade reading level and writing forms appropriate for them will require extensive additional work. (Paasche-Orlow, et al, 2003)

Respondents to a survey of cancer researchers indicated that the HIPAA authorization language made patients “confused” and “frustrated,” and that the long forms were “very off-putting,” were “much harsher in tone than regular consent forms,” and that “participants are turned off by HIPAA packets.” One respondent added, “all of the informed consents, which were already daunting, have been made more so, and less understandable, placing more burden on the subject and adding more costs to the project.”(Greene et al 2008)

The added burden of the authorization form makes patients less inclined to enroll in clinical studies. Studies done of recruitment to the same clinical trial before and after HIPAA have documented an approximately 75 percent decline in enrollment as well as a tripling in the amount of time it takes to enroll each patient after HIPAA was instituted. (Ness, 2005, Wolf and Bennet, 2006) One study on the effectiveness of an education strategy to inform veterans about a clinical trial to test whether vitamin supplements help prevent cancer was already underway when HIPAA was implemented. In the pre-HIPAA phase, researchers recruited seven patients a week with an average recruitment time of 4.1 hours. In the post-HIPAA phase, researchers recruited only 1.9 patients per week with an average recruitment time of 14.1 hours. (Wolf and Bennet, 2006)

Similarly, a study on preventing the pregnancy complication preeclampsia was underway when HIPAA came into effect. Researchers recruited an average of 12.4 women a week during the pre-HIPAA time period. After that recruitment dropped to 2.5 women a week, when researchers were required to seek HIPAA authorization from patients to use their medical records. (Ness, 2005) One large study found nearly twice as many patients agreed to participate in research if not required to return a HIPAA authorization form than those required to do so. (Beebe et al, 2007) Another study examining the potential impact of the HIPAA Privacy Rule on data collection in a registry of patients with acute coronary syndrome found consent to participate in a health related telephone survey declined from 96.4 percent when consent could be obtained over the phone to 34.0 percent post-HIPAA when consent had to be obtained in writing, supporting the notion that written consent is a burden to individuals who are interested in participating in health research. (Armstrong et al, 2005)

Some of the decline in research enrollment after being required to read and sign an authorization form could perhaps be due to patients more fully understanding the privacy risks involved with the research and concluding the risks outweighed the benefits in their particular cases. Yet interestingly, one study found the main reason given for not participating in clinical research was poor understanding of the authorization form. (Dunlop et al, 2007)

The increased time it takes to enroll patients in research studies due to HIPAA could also deter physicians from referring patients for evaluation, thereby limiting patient knowledge of opportunities to participate in research. One study found that oncologists were less likely to refer patients for participation in a clinical trial if they perceive the paperwork to be onerous. (Seminoff et al, 2000) Half of patient accruals to trials in the U.S. come from community-based
practices, even though more than three-quarters of cancer care is delivered in these community settings--a large gap between expected and actual accruals. Unlike other health care systems, in which physicians are paid salaries and thus can spend more time enrolling patients in clinical trials without impacting their income, physicians in community-based or even academic practices often generate less income if they spend more time enrolling patients in clinical trials. Perhaps partially for this reason, the U.S. ranked 6th in countries doing the most clinical trials. (IOM, 2008)

The time consuming enrollment of patients in studies due to the consent and authorization process also contributes to low enrollment--only between 3 and 5 percent of patients with a new cancer diagnosis in 2008 enrolled in clinical trials. (IOM, 2010a) When enrollment in a clinical trial is very slow, the trial can be closed or abandoned, much to the frustration of the patients who did enroll, let alone those never given the opportunity to participate. Only about 60 percent of cancer clinical trials supported by NCI are completed and published. Many are abandoned due to insufficient enrollment. (IOM, 2009b) This is unfortunate, given that the standard oncology clinical practice guidelines recommend the best management of cancer patients is achieved through participation in a clinical trial. (National Comprehensive Cancer Network, 2009)

In sum, the HIPAA Privacy Rule slows down the discovery process, limits patients’ options to participate in research, and limits access for many cancer patients to state of the art cancer care.

B. Fosters research findings with limited relevance to patients: Enrollment bias

Researchers try to enroll the broadest spectrum of patients in their studies to ensure that their conclusions are likely to be widely applicable to all patients, rather than just those from certain economic, ethnic, or educational groups. However, studies indicate that patients who sign their HIPAA authorization forms and agree to participate in clinical studies are different from those who decline such authorization and participation, creating what is known as “selection bias.”

One study found that the Privacy Rule’s authorization requirement deterred African-Americans from participating in health research. (Dunlop et al, 2007) Other studies have found that people who sign HIPAA authorization forms were more likely to be Caucasian, older, and sicker than those who choose not to sign. (Armstrong et al, 2005; Kho et al, 2009, Woolf 2000) Surveys of researchers and registries have also found many respondents acknowledging that the Privacy Rule had introduced selection bias and inadequate sample representation into their health research. (Walker, 2005; Deapen, 2006)

In one survey, 74 percent of those researchers that responded reported they had experienced problems with selection bias, with the most commonly cited reason for such selection bias cited being that fewer patients have agreed to participate in research since the Privacy Rule was implemented. In addition, 42 percent of the respondents reported that health clinics serving disadvantaged populations are not participating in research because of being unable to meet all of the Privacy Rule requirements. The end result has been an underrepresentation of minority populations in many research studies. (Walker, 2005)

In another survey of cancer registries, 36 percent of respondents reported that the Privacy Rule had introduced selection bias into a research project. (Deapen, 2006) This skewed representation
of certain population groups in clinical studies is likely to invalidate or limit the application of the findings to a broader group of patients, especially those from traditionally underserved populations. (Kho et al, 2009) Another researcher who responded to a survey recognized that concerns about HIPAA violations impeded the recording of patient interviews on digital recorders, such that HIPAA “…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 care delivery.” (Greene et al, 2008) The unintentional enrollment bias created by HIPAA leads to research findings that are only relevant to the participating populations.

C. Hampers personalized medicine research dependent on biospecimens

In the search for better cancer treatments, one way for research participants to derive broader impact from their medical data and biospecimens is to have those resources available for other studies in addition to the ones for which they were originally collected. Currently, the Privacy Rule does not allow for reuse of patient data and specimens unless trial participants authorize the use of their information and biospecimens for specifically defined future studies. This requirement is a major impediment to health research because of the impracticality and difficulty of finding the original research subjects to acquire their authorizations. Such efforts could take years or even decades and generate unwarranted expense. (IOM, 2009a)

By limiting future data uses, scientists are unable to access a wealth of information contained in these stored records. This data is particularly useful when searching for cancer causes or “biomarkers” of cancer aggressiveness or responsiveness to specific treatments. Such “personalized medicine” research is a major thrust in oncology. With growing awareness that there are a multitude of cancer subtypes, each of which may have different causes or respond to different targeted treatments, doctors are now trying to better focus the application of these targeted therapies to increase response rates and decrease toxicity.

For example, using tumor biospecimens, researchers can identify cancer patients most likely to benefit by particular therapies. For example, the cancer drug Herceptin is effective in breast cancer patients that have several copies of a specific gene called HER-2 in their tumors. (IOM, 2007) The lung cancer drug Iressa only appears to be effective in patients with an EGFR mutation that is particularly prominent in Asian populations. (Saijo, 2010) In colon cancers with a particular mutation in the gene KRAS, patients receive no benefit from certain drugs and experience only toxicity. Other patients with different mutations do benefit.(De Roock, 2010) Clearly understanding which patients have which mutations determines optimal personalized treatment. “Without biomarker studies to identify the biological subsets of patients, some patients could be at a disadvantage when making treatment decisions,” noted an IOM report. (IOM, 2010a)

These personalized medicine findings are not unique to cancer. In patients with heart disease undergoing cardiac evaluation, certain mutations in genes coding for particular enzymes determine the risk of potential coronary thrombosis even with optimal therapy. Personalized medicine research to discern these biomarkers of treatment responsiveness depends on the use of archived samples and medical records. Without these biomarkers, some patients will needlessly receive ineffective treatments, while others will be denied therapy specifically tailored to their particular subtype of cancer. (IOM, 2010b)
Three Institute of Medicine reports have cited the problems created by HIPAA with respect to biomarker development, including barriers to using specimens already available for developing biomarker-based tools for cancer screening, diagnosis, and treatment, (IOM, 2006) barriers to accessing identifiable patient health information that is properly protected to conduct meaningful research, (IOM, 2007) and the delays and inefficiency created by HIPAA by hindering the use of existing data and tissue resources. (IOM, 2009a) A survey of members of the American Society of Clinical Oncology (Goss et al, 2009) also identified the authorization process as the most significant challenge to complying with the Privacy Rule, especially for future research projects relying on stored tissue and databases.

The current authorization requirement limits the impact patients can have in cancer research, and their ability to foster and receive personalized medicine.

D. Hampers research dependent on stored clinical data

The need for patient authorization to use stored clinical data that has already been collected, and the limited value of using de-identified or limited datasets from previously conducted studies, has seriously affected the amount and quality of health research that is done using these resources. More than one third of those who responded to a national survey of epidemiologists reported that they had a high level of difficulty in accessing de-identified information. (Ness, 2007) Another survey of cardiologists found that only about one-third of the respondents attempted to use de-identified data for research. Of these, about three-quarters reported the process was difficult. (Ring, 2007) The inability to easily link de-identified data to the same patients in multiple databases also is a major deterrent. In one survey of researchers in a cancer research network, a respondent commented in a follow-up interview that there are “…too many hoops to jump through in order to link data back once de-identified. Not worth the hassle and that’s too bad for research.” (Greene, 2008)

Many researchers opt not to use de-identified data because it lacks the complete information they need to conduct their studies. One study found that a de-identified dataset that conformed to HIPAA requirements had 31 percent fewer unique data elements than one that had been left intact. This dataset was compiled from patient records housed in an integrated healthcare facility’s pharmacy, administrative and financial files. Much of the information lost when the data was de-identified was of the type of most benefit to researchers, such as time between episodes of care. The investigators in this study concluded that de-identified data removes too much information to produce data useful for conducting good research. (Clause, 2004)

Another study found that for an international multicenter clinical trial testing a treatment for traumatic brain injury, many of the U.S. screening logs had a large amount of missing data due to overly conservative interpretations of HIPAA, compared to the screening logs from the European sites. (Kompanje and Maas, 2006) The degree of data specificity declined with the introduction of HIPAA, the researchers documented. (Maas et al, 2005) This suggests that not only does the Privacy Rule hamper clinical research in this country, but it may also hamper U.S. participation in international clinical studies and drive more trials to move overseas.

Health services research, comparative effectiveness research, and epidemiology research have especially been impacted by the HIPAA Privacy Rule, because of the dependence of these types
of research on stored medical records. The discoveries made in these studies are important for identifying ways to improve patient care in real-world settings, as distinct from the more controlled clinical trials. This type of research is also critical to a “rapid learning healthcare system” that uses the large amounts of data collected in healthcare systems and disease registries to quickly determine what treatments work best for what types of patients, and when those treatments should be given. Unfortunately researchers cannot answer these questions unless the datasets they need are complete and rapidly available, both of which HIPAA impedes.

In a survey of researchers who requested a waiver from an IRB to do their research, 59 percent reported the availability of existing datasets has been impacted by the Privacy Rule and 62 percent of such respondents reported that the use of de-identified data had a negative impact on research. (Helms, 2008) One study compared two similar pediatric health service studies done pre- and post-HIPAA. This study found that only 21 out of the same 27 hospitals asked to participate in both studies agreed to participate in the second post-HIPAA study. The six hospitals that declined to participate in the post-HIPAA study were all community hospitals. The authors attributed that decline in participation to the complex requirements of the Privacy Rule and heightened perceptions of institutional risk being involved in the study. (Newgard et al, 2005) Given that most patient care is delivered in community hospitals, the failure of these hospitals to participate in health services research due to HIPAA concerns, limits the relevance of studies.

Often a hospital’s reluctance to release its patient data for studies is due to misinterpretation of complex and confusing HIPAA standards and concerns about legal liability. For example, HIPAA specifies that patient authorization is not required for research related to public health efforts. Such efforts involve the collection of patient information for cancer registries, and the use of that information in state and federal studies. These studies address such important issues as whether some cancers are becoming more common, and what screening practices are most effective. Unfortunately, several cancer registries reported that physicians or hospitals cited complying with HIPAA when refusing to provide patient information to cancer registries. This misinterpretation has caused cancer cases to be underreported, and has impeded the timely reporting of data needed to determine appropriate cancer prevention and care. (Deapen, 2006)

Hospitals also cite HIPAA as a reason for not releasing patient health records for research. “In 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.” (Greene et al, 2008)

A survey of cancer registries found that 68 percent of respondents reported that HIPAA delayed a research project or caused it to take longer than it would have taken pre-HIPAA. (Deapen, 2006) Another study of three health services research projects aimed at improving healthcare for minorities found that HIPAA requirements made health organizations more hesitant to let researchers access previously collected patient data, while at the same time making it more challenging to recruit patients to original studies. In one of the research projects, a study of the effectiveness of a school-based educational program for childhood obesity prevention, privacy regulations prevented the researchers from directly contacting the parents of school children about participation in the project. Instead they had to rely on school personnel, who were
untrained in the process and had other high priority responsibilities that interfered with their ability to make those contacts. Another health research project attempted to assess whether there were unnecessary hospital emergency room visits among Medicaid patients due to their inability to access non-emergency care from their providers. Because of HIPAA regulations, hospitals declined researchers’ access to the electronic health records of the patients who participated in the researchers’ survey. Without that information, researchers could not conduct their planned in-depth analyses of factors leading to emergency care, limiting the study’s quality. “Overall HIPAA complicates the research process and requires more resources and longer time to conduct [health services] research,” the investigators concluded. (Shen et al 2006)

Data mining, using previously collected data to conduct new studies, is often done in comparative effectiveness research. This research can reveal the superiority of some treatments over others for the same condition, and other evidence about the safety and effectiveness of different medical interventions for the same disorder. Comparative effectiveness research is also performed by reusing previously collected biospecimens to detect biomarkers that indicate what subpopulations of patients have better outcomes with a particular treatment versus another. Such studies are needed when oncologists and their patients are considering which cancer treatments to pursue. Comparative effectiveness research has also been cited as a way to assess whether newer (and often much more expensive) treatments are more effective than traditional therapies. Recognizing the importance of comparative effectiveness research, Congress recently provided more than $1 billion of funding to support such studies. Currently, as conservatively interpreted, the Privacy Rule requirements regarding data mining and the “reuse” of data and biospecimens collected in previous studies could inhibit attempts to expand comparative effectiveness research, thereby limiting the knowledge needed when doctors and their patients make treatment decisions. (IOM, 2010a)

Another major activity that relies on data mining and medical chart reviews is healthcare quality improvement activities. Physicians, hospitals and other healthcare organizations, or insurers frequently do these reviews to determine how to improve the healthcare delivery or to discover administrative practices that improve safety, quality, and efficiency in their institutions. Chart reviews can also suggest certain trends, such as that cancer patients who are obese respond less favorably to chemotherapy, indicating topics that could be explored further with clinical studies. With the advent of HIPAA, however, many institutions perceive that the review of patient records by someone other than a direct care provider requires IRB review, especially if there is intent to publish the findings. (Lynn et al, 2007)

Some have even questioned the ethical consequences of HIPAA, noting that both patients and providers have an ethical obligation to participate in quality improvement efforts if they wish to benefit from medical advances and improved care. HIPAA impedes these efforts when the vaguely defined Privacy Rule is frequently misinterpreted as requiring physicians to obtain an IRB waiver in order to review medical charts for quality improvement purposes. (Lynn, 2007)

E. Increases the time and expense of clinical trial development

Prior to conducting a clinical trial, researchers must expend a significant amount of time preparing their research protocol for review by IRBs and other scientific and regulatory bodies to ensure the study will be conducted properly and ethically, and will conform to regulations regarding patient safety. These preparations can be complex and time consuming, and in some
cases the steps required to develop and activate a clinical trial may require as much or more time than the actual completion of a trial. (Dilts, 2008) These start-up costs, which amount to about $5,000 to $8,000 per patient for a large clinical trial, are largely due to the regulatory requirements of IRBs and governmental agencies, and account for a significant part of clinical trial costs. According to the NIH, (http://clinicaltrials.gov/ct2/info/understand#Q18), large clinical trials typically have between 1,000 to 3,000 patients, so start up costs could total as much as $24 million for one of these large studies. Additional regulatory requirements must be met during and after the study is completed. In total, 35 percent of clinical research costs are spent on compliance with regulatory requirements. (IOM, 2008)

HIPAA requirements have increased the regulatory burden on research, especially the Privacy Rule requirements for authorization or waiver of authorization by an IRB. A review of applications for IRB exemption at the University of Wisconsin pre-and post-HIPAA found the percentage of projects that required full IRB committee review increased from zero percent pre-HIPAA, to 16 percent post-HIPAA (a larger percentage of studies became ineligible for IRB exemption or expedited IRB review). (O’Herrin et al, 2004)

In addition, the vaguely worded language in the Privacy Rule has increased the amount and length of IRB reviews, and the amount of time and resources needed to develop and review clinical trial protocols. In a recent editorial, one physician noted the increased costs of paying for the growing group of support staff who submit research protocols, copy consent and authorization forms, and monitor the IRB websites: “That money pays for bureaucracy, not for patient care, not for creation of new knowledge,” he said. (Cohen, 2008) The increased costs linked to complying with HIPAA have made research less affordable and less efficient.

The added time required to comply with HIPAA also slows down the pace of discovery. Of the 1,527 epidemiologists who responded to a survey on how the HIPAA Privacy Rule had affected their research, 87 percent (1,328) reported an increase in the time required for preparing a research proposal for review by an IRB. (Ness, 2007) Such preparation includes modifying and resubmitting their protocols for another IRB review after a previous review requested changes.

One survey of researchers who were part of a clinical cancer research network found that respondents were required to resubmit research projects for a median of two more additional IRB reviews, and spent a median of 20 additional person hours to address IRB concerns after the Privacy Rule was implemented. Twenty percent of respondents reported they had to resubmit their research protocols for additional IRB reviews four or more times. In one-third of study protocols, changes were due to an IRB requirement, most of which were related to patient privacy requirements of HIPAA. In one case, compliance with new HIPAA procedures added 1,000-2,000 hours and $100,000-200,000 in unanticipated costs. Another respondent reported his project required an additional year to address HIPAA constraints, leaving no funds in the study’s budget for analysis and reporting. (Greene et al, 2008)

These delays and costs due to compliance with HIPAA set back the start of research, delaying patient access to promising new treatments, or slowing comparative effectiveness conclusions. In some cases, these administrative delays force researchers to abandon studies and return grant funding, or they may deter them from starting new studies. As one cancer researcher noted “the
onerosous 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.” (Greene et al, 2008)

**F. Fosters rejection or abandonment of clinical studies**

In the University of Wisconsin study previously quoted, researchers abandoned more than three-quarters of study protocols that required full IRB committee review after HIPAA, because of the time and resources necessary to submit their research protocols to such reviews. Most of these abandoned studies were chart reviews, and there was no evidence that the full IRB review was needed to improve patient privacy. (O’Herrin et al, 2004) In the previously cited survey of health services researchers, of those that reported requesting a waiver from an IRB to conduct their research, only 40 percent were successful in accessing data from an existing dataset in original form using the approved waiver. (Helms, 2008)

Even studies already in progress have been abandoned due to HIPAA requirements. A survey by the Agency for Healthcare and Research Quality found that 45 percent of respondents had a study that had been stopped or changed because the protocol could not comply with HIPAA. Studies that were ended included follow-up studies of patients tracked through several different health facilities, studies involving community health centers and rural sites, and research evaluating government programs and clinical interventions in order to improve patient population health. (Walker, 2005) Researchers had to abandon one large, 25-year old longitudinal study of how ethnicity, various procedures, and medications affect heart disease and stroke survival after HIPAA was implemented because they were unable to obtain a waiver of authorization to use patients' medical records. (Kaiser, 2006) In addition, among 13 investigators who responded to a survey of clinical cancer researchers about the impact of HIPAA, six reported they abandoned cancer genetic studies because of problems with IRBs, who were most concerned about the privacy of cancer patients and their families. (Goss, 2009)

The rejection or abandonment of clinical studies due to HIPAA restrictions limits patients’ opportunities to participate in health research, discourages clinicians from conducting future studies, makes research less efficient, and slows down the pace of discovery. The discontinuing of clinical studies also wastes the contributions of those patients who had already agreed to participate.

**G. Increases the time and cost of large, multi-site studies**

The vagueness and lack of specificity of the Privacy Rule has also fostered varying IRB interpretations that have hampered multi-site research. In a survey of clinical cancer researchers, several investigators noted that different institutions’ IRBs have different approaches to complying with the Privacy Rule and this can impede important research, including studies of late effects of cancer treatment, and research on the role certain genes play in cancer. (Goss, 2009) Another survey of cardiologists found that most reported the Privacy Rule has had a detrimental effect on the efficiency of multi-center health research because of different IRB interpretations of the same research protocol. (Ring, 2007) Moreover, in a survey of health services researchers, three percent reported they were unable to proceed with a multi-site study
because they were unable to resolve disagreement among IRBs at the different sites. (Helms, 2008)

One consequence of variable IRB interpretations brought about by vague HIPAA regulations is inconsistent patient protections. One survey of health investigators found that of those respondents that participated in multi-center research, about half reported that the concerns about the same study protocol raised by the IRBs that reviewed it varied considerably, with little consistency across all IRBs. Consequently, the study protocol was modified differently for the different centers that participated. (Greene, 2008) In one study of maternally linked birth records in which 19 hospitals participated, none of the hospitals agreed to rely on the researcher’s own institution’s IRB approval of the study, and all 19 required different application forms, consent, and procedures for complying with the Privacy Rule. Nine of the sites requiring full review by their IRB cited HIPAA concerns for not allowing expedited review or relying on other IRB decisions. (Lydon-Rochelle and Holt, 2004) Several other studies have noted significant variation in IRB responses to identical protocols. (Stair, 2001; Helfand, 2009; Kimberly, 2006; McWilliams, 2003; Sherwood, 2006)

Inconsistent IRB reviews also increase the time and expense of multi-site trials and the validity of their findings. One study of psychosocial outcomes after prophylactic mastectomy found having multiple (6) IRBs review the same study protocol lengthened the study timeline, increased expenses, and created protocol variability. Resolving such IRBs concerns took two to three rounds at each site, added additional costs at three of the sites, and made it impossible to achieve uniform study methods across sites. (Greene, 2006) A lack of such uniform study methods can invalidate the study’s results or limit their application. Another report from the National Initiative on Cancer Care Quality documented that despite using an IRB-approved standardized protocol and consent form, nearly one-third of participating institutions in their multi-center project to improve cancer care required protocol modifications, adding more than a year to the project timeline. (Schneider, E. et al, 2004)

Varying IRB interpretations of HIPAA dissuades researchers from engaging in large, multi-site studies. “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,” said one cancer researcher when responding to a survey on how HIPAA affects research. (Greene, 2008) Unfortunately, multi-site studies are necessary to identify the causes and treatments for rare cancers as few clinical research centers have enough patients with these rare diseases at one treatment site. Pharmaceutical companies also rely on large, multi-center research to test new cancer treatments for more common cancers. Delays in the completion of these types of studies increases the amount of time it takes for patients to receive new, more effective treatments.

IV. HIPAA RESEARCH COSTS

As the previous section makes clear, there are numerous explicit and implicit costs due to the Privacy Rule. These costs include the increased cost of staff time and additional resources needed to implement and carry out long and more labor-intensive studies due to increased
paperwork and/or the inability to reuse clinical data and specimens. There are also increased costs due to more time-consuming IRB reviews and patient accruals.

Shortly after HIPAA became effective, several researchers began to document the costs of implementing and complying with the Privacy Rule. Johns Hopkins University estimated that the cost of complying with HIPAA for research and health care operations was about $2 million annually, for the first two years after the legislation was implemented. (Friedman, 2006) Another study found that the implementation of HIPAA midstream in a clinical trial led to a 75-hour increase per month in staff time spent updating work logs, and a 77-hour increase per month in time spent on HIPAA implementation tasks, which amounted to a 70 percent increase in staff hours above the monthly base workload. (Williams et al, 2007) Other researchers noted that the impact of complying with the HIPAA Privacy Rule on data collection in a registry of patients with acute coronary syndrome was $8,704.50 the first year, and an additional $4,558.50 for each year thereafter. Although the authors did not report the total expenditure of the study, they stressed that this was a substantial increase in the study’s budget. (Armstrong et al, 2005)

In addition, respondents to a survey of clinical investigators in a cancer research network reported that HIPAA led to a median of 20 additional staff hours needed to comply with the regulation, and 12 percent reported 100 or more staff hours were required. (Greene et al, 2008) One of these respondents in a structured interview documented that compliance with HIPAA procedures needed about 1,000 to 2,000 more staff time hours and added $100,000 to $200,000 to the cost of research. Another study concluded as early as 2006 that the initial HHHS estimate that the research provisions of the Privacy Rule would cost $10 million to implement the first year and $146 million over 10 years had already been realized. The researchers of this study indicated that the added costs have led to the need for researchers to acquire more funding, and have discouraged investigator-initiated research. (Nosowsky, and Giordano, 2006)

The substantially increased expenses tied to complying with HIPAA has made health research less efficient and affordable, closing some research avenues and ultimately impeding progress in delivering better care to patients.

V. HIPAA OPPORTUNITY COSTS

The opportunity costs resulting from the HIPAA Privacy Rule stem from several trends. When researchers abandon studies, results are not realized. When research is hampered by the use of de-identified data, results are not as meaningful or useful. When accrual is hampered by bureaucratic hurdles, the strength and broad applicability of findings is limited. When previously acquired data are inaccessible, research is not initiated and an investment is rendered useless. When the regulatory environment in the U.S. becomes unattractive or infeasible for drug developers, patient access to trials and the related economic benefits of industry migrate overseas.

With the expectation that the work of developing a clinical protocol may be for naught because of rejection by an IRB, many clinicians are deterred from undertaking clinical research. A survey of investigators at a large Health Maintenance Organization (HMO) research network in Seattle found that 65 percent of respondents agreed they were hesitant to pursue new study ideas
due to the Privacy Rule. (Greene, et al, 2008) Studies not pursued because of HIPAA burdens included studies of drug safety, cancer care delivery, and cancer screening. In a survey of health services and health policy researchers, 10 percent of respondents said they considered developing or actually developed a study, but did not submit the study protocol to an IRB because they thought it would not get approved due to the IRB’s conservative interpretation of HIPAA. In the same survey, 13 percent said an IRB prevented a study in which they were involved from moving forward due to concerns about violating HIPAA. (Helms, 2008) A survey of cardiologists on the effect of HIPAA on their research found that among those who attempted to obtain a waiver of authorization from an IRB to conduct their research, 69 percent reported that waiver was hard to attain. (Ring, 2007)

Community-based physicians are especially likely to be deterred from doing clinical research as many work at hospitals that do not have an IRB to review their research protocols. One physician noted that he had wanted to write a journal article describing an improved method of calculating appropriate airway pressure to apply to patients with sleep disorders, which he had developed by reviewing his own patient’s charts. This method would allow patients to avoid an additional sleep study after being identified as having sleep apnea or other sleep disorders. Unfortunately the physician was unable to share his method with others because he was told publishing his findings would require an IRB review, and he did not have access to an IRB in his practice. (Shipman, 2009)

Other studies suggest that regulatory burdens, in general, deter clinicians from conducting clinical studies. Only 13 percent of physicians are clinical investigators, and one survey found that about one quarter of respondents cited the main reason for not conducting clinical research was the paperwork burden. (Taylor, 2004) “One of the often cited reasons why physicians do not participate in clinical research is excessive regulatory burdens,” noted a recent IOM report on cancer clinical trials. (IOM, 2010a) This report pointed out that most patients in cancer clinical trials enter from community-based practices with fewer resources to support participation in a clinical trial, including clinical research nurses that have the time to acquire informed consent and HIPAA authorization from patients.

Many physicians first develop an interest in conducting clinical research after they are given the opportunity to do such research during their medical training. This research usually involves reviewing medical charts to discern noteworthy trends. Such quality improvement research is often the initial exposure of medical trainees to patient-oriented research. (Infectious Diseases Society of America, 2009; Sataloff, 2009) The Privacy Rule requirement for IRB review and waiver of authorization for some exploratory studies and clinical chart reviews has made it nearly impossible for medical students to conduct such research during the limited time frames of their clinical rotations. This restriction creates missed opportunities for physicians-in-training to be exposed to and become inspired to do clinical research, and consequently results in missed opportunities to acquire the clinical insights and subsequent improved patient care that such research can provide.

The HIPAA Privacy Rule also discourages mentoring that might spark a clinical research career. “Students who are interested in investigating potential careers in health science are having a very difficult time “job shadowing”. Many hospital and clinics have stopped allowing students to
shadow,” said a clinical researcher in response to a survey. (Greene, 2008) Another physician added, “HIPAA obstacles to medical research constitute a threat to medical education and good clinical care and should be addressed.” (Sataloff, 2009)

Global outsourcing of clinical trials is an increasing trend and contributes to the loss of global leadership in the clinical trial arena for the U.S. The increased time it takes to develop and conduct clinical trials because of the Privacy Rule’s requirements for additional authorization forms and IRB reviews has contributed, in part, to the declining number of clinical trials being done in the United States and instead being done overseas. Between 1997 and 2005, the percentage of clinical trials done in this country fell from 85 percent to 65 percent. (IOM, 2008) Among other factors, HIPAA has increased the cost and lowered recruitment efficiencies of clinical trials, and increased the regulatory burden. These factors are cited as the main drivers of the growing trend for industry to conduct clinical trials overseas. (Agres, 2005; Normile, 2008) If this trend to outsource clinical trials continues, “the ability of the U.S. to maintain a critical mass of expertise to conduct clinical trials is questionable. If clinical trials are not conducted in the U.S., patients could lose access to promising new therapies as they develop, and in some cases the results of clinical trials may have less relevance to U.S. patient populations,” noted an IOM report on the national cancer clinical trials system. (IOM, 2010a)

Most importantly, HIPAA is directly impacting patients. The difficulty caused by the Privacy Rule to reuse patients’ collected medical data and biospecimens, essentially limits the access researchers have to these resources that patients have so willingly offered with the hopes that it may further progress made on understanding and treating their disorder. One cancer patient advocate was highly critical of the Privacy Rule at a recent IOM workshop, stating that the rule needs to work for patients and not against them, and that it creates paperwork nightmares for patients. She pointed out that often patients want access to their own biospecimens and medical data when new tests and treatments become available, yet the way in which institutions tend to interpret the Privacy Rule can prevent such access. (IOM, 2009b) HIPAA slows the progress of developing new and more effective treatments for disorders, which is a major opportunity cost for those patients with these disorders and their loved ones, who may not have time on their side.

ORGANIZATIONS CRITICAL OF HIPAA’S NEGATIVE IMPACT ON HEALTH RESEARCH
Several organizations have voiced their criticism of HIPAA’s negative impact on health research. In addition to C-Change, these organizations include the:

- Institute of Medicine
- President’s Council of Advisors on Science and Technology
- American Society of Clinical Oncology
- National Cancer Advisory Board of the National Cancer Institute
- National Committee on Vital and Health Statistics
- Association of American Medical Colleges
- Association of American Universities
- Biotechnology Industry Organization
- Pharmaceutical Research and Manufacturers of America
- Secretary’s Advisory Committee on Human Research Protections
Infectious Diseases Society of America
Society for Epidemiologic Research
Federation of American Societies for Experimental Biology

One group of individuals and organizations representing America’s leading research universities, medical schools, hospitals, scientific societies, health care analysts, pharmaceutical, medical device, and biotechnology firms noted in their 2001 letter to HHS that unless the Privacy Rule was substantially amended, it will “…harm patients and scientific innovation by creating significant obstacles to the conduct of biomedical epidemiologic, health services, and other research.” This letter concluded by stating “The Privacy Rule can be and must be amended to better serve the public interest in sustaining the research enterprise.” (http://www.faseb.org/portals/0/pdfs/opa/aamc8x14x1.pdf, accessed 12/1/10) Some of the criticisms these organizations raised were addressed in subsequent HHS rulings, but many still remain.

The National Committee on Vital and Health Statistics noted in their 2004 letter to HHS that “unless the Privacy Rule interpretation is changed, it will be exceedingly difficult to compile research repositories, including repositories containing collections of biological specimens linked to medical records, which are essential to many forms of research.” (http://www.ncvhs.hhs.gov/04030512.htm, accessed 12/1/10)

More recently, ASCO expressed its concern in a 2009 letter to HHS that “…cancer patients’ willingness to bank their specimens and clinical data for the purposes of future research and to have these data made available for research…” was being compromised by the Privacy Rule. This organization urged the HHS to take action on this matter so as to “…yield immediate and significant improvement in our understanding of the molecular basis of cancer and benefit patients with cancer and those at risk for cancer.” The ASCO letter went on to state that “ASCO members are already reporting a negative impact of the authorization requirement for future use on important cancer research efforts. This will only intensify as physicians and researchers in the future rely on the study of banked biospecimens to inform personalized decisions about the use of molecularly based cancer treatments and the development of molecular diagnostic tools that are poised to make important gains in our understanding of cancer.” (http://www.asco.org/ASCOv2/Department%20Content/Cancer%20Policy%20and%20Clinical%20Affairs/Downloads/Correspondence%20Letters/ASCO%20to%20OCR%20OHRP%20re%20SACHRP%20recs.pdf) ASCO, the IOM, and SACHRP all recommended that the Privacy Rule apply the Common Rule standard consent form that permits consent to certain future research uses of patients’ medical records and biospecimens.

These organizations and some of the other ones previously mentioned, have conveyed to the HHS criticisms about other aspects of HIPAA, including its requirement to account for disclosures of protected health information for research purposes, its standards for de-identification of data, and its negative impact on patient participation in studies, with a particular lack of minorities, less-educated, and low-income individuals included in study populations. These organizations have also voiced concern about HIPAA’s adverse effects on international research opportunities, registries and other public health tools, as well as its burdensome process for obtaining an authorization or waiver of authorization. (IOM, 2009a)
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<th>Topic</th>
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<th>Recommendations</th>
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<tr>
<td></td>
<td>Accounting for disclosures of protected health information (PHI) for research purposes</td>
<td>Creates excessive paperwork for Covered entities and has resulted in some covered entities refusing to make PHI available to researchers.</td>
<td>NCVHS</td>
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<td>Standards for deidentification of data</td>
<td>Loss of ability to carry out research because of loss of information, cost, and administrative burden.</td>
<td>AAMC, SACHRP</td>
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<td></td>
<td>Recruitment of research subjects</td>
<td>1. Institutional Review Boards (IRBs) already consider recruitment as part of their study oversight.</td>
<td>NCVHS</td>
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<td>2. Artificial distinction between internal and external researchers exists.</td>
<td>AAMC, SACHRP</td>
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<td>3. Identification and contacting potential research participants are considered different activities.</td>
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<td>4. Creation of biased populations in studies, especially too few less-educated, low-income individuals.</td>
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<td></td>
<td>1. Eliminate the accounting for disclosures requirement for research (AAMC, SACHRP).</td>
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<td>2. HHS should issue guidance to provide covered entities with ways to fulfill this requirement in a convenient and practical manner (NCVHS).</td>
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<td>HHS should review standards to reduce the number of categories removed from deidentification data.</td>
<td>AAMC, SACHRP</td>
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<td>1. HHS should classify research recruitment as a health care operation, obviating the need for authorization and allaying confusion (SACHRP).</td>
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<td>2. If “1” is rejected, HHS should provide additional formal Guidance on contacting potential research participants and HHS should end differential treatment of internal and external researchers for purposes of identifying and contacting potential participants (SACHRP, NCVHS).</td>
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Table 3 (Continued)

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<th>Topic</th>
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<tr>
<td>Databases and tissue repositories:</td>
<td>Loss of future research opportunities; confusion regarding combined authorization.</td>
<td>1. When an IRB has approved a consent form that permits future uses under the Common Rule standard, the same should apply under the Privacy Rule. Permit combining research authorization for a clinical trial and for banking data and materials collected as part of the trial in a single form (NCVHS, SACHRP). 2. Eliminate the restriction on the use of data for unspecified future research, or allow a less specific description of the intended use (NCAB). 3. Clarify how identified datasets collected under a broad authorization to create a database could be released to researchers through the use of a waiver of authorization, a limited dataset, or by deidentifying the information.</td>
<td>NCVHS, SACHRP, NCAB</td>
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<td>Future uses of research data and</td>
<td>Discrepancies between the Common Rule and the Privacy Rule create challenges for IRBs and Privacy Boards that must make decisions about such things as waivers of authorization.</td>
<td>1. Revise categories of research not requiring authorization to include research determined by IRB to be exempt from Common Rule requirements (SACHRP). 2. HHS should provide further interpretation, guidance, and technical assistance to help the research community to understand the relationship between the Privacy Rule and the Common Rule (NCVHS).</td>
<td>NCVHS, SACHRP</td>
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<td>Biological materials</td>
<td>The process for obtaining an authorization or waiver of authorization is burdensome, and discourages research from being conducted.</td>
<td>1. Authorization and waiver of authorization requirements should be eliminated for research purposes. Research disclosures are adequately protected by the Common Rule (AAMC). 2. Continue to require authorization or waiver of authorization for research, despite the administrative burden (NCVHS).</td>
<td>NCVHS, AAMC, NCAB</td>
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<td>IRB waiver of authorization</td>
<td>Authorization and informed consent can be combined into a single document. Under the Common Rule, IRBs must review informed consent documents. However, the Privacy Rule does not require IRBs to review authorization forms.</td>
<td>HHS should clarify that nothing in the Privacy Rule prevents IRBs from reviewing authorization forms when considering the adequacy of privacy and confidentiality of subjects under the Common Rule.</td>
<td>NCVHS</td>
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<td>Genetics research</td>
<td>It is unclear whether DNA samples can ever be deidentified because analyzing the samples could reveal unique DNA identifiers of the individual.</td>
<td>HHS should clarify whether DNA samples can be considered deidentified data.</td>
<td>NCVHS</td>
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<td>Types of covered entities</td>
<td>Academic medical centers cannot organize in a manner that reflects the functional operations of the medical school, affiliated practice plans, and teaching hospital.</td>
<td>The covered entity status, hybrid entity status, and affiliated covered entity status should be redefined to reflect the function served by the different parts of the organization, not the organizational form of the organization.</td>
<td>AAMC</td>
</tr>
<tr>
<td>Transition provisions</td>
<td>The implementation of the Privacy Rule could hamper studies already under way</td>
<td>For research begun before the Privacy Rule took effect, grandfathers research that did not receive IRB review or oversight because it was exempt under Common Rule.</td>
<td>SACHRP</td>
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</table>
In 2010, HHS put forth a Notice of Proposed Rule-making in response to provisions in the Health Information Technology for Economic and Clinical Health (HITECH) Act, which called for stronger privacy protections for health information. Proposed modifications could potentially address the concern about the inability of patients to authorize future use of the biospecimens and data. (http://edocket.access.gpo.gov/2010/pdf/2010-16718pdf) However, other proposed modifications could further hamper health research. (Cate and Crosley, 2010; Kean, 2010) A final ruling on the proposed modifications is expected from the agency in 2011, according to a representative from HHS. (Andra Wicks, personal communication 12/2/10)

The President’s Council of Advisors on Science and Technology (PCAST) released a report in December 2010 on health information technology in which it noted that HIPAA is obsolete, given recent advances in information technology. This report notes that HIPAA has the unintended consequence of leading organizations to equate privacy protection to data sequestration, which has proved detrimental to medical research and is potentially detrimental to medical care. The report added that the modifications HITECH makes to HIPAA will further stifle innovation, while offering little additional real-world privacy protection. The PCAST report recommended reformulating HIPAA provisions so that they “…ensure both patient privacy and patient benefit from medical research, in a world where medical data are increasingly in electronic form, and where there is a growing need for real-time or near-real-time aggregated data to improve healthcare.” (PCAST, 2010)

VI. CONCLUSION

The HIPAA Privacy Rule has not significantly improved patient privacy protections, and instead has needlessly hampered health research. The barriers imposed by HIPAA are typically expressed in terms that are meaningful to researchers including selection bias, inefficiency,
procedural burdens, increased costs, and abandoned studies. Translating these barriers into a patient perspective, the selection bias driven by HIPAA creates challenges to finding treatments applicable to all types of patients, thereby perpetuating health disparities. HIPAA also delays comparative effectiveness studies, which can identify the most effective therapies more rapidly for patients. The additional burdens to the patient consent process makes the patient experience more complicated, confusing, and unpredictable. In addition, HIPAA dishonors the trust that patients have in researchers when studies are abandoned and experimental treatments are no longer available. The resulting cost burden of these barriers weighs heavily on the healthcare and research system in terms of time, dollars, and the opportunity costs.

As Eric Cohen of the Medical College of Wisconsin noted, “By establishing these [HIPAA] impediments, we are compromising ourselves. By trying to reduce risk we are risking our future. We are hobbling research. We are not learning what we need to learn to make the world a better place.” (Cohen, 2008)

Efforts should be made to exempt health research from the HIPAA Privacy Rule. Simultaneously, oversight of research that more effectively ensures security protections and does not hamper biomedical research should also be implemented. As the IOM report on HIPAA notes “…if society seeks to derive the benefits of medical research in the form of improved health and health care, information should be shared to achieve that greater good, and governing regulations should support the use of such information, with appropriate oversight.” (IOM, 2009)
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