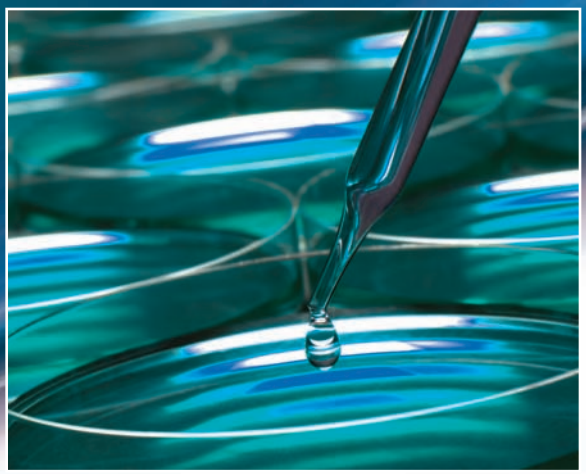

Empire State Stem Cell Board

2007-08 ANNUAL REPORT

Message from the Commissioner of Health

With the support of Governor David A. Paterson and the State Legislature, much progress has been made in getting New York's stem cell research program off to a strong start. While Lieutenant Governor, Mr. Paterson was instrumental in passing legislation that created the Empire State Stem Cell Fund and Board, committing $600 million over 11 years to an endeavor that could potentially become the greatest scientific undertaking in the history of this state.

In addition to the Governor's longstanding commitment to stem cell research, I want to acknowledge that this initiative could not have occurred without the support of the medical, scientific, voluntary health and patient advocacy communities who urged the state to embrace this promising field of science. I thank them all for their continuing support.

Above all, I thank the preeminent leaders in the fields of science, health, business, patient advocacy and ethics who join me as members of the Empire State Stem Cell Board. It has been a pleasure to work with this group. As members of the Board's Funding Committee or Ethics Committee, they have worked tirelessly to ensure the success of this stem cell research initiative.

In its first six months of operation, the Board accomplished a great deal. It has issued funding mechanisms that will provide more than $125 million in support to scientists and educational and research institutions. The research funded by this initiative offers the hope of new treatments, therapies and even cures for some of the most serious diseases. The funding will also create an economic stimulus to New York's biomedical industry.

The Board also developed interim ethical guidelines for the conduct of funded research and engaged in conversations about significant principles underlying the research, including the appropriate sources of stem cells and access to the results of funded research. We also had healthy discussions about what types of research and related activities to fund, which have resulted in the development of an impressive strategic plan.

We want New York's stem cell research to be world-class, but not only in the sense that it leads to breakthroughs in the prevention and treatment of diseases. We also want the research to be world-class in its adherence to the most widely accepted and reviewed ethical, medical and scientific standards. With increased stem cell research capacity, New York will be in a stronger position to help lead the way in biomedical discoveries that offer hope to millions who suffer with debilitating diseases.

Richard F. Daines, M.D.
Commissioner, New York State Department of Health
Chair, Empire State Stem Cell Board

Message from the Executive Director of NYSTEM

Shortly after legislation was enacted creating the Empire State Stem Cell Trust and Board, we learned that the Department of Health, and in particular the Wadsworth Center, was being given responsibility for administering the state's stem cell initiative. Our experience administering breast cancer and spinal cord injury research grants for the Department would prove to be critical in meeting the high expectations of this program.

Initially, we depended on current Wadsworth staff – scientists, fiscal, administrative, program and communication experts. We were also fortunate in persuading Judy L. Doesschate, a Department attorney who had worked with us and with several other Department boards, to join the team as Director of Board Operations.

The group's first goal was to survey the status of stem cell research in New York. They traveled statewide interviewing investigators, and produced "Stem Cell Research in New York State: A Snapshot," together with a directory of stem cell researchers. The NYSTEM (New York State Stem Cell Science) staff, as they would come to be known, also learned a great deal through discussions with the New York Stem Cell Foundation and from contacts with other state-supported stem cell research programs and members of the Interstate Alliance on Stem Cell Research.

Within 77 days of the first meeting of the Empire State Stem Cell Board on October 22, 2007, $14.5 million in research support was awarded to 25 institutions throughout New York, and the contracts were executed soon thereafter. This remarkable achievement came about because of the very able assistance we received from colleagues throughout the Department of Health, most especially, the fiscal management group, and from other state agencies, including the Office of the State Comptroller and the Attorney General. Our second round of requests for applications has brought an extraordinary response; some 500 letters of intent were received to apply for $109 million available in funding.

Even before these requests for applications were issued and awards announced, the NYSTEM program has had a crucial impact, galvanizing interactions and collaborations among stem cell investigators statewide. This effect is early evidence that the opening phrase of the Board's mission statement – "To foster a strong stem cell research community in New York State..." – is a sound premise and promise, and that the goal of accelerating scientific knowledge about stem cell biology and the development of therapies and diagnostics is well within our reach.

Lawrence S. Sturman, M.D., Ph.D.
Executive Director
New York State Stem Cell Science

1 Empire State Stem Cell Board Members

Richard F. Daines, M.D., is the fourteenth New York State Health Commissioner. Prior to becoming Commissioner, Dr. Daines was the President and CEO of St. Luke's-Roosevelt Hospital Center from January 1, 2002, until January 2007. Prior to joining the Hospital Center as Medical Director in 2000, he served as Senior Vice President for Professional Affairs of St. Barnabas Hospital in the Bronx, New York since 1994 and the Medical Director from 1987 to 1999. Dr. Daines received a Bachelor of History degree from Utah State University in 1974 and served as a missionary for the Church of Jesus Christ of Latter-day Saints in Bolivia, 1970-1972. He received his medical degree from Cornell University Medical College in 1978. He served a residency in internal medicine at New York Hospital and is Board Certified in Internal Medicine and Critical Care Medicine (1987-1997). *(F, E)*

David C. Hohn, M.D., is President Emeritus and Executive Director of Health Policy at Roswell Park Cancer Institute (RPCI), where he served for 10 years as President and CEO. Dr. Hohn continues his national leadership role in health policy issues, especially as they relate to cancer research and treatment and training the next generation of cancer specialists. During his tenure as RPCI President, Dr. Hohn was widely credited with re-establishing the Institute as a leader in the national cancer community. He implemented the Institute's first strategic plan focused on making RPCI internationally and nationally competitive in cancer science; led the restructuring of RPCI as a public benefit corporation; stabilized funding and increased revenue; recruited over 160 senior leadership faculty, top-tier clinicians and scientists; completed the $250 million renovation and rebuilding of the Institute campus; and implemented an innovative managed care strategy which opened regional access to RPCI. As Principal Investigator of the National Cancer Institute Cancer's Center Support Grant, Dr. Hohn led the successful renewal of Roswell Park's designation as a comprehensive cancer center – a designation the Institute has held continuously since 1974. Dr. Hohn came to RPCI from the University of Texas M.D. Anderson Cancer Center where, as Vice President for Patient Care from 1993 to 1997, his responsibilities included oversight of all clinical departments, clinical research programs and the protocol office. *(F, E)*

(F) = Member of the Funding Committee
(E) = Member of the Ethics Committee

Kenneth Adams, M.B.A., is President and CEO of The Business Council of New York State, which represents more than 3,000 member businesses, chambers of commerce and professional and trade associations. The Business Council's mission is to create an economic renaissance for New York State by shaping public policy to improve New York's economy. Prior to joining The Business Council in November 2006, Mr. Adams was the President of the Brooklyn Chamber of Commerce. Under his leadership, the Brooklyn Chamber more than doubled its membership and significantly increased the impact of its marketing, advocacy and small business services. Mr. Adams substantially increased the Chamber's annual budget, launched 10 new economic development initiatives and improved the Chamber's relationships with government officials. Before joining the Brooklyn Chamber in 1995, he was the Director of the MetroTech Business Improvement District (BID) in Downtown Brooklyn. Under Mr. Adams' leadership, the BID augmented its services, improved community relations and received citywide recognition for its management and programs. He was the founding Executive Director of New York Cares, which he ran from 1988 to 1994, managing the organization's growth from 500 to 6,000 volunteers serving in citywide social service and community revitalization projects. He was also appointed by the Governor to serve on the Commission to Modernize the Regulation of Financial Services and the Children's Cabinet Advisory Group. *(F)*

Fr. Thomas Berg, Ph.D., is Adjunct Professor of moral philosophy at the Regina Apostolorum Pontifical College in Rome, Italy. A Roman Catholic priest, he is member of the Legionaries of Christ and teaches at the congregation's house of studies in Thornwood, New York, where he also is founder and Executive Director of The Westchester Institute for Ethics & the Human Person. Fr. Berg received his M.A. in Liberal Studies from Wesleyan University in 1997, and his Ph.D. in Philosophy from Regina Apostolorum in 1999. He specializes in natural law theory, personhood theory and biomedical issues dealing with the beginning of life. For the past five years, he has dedicated most of his philosophical research to the question of the moral status of the human embryo. Working with members of the President's Council on Bioethics, he has organized an interdisciplinary group of scientists, philosophers and moral theologians to engage in an on-going study of the moral and scientific feasibility of Altered Nuclear Transfer and other non-embryo-destructive sources of human pluripotent stem cells. He has recently co-edited a volume of essays by Catholic moral theologians entitled, "Human Embryo Adoption: Biotechnology, Marriage, and the Right to Life." He also sits on the boards of The Institute for the Psychological Sciences in Arlington, Virginia, and the University of Sacramento in Sacramento, California. *(E)*

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Bradford C. Berk, M.D., Ph.D., is the Senior Vice President for Health Sciences at the University of Rochester and CEO of the Medical Center and Strong Health. Dr. Berk received his medical and doctoral degrees from the University of Rochester. He has served on the faculties of Harvard Medical School, Emory University and the University of Washington. He previously was Chairman of Medicine (1999-2006) and Chief of the Cardiology Unit (1998-2003) at the University of Rochester. In addition, he was Director of the AB Cardiovascular Research Institute. Dr. Berk is a fellow of the American Heart Association and the American College of Cardiology, and a member of the Association of American Physicians. Dr. Berk is past-president of the North American Vascular Biology Organization (NAVBO). He is Consulting Editor for *Circulation* and *Circulation Research* and is on the editorial boards of *Arteriosclerosis, Thrombosis, and Vascular Biology* and the *Journal of Clinical Investigation*. Dr. Berk has published more than 200 articles, chapters and books. His research interests include molecular biology of renin-angiotensin-aldosterone system; regulation of endothelial cell function especially by shear stress; the role of oxidative stress in vascular injury biology; and the genetic mechanisms of vascular remodeling. *(F)*

Nancy Neveloff Dubler, LL.B. is the Director of the Division of Bioethics, Department of Family and Social Medicine, Montefiore Medical Center and Professor of Bioethics at the Albert Einstein College of Medicine. She received her LL.B. from the Harvard Law School. Ms. Dubler directs the Bioethics Consultation Service at Montefiore Medical Center as a support for analysis of difficult clinical cases presenting ethical issues in the health care setting. This service uses mediation as its process. She lectures extensively and is the author of numerous articles and books on termination of care, home care and long-term care, geriatrics, adolescent medicine, prison and jail health care and AIDS. She is Co-Director of the Certificate Program in Bioethics and the Medical Humanities, conducted jointly by Montefiore Medical Center/ Albert Einstein College of Medicine with Cardozo Law School of Yeshiva University. Her most recent books are *The Ethics and Regulation of Research with Human Subjects*, Coleman, Menikoff, Goldner and Dubler, LexisNexis, 2005, and *Bioethics Mediation: A Guide to Shaping Shared Solutions*, co-author, Carol Liebman, United Hospital Fund, New York, New York, 2004. She often consults with federal agencies, national working groups and bioethics centers. *(E)*

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Richard W. Dutton, Ph.D., was born in Great Britain, where he earned a Ph.D. in Biochemistry from London University, London, and a Masters of Arts and Bachelor of Arts degree in Biochemistry from the Cambridge University, Cambridge. He spent many years as a Professor in the Department of Biology for the University of San Diego, including service as Department Chair from 1986-198, and is currently a member of the Trudeau Institute, Inc., Saranac Lake, New York. He served as President of the American Association of Immunologists (AAI) and was awarded a Lifetime Achievement Award for his distinguished scientific accomplishment and extraordinary service to the AAI in April 2004. In the past he has held membership in various organizations and received many awards, such as the American Cancer Society Faculty Research Award. He has more than 200 publications to date and was elected a fellow of the American Association for the Advancement of Science: 2007. *(F)*

Robin Anthony Elliott, M.A., has been Executive Director of the Parkinson's Disease Foundation, Inc. since October 1996. He has been active in development, communications and not-for-profit management in New York City for more than 35 years, serving as Vice President for Development and External Affairs at Teachers College, Columbia University (1988-95) and at Hunter College, the City University of New York (1982-88); as Deputy to the Chancellor for University Relations at the City University of New York (1979-82); and as Director of Information and Education for Planned Parenthood Federation of America (1971-79). Mr. Elliott grew up in southern England and received his B.A. from Magdalen College, Oxford University and his M.A. in American Government and Politics from Columbia University. Avocationally, he is active in reproductive health and rights, including as Member of the Board of Directors of Advocates for Youth, a Washington-based organization he co-founded in 1980 and has served on the vestry of St. Michael's Church on West 99th Street and the boards of directors of the St. Cecilia Chorus and Community Health Charities. Until recently, he was Chair of New Yorkers for the Advancement of Medical Research, a pro-stem cell research coalition of disease advocacy groups, scientists and universities and citizens' groups. *(F)*

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Brooke Ellison, M.A., has worked as an advocate for stem cell research for nearly a decade. In 1990, at the age of 11, she was in an accident that left her paralyzed from the neck down and dependent on a ventilator to breathe. However, Ms. Ellison never let her physical situation stand in the way of what she could achieve, and she graduated with honors from Harvard University in 2000 and from Harvard's Kennedy School of Government in 2004. In 2002, she published an autobiography, *Miracles Happen*, which was later made into a movie directed by Christopher Reeve. For more than a decade, she has worked across the country as a public speaker, delivering her message of hope, optimism and strength in the face of obstacles, using her own experiences as a vehicle to convey the message. Ms. Ellison was a candidate for New York State Senate in 2006, focusing on the need for New York to embrace funding for stem cell research. She has continued her work in the field of stem cell research and in July of 2007 formed a non-profit organization, The Brooke Ellison Project, to educate and mobilize on behalf of the research. In addition, working with leading scientists and advocates in the field, she is presently working on a documentary to provide information on stem cell research. *(E)*

Gerald D. Fischbach, M.D., is the Scientific Director of the Simons Foundation, where he oversees the Simons Foundation Autism Research Initiative. Formerly Dean of the Faculties of Health Sciences at Columbia University and former Director of the National Institute of Neurological Disorders and Stroke at the National Institutes of Health (NIH) from 1998-2001, he received his M.D. degree in 1965 from Cornell University Medical School and interned at the University of Washington Hospital in Seattle. He began his research career at the NIH, serving from 1966 to 1973. He subsequently served on the faculty of Harvard Medical School, first as Associate Professor of Pharmacology from 1973–1978, and then as Professor until 1981. He then was the Edison Professor of Neurobiology and Head of the Department of Anatomy and Neurobiology at Washington University School of Medicine. In 1990, he returned to Harvard where he was the Nathan Marsh Pusey Professor of Neurobiology and Chairman of the Neurobiology Departments of Harvard Medical School and Massachusetts General Hospital until 1998. Throughout his career, Dr. Fischbach has studied the formation and maintenance of synapses, the contacts between nerve cells and their targets through which information is transferred in the nervous system. He is a member of the National Academy of Sciences, the American Academy of Arts and Science, the Institute of Medicine, a fellow of the American Association for the Advancement of Science, a non-resident Fellow of the Salk Institute and past-President of the Society of Neuroscience. *(F)*

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Samuel Gorovitz, Ph.D., former Dean of Arts and Sciences at Syracuse University, led in the development of the field of medical ethics and has published extensively on other topics in philosophy and public policy. He has given more than 200 invited lectures in dozens of countries on five continents and in 1989 led a National Institutes of Health regional workshop on research with human subjects. His publications include more than 120 articles, reviews and editorials in philosophical journals, medical journals, public policy journals and newspapers. He is a co-author of *Philosophical Analysis* and an editor of several anthologies. His two most recent books are *Doctors' Dilemmas: Moral Conflict and Medical Care* and *Drawing the Line: Life, Death, and Ethical Choices in an American Hospital.* In fall 1996, he served as the Baker-Hostetler Professor of Law at Cleveland Marshall College of Law and in fall 1998 was Visiting Scholar in the Department of Science and Technology Studies at Cornell University. Since 1988 he has served, by gubernatorial appointment, on the New York State Task Force on Life and the Law. He was Dearing-Daly Professor of Bioethics and Humanities at the SUNY Upstate Medical University from 2001-2004 and for 2004-05 was Visiting Professor of Philosophy and Bioethicist in Residence at Yale. He is Founding Director of the Renée Crown University Honors Program and Professor of Philosophy at Syracuse University. *(E)*

Bruce Holm, Ph.D., is Executive Director of the NYS Center of Excellence in Bioinformatics & Life Sciences. He also is Senior Vice Provost and Professor in the Departments of Pediatrics, Obstetrics and Gynecology, and Pharmacology and Toxicology at the State University of New York at Buffalo. Dr. Holm's research centers on the development of therapeutics for treatment of critical care patients, and he has co-founded two biotechnology companies that have developed and received Food and Drug Administration approval for life-saving drugs used in both newborn infants and adults. He holds several patents for lung surfactant replacement drugs currently on the market. He received a Research Career Award from the Heart, Lung and Blood Institute of the National Institutes of Health in 1991 and has been principal investigator on a variety of NIH, Howard Hughes Medical Institute, Department of Defense, NASA and Markey Trust funded projects totaling more than $50 million in current active federal grant support. Dr. Holm has published more than 250 papers, book chapters and abstracts on such topics as the biology of lung development; the use of surfactant therapy; and molecular therapeutics in acute diseases. *(F)*

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Hilda Hutcherson, M.D., FACOG, is the Associate Dean in the Office of Diversity and a Clinical Professor of Obstetrics and Gynecology at Columbia University College of Physicians and Surgeons. Dr. Hutcherson is a fellow in the American College of Obstetricians and Gynecologists and a member of the National Association of Medical Minority Educators, National Medical Association, North American Menopause Society and the American Medical Women's Association. She is the former director of the Pediatric and Adolescent Gynecology Program and Co-Director of the Center for Women's Health at Columbia University Medical Center. Dr. Hutcherson serves on the Advisory Boards of the Columbia University Summer Research Fellowship Program, the Doris Duke Clinical Research Fellowship Program, the Associated Medical Schools Diversity and Community Affairs and the New York City Health Literacy Fellowship. She has received numerous awards for teaching and patient advocacy. Dr. Hutcherson has maintained a clinical practice in Obstetrics and Gynecology since 1985. *(F)*

Robert Klitzman, M.D., is an Associate Professor of Clinical Psychiatry (in Socio-medical Sciences) in the College of Physicians and Surgeons and the Joseph Mailman School of Public Health at Columbia University. He co-founded and for five years co-directed the Columbia University Center for Bioethics and is currently the Director of the Ethics, Policy and Human Rights Core of the HIV Center and a member of the Division of Psychiatry, Law and Ethics. Dr. Klitzman has written numerous articles, chapters and six books, examining ethical, social, psychological and policy issues related to stem cells, research ethics, genetic testing, reproductive decision-making, privacy of genetic and other health information, IRB decision-making, professional education and other areas. His most recent book, *Mortal Secrets: Truth and Lies in the Age of AIDS*, examines views of medical privacy and ethical decision-making related to HIV and other realms and implications for public policy. He also has engaged in public education in medical ethics, writing about these issues for the New York Times and elsewhere. Dr. Klitzman has received several honors and awards for his work, including fellowships from the Aaron Diamond Foundation, the American Psychiatric Association, the Russell Sage Foundation, the Commonwealth Fund and the Rockefeller Foundation. *(E)*

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Vivian S. Lee, M.D., Ph.D., M.B.A., is Vice Dean for Science, Senior Vice-President and Chief Scientific Officer of the NYU Medical Center. She also is Professor and Vice-Chair for Research in the Department of Radiology and Professor of Physiology and Neuroscience. A practicing MRI radiologist, Dr. Lee is the principal investigator of three National Institutes of Health research grants and serves as a charter member of the Medical Imaging NIH study section. She is a Fellow and President-Elect of the International Society for Magnetic Resonance in Medicine. Dr. Lee has authored over 100 peer-reviewed publications and a recent textbook, *Cardiovascular MRI: Physical Principles to Practical Protocols*. Her research focuses on the development of quantitative functional MRI for the improved understanding of physiology and disease. Dr. Lee was awarded a Rhodes Scholarship to study at Oxford University, where she received a doctorate in medical engineering. She earned her M.D. at Harvard Medical School, completed her residency in Diagnostic Radiology at Duke and was a fellow in Body and Cardiovascular MRI and Thoracic Imaging at New York University. Dr. Lee completed an M.B.A. at NYU's Stern School of Business in 2006. *(E)*

Rev. H. Hugh Maynard-Reid, D.Min., BCC., CASAC, is the Director of Pastoral Care Department in the North Brooklyn Health Network of the Health and Hospital Corporation (HHC) in New York City. He is a Board Certified Chaplain and a Credentialed Addiction and Substance Abuse Counselor by the State of New York. He also has Certification in Human and Medical Bioethics. Previously, Rev. Dr. Maynard-Reid served as a Minister for 15 years in New York City. He was also the Associate Professor of Old Testament and Biblical Studies at Northern Caribbean University (formerly West Indies College) and Adjunct Professor at Andrews University. He is a member of the Association of Professional Chaplains and serves on the Regional Certification team and the Multi-cultural committee. He is an Advisory Member of Catholic Health Services of Long Island Pastoral Education and Chaplaincy services. He served as a member of the Institutional Review Board and Health Research Council and is a member of the Ethics Committee of the North Brooklyn Health Network. As a member of the Brooklyn Ecumenical Advisory his community services work centers on community leaders' health education. *(E)*

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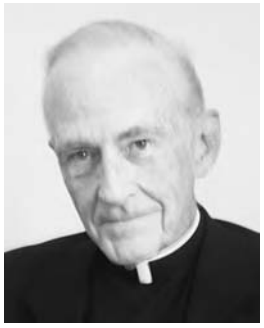

Rev. Monsignor William Smith, S.T.D., is a Professor of Moral Theology at St. Joseph's Seminary, Dunwoodie, Yonkers, New York and a Roman Catholic priest ordained in 1966 for the Archdiocese of New York. Monsignor Smith received his B.A. in philosophy in 1961 from St. Joseph's Seminary and College. He received his M.Div. in 1965 and his M.A. in theology in 1966 from St. Joseph's Seminary. He received his S.T.D., a doctorate in moral theology in 1971 from The Catholic University of America in Washington, D.C. Since 1971, he has been the Professor of Moral Theology at St. Joseph's Seminary and was the Dean of the Faculty, teaching fundamental moral theology and medical ethics from 1977 through 1988 and again from 2000 through 2005. Monsignor Smith holds the Margaret Leibman Berger Chair in Medical Ethics. He is a member of the Ethics Committee of St. Vincent's Hospital in Manhattan and Calvary Hospital in the Bronx. *(E)*

Michael A. Stocker, M.D., M.P.H., was the Chief Executive Officer of Empire Blue Cross Blue Shield from 1994 until 2005, when Empire was acquired by WellPoint, a company composed of 14 Blue Cross Blue Shield plans across the country. Dr. Stocker retired from WellPoint in April 2007. Prior to joining Empire, Dr. Stocker was President of CIGNA Health Plans. He also served as Executive Vice President and General Manager of U.S. Healthcare for the New York market. He was Medical Director at ANCHOR, a staff model HMO at Rush Presbyterian St. Luke's Medical Center in Chicago for five years. He also was Associate Chairman and Program Director of the Department of Family Practice at Cook County Hospital in Chicago and practiced medicine in Chicago for 12 years. Dr. Stocker earned his undergraduate degree from the University of Notre Dame and his medical degree from the Medical College of Wisconsin. He received his residency training at the Mayo Clinic and at the University of California and is Board Certified in Internal Medicine and Family Practice. He also received a Master of Public Health from the University of Michigan. Dr. Stocker is a member of several boards and organizations including the Albert Einstein College of Medicine and the Arthur Ashe Institute for Urban Health. *(F)*

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Daniel P. Sulmasy, O.F.M., M.D., Ph.D., a Franciscan Friar, holds the Sisters of Charity Chair in Ethics at St. Vincent's Hospital, Manhattan, and serves as Professor of Medicine and Director of the Bioethics Institute of New York Medical College, Valhalla, New York. He received his A.B. and M.D. degrees from Cornell University and completed his residency, chief residency and post-doctoral fellowship in General Internal Medicine at the Johns Hopkins Hospital. He received his Ph.D. in philosophy from Georgetown University in 1995. From 1991 to 1998, he served on the faculty at Georgetown, where he was Director of the Center for Clinical Bioethics and Senior Research Scholar of the Kennedy Institute of Ethics. He was appointed by the Governor to the New York State Task Force on Life and the Law in 2005. His research interests include the ethics of end-of-life decision-making, ethics education and spirituality in medicine. He is the author of four books, *The Healer's Calling, Methods in Medical Ethics, The Rebirth of the Clinic* and *A Balm for Gilead*. He serves as editor-in-chief of the journal, *Theoretical Medicine and Bioethics*. His numerous articles have appeared in medical, philosophical and theological journals and he has lectured widely both in the U.S. and abroad. *(E)*

Robert N. Swidler, M.A., J.D., is General Counsel to Northeast Health, a not-for-profit health care system in New York's Capital Region that includes hospitals, nursing homes, home care, senior residences and other affiliates. Previously, Mr. Swidler was a partner at Hiscock & Barclay; Deputy Commissioner and Counsel to the NYS Office of Mental Health; and Assistant Counsel to Governor Mario Cuomo. From 1985-90, Mr. Swidler was Staff Counsel to the New York State Task Force on Life and the Law, where he helped develop the Task Force's proposals on brain death, DNR orders, health care proxies and organ transplantation. Mr. Swidler has written numerous articles on health law topics and co-authored chapters in the *Legal Manual for New York Physicians* on informed consent and life-sustaining treatment decisions. He was Chair of the NYS Bar Association Health Law Section in 1999-2000 and is currently Editor of the Association's *Health Law Journal*. He is also a member of the faculty of the Alden March Bioethics Institute in Albany. Mr. Swidler is a graduate of Columbia Law School ('82) and SUNY Binghamton (BA '77, MA '78). *(E)*

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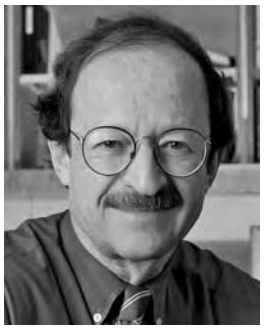

Harold Varmus, M.D., former Director of the National Institutes of Health and co-recipient of the 1989 Nobel Prize in Physiology or Medicine, has served as the President and Chief Executive Officer of Memorial Sloan-Kettering Cancer Center in New York City since January 2000. Dr. Varmus received the Nobel Prize (jointly with Michael Bishop) for elucidating the molecular and genetic mechanisms that underlie the transformation of a normal cell to a cancerous one. He is a member of the National Academy of Sciences and the Institute of Medicine and has received the National Medal of Science, the Vannevar Bush Award and several honorary degrees. In addition to authoring over 300 scientific papers and four books, Dr. Varmus has been an advisor to the federal government, pharmaceutical and biotechnology firms and many academic institutions. He served on the World Health Organization's Commission on Macroeconomics and Health from 2000 to 2002; is a co-founder and Chairman of the Board of Directors of the Public Library of Science; chairs the Scientific Board of the Grand Challenges in Global Health at the Bill and Melinda Gates Foundation; and is involved in initiatives to promote science in developing countries, including the Global Science Corps. His research at the Sloan-Kettering Institute mainly addresses molecular mechanisms of oncogenesis, using mouse models of human cancer. *(F)*

Madelyn Wils is Executive Vice President of the Planning, Development and Maritime Division of the New York City Economic Development Corp (NYCEDC). She is responsible for most of the city's area-wide revitalization plans throughout the five boroughs. Prior to joining NYCEDC, Ms. Wils served as President of the Tribeca Film Institute. She managed the expansion of the organization, from programming a 10-day film festival into a diverse institution offering year-round cultural and educational events. From 2000 to 2005, she served as Chair of Community Board One in Lower Manhattan, where she played an integral role in the rebuilding of Lower Manhattan. Ms. Wils led the development of the Master Concept Plan for the East River Waterfront and was awarded "The Visionary Award" from the New York League of Conservation Voters for her efforts. She negotiated significant capital projects for her community, including new schools and parks, community facilities, Little League fields and a library in Battery Park City. Ms. Wils was a founding board member of the Lower Manhattan Development Corporation and The Hudson River Park Trust. She has served on other boards, including the Alliance for Downtown New York, the Battery Conservancy and the Lower Manhattan Cultural Council. *(E)*

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2 Activities of the Empire State Stem Cell Board

Introduction

The Empire State Stem Cell Board (ESSCB) was created within the Department of Health by Chapter 58 of the Laws of 2007 (Public Health Law, Article 2, Title V-A) to award grants for basic, applied, translational and other research and development activities that will advance scientific discoveries in fields related to stem cell biology. The ESSCB is composed of two committees: the Funding Committee and the Ethics Committee. Each committee has 13 members, six of whom are appointed directly by the Governor, another six who are appointed by the Governor upon the nomination of legislative leaders, as well as the Commissioner of Health, who serves as the chair of each committee and of the entire Board. The Ethics Committee is charged with making recommendations to the Funding Committee regarding ethical, scientific and medical standards for funded research, including clinical trials. The Funding Committee is responsible for: providing an independent scientific peer review process to review grant applications; soliciting grant applications; developing application eligibility criteria, standards and scoring methods; evaluating submitted proposals; and making recommendations to the Commissioner of Health for the award of grants.

In the Board's first nine months of operation, the Ethics Committee met eight times, the Funding Committee met seven times, and the full Board met three times. All meetings were webcast in accordance with Executive Order 3 and were open to the public with advance registration. Strong and active efforts are underway to ensure that the public has access to information regarding the Board's activities and the programs and research supported with public funds. Prior to the first Board meeting, an Internet website, www.stemcell.ny.gov, along with an e-alert system, was established to help inform the public. Meeting minutes from each Board meeting, as well as the Board's bylaws, research guidelines, press releases and funding opportunity announcements are all made available on the website.

The Inaugural Meeting – A Quick Start

The Empire State Stem Cell Board held its inaugural meeting on October 22, 2007, less than two months after the appointment of the Board's first member. At that meeting, the Board was provided with information regarding its statutory authority, the Public Officers Law, the Open Meetings Law and other relevant statutes. The Board adopted by-laws to establish its governance structure and operating principles and approved guidelines for observers. The by-laws adopted by the Board set forth standards for independent scientific peer review of all funding applications and a stringent code of ethics to help ensure that the Board funds only meritorious research proposals and proceeds as to engender the public trust. Then Lieutenant Governor Paterson, a long-time advocate of stem cell research, attended the meeting and addressed the Board, expressing his appreciation to the members of the Board for their willingness to serve.

Through the full Board meeting and meetings of both the Funding and Ethics Committees, members also engaged in discussions that have laid the foundation

for many of their activities throughout the remainder of the year. Members were encouraged to attend meetings of both the Ethics and Funding Committees since the information presented and discussions held were relevant to the work of both Committees.

Establishment of an Independent Peer Review Panel and Merit Review Process

The enacted statute establishing the Empire State Stem Cell Board mandates that the Funding Committee provide for an independent scientific peer review panel and merit review process. In response to this mandate, the Funding Committee authorized a Request for Proposals (RFP) to solicit bids from contractors with sufficient capacity and skill to assist the Board by providing for the independent scientific peer review of grant applications. The RFP was issued in early November 2007, and a vendor was approved by the Funding Committee at its January 7, 2008, meeting. NYSTEM staff, with input and guidance from members of the Funding Committee, is working with the vendor to identify qualified peer reviewers. The Department of Health has also obtained approval to require researchers expecting to apply for funding under specific funding mechanisms to submit a letter of intent to facilitate planning and expedite the peer review process.

Standards for Research

At the October 22, 2007, meeting, the Board spent considerable time identifying and discussing potential scientific, medical and ethical standards to be applied to stem cell research funded by New York. Dr. Jonathan Moreno presented information regarding the National Academies of Science Guidelines on Human Embryonic Stem Cell Research (NAS Guidelines) that were developed by a committee of national experts co-chaired by Dr. Moreno. The NAS Guidelines provide substantial guidance on issues of informed consent, payment for gamete donors, donor privacy, appropriate institutional oversight and unethical research. The Board was also presented with information regarding other state stem cell research funding programs, the potential impact of interstate variations in standards on the ability of researchers to collaborate across state lines and the potential application of federal Food and Drug Administration requirements relating to the use of stem cell lines in therapeutic applications. The Ethics Committee also identified numerous issues for further study and consideration.

On November 30, 2007, the Ethics Committee met and considered recommendations for standards to be applied to the first round of funded grants. The Committee relied predominantly on the prior extensive work of nationally and internationally recognized experts who had participated in development of the NAS Guidelines and the International Society for Stem Cell Research (ISSCR) Guidelines for human embryonic stem cell research. The Committee recommended that research involving the use of human embryonic stem cells (hESC) in the first round of funding adhere to the guidelines developed by either of these bodies, with some modifications. The most significant modification recommended by the Ethics Committee was to exclude the use of first round funding for creating new hESC lines, or to support research involving human somatic cell nuclear transfer, human parthenogenesis, introduction of non-human cells into human embryos, or introduction of hESC into non-human animals at any stage of embryonic, fetal or postnatal development. The Ethics Committee recognized that its members and the public held differing views about the merits of supporting these categories of research, and that the Committee had not yet undertaken a substantive discussion about those merits. As a result, the Ethics Committee thought it reasonable to withhold funding of such research for the imminent first round, to allow for further discussion.

The Funding Committee adopted the recommendations of the Ethics Committee except for this last modification of the NAS and ISSCR Guidelines. Funding Committee members expressed concerns regarding this last recommendation, including: its application to research involving chimeras that are not ethically controversial; lack of a time limit for these restrictions; similarities of the restrictions to the current federal funding restrictions; and perception that this restriction would create regarding the intent of the state program and the funding of scientifically meritorious research.

Following these initial interim recommendations, the Ethics Committee turned its attention to the policies and practices of Embryonic Stem Cell Research Oversight (ESCRO) committees since the NAS and ISSCR Guidelines rely heavily on ESCRO oversight for the ethical conduct of hESC research. At the Committee's request, staff conducted a survey of ESCRO committees operating in New York State and their policies and practices. The Committee also engaged in a thought-provoking dialogue with Henry Greely, a professor of law at Stanford University and chair of the California Advisory Committee on Human Embryonic Stem Cell Research. Based on this information, the federal regulations governing Institutional Review Boards (IRBs) and the protection of human subjects, as well as articles written about ESCRO committees and their practices, the Ethics Committee crafted several new, detailed recommendations. The Ethics Committee's revised recommendations expanded upon the NAS and ISSCR guidelines for ESCRO committee composition, included specific requirements for written documentation of ESCRO committee policies and procedures and addressed conflict of interest issues. In keeping with Dr. Greely's counsel, the Committee also recommended that state-funded research involving human pluripotent stem cells be subject to ESCRO committee oversight. These revised recommendations were presented to the Funding Committee at its March 28, 2008, meeting and were adopted with minor, clarifying modifications.

During the year, the Ethics Committee also has explored different viewpoints regarding the status of the human embryo. The Committee was provided with published articles representing a variety of perspectives and engaged in extensive collegial, frank and courteous discussions on the topic, as reflected in meeting minutes. While the Committee has acknowledged that it is unlikely to reach complete agreement, the members reached a consensus that human embryos are deserving of respect.

The Ethics Committee has identified additional ethical, scientific and medical issues for study (as set forth in Chapter 5 of the ESSCB's Strategic Plan) and is currently considering the issue of informed consent of gamete donors.

Intellectual Property Issues

The statute creating the ESSCB requires that all grants be subject to intellectual property agreements that set forth the scope, if any, of the state's financial or other interests in the commercialization of the results, products, inventions and discoveries emanating from state-funded research. In keeping with this mandate, the Funding Committee has imposed several requirements applicable to intellectual property rights. Principal among these are standards ensuring public access to the published results of state-funded research, sharing of research-developed products and methodologies among the research community and the right of the state to protect or commercialize state-funded discoveries that may be patentable and marketable if the grantee fails to do so.

The ESSCB also has discussed development of additional intellectual property requirements or limitations to enable the state to reap the benefits of its investment. The Board has studied California's complex regulatory framework that requires a return on the

state's investment if certain conditions are met. The Funding Committee has concluded it should explore other alternatives that may be less burdensome, so that the Board's policies do not serve as a disincentive to translational research and needed collaborations with industry. The Funding Committee plans to continue to explore these issues and attempt to identify creative strategies to derive benefits for the residents of the state without undermining the mission and goals of the Board and the underlying stem cell research program.

Funding Proposals

At the inaugural meeting in October 2007, the Funding Committee met and approved the issuance of the Board's first Request for Applications (RFA). This initial solicitation was designed to provide a rapid influx of flexible funding to invigorate stem cell research efforts at institutions throughout New York State. As described more fully in Section 4 of this report, the Funding Committee approved awards to 25 institutions at its January 7, 2008, meeting. At that same meeting, the Funding Committee approved the release of four additional RFAs. The new RFAs seek proposals to stimulate stem cell research broadly through:

- **Consortia Planning Grants –** to encourage collaborations among new and established stem cell investigators within and among New York State institutions and in partnership with non-New York State investigators and corporations. These collaborations are likely to result in the creation of a comprehensive stable infrastructure to support expansion of the state's stem cell research community.
- **Facilities and Equipment Grants –** to support the establishment and operation of multi-institutional core facilities and specialized equipment for maximizing the expertise, efficiency and quality of stem cell research.
- **Investigator-Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) in Stem Cell Research –** to fund investigations of stem cell biology that will increase understanding of the unique properties of stem cells and allow their use to treat disease, and to make awards for well-developed basic, translational or pre-clinical research, or for preliminary testing of novel or high-risk hypotheses.
- **Targeted Investigations of Pluripotent Stem Cells –** to support the development of improved methods for deriving pluripotent stem cell lines; defining their reprogramming mechanisms; and comparing the utility of induced pluripotent stem (iPS) cells with embryonic and other pluripotent stem cells for use in disease models and potential therapeutic applications. Induced pluripotent stem cells, like embryonic stem cells, have the potential to develop into all types of cells.

In addition, based on recommendations of the Ethics Committee, the Funding Committee approved two RFAs related to ethical, legal, and social issues and education regarding stem cell science:

- **Summer Undergraduate Experience in Stem Cell Research –** provides funding for post-secondary institutions or non-profit organizations with demonstrated capabilities to establish a 10-week summer internship program for undergraduates focused on the students' independent role in, and presentation of, results from a stem cell biology-related research project. Components of the program may include special seminars, workshops or field trips, and must include an ethics seminar, as well as a career development seminar.

- **Development and Implementation of College and University Curricula Concerning Stem Cell Science and Related Ethical, Legal and Societal Implications –** supports development of an undergraduate-level course, or modules within a course, on stem cell science and its ethical, legal and social implications, providing balanced perspectives. All curricula developed with this funding will be made available to NYSTEM for public dissemination.

With the release of these new RFAs and the draft Strategic Plan in place, the Funding Committee plans to continue to identify research areas that would benefit from state funding proposals. Although no decisions have been made, funding for stem cell research consortia, routine solicitation of investigator-initiated awards, training programs, secondary school initiatives, new faculty career awards and innovative science proposals are most prominent in the Funding Committee's discussions.

Strategic Planning

One of the primary activities of the ESSCB and its Committees during the Board's first nine months of operation has been development of the Board's Strategic Plan, intended to guide the work of the Board and its funding activities during the course of the next five years. The strategic planning process began with the Board's first meeting, when the Board was presented with a summary of current stem cell investigations in New York State and the views of the scientific community regarding potential funding opportunities. Board members also discussed the need to develop a strategic plan, determined a process for such development and described the final product envisioned. Members expressed a clear preference for a primarily Board-developed product that would retain substantial flexibility for funding proposals as the science and research communities evolve in this area.

The Board's Strategic Plan, explained more fully in Section 6 of this report, was developed through an iterative, collaborative process that drew on the talents and expertise of members of both the Funding and Ethics Committees, under the guidance of an experienced scientific writer with additional input and support from NYSTEM staff. A Strategic Plan Coordinating Committee (SPCC) was formed to guide the process and prepare the mission statement, program goals and evaluation plans for the initial draft of the Strategic Plan. The SPCC held seven in-person and teleconference meetings from December 2007 to March 2008 to discuss and hone the structure and content of the Strategic Plan. During the course of 11 meetings, both the Funding and Ethics Committees discussed the strategic planning process and commented on preliminary drafts of the plan. An Ethics Strategic Planning Workgroup also met to refine the elements of the Strategic Plan related to ethical, legal, and social issues and education. At its full Board meeting on May 13, 2008, the Board agreed to post the draft Strategic Plan on the NYSTEM website for public comment before considering the plan for formal adoption at its June meeting. The draft, with some modifications, was formally adopted as the Strategic Plan on June 27, 2008.

Annual Meeting for Funded Scientists

Initial Empire State Stem Cell Board solicitations required funded scientists to set aside monies to allow attendance to at least one NYSTEM-sponsored symposium or similar event and present research findings. This requirement facilitates the goal of making the results of state-funded research available to the public and other scientists to maximize the potential benefit to New York residents and society in general. The Board has undertaken initial plans for annual meetings of funded

scientists to be held in the spring of 2009 and the spring of 2010. The meetings are expected to include speakers, break-out sessions and poster sessions for funded scientists to have ample opportunity to discuss their findings and interact with other stem cell scientists throughout the state, as well as other interested individuals and scientists.

ESSCB Board Meetings and Locations

Date	Location	Committee
October 22, 2007	New York City	ESSCB Board/Ethics & Funding Committees
November 30, 2007	New York City	Ethics Committee
December 13, 2007	New York City	Funding Committee
January 7, 2008	New York City	Funding Committee
January 17, 2008	Albany	Ethics Committee
February 15, 2008	New York City	Funding Committee
February 22, 2008	New York City	Ethics Committee
March 13, 2008	Albany	Ethics Committee
March 28, 2008	Albany	Funding Committee
April 1, 2008	New York City	Ethics Committee
May 13, 2008	Albany	ESSCB Board/Ethics & Funding Committees
June 27, 2008	New York City	ESSCB Board/Ethics & Funding Committees

3 Administrative Expenses

A five-year contract in the amount of $8,583,312 has been awarded to the American Institute of Biological Sciences (AIBS) to perform peer review services for applications received in response to RFAs. At a minimum, AIBS will:

- Receive applications and screen for compliance with ESSCB-established criteria and other application requirements and standards, including, but not limited to, conflict of interest, human subjects research, vertebrate animal research and human embryonic stem cell research.
- Coordinate, manage and provide support for the performance of independent scientific and technical merit peer review of research applications by qualified individuals.
- Implement and follow procedures for an established and systematic process of reviewing applications to ensure compliance with ethical standards of conduct and high-quality research.
- Submit written reports and summaries of each peer review conducted.
- Provide written reports to document efforts made during the reporting period to continuously improve services.
- Supply support services, such as conference management and travel logistics.

Additional administrative expenditures in the first year of the program (State Fiscal Year 2007-2008) total approximately $218,500. Costs for the first year of the program are relatively small because the NYSTEM program was not fully staffed before the end of the fiscal year.

Administrative expenditures for 2007–2008:

- Personal services costs – $95,000;
- Supplies – $16,000;
- Equipment – $14,000;
- Travel – $18,000;
- Website design – $15,500;
- Strategic planning consultant – $15,000;
- Board meeting expenses – $45,000.

4 Grants Awarded/ Grants in Progress

Merit Peer Review

NYSTEM received three high-quality proposals in response to a Request for Proposals issued on November 5, 2007, for an Independent Scientific and Technical Merit Peer Review Contractor. On January 7, 2008, the Funding Committee voted to authorize the Department of Health to proceed with negotiation of a contract with the successful bidder, AIBS. The start date for this five-year contract was April 1, 2008.

Institutional Development Awards

On January 7, 2008, the Funding Committee approved awards totaling $14.5 million to support stem cell research and training at 25 institutions that responded to an RFA issued on November 14, 2007. The one-year institutional development awards were designed to increase the capacity of New York State research institutions to engage in stem cell research. Together, these awards allocate $6.1 million for direct stem cell research, $7.4 million for stem cell research infrastructure and $1 million for stem cell research training.

Institution	Total Projects	Bridge	Supplemental	Core Facility/ Equipment	Training/ Conference Travel	Funds Awarded
Albert Einstein College of Medicine Yeshiva University	4			4		$ 999,933
City College of New York (CUNY)	7			1	6	$ 198,000
Cold Spring Harbor Laboratory	4		4			$ 380,933
Columbia University Morningside	1			1		$ 1,000,000
Columbia University Medical Center	2			2		$ 1,000,000
Cornell University Ithaca	11	2	5	1	3	$ 1,000,000
Hunter College (CUNY)	2		1		1	$ 155,980
Memorial Sloan Kettering Institute for Cancer Research	10		7	2	1	$ 1,000,000
Montefiore Medical Center	1			1		$ 150,899
Mount Sinai School of Medicine	4		2	1	1	$ 1,000,000
New York Medical College	2		1		1	$ 215,718
New York State Psychiatric Institute	1			1		$ 504,809
New York University	1			1		$ 553,586
New York University School of Medicine	10		9	1		$ 999,715

Continued

Institution	Total Projects	Bridge	Supple-mental	Core Facility/ Equipment	Training/ Conference Travel	Funds Awarded
Ordway Research Institute	1		1			$ 100,000
Polytechnic University of New York	1				1	$ 100,000
Rockefeller University (The)	2			2		$ 768,426
Roswell Park Cancer Institute	12	2	1	1	8	$ 419,442
State University of New York Buffalo	5	1	3	1		$ 606,422
State University of New York Downstate Medical Center	4		1	3		$ 192,267
State University of New York Stony Brook	9		7	2		$ 871,000
State University of New York Upstate Medical	1			1		$ 196,581
Trudeau Institute	2		2			$ 101,457
University of Rochester School of Medicine/Dentistry	18	1	16	1		$ 1,000,000
Weill Cornell Medical College	12		9	2	1	$ 997,382
TOTALS	**127**	**6**	**69**	**29**	**23**	**$14,512,550**

5 Stem Cell Research Institutional Development Abstracts

Albert Einstein College of Medicine, Yeshiva University **$999,933**
Harry Shamoon, M.D.

Cell Production Core, Epigenetics and Reprogramming Core, Cell Transplantation Core

Three core functions developed through the NYSTEM award will support stem cell research in diverse diseases, including hemophilia, anemia, heart disease, liver diseases and brain disorders. Additionally, research supported by the award will impact the science of developmental biology, cancer and aging research. A Cell Production Core will be created within the Einstein Center for Human Embryonic Stem Cell (hESC) Research. The core will provide hESCs and feeder cells to support research in the biology and applications of hESCs. Large-scale production of stem cells (100 million to one billion cells) is necessary for advancing research in these areas. An Epigenetics and Reprogramming Core will facilitate the use of new genetic technologies for stem cell research. The Core will support high-throughput technologies to characterize genetic changes in stem cells, including stem cells derived from reprogramming of mature cells (so-called induced pluripotent stem cells, or iPS) and of differentiated cells generated from stem cells that can be used to learn more about cancer and inherited diseases. A Cell Transplantation Core will provide animal models for studying stem cells. To verify that stem cells can differentiate into multiple lineages, native or modified cells will be transplanted into animals followed by analyses at various intervals to establish that stem cells can indeed generate desired types of mature cells. Furthermore, these models will establish whether stem cells can repopulate organs and restore deficient functions.

City College of New York (CUNY) **$198,000**
John M. Tarbell, Ph.D.

Stem Cell Research Institutional Development: Training and Core Equipment

A group of faculty members from the Biomedical Engineering Department and the Sophie Davis Medical School at the City College of New York (CCNY) are either actively working on or planning work in several areas of stem cell research. Projects are under way using mouse embryonic stem cells or adult human mesenchymal stem cells from bone marrow. Proposals to fund stem cell research have been submitted to the National Institutes of Health. Nevertheless, overall stem cell research at CCNY is in its infancy, and this Development Grant provides critical funds for training and core equipment that will move stem cell research at CCNY to the next level. Although faculty currently have the ability to conduct research related to stem cells, comprehensive training in core methods for individuals who conduct stem cell research will provide the foundation for development of long-term research capabilities using human embryonic stem cells at CCNY. Isolation and characterization of stem cells are the first critical steps in most stem cell research projects. A fluorescence-activated cell sorting (FACS) system is essential equipment for stem cell characterization and isolation with high purity. Currently, the Biomedical Engineering Department, home of four faculty members participating in this proposal, has no FACS system. The funds from this NYSTEM Institutional Development Grant will provide a critical FACS machine to enhance the future of stem cell research at City College.

Cold Spring Harbor Laboratory **$380,933**
David L. Spector, Ph.D.

Supplements for Studies of the Molecular Mechanisms Regulating Stem Cells in Development, Neurogenesis and Cancer

Cold Spring Harbor Laboratory (CSHL)'s stem cell research program takes a multi-pronged approach with a common goal: to determine the molecular mechanisms regulating stem cell activity. This research is important for the future development of stem cell-related therapies, as it is important to control therapy actions to ensure safety and effectiveness. Using animal, plant and U.S. Department of Health and Human Services-approved human cell lines, CSHL investigators study how stem cells are controlled in cancer, the brain and in plant development. In cancer, this work involves identifying genes regulating stem cell activity and dissecting the signaling pathways controlling stem cell growth. CSHL neuroscientists examine how new neurons arise from stem cells in the adult brain and how this process is related to neurological conditions and mood disorders. Finally, using plants as a model system, researchers will address questions that are difficult to answer in other systems regarding molecular mechanisms regulating stem cell activity. Stem cell-directed therapy has the potential to become a powerful tool against many diseases. CSHL's program is committed to understanding the basic mechanisms regulating stem cells, which will facilitate the progress of developing these therapies. This is an emerging area at CSHL, and NYSTEM funding has provided the initial resources to enable its success.

Columbia University Morningside **$1,000,000**
Gordana Vunjak-Novakovic, Ph.D.

Functional Imaging Core for Stem Cell Research

The Columbia University Morningside NYSTEM-funded project is for an imaging core for stem cell research. This funding is used exclusively to purchase equipment: a two-photon/confocal microscopy system, an *in vivo* imaging system, microplate reader and automated histology facility and to create a state-of-the-art functional imaging facility within the Department of Biomedical Engineering. At the same time, the Comparative Proteomics Center at the Department of Biology will be expanded with the addition of a new high-resolution mass spectrometer. Under the direction of Gordana Vunjak-Novakovic, 26 investigators from six Columbia University Morningside departments will benefit from these new research facilities. The goal is to move stem cell research from the "flat biology" of Petri dishes to controllable three-dimensional models and to study in real time and with high fidelity the self-renewal and differentiation of stem cells. Researchers expect that they will have the capacity to develop entirely new research paradigms, new imaging strategies and new approaches to engineer human tissues that simply do not exist for stem cell research at this time.

Columbia University Medical Center **$1,000,000**
James E. Goldman, Ph.D.

FACS Core, Ultradeep Sequencing Core and Ultrasound-Guided Microinjection Core Facilities for Stem Cell Research

Columbia University Medical Center's stem cell research community ranges from those probing the basic mechanisms of stem cells to clinicians dealing directly with such devastating diseases as diabetes, amyotrophic lateral sclerosis (ALS), cancer and others for which the potential of stem cell therapy is being explored. NYSTEM investments may accelerate the impact of fundamental discoveries on practical therapy. Ultimately, the goal is to use stem cells as a proxy to model and study human diseases, and as an unlimited source of cells for cell-based drug discovery and cell replacement therapy. To this end, the NYSTEM Institutional Development Award, together with matching funds from the Tow and Spitzer Foundations, is being used to create three core facilities: a Fluorescence-Activated Cell Sorting Core, an Ultradeep Sequencing Core and an Ultrasound-Guided Microinjection Core Facility. The facilities established with NYSTEM funds will enable tangible extension of stem cell research efforts by more than 60 investigators institution-wide.

Cornell University **$1,000,000**
Alexander Yu. Nikitin, M.D., Ph.D.

Accelerating Development of Cornell Stem Cell Research: Supplements, Equipment and Training

NYSTEM funding supports a number of investigators working in stem cell research at Cornell University, Ithaca. The main areas of research funded by NYSTEM include: deriving, maintaining and selectively differentiating embryonic and adult stem cells and reprogrammed pluripotent cells to recreate the temporal and spatial environment encountered in developing and adult tissues; and understanding the relevance of fundamental processes governing the control of stem cells to diseases such as cancer. NYSTEM funding has also accelerated development of a Cornell Stem Cell Program (http://stemcell.cornell.edu) and provided vital support for enhancement of stem cell-related core facilities. The main goals of the Cornell Stem Cell Program are to provide the necessary opportunities and structure for coordinating activities of investigators involved in stem cell research; to promote cross-campus interactions and enhance the existing platform for teaching and training in stem cell biology. With the help of NYSTEM funding, the program finances travel to stem cell meetings and conferences, supports seminar series featuring distinguished guest speakers and organizes an Annual Stem Cell Research Symposium. NYSTEM support has also allowed acquisition of equipment for analyzing and purifying rare stem cells in the body. This is a first step towards creating a Stem Cell Core that will provide essential services to numerous investigators throughout Cornell.

Hunter College (CUNY) **$155,980**
Ann S. Henderson, Ph.D.

Stem Cell Research Institutional Development: Research and Training

Two projects at Hunter College benefit from NYSTEM funding. The first is carried out in the laboratory of Ben Ortiz and the second in the laboratory of Paul Feinstein. Both laboratories are housed in the Department of Biological Sciences. The Ortiz laboratory is investigating genes responsible for T-cell development and function and how they are regulated. T cells coordinate most immune responses, including those that fight disease and maintain health, as well as those that reject transplanted tissue and produce autoimmunity. A recent discovery has made it possible to obtain T cells from mouse embryonic stem cells. This discovery facilitates the study of how T cells develop and the regulation of genes that bring about that developmental process. These studies can lead to the engineering of "designer" T cells. Such cells could, for example, target tumor cells or resist HIV infection. The second study is focused on investigation of the amazing ability of embryonic stem (ES) cells to develop into any type of adult tissue. This attribute is important because human ES cells with this capacity could ultimately provide tissue replacement therapies. Tissue rejection, however, is a special problem since each individual would require "custom" ES cells. Understanding how to generate "custom" ES cells for each individual opens the door to ES cell-based therapies for curing genetically derived diseases.

Memorial Sloan-Kettering Institute for Cancer Research **$1,000,000**
Lorenz Studer, M.D.

Accelerating MSKCC Stem Cell Research: Supplements, Equipment and Training

Memorial Sloan-Kettering Cancer Center (MSKCC) has been a leader in stem cell biology research for many years and is active in many areas, including: hematopoietic and umbilical cord blood, mesenchymal, cancer, neural and embryonic stem cell research, as well as in fundamental aspects of differentiation and development. NYSTEM funds are supplementing seven ongoing research projects in these various areas to provide specialized training in the use of established hES cells and to obtain critical shared equipment for and support of core facilities. MSKCC is committed to continue its strong support for stem cell research at the institution by working together with private, federal and state institutions to leverage available resources and enable the next breakthroughs in stem cell biology.

Montefiore Medical Center **$150,899**
Brian P. Currie, M.D., Ph.D.

Core Equipment for a Cellular Therapeutics Facility

Montefiore Medical Center is committed to support stem cell and cellular therapeutics research. In collaboration with the medical school – the Albert Einstein College of Medicine – the two institutions are dedicated to bring basic research advances into clinical practice. To that end, a new Cellular Therapeutics Facility is being constructed to meet the current good manufacturing practices (cGMP) requirements of the Food and Drug Administration. This facility will support development of clinical research projects that make use of various human adult stem cells, umbilical cord blood-derived stem cells and fetal human liver cells; it will be overseen by Dr. Ljiljana V. Vasovic, who has extensive experience in this arena and who will provide the bridge between the Cellular Therapeutics Facility and the Montefiore Medical Center Progenitor Cell Processing Laboratory. NYSTEM funds are being used to obtain specific equipment for use in this facility. The Cellular Therapeutics Facility represents the next stage of developing the capacity to translate stem cell research.

Mount Sinai School of Medicine **$1,000,000**
Ihor R. Lemischka, Ph.D.

Institutional Development Support of Stem Cell Research and Core Facilities

The Black Family Stem Cell Institute at the Mount Sinai School of Medicine (MSSM) has established the goal of bringing the newest discoveries in the field of stem cell science into the arena of clinical medicine. MSSM has committed significant resources to facilitate this goal, including the complete renovation of 10,000 square feet of space designated to house five to six newly recruited stem cell faculty members. A central mission is to build interactions with the numerous outstanding clinical and translational research efforts already in existence at MSSM. A major vehicle for instituting such interaction is the existing human embryonic stem cell core facility. The differentiation of hES cells in culture into multiple lineages offers unprecedented opportunities to understand the earliest stages of human development, to generate differentiated cell types for future cell replacement therapies and open avenues to understanding the causes of complex diseases. The NYSTEM-supported projects involve investigation of methods for culture and efficient differentiation of hES cells and identification of gene products and pathways essential for the maintenance of the pluripotent, self-renewing state. These studies will also enable understanding and exploitation of induced pluripotent stem (iPS) cell technology.

New York Medical College **$215,718**
Thomas H. Hintze, Ph.D.

Stem Cell Research Institutional Development: Supplementing Research and Training

Two areas for use of NYSTEM funding were identified at New York Medical College. The first was supplemental funding to continue and enhance investigations of the identification of adult cardiac and coronary vascular stem cells in the human heart. A vascular progenitor cell and a cardiac progenitor cell have been identified (in the heart), and these appear to integrate into the adult mammalian myocardium, resulting in the formation of both new blood vessels and new cardiomyocytes. The vascular progenitor cells, when injected into the region distal to a critical coronary artery stenosis, organize into blood vessels, and preliminary data suggest that these new vessels deliver blood flow to the ischemic myocardium. These cells are being grown and will be available to the scientific community. The second use of NYSTEM funding has been to create a Translational Cardiac Stem Cell Core to facilitate the growth of stem cell biology and potentially therapeutics at this institution. To this end, two new faculty members with experience in cardiovascular stem cell biology have been hired. Space has been designated, and, through collaboration with Westchester Medical Center, equipment is being purchased and staff, students and fellows recruited. The Core is expected to be active by September 2008.

New York Psychiatric Institute **$504,809**
Rene Hene, Ph.D.

Contribution of Hippocampal Neurogenesis to the Action of Antidepressant Medications: From Mice to Men

Most antidepressants have a delayed onset of therapeutic efficacy. This delay has led to the neurotrophic hypothesis which postulates that, downstream of the increases in monoamines elicited by antidepressants, growth-related events such as dendritic remodeling and neurogenesis (i.e. generation of new neural cells from neural stem cells) take place in various limbic areas. Dr. Hene's laboratory has shown that mice lacking hippocampal neurogenesis no longer respond to the selective serotonin reuptake inhibitor (SSRI) fluoxetine and the tricyclic desipramine in two chronic models of antidepressant response: the novelty-suppressed feeding test and the chronic unpredictable stress paradigm. These results suggest that hippocampal neurogenesis is required for the effects of antidepressants at least in these two animal models. The goal of this proposal is to further dissect this phenomenon in rodents and to extend our findings to humans. First, two new imaging strategies for neurogenesis (cerebral blood volume and magnetic resonance spectroscopy) will be validated in rodent models and then tested in depressed patients to determine whether these biomarkers are related or not to the antidepressant response. The studies at the New York Psychiatric Institute should considerably advance the understanding of the mechanisms of action of antidepressant medications and open new therapeutic avenues for the treatment of depression-related disorders.

New York University **$553,586**
Daniel L. Stein, Ph.D.

A High-Throughput Sequencing Core for Stem Cell Research

New York University (NYU) will use its NYSTEM grant to acquire powerful new sequencing technologies in order to advance research into the analysis of what makes stem cells different from other cells. The great potential of stem cells for regeneration therapy rests on their ability to produce many or all other kinds of cells in an organism. Thus, one major question to address is which genes (and other factors) make stem cells function differently from other cells. Previous technologies have relied on miniature "probes" to test for the presence of an active gene. However, this probe approach limits sensitivity and can miss certain genes. High-throughput sequencing technology indiscriminately samples the contents of cells and asks what is present, providing a more comprehensive view of stem cells and greater sensitivity, which allows detection of unique aspects of stem cells. NYU researchers will use high-throughput sequencing technology to analyze stem cells to ask how they are different on many different levels, including active genes, small regulatory RNAs and chromatin states of DNA. This new technology will be utilized by researchers working on a variety of different models, including animals, invertebrates and plants.

New York University School of Medicine **$999,715**
Ruth E. Lehmann, Ph.D.

Stem Cell Research Supplements, Training and Core Equipment

New York University Langone Medical Center (NYULMC) will use the NYSTEM Institutional Development Award to supplement funding for work already underway in NYULMC's Kimmel Center for Stem Cell Biology, as well as to acquire state-of-the art equipment and create training programs to attract more researchers to the stem cell field. The funding from New York State will support research toward a better understanding of how stem cells renew themselves and how they interact with specific niches in the body. Funds will benefit nine research projects exploring: the genetic pathways that regulate cancer stem cells of the immune system; the regulation of neural stem cells as vehicles for neural regeneration; and identification and analysis of stem cells and progenitor cells of the intestine, prostate, heart and gonad. The grant will also make possible the purchase of a high-speed cell sorter to accurately purify the minute populations of stem cells on which such research is based.

Ordway Research Institute **$100,000**
Stewart Sell, M.D.

Bone Marrow Stem Cell Origin of Breast Cancer

The possibility that breast cancer may derive from bone marrow-derived stem cells (BMDSCs) is being tested by transplantation of BMDSCs from transgenic male mice bearing a strong mammary cancer oncogene under the control of a mammary gland-specific promoter (MMTV) to lethally irradiated female recipients of the same inbred strain. If the BMDSCs migrate to the breast and, under the influence of the microenvironment of the breast tissue or by fusion with breast cells, express mammary epithelial phenotype, the mammary-specific promoter will be activated, the transgene expressed in the mammary epithelial cells and cancer will develop. The NYSTEM grant has allowed Ordway to finish a preliminary experiment in which breast cancer cells containing Y chromosomes (male cells) were seen in 1/8 of irradiated female recipients of transgenic male bone marrow. This tumor was diploid, suggesting transdifferentiaton of BMDSCs into breast epithelial cells. The laboratory is now preparing experiments to study conditions (increased circulation of BMDSCs, pregnancy, hormone treatment, etc.) that may increase the incidence of breast cancer arising from BMDSCs. The researchers also plan to determine whether breast cancer in the transgenic mice may be prevented by transplantation of normal bone marrow.

Polytechnic University **$100,000**
Kalle Levon, Ph.D.

Multifunctional Scaffolds for Stem Cell Growth Design and Control

Mechanical support by scaffolding is needed for stem cells to grow in a coordinated manner *in vivo*. Additionally, such scaffolding can be used to store and release growth factors and other chemicals pertinent to optimal cell differentiation and proliferation. NYSTEM funding will support an integrative program between Polymer Science and Engineering, Biomedical Engineering and Bioinformatics at Polytechnic University, which provides investigators with the opportunity to participate in the interdiscplinary area of tissue engineering with expertise in polymer science. Just as nanofibers for biosensing and nanogel particles for drug delivery applications have been previously prepared, this expertise is now being combined for preparation of multifunctional 3D nanofiber/nanogel scaffolds with the possibility for dimensional control of the electrostatic behavior of the scaffold. PC12 cells in electrospun polymerfiber scaffold are an example. Polytechnic's collaborators include Memorial Sloan-Kettering Cancer Center and SUNY at Stony Brook.

The Rockefeller University **$768,426**
Michael W. Young, Ph.D.

FACS Sorting and Multi-Photon Microscopy Facilities for Stem Cell Research

Stem cell-based therapies hold particular hope for treating cancer, diabetes, heart disease, stroke, spinal cord injury and neuro-degenerative disorders such as Parkinson's disease. In addition, stem cell research is helping to advance understanding in areas such as blood disorders/sickle cell disease, birth defects and childhood developmental disorders, epilepsy, HIV/AIDS and hearing loss. These conditions are currently under study at The Rockefeller University (RU). Advanced instrumentation is essential for further development of RU stem cell programs, designed to accelerate research and open up new avenues in the rapidly growing field of stem cell biology. The NYSTEM Institutional Development award will advance the University's stem cell research capabilities through the purchase of a fluorescence-activated cell sorter (FACS) and a multi-photon microscope, to be integrated into existing centers. Stem cell work is performed in more than a dozen of RU's 75 laboratories by scientists from a diverse range of disciplines and research areas, including cell and developmental biology, biochemistry, medical genetics, genomics, immunology, skin cell biology, infectious disease research, cancer biology and the neurosciences. Ongoing investigations are shedding new light on the basic mechanisms of stem cells. Enhanced cell sorting and imaging promise to bring these studies to fruition.

Roswell Park Cancer Institute **$419,442**
Andrei Gudkov, Ph.D., D.Sc.

Supplementary Funding, Specialized Training and Shared Equipment for Stem Cell Research

Roswell Park Cancer Institute (RPCI) scientists and clinician-scientists strive to develop and improve cancer treatment through innovative translational research programs aimed at understanding, preventing and curing cancer. Multiple RPCI laboratories have long-standing research programs exploring the role of stem cells in the etiology and pathogenesis of cancer and in the recovery of the cancer patient from cancer therapy, and an equal number of laboratories are initiating programs that apply their expertise and models to further understanding of the complex role of stem cells in cancer. RPCI investigators are focused on the following areas of stem cell research in cancer: 1. developing new pharmacological agents for therapeutic targeting of stem cells, including protection and mobilization of benign stem cells and selective killing of cancer stem cells; 2. identification and characterization of cancer stem cells and identification of their contribution to recurrent cancer and metastatic cancer; and, 3. characterization of the role of tissue microenvironment in transformation and growth in tissue regeneration and stimulation of anti-cancer responses.

State University of New York at Buffalo **$606,422**
Kenneth M. Tramposch, Ph.D.

Institutional Development of Stem Cell Research with Supplements and a Multi-Photon Microscopy Core

The centerpiece of the Stem Cell Program at the University at Buffalo (UB) is the program's physical workspace at the New York State Center of Excellence in Bioinformatics and Life Sciences and positions a genomic research core and high performance computing center directly adjacent to a planned stem cell core facility. This unique environment allows researchers, scientists and clinicians from many backgrounds and specialties to combine their expertise in exploration of stem cells and their potential as therapies. The overarching vision of the program is the exploration of basic stem cell biology to provide the necessary foundation for developing treatments of major debilitating and life-threatening diseases affecting New Yorkers. Through an understanding of the role and function of stem cells in normal development and disease, UB researchers seek to capture and direct the innate capabilities of stem cells to treat diabetes, stroke, cardiovascular disease and many other conditions. SUNY at Buffalo believes that this collaborative research environment will support the translation of basic research to clinical care and, when coupled with investment in commercialization, will enhance the economy of New York.

State University of New York Downstate Medical Center **$192,267**
Gladys Teitelman, Ph.D.

Core Facilities and Supplementary Funding for Stem Cell Research

Stem cell work is being pursued in several critical areas at SUNY Downstate Medical Center, with special emphasis on translational research into clinically relevant interventions. Embryonic stem cells are developed for use as therapy to replace cells lost during heart failure and in instances of muscle disorders. Another area of investigation is isolation, characterization and transplantation of blood-derived stem cells for treatment of cancers of the immune system. Research is also being pursued in diabetes. To this end, therapies are devised for the control of high blood glucose using recently discovered progenitors of insulin-producing cells present in adults. Finally, a group of neuroscientists is developing strategies to induce differentiation of embryonic stem cells into various neuronal types useful for transplantation into the brain and retina. These programs are now being actively developed and provide the basis for expansion of stem cell research at Downstate, a goal that will be facilitated by the funds provided for this purpose by the NYSTEM Institutional Development Grant.

State University of New York at Stony Brook **$871,000**
Peter R. Brink, Ph.D.

Shared Equipment and Supplemental Funding for Stem Cell Research

Stem cell-based therapeutics is a new and exciting research avenue that has great potential for clinical applicability. Stem cells represent an autologous or allogenic delivery system able to, in principle, deliver small molecules focally or systemically. This general tenet has been the driving force in Stony Brook's stem cell initiative. Stony Brook's projects include the use of stem cells to repair the heart and regenerate skin electrically. The stem cell group applies NYSTEM support in seven laboratories, where both adult stem cell and embryonic (approved lines) stem cell projects are being pursued. The group organizes seminar series and group research meetings to allow for better integration among stem cell laboratories on campus. Stony Brook has established collaborations with researchers at Columbia University and Worcester Polytechnic Institute as part of a newly initiated project on mechanical repair of the heart. The investigators are purchasing common-use equipment for cell culture and experimentation in the form of incubators and hoods and a confocal microscope to further strengthen intra-university ties.

State University of New York Upstate Medical Center **$196,581**
Gerold Feuer, Ph.D.

Whole-Mouse Imaging Core for Stem Cell Research

The Center for Humanized Severe Combined Immunodeficient (HU-SCID) Mouse Models at SUNY Upstate Medical University is a unique facility and research unit created to foster interdisciplinary scholarship and research focused on developing and utilizing HU-SCID mice. These mice support development and maturation of a human immune system following inoculation of human stem cells. This is a novel animal model with the potential to become a broad platform for investigations of stem cell biology, as well as a novel model to study human viral infections and cancer stem cells. The focus of this highly specialized Center is to better understand disease pathogenesis and develop preclinical models to test novel anti-virals, vaccines and chemotherapeutic drugs.

Upstate has used the NYSTEM Institutional Development Award to purchase an IVIS 200 whole-mouse imaging system. The IVIS 200 uses a specialized camera to detect both bioluminescent and fluorescent light signals emitted from stem cells implanted in SCID mice. The ability to quantify and localize human stem cell development within SCID mice using this bioluminescent imaging system is an important technological advance which will greatly accelerate experiments involving *in vivo* human stem cell maturation and development. Major advances in understanding human stem cell biology will arise from applying *in vivo* imaging to the studies underway at SUNY Upstate Medical University.

The Trudeau Institute **$101,457**
Troy D. Randall, Ph.D.

Supplemental Funding of Stem Cell-Related Research

The Trudeau Institute operates programs in two areas of stem cell research. The first program is focused on determining the role of mesenchymal stem cells in generating and supporting niches in the lung that support local immune responses to pathogens like *Mycobacterium tuberculosis* and influenza virus. An important question in this area is whether the stromal cells in the lung are derived from circulating mesenchymal stem cells that come from the bone marrow or whether the stromal cells are formed by mesenchymal stem cells that reside in the lung itself. A second program is focused on understanding how hematopoietic stem cells generate fully functional T cells in aged individuals. Since aged individuals have well-demonstrated defects in T-cell responses and poor T-cell output, it is essential to understand how T cells are generated by aged stem cells and whether those "new" T-cells respond appropriately to vaccination or infection. The availability of supplemental funds from the NYSTEM program will allow Trudeau researchers to increase their efforts on both of these projects dramatically. Ultimately, the results from these projects will be used to design novel vaccination or therapeutic strategies that will prevent or reduce an individual's susceptibility to infectious disease.

University of Rochester **$1,000,000**
David S. Guzick, M.D., Ph.D.

Research Supplements and a High-Throughput Screening Instrumentation for Stem Cell Research

The University of Rochester is home to more than 40 laboratories, in more than 10 different departments, engaged in multiple aspects of stem cell research. Areas of research pursued range from the most basic avenues of scientific discovery to the cutting edges of clinical translation. NYSTEM funding is being used to enable 18 of these laboratories to accelerate their research into a wide range of topics. Examples of research supported include: development of better treatments for cancer, spinal cord injury and fracture repair in the elderly; discovery of the basic general principles that underlie the normal function of stem and progenitor cells of multiple types and in multiple species; analysis of the effects of oxidative stress on a wide range of progenitor cell populations; and establishment of a high-throughput screening laboratory for discovery of pharmacological agents able to help in achieving many clinical and research goals. This funding has been dispersed under the guidance and auspices of the University of Rochester Stem Cell and Regenerative Medicine Institute, which links together the multiple stem cell laboratories across the campus.

Weill Medical College of Cornell University **$997,382**
Harry M. Lander, Ph.D.

Echocardiography and Stem Cell Physiology Core Facilities, Specialized Training Programs and Supplemental Funding for Stem Cell Research

Stem cell research at Weill Cornell Medical College mainly focuses on cancer biology, neurodegenerative disorders, lung disease and reproductive biology. The NYSTEM Institutional Development Grant allowed nine projects to receive supplemental funding to further programs studying: how normal cells become cancerous; how brain neurons develop and what happens to them in disease states such as Parkinson's or Alzheimer's; and how the vascular system responds to stimuli which lead to heart disease. In addition, the funds helped train a postdoctoral student studying the mechanism by which stem cells can be turned into neuronal cells in the brain. Finally, these funds also allowed two central core facilities to be established to help promote stem cell research. One core, the Echocardiography Core, allows analysis of mouse models of disease using sound waves (ultrasound). This technology allows following the development of the mouse over its lifetime. Another core, the Stem Cell Physiology Core, allows assessment of the health and normal function of neurons derived from embryonic stem cells that have been transplanted into a recipient mouse brain. The need for rigorous physiological characterization of neurons in brain models is critical for many projects studying disorders of the brain.

6 Strategic Plan/ Executive Summary

Stem Cell Research: Progress and Promise

Stem cell research has captured the attention of the general public and scientists alike because of its potential to transform the treatment of countless human diseases. If researchers can develop safe, reliable methods to turn stem cells into a source of replacement cells for diseased or damaged tissues, millions of people living with devastating diseases or injuries could benefit. Indeed, stem cell therapy is already in use for some cancer patients who receive bone marrow or umbilical cord blood transplants, as well as for burn victims treated with stem-cell-generated skin grafts.

Stem cells can be derived from a variety of sources, primarily embryonic and adult tissues. Human embryonic stem cells–which in theory could be directed to become any of the 200 or so cell types of the body, were first isolated and grown in a laboratory in 1998. This landmark research advance gave new hope to the possibility that currently incurable conditions, such as amyotrophic lateral sclerosis, type 1 diabetes, spinal cord injury, Parkinson's disease and many others, could be treated and possibly reversed with stem cell-based regenerative medicine. The ongoing discovery of stem cells in adult tissues, such as the liver, brain and fat, has provided another potential source of replacement cells, if researchers can find ways to harness their therapeutic potential. Notwithstanding the substantial progress made over the past decade, important challenges remain before the full potential of either embryonic or adult stem cell research is realized by individuals living with disease or injury. In parallel with scientific progress, stem cell research has raised important ethical, legal and social issues that call for an open dialogue within the research community and with the public. Specifically, the use of human embryos in stem cell research generates unique concerns that go beyond the general expectations of public accountability, respect for research participants and scientific integrity that are common to all biomedical research disciplines.

NYSTEM: New York State Investment in Stem Cell Research

As the location of many world-class biomedical research organizations, New York is well-positioned to be a leader in the field of stem cell research and policy. In 2007, New York joined a growing number of states that are investing public funds in the support of stem cell research. The 2007-2008 enacted budget created the Empire State Stem Cell Trust Fund with a commitment of $600 million in state funds over 11 years. In parallel, the Empire State Stem Cell Board (hereafter referred to as the "Board") was established and charged with making grants for basic, applied, translational and other research and development activities that will advance stem cell research in New York State. The Board functions through two standing committees. The Funding Committee oversees the solicitation, review and award of research grants supported by the Trust Fund. The Ethics Committee is responsible for making recommendations to the Funding Committee with respect to scientific, medical and ethical standards related to stem cell research in New York State. The Trust Fund is administered by the New York State Department of Health through the New York State Stem Cell Science/NYSTEM program under the direction of the Board.

A Strategic Framework for Stem Cell Research Support in New York State

This Strategic Plan sets forth the Board's vision for the use of the Trust Fund over the next five years. To maintain its ability to capitalize on breakthrough discoveries in the rapidly evolving stem cell research field, the Board views this Plan as a "living" document that will be re-assessed each year as a rolling five-year plan. The Board has defined five overarching categories to organize the goals and expenditures of the Trust Fund. Within this framework, a projected range of funding support has been allocated to each category (see table below). As the Board reviews progress and funding priorities each year, the target distribution of the Trust Fund will be re-evaluated to ensure that the NYSTEM program responds to progress in stem cell science and continues to support the overall mission of the Board.

For each category, the Board has formulated a mission statement to describe how expenditures in that category will contribute to the achievement of its overall mission. In addition, the Board has articulated specific goals to guide development of NYSTEM funding initiatives and other activities that will support the stem cell research enterprise in New York State.

Categories and Target Distribution of the Empire State Stem Cell Trust Fund

Category	Percent	Target Plan Expenditures (5-Year)
Research	65–80%	$195,000,000 – $240,000,000
Scientific Training	4–10%	$12,000,000 – $30,000,000
Infrastructure Development	10–15%	$30,000,000 – $45,000,000
Ethical, Legal and Social Issues, and Education	3–5%	$9,000,000 – $15,000,000
Administration	3–5%	$9,000,000 – $15,000,000
TOTAL	**100%**	**$300,000,000**

Research

Mission: Support innovative basic, translational and clinical research that builds on the potential of stem cells to detect, treat and cure human diseases.

The Board will invest the majority of the Trust Fund in the direct support of stem cell research and development. Research funds will be used for investigator-initiated projects that propose innovative directions in stem cell research, as well as targeted projects designed to capitalize on emerging opportunities. The goals of the program include understanding basic stem cell biology; deriving and characterizing new human pluripotent stem cell lines, including disease-specific lines; using those new lines to understand disease mechanisms and develop new therapeutic strategies; testing promising new therapies and diagnostic methods in preclinical models and early phase clinical trials; and developing mechanisms to support research collaboration within New York State and between New York researchers and their colleagues located elsewhere.

Scientific Training

Mission: Ensure a robust, interactive stem cell research community in New York State by providing training opportunities to support the entry of new and established investigators into stem cell research.

The Board will devote substantial, directed resources to training programs for stem cell scientists at all career stages including students

and fellows in training; newly independent investigators who are launching careers in stem cell research; and established investigators with expertise that could be applied to stem cell research. In addition, conferences and workshops will be developed to foster communication, collaboration and synergy within the New York State stem cell research community.

Infrastructure Development

Mission: Expand stem cell research capacity in New York State by establishing and ensuring access to appropriate infrastructure and resources.

The Board has allocated funds for institutions to develop infrastructure that will allow all interested New York State researchers access to critical resources for stem cell research. State-of-the-art facilities within institutions or at multi-institutional centers may be established to provide bioproduction or high-throughput screening capabilities, specialized equipment, technical support and other resources for cutting-edge stem cell research. Resources for administrative support and regulatory guidance will foster translation of basic discoveries into clinical applications.

Ethical, Legal and Social Issues and Education

Mission: Ensure that stem cell research in New York State adheres to the highest standards of medical ethics and that the ethical, legal and social implications of advances in stem cell research are appropriately addressed by engaging diverse communities in research, scholarship and education on these issues.

The Board recognizes the need to increase understanding of fundamental ethical, legal and social issues related to stem cell research. These issues will be addressed by open dialogue within and among the Ethics Committee and the Funding Committee of the Board, the public at large and other private and public agencies, including other state governments, with an interest in stem cell research policies. Funds will be used to support research and to engage diverse communities within New York State in ways that enhance understanding of stem cell research, the ethical, legal and social issues affecting this research field and the impact of this research on society.

Administration

Mission: Manage the Empire State Stem Cell Trust Fund under the highest standards of accountability and integrity on behalf of the people of New York State.

Administrative functions, such as instituting a rigorous peer review process, program development and evaluation and implementation of contract processes, will be carried out by the New York State Department of Health's Wadsworth Center in a manner that engenders public trust in the NYSTEM program. The Board is committed to ensuring public access to information regarding its activities and programs and to the outcomes of NYSTEM-funded research, training and development.

Benefits of Promoting Stem Cell Research in New York, Evaluation and Public Accountability

Mission: Ensure New York State preeminence in the application of knowledge derived from stem cell research for the greater public good and the generation of long-term support for stem cell research.

The evaluation of the NYSTEM program and ensuring public accountability are integral functions of this initiative. The Board is required to report annually to the public on its activities, grants awarded, grants in progress, research accomplishments and future directions. Moreover, the Board will develop intellectual property, technology transfer and fiscal policies to assure broad access to the results

of NYSTEM-funded research. Importantly, the economic and other benefits derived from the State's investment in stem cell research will be assessed at regular intervals to maximize support for funding stem cell science and to use state funds to leverage additional commitments to stem cell research in New York. These activities will enable the Board to make informed decisions about program priorities and directions and ensure that the promise of stem cell research is realized by and for the people of New York State.

7 Appendix 1: Public Health Law Article 2, Title 5-A

EMPIRE STATE STEM CELL BOARD

§ 265. Definition. As used or referred to in this title, unless a different meaning clearly appears from the context "stem cell" means stem or progenitor cells that divide and are capable of generating one or more different types of progeny. Stem cells and their progeny can potentially repair or replace specific tissues or be used to develop disease models.

§ 265-a. Empire state stem cell board. 1. The empire state stem cell board ("board"), comprised of a funding committee and an ethics committee, both of which shall be chaired by the commissioner, is hereby created within the department for the purpose of administering the empire state stem cell trust fund ("fund"), created pursuant to section ninety-nine-p of the state finance law. The board is hereby empowered, subject to annual appropriations and other funding authorized or made available, to make grants to basic, applied, translational or other research and development activities that will advance scientific discoveries in fields related to stem cell biology.

2. No grants made available in the fund from any source shall be directly or indirectly utilized for research involving human reproductive cloning.

3. Notwithstanding any other provision of law, the board shall have the authority to adopt by laws to govern its proceedings including but not limited to rules respecting quorums and the number of votes needed to require the award of grants. No grants may be awarded by the board prior to the establishment of bylaws that must include merit based peer review application guidelines. Such bylaws must be approved by the funding committee.

4. Grants may be made for one or more years, provided, however, that no grant shall be made for which the annual commitment is more than fifteen percent of the total funds available in any year. However, no single institution shall be awarded more than twenty-five percent of the total amount appropriated. This limitation shall be considered separately for each new

proposal without aggregating any prior year approvals that may fund research activities. This requirement shall be determinative, unless two-thirds of the funding committee approves a higher limit for a particular grantee.

5. The existence of the empire state stem cell board shall continue until there are no longer any assets or money available for distribution.

§ 265-b. Funding committee. 1. There shall be a funding committee which shall have thirteen members appointed by the governor, except for the commissioner who shall serve as an ex officio member. Six members shall be appointed directly by the governor; two shall be appointed on the nomination of the temporary president of the senate; two shall be appointed on the nomination of the speaker of the assembly; one shall be appointed on the nomination the senate minority leader and one shall be appointed on the nomination of the assembly minority leader. A member of the funding committee shall also serve on the ethics committee.

2. The funding committee shall perform the following functions:

(a) Provide for an independent scientific peer review committee composed of individuals with expertise in the field of biomedical research who shall review grant applications based on the criteria requirements and standards adopted by the funding committee, and make recommendations to the funding committee for the award of grants;

(b) develop criteria including an appropriate competitive scoring method, standards, and requirements for considering funding applications and for awarding research grants, including but not limited to recommendations for the overhead/indirect component of such grants for the development and submission of funding applications by New York state based consortia;

(c) recommend standards for the scientific and medical oversight of awards;

(d) solicit through requests for proposals and otherwise, and to accept proposals for research projects including grant applications;

(e) review grant applications based on the criteria, requirements, and standards adopted by the funding committee utilizing a process that gives due consideration to the amount of nonpublic funds contributed by the project sponsor, including cash, in-kind personnel, equipment or materials, donations, the opportunity to leverage funds, including federal, private and not-for-profit funds reasonably anticipated to be received by the project sponsors; provided, however, that nonpublic funds shall only be considered as a factor by the funding committee when reviewing applications of equivalent merit as determined by the independent scientific peer review committee;

(f) make recommendations to the commissioner for the award of research therapy development and clinical trial grants; and

(g) recommend standards for the evaluation of grantees to ensure that they comply with all applicable requirements, including, but not limited to, conducting peer group progress oversight reviews of grantees to ensure compliance with the terms of the award and report to the commissioner any recommendations or subsequent action. Such standards shall mandate periodic reporting by grantees.

3. With the exception of the ex officio member, the funding committee shall be divided into three classes. Of the three classes, the first class appointed shall include three of the governor's appointees, one appointee nominated by the temporary president of the senate, and one appointee nominated by the speaker of the assembly and shall serve for a term ending one year from the effective date of this title. The second class shall include two of the governor's appointees, one appointee nominated by the minority leader of the senate, and one appointee nominated by the minority leader of the assembly and shall serve for a term ending two years from the effective date of this title. The third class shall include the final governor's appointee, one appointee nominated by the temporary president of the senate, and one appointee nominated by the speaker of the assembly; and shall serve for a term ending three years from the effective date of this title. Subsequently, each member appointed shall serve a term of three years and no more than two terms of three years each. A vacancy in the membership of the board shall be filled for the unexpired portion of the term in the same manner as the original appointment.

§ 265-c. Ethics committee. 1. There shall be an ethics committee which shall have thirteen members appointed by the governor, except for the commissioner who shall serve as an ex officio member. Six members shall be appointed directly by the governor; two shall be appointed on the nomination of the temporary president of the senate; two shall be appointed on the nomination of the speaker of the assembly; one shall be appointed on the nomination of the senate minority leader; and one shall be appointed on the nomination of the assembly minority leader. A member of the ethics committee shall also serve on the funding committee.

2. The ethics committee shall make recommendations to the funding committee regarding:

(a) scientific, medical, and ethical standards;

(b) standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients, including, but not limited to standards for safe and ethical procedures for: obtaining materials and cells for research; clinical efforts for the appropriate treatment of human subjects in medical research; and ensuring compliance with patient privacy laws;

(c) oversight of funded research to ensure compliance with the standards described in paragraphs (a) and (b) of this subdivision; and

(d) relevant ethical and regulatory issues.

3. With the exception of the ex officio member, the ethics committee shall be divided into three classes. Of the three classes, the first class appointed shall include three of the governor's appointees, one appointee nominated by the temporary president of the senate, and one appointee nominated by the speaker of the assembly; and shall serve for a term ending one year from the effective date of this title. The second class shall include two of the governor's appointees, one appointee nominated by the minority leader of the senate, and one appointee nominated by the minority leader of the assembly; and shall serve for a term ending two years from the effective date of this title. The third class shall include the final governor's appointee, one appointee nominated by the temporary president of the senate, and one appointee nominated by the speaker of the assembly; and shall serve for a term ending three years

from the effective date of this title. Subsequently, each member appointed shall serve a term of three years and no more than two terms of three years each. A vacancy in the membership of the board shall be filled for the unexpired portion of the term in the same manner as the original appointment.

§ 265-d. Members. 1. The members of the funding and ethics committees shall serve without compensation, but shall be entitled to reimbursement for actual and necessary expenses incurred in the performance of their official duties. Such members, except as otherwise provided by law, may engage in private employment, or in a profession or business.

2. The provisions of section seventeen of the public officers law shall apply to members of the committees.

3. The provisions of article seven of the public officers law shall apply to meetings of the funding and ethics committees.

§ 265-e. Public and financial accountability standards. 1. Report. The board shall issue an annual report to the public, which sets forth its activities, grants awarded, grants in progress, research accomplishments, and future program directions. Each annual report shall include, but not be limited to the following:

(a) number and dollar amounts of research and facilities grants;

(b) grantees for the prior year;

(c) board's administrative expenses;

(d) summary of research findings, including promising new research areas; and

(e) strategic plan of the board.

2. Conflicts of interest. No employee of the board or member of the funding or ethics committees shall make, participate in making, or in any way attempt to use his or her position to influence a decision to approve or award a grant, loan, or contract to:

(a) his or her employer or relative, or any entity in which the employee, member of the board, or member of the advisory counsel or the relative of any such individual has a financial interest; or

(b) an organization in which such employee, member of the board, member of the advisory counsel, or any relative of any such individual is an officer, director or partner of such organization.

3. Patent royalties and license revenues. The board shall establish standards that require that all grants be subject to intellectual property agreements that establish the scope, if any, of the state's ownership or other financial interest in the commercialization and other benefits of the results, products, inventions and discoveries of state-funded stem cell research, and shall also include consideration in such agreement for amounts of funding from sources other than the state.

4. Contributions to the board. Notwithstanding any other provisions of the law to the contrary, the board is authorized to receive contributions from any governmental entity, for profit and not-for-profit corporation, association or person.

§ 235-f. Severability. If any clause, sentence, paragraph, section or part of this title shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section or part thereof, directly involved in the controversy in which such judgment shall have been rendered.

April 1, 2007

8 Appendix II: Bylaws of the Empire State Stem Cell Board

I. OFFICERS

1. The officers of the Empire State Stem Cell Board ("Board") shall be the Chair and Vice-Chair. The Chair shall be the Commissioner of Health or his or her designee. The Chair shall select a Board member to serve as Vice-Chair. The Vice-Chair shall serve for one year or until his or her successor has been selected.
2. The Chair may appoint a Board member to preside during the absence of the Chair and Vice-Chair from any meeting.

II. OFFICER DUTIES

1. The Chair shall be responsible for the general supervision of the work of the Board. The Chair shall represent the Board before the Governor, committees of the Legislature, or other public authorities, and may request any member or members to appear with him or her, or in his or her stead.
2. The Chair shall preside at meetings of the Funding Committee, the Ethics Committee, and the full Board.
3. The Vice-Chair, in the absence of the Chair or his or her designee, shall perform the duties of the Chair.

III. EXECUTIVE SECRETARY

1. The Board shall ask the Department of Health to designate a Department employee to serve as the Board's Executive Secretary ("Secretary").
2. The Secretary shall prepare and send official notices of actions of the Ethics Committee, the Funding Committee, and the full Board, and shall administer the daily business of the Board and its committees under the general direction of the Chair. The Secretary shall send a copy of the minutes of each meeting of the Board and its committees to each member of the respective body ten calendar days prior to the next meeting of such committee or Board. The minutes, as approved or corrected, shall serve as the official record of the meetings of the Board and its committees. The Secretary shall make approved minutes available to the public and provide access to records requested pursuant to the Freedom of Information Law. The Secretary shall make announcements to the media and public of scheduled meetings as required by the Open Meetings Law.

IV. OFFICE OF THE BOARD

1. The official headquarters of the Board shall be at the offices of the Department of Health, Albany, New York.
2. The Secretary shall be responsible for the safekeeping of all minutes, records, documents, correspondence and other items belonging to the Board and its committees at the official headquarters of the Board.
3. Every member of the Board and its committees shall have access during the ordinary office hours of the Department of Health to all such minutes, records, documents, correspondence and other items belonging to the Board and its committees. Members of the Board and its committees shall provide the Secretary with reasonable notice of any documents and other items to be accessed.
4. The Secretary shall designate a person to be in charge of all such minutes, records, documents, correspondence and other items belonging to the Board during his or her absence from the office.

V. MEETINGS OF THE BOARD

1. Meetings.

   The Chair of the Board may call a meeting of the full Board as frequently as deemed necessary to coordinate the activities of the Ethics Committee, Funding Committee and any other committees, or for any other purpose relating to stem cell research or the work of the Board.

2. Meeting Notification.

   The Secretary shall notify each Board member of Board meetings and shall send an agenda and related materials to his or her usual address not less than ten calendar days before the meeting.

3. Quorum.

   A majority (thirteen members) of the members of the full Board (twenty-four members) shall constitute a quorum for the transaction of any business or the exercise of any power or function of the Board and all matters requiring action shall be passed by a vote of a majority of the voting members of the full Board. For the purposes of these by-laws "full Board" shall mean the total number which the Board would have, as established in statute, were there no vacancies or disqualifications.

4. Open Meetings.

   All Board meetings shall be noticed and conducted in accordance with the requirements of Article 7 (Open Meetings Law) of the Public Officers Law. Such meetings shall be open to the public except when otherwise provided by law. Guidelines for observers shall be adopted by Board and shall apply to all Board and committee meetings.

5. Conduct of Meetings and Order of Business.

   Except as provided below, all meetings shall be conducted in accordance with Robert's Rules of Order Newly Revised, and a record of each vote shall be maintained. The normal method of voting shall be by roll call. A roll call vote on any question shall be taken by ayes and nays, abstentions noted, and a record of how each member voted entered in the Minutes. The order of business may be altered at the Chair's discretion or upon the request of a Board member.

VI. COMMITTEES OF THE BOARD

1. The primary work of the Board shall be performed by its two standing committees: the Funding Committee and the Ethics Committee.

   a. The Funding Committee shall be composed of thirteen members who shall be appointed in accordance with Title 5-A of Article 2 of the Public Health Law. The Commissioner of Health or his or her designee shall serve as the Chair of the Funding Committee. The Funding Committee shall be responsible for performing the following functions:

      1) provide for an independent scientific peer review panel composed of individuals with expertise in the field of biomedical research who shall review grant applications based on the criteria, requirements and standards adopted by the Funding Committee, and make recommendations to the Funding Committee for the award of grants;

      2) develop criteria, including an appropriate competitive scoring method, standards, and requirements for considering funding applications and for awarding research grants, including but not limited to, recommendations for the overhead/indirect component of such grants and for the development and submission of funding applications by New York State based consortia;

      3) recommend standards for the scientific and medical oversight of awards;

      4) solicit through requests for proposals and otherwise, and accept proposals for research projects, including grant applications;

      5) review grant applications based on the criteria, requirements, and standards adopted by the Funding Committee utilizing a process that gives due consideration to the amount of nonpublic funds contributed by the project sponsor, including cash, in-kind personnel, equipment or materials, donations, the opportunity to leverage funds, including federal, private and not-for-profit funds reasonably anticipated to be received by the project sponsors, provided, however, that nonpublic funds shall only be considered as a factor by the Funding Committee when reviewing applications of equivalent merit as determined by the independent scientific peer review panel;

      6) make recommendations to the Commissioner of Health for the award of grants from the Empire State Stem Cell Trust Fund for basic, applied, translational and other research, including clinical trials and therapy, and development activities that will advance scientific discoveries in the fields related to stem cell biology;

7) recommend standards for the evaluation of grantees to ensure that they comply with all applicable requirements, including, but not limited to, conducting peer group progress oversight reviews of grantees to ensure compliance with the terms of the award and report to the Commissioner any recommendations or subsequent action. Such standards shall mandate periodic reporting by grantees; and

8) ensure that the recommendations of the Funding Committee are consistent with the restrictions contained within Public Health Law Article 2, Title 5-A, including, but not limited to:

i. No grants shall be made available directly or indirectly for use in research involving human reproductive cloning;

ii. Unless two-thirds of the Funding Committee approves a higher limit for a particular grantee:

a. No grant shall be made for which the annual commitment is more than fifteen percent of the total funds available in any year;

b. No single institution shall be awarded more than twenty-five percent of the total amount appropriated, provided, however, that prior year approvals shall not be aggregated when applying such limitation.

b. The Ethics Committee shall be composed of thirteen members who shall be appointed in accordance with Title 5-A of Article 2 of the Public Health Law. The Commissioner of Health or his or her designee shall serve as the Chair of the Ethics Committee. The Ethics Committee shall be responsible for making recommendations to the Funding Committee regarding:

1) scientific, medical and ethical standards;

2) standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients, including, but not limited to standards for safe and ethical procedures for: obtaining materials and cells for research; clinical efforts for the appropriate treatment of human subjects in medical research; and ensuring compliance with patient privacy laws;

3) oversight of funded research to ensure compliance with the standards described in paragraphs (1) and (2) of this subdivision; and

4) relevant ethical and regulatory issues.

2. Ad Hoc Committees.

The Board may, at any time, appoint a special committee on any subject within the purview of the Board. Each such committee shall consist of one or more Board members and may include non-Board members. All such special committees not previously discharged by the Board shall be considered discharged one year following their appointment, unless the Board shall move to continue them. For the purposes of these by-laws, the Independent Scientific Peer Review Panel shall not be considered to be a “committee” of the Board.

3. Regular Meetings.

   The meetings of the Funding Committee, the Ethics Committee and any ad hoc committees shall be held as frequently as deemed necessary by the Chair to accomplish the work of such committees.

4. Meeting Notification.

   The Secretary shall notify each committee member of committee meetings and shall send an agenda and related materials to his or her usual address not less than ten calendar days before the meeting.

5. Quorum.

   a. A majority (seven members) of the members of the full Ethics Committee (thirteen members) shall constitute a quorum for the transaction of any business or the exercise of any power or function of the Ethics Committee and all matters requiring action shall be passed by a vote of a majority of the members of the full committee. For the purposes of these by-laws, "full committee" shall mean the total number which the committee would have, as established in statute, were there no vacancies or disqualifications.

   b. A majority (seven members) of the members of the full Funding Committee (thirteen members) shall constitute a quorum for the transaction of any business or the exercise of any power or function of the Funding Committee and all matters requiring action shall be passed by a vote of a majority of the members of the full committee. For the purposes of these by-laws, "full committee" shall mean the total number which the committee would have, as established in statute, were there no vacancies or disqualifications.

   c. A majority of the members appointed to any ad hoc committee shall constitute a quorum for the transaction of any business or the exercise of any power or function assigned to it by another committee or the full Board. All matters requiring action shall be passed by a vote of a majority of the members of the committee.

6. Open Meetings.

   All committee meetings shall be noticed and conducted in accordance with the requirements of Article 7 (Open Meetings Law) of the Public Officers Law. Such meetings shall be open to the public except when otherwise provided by law. Guidelines for observers adopted by the Board shall apply to all committee meetings.

7. Conduct of Meetings and Order of Business.

   Except as provided below, all committee meetings shall be conducted in accordance with Robert's Rules of Order Newly Revised, and a record of each vote shall be maintained. The normal method of voting shall be by roll call. A roll call vote on any question shall be taken by ayes and noes, abstentions noted, and a record of how each member voted entered in the Minutes. The order of business may be altered at the Chair's discretion or upon the request of a committee member. A portion of each committee meeting shall be set aside for the development of an agenda for the next committee meeting.

8. Committee Minutes and Reports.

   Minutes of the committee and any report should, in addition to reporting any recommendations of the majority of the committee, summarize any significant deliberations leading to such recommendations as well as opinions or recommendations of committee members who did not support the majority recommendations.

9. Absences.

   Any member who fails to attend three consecutive meetings of a committee shall, unless excused by a formal vote of the committee, be deemed to have vacated his or her position.

VII. INDEPENDENT SCIENTIFIC PEER REVIEW PANEL AND MERIT BASED PEER REVIEW APPLICATION GUIDELINES

1. Establishment of Independent Scientific Peer Review Panel.

   The Funding Committee shall provide for the establishment of one or more Independent Scientific Peer Review Panels (ISPRP) as needed to review applications submitted to the committee. An ISPRP shall be composed of individuals with expertise in biomedical research. Members of the ISPRP shall be individuals who have demonstrated scientific excellence through their own research and publications, are respected in the scientific community, have a breadth of expertise in biomedical research or expertise in an area relevant to the applications submitted, demonstrate an ability to perform reviews fairly, present ideas and comments clearly, and are willing to commit to performing the work required by the ISPRP. To reduce the potential for conflicts of interests by members of the ISPRP, members of the panel shall not live or work in New York State and shall provide sufficient information, in the time and manner prescribed by the convener of the panel, to enable the convener to identify any potential conflicts of interest.

2. Responsibilities of the Independent Scientific Peer Review Panel

   The ISPRP shall perform the following functions:

   a. review and rank applications based upon criteria, requirements and standards adopted by the Funding Committee for the specified requests for proposals or requests for applications; and

   b. make recommendations to the Funding Committee for the award of grants and contracts.

3. Merit Based Peer Review Guidelines

   The following guidelines shall be followed for the review of grant applications:

   each application shall be reviewed by at least two reviewers, at least one of whom shall be responsible for preparing a written evaluation of the application prior to the meeting of the ISPRP, using the criteria, requirements and standards established by the Funding Committee; applications shall be assigned to members of the ISPRP based upon their expertise and the absence of any conflicts of interest;

a. reviewers shall not review an application when:

1) the funding decision may benefit the reviewer, his or her employer, a relative, a close associate, or any organization in which the reviewer, relative or close associate is an officer, director or partner;

2) the reviewer has a professional relationship or a shared financial interest with another reviewer or the applicant; or

3) the reviewer is aware of any circumstances that could create the perception of a conflict of interest.

b. if a reviewer concludes that he or she should not review an assigned application because of an actual or potential conflict of interest, insufficient expertise to review the application, or any other reason, he or she should advise the convener of the panel or other designee of the Board of such incapacity immediately;

c. members of the ISPRP shall keep the contents of each application confidential and shall not misappropriate or plagiarize the intellectual property of the applicant;

d. members of the ISPRP shall keep the discussions of the review and merit of the application confidential and shall not discuss the review or communicate to investigators, their organizations, or any unauthorized person, the panel's deliberations and evaluations;

e. members of the ISPRP shall recuse themselves from any discussions when there is a real or apparent conflict of interest that would have precluded the member from reviewing the application initially; and

f. prior to making a recommendation to the Funding Committee, the reviewers shall discuss each application and its relative merits thoroughly within the ISPRP and prepare a summary of the discussion and its evaluation for the Funding Committee, provided, however, the ISPRP, consistent with the provisions of a specific request for applications, may establish procedures for a streamlined review of the submitted applications based upon the evaluations and scores of the initial reviewers identifying the weakest applications, which may remain undiscussed and unscored.

4. Notwithstanding the foregoing, under exceptional circumstances, when soliciting applications, the Funding Committee may decide that the goals of a particular request for applications, the specific types of activities to be funded, and the committee's established objective criteria and/or possible reliance on previous similar independent peer reviews, have rendered the review of applications by a Board-established ISPRP unnecessary.

VIII. CODE OF ETHICS AND CONFLICT OF INTEREST

1. Code of Ethics.

Members of the Board shall comply with Section 74 (Code of Ethics) and 78 of the Public Officers Law. No member of the Board should have any interest, financial or otherwise, direct or indirect, or engage in any business or transaction, or professional activity, or incur any obligation of any nature, which is in substantial conflict with the proper

discharge of his or her duties as a Board member. Members should exercise their duties and responsibilities as Board members in the public interest of the inhabitants of the State, regardless of their affiliation with, or relationship to, any institution, organization, facility, agency, program, activity, category of provider, or interest group. The principles that should guide the conduct of Board members include, but are not limited to, the following:

a. A Board member should endeavor to pursue a course of conduct that shall not raise suspicion among the public that he or she is likely to be engaged in acts that are in violation of his or her trust as a Board member.

b. No Board member should accept other employment which will impair his or her independence of judgment in the exercise of his or her duties as a Board member.

c. No Board member should disclose confidential information acquired by him or her in the course of his or her duties as a Board member, or by reason of his or her position as a Board member, nor use such information to further his or her personal interests.

d. No Board member should accept other employment or engage in any business or professional activity which will require him or her to disclose confidential information which he or she has gained by reason of his or her position as a Board member.

e. No Board member should use, or attempt to use, his or her position as a Board member to secure unwarranted privileges or exemptions for himself or herself or others.

f. No Board member should engage in any transaction as a representative or agent of the State with any business entity in which he or she has a direct or indirect financial interest that might reasonably tend to conflict with the proper discharge of his or her duties as a Board member.

g. A Board member should not make personal investments in enterprises which he or she has reason to believe may be directly involved in decisions to be made by him or her as a Board member or which shall otherwise create substantial conflict between his or her duty as a Board member to act in the public interest and his or her private interest.

h. A Board member should not by his or her conduct give reasonable basis for the impression that any person can improperly influence him or her or unduly enjoy his or her favor in the performance of his or her duties as a Board member, or that he or she is affected by the kinship, rank, position or influence of any party or person.

i. To preserve the public trust, Board members are prohibited during the tenure of their appointment from applying for, or receiving support from, the Board and the Empire State Stem Cell Trust Fund created pursuant to Title 5-A of Article 2 of the Public Health Law and section 99-p of the State Finance Law, or from having any role (other than routine professional and collegial interest in the success of their institution or department) in proposals submitted for consideration by, or in research or proposals supported by, the Board and the Empire State Stem Cell Trust Fund.

2. Conflict of Interest – Applications and other Pending Matters.

This section applies both to activities of the full Board and its committees.

a. Absolute Disqualifications.

1) No member of the Board or of a committee of the Board shall make, participate in making, or in any way attempt to use his or her position to influence a decision to approve or award a grant, loan or contract to:

i. His or her employer or relative, or any entity in which the member of the Board, or his or her relative, has a financial interest; or

ii. An organization in which such member of the Board, or his or her relative, is an officer, director or partner of such organization.

2) When a Board or committee member, or his or her family has an interest, financial or otherwise, whether as owner, officer, director, fiduciary, employee, colleague, consultant, or supplier of goods or services, in an entity, institution, organization, facility, agency or program (hereafter collectively referred to as "entity") whose application is before the Board or a committee of the Board for consideration or determination for a grant from the Empire State Stem Cell Trust Fund created pursuant to section 99-p of the State Finance Law, that member shall (i) identify such interest to the Board or committee at any meeting when the application or request is to be considered, (ii) absent himself or herself from any portion of any meeting when such application is considered, and (iii) not participate in any vote of the Board or committee on such application. For purposes of this Article, "family" shall include a spouse, children, sibling, and any relative living in the member's household.

b. Disclosure and Possible Disqualification.

When a Board or committee member, or his or her family member has (i) any of the above-noted interests in an entity the status of which might reasonably be affected by another entity whose grant application is before the Board or a committee of the Board, or (ii) when a member has any other interest or association which might reasonably be construed as tending to embarrass the Board or elicit public suspicion that he or she might be engaged in acts in violation of his or her trust as a Board member, the member shall disclose such interest or association at the time the application or other matter is formally considered by the Board or committee, so that the Chair and, if necessary, the Board or committee can then determine whether the member's participation in the discussion or the vote on the application by the Board or by the committee or on the other matter would be proper.

c. Procedure.

Prior to the discussion of a grant application, the Chair of the Board or committee shall request that Board members and committee members disclose all actual or potential conflicts and, when appropriate, explain the conflicts. In the case of conflicts constituting Absolute Disqualifications, the members with such conflicts shall immediately leave the meeting and remain absent during the period when the application is under consideration. In the case of conflicts constituting possible disqualifications, the Chair of the Board or committee shall rule upon such conflicts subject to appeal by motion to the Board or committee that may override the Chair's decision by the affirmative vote of a majority of those present, excluding those members who are the subject of the vote.

d. Disclosure of Committee Interests to Board Meetings.

When the Chair of any committee reports the committee's deliberations and recommendations on a matter to the Board, the committee Chair shall indicate in the report all interests or associations disclosed by the committee members and state how such members voted with respect to the committee's recommendations.

e. Additional Restrictions.

The following conflicts of interest rules shall also apply to Board members:

1) No member shall receive, directly or indirectly, or enter into any agreement express or implied, for compensation, in whatever form, for the appearance or rendition of services by himself or another against the interest of the Board in relation to any case, proceeding, application or other matter before, or the transaction of business by himself or another with, the court of claims.

2) No member of the Board shall accept any gift or gratuity of more than nominal value where the circumstances would permit the inference that the gift was intended to influence him or her as a member of the Board, or that the gift constituted a tip, reward, or sign of appreciation for any act performed as a member of the Board.

f. Annual Disclosure Statement.

Members of the Board shall comply with the provisions of Public Officer Law § 73-a concerning financial disclosures and shall provide the Secretary of the Board with a statement of employment and other interests in sufficient detail to help the Executive Secretary and Chair assess potential conflicts of interests of Board members regarding matters pending before the Board.

g. Violation of Provisions.

If any member knowingly and intentionally violates these provisions, the Board or its Chair shall refer the matter to the Commissioner of Health for appropriate action.

IX. BOARD REPORTS AND ACCOUNTABILITY

1. The Board shall issue an annual report to the public which sets forth its activities, grants awarded, grants in progress, research accomplishments, and future program directions. Each annual report shall include, but not be limited to, the following:

a. Number and dollar amounts or research and facilities grants;

b. Grantees for the prior year;

c. Board's administrative expenses;

d. Summary of research findings, including promising new research areas; and

e. Strategic plan of the Board.

2. The Board shall establish standards that require that all grants be subject to intellectual property agreements that establish the scope, if any, of the State's ownership or other financial interest in the commercialization and other benefits of the results, products, inventions and discoveries of state-funded stem cell research, and shall also include consideration in such agreement for amounts of funding from sources other than the State.

X. ADOPTION AND AMENDMENT OF BYLAWS

1. These bylaws shall be adopted by an affirmative vote of a majority of the members of the Board, provided, however, that the merit based peer review application guidelines shall be first be approved by an affirmative vote of a majority of the members of the Funding Committee.

2. These bylaws may be amended upon the affirmative vote of a majority of the members of the Board at any regular or special meeting, provided that a copy of the proposed amendment and notice of the proposed action has been sent by the Secretary to each member of the Board at least thirty days prior to the vote.

3. Notwithstanding the foregoing, the Funding Committee may amend the provisions of these bylaws establishing the merit based peer review application guidelines upon the affirmative vote of a majority of the members of the Funding Committee, at any regular or special meeting of such committee, provided that a copy of the proposed amendment and notice of the proposed action has been sent by the Secretary to each member of the Board at least thirty days prior to the vote.

Adopted October 22, 2007

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