

FROM THE FIELD...

•The Veterans in Partnership Network (VISN 11) has established an innovative program called the Corporate Ethics Committee to identify and address clinical and organizational ethics issues VISN-wide. This program may serve as a useful model for others wishing to develop Integrated Ethics Programs at the Network level.

•The Education Sub-Committee of the Portland VA Medical Center's Clinical Ethics Committee has launched a new type of "Ethics Rounds" that other facilities may wish to emulate. To improve their effectiveness, the committee proactively identifies areas for targeted educational interventions.

To find out more go to:
www.va.gov/vhaethics/field6.cfm

IN THE LITERATURE...

Cherniack EP. Informed consent for medical research by the elderly. *Exp Aging Res.* 2002;28(2):183-98.

Emanuel EJ, Grady C, Wood A. The crisis in human participants research: identifying the problems and proposing solutions. Presented to *The President's Council on Bioethics*. September 2002.

Guinn DE. Mental competence, caregivers, and the process of consent: research involving Alzheimer's patients or others with decreasing mental capacity. *Q Camb Healthc Ethics.* 2002;11(3):230-245.

To read abstracts and get links to full articles, visit us at: www.va.gov/vhaethics/literature6.cfm

ON OUR WEB SITE...

Recent additions to our Web site:

The National Center for Ethics in Health Care is in transition! To better reflect the Center's mission, our name has changed from the National Center for Ethics to the National Center for Ethics in Health Care. Concurrent with this change, the main office of the Center has been relocated from White River Junction to Washington, DC. Visit our Web site often as it is updated to reflect these changes at: www.va.gov/vhaethics or vawww.va.gov/vhaethics



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inthisissue

- **Best Practices:** Informed Consent for Research
- **Policy Perspectives:** The HIPAA Privacy Rule and Its Impact on Research
- **Ethics Rounds:** A Case of Quality Improvement

about the center

The National Center for Ethics in Health Care is VHA's primary office for addressing the complex ethical issues that arise in patient care, health care management, and research. Founded in 1991, the Center is a national program with offices in Washington, DC, New York, NY, and Seattle, WA. To learn more go to: www.va.gov/vhaethics

our mission

The mission of the National Center for Ethics in Health Care is to clarify and promote ethical health care practices within VHA and nationwide.

Send us your

feedback

Please send any questions, comments, or address changes to the address above, or e-mail us at vhaethics@hq.med.va.gov.

spotlightevents

Major Change in VHA's Do Not Resuscitate (DNR) Policy

Effective October 24, VHA's DNR policy no longer limits DNR orders to patients who are terminally ill. This change is reflected in VHA Handbook 1004.3, *Do Not Resuscitate (DNR) Protocols Within the Department of Veterans Affairs (VA)*. The handbook is available on-line at: www.va.gov/vhaethics/download/DNRpolicy.doc

Meanwhile, the Center continues work on a comprehensive policy on ethical issues in end-of-life care to replace the existing DNR policy.

VA Conference Proceedings Published in Medical Care

The September 2002 Supplemental issue of *Medical Care* features the proceedings of the "Making Informed Consent Meaningful: A State of the Art Conference", jointly sponsored by VA's Office of Research and Development, the National Center for Ethics in Health Care, and the Hastings Center.

To read more about these events, visit: www.va.gov/vhaethics/spotlight6.cfm

bestpractices

Informed Consent for Research

by Claire W. Maklan, PhD, MPH
National Center for Ethics in Health Care

"The ability to obtain valid informed consent is a skill that can be learned and taught just like any other clinical skill." – Philip W. Lavori

Valid and meaningful informed consent is the cornerstone of the ethical conduct of clinical research – but obtaining informed consent is not a simple or certain process. Despite established procedures for obtaining the informed consent of volunteer research subjects, important questions remain about how to ensure that the risks and benefits of participating in research are accurately communicated and understood. To assess the quality of informed consent, and ultimately to improve it, VA's Cooperative Studies Program (CSP) in the Research and Development Office has initiated a major new study called "Enhancing the Quality of Informed Consent" (EQUIC). EQUIC will result in a series of tools to assist researchers in adapting and implementing best practices in the informed consent process and, thereby, help ensure the ethical conduct of research.

EQUIC represents an important and novel approach to issues surrounding informed consent. It recognizes that – just as for medical treatment – procedures for obtaining informed consent should be based on evidence.



This study proceeds from the rationale that:

"Clinicians practice accepted state-of-the-art medicine while simultaneously innovating and improving it. In the same way, we must employ accepted methods of informed consent while seeking to innovate and improve them. ...[And we must recognize that] as in medicine, innovation may also have unintended and unknown consequences and, more importantly, innovations intended to improve informed consent may not actually do so."

For additional on-line materials on informed consent and the EQUIC project, go to: www.va.gov/vhaethics/best6.cfm

www.va.gov/vhaethics

Final Changes to the HIPAA Privacy Rule

Final changes to the HIPAA Privacy Rule became effective on October 15, 2002. The Privacy Rule is designed to maintain strong protections for individually identifiable health information. The final changes strengthen these protections while attempting to minimize unintended effects on health care quality and access. The Privacy Rule is available on the Web at: www.hhs.gov/ocr/hipaa/privrulepd.pdf. The impact of HIPAA on human subjects protections is discussed in our *Legal Briefs* column (right).

Institute of Medicine Report on Protecting Research Participants

The Institute of Medicine issued a report in October calling for a complete overhaul of the IRB system. The report cites several reasons why change is necessary, including gaps in the current IRB system and differences in the requirements for federally-funded versus privately-funded research. The report, entitled *Responsible Research: A Systems Approach to Protecting Research Participants*, is available on-line at: www.iom.edu/iom/iomhome.nsf/Pages/Recently+Released+Reports

American Society for Bioethics and Humanities 5th Annual Meeting

The 5th Annual Meeting of the American Society for Bioethics and Humanities was held October 24-27, in Baltimore. Ellen Fox, MD, presented the results of a national research study, *Ethics Consultations in U.S. Hospitals*, in which 600 randomly selected hospitals were surveyed to determine the prevalence of ethics consultations in U.S. hospitals, who performs ethics consultation, and how it is performed. After Dr. Fox's presentation, Stuart Youngner, MD, and Jackie Glover, PhD, commented on these important findings. The abstract of the study is available at: www.va.gov/vhaethics/abstract_6.cfm



Ellen Fox, MD
Director, National Center for Ethics in Health Care

a word from:

This issue of *news@vhaethics* is focused on ethical issues in human subjects research. These issues are crucial for VHA: as a major Federal sponsor of medical research, we are responsible to thousands research subjects. The protection of human research subjects has been a "hot button" issue lately, especially with regard to regulatory and compliance issues. But research ethics involves more than regulatory compliance. Compliance and ethics differ in that compliance is generally concerned with making sure that conduct conforms to specific rules, especially external legal or regulatory requirements, while ethics is generally concerned with clarifying and promoting ethical practices that may or may not be clearly defined. In VA

Central Office, the National Center for Ethics in Health Care works hand-in-hand with the Office of Research and Development (which develops national policy) and the Office of Research Compliance and Assurance (which promotes research conduct in conformance with regulations and policies). Ethical issues in health care should not be considered in a vacuum, but within a real-world context. To this end, this issue of *news@vhaethics* provides updates on pertinent regulatory changes, and explores ethical aspects of human subjects research that are not spelled out in law. We hope you find this newsletter useful and, as always, invite your feedback.



legal briefs

The HIPAA Privacy Rule and Its Impact on Research

by Kelly Fitzpatrick, JD
news@vhaethics contributor

Individuals who are acquainted with federally funded research on human subjects also are well acquainted with the Common Rule and its requirements. They may not be as familiar, however, with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), particularly the Privacy Rule contained in HIPAA and the recently approved modifications relating to research, which went into effect October 15. This article will compare relevant sections of the original Privacy Rule and the modifications as they relate to biomedical research. As will become apparent, the modifications

reduce redundancy in requirements imposed by both the original Privacy Rule and the Common Rule. More important, the changes eliminate the need for a parallel but separate track of requirements—one for the Privacy Rule and the other for the Common Rule—that might have impeded research.

Congress created HIPAA with the intention of improving the health care system by making health benefits portable and continuous, increasing penalties for health care fraud, and simplifying health insurance administration. The goal of the Privacy Rule, as a corollary to HIPAA, is to protect patients' rights regarding their individually identifiable health information, given the significant harm that could result from unregulated access to and use of an individual's personal health information. In the research context, the Privacy Rule fills a significant gap.

To read more about how the HIPAA regulations will affect research, visit: www.va.gov/vhaethics/briefs6.cfm

Can Dying Patients Consent to Research?

by David Casarett, MD, MA
Center for Health Equity Research and Promotion
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Research involving patients near the end of life is vitally important, but raises significant ethical concerns because of the potentially diminished decision-making capacity of the research subjects who enroll. Decision-making capacity refers to the ability to understand information, appreciate how that information applies to one's own situation, reason through that information, and express a choice. Concerns about decision-making capacity often arise in patients who are critically ill or nearing the end of life



ethics rounds

A Case of Quality Improvement

by Robert A. Pearlman, MD, MPH
National Center for Ethics in Health Care

In recent months, national attention has been focused on deficiencies in health care quality. Notably, the Institute of Medicine report entitled *Leadership by Example* called upon the federal government to take the lead in improving the quality of care provided by the nation's health care programs, while lauding VA's quality improvement (QI) efforts as "among the best in the nation."

Another topic that has received national attention lately is the system for protecting human research subjects. The media

question of the month

The Ethics Rounds article in this issue examines the ethical implications of the difficulty distinguishing QI from human research protocols. What is the best way to ensure that QI projects are conducted in an ethical manner? Should QI projects ever be required to go through a formal institutional review process? Or, are the pitfalls to such an approach too burdensome to ensure the ethical conduct of QI? Tell us what you think at www.va.gov/vhaethics/question6.cfm

Each issue of *news@vhaethics* includes a question about a clinical, organizational or research ethics issue. Your participation is important to us – please go to our Web site at www.va.gov/vhaethics to register your opinion! You can also see how others responded and join a discussion on the topic.

due to the likelihood that one or more elements of decision-making capacity are affected by the underlying illness. Decision-making capacity is of even greater concern when dying patients become the potential subjects of research. However, not all research subjects near the end of life need to be formally assessed for decision-making capacity, which can make it difficult to determine if and when such an assessment needs to occur.

How should investigators and IRBs determine when decision-making capacity

needs to be formally assessed in prospective research subjects who are near the end of life? In determining the need for formal assessment, investigators and IRBs should consider the characteristics of the study population, as well as the risks and potential benefits involved.

To read the rest of this article, go to our Web site at: www.va.gov/vhaethics/nec6.cfm



has been full of stories about major university research programs being shut down, research participants being injured or dying, and national commissions calling for the system to be overhauled. In response, institutions are intensifying their efforts to assure ethical research practices. While quality improvement and research oversight have been sharing the limelight, they are connected in another way as well. Some worry that intense scrutiny of the research oversight system – although well intentioned and necessary – will have the unintended effect of impeding the progress of QI. Why? Differentiating between QI and research is not always easy. Moreover, QI projects may raise

some of the same ethical concerns that apply to research (e.g., consent, privacy, fairness). Some institutions are reacting to these pressures by treating QI projects as if they were research – that is, by requiring IRB review. This is problematic for several reasons. First, IRBs are already overburdened and not equipped to handle a substantial increase in workload. Second, the standards that apply to IRBs are in some ways ill-suited to QI. Third – and probably most importantly – IRB processes can be cumbersome and therefore discourage improvement efforts.

For a real-life example that illustrates this problem go to: www.va.gov/vhaethics/ethicsrounds6.cfm

