

From the Fall 2000 Newsletter

IN THE LITERATURE

Here we highlight important articles from the literature in clinical, organizational and research ethics.

Goold SD, Williams B, Arnold RM. Conflicts regarding decisions to limit treatment. *JAMA*. 2000;283:909-914

To read the abstract and the article go to
<http://jama.ama-assn.org/issues/v283n7/full/jsc90064.html>

Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283:2701-2711.

The following abstract appeared in JAMA:

Many believe that informed consent makes clinical research ethical. However, informed consent is neither necessary nor sufficient for ethical clinical research. Drawing on the basic philosophies underlying major codes, declarations, and other documents relevant to research with human subjects, we propose 7 requirements that systematically elucidate a coherent framework for evaluating the ethics of clinical research studies: (1) value-enhancements of health or knowledge must be derived from the research; (2) scientific validity-the research must be methodologically rigorous; (3) fair subject selection-scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects; (4) favorable risk-benefit ratio-within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review-unaffiliated individuals must review the research and approve, amend, or terminate it; (6) informed consent-individuals should be informed about the research and provide their voluntary consent; and (7) respect for enrolled subjects-subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored. Fulfilling all 7 requirements is necessary and sufficient to make clinical research ethical. These requirements are universal, although they must be adapted to the health, economic, cultural, and technological conditions in which clinical research is conducted.

To read the full text of this article go to
<http://jama.ama-assn.org/issues/v283n20/full/jsc90374.html>

Blake DC. Organizational ethics: creating structural and cultural change in healthcare organizations. *J Clin Ethics*. 1999;10:187-193.

The following is excerpted from the article:

Although there is surely nothing wrong with and much to commend about the view of healthcare ethics as either public policy and public education, or professional training and standards, or academic scholarship and instruction, there may be no reason to limit the field to these forms alone. Accordingly, I prefer to see in the advent of organizational ethics an opportunity to set healthcare ethics on a course that may be at best underdeveloped and at worst unexplored by healthcare ethicists. The new course is ethics aimed at structural and cultural changes in healthcare organization, and ethics performed more as an exercise in operations and management, and less as a theoretical, cognitive, or scholarly exercise.... In 1998, the St. Joseph Health System introduced to its ethics committees a model for the ethics committee of the future. The model was proposed partly in response to the growing demand for policies and programs in organizational ethics. Developing policies on organizational ethical issues-as seen by JCAHO standards-did not appear to be a fruitful response.... The alternative chosen by the St. Joseph Health System was to attempt an entirely new committee that could be as much a platform for effecting improvements regarding business issues as it would be for effecting improvements regarding clinical issues. Dubbed "A Model for the Next Generation of Healthcare Ethics Committee," the model for this committee was based on four ideas that had emerged from the successes and failures of ethics committees within this health system and elsewhere. First, ethics committees should be proactive. They should not simply "work" in reaction to problem cases presented to them. Second, ethics committees should be organizationally integrated and not isolated. The celebrated independence of the ethics committee often brings with it marginalization within an organization. Third, ethics committees should be held accountable by measurable outcomes and not simply good intentions. Whether a chair, a committee member, or even the committee itself continues to serve the organization should not be based solely on the fact that they are good people with good intentions. Finally, ethics committees should be oriented by institutional values, and not simply the (legal) rights of patients.