

## Concerns about Privacy Are a Substantial Barrier to Participation in Medical Research

*New Survey Suggests Ways to Address These Concerns*

A survey of the public, including samples of those who have participated in or declined to participate in medical research, shows that concerns about the privacy of medical records and distrust of those conducting the research are major reasons why many people decline to participate. The survey also suggests strategies that could be used to address these privacy concerns and increase participation.

This new survey was conducted by Harris Interactive with Dr. Alan Westin, Professor of Public Law and Government Emeritus, Columbia University and Director, Health Privacy Program, Privacy Consulting Group. The survey was commissioned by the Institute of Medicine's Committee on "Health Research and the Privacy of Health Information: The HIPAA Privacy Rule." The survey was based on a nationwide survey of 2,392 adults surveyed online between September 11 and 18, 2007. The sample included 349 adults who had participated in medical research using personal medical records and 193 adults who had been asked to participate but had declined to do so.

The full survey report by Professor Westin can be viewed at <http://www.iom.edu/CMS/3740/43729.aspx>.

### Participation in Medical Research

Overall, 13 percent of U.S. adults say that they had participated in medical research using their "personally- identified medical or health information." In general, people over 50 are twice as likely to have participated as people under 50, and African-Americans are about twice as likely to have participated as Whites or Hispanics.

Eight percent of all adults say they were invited to participate in medical research using their personally identifiable medical records, but decided not to participate.

**Table 1**  
**Ever Participated in Research That Used Your Personal Health Information**  
"Have you ever participated in a research study that used your personally identified medical or health information?"

Base: All Adults

Yes: Participated	Total (%)
All adults	13
<b>Race</b>	
White	12
African-American	23
Hispanic	10

Yes: Participated	Total (%)
<b>Age</b>	
18-24	6
25-29	10
30-39	8
40-49	10
50-64	19
65+	20

**Table 2**  
**Ever Refused to Participate in Research That Would Have Used Personal Health Information**

“Have you ever been asked to have your personal medical or health information used in a health research project but you decided not to participate?”

Base: All Adults

Yes: Refused	Total (%)
All adults	8
Race	
White	7
African-American	13
Hispanic	10

### Concerns About Privacy and Lack of Trust Are Important Reasons for Not Participating in Medical Research.

When shown a list of seven reasons why they decided not to participate, the reason given most frequently (30%) is “I was concerned my personal information would not be kept private and confidential.” The third most common reason (22%) is “I didn’t have trust in the people or organization conducting the research.”

Two other reasons, unrelated to privacy concerns, are given for declining to participate – 24 percent say they were worried that “participation would be risky, painful or unpleasant,” and 16 percent say that “the research would not have helped my health condition.”

It should also be noted there may be other important reasons for not participating in medical research. Fully 23 percent of those who decided not to participate say they had other reasons and 16 percent say that none of the reasons on the list were their reasons.

**Table 3**  
**Reasons for Not Participating**

“Which of the following reasons did you have for not participating?”

Base: Decided Not to Participate

	Total
	%
I was concerned my personal information would not be kept private and confidential	30
I worried that participation would be risky, painful or unpleasant	24
I didn’t have trust in the people or organization conducting the research	22
The research would not have helped my health conditions	16
The research would not have helped the health of present or future members of my family	6
I didn’t think the research was important	6
The research would have been costly for me or my family	5
Other	23
None of these	16

Note: Multiple Response question.

## The Research Experience: Large Majorities Report That Their Participation Was Comfortable

Overall most participants (58%) report that their participation was “a very comfortable experience” or that it was “somewhat comfortable” (28%). Only a small minority of participants in medical research using their personally identifiable medical information report that it was “not a very comfortable experience” (10%) or “not a comfortable experience at all” (3%). However it should be noted that these small percentages represent more than three million people who may, in turn, have described their unpleasant experiences to others, and therefore have reduced participation in other research.

The survey found that participants to medical research studies were recruited in many ways, the most common being through a doctor or clinic (18%), an advertisement (15%) or by mail (7%).

Most participants believe that they were generally “very informed” (50%) or “somewhat informed” (35%) about the purposes and proceedings of the study before it started. However that leaves a small minority who felt they were “not very informed” (12%) or “not at all informed” (4%).

The personal health information used in the research came mainly from personal health information provided by the participants (69%), blood, tissue samples or test results (38%), medical records from their doctors’ offices (25%), or from other medical facilities (20%).

Only two percent believe that their personally-identified health information was given to someone outside the research staff. More than half (59%) reported that this did not happen but many say they do not know (38%).

**Table 4**  
**How Comfortable Was Participation in Research**

“Overall, which one of the following statements best describes what you felt about participating in this health research study?”

Base: Have Participated in Research Study

	Total
	%
This was a very comfortable experience	58
This was a somewhat comfortable experience	28
This was not a very comfortable experience	10
This was not a comfortable experience at all	3

**Table 5**  
**How Participants in Research Were Recruited**

“If you have participated in more than one health study, please use the most recent one for your answers. How were you recruited to participate in the study?”

Base: Have Participated in Research Study

	<b>Total</b>
	%
Personal health information that I supplied to the researchers by a questionnaire or interview	69
A specimen or sample of my blood or tissue or results of a test done in the study	38
My medical record in a doctor’s office	25
My medical record in a health care facility	20
My participation record in a pharmacy	4
My medical information from a disease registry, such as a cancer registry, an HIV registry, or other data base	4
Some other source	7
I don’t know or cannot recall	12

**Table 6**  
**How Well Informed Were Participants About the Purposes and Procedures of the Research**

“How informed did you feel about the purposes and procedures of the study before it started?”

Base: Have Participated in Research Study

	<b>Total</b>
	%
Very informed	50
Somewhat informed	35
Not very informed	12
Not at all informed	4

**Table 7**  
**Sources of Personal Information Used in Research**

“Where did the researcher get your personal medical or health information that was used in this study?”

Base: Have Participated in Research Study

	<b>Total</b>
	%
Personal health information that I supplied to the researchers by a questionnaire or interview	69
A specimen or sample of my blood or tissue or results of a test done in the study	38
My medical record in a doctor’s office	25
My medical record in a health care facility	20
My participation record in a pharmacy	4
My medical information from a disease registry, such as a cancer registry, an HIV registry, or other data base	4
Some other source	7
I don’t know or cannot recall	12

**Table 8**

**Personal Information Given to Anyone Outside the Research Staff**

“To your knowledge, was any of your personally-identified medical or health information used in this study ever given to anyone outside the research staff?”

Base: Decided Not to Participate

	Total
	%
Yes, my personally-identified medical or health information was given to someone outside the research staff.	2
No, my personally-identified medical or health information was not given to someone outside the research staff	59
I don't know or recall if my personally-identified medical or health information was given to someone outside the research staff	38

**Different Groups Have Very Different Attitudes to Steps Needed to Get Their Participation**

There is absolutely no consensus on what medical researchers need to do to obtain public participation in their studies. At one end of the spectrum, 13 percent of adults say “I would not want the researchers to contact me or to use my personal medical or health information under any circumstances.” At the other end of the spectrum, 19 percent say “my consent to use my personal medical and health information would not be needed as long as the study never revealed my personal identity and it was supervised by an Institutional Review Board.” A further eight percent say that they would be “willing to give a general consent in advance to have my personally-identified medical or health information used in future research projects without the researchers having to contact me.”

However, a substantial plurality (38%) say that they “would want each research study seeking to use my personally-identified medical or health information to first describe the study to me and get my specific consent for such use.”

Analysis of these replies show some differences between Whites, African-Americans and Hispanics (with the latter more likely to be unsure), but the general pattern of their responses are similar.

The survey also looked at the replies of people with disabilities, those who had used mental health services, those with a sexual condition or who had had an alcohol or drug problem, to see if their replies were substantially different. In general, the first three groups were somewhat more likely to say that they would want a full description of the study, but none of those were more likely than the average to say they would not want to be contacted or to have the information used under any circumstances.

**Table 9**  
**Opinions on Various Situations**  
“In these situations, which is closer to your opinion?”

Base: All Adults

	Total	Race			Respondents Who Had			
		White	Black	Hispanic	Disabilities	Used Mental Health	Sex Condition	Alcohol/ Drug Problem
	%	%	%	%	%	%	%	%
I would want each research study seeking to use my personally-identified medical or health information to first describe the study to me and get my specific consent for such use	38	39	45	28	40	44	49	35
My consent to use any personal medical and health information would not be needed as long as the study never revealed my personal identity and it was supervised by an Institutional review Board	19	20	16	18	16	23	17	30
I would not want the researchers to contact me or to use my personal medical or health information under any circumstances	13	14	12	9	13	8	8	5
I would be willing to give a general consent in advance to have my personally-identified medical or health information used in future research project without the researchers having to contact me	8	8	6	6	8	7	10	9
Researchers would be free to use my personal medical and health information without my consent at all	1	1	1	5	1	1	5	1
Not sure	20	18	20	33	22	16	12	19

### Reasons Why Many Participants Would Want Specific Consent

The 38 percent of all adults who say they would require a description of the study to get their specific consent for the use of their personal medical information were asked for their main reasons. Most of them agree with several reasons presented in the survey. Those given most often were that they wanted “to know what the purposes of the research are before I consent” (80%), “knowing about the specific research study and who would be running it would allow me to decide whether I trusted them or not” (62%), and “I would be worried that my personally identi-

fied medical or health information may be disclosed outside the study” (54%). In addition, almost half (46%) say that they would “want to know whether the research could help my health condition or those of my family.”

**Table 10**  
**Why Potential Participants Would Want Specific Consent**

“If you think there should be specific consent for each research project, what are the main reasons for your not wanting to give advance general consent or to have your information used without consent?”

Base: Would Require Specific Consent

	Total
	%
I would want to know what the purposes of the research are before I consent	80
Knowing about the specific research study and who would be running it would allow me to decide whether I trusted them or not	62
I would be worried that my personally-identified medical or health information may be disclosed outside the study	54
I would want to know whether the research could help my health conditions or those of my family	46
Other	3

### **Majorities Generally Trust Their Own Doctors, Hospitals and Researchers – But Only “Somewhat” – and They Are Not Confident That Federal and State Laws Protect Them**

Most people (83%) generally trust their own health care providers to protect the privacy of their personal medical records, but only 30 percent say that they trust them “strongly.”

Health researchers are also generally trusted by most people (69%), but far fewer trust them “strongly” (11%). However, fully 58 percent of adults agree that the privacy of their medical and health records are not adequately protected by Federal and State laws. And 50 percent say that “even if nothing that identifies me were ever published or given to an organization making consumer or employee decisions about me, I would still worry about a professional health researcher seeing my medical records.”

In reviewing these data, readers should note that the high level of agreement with these statements does not imply that everyone has thought about the issue before they were interviewed. The survey measures how people react to the statements when they are presented to them.

**Table 11**  
**Degree of Agreement or Disagreement**  
“Please indicate whether you agree or disagree with the following statements.”

Base: All Adults

	<b>AGREE (NET)</b>	Strongly Agree	Somewhat Agree	<b>DISAGREE (NET)</b>	Somewhat Disagree	Strongly Disagree
	%	%	%	%	%	%
I generally trust my health care providers – doctors – and hospitals – to protect the privacy and confidentiality of my personal medical records and health information	<b>83</b>	30	54	<b>17</b>	12	5
Health researchers can generally be trusted to protect the privacy and confidentiality of the medical records and health information they get about research subjects	<b>69</b>	11	58	<b>31</b>	24	7
The privacy of personal medical records and health information is not protected well enough today by federal and state laws and organizational practices	<b>58</b>	17	41	<b>42</b>	33	10
Even if nothing that identifies me were ever published or given to an organization making consumer or employee decisions about me, I still worry about a professional health researcher seeing my medical records	<b>50</b>	12	38	<b>50</b>	35	15

### **So What? An Analysis by Professor Alan Westin**

*Alan Westin's Commentary on the Survey Findings and Their Implications*

*As noted in the opening of this report, the IOM Committee commissioned this survey as an input to its project investigations and policy consideration. As such, it represents one resource in a wide-ranging set of studies the Committee has obtained on conducting health research under the HIPAA Rule, including other relevant public opinion surveys, health research expert assessments, and advocacy presentations reflecting the full range of policy positions on the Committee's issues.*

*I offer, in conclusion, some overall judgments on how I see these survey results relating to the health research and privacy issues under the consideration of the Institute of Medicine (IOM) Committee. These comments draw on my experiences in serving as the advisor to seven other national surveys on health privacy issues from 1993 to the present; in conducting field studies of how computerization from the 1970s to today has affected privacy interests and prompted protective laws and*

*organizational policies; in serving as a privacy consultant since the 1960s to several dozen health care institutions, research organizations, and healthcare technology firms; and as an expert witness advocating federal health privacy legislation in various Congressional hearings since the 1970s.*

## **1. The Intensity of Health Privacy Concerns**

*Our results confirmed what many other recent and current surveys have found – that large majorities of the public continue to hold strong privacy perspectives in the handling of their personal health information (PHI), especially when secondary uses are involved. Our survey found that 58 percent of the public does not believe that federal and state laws and organizational practices provide enough privacy protection today for consumers’ personal health information. Though we did not ask about it directly, other surveys have found that concerns over the security of health information and continuing well-publicized data breaches involving PHI are part of this “privacy” concern.*

*This suggests that any set of solutions to the process of obtaining PHI for health studies will have to find ways to meet – and satisfy – the privacy and data security concerns of a rather skeptical public majority.*

*It also suggests to me, apart from the IOM project, that writing updated health privacy protections for when health care reform is taken up in the next Congress, or when federal funding for Electronic Health Record (EHR) programs is considered, will draw a strong advocacy drive and much public support. (Indeed, this is already taking place in Congressional consideration of EHR funding bills. See, for example, Proposed Amendment to S. 1693, introduced by Senator Leahy (D-Vt), “to provide for the privacy and security of protected health information in the adoption of a nationwide interoperable health information technology system.”)*

## **2. Interpreting the Recruitment Alternatives**

*As we reported, none of the five alternative responses to our question about respondents’ willingness to have their PHI used in health research could command a majority, and 20 percent of respondents could not even make a choice.*

*The largest group – 38 percent – would insist on having the study described to them and obtaining their specific consent. Many important demographic groups chose this option by 43 percent to 51 percent, and persons who have actually participated in health studies hold this view at 44 percent. Though these respondents were informed in the set-up question that researchers were concerned about the costs, delays, and sampling issues in requiring such notice and express consent, four out of ten respondents did not find those arguments sufficient to persuade them to forego the notice and specific consent procedures.*

*I see a possibility that satisfying the first condition – describing the study and its executors – might sometimes obviate the desire for express or positive consent from some members of the 38 percent group we identified. In some cases – namely, where the research is seen by the individual as socially valuable and the researchers as “trustworthy” – there might be an opt-out choice. That is, having been given*

*a description of the purposes of the research and the organization/researchers conducting it, a patient might be informed that his or her PHI would be used unless the potential participant objected.*

*We did not pose that procedure in the IOM survey. But my sense, gained from having conducted many surveys where the opt-out and opt-in choices were posed in various consumer settings, is that a significant segment of the 38 percent privacy-concerned respondents would find full notice and an opt-out choice to be satisfactory. Having a “privacy veto” could well be seen as acceptable for what were judged to be socially-valuable health studies by trusted researchers.*

*I found it especially interesting that only 19 percent of respondents were willing to have their PHI used without consultation if their anonymity was assured and there was IRB review. Those two elements make up what many health researchers hope potential participants in health studies would find sufficient.*

*However, I believe that if those two elements were combined with notice (the study description) more than 19 percent might be willing to have their PHI used without a specific choice. I take this view because several surveys summarized in Appendix D suggest that the specific nature and goals of a research study and perceptions by respondents about the trustworthiness and social value of various types of health researchers are key factors in an individual’s decision whether to participate on a health research study.*

### **3. Implications of the Survey for Future Health Data Systems**

*While the IOM study focuses on the here and now, it seems to me valuable to think about the implications of the IOM survey for emerging EHR programs and Net-based personal health record (PHR) systems. While still limited, these programs promise to create vast pools of PHI which – if they could be used in health research – could dramatically enhance epidemiological, public-health, drug-impact, genetic, and other fundamental health studies. Many health researchers see such “health data mining” as a major goal for health research in the coming decades.*

*However, getting such uses accepted would, I believe, require institutionalizing the two fundamental conditions that the IOM survey documented as majority public conditions – description of the studies to be undertaken and an individual choice mechanism – whether an opt-out or an opt-in. If notice and a choice mechanism were acceptable to EHR/PHR participants, there could even be solicitation of a general advance acceptance by individuals to have their PHI used – with anonymity assured and IRB review – for designated classes of health studies and by specified types of researchers.*

*It would be important to do surveys of EHR and PHR system participants to learn what processes of notice and consent were acceptable and in what different kinds of research situations, and then to do post-study surveys to assess satisfaction levels with the conduct and outcomes of the studies. This would also help health researchers to engage in more of a partnership relation with health-data subjects, and thereby enhance overall public support for health research.*

## Methodology

This survey was conducted by Harris Interactive with Dr. Alan Westin, Professor Public Law and Government Emeritus, Columbia University and Director, Health Privacy Program, Privacy Consulting Group. The survey was commissioned by the Institute of Medicare Committee on “Health Research and the Privacy of Health Information: The HIPAA Privacy Rule.” and was based on a nationwide survey of 2,392 adults surveyed online between September 11 and 18, 2007. The sample included 349 adults who had participated in medical research using personal medical records and 193 adults who had been asked to participate but had declined to do so.

Figures for age, sex, race, education, region and household income were weighted where necessary to bring them into line with their actual proportions in the population. Propensity score weighting was also used to adjust for respondents’ propensity to be online.

All sample surveys and polls, whether or not they use probability sampling, are subject to multiple sources of error which are most often not possible to quantify or estimate, including sampling error, coverage error, error associated with nonresponse, error associated with question wording and response options, and post-survey weighting and adjustments. Therefore, Harris Interactive avoids the words “margin of error” as they are misleading. All that can be calculated are different possible sampling errors with different probabilities for pure, unweighted, random samples with 100% response rates. These are only theoretical because no published polls come close to this ideal.

Respondents for this survey were selected from among those who have agreed to participate in Harris Interactive surveys. The data have been weighted to reflect the composition of the adult populations of the respective countries. Because the sample is based on those who agreed to participate in the Harris Interactive panel, no estimates of theoretical sampling error can be calculated.

*These statements conform to the principles of disclosure of the National Council on Public Polls.*

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