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I. BACKGROUND

There is little dispute that protecting the privacy of medical information and ensuring access to medical information for research are both admirable goals. Failure to adequately protect medical information may result in serious harm to health care consumers including stigmatization, discrimination, or loss of employment.¹ Giving consumers the ability to choose or consent to how their information is used is often seen as a means by which consumers can protect themselves against these potentially adverse repercussions.² At the same time, research based on medical records ("medical records research") has led to significant discoveries in health care,³ such as the finding that supplementing folic acid during pregnancy can prevent certain birth defects.⁴ Often this research requires reviewing thousands of medical records, making it difficult if not impossible, to obtain the consent of all consumers whose records are used. Reconciling these interests has proven to be difficult.⁵

A. Privacy Protections for Medical Records Research before HIPAA

For over a decade, the primary source of privacy standards for much medical records research has been the "Common Rule," a set of regulations designed to protect human subjects in federally funded research.⁶ Under the Common Rule, institutional review boards (IRBs) have the responsibility for ensuring that federally funded research (including medical records research) adequately protects the privacy of the research subjects and maintains the

1. See, e.g., Sonia W. Nath, Note, *Relief for the E-patient? Legislative and Judicial Remedies to Fill HIPAA's Privacy Gaps*, 74 GEO. WASH. L. REV. 529, 529-30 (2006) (describing medical privacy violations).

2. See June Mary Zekan Makdisi, *Commercial Use of Protected Health Information Under HIPAA's Privacy Rule: Reasonable Disclosure or Disguised Marketing?*, 82 NEB. L. REV. 741 (2004).

3. See generally Standards for Privacy of Individually Identifiable Health Information, 64 FED. REG. 59918 (preamble to rule proposed Nov. 3, 1999) (discussing the benefits of health records research). See also Meredith Kapushion, Comment, *Hungry, Hungry HIPAA: When Privacy Regulations Go Too Far*, 31 FORDHAM URB. L.J. 1483 (2004).

4. CENTER FOR DISEASE CONTROL, RECOMMENDATIONS FOR USE OF FOLIC ACID TO REDUCE THE NUMBER OF CASES OF SPINA BIFIDA AND OTHER NEURAL TUBE DEFECTS, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/0019479.htm>.

5. For similar statements of the problem, see Stacey A. Tovino, *The Use and Disclosure of Protected Health Information for Research Under the HIPAA Privacy Rule: Unrealized Patient Autonomy and Burdensome Government Regulation*, 49 S.D. L. REV. 447, 447-8 (2003-2004); Marie C. Pollio, Note, *The Inadequacy of HIPAA's Privacy Rule: The Plain Language Notice of Privacy Practices and Patient Understanding*, 60 N.Y.U. ANN. SURV. AM. L. 579, 579-80 (2004).

6. See Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46, Subpart A (setting out the Department of Health and Human Services' regulations governing human subject research). Other federal agencies have similar requirements.

confidentiality of patient data.⁷ To conduct medical records research, researchers generally are required to obtain the informed consent of all the patients whose records they would like to review unless an IRB waives this requirement. An IRB may waive the informed consent requirement if it decides that the proposed research involves "no more than minimal risk," that the waiver "will not adversely affect the rights and welfare of subjects," and that the research "could not practicably be carried out without the waiver."⁸ Until the implementation of the privacy regulations under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA Privacy Rule" or "Privacy Rule"), granting waivers for medical records research was generally the norm. Even when researchers are required to obtain informed consent, the Common Rule permits them, in certain limited circumstances, to use a general informed consent (subject to IRB limitations) in which patients consent to the use of their medical information for a limited class of unspecified future research.⁹ While federal funding can be suspended or withdrawn from an institution violating the Common Rule, there is no authority to impose penalties directly on individual researchers for violations.¹⁰

B. The HIPAA Privacy Rule and Research¹¹

Pursuant to authority granted to it in HIPAA, the U.S. Department of Health and Human Services ("HHS") issued standards for the protection of individually identifiable health information (the Privacy Rule).¹² The Privacy Rule directly applies only to health plans, certain health care providers, and

7. The Common Rule also sets standards for the general composition of IRBs. Under the Common Rule, IRBs must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. They also must be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. *Id.* at § 46.107 (2005).

8. *Id.* at § 46.116 (2005).

9. See U.S. DEP'T OF HEALTH AND HUMAN SERVICES, NIH Publication No. 03-5428 INSTITUTIONAL REVIEW BOARDS AND THE HIPAA PRIVACY RULE, 15 (August 2003) at http://privacyruleandresearch.nih.gov/pdf/IRB_Factsheet.pdf.

10. See 45 C.F.R. § 46.123 (2005).

11. See also Charity Scott, *Is Too Much Privacy Bad for Your Health? An Introduction to the Law, Ethics, and HIPAA Rule on Medical Privacy*, 17 GA. ST. U. L. REV. 481 (2000).

12. Standards for Privacy of Individually Identifiable Health Information, 65 FED. REG. 82461, 82691 (Dec. 28, 2000) (hereinafter Final Privacy Rule) and 67 FED. REG. 53182 (Aug. 14, 2002) (hereinafter Modified Final Rule). For further discussion, see generally John F. Olinde & Hal McCard, *Who is Regulated by the Privacy Rule and What Information Does HIPAA Protect?*, 72 DEF. COUNS. J. 158 (2005); Kristen B. Rosati, *Human Genetic Sampling and the HIPAA Privacy Standards*, 45 JURIMETRICS J. 251 (2005); Symposium, *Living with the HIPAA Privacy Rule*, 32 J.L. MED. & ETHICS 73 (2004); Symposium, *The HIPAA Privacy Rule: Reviewing the Post-Compliance Impact on Public Health Practice and Research*, 31 J.L. MED. & ETHICS 70 (2003).

health care clearinghouses (“covered entities”)¹³ and sets restrictions on how these entities may use identifiable health information and disclose it to others.¹⁴ Researchers generally are not subject to the Privacy Rule’s restrictions.¹⁵

Partially in response to a U.S. General Accounting Office report that suggested that Common Rule procedures for medical records research may not adequately ensure the confidentiality of medical records and to address the fact that the Common Rule did not cover all researchers, the HHS included in the HIPAA Privacy Rule, provisions governing the disclosure of medical information for research.¹⁶ Thus, although the Privacy Rule does not directly regulate the activities of IRBs or researchers, it restricts the manner in which health care providers can use and disclose identifiable health information for research purposes.¹⁷

The Privacy Rule’s research provisions attempt to mirror the requirements of the Common Rule by permitting health care providers to share identifiable health information with researchers only if all patients whose information is to be disclosed have given written authorization or an IRB (or privacy board, if federal funding is not involved) has waived the authorization requirement.¹⁸ Under the Privacy Rule, separate authorizations must be obtained for each research project: general authorizations for future unspecified research are not permitted.¹⁹ To be compliant with HIPAA, a waiver can be issued by an IRB that has determined that 3 criteria have been met: 1) the research could not “practicably” be conducted without identifiable information, 2) the research involves minimal risk to privacy, and 3) obtaining written authorization from all patients is not “practicable”.²⁰ Researchers can avoid obtaining authorizations or HIPAA-compliant waivers if they utilize de-identified medical information (which has had every one of eighteen identifiers removed or been statistically determined to pose only a very small risk of

13. 42 U.S.C. § 1320d-1; Administrative Data Standards and Related Requirements, General Administrative Requirements, 45 C.F.R. §160.103 (defining “covered entity”), Administrative Data Standards and Related Requirements, Privacy of Individually Identifiable Health Information, 45 C.F.R. §164.500.

14. 45 C.F.R. § 164.502 (generally prohibiting the use or disclosure of protected health information except as permitted or required by the Privacy Rule or as authorized by the individual who is the subject of the information).

15. U.S. DEP’T OF HEALTH AND HUMAN SERVICES, PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH: UNDERSTANDING THE HIPAA PRIVACY RULE at 1 (2005) available at http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf [hereinafter RESEARCH AND HIPAA GUIDE].

16. 65 FED. REG. at 82691 (preamble to Final Rule).

17. RESEARCH AND HIPAA GUIDE, *supra* note 15.

18. Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53182, 53230 (preamble to Modified Final Rule) (Aug. 14, 2002).

19. RESEARCH AND HIPAA GUIDE, *supra* note 15.

20. 45 C.F.R. § 164.512(i)(1)-(2). See also, Rosati, *supra* note 12, at 265; Jack A. Rovner, *Making Sense of HIPAA Privacy: Solutions for Complex Compliance Dilemma*, 37 J. HEALTH L. 399 (2004).

identification for subjects) or "limited data sets" (which have had all of the obvious identifiers removed).²¹ However, many researchers find that information that has been de-identified to this extent is less than useful.

Those who violate the Privacy Rule may be subject to civil and criminal penalties.²² However, it appears that these penalties only may be imposed on covered entities (*i.e.*, health plans, health care providers and health care clearinghouses to whom the substantive requirements of the Privacy Rule apply).²³ Because researchers generally are not covered by the Privacy Rule, neither are they subject to the civil and criminal penalties imposed by the Rule. In contrast, covered health care providers who wrongfully disclose protected health information to researchers may be subject to these penalties.

The Privacy Rule reflects many significant modifications made during the rule-making process to address researcher concerns.²⁴ Many researchers, however, continue to strongly criticize the research provisions and to press for revisions of the Rule.²⁵ Among other things, researchers express concern that the Rule is ambiguous, that IRBs are confused about and have widely varying interpretations of the waiver criteria, and that, consequently, research is being adversely impacted.²⁶ Some researchers, noting that the Privacy Rule's requirement that separate authorizations be obtained for each specific research project is contrary to the Common Rule, recommend that if the Privacy Rule's authorization or waiver requirements are not eliminated, the Rule be modified to permit the use of general authorizations that provide consent

21. See U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH SERVICES RESEARCH AND THE HIPAA PRIVACY RULE, at 4 (discussing de-identified data and limited data sets in research) (May 2005) available at <http://privacyruleandresearch.nih.gov/pdf/HealthServicesResearchHIPAAPrivacyRule.pdf>.

22. 42 U.S.C. §§1320d-5 and 1320d-6.

23. Scope of Criminal Enforcement under 42 U.S.C. § 1320d-6, Mem. Op. Off. Legal Counsel (2005) available at http://www.usdoj.gov/olc/hipaa_final.htm.

24. For example, in response to researcher comments on the proposed rule, waiver criteria were significantly modified before the issuance of the Final Privacy Rule in 2000. See *Preamble to Final Rule* 65 Fed. Reg. at 82690-82700. Additionally, limited data sets were created in response to researchers concerns about de-identifying data. U.S. Department of Health and Human Services, *Preamble to Proposed Rule, Standards for Privacy of Individually Identifiable Health Information*, Federal Register, 67 (March 27, 2002) 14793-14797 and *Preamble, Modified Rule* at 53232-53238.

25. The HIPAA Privacy Rule may be altered, but no more than once every twelve months. Health Insurance Portability and Accountability Act, 42 U.S.C. §1320d-3 (2005).

26. *Privacy in Health Care and Society, Hearing Before the Nat'l Comm. on Vital and Health Statistics, Subcomm. on Privacy and Security* (February 23, 2005) [hereinafter *Privacy Hearing*] (testimony of Bernard Lo, University of California, San Francisco) available at <http://www.ncvhs.hhs.gov/050223tr.htm>; *Implementation Issues under the HIPAA Privacy Rule, Hearing Before the Nat'l Comm. on Vital and Health Statistics, Subcomm. on Privacy and Security* (Nov. 20, 2003) [hereinafter *Implementation Hearing*] (testimony of James Roberts, Magee-Womens Research Institute at the University of Pittsburgh) available at <http://www.ncvhs.hhs.gov/031120p4.htm>; *Id.* (Nov. 19, 2003) (testimony of Association of American Medical Colleges) available at <http://www.ncvhs.hhs.gov/031120p2.pdf>.

to use medical information for future, unspecified research.²⁷ Others have suggested exempting medical records research from the Privacy Rule, asserting that research violations of acceptable privacy standards should be addressed through other existing laws, regulations and institutional requirements.²⁸

Discontent with the Privacy Rule's research provisions will likely grow both as implementation difficulties continue to surface and as the potential for using electronic medical records for research becomes a reality.²⁹ The current administration has made the development of an electronic-based National Health Information Infrastructure a priority and has expressly included research as one of the core functions of such a system.³⁰ One prominent medical ethicist has made the acknowledgedly provocative suggestion that in order to take full advantage of electronic medical records, certain types of medical records research should be exempt from *both* the Common Rule and the Privacy Rule restrictions.³¹

For their part, privacy advocates generally have asserted that ensuring privacy will improve both the quality of care and the information available to researchers during the prolonged rule-making process. They have contended that if patients do not trust providers to maintain confidentiality, then in turn, they may withhold or misrepresent important information. One medical ethicist expressed the belief that IRB waivers of the authorization requirement should be "used sparingly."³²

Patients, whose interests may vary somewhat from advocates and ethicists, have had little input into this debate. Although health care consumers filed thousands of comments during the rule-making process,³³ few addressed issues related to research in any detailed fashion.³⁴ Renewed efforts to modify

27. *Implementation Hearing* (Roberts testimony) and (summary of testimony of Indiana University School of Medicine (IUSM) & Indiana University Purdue University Indianapolis (IUPUI) Research Community), available at <http://www.ncvhs.hhs.gov/031120p1.htm>.

28. *Implementation Hearing* (testimony of Association of American Medical Colleges) *supra* note 26.

29. See, e.g., Comment, *HIPAA's Headaches: A Call for a First Amendment Exception to the Newly Enacted Health Care Privacy Rules*, 53 U. KAN. L. REV. 479 (2005) (arguing that "courts should either overturn the law [HIPAA] or create numerous exceptions to it" on public interest grounds).

30. Helga E. Rippen, and William A. Yasnoff, *Building the National Health Information Infrastructure J. OF AHIMA*, May 2004 at 20-26.

31. *Privacy in Health Care and Society Hearing*, *supra* note 26 (Lo B., Testimony before NCVHS).

32. George J. Annas, *Medical Privacy and Medical Research - Judging the New Federal Regulations*, 346 NEW ENG. J. MED. 216-220 (Jan. 17, 2002).

33. Avrum Goldstein, *A Behind the Scenes Force for Privacy*, WASHINGTON POST A-21 (April 28, 2003).

34. *Issues in HHS's Proposed Rule on Confidentiality of Personal Health Information, Hearing before the Senate Comm. on Health, Education, Labor and Pensions* (April 26, 2000) (testimony of United States General Accounting Office at 10) available at

the Privacy Rule have generated little, if any, public response from patients, privacy advocates or medical ethicists. Furthermore, the emergence of a national health information infrastructure raises new concerns that have yet to be addressed thoroughly by these stakeholders.

As the landscape surrounding the use of medical records for research continues to evolve, it becomes crucial to re-examine the legal standards for utilizing medical records for this purpose.³⁵ It is imperative to know patient views on these standards before medical records become widely available to researchers through a national health information infrastructure.³⁶ Lack of informed patient input could potentially derail the development of such a system.³⁷

II. METHODOLOGY

Between July 2003 and July 2004 we conducted a series of intensive focus groups utilizing the deliberative democracy model (described below) along with individual and group surveys with patients at Veterans' Administration (VA) medical centers to determine how they thought the research provisions of the Privacy Rule should be interpreted. We also sought to determine what patients thought should be the optimal rules under which researchers may obtain medical records for conducting medical records research. Our goal was to document these views and to determine whether views changed when patients received additional substantive information and discussed the issues with others.

To ensure participants received balanced information about the relevant issues, our team included both a privacy advocate expert and a research advocate expert. The experts participated in developing survey and protocol design as well as answering questions and presenting the views of the respective sides during the deliberative sessions. They did not, however, perform any of the analyses. We also had a Steering Committee of national experts with extensive expertise and practical experience in legal, scientific and ethical aspects

<http://www.gao.gov/archive/2000/he00106t.pdf>.

35. For an overview of the evolving legal landscape, see Merideth C. Nagel, *Litigation after HIPAA's Patient Privacy Regulations*, 15 NO. 5 HEALTH LAW. 14 (2003).

36. To our knowledge, there has been no sustained empirical effort to investigate the attitudes of patients towards disclosure of medical information. For a look at how HIPAA has impacted health care providers, see Richard H. Sanders & Kathryn L. Stevens, *The More Things Change, the More They Stay the Same: An Analysis of the Impact of the HIPAA Privacy Rule on Illinois Mental Health Providers*, 7 DEPAUL J. HEALTH CARE L. 43 (2003). For non-empirical discussion of the impact of HIPAA on patients, see Diane Kutzko, et al. *HIPAA in Real Time: Practical Implications of the Federal Privacy Rule*, 51 DRAKE L. REV. 403 (2003).

37. For example, the development of a national electronic medical record system in the United Kingdom was threatened when family doctors urged a boycott of the system due to privacy concerns. See Nicholas Timmons, *Doctors Pained by System for Electronic Records*, FINANCIAL TIMES (London), June 19, 2004, (National News) at 2.

of the privacy/research debate review the background materials, protocol, briefing materials, and results for completeness and balance.

We selected a randomized sample of patients (stratified by age, race, and visit frequency) from four geographically diverse Veterans Affairs (VA) facilities to participate in our baseline and follow-up phone surveys. We stratified that sample of patients into three groups based on number of clinic visits and age to ensure a balanced representation of light, moderate, and heavy users of the VA healthcare system and of age. We used the number of clinic visits and age as proxies to indicate higher likelihood of mobility, morbidity, or chronic health issues. Ensuring balanced numbers of older and heavier users of the healthcare system would allow us to gain insight into whether these patients are more sensitive about researchers using their medical records or whether they have special incentives to want more research compared to those who may have a lower burden of illness. We stratified by race to help ensure the deliberation groups would be balanced with respect to race. We invited those who completed the baseline survey to an all-day deliberative session. At each of the four sites, we randomly assigning each subject to one of 9-10 deliberative groups comprised of 4-6 individual participants. We obtained IRB ethics approvals for this study from each of the four sites.

We used a deliberative democracy model to conduct our group sessions. In the deliberative democracy model, participants are presented with balanced briefing material and afforded the opportunity to engage in dialogue with experts and each other based on questions they develop in small groups. The method aims at obtaining opinions representative of those that the public would reach if people had the opportunity to become more informed and engaged by the issues.³⁸

Our deliberative sessions were designed to elicit both qualitative and quantitative data on group opinions. We began the deliberation session by presenting background information about how medical records could be used, how medical records research is conducted, and a basic explanation of the research provisions of the HIPAA Privacy Rule. The remainder of the day was comprised of two deliberation cycles, conducted according to a written protocol designed to take veterans assigned to small groups, step-by-step through the deliberative process.

In the first cycle, groups were instructed to deliberate and develop advice on what factors VA research boards should look at in deciding whether researchers had met the following Privacy Rule criteria for being able to obtain medical records without patient authorization: 1) the research could not

38. Michael Neblo, *Thinking Through Democracy: Between the Theory & Practice of Deliberative Politics*, ACTA POLITICA, 40, no. 2 152-164 (2005). See also AMY GUTMANN & DENNIS THOMPSON, *DEMOCRACY AND DISAGREEMENT* (1996); *DELIBERATIVE POLITICS: ESSAYS ON DEMOCRACY AND DISAGREEMENT* (Stephen Macedo, ed., 1999); *DEBATING DELIBERATIVE DEMOCRACY* (James S. Fishkin & Peter Laslett, eds. 2003); *DELIBERATIVE DEMOCRACY: ESSAYS ON REASON AND POLITICS* (Jon Elster, ed. 1997).

“practicably” be conducted without identifiable information, 2) the research involves minimal risk to privacy, and 3) obtaining written authorization from all patients is not “practicable.”³⁹ A privacy expert and a research expert informed the groups of the respective stakeholders’ views and answered participants’ questions. In the second cycle, we asked small groups to deliberate about whether the provisions of the Privacy Rule that allow researchers to obtain medical records without permission were acceptable the way they are currently written or whether the provisions should be changed. In this cycle, the moderator presented four hypothetical hospitals representing a range of methods for researchers to obtain data. The research policies of the hospitals included 1) maintaining the status quo; 2) patients could opt out of having their records used for research; 3) patients could sign a general permission form that allowed their medical records to be used for research without having to be asked every time; and 4) researchers must ask patients for their permission every time they wanted to use their records for research. After the privacy expert and research expert commented on the policies of these hypothetical hospitals and responded to questions from the participants. The small groups were then asked to select their preference among these hospitals.

We obtained quantitative measures by administering a group-level survey immediately after each round of deliberation. The surveys contained key measures for determining the group’s opinions about the importance of research, obtaining permission before using identifiable medical information for medical records research studies, and the relative importance of factors to be considered when deciding whether or not to allow researchers to have access to identifiable medical information without permission. We asked participants to respond to the surveys as a group after coming to agreement about the best response to each item.

All deliberations were audio-recorded. We randomly selected from each location, deliberations from four groups who fully engaged in the deliberation (a 40% sampling of groups) to transcribe verbatim. The verbatim transcripts along with written recommendations from all groups were used to conduct the qualitative analyses. Staff from the project team, along with experts in qualitative analyses, conducted the coding and analysis of the deliberation.

We administered surveys to individual participants at the time of recruiting, during the deliberation session and 4-6 weeks after the session. The baseline telephone survey elicited patient satisfaction and trust with their health-care provider, attitudes about privacy, familiarity with HIPAA, and general demographic information. Surveys administered during the administrative session included measures specific to the topics being deliberated including: the importance of obtaining patients’ permission to use their medical records for research and the factors that should be considered in deciding whether

39. See 45 C.F.R. 164.512.

researchers should have to contact patients to use their medical records for research. The follow up telephone surveys included the same questions.

III. STUDY LIMITATIONS

The patient population we studied (veterans) was generally older and disproportionately male in comparison to the general population. Participants' relationships with the VA, the health care provider/health plan whose research practices they were asked to deliberate, are not typical of the relationships most healthcare consumers have with their health care providers. Many veterans receive free or substantially reduced-cost health care from the VA (most of it at VA medical centers and clinics), which may generate a sense of obligation towards or trust in the VA. Furthermore, unlike traditional health plans the VA does not reduce medical care coverage or increase costs for VA medical center health services when a veteran becomes increasingly ill. However, participants in our study demonstrated a level of concern about invasion of privacy in general (73%) similar to that voiced by the general public (74%).⁴⁰ Our participants also received substantial information about privacy and research issues and spent the better part of a day reaching their informed conclusions. Moreover, our results are fairly consistent with general (non-HIPAA specific) studies of patients' perspectives of research and privacy conducted with other populations.⁴¹

IV. RESULTS

A. Knowledge of HIPAA and Research

Participants had limited knowledge about the HIPAA Privacy Rule and research going into the deliberative session. At baseline, seventy-five percent (75%) of the participants did not know that medical records could be used in some research studies without patient permission. Thirty-nine percent (39%) had not even heard of HIPAA prior to the study.

B. Willingness to Permit Information to be Used for Research

The majority of participants (86%) agreed that it was "very to critically" important to be able to conduct medical records research in the VA system. A similar percentage of participants (87%) indicated that they would be inclined to give permission to a VA researcher to use their medical record for research

40. California HealthCare Foundation, *Medical Privacy and Confidentiality Survey—Final Toplin* (January 1999), available at <http://www.chcf.org/topics/view.cfm?itemID=12500>.

41. Donald J. Willison et al., *Patients' Consent Preferences for Research Uses of Information in Electronic Medical Records: Interview and Survey Data*, 326 BRIT. MED. J. 373 (15 Feb. 2003); Nancy Kass et al., *The Use of Medical Records in Research: What Do Patients Want?* 31 J.L. MED. & ETHIC 429-433 (2003).

Many participants stated during deliberations that they would be willing to let their records be used for research provided that the data did not directly identify them. One particular participant articulated that "...I think it [research] is important. That's just my feelings. But I don't have any problems with them using my records but they use, they strictly use a number. They don't use my name. It goes into the record as a number not a name..."

C. Desire to Have Some Control Over Medical Records

Although participants expressed willingness to have their medical records used for research, they also consistently voiced the desire to have some control over the use of their medical records for this purpose. During the first cycle of deliberation, in which participants were to consider the criteria for waiving patient authorization, all but one group spontaneously questioned whether researchers should be allowed to obtain patients' health information *at all* without patient permission.⁴² In response to a later-administered group survey, 86% of the groups stated that it was "very to critically" important for the VA to ask a patient at least once whether researchers can use their medical records for future medical records research.⁴³ When asked to select their preference among the four hypothetical hospitals representing a range of methods for researchers to obtain data, only 12% of the groups chose the hospital which represented the status quo, where the IRB decides, on its own, whether a researcher must obtain patients' authorization to use their medical records for research. Eighty-eight percent of the groups preferred hospitals in which patients had some control over their medical records being used for research.

The majority of groups that wanted some say in whether their medical records were used for research were not opposed to obtaining general permission for future research. Only 18% of the groups preferred the hypothetical hospital which requires researchers to obtain patients' permission every time they want to use their medical records for research. The majority of groups (59%) chose the hospital where patients would be asked once if their medical records could be used for future research. When the groups were asked whether there was anything they would change about their choice to make the hospital act exactly as they wanted, some of these groups stated that they would prefer that patients be asked once a year whether their medical records could be used for research. Additionally, a number of groups recommended

42. This concern first spontaneously manifested itself in a pilot study we conducted to test the protocol and deliberative process. We revised our protocol in the full study to specifically accommodate this concern.

43. Individual surveys reflected similar, but less pronounced preferences. 76% percent of the participants individually held the belief that it was very to critically important to ask patients at least once whether their medical records could be used for research.

that patients be allowed to control and determine which parts of their medical records are available for research.

D. Waiver Criteria

The groups deliberated about the Privacy Rule's criteria that IRBs must use to determine whether researchers may obtain identifiable health information without patient authorization. Group discussion on the waiver criteria focused on how to interpret the two following criteria: (1) The use or disclosure of information involves no more than a minimal risk of privacy to the individual; and (2) The research "could not practicably be carried out without the waiver". With respect to minimal risk, many participants wanted assurance that someone would be held accountable for privacy violations. Participants who felt strongly about this suggested that individuals violating patient's privacy should face penalties such as being fired, paying fines, or serving jail time. Groups also believed that it was important to consider who was conducting the study (generally trusting VA researchers more than others), the purpose of the study, and the sensitivity or stigma attached to the health condition or information being studied in evaluating risk.

The groups failed to reach consensus on what factors should be considered in determining whether it was "practicable" to do the research without patient authorization. About half the groups felt that the following two factors were the major or most important factors to consider under the "practicability" standard: 1) Having to contact each patient first would make the study less scientifically accurate (49%); 2) Having to contact each patient would make the results less useful in improving medical care (50%).⁴⁴ Fewer groups (26-30%) thought that cost, affordability, or impracticability of having to get permission were at least major factors to consider. As one participant stated, "It's influenced by time and money. How much money do you want to spend on it? Time? How much time is it going to take?" Other participants were unsympathetic to the increased costs and amount of time involved with obtaining permission, commenting that, "...if you can't afford it don't do it".

During deliberation, participants had strong reactions to the term "practicability," characterizing it as a "weasel word" that could be used to "...mean anything you want it to." Some participants called for the Privacy Rule, especially this criterion, to be written with terms that are easily understood by all.

44. Individuals voiced similar preferences when polled anonymously, with 51% believing that accuracy of the study should be a major or one of the most important factors to consider and 52% believing that usefulness should be a major or one of the most important factors.

V. RECONCILING INTERESTS

As the national health information infrastructure develops and researchers continue to press for changes to the Privacy Rule to take advantage of electronic medical information, it is important for policy makers to also continue to consider the views of those whose medical records are used for research: patients. While the Privacy Rule should not needlessly thwart medical records research, neither should it marginalize patients' concerns. It may be possible to reconcile these interests, at least with respect to some issues, in a manner that is satisfactory for all stakeholders.

A. Authorization

Perhaps the greatest issue dividing researchers and patients is whether researchers should be able to access medical records without individual patient authorization. In considering researchers' requests to scale back or even eliminate authorization requirements, policy makers should give adequate consideration to the desires of patients. Our analysis suggests that the majority of patients would oppose granting such requests unless, at a minimum, patients are informed that their medical records might be used for research and have an opportunity to opt-out. Our participants recognized the value of research and would willingly allow their medical records to be used for research (at least by certain entities), yet still felt that it was essential that they be asked at least once whether their records can be used for this purpose. These findings seem to reflect not only the desire to have some control over information that can be extremely personal but also the desire to be shown some degree of personal respect. Our study adds to the growing body of studies that consistently show that patients want a say in whether their medical records are used for research.⁴⁵

One possibility for reconciling these competing interests is the use of general or blanket authorizations for research, as suggested by prior studies.⁴⁶ Researchers have requested that the Privacy Rule be revised to permit the use of general consents and it appears that many patients support this policy. Although, from a privacy perspective, general authorizations are not ideal since patients are not fully informed of the research for which their records will be used, they were preferred by participants over the status quo where IRBs are the sole arbiters of whether individual authorization should be obtained.

B. Clarify Waiver Criteria

Both researchers and patients believe the criteria for determining whether a researcher may receive a waiver for obtaining individual authorization to

45. Kass et al., *supra* note 33.

46. *Id.*

use medical records for a research project are ambiguous and subject to varying interpretations. As one participant succinctly stated “[P]racticability needs to be clearly defined for the Review Board in order to remove the ambiguity from the definition.” Some of this ambiguity could be clarified if either the Privacy Rule (or guidance) listed specific factors which should be considered in determining whether it was practicable to do the research without individual authorization. The particular factors that IRBs should consider and their relative weight, are of course, subject to additional debate. However, many patients in this study appeared to agree with researchers that IRBs should consider the effect of requiring individual authorization on the study’s scientific accuracy and usefulness in improving medical care when deciding whether to grant a waiver.

C. Accountability/Penalties

Under the Privacy Rule a health care provider is potentially liable for wrongfully disclosing health information to a researcher. The Privacy Rule, however, does not directly regulate researchers per se, and does not penalize researchers who violate privacy standards. Many researchers believe that this regulatory scheme results in health care providers being reluctant to give them access to medical record data and have suggested removing research from the Privacy Rule to overcome this barrier. Our study showed that patients want assurance that someone will be held accountable for privacy violations. Many participants suggested that individuals violating patients’ privacy should face penalties such as being fired, paying fines, or serving jail time. Policy makers could reconcile the interests of these two groups by shifting liability directly to researchers who violate acceptable privacy standards. This approach might relieve some of the anxiety of health care providers about furnishing medical record information. It would also appear to satisfy patients’ desire that the violating individual be held directly accountable. Indeed, in the past, some researchers have suggested this approach may be appropriate.⁴⁷ Because the parameters defining who is covered by the Privacy Rule are set by statute, this change would have to be instituted by Congress.

VI. CONCLUSION

With the emergence of electronic medical records, it is likely that some of the interests of researchers and health care consumers will continue to diverge. It appears that researchers will want full and easy access to the records and many consumers will want control over who has access to their health information and the scope of information to which they have access. It will be difficult to reconcile these opposing positions. However, the researchers

47. Jennifer Kulynych, and David Korn, *The Effect of the New Federal Medical-Privacy Rule on Research*, 346 NEW ENG. J. MED. 201-205 (2002).

and health care consumers have taken fairly comparable positions on other aspects of the Privacy Rule that potentially should be changed. By initially focusing on issues where the stakeholders interests are sufficiently aligned (such as using general authorizations), policy makers may be able to make some progress toward making the Privacy Rule more effective for all stakeholders.