

3.5 Overall Structure of the Study Team

The Safe Harbors Research Team

This proposal meshes an experienced and diverse team of researchers with significant background in health policy, health law, social sciences, bioinformatics, emergency medicine, and radiology (Figure). The Co-Principal Investigator, **Associate Professor Alan Storrow**, is an NIH R01-funded physician-scientist who currently is Associate Director of an innovative and highly successful research division. He possesses a unique vantage point regarding study design, the mechanics of research in the emergency environment, the collection of ED data, and analysis of results. He will also provide valuable insight and feedback to Professor Blumstein, especially in the context of emergency medicine. Dr. Storrow has extensively studied and published on numerous topics related to this proposal's specific aims, such as risk stratification of ED patients and ED diagnostic testing. His expertise in the clinical aspects of health care delivery to the acutely ill and injured will be critical in the implementation of safe harbors.

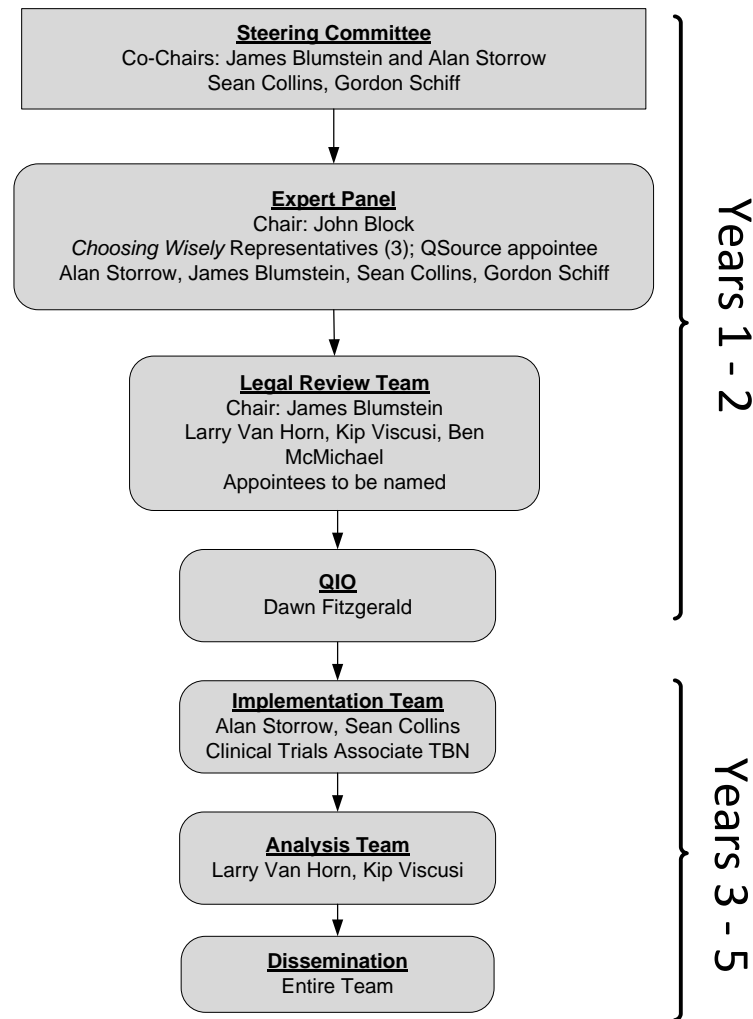


Figure. The Safe Harbor Team

The Co-PI, **Professor James F. Blumstein**, is a distinguished faculty member within the Vanderbilt University School of Law, the director of the Vanderbilt Health Policy Center, and a member of the *National Academy of Medicine*. As University Professor of Constitutional Law and Health Law & Policy, he holds tenured appointments in the Vanderbilt Law School and the Vanderbilt Medical School. He is a nationally recognized leader in health law and policy and has written on medical malpractice law. He pioneered the re-conceptualization of practice guidelines into malpractice safe harbors, making use of the existing statutory authority of QIOs to implement that strategy.

The idea for this proposal stems from Professor Blumstein's longstanding work with Professional Standards Review Organizations (PSROs), now QIOs. In early work on medical care rationing, he noted the QIO legislation "contains a provision that immunizes from malpractice liability a physician who practices in conformity with the standard set forth" by the QIO. The statutory provision was directed at defensive medicine, eliminating the excuse from practitioners who claim "fear of malpractice liability causes them to order more costly tests than ordinarily called for in their clinical judgment." In more recent work, Professor Blumstein observed that the QIOs' authority to specify a binding standard of care persisted in federal law: "QIOs possess the statutory authority to develop standards that would serve as controlling legal standards in medical malpractice litigation." Since easily studied and achievable targets were present in emergency medicine, it was decided to concentrate on this specialty to demonstrate not only approach feasibility, but also evaluate effects on costs and quality.

Dr. W. Kip Viscusi is the University Distinguished Professor of Law, Management, and Economics at Vanderbilt University. He has a Ph.D. in economics and has broad expertise in statistical analysis; the focus of his academic research has been on the econometric analyses of large databases related to health and safety. He has published numerous empirical papers on medical malpractice and tort reform, dating back to the 1980s. He has been ranked as the number one contributor to the fields of health economics (by *Health Economics*) and the analysis of risk and insurance (by *Journal of Risk and Insurance*). In addition to his economic research, he has been closely involved in multiple quantitative analyses of legal issues. He has held tenured positions in two law schools, Harvard and Vanderbilt.

Larry Van Horn, Associate Professor of Economics and Management, is Executive Director of Health Affairs at the Owen Graduate School of Business Administration at Vanderbilt University and the Director of the Office of Sustainable Health Care Finance within the Institute of Medicine and Public Health. Professor Van Horn is a health economist with significant expertise in the use of administrative data to assess outcomes, such as evaluating provider behavior in the in-hospital setting. His data procurement and programming expertise are particularly relevant for this project. Professor Van Horn has worked for the last five years with the administrative team of VUMC on the compilation and execution of a system-wide Enterprise Data Warehouse. This database combines all data from the Medipac and Epic systems, with electronic information to allow large-scale analyses of care delivery and the impact on our patient population. Professor Van Horn will partner with Drs. Viscusi to ensure accurate and efficient data collection and analysis.

Dr. Sean Collins, Professor, Vice Chairman for Research and Academic Affairs, and Director of the Clinical Trials Center in the Department of Emergency Medicine, will participate in safe harbor development in Phase 1, and oversee implementation of the safe harbors in Phases 2 and 3. This will include training of the study team as well as the emergency providers who will be utilizing the safe harbors during clinical encounters. Under Dr. Collins' leadership the clinical trials center is capable of enrolling patients between 0500 and 2200 daily. There are multiple layers of research staff available to enroll patients, including study assistants, study coordinators and physicians. Dr. Collins will also be available to answer questions from study staff and ED providers throughout phase 2 and 3.

Dr. Gordon Schiff will consult and provide his special expertise to the VUMC team, Qsource, and Expert Panel on safe harbor development and dissemination. Dr. Schiff is Safety Science Director for the Harvard Medical School Center for Primary Care Academic Innovations Collaborative. He is Associate Director of Brigham and Women's Center for Patient Safety Research and Practice and Associate Professor of Medicine at Harvard Medical School. He brings exceptional experience in patient safety and diagnosis error. He is the recipient of the 2005 Institute of Medicine Chicago (IOMC) Patient Safety Leader of the Year award, and the Institute for Safe Medical Practices (ISMP) 2006 Lifetime Achievement award and the 2010 Rx for Excellence in Quality Award from the Massachusetts Medical Law Report. In 2006 he was selected by Modern Healthcare as one of the top "30 People for the Future" in medicine.