

# University of Virginia



Center for Biomedical Ethics  
Program in Ethics and Policy in  
Healthcare Systems



*Proactive*

*Multidisciplinary*

*Integration of the Theoretical  
and Empirical*



## Program in Ethics and Policy in Healthcare Systems

One of the enduring characteristics of the University is its commitment to integrity and high ethical standards. Long known for the Honor system, which has governed student conduct for more than a century and a half, the University has established complimentary programs that underscore its historical emphasis on responsible and ethical behavior. The Program in Ethics and Policy in Healthcare Systems is one of the University's latest endeavors dedicated to achieving this goal.

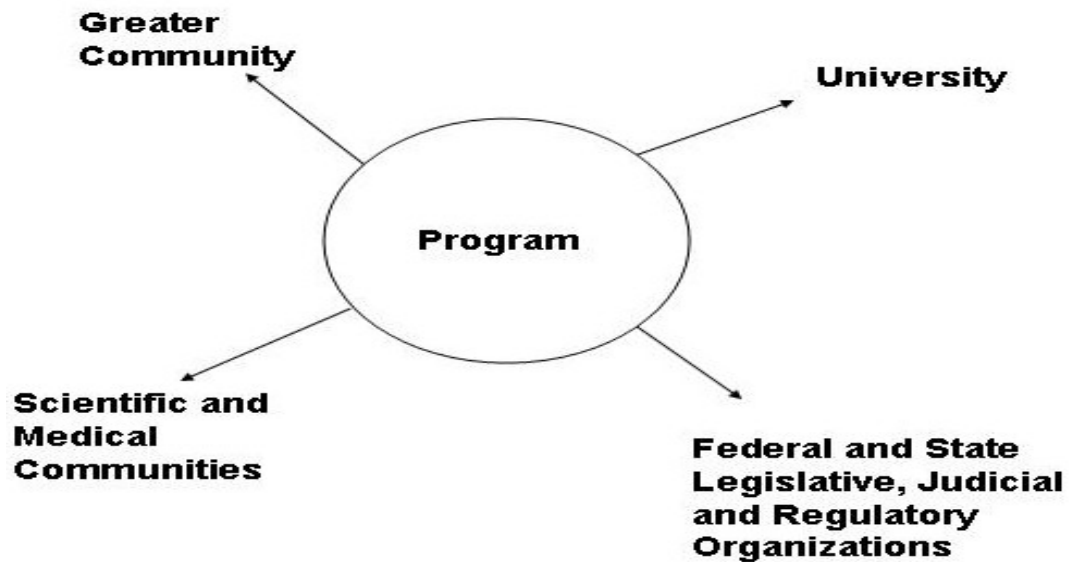
The Program is devoted to helping those in the public sector who are charged with making decisions to respond to the challenges facing healthcare systems. Our faculty are dedicated to conducting research designed to inform public policy and to meeting educational needs. The Program is supported by the Dean of the School of Medicine and is organized around an interdisciplinary approach that integrates the commercial and business ethics perspectives with other ethical, legal, and social issues.

The Program's vision concerning the intersection of ethics and public policy embraces the concept that ethical standards should shape public policy, rather than the reverse. The Program's approach to forming public policy guidance is innovative in that it is proactive, interdisciplinary and grounded in empirical data as well as traditional theoretical analyses. We call it the "PIE" approach and believe each slice is essential to sound future public policy.

One of the most important distinguishing features of the program is that it is removed from potential financial influence in that the program does not accept research grants or gifts from private industry that may be affected by or have the appearance of being affected by the Program's recommendations.



### Whom Does the Program Serve?





## Program Faculty

Patricia M. Tereskerz, J.D., Ph.D.  
*Program Director*

Ann E. Mills, M.sc.(Econ), M.B.A.  
*Program Co-Director*

## Affiliated Faculty

Donna T. Chen , M.D., M.P.H.  
Walter S. Davis, Jr., M.D.

Paul A. Lombardo, Ph.D., J.D.  
Jonathan D. Moreno, Ph.D.

## Selected Publications

Tereskerz PM, Moreno J. Ten steps to developing a national agenda to address financial conflicts of interest in industry sponsored clinical research. *Accountability in Research*. April-June 2005. 12:139-155.

Mills, AE. Tereskerz, PM, Davis, WS. "Is Evaluating the Ethics Consultation on the Basis of Cost a Good Idea?" *Cambridge Quarterly of Health Care Ethics*. 14: No. 1, Winter 2005 pgs. 54-66.

Tereskerz PM, Pearson RD, Jagger J. Infected physicians and invasive procedures: national policy and legal reality. *Milbank Quarterly* 77(4)511, 1999.

Tereskerz PM. Research accountability and financial conflicts of interest in industry-sponsored clinical research: a review. *Accountability in Research*. 10:137-152, 2003.

Lombardo PA. Genetic Confidentiality: What's the Big Secret? 3 *University of Chicago Law School Round Table* 589 (Winter, 1996).

Chen DT, Miller FG, Rosenstein DL. Clinical research and the physician-patient relationship. *Annals of Internal Medicine*, 2003;138(8):669-72.

## Education

- Conference: The New Medicine: **The Ethics and Policy of Regenerative and Replacement Therapy** March 16-17, 2006.
- Internship for selected summer scholars seeking admission to medical, law, or business schools.
- Medical Elective: Ethics in Healthcare Systems
- Student Research Interns
- Fellows Program



## Selected Research

- Assessment of empirical data on the roles of existing laws and policies regarding enforcement of intellectual property rights and their effect on scientific advancement and commercialization with regard to genetic technologies.
- Projected impact on the new CREATE patent legislation on scientific innovation and technology transfer in the biomedical sciences.
- Development of recommendations, grounded in empirical data, for best practices in the consideration and management of financial arrangements between sponsors and investigators conducting clinical trials used by the FDA in the approval process of new molecular entity drug applications
- Identify guidance and analyze ethical issues related to the structure and standard operation procedures of data monitoring committees.
- Evaluation of the scientific and economic propriety of off-label drug use sanctioned by federally recognized directories used for Medicare/Medicaid reimbursement decisions.
- Assessment of the potential for commercial bias in continuing medical education for physicians.
- Evaluation of the feasibility of a junk food tax to subsidize healthcare insurance for the economically disadvantaged.
- National assessment of financial conflicts of interest among principal investigators and proposed guidance to manage the conflicts.
- Assessment of the ethical ramifications of robotic surgery.

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