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Recommendations for the Ethical Conduct of Quality Improvement

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INTRODUCTION

In the last few decades, quality improvement (QI) activities have assumed increasing importance and influence in healthcare. While no single definition of QI is widely agreed on, QI activities are generally understood to be cycles of action, linked to assessment, with a goal to improve the process, outcomes, and efficiency of healthcare services.[1] Healthcare quality is now routinely assessed through customer satisfaction surveys, clinical performance measures, and analyses of patient databases. But quality assessment does not always translate to quality improvement—for QI to occur, the information produced by quality assessment must be translated into systematic improvements in healthcare practices. A wide range of approaches has been used to promote improvement. These include educational interventions, performance incentives, regulatory and policy requirements, and information technologies, such as automated alerts to provide feedback to providers. When linked with the ongoing assessment of quality, such approaches have been lauded as highly effective in improving the quality of care.[2]

The basic principles of healthcare ethics are well established and include respect for autonomy, beneficence, nonmaleficence, and justice.[3] More specific ethical standards relating to medical treatment are described in a variety of sources, including codes of ethics, professional guidelines, consensus statements, published scholarly literature, and organizational policies. Ethical standards relating to research are also described in, for example, *The Belmont Report*, reports from the National Bioethics Advisory Commission (NBAC), and federal regulations.[4] In contrast, ethical standards for QI have not been clearly or thoroughly articulated.[5] For example, how do the ethical standards for treatment or research, such as those pertaining to confidentiality and informed consent, apply to QI activities? The answer is far from clear.

This article, which draws on a report by the Veterans Health Administration's (VHA) National Ethics Committee (NEC), is a preliminary attempt to fill this gap by providing practical recommendations for the responsible conduct of QI.

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IS QI RESEARCH, TREATMENT— OR SOMETHING ELSE?

While the field of quality improvement is progressing rapidly, the concept of QI is constantly evolving and the dividing line between QI and other activities is not always clear. Although most activities can be easily categorized either as QI or not QI, some activities can be more difficult to categorize. At times, for example, it may be difficult to distinguish between QI and research.[6] In the "Common Rule," research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[7] Although elegant in its simplicity, this definition is problematic in several respects. First, the definition is tautological in that the word "research" is contained in the definition itself. Second, it is not clear when knowledge should be considered "generalizable." Although the U.S. Department of Health and Human Services (DHHS) recently attempted to address this question regarding the use of personal health information, the answer is still not clear-cut:

> We understand knowledge to be generalizable when it can be applied to either a population inside or outside of the population served by the covered entity. Therefore, knowledge may be "generalizable" even if a research study uses only the protected health information held within a covered entity, and the results are generalizable only to the population served by the covered entity.[8]

Another problem with the definition of research provided in the "Common Rule" is that it hinges on the purpose for which the activity was designed, that is, the investigator's intent. But intent may be difficult to define, even for the investigator.[9] Moreover, projects may be intended for more than one purpose. For example, a single project may be designed both to improve healthcare operations in a particular setting as well as to produce knowledge that can be applied in other settings.

A variety of other criteria to clarify the distinction between QI and research have also been proposed. These include whether the clinician-patient relationship is disrupted, whether an activity requires specific recruitment, whether the patients involved in an activity directly benefit from the knowledge to be gained, and whether additional risks are imposed to make the results generalizable.[10] In addition, NBAC has argued that a key distinction is whether the program in question is new or already established:

> If the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants. Evaluation is a program monitoring tool, and the information gained will immediately benefit the program and/or the individuals involved. However, when quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is human participant research and subject to the oversight system.[11]

While all of these criteria are plausible, no clear consensus has yet developed on how to distinguish QI from research. Further, some activities—such as demonstration projects or program evaluations—may not be "pure" examples of either QI or research, but rather a "hybrid" of the two. This problem was aptly summarized in a recent report by the Institute of Medicine:

> As an applied field of study, Health Services Research (HSR) is closely related to non-research investigations that are directed toward assessing and improving the quality of operations in healthcare organizations. Indeed, HSR and healthcare operations form two ends of a continuous spectrum. Some HSR projects are clear examples of research; applying scientific methods to test hypotheses and produce new, generalizable knowledge. Other projects are certainly clear examples of internal exercises to assess the quality of the operations of the specific organization with no intention of producing generalizable knowledge. Many of these quality assessment or quality improvement (QA or QI) exercises are never intended to have any application beyond the specific unit within the organization that carries out the operation. In fact, many projects may start out as operations assessment and then become more like research, and

> many research projects involve doing very much what would be done in an internal operations assessment. As a result, for many projects, it is difficult to decide whether they are more like research, or more like QA or QI.[12]

As with the distinction between QI and research, the distinction between QI and treatment is not always clear. For example, it is a common practice in medicine for physicians to try therapies or administer drugs in a manner that differs from generally accepted practice standards.[13] Presumably, physicians also monitor the outcomes of these activities, at least informally, in an effort to improve care. When should such activities be considered QI rather than treatment? DHHS defines treatment as follows:

> Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to the other.[14]

In contrast, DHHS classifies QI under "health care operations," defined as:

> Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.[15]

DHHS further explains, "Treatment refers to activities undertaken on behalf of a single patient, not a population." Therefore, when a physician administers a therapy with the intent of improving care for that patient alone, the activity should be considered treatment; but if the physician administers the same therapy as part of a larger activity that is designed to improve care for a population of patients, the activity should be considered QI. But again, this distinction may not be particularly helpful, since many activities are intended to improve care both for individual patients and for a population.

Although some activities are clear-cut examples of either treatment, QI, or research, some activities cannot be so easily categorized. To the extent that QI differs from both research and treatment, however, the ethical frameworks that have been developed for these other areas may not be applicable. This report presents a new framework for thinking about the ethical conduct of QI.

WHY RECOMMENDATIONS FOR THE ETHICAL CONDUCT OF QI?

In the United States, as in other countries, a range of specific safeguards protects patients in the clinical setting. For example, physicians and other healthcare professionals have a widely recognized fiduciary duty to promote the interests of their patients. Professional ethics standards also require healthcare providers to protect patients' confidentiality and assure informed consent. Clinical behaviors are routinely scrutinized by peer review and other oversight mechanisms. Licensing standards, accreditation requirements, and statutory and case law further protect patients' interests. Healthcare providers who violate professional, regulatory, or legal standards are subject to a variety of sanctions and disciplinary actions.

Similarly, various government regulations, organizational policies, and professional guidelines have been developed to protect patients involved in research involving human subjects.[16] For example, federal law requires that, except for carefully defined exceptions, research at organizations that receive federal funding for research be reviewed by an institutional review board (IRB). This review must assure that informed consent is obtained from each subject, when appropriate; that research risks are reasonable in comparison to expected benefits; and that subjects are selected equitably.[17]

In contrast, there are no equivalent procedures to protect the rights and welfare of patients in QI activi-

ties. Yet there are at least six reasons why special protections for patients involved in QI activities may be warranted. First, the lack of a clear-cut distinction between QI and research, paired with the absence of clear ethical standards for the conduct of QI, provide a powerful incentive for investigators to "game" the existing system of protections by designating projects as QI rather than as research.[18] By doing so, they can avoid many of the time-consuming processes of research review, including stringent requirements for informed consent.[19] Until parallel standards are developed for QI, there will be a strong motivation to circumvent the system of research protections in favor of the more permissive environment of QI. For example, in one QI project, investigators initiated a program of pre-operative ultrasound screening in an attempt to prevent pre-operative blood clots, but later discontinued the program when it proved ineffective.[20] Some would argue that this project, approved as QI, was actually research, and should have been reviewed as such. Although the prevalence of this problem is not known, several other examples of research-like projects that have been labeled QI—and many more projects that are neither clearly QI nor clearly research—have come to the attention of the NEC; for example, through requests for guidance from the Ethics Consultation Service at VHA's National Center for Ethics in Health Care.

Second, some healthcare institutions are responding to the lack of a clear-cut distinction between research and QI by treating all QI projects as if they were research—that is, by requiring IRB review. This is problematic for several reasons. IRBs are already overburdened and are not equipped to handle a substantial increase in workload. The standards that apply to IRBs are in some ways ill-suited to QI. And, perhaps most importantly, IRB processes can be cumbersome and therefore discourage improvement efforts. Establishing specific protections for patients involved in QI might help to alleviate this problem.

Third, while QI is essential to good patient care and has brought tremendous benefits, QI activities are not entirely without potential burdens or risks to the patients involved. For example, psychosocial or financial harm can result from improper disclosure of personally identifiable information from databases. Embarrassment or resentment can result from being asked to address personal or sensitive topics in questionnaires. And patients may be inconvenienced or even potentially harmed by innovations intended to improve care. The actual frequency and severity of the potential burdens or risks associated with QI is completely unknown, however, because QI projects are rarely tracked and reported in a systematic fashion.

Fourth, QI projects can create potential conflicts of obligation. Whereas treatment activities are primarily designed to enhance the well-being of an individual patient,[21] QI activities are primarily designed to improve the process, outcomes, and efficiency of healthcare services. When healthcare providers are involved in QI activities, they may face conflicts between their obligations to each individual patient and their obligations to all patients cared for by the system. For instance, a QI project might call for functional assessments to be performed on all patients in a new intensive case management program after one, three, and six months. Though such assessments may seem harmless, they are not entirely without risk. For patients who do not have paid medical leave from their jobs, the extra time required to complete these assessments might have a significant financial impact. For mental health patients with paranoia or obsessive thinking, repeated assessments could conceivably exacerbate these problems. Under such circumstances, physicians participating in the QI project would need to weigh their obligations to the individual patient against their obligations to improve care for all patients through QI.

Fifth, patients involved in QI may not always be able to protect their own interests. Patients may assume, incorrectly, that everything done to them in the clinical setting is intended to benefit them and them alone, or patients who are dependent on the healthcare system for their care may feel compelled to do whatever is asked of them for fear that they may jeopardize the care they receive. In this sense, patients involved in QI projects could be unwittingly used as means toward an end.

Finally, most healthcare professionals have easy access to patients and patients' records, but not all are trained in QI principles and methods. While ongoing QI efforts are encouraged, some QI activities may be poorly designed and unlikely to yield useful results, in which case not even minor burdens to patients can be justified. These concerns may be amplified as healthcare organizations offer financial rewards for involvement in QI activities.[22]

Thus, activities that are determined to be QI (as opposed to research or treatment) are not immune from ethical concerns about protecting patients. Instead of focusing on the distinction between QI and other activities, healthcare organizations should focus on assuring that the rights and interests of all patients are adequately protected, including those involved in QI. At the same time, however, healthcare organizations should take care that efforts to protect patients do not unnecessarily encumber the QI process. Healthcare professionals and organizations have an ethical obligation to monitor and improve the quality of care they provide.[23] By ensuring that healthcare providers adhere to standards of care, and by making efforts to minimize deviations from standards, an organization is taking important steps to safeguard the well-being of its patients. Thus, the ethical imperative to adequately protect patients must be balanced against the ethical imperative to continuously improve the care of patients. The principles and procedures suggested below aim to achieve this balance.

ETHICAL PRINCIPLES TO GUIDE QI

Principle 1: QI activities should produce benefits that outweigh their potential burdens or risks. In QI, as in treatment and research, it is unacceptable to impose even relatively minor burdens on patients unless a project can reasonably be expected to be valuable.[24] Therefore, QI projects should be well-designed, and the measures they use should be reliable and valid. To increase the likelihood of benefit, QI projects should be conducted by well-supervised personnel with adequate training in QI principles and methods or with access to consultative advice.

In addition, efforts should be made to anticipate and minimize even minor harms to patients that could result from QI activities. For any given QI project, potential inconveniences or other burdens to individual patients should be justifiable when weighed against the expected benefits to be gained, including benefits to participating patients, future patients, or the healthcare organization. Because the goal of QI is to improve the process, outcomes, and efficiency of healthcare services, the benefits of a QI project should be considered in relation to that goal.

Principle 2: QI activities should respect each patient's right to self-determination. A patient's right to self-determination is well-established in law[25] and in ethics.[26] Each patient's right to have his or her healthcare choices respected deserves the same respect in QI as it receives in treatment and in research. Although informed consent is the standard process by which respect for patients' choices is ensured,[27] an exhaustive informed consent process is not always practical. In practice, many minor treatments or procedures (such as splinting a broken finger or drawing blood for routine tests) are performed on the basis of "presumed consent" or after only a cursory informed-consent discussion.[28] Furthermore, the patient's signature on a consent form is required only for a minority of treatments or procedures.[29] In research, too, there are accepted circumstances under which the requirement of informed consent is waived entirely, or for which verbal consent, but not written consent, is required.[30]

In general, the thoroughness of the informed-consent process should be proportionate to the potential burdens or risks associated with the intervention. For instance, in clinical practice, physicians typically explain potential burdens in greater detail as the risks of a test or treatment increase.[31] Similarly, in research, standards are codified in federal regulations in which the need for written documentation of informed consent depends on the study's risks.[32]

In most cases, specific informed consent for a particular QI project is not required. Instead, "general" or "blanket" consent to QI activities (as might occur during a patient's admission to an in-patient facility) is generally sufficient for QI activities that pose no significant burdens or risks beyond those the patient would otherwise experience. On the other hand, when activities require the patient's cooperation (as in, for example, a customer satisfaction survey), patients should be informed that their participation in the activity is optional and that refusal to participate will not jeopardize their care. In addition, explicit informed consent is necessary whenever a QI activity involves significant burdens or risks. In some cases, consent may not be a reasonable option (for example, a QI project in which attempts at cardiopulmonary resuscitation are video-

taped). For such cases, formal provisions should be made for proxy consent or waivers of consent, just as they are in clinical care and research.[33]

Principle 3: QI activities should preserve patients' privacy and confidentiality. In both research and treatment, demonstrating respect for patients' privacy and confidentiality is essential. In research, investigators often use codes to identify individuals, and may "de-link" these identifiers to protect the privacy of individual patients. These strategies offer important protections. Indeed, federal regulations that determine the need for research review are tied to the extent to which data can be recorded anonymously.[34] Similarly strict requirements exist in the treatment setting. An example is the requirement for certification established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that facilities must demonstrate respect for "the needs of patients for confidentiality, privacy, and security."[35] In addition, the final privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) underscore the importance of protecting personal health information in the contexts of medical treatment, healthcare operations, and research.[36]

To assure that privacy is protected and confidentiality maintained, all QI activities should be conducted within the context of a healthcare setting in which accepted clinical standards for privacy and confidentiality are upheld. QI activities are an integral part of the healthcare organization's activities, and, as a result, the systems and protection that support privacy and confidentiality standards for clinical practice must be present. For example, access to confidential patient information should occur on a "need to know" basis, and information should generally be stripped of patient identifiers before it is exported.

Staff members with access to QI data should receive formal training regarding their organization's privacy and confidentiality policies and should agree as a matter of record to respect these policies. The organization might also maintain systems—such as an audit trail of access to information—to monitor and trace breaches of confidentiality. Finally, data analysis should make use of anonymous, or "de-identified," data whenever possible. Where this is not possible, QI activities should identify patients by codes to limit potential breaches of confidentiality. In both linked and de-identified databases, data privacy officers may be very helpful; for example, they can ensure that the codes for linked data are maintained securely and that "de-linked" data are rendered anonymous before they are released.[37]

Principle 4: QI activities should be fairly distributed across patient groups. Fairness is a central principle of the ethical conduct of research, and of the ethical practice of clinical medicine.[38] In research, fairness includes equal access to the potential benefits of research, and equal exposure to its burdens.[39] In clinical care, fairness requires that patients have equitable access to medical services and are not treated in a discriminatory fashion.

In QI activities, justice suggests two requirements. First, the potential burdens or risks of any QI activity should be distributed fairly across the population under study. For instance, risks of a loss of confidentiality, or burdens of surveys or questionnaires, should not be borne disproportionately by a single group, unless that group would also be expected to benefit disproportionately from the QI activity. Second, the potential benefits of a QI activity should be distributed fairly. For instance, an intervention designed to improve cardiac care should be implemented across a broad cross section of cardiac patients for whom the results would be relevant.

ASSURING THE ETHICAL CONDUCT OF QI

The effectiveness of protections for patients depends on the identification of a person or group who is responsible for the ethical conduct of the particular activity in question. For research activities, this person is the principal investigator; in medical practice it is most often the attending physician. For QI projects, however, the responsible person is not always clear. Indeed, QI activities may be conducted across organizations or units of service, and may be the product of collaboration between clinical and administrative personnel. Nevertheless, it is important to identify the individual who is ultimately accountable for the appropriate

conduct of a given QI project, and who has the authority to assure that applicable ethical standards are followed.

In addition to the need to define a locus of responsibility for individual QI projects, there is also a need to define an administrative locus of responsibility for all QI activities that take place within a healthcare organization or an organizational subunit. QI is not an activity that is performed by an individual acting in isolation, but by a group of individuals acting on behalf of an organization. Furthermore, to be effective, QI must have organizational support: specifically, it must involve individuals with the authority to impose corrective action in response to assessment results.[40] Organizations should have one or more designated QI program office, standing committee, or other administrative entity that has specific responsibility for QI oversight.

As a matter of good management, organizations should not wait for problems to arise, but rather should promote the ethical conduct of QI proactively using a systematic approach. This approach should include educating individuals about relevant policy, tracking QI projects, handling questions and complaints, assessing adherence to requirements, and instituting corrective action when necessary.

For all QI activities, consideration should be given to potential ethical concerns before an activity is performed. The level of scrutiny should correspond to the potential burdens and risks of the QI activity: activities that involve greater burdens or risks require more thorough scrutiny. For those that involve minimal burdens or risks beyond those inherent to the clinical encounter itself (for example, projects involving only retrospective or concurrent review of existing clinical data, routine patient satisfaction surveys, or educational interventions designed to promote evidence-based practices), self-regulation and retrospective review by the QI activity leader and the office that oversees QI may be sufficient to assure that ethical issues have been adequately addressed. But for other types of QI activities (for example, those involving evaluation of an innovative clinical program or service, collection of new data from patients other than by routine satisfaction surveys, or systematic assignment of interventions), a formal, prospective, external review process may be appropriate. Whenever burdens or risks are substantial enough to warrant formal review, and whenever there is an expectation of results worthy of publication, it is prudent to consider whether the QI activity contains one or more components that meet the definition of research found in the "Common Rule," and therefore require IRB review.

Who should conduct a formal review, when one is necessary? Possibilities include an interdisciplinary group that is convened specifically for this purpose; a pre-existing group outside the QI office but within the organizational unit, such as an ethics committee; or a group outside the organizational unit, such as a multisite review committee. In any case, the group should include individuals who are familiar with QI methods and individuals who are familiar with ethical standards, but should not include individuals who are involved in the QI project under review.

CONCLUSION

Beyond the general recommendations above, we will not suggest any specific policies or procedures for assuring the ethical conduct of QI. Before a particular approach can be recommended, a variety of approaches should be tried and their results compared. Moreover, we are not convinced that there is one best solution for all healthcare organizations. A policy developed for a large tertiary-care medical center might be wholly inappropriate for a community clinic or nursing home. Similarly, a policy developed for a setting in which QI includes large-scale, methodologically rigorous data collection efforts might not make sense for another setting in which QI includes only small-scale cycles of designing, implementing, and assessing modest interventions intended to improve performance in specific, limited settings. For these reasons, we recommend that healthcare organizations use the general guidance provided in this report to develop their own unique policies and procedures that are appropriate to the types of QI activities they perform.

Our recommendations offer a starting point for thinking about how best to protect patients who are involved in QI activities (see table 1). Additional discussion is needed at several levels: within healthcare

organizations to translate the general guidance offered here into specific policy, between and among health-care organizations to ensure that protections are fair and consistently implemented, and that they function well, and at the societal level to assure that all patients receive the ethical treatment they deserve.

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DISCLAIMER

The views expressed in this article do not necessarily represent the views of the Department of Veterans Affairs or the official policy of the Veterans Health Administration.

NOTES

1. E.C. Nelson et al., "Building measurement and data collection into medical practice," *Annals of Internal Medicine* 128, no. 6 (1998): 460-6; G.J. Langley et al., *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance* (San Francisco, Calif.: Jossey-Bass, 1996); D.M. Berwick, "Developing and testing changes in delivery of care," *Annals of Internal Medicine* 128, no. 8 (1998): 651-6.

2. Berwick, see note 1 above; J.B. Perlin, "Quality outcomes of the Performance Management Program in 'the new VA'," *Medical Outcomes Trust Monitor* 5 (2000): 11-17; E.J. Gaucher and R.J. Coffey, *Total Quality in Health Care: From Theory to Practice* (San Francisco, Calif.: Jossey-Bass, 1993); M.D. Merry, "Total quality management for physicians: translating the new paradigm," *Quality Review Bulletin* 16, no. 3 (1990): 101-5.

3. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics,* 4th ed. (Oxford: Oxford University Press, 1994).

4. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, *The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, D.C.: U.S. Government Printing Office, 1981); National Bioethics Advisory Commission (NBAC), *Ethical and Policy Issues in Research Involving Human Participants* (Bethesda, Md.: Government Printing Office, 2001); *Protection of Human Subjects,* 45 *CFR* § 46 (2000).

5. J. Lynn, J. Johnson, and R.J. Levin, "The ethical conduct of health services research: a case study of 55 institutions' applications to the SUPPORT project," *Clinical Research* 42, no. 1 (1994): 3-10.

6. D. Casarett, J. Karlawish, and J. Sugarman, "Determining when quality improvement activities should be reviewed as research: proposed criteria and potential implications," *Journal of the American Medical Association* 283, no. 17 (2000): 2275-80; V. Choo, "Thin line between research and audit," *Lancet* 352, no. 9125 (1998): 337-8; R.J.M. Snijders et al., "UK multicentre project on assessment of risk of trisomy 21 by maternal age and fetal nuchal-translucency thickness at 10-14 weeks of gestation," *Lancet* 352, no. 9125 (1998): 343-6; C.B. Summerton, "Hepatitis C in asymptomatic blood donors. Did ethics committee approve study?" *British Medical Journal* 310, no. 6974 (1995): 260; D.J. Mutimer et al., "Hepatitis C in asymptomatic British blood donors with indeterminate seropositivity," *British Medical Journal* 309, no. 6958 (1994): 847-8.

7. *Protection of Human Subjects,* see note 4 above.

8. Department of Health and Human Services, "HHS Response to Comments on HHS Final HIPAA Privacy Rules, Section 164.50," *http://www.bricker.com/attserv/practice/hcare/hipaa/hipaaindex.asp* (accessed 31 May 2002).

9. Casarett, Karlawish, and Sugarman, see note 6 above.

10. A. Brett and M. Grodin, "Ethical aspects of human experimentation in health services research," *Journal of the American Medical Association* 265, no. 14 (1991): 1854-7; R.D. Truog et al., "Is informed consent always necessary for randomized, controlled trials?" *New England Journal of Medicine* 340, no. 10 (1999): 804-7.

11. National Bioethics Advisory Commission (NBAC), see note 4 above.

12. Institute of Medicine, Committee on the Role of Institutional Review Boards in Health Services Research, *Protecting Data Privacy in Health Services Research* (Washington, D.C.: National Academy Press, 2000).

13. National Bioethics Advisory Commission (NBAC), see note 4 above.

14. See note 8 above.

15. Ibid.

16. World Medical Association, *International Code of Medical Ethics; amended by the 52nd World Medical Assembly* (Ferney-Voltaire, France: World Medical Association, 2000); "The Nuremberg Code," in B. Brody, *The Ethics of Biomedical Research: An International Perspective* (New York: Oxford University Press, 1998), 213; Royal College of Physicians, "Research Involving Patients," in B. Brody, *The Ethics of Biomedical Research: An International Perspective,* 315-20.

17. *Protection of Human Subjects,* see note 4 above.

18. Casarett, Karlawish, and Sugarman, see note 6 above.

19. *Protection of Human Subjects,* see note 4 above.

20. J.R. Hopkins, "Financial incentives for ambulatory care performance improvement," *Joint Commission Journal on Quality Improvement* 25, no. 5 (1999): 223-38.

21. National Bioethics Advisory Commission (NBAC), see note 4 above.

22. Hopkins, see note 20 above.

23. E. Bellin and N.N. Dubler, "The quality improvement/research divide and the need for external oversight," *American Journal of Public Health* 91, no. 9 (2001): 1512-7.

24. B. Freedman, "Scientific value and validity as ethical requirements for research: a proposed explication," *IRB* 9, no. 6 (1987): 7-10; D.R. Rutstein, "The ethical design of human experiments," in *Experimentation with Human Subjects,* ed. P.A. Freund (New York: George Braziller, 1970), 383-401.

25. *Pratt v. Davis,* 118 Ill. App. 161 (1905); *Mohr v. Williams,* 95 Minn. 261, 104 NW 12 (1905); *Schloendorff v. Society of New York Hospitals,* 211 N.Y. 125, 105 NE 92, 32 (1914).

26. R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986); President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral research, *Making Health Care Decisions. A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship,* vol. 1-3 (Washington, D.C.: U.S. Government Printing Office, 1982).

27. *Salgo v. Leland Stanford Jr. Univ. Board of Trustees,* 154. Cal. App. 2d 560, 317 P.2d 150 (1957); B.C. White, *Competence to Consent* (Washington, D.C.: Georgetown University Press, 1994); Faden and Beauchamp, see note 26 above.

28. C.H. Braddock et al., "Informed decision making in outpatient practice: Time to get back to basics," *Journal of the American Medical Association* 282, no. 24 (1999): 2313-20.

29. Veterans Health Administration, *VHA Handbook 1004.1* (Washington, D.C.: 1 August 1996).

30. *Protection of Human Subjects,* see note 4 above.

31. See note 28 above.

32. *Protection of Human Subjects,* see note 4 above.

33. Food and Drug Administration, "Protection of Human Subjects: Informed Consent and Waiver of Informed Consent in Certain Emergency Research; final rules," I. 61 (1996): 51497-51531; *Protection of Human Subjects,* see note 4 above.

34. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, see note 4 above.

35. Joint Commission on Accreditation of Healthcare Organizations, *2004 Hospital Accreditation Standards* (Chicago: Joint Commission Resources, 2000), RI.2.130. *http://www.jcaho.org/accredited+organizations/hospitals/standards/new+standards/2004+ standards.htm* (accessed 7 July 2003).

36. See note 8 above.

37. Casarett, Karlawish, and Sugarman, see note 6 above; U.S. General Accounting Office, *Medical Records Privacy: Access Needed for Health Research, but Oversight of Privacy Protections Is Limited* (Washington, D.C.: U.S. General Accounting Office, 1999); EU Directive 95/46/EC, "Directive on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data," Publication HEHS-99-55, *http://www.gao.gov/archive/1999/he99055.pdf.*

38. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, see note 4 above.

39. Ibid; J.P. Kahn, A.C. Mastroianni, and J. Sugarman, ed., *Beyond Consent: Seeking Justice in Research* (New York: Oxford University Press, 1998).

40. Faden and Beauchamp, see note 26 above; President's Commission, see note 26 above.