

HIPAA Privacy Rule: Exploration of Patient & Caregiver Perspectives

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EXECUTIVE SUMMARY

BACKGROUND AND METHOD

The National Health Council (NHC) is committed to ensuring that the broadest possible range of health research is conducted as expeditiously as possible, in the hope that each new change can improve health and bring patients closer to prevention, early diagnosis, more effective, easily tolerated, manageable and comfortable treatments, and even cures. Accordingly, the NHC is exploring ways to reduce barriers to health research.

The NHC commissioned Balch Associates to conduct nine computer-assisted telephone mini-focus groups during the period December 2011 to February 2012 to explore patient and caregiver views on the HIPAA Privacy Rule and its ramifications for medical research. The focus groups were funded by the National Institutes of Health grant, Protecting Privacy in Health Research (RC1 CA146501-01), in partnership with the Indiana University Center for Law, Ethics, and Applied Research in Health Information. The 59 participants in the mini-focus groups came from across the continental United States. They included adult patients, family caregivers of children with severe chronic physical conditions, and family caregivers of adults with chronic mental conditions that limit their ability to live independently. All participants were age 21 or older, actively used the Internet to enter data online, were interested in medical research, and had engaged in advocacy on some policy at organizational levels ranging from the workplace to the federal government. At the time of the interviews all patients had public or private health coverage, including prescription drug coverage.

KEY FINDINGS

No participant had been aware of the HIPAA Privacy Rule prior to the focus groups. Even after reading a concept—a carefully crafted multi-page document that described the Privacy Rule and its role in health research—participants often confused the Privacy Rule with the HIPAA papers they have had to sign before a patient can be treated, such as privacy, consent to treatment, and financial responsibility.

All participants considered medical research essential to advance the discovery of better treatments and cures. Some had benefitted personally from clinical research or knew of examples where research had benefitted family members or friends. They hoped that additional people, including themselves, family, friends, and more would benefit from medical research as well.

They particularly appreciated the advantages of computerized records-based research. Although most participants had a limited understanding of the intricacies of records-based research, they saw that it can reduce inconvenience to patients, and offers value for developing more personalized treatments.

They were willing to participate in records-based research. In general, participants were willing to have their own medical records or those of loved ones used in medical research in at least some circumstances. No one said they were completely unwilling to do so. Most insisted on the deletion of what they considered “personal” data, such as name, Social Security number, postal

and e-mail addresses, and telephone numbers, but did not object to the inclusion of age, gender, race, and even general geographic data.

Participants saw no need for continual re-authorizations. Most wanted to provide authorization to use their records for research, but also saw no need for continual re-authorizations. Many favored a one-time “approval” for ongoing use of their records, but some would limit use of their records to a specific health condition or for a limited time.

Participants were surprised, disappointed, and angry to learn that the presumably well-intentioned HIPAA Privacy Rule was impeding the medical research needed for better treatments and cures. Adding insult to injury, they were further shocked and enraged to learn that while the “authorization” process for their medical records was impeding research, no authorization was required for a purpose they found no value in: marketing.

All agreed that the Privacy Rule needs to be changed (“overhauled”) or eliminated to extend and improve patients’ lives.

Participants were willing and eager to take a variety of actions to have the Privacy Rule changed or eliminated. They were willing to write to their Congressional Representatives or Senators or speak personally with them; contact family, friends (both real and technologically-mediated) and their health care providers to “spread the word”; and seek help from organizations they trust, such as patient advocacy organizations.

Once introduced to the National Health Council, all participants eagerly welcomed its help. They saw a role for the NHC in developing and disseminating a petition and directing signatories to the relevant congressional decision-makers. They considered the NHC perfect for the breadth of its patient advocacy member organizations and its expertise in advocacy for patient-centered health policies.

KEY CONCLUSIONS

In view of the broad range of the patient and caregiver participants and the richness and consistency of these findings, we suggest several general conclusions and recommendations for action.

Once patients and caregivers understand the effects of the HIPAA Privacy Rule on medical records research they are likely to become willing and eager to change the rule or have it—though not all of HIPAA—eliminated.

Communicating clearly about how the HIPAA Privacy Rule impedes medical records-based research is a challenge. The rule is too complicated for most patients or caregivers to understand fully when first exposed to it. This in-depth, deliberative qualitative research suggests that the communication is best done in steps or stages, not all at once, with an initial focus on three critical basics:

1. **Explain what records-based research is and provide examples of it**, so that patients and caregivers can understand its value and replace their images of a

researcher “doing something” to a patient or looking over a patient’s file with images of a computer analyzing thousands of records

2. **Describe the HIPAA Privacy Rule in concrete terms that patients and caregivers can relate to their own experiences**, yet distinguish it from the privacy notices and other HIPAA-mandated paperwork routinely signed when visiting health care providers. For an example, see Version 3 of the concept participants saw (p. 22).
3. **Explain the ramifications of the HIPAA Privacy Rule, specifically how the extensive authorization process discourages records-based research and wastes money and time, thereby impeding the discovery of better treatments and cures.** It seemed unnecessary and even counterproductive to address other ramifications, such as how the rule in fact does not protect privacy, or that other safeguards, such as the Common Rule, already exist. These are too esoteric for patients and caregivers.

Although patients and caregivers will generally support changes to the HIPAA Privacy Rule once they understand it, getting agreement on what changes to make in the HIPAA Privacy Rule is another challenge. The focus group findings suggest that patients and caregivers will want patient name, Social Security number, and postal and email addresses deleted from records to be used for research. They will also support some kind of simplification of the process for authorizing the use of their medical records for health research.

As a national organization focused on patient-centered health care advocacy, the National Health Council would likely be welcomed by patients and caregivers as a leading organizer and communicator on this issue.

BACKGROUND

Medical research is increasingly using aggregated information from patient medical records to make key discoveries about the value of certain treatments, the positive and negative side effects of existing medicines, and the dangerous interactions of drugs and other substances. The Health Insurance Portability and Accountability Act (HIPAA) includes a set of federal standards, called the HIPAA Privacy Rule, which are intended to protect the privacy of individuals' medical records and other personal health information (PHI). However, when applied to health research the Privacy Rule duplicates other research protections and impedes information-based research. Health research conducted or supported by the U.S. government is already subject to federal regulations, including privacy protections, collectively known as the "Common Rule." The HIPAA Privacy Rule complicates the pre-existing Common Rule with new rules that add terms and procedures inconsistent with the Common Rule, adding delays and costs and discouraging researchers from initiating research.

In 2009 the Institute of Medicine's Committee on Health Research and the Privacy of Health Information concluded that the HIPAA Privacy Rule does not protect privacy as well as it should, and that it impedes important health research. The Committee recommended that the U.S. Department of Health and Human Services (HHS) exempt health research from the HIPAA Privacy Rule. The exemption would parallel those that already exist for other, arguably less important, uses of health data.

As recommended by the IOM, HHS would fill any gaps in existing privacy protection by establishing substantive requirements to protect the security and integrity of health information, ensure that information is made untraceable to individual patients as fully as possible consistent with health research needs, guarantee that the information is reused only for research, and establish strong oversight and other mechanisms to facilitate transparency, ensure accountability, and promote trust.

The National Institutes of Health awarded the Indiana University Center for Law, Ethics, and Applied Research in Health Information (CLEAR Health Information) a grant, Protecting Privacy in Health Research (RC1 CA146501-01), to make recommendations on five elements of the IOM's report:

- (1) the meaning of "strong security safeguards";
- (2) the ethical and technical dimensions of conducting research with deidentified PHI (personally identified health information) under the Common Rule without first obtaining individual consent;
- (3) the use of PHI for multi-center research and practical measures for making data broadly available for research, both domestically and internationally;
- (4) the regulatory framework necessary to achieve the high degree of privacy protection promised by the IOM committee report; and
- (5) oversight mechanisms to facilitate efficient and effective compliance.

To explore how patients and their family caregivers exposed to the HIPAA privacy rule understand and feel about the rule and practical approaches to carry out the IOM's recommendations, the NHC and CLEAR Health Information commissioned Balch Associates to conduct qualitative research, funded by the NIH grant.

METHOD

PROCEDURES

Communicating with families about the HIPAA Privacy Rule's impact on health research is challenging because it requires them to understand esoteric aspects of health research and federal regulatory processes. We first drafted a message concept in the form of a short document that used patient-centered language to explain the challenge presented by the HIPAA Privacy Rule and possible solutions to it. The message concept covered three topics:

- (1) the nature and benefits of records-based health research;
- (2) the Privacy Rule and key problems it creates for patients and researchers; and
- (3) the IOM solution to protect health information and eliminate the HIPAA Privacy Rule.

We sent the concept to focus group participants in advance and then used it as a discussion platform in iterative rounds of nationwide computer-assisted telephone (CAT) mini-focus groups. Mini-focus groups, moderated discussions with 4-7 people, are a cost-efficient way to get in-depth reactions to ideas and messages from a substantial number of people. From mid-December 2011 to early February 2012 we conducted three rounds of mini-focus groups, with a few weeks between each round, to allow time to revise the concept to incorporate participants' feedback. (See *Concept Iterations* for all three versions on pp.19 – 29.)

Each round of mini-focus groups included one session with each of three patient/caregiver segments:

- Patients with severe chronic physical conditions
- Family caregivers of children with severe chronic physical conditions
- Family caregivers with primary responsibility for adult patients with chronic mental illness that limit the individual's ability to live independently.

A market research firm recruited all participants from their private national database and supplemented their efforts through Internet outreach as needed. All were screened to be active Internet users who entered data online often (e.g., to pay bills, e-mail, make purchases, or post on social media vehicles). They also reported an interest in medical research and had engaged in advocacy on some policy at any organizational level, from the workplace to the Federal government.

Each group was moderated by one of three experienced moderators working from a discussion guide. The discussion guide was structured to take participants through the concept section by section, getting participants' reactions to each section in turn (see *Concept Iterations*, pp. 19-29). As with the concept, it was revised after the first and second round of groups, based on feedback from participants.

The recruitment screening questionnaire and one example of each version of the discussion guide are provided in the appendix.

PARTICIPANT CHARACTERISTICS

A total of 59 participants came from varied geographic, demographic, and health-related conditions. They were from 15 states across the U.S.: Arizona, California, Colorado, Delaware, Florida, Georgia, Illinois, Nevada, New York, North Carolina, Ohio, Pennsylvania, Texas, Virginia, and Wisconsin. Thirty characterized their location as urban, 24 characterized theirs as suburban, and five characterized theirs as rural.

Forty participants were women and 19 were men. Participants were racially and ethnically diverse: though most classified themselves as Caucasian, 14 said they were African American or Black, 8 identified as Hispanic, and a few identified as members of another racial/ethnic group or multiple racial/ethnic groups. Participants' educational attainment varied: 12 had master's degrees; 24 had bachelor's degrees; 6 had earned an associate's degree or technical certificate; 14 had some post-high school education (no degree), and 3 were high school graduates.

Participants in each of the three segments were touched by a variety of serious chronic health conditions:

- **Twenty-one were family caregivers of adults with mental conditions** that limit independent living, including: dementia, clinical depression, multiple strokes, advanced Alzheimer's, bipolar disorder, and anxiety disorder.
- **Nineteen were adult patients with severe physical conditions**, including debilitating arthritis, high blood pressure, congestive heart failure, heart attack, osteoporosis, hepatitis C, liver fibrosis, COPD, Type 2 diabetes, HIV, multiple sclerosis, lupus, lung cancer, breast cancer, liver cancer, chronic nerve damage, sarcoidosis, quadriplegia, obstructive sleep apnea, and frequent kidney stones.
- **Nineteen were family caregivers of young children with serious physical conditions**, including cystic fibrosis, severe allergies (requiring hospitalization or epi-pen), ADHD (under 24 hour observation), spina bifida, epilepsy, congenital heart defects, Type 1 diabetes, Stage 4 cancer (Alveolar Rhabdomyosarcoma), pulmonary hypoplasia, severe eczema, hypotonia, and global developmental delay.

NOTE ON METHOD

Qualitative research techniques provide rich, in-depth information and are flexible enough to permit exploration of emerging topics. They are therefore ideally suited to the types of research questions posed in this study, which focus on understanding what and how people think, feel, and behave. As with all qualitative research findings, results reported here provide insights into target audience members' reactions and ideas that would be unattainable with structured quantitative research. The findings are not statistically projectable to some larger group.

DETAILED FINDINGS

In this section, participants' reactions to the ideas in the concept statement are discussed first, followed by their thoughts about actions they could take to address the issue. Direct quotations from participants are italicized or enclosed in quotation marks.

NO PARTICIPANTS WERE AWARE OF THE HIPAA PRIVACY RULE BEFORE THE FOCUS GROUPS

Before the focus groups, no participant was aware of the HIPAA Privacy Rule or its relationship to health research. Initially they assumed that the HIPAA forms they sign before treatment also authorize health research.

I didn't know any of this. I didn't think about any of this and it's so important.

I never read this or heard this anywhere and I read a lot of medical news and try to stay updated on what's new and I've never ran into this before.

Patients and caregivers were not likely to distinguish among the many forms they sign at a doctor's office (privacy, consent to treatment, financial responsibility, etc.). After becoming aware of the HIPAA Privacy Rule, they tended to assume that papers releasing their health records for payment would also release their information for research.

You sign that paper whenever you go to the doctor. I thought it was just preventing other people, regular people, getting your information. I didn't realize they were blocking it from other doctors to pass on information that could be helpful.

Caregivers of adults with chronic mental conditions and patients who are also caregivers often referenced their issues in getting access to medical records. It will be important to distinguish this issue from the issues of the HIPAA Privacy Rule and consent/authorization to use records for research.

I understand the rule of privacy, but with documentation, power of attorney, and so forth, they won't even let me know or ask questions to help my dad.

The way the rules have been explained to me as a patient and also as a caregiver, I've always understood that we have to sign the papers again before any type of a specific research study's been done, or before anybody's admitted for a hospitalization, or even for medical care.

I gathered, I think, two perspectives on it. One was from the research perspective where HIPAA can hold up research and from a caregiver's perspective, it can also make – helping your loved one with their medical records, prescriptions, which I've experienced myself. It can make it difficult.

THEY CONSIDERED MEDICAL RESEARCH ESSENTIAL TO DISCOVERY OF BETTER TREATMENTS AND CURES

After reading and discussing the concept, all participants understood and agreed that medical research is essential for advancing the discovery of better treatments and cures. Some had benefitted personally from clinical research or seen others do so; others hoped that they and others would benefit from medical research as well.

Research drives medical advancement.

It sounds like most of us that are here today are here because of research that was done in the past that's helped us keep our health or return to health or keep our diseases under control.

My husband has severe diabetes and his was really bad and because of all the new drugs especially the long-lasting drugs, he only has to take one injection of insulin a day. So the research is definitely helping with sugar diabetes. It's advanced a lot since my mother had it years ago, the treatment.

I have spasmodic dysphonia and I've been getting Botox injections for 30 years - without which I could not talk - in my throat. I have to drive twelve hours roundtrip every three months to get an injection and I thank God for research or I wouldn't be sitting here talking.

I feel it's been working a lot for some people and generally speaking, it's been working for me. Like I said, I've been in my death bed for a few times and I'm up and running again. So I could be one of the ones that could say I'm proud to be alive still.

THEY SAW PARTICULAR VALUE IN RECORDS-BASED RESEARCH

Many appreciated the advantages of computerized records-based research, such as its ability to analyze thousands of records quickly without inconveniencing patients and the ability to make treatments more personalized. One even thought that record-based information could substitute for clinical trials.

If there was sort of like this database, if this was the information that doctors could connect with previous patients, then I wouldn't have had to go through everything I went through because nobody knew what was wrong with me.

It's so great, I think, to analyze thousands of records. The researchers don't have to take the time to meet with each patient because they've already met with their doctors and it's in the records.

I've got a condition that still a lot is not known about how to treat it. As a result I would be really gung ho about more intense research... To the extent that this

type of approach to research might yield some more personalized specific treatment for me is a good thing. It offers more hope.

I think what I see here is instead of having to start new research and develop methods right now and spend money to investigate, we already have this information available and as long as we aren't using the patient's personal information, we have all the information we would get from a new trial already in the computers. So therefore, it saves a lot of time.

THEY WERE WILLING TO PARTICIPATE IN RECORDS RESEARCH

In general, participants were willing to have their own health records, or those of loved ones, used in medical research in at least some circumstances. No one said they were completely unwilling to participate in such research.

I wasn't aware that our medical records were open to being researched, but I'm fine with that so long as they [redact] personal information like names and socials and stuff like that, but I am impressed with the advances they can make by doing that.

We felt very comfortable with allowing [my husband's] information to be shared because we knew in the future, down the road, it would make some changes for people who are going through the same thing that we were going through. If some of that research wasn't done, he could have been going through a year of chemo instead of six months of chemo. We really saw the benefit of being able to have medical records shared and information shared to be able to better assess what is really needed for a certain disease.

I would gladly open up my medical records for research because that's what they're for, for helping other people. I would look at something for that form like an option such as like what we have in our driver's license when you want to donate your organs. I would look at it that same way.

Nearly all participants thought records should be stripped of what they considered personally identifiable information: name, Social Security number, postal and email addresses, and phone numbers. A few even wanted the deletion of such personally identifiable information to be the default option, required by law:

If the default is that by law name, address, e-mail and phone are automatically deleted, that's great. If you got to say, "Hey, wait a minute. Check these boxes to do so" that presents a great risk to those that don't read the fine print or check the boxes. Or potential great risk.

I'm saying that once your records leave your doctor's office, say for a national research database, that all your personal information be excluded from your physical characteristics.

Some also put other limitations on use of their records, such as allowing them to be used (a) only to study or identify treatments for a specific health condition, (b) for a limited amount of time, or (c) with an option to change their mind and discontinue use of their records at any time. Others would “release everything,” including their perceived personally identifiable information. A few also noticed a disadvantage to deleting common personal information.

The thing that really stood out to me is that if it's for the same disease and you want to help in the future, you can't even sign a paper that says so, and that's the thing that stood out for me, that if you could just – if there could be some sort of rule that you just sign it just once and as long as it's for that specific disease, they don't have to have you sign it over and over and over each time they want to do another study, that you're automatically in the database for that but right now, it's such that you cannot sign the paper that says you can do that. I think that would be a key thing, if they could have that available.

Or sign it for – have it set for like five years or ten years that way you can do the research and continue and if it's done in ten years, then fine, you have all the information. If it's not, then you re-sign.

I think there should be an option to opt-in for maybe [your] lifetime or a certain duration that your records can be researched and available but there should also be an opt-out message just in case you do change your mind.

Others would “release everything,” including their name, Social Security number, addresses, and phone numbers and potentially embarrassing—and potentially valuable— health history.

I think we all each other have a choice to make whether we really would like it released or not, because I would release anything I've been through and I've been through a lot of weird things. I wouldn't care if they had my address, my name, anything else. In my family there's Huntington's disease. So I can see areas where people would not want their names or their confidential information released. So there ought to be a choice that we could make whether we wanted it released or not to help the researchers because I would be willing to release everything.

I have quite a few medical things in my history – different things. The latest thing is my chronic pain in my damaged nerve. I would want them to use every little bit [of my information] they could to help another person or another group of people. I want my information to be used for anybody it can ever help.

A few even noted an important disadvantage to deleting personally identifiable information:

To me there is good to it but there's also bad to it because by deleting a lot of that information I know you're given a number when you do this research. They give you a number instead of a name but sometimes it gets lost in the meaning and that

patient could have been helped with some of that personal information and it's gone. Then there is nothing you can do.

It could be an asset or a liability. It could work both ways. You got to worry about the personalization of the data. Also, like if it's deleted, then you got to worry about you getting that back.

THEY SAW NO NEED FOR CONTINUAL RE-AUTHORIZATION

Most participants thought they should be able to sign a lasting authorization for research use of medical records that are stripped of name, Social Security number, postal and email addresses, and phone numbers. Many wanted to sign a “blanket” authorization that would cover all types of health research using medical records. Others wanted to authorize a specific type of research (for example, on one health condition), but would want to be re-contacted if researchers wanted to use their records for another type of study.

... [A]s far as I'm concerned, as long as they take out things like Social Security number and names, then I would not have issues with them... using the data again, but they ought to have maybe some kind of permission slip where you can fill out for your child as long as you're under 18 that they can join any study or use the research for any study. I guess that's it.

Honestly, I can't say that there would ever be an instance where I wouldn't want my child's records to be in the database that would help for research. Research is beneficial. That's a no-brainer. I can't see why they can't pass something to where we can sign just one blanket paper that covers putting our child and their information into the database. It's just their medical records. Nobody's going to be able to steal their identity or anything silly like that. It's just their medical records. Why can't we sign a paper and say, "All my child's medical records can go into this database and it can be used for any medical research."?

They should have an all-purpose release of information form that somebody could sign with the understanding that their data may be used also in the present as well as the future.

I feel like you should be able to have one signature and it covers everything because as research goes on and on, there are new discoveries that actually could be [unintelligible] a stumbling block to keep new technology from developing and being able to save lives.

I would rather be it do an all one-stop shop, sign the name one time and let them go on, do whatever they need to be done for future blah, blah, blah and then that way, you wouldn't have to track down my dad because now he's in a grave or whatever.

THEY WERE ANGRY ABOUT THE PRIVACY RULE'S EFFECT ON RESEARCH

Participants commonly reacted to the information about the HIPAA Privacy Rule and its impact on research with surprise, disappointment, or anger.

They were surprised about HIPAA's negative impact on health research.

I was horrified. I didn't know that [slowing and blocking research] was happening.

They were disappointed that the Rule may have deprived patients of much-needed new treatments or cures.

If these medical records weren't slowed down and all this repetitive authorization, keeping things from keeping the ball rolling I can only imagine. We would have had better research, better medication ten, fifteen years ago because I'm sure the technology is there.

Prior to reading your document, it didn't occur to me that this law was infringing on research but after reading it and then coming to the conclusion that this law has been in place for sixteen years, the first thing I thought of was caring for someone who's in advanced years of a disease that is being researched, you have to wonder if this law were not preventing certain types of research from moving forward with my current situation of my loved ones be different.

They were also angry to learn that the Rule impedes medical research even while it allows their personal information to be shared without their authorization for marketing purposes.

That is really an invasion of my privacy and it's not helping medical research for you to send me marketing on the next pill that you want me to take.

I'm surprised about that. I don't know how people who are interested in marketing could get access to that and people who are doing research cannot. I want research to be continued and any way that they can get information, I don't think HIPAA should come in between it.

The most blatant [invasion of privacy] would be the marketing exclusion that companies that wish to market to you can get access to that data and one isn't protected by HIPAA from that.

The last people that you want to have your data have free access and the people that you'd most want to have your data, the researchers, don't have access. It's absolutely upside-down.

A few participants in different groups cautioned that there is broad support for HIPAA, so communications about the Privacy Rule will have to make it clear that one aspect of HIPAA is problematic, not the whole act.

There are a lot of people supporting HIPAA. HIPAA's a good thing. So I think you need to just make them understand somehow that you're not going to have your privacy invaded. It's not about the individual privacy. It's about helping the doctors to form this database to use the research.

I don't find anything wrong with the HIPAA laws. I think they're important to protect the patient and I think they're necessary.

THEY WANTED TO "FIX" THE PRIVACY RULE

Throughout the focus groups, participants wanted to see changes to the HIPAA Privacy Rule.

[I] completely agree that it is time to fix the HIPAA Privacy Rule.

It doesn't shock me that that's what the rules are, it's just the way that things are today, but I definitely think it needs to be changed.

My feeling is that in this country, we have too many rules. Some of these rules actually work against us. So any kind of rules which is going to slow down the progression of research for new medicine, I think those rules should be taken out.

I know that privacy rules are there to protect our privacy but when it comes down to health, in research, to save lives and extend people's lives, I think that's very important and that should be considered heavily. That's why I feel that this privacy rule should be overhauled.

ACTIONS THEY WOULD TAKE

The focus group participants were willing and eager to take action, though they could think of relatively few ideas on their own. They focused on "getting the word out" so that many people would know about it and also be eager to act. Members of each focus group suggested using social media, such as YouTube and Facebook. Though most could not offer specifics about how they would use these channels, some could.

[I would basically keep it] very personal. I would talk about my situation with my son and how he has cystic fibrosis and talk about if I keep it individual somebody might relate to me. I'll go in my support group where I talk to other mothers who have similar situations and I think when people can relate that's when things get done.

I'm sure those of us who are associated with specific diseases are already signed up with those diseases' action committees and they email us all the time. They could put a petition online where all we have to do is sign it online and forward that link to other people in our contact list. That would be the easiest and fastest way for them to get the signatures they need.

I guess until this discussion I didn't put much thought into HIPAA as it pertains to research and today, the entire web - social media is getting very popular. Let's say the Facebook, for example. Someone had a Facebook page dedicated to changing the HIPAA Privacy Law.

Each group also brought up contacting members of Congress through petitions or form letters. Other ideas included sharing the information with friends, family and neighbors, sharing information with their children's doctors or school parent-teacher associations, or "walking in a marathon."

You could write to [a] public office, you could write to—like they say—the Department of Health and whatnot and I would definitely write to an office to get it changed so then it wouldn't interfere with research.

I hope that this discussion would guide me in the right direction of who to address the letter to, to get this policy changed and that's something that I definitely would look into doing because I believe – I really believe that they didn't intend to do wrong but the policy has gone in the wrong direction and so I definitely would do something to help change it.

JOIN WITH PATIENT ADVOCACY GROUPS

A few participants in a group of caregivers of adults with chronic mental conditions raised the need for an advocate if they are going to change the HIPAA Privacy Rule.

[There] has to be someone advocating, maybe someone in the medical field that doesn't have anything that's at stake, someone that doesn't care about getting sued. I don't know who that would be, but someone that could advocate and say, "Okay, these are the concerns that – we had a little public forum. We've had people from different walks of life and these are their concerns.

You'll definitely need an attorney to represent your group, someone who can speak the language of Washington, and you'll just [start] to do like a grassroots movement and move from the local arena to state and then go federal.

When asked whether there were any organizations they might work with to bring about changes to the HIPAA Privacy Rule, participants typically mentioned organizations that represent patients and caregivers affected by various specific diseases.

... like if somebody has Parkinson's, there is a Parkinson's Action Network and then you can go to them for advice... they might be able to offer you a suggestion in addition to contacting your local representatives or things like that.

I'm already on the local board of the Epilepsy Foundation so I'd discuss it with them and see what their standpoint is and also I volunteer with NAMI so I would

also discuss it with them and see what their point of view is on it as well and see if they could do something about it.

Some participants also noted that different patient advocacy organizations might have different agendas.

I mean if you're going to go through one typical organization, you're only going to get one side of the story, so you would have to go to organizations that may be based off of what care you're giving at the moment. If you're caring for somebody with Alzheimer's, you may need to go to a diabetes one so that you can see what that aspect of it is because most of those organizations only focus on laws and things that are trying to be passed that are based off of what they do.

I mean obviously each organization is going to have their own agenda. I mean if it's Alzheimer's, they're going to be about Alzheimer's; if it's diabetes, they're going to be about diabetes. So I'm kind of in the middle.

Though no one spontaneously mentioned the National Health Council, when the moderator described it, participants thought the NHC could be quite helpful by getting the word out through mass and social media and by providing resources.

Well, I think I'd want this National Health Council as the ombudsman organization to take the lead and putting out the statement sharing much of the information that was shared in this paper but only in a very capsulized, abbreviated manner with links to get more information as needed and then you know, have people like or comment on this. I would not want to be the one to distill the information personally and put it out there. I don't think I would be as competent and capable of doing that as someone like this organization would.

I right now am on the email list of about 10 different progressive organizations that I like and they have all my personal data: name, address, phone, email, all of that, so they send me a pre-formatted letter that automatically they send out to my congressmen, my senators, the individual companies. All I've got to do is click "send message" and it's like I sent them a letter. So it really rapidly facilitates advocacy in a way that those of us, including myself, who are lazy, wouldn't do [it] on their own.

I would add the caveat, though [to working with individual patient advocacy organizations] that there's a certain point in which you get information overload. As you mentioned there are a lot of other organizations that were not mentioned here [in the National Health Council member list]. So at a certain point if I got too many of those I would tune out as opposed to you know, amalgamating and concentrating the influence under one ombudsman organization like the National Health Council.

DETAILED CONCLUSIONS

Since it is highly likely that patients and caregivers are unaware of the HIPAA Privacy Rule, the first necessity to bring about patient-centered change is to discuss the Rule and how it affects the discovery of better treatments and cures by impeding health research. The conclusions below are strongly suggested by participants' reactions to the iterations of the concept they read and discussed. Reactions to the specific language used in the concept iterations are discussed in the *Concept Iterations* section beginning on page 18.

The HIPAA Privacy Rule's effect on medical research is a very complex topic to communicate to patients and caregivers. People need to understand records-based health research, which is unfamiliar to many, what the HIPAA Privacy Rule is, and, finally, how it affects the conduct of records-based research. Communicating these three ideas successfully requires identifying what to talk about, how to talk about it so that people will not be distracted or confused, and—equally important—what *not* to talk about. Since so much of the information on this topic is new to most people, they need time to learn the basics before they can process the finer points. These focus groups provided many insights into what to include in initial communications about the Privacy Rule's impact on health research.

Here are some general suggestions for communications on this topic. The *Concept Iterations* section discusses the specific concept statement we used for this project, how we revised it, and what led us to each revision decision.

- Starting with a discussion of health research, including examples of valuable records-based research, is important to provide context for subsequent discussion of the Privacy Rule and its impact. When thinking about health research, most people tend to think of clinical trials or a doctor “doing something” to a patient, so concrete examples make records-based research easier to visualize and understand for the many people unfamiliar with it. However, there are some caveats:
 - **Avoid examples that are too novel** (such as the CPR example originally used in the concept) that distract people from the main points by over-focusing them on specifics. Unlike the more general examples used in the concept (such as making cancer less lethal and more manageable), CPR procedures are widely recognized and used by lay persons, but the recent research-based change of eliminating mouth-to-mouth resuscitation was not; as a result, the discrepancy between what they thought they knew and what they read commanded too much attention.
 - **Emphasize—possibly more than once—that these types of studies involve a computer analyzing thousands of health records** (all with what participants considered PHI redacted: name, Social Security number, postal and email addresses, and phone numbers). Since this type of research is relatively unfamiliar, people seem to revert to “seeing” a researcher working with a patient or looking through an individual's medical file.

- **Clarify the difference for patients and caregivers between consenting to have patient records used for health research and signing the many other forms they sign at a doctor's office** (privacy, consent to treatment, financial responsibility, etc.). After becoming acquainted with the HIPAA Privacy Rule, they tend to assume that papers releasing their health records for payment would also release their information for research. It is difficult to convey that the authorization to use records in medical research is different from that form.
- **As a national organization focused on patient-centered health care advocacy, the National Health Council would likely be welcomed by patients and caregivers as a crucial organizer and communicator on this issue.** Such a credible, resourceful source can greatly enhance the distribution and effectiveness of the advocacy message.

CONCEPT ITERATIONS

To introduce participants to the HIPAA Privacy Rule and its impact on health research, we developed a concept statement that covered three topics:

- (1) the nature and benefits of records-based health research;
- (2) the Privacy Rule and key problems it creates for patients and researchers; and
- (3) the IOM solution to protect health information and eliminate the HIPAA Privacy Rule.

Prior to the focus groups, participants were asked to review the concept statement. They then discussed each page during the focus groups sessions.

The concept statement was revised after the first three groups and again after the second three groups. Major changes between iterations are described below. Each iteration is shown side-by-side on the pages at the end of this section.

CHANGES FROM VERSION 1 TO VERSION 2

Changes to each section of the concept statement were as follows.

The Value of Health Research:

- In the examples of health research, the reference to recent research-based changes in CPR was removed because the statement about mouth-to-mouth resuscitation wasting time without helping to save lives was so surprising that many participants focused on it rather than on the main point of the section, which is to illustrate some of the many ways in which analyzing large numbers of medical records can lead to advances in treatment.
- In addition, new examples of conditions that have been improved by research were added to engage a broader range of participants more personally. Conditions mentioned were osteoporosis, lupus, Alzheimer's, and asthma.
- In the initial three groups, participants gravitated toward a concept of research in which people take experimental drugs as in clinical trials. To broaden the context we added a reference conveying that research also yields valuable results for prevention as well as treatment, and provided the example of heart disease as a case in point.
- In discussing medical records research, we added a description focusing on computer analysis ("One approach they use is to have computers analyze the medical records of many thousands of patients..."), to ease concern that a person might sift through a patient's highly personal data. This new section also emphasized that any data that might identify a patient is deleted in such research.
- To clarify confusion that all health research is treatment oriented, we added the idea that "This research does not require any new treatment—it just uses information that already exists...."

An Important Barrier to Health Research: The HIPAA Privacy Rule

- The change to this section was small but significant: we deleted any mention that the Privacy Rule does not protect privacy as well as it should. This point was so perplexing that participants had difficulty moving on to discuss other issues. They were concerned about a potential breach of privacy, and frustrated by the occurrence of unintended consequences. The concept was revised to mention only one major problem—that research is slowed or blocked.

How the Privacy Rule slows and blocks research

- A phrase about who signs papers allowing research, “or lawful representative,” was added to “patient,” because several participants in the first round of groups mentioned that as caregivers they sign all paperwork.
- The word “authorization” was deleted because it caused confusion.
- An additional mention was added stating that identifying information is deleted, and that computers, not people, analyze the data.
- The idea that many patients *expect* their data to be used for research was deleted. In the first round of groups it appeared to be too broad a statement.

How the Privacy Rule falls short on protecting patient privacy

- As mentioned above, discussion of the lack of privacy protection was eliminated to avoid confusion.

CHANGES FROM VERSION 2 TO VERSION 3

In various places as noted below, new subheadlines were added to break up large blocks of text and better “signpost” key messages.

The Value of Health Research

- Participants understood this section clearly, agreed with its points, and found nothing confusing. It remained unchanged.

New Subheadline: How Analysis of Medical Records Leads to Better Treatments or Cures

- The term “clinical trials” was added and explained to distinguish it from medical records research. Some participants had used the term “clinical trials” in earlier groups and its use created confusion.

An Important Barrier to Health Research: The HIPAA Privacy Rule

- We added the distinction that HIPAA was the law that was enacted, and the Privacy Rule was a regulation created later to help implement the law. That distinction had been confused in earlier discussion.
- We added a footnote with a complete citation for the IOM report because some participants had questioned the authority, reliability, and/or objectivity of the information in the prior concept statement.

How the Privacy Rule slows and blocks research

- A distinction was added to clarify the difference between HIPAA papers signed for any visit to a doctor's office and consent papers for research. In prior groups, some people thought the papers they signed at each doctor's office were also authorizing research.

New Subheadline: Removing the Barriers to Health Research (This section replaced the prior "Summary" section.)

- A new section was added to offer participants potential solutions to the problems created by HIPAA and the Privacy Rule, and a call to action. Patient advocacy groups were suggested, along with the National Health Council as an umbrella, to provide support for action.

First Section: The Value of Health Research		
Version 1 (Focus Groups 1-3)	Version 2 (Focus Groups 4-6)	Version 3 (Focus Groups 7-9)
<p>If you or someone you care for has a chronic disease or health condition, you know that health research has brought tremendous advances in quality of life over the last several decades. Whether it is cancer or heart disease, diabetes or asthma, Parkinson's or depression—new research discoveries have made symptoms more manageable, extended life expectancy, or even discovered cures.</p> <p>Health research has led to major successes that have helped millions of people. To name just a few, health research has:</p> <ul style="list-style-type: none"> • made many kinds of cancer, including breast cancer, leukemia, and prostate cancer, more manageable and less likely to be life-threatening. • revealed that taking aspirin immediately following a stroke greatly reduces the chance of another stroke. • found that mo-to-mouth resuscitation wastes valuable time in CPR and does not help save lives. The new recommended method for CPR is to do chest compression only. <p>As health researchers develop new drugs, devices, diagnostic tests, and therapies, they collect information about how these treatments affect patients. One approach they use is to study medical records of patients over time to determine what works best for people with similar conditions and symptoms. This approach offers great promise for developing personalized medicine, but it takes thousands of medical records over many years to identify the patterns that improve understanding of each disease. When researchers are able to study thousands of medical records, they may even be able to identify</p>	<p>If you or someone you care for has a chronic disease or health condition, you know that health research has brought tremendous advances in quality of life over the last several decades. Whether it is cancer or heart disease, diabetes or asthma, Parkinson's or depression—new research discoveries have made symptoms more manageable, extended life expectancy, or even found cures.</p> <p>Health research has led to major successes that have helped millions of people. To name just a few, health research has:</p> <ul style="list-style-type: none"> • made many kinds of cancer, including breast cancer, leukemia, and prostate cancer, more manageable and less likely to be life-threatening. • revealed that taking aspirin immediately following a stroke greatly reduces the chance of another stroke. • developed tests that identify many diseases, such as osteoporosis, lupus, Alzheimer's, and asthma in their earliest, most treatable stages. • found ways to prevent or reduce heart disease by an amazing 40% in the last 30 years. This "silent killer" that used to kill millions every year is now highly manageable with diet, exercise and/or medication. <p>As health researchers develop new drugs, devices, diagnostic tests, and therapies, they collect information about how these treatments affect patients. One approach they use is to have computers analyze the medical records of many thousands of patients to determine what works best for people with similar conditions and symptoms. Typically, personal information that may identify the patient is deleted from the records. The computers then look at the data on conditions, symptoms, treatments and results to find patterns and differences that provide clues to researchers. This research approach does not require any new treatment—</p>	<p>If you or someone you care for has a chronic disease or health condition, you know that health research has brought tremendous advances in quality of life over the last several decades. Whether it is cancer or heart disease, diabetes or asthma, Parkinson's or depression—new research discoveries have made symptoms more manageable, extended life expectancy, or even found cures.</p> <p>Health research has led to major successes that have helped millions of people. To name just a few, health research has:</p> <ul style="list-style-type: none"> • made many kinds of cancer, including breast cancer, leukemia, and prostate cancer, more manageable and less likely to be life-threatening. • revealed that taking aspirin immediately following a stroke greatly reduces the chance of another stroke. • developed tests that identify many diseases, such as osteoporosis, lupus, Alzheimer's, and asthma in their earliest, most treatable stages. • found ways to prevent or reduce heart disease by an amazing 40% in the last 30 years. This "silent killer" that used to kill millions every year is now highly manageable with diet, exercise and/or medication. <p>How Analysis of Medical Records Leads to Better Treatments or Cures</p> <p>As health researchers develop new drugs, devices, diagnostic tests, and therapies, they collect information about how these treatments affect patients. One approach they use is to have computers analyze the medical records of many thousands of patients to determine what works best for people with similar conditions and symptoms. Typically, personal information that could identify a patient is deleted from the records. The computers then look at the data on conditions, symptoms, treatments and results to find patterns and</p>

First Section: The Value of Health Research		
Version 1 (Focus Groups 1-3)	Version 2 (Focus Groups 4-6)	Version 3 (Focus Groups 7-9)
<p>characteristics that are associated with specific diseases, and potentially develop personalized treatment based on those characteristics.</p> <ul style="list-style-type: none"> In an example of personalized treatment approaches, health researchers found that for people with diabetes, a form of insulin that could be inhaled through the nose helps millions of patients manage their symptoms better, but for people who also have asthma, emphysema, or other lung diseases, it is dangerous. In another personalized approach, health researchers discovered that although the blood thinner Coumadin saves lives for millions of people prone to blood clots, heart attacks, or stroke, it causes life-threatening internal bleeding for people with certain health characteristics. 	<p>it just uses the information that already exists in the medical records. It offers great promise for developing personalized medicine, but it takes thousands of medical records over many years to identify the patterns that improve understanding of each disease. When researchers are able to study medical records in this way, they may even be able to identify characteristics that are associated with specific diseases, and potentially develop personalized treatment based on those characteristics.</p> <ul style="list-style-type: none"> In an example of personalized treatment approaches, health researchers found that for people with diabetes, a form of insulin that could be inhaled through the nose helps millions of patients manage their symptoms better, but for people who also have asthma, emphysema, or other lung diseases, it is dangerous. In another personalized approach, health researchers discovered that although the blood thinner Coumadin saves lives for millions of people prone to blood clots, heart attacks, or stroke, it causes life-threatening internal bleeding for people with certain health characteristics. 	<p>differences that provide clues to researchers.</p> <p>This research approach uses the information that already exists in medical records. It does not require any new or experimental treatment like the research conducted in clinical trials. Research with medical records offers great promise for developing personalized medicine, but it takes thousands of medical records over many years to identify the patterns that improve understanding of each disease. When researchers are able to study medical records in this way, they may even be able to identify characteristics that are associated with specific diseases, and potentially develop personalized treatment based on those characteristics.</p> <ul style="list-style-type: none"> In an example of personalized treatment approaches, health researchers found that for people with diabetes, a form of insulin that could be inhaled through the nose helps millions of patients manage their symptoms better, but for people who also have asthma, emphysema, or other lung diseases, it is dangerous. In another personalized approach, health researchers discovered that although the blood thinner Coumadin saves lives for millions of people prone to blood clots, heart attacks, or stroke, it causes life-threatening internal bleeding for people with certain health characteristics.

Second Section: An Important Barrier to Health Research: The HIPAA Privacy Rule		
Version 1 (Focus Groups 1-3)	Version 2 (Focus Groups 4-6)	Version 3 (Focus Groups 7-9)
<p>Unfortunately, it is becoming harder for researchers to conduct the studies to move medicine forward. One reason is the Privacy Rule created under a law called the Health Insurance Portability and Accountability Act, or HIPAA.</p> <p>The HIPAA law was intended to help health records move from your provider (such as your doctors or hospital) to the insurance company to process payment—and to protect the privacy of your health information. But the HIPAA Privacy Rule affects health research in ways that were never intended or expected.</p> <p>The Institute of Medicine (IOM), an independent, highly respected nonprofit organization, convened a panel of experts in health care, medical research, health law, medical ethics, and data security to study HIPAA’s effects on health research and privacy. Their report pointed out two big problems with the HIPAA Privacy Rule that may concern you: (1) the rule has slowed or blocked health research, and (2) it does not protect patient privacy as well as it should.</p>	<p>Unfortunately, it is becoming harder for researchers to conduct the studies to move medicine forward. One reason is the Privacy Rule created under a law called the Health Insurance Portability and Accountability Act, or HIPAA.</p> <p>The HIPAA law was intended to help health records move from your provider (such as your doctors or hospital) to the insurance company to process payment—and to protect the privacy of your health information. But the HIPAA Privacy Rule affects health research in ways that were never intended or expected.</p> <p>The Institute of Medicine (IOM), an independent, highly respected nonprofit organization, convened a panel of experts in health care, medical research, health law, medical ethics, and data security to study HIPAA’s effects on health research and privacy. Their report pointed out a major problem with the HIPAA Privacy Rule that may concern you—the rule is slowing down, or even blocking, health research.</p>	<p>Unfortunately, it is becoming harder for researchers to conduct the studies to move medicine forward. One reason is a law called the Health Insurance Portability and Accountability Act, or HIPAA, and the “Privacy Rule” that was created after the law was passed to help implement it.</p> <p>The HIPAA law was intended to help medical records move from your provider (such as your doctors or hospital) to the insurance company to process payment—and to protect the privacy of your health information. But the HIPAA Privacy Rule affects health research in ways that were never intended or expected.</p> <p>The Institute of Medicine (IOM), an independent, highly respected nonprofit organization, convened a panel of experts in health care, medical research, health law, medical ethics, and data security to study HIPAA’s effects on health research and privacy. Their report¹ pointed out a major problem with the HIPAA Privacy Rule that may concern you: the rule is slowing down, or even blocking, health research.</p>

¹ Nass, Sheryl J., Levit, Laura A. Gostin, Lawrence O., Editors; Committee on Health Research and the Privacy of Health Information. *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*. National Academies Press, 2009. Print. Web, <http://www.iom.edu/Reports/2009/Beyond-the-HIPAA-Privacy-Rule-Enhancing-Privacy-Improving-Health-Through-Research.aspx>

Third Section: How the Privacy Rule slows and blocks health research		
Version 1 (Focus Groups 1-3)	Version 2 (Focus Groups 4-6)	Version 3 (Focus Groups 7-9)
<p>The HIPAA Privacy Rule requires researchers to get a patient to sign papers (called “authorization”) again and again for each specific research study that could be helped by that patient’s medical record information. Though that may sound like a good idea, it means that if you want to allow your health information to be used for ongoing research about your disease in the future, you cannot sign a paper that says so. Researchers would still have to re-contact you—and every other patient who wants to share their medical records—every time they want to add data from your records to any study.</p> <p>The requirement for getting authorization again and again makes it much more expensive, time consuming, or even impossible to do the large scale, long-term research studies needed to understand diseases and how to treat them. Researchers must track down patients (who may have moved, changed their phone numbers or e-mail addresses, or even died), to get them to sign forms again and again. Few organizations can afford that, so they don’t even try to do the research. Those few who can complete the research waste so much time and money on paperwork that it takes much longer to conduct the research and slows down the discovery of treatments and cures.</p> <p>Surprisingly, while the HIPAA Privacy Rule is so strict about health research, it allows medical records to be used <i>without</i> patient authorization for other reasons, including reporting infectious diseases, access by courts, access by insurance companies, and marketing.</p> <p>Ironically, many patients expect that their health information will be used for research in general, and do not feel the need to provide consent for their health records to be used in one study after another.</p>	<p>The HIPAA Privacy Rule requires researchers to get a patient or lawful representative to sign papers again and again for each specific research study that could be helped by that patient’s medical record information. Though that may sound like a good idea, it means that if you want to allow your health information to be used for ongoing research about your disease in the future, you cannot sign a paper that says so. Researchers would still have to re-contact you—and every other patient who wants to share their medical records—every time they want to add data from your records to any study. (As usual, any information that would identify a person is deleted and a computer analyzes the data for researchers.)</p> <p>The requirement for getting signatures again and again makes it much more expensive, time consuming, or even impossible to do the large scale, long-term research studies needed to understand diseases and how to treat them. Researchers must track down patients (who may have moved, changed their phone numbers or e-mail addresses, or even died), to get them to sign forms again and again. Few organizations can afford that, so they don’t even try to do the research. Those few who do try to do the research waste so much time tracking down patients to get signatures that it takes much longer to conduct the research and slows the discovery of treatments and cures.</p> <p>Surprisingly, while the HIPAA Privacy Rule is so strict about health research, it allows medical records to be used <i>without</i> patient authorization for other reasons, including reporting infectious diseases, access by courts, access by insurance companies, and marketing.</p>	<p>As a patient or lawful representative of a patient, you are familiar with the HIPAA papers you must sign allowing your doctor or hospital to use your medical records for insurance payment. Maybe you have never been asked to allow records to be used for health research, but if you were, HIPAA rules would require you to sign a much more extensive level of paperwork.</p> <p>The HIPAA Privacy Rule, however, requires researchers to get a signature <i>again and again</i> for <i>each specific research study</i> that could be helped by a patient’s medical record information. Though that may sound like a good idea, it means that if you want to allow your medical record to be used for ongoing research about your disease in the future to help thousands of patients with the same condition, you cannot sign a paper that says so. Researchers would still have to re-contact you—and every other patient who wants to share their medical records—every time they want to add data from your records to any study. (As usual, any information that would identify a person is deleted and a computer analyzes the data for researchers.)</p> <p>The requirement to get each patient’s or their lawful representative’s signature again and again makes it much more time consuming, expensive, or even impossible to do the large scale, long-term research studies needed to understand diseases and how to treat them. Researchers must track down patients (who may have moved, changed their phone numbers or e-mail addresses, or even died), to ask them to sign forms again and again. Few organizations can afford that, so they don’t even try to do the research. Those few who do try to do the research spend so much time and money tracking down patients for signatures that it takes much longer to conduct the research and slows the discovery of treatments and cures; sometimes they don’t even finish the research.</p> <p>Surprisingly, while the HIPAA Privacy Rule is so</p>

Third Section: How the Privacy Rule slows and blocks health research		
Version 1 (Focus Groups 1-3)	Version 2 (Focus Groups 4-6)	Version 3 (Focus Groups 7-9)
		<p>strict about health research, it allows medical records to be used <i>without</i> patient authorization for other reasons, including reporting infectious diseases, access by courts, access by insurance companies, and marketing.</p> <p>The HIPAA Privacy Rule has been turned upside down. Although nobody ever intended it to, the way it's being implemented in the health care system, it's blocking the progress of health research for new treatments and cures.</p>

Fourth Section: How the Privacy Rule falls short on protecting patient privacy		
Version 1 (Focus Groups 1-3)	Version 2 (Focus Groups 4-6)	Version 3 (Focus Groups 7-9)
<p>In addition to interfering with health research, the HIPAA Privacy Rule does not adequately protect your privacy. For example, it does not require providers to store your records securely, limit access to them, and monitor their actual use. Requiring you to sign an authorization from each time your records are used helps ensure that they are used only with your permission. But in the long run it does nothing to ensure that researchers adequately safeguard your privacy.</p>	<p>Not in this version.</p>	<p>Not in this version.</p>

Fifth Section: Title varied; see below		
Version 1 (Focus Groups 1-3)	Version 2 (Focus Groups 4-6)	Version 3 (Focus Groups 7-9)
<p>Summary</p> <p>The HIPAA Privacy Rule is not protecting your privacy adequately, and it's impeding the progress of health research and better treatments and cures for you and your loved ones.</p> <p>It's time to fix the HIPAA Privacy Rule.</p>	<p>Summary</p> <p>The HIPAA Privacy Rule has been turned upside down. Although nobody ever intended it to, the way it's being interpreted in the health care system, it's blocking the progress of health research.</p> <p>It's time to fix the HIPAA Privacy Rule.</p>	<p>Removing the Barriers to Health Research</p> <p>What can be done about this? Fortunately, there is a concrete solution which brings hope for positive change, and you can help. You probably want to contribute all you can to medical research, for yourself or your loved ones, and for future generations.</p> <p>Health advocates from more than 40 nonprofit patient advocacy organizations large and small, such as the American Cancer Society, the American Diabetes Association, Epilepsy Foundation, National Multiple Sclerosis Society of America, Parkinson's Action Network, and Spina Bifida Association are coming together to support a solution. Under the umbrella of the nonprofit National Health Council, they are organizing to change HIPAA.</p> <p>When the time is right, patient advocacy groups will ask people like you to email, write or call their Senators and House Representative, as well as the Department of Health and Human Services. These organizations will ask you to tell policymakers you want HIPAA changed so that it stops interfering with health research.</p> <p>It's time to change HIPAA. People in Washington need to hear from you on this topic. You are the critical link, because your personal story makes it real. If real people like you don't speak up, it may never change. But with the support of thousands of people like you, it will change.</p>