

## Speaker Biographical Sketches

### ***Jason Adair, Director of Business Development, MedImmune, Inc.***

Mr. Jason Adair currently serves as Director of Business Development at MedImmune, the biologics arm of AstraZeneca Biopharmaceuticals, where he leads the biologics licensing efforts related to respiratory, inflammatory and autoimmune disease; cardiovascular and metabolic disease; biosuperiors; personalized healthcare; and major collaborations with universities and research institutes. Over the last 7 years, he has also served MedImmune as a product manager leading consumer marketing for Synagis and a corporate project manager leading product development teams. Prior to joining MedImmune, Jason was an analytical chemist at Novartis Crop Protection and started his career as an officer in the United States Army. He holds a master of business administration from the Tuck School of Business at Dartmouth College and a bachelor's degree in chemistry from Wake Forest University.

### ***Henry Ahn, MBA, Program Manager, Technology Funding Programs, Maryland Technology Development Corporation (TEDCO)***

Mr. Ahn manages a variety of funding programs for the Maryland Technology Development Corporation (TEDCO), including the Maryland Technology Transfer Fund, recognized by Entrepreneur Magazine as the nation's most active early stage investor. Prior to joining TEDCO, Mr. Ahn was a technology licensing associate at Upstate Biotechnology, Inc. (now a Merck company), where he was involved with various aspects of technology transfer and supplier relations with government and academic institutions around the world. Additionally, Mr. Ahn has a total of five years of research experience in the field of immunology (including graduate work), and he has been involved with several start-ups and other start-up activities in the Houston area. Mr. Ahn is involved with various organizations in the region, serving on a selection committee and/or acting as a coach/judge for Grubstake Breakfast, Early Stage East, University of Maryland Business Plan Competition, MidAtlantic Bio, and MoshPit, among others. Mr. Ahn is a member of the Licensing Executive Society.

Mr. Ahn has an M.B.A. from Rice University, an M.S. in biotechnology from the University of Tennessee, Knoxville, and a B.S. in biomedical engineering from Boston University.

### ***Michael Amey, Associate Dean Research Administration, Johns Hopkins University School of Medicine***

Michael Amey, Associate Dean Research Administration at the Johns Hopkins University School of Medicine, has been directing Research Administration there for 30 years. During his tenure, the School of Medicine's annual research budget has grown from \$90 million to \$700 million, including all federal non-profit and commercial sponsored funding. He has played an important role in a number of projects, such as the creation of the Center for Inherited Disease Research, Web-based compliance training, an access to financial information web project, and Institutional Review Board redevelopment. He also has directed research compliance systems planning, development of a clinical research management system and Lean Six Sigma revision of the clinical research process.

Amey joined the Department of Medicine in 1975 as Financial Manager for University Affairs, and in 1977, was promoted to Associate administrator for University Affairs. He became Director of Research Administration at the School of Medicine in 1980, Assistant Dean, in 1986, and Associate Dean in 2003.

He is also currently a member of Board of the Council for Government Relations (COGR), The Johns Hopkins Institutional Compliance Committee and the Johns Hopkins University Research Oversight Committee.

***Clara Asmail, Senior Technical Advisor, Manufacturing Extension Partnership, National Institute of Standards and Technology***

Clara Asmail joined the Manufacturing Extension Partnership (MEP) at the National Institute of Standards and Technology (NIST) as Senior Technical Advisor in July 2010 where she is responsible for developing approaches to provide small R&D and manufacturing businesses with the services and access to resources that can help them grow and improve their productivity. She works closely with federal SBIR programs and their awardees to cultivate partnerships with the MEP network in order to enhance the commercialization of SBIR research results. Prior to this, Clara managed the NIST SBIR Program since 2001. She was also responsible for marketing NIST technologies. In those roles she proposed, designed and implemented an innovative NIST-wide Technology Transfer program facilitating the transfer of federal technology to industry by leveraging the SBIR Program for seed funding along with access to federal research assets. This SBIR TT approach is currently being implemented and/or considered by several other agencies. As a CRADA and Licensing Officer at NIST from 1998 to 2002, Clara executed several licenses, more than 50 CRADAs and conducted more than 30 commercialization assessments on inventions disclosed from the NIST Labs.

Previously, Clara was Project Leader for Optical Scatterometry research in the Physics Laboratory in NIST. There she published 19 peer reviewed articles and established BRDF competency at NIST. She was actively involved in standards committees work in her area of research, cooperating with Sematech, ASTM, ISO and other federal agencies.

Clara holds two M.S. degrees, one in Optical Sciences from the University of Arizona and the other in Physics from Tulane University, and a B.S. in Physics from Fordham University.

***Lawrence Boerboom, PhD, Chief, Cardiovascular and Respiratory Sciences Integrated Review Group, Center for Scientific Review, NIH***

Dr. Lawrence Boerboom is Chief of the Cardiovascular and Respiratory Sciences Integrated Review Group within the Center for Scientific Review. He also serves as the Scientific Review Officer for the Cardiovascular Sciences Small Business Study Section. After receiving his Ph.D. in physiology, Dr. Boerboom served a postdoctoral fellowship at the Cardiovascular Research Institute of the University of California, San Francisco. He then joined the faculty of the Medical College of Wisconsin, holding a primary appointment in cardiothoracic surgery, a secondary appointment in physiology and also serving as director of Cardiovascular Surgical Research. His research focused on factors influencing myocardial blood flow, cardiac function and vascular bypass graft atherosclerosis. After 20 years in this position, he went to LifeCell Corporation to serve as director of research, where he led a team focused on developing tissue-engineered medical devices. Dr. Boerboom joined the NIH in 2004.

***Michael Borenstein, PhD, Biostat***

Michael Borenstein earned his doctorate at New York University in 1980. From 1980 to 2000 he served as Director of Biostatistics at Long Island Jewish Medical Center, while working part-time as Director of Biostat, Inc., a company that develops statistical software for medical and social science research.

In 2000 Dr. Borenstein left the hospital to work full-time at Biostat. In that position he has served as PI on a series of SBIR grants that were funded by NIMH, NIA, and NIDA. These grants were used to develop programs for power-analysis and for meta-analysis. These programs have become the best-selling programs in their respective fields, currently used by more than 50,000 researchers around the world.

Dr. Borenstein teaches courses on meta-analysis and power analysis, and frequently presents workshops on these topics at conferences and universities, as well as organizations such as the NIH, FDA, and CDC.

***Robert Brooke, Director, Federal Funding Programs, Center for Innovative Technology (CIT)***

Robert Brooke is responsible for the development and statewide outreach coordination of CIT's Federal Funding Assistance Program in the Commonwealth of Virginia. Mr. Brooke has developed a comprehensive suite of training and mentoring programs designed to assist firms at each stage of the SBIR process and has created special workshops to meet the growing needs of Virginia's firms.

With CIT since 2001, Mr. Brooke has worked closely with small technology firms for more than 17 years. Prior to CIT, he was the Marketing Manager for a unit of L-3 Communications in Reston, Virginia. Prior to that, he worked as the Marketing Program Manager for The ASCII Group, Inc., a national consortium of independent computer resellers, VARs and integrators. While in that capacity, Mr. Brooke coordinated the development of partnership programs, services and training that assisted the competitive business efforts of 1,500-plus small- and medium-sized technology companies.

Mr. Brooke earned a B.S. in Marketing Management at Virginia Polytechnic Institute and State University.

***Patricia A. Brown, V.M.D., M.S., Diplomate ACLAM, Director, Office of Laboratory Animal Welfare, NIH***

Dr. Pat Brown currently serves as the Director, Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH). OLAW oversees the use of animals in NIH-supported biomedical and behavioral research by providing guidance and interpretation of the *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy); monitoring compliance with the PHS Policy; evaluating all allegations or indications of noncompliance with Federal animal welfare requirements; and supporting educational programs that further the humane care and use of research animal subjects. She received her Bachelor of Science degree in Animal Science from the Pennsylvania State University and her veterinary degree from the University of Pennsylvania. She served in the U.S. Air Force for eight years and while on active duty earned a Master of Science degree in Laboratory Animal Medicine from the M.S. Hershey Medical Center, Pennsylvania State University, Hershey, PA. She joined the NIH in 1986 and served in clinical and management positions in the Veterinary Resources Branch, the National Cancer Institute and the Office of Animal Care and Use before joining OLAW in 2006 as the Director.

***Ronald Brown, PhD, Director, Research and Development, Quality Biological, Inc.***

Dr. Ronald L. Brown received his Ph.D. from The University of Texas, M. D. Anderson Cancer Center, Houston, Texas. He presently is Director of Research and Development at Quality Biological, Inc. and is involved in the development of reagents and culture conditions for hematopoietic stem cell proliferation and differentiation. He has successfully written several SBIR grants in this area as well as acted as a reviewer on SBIR Study Sections. Using the SBIR program he has successfully developed, patented and brought to the global marketplace serum-free reagents for the expansion/differentiation of hematopoietic stem cells.

***John Burke, Assistant Grants Compliance Officer, Office of Policy for Extramural Research Administration, NIH***

John Burke has been an Assistant Grants Compliance Officer in NIH's Division of Grants Compliance and Oversight in the Office of Policy for Extramural Research Administration (OPERA) since 2007. Mr. Burke has over 15 years of government experience at both the Federal and State levels, including grants management for Substance Abuse and Mental Health Services Administration (SAMHSA), the US Department of Justice, and the State of California Administrative Office of the Courts where he was responsible for the management of all problem-solving court (drug courts, domestic violence courts, homeless courts, etc.) grant funding. He also has extensive private sector experience, including corporate logistics and distribution management for The GAP Cardservice International, and Manhattan Bagel. Mr. Burke holds a Master's Degree in Administrative Management / Public Administration from the University of Maryland and a Bachelor's Degree in Advertising from San Jose State University.

***Carole Carey, Director of International Staff, Center for Devices and Radiological Health, FDA***

Carole C. Carey is the Director of International Staff, Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), Center for Devices and Radiological Health (CDRH), US FDA. Ms. Carey began her career in the FDA Medical Device Program as a scientific reviewer in the Division of Cardiovascular Devices and subsequently attained the status of Expert Regulatory Scientist. In 2003-2005 she served as a Mansfield Fellow and trained with regulatory counterparts in Japan's Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceutical and Medical Devices Agency (PMDA). In her current role as international advisor, she provides technical support and regulatory training related to medical device regulatory matters to foreign government officials, international organizations, industry, and academic institutions. Ms. Carey also coordinates global harmonization efforts and international collaborative programs. Prior to FDA, Ms. Carey worked in R&D at W.R. Grace Research and in an energy and environmental consulting firm with government contracts. Ms. Carey earned her Bachelors degree in Electrical Engineering at Johns Hopkins University and a Masters degree in Engineering at Loyola College in Baltimore, MD. She is a Senior Member of IEEE (Institute of Electrical and Electronics Engineers) and Standards Committee of IEEE Engineering in Medicine and Biology Society.

***Lydia Carson, Vice President of Licensing, Eureka! Ranch International***

Lydia Carson serves as Vice President of Licensing for Eureka! Ranch International. Eureka! Ranch helps companies large and small accelerate profitable growth.

She is also Founder, President, and CEO of Balm Innovations, LLC, a University of Arkansas for Medical Sciences (UAMS) Arkansas BioVentures firm. Lydia established Balm Innovations in 2004 to commercialize Omnibalm<sup>®</sup>, a topical cream for skin irritations developed by a UAMS pharmaceutical researcher.

From 2001 through 2007, Lydia served as Vice President Industry of the Arkansas Science & Technology Authority and as Director of Arkansas Manufacturing Solutions (AMS). AMS is one of 60 Manufacturing Extension Partnership (MEP) centers funded in part through the U.S. Department of Commerce.

Prior to becoming Director, Lydia was an AMS Field Engineer, providing management and technical consulting services to Arkansas' manufacturers. She has also held engineering and leadership roles at Lexmark International and Ford Motor Company, North American Design.

Lydia graduated from Vanderbilt University with a Bachelor of Engineering in Mechanical Engineering and earned an MBA through the University of Arkansas at Little Rock Executive MBA program. She also holds a Vanderbilt Executive Development Institute Certificate from the Owen Graduate School of Management and has obtained numerous other certifications, including Six Sigma Black Belt and ISO 9000 Lead Auditor.

The U.S. Secretary of Commerce appointed Lydia to serve on the Arkansas District Export Council (DEC), and she was appointed to the MEP National Advisory Board, on which she served as Vice Chair through August 2010. She serves on the American Society of Mechanical Engineers (ASME) Innovation Committee and the board of the Arkansas State Chamber of Commerce as Chair of the Arkansas Small Business Council. Lydia is also a board member for the Central Arkansas Chapter of the National Association of Women Business Owners (NAWBO).

Lydia is an active member of the American Society for Quality (ASQ) and Arkansas Economic Developers. She participated in the inaugural class of Leadership Arkansas and was selected to *Arkansas Business 40 under 40*.

***Jack Chirikjian, PhD, Founder & Chairman, Edvotek, Inc.***

Dr. Chirikjian is a member of the Department of Biochemistry and Molecular Biology and the Founding Director of the M.S. program in Biotechnology that has graduated over 300 students from Georgetown. He has mentored and graduated many PhD students who pursued various careers in academics, industry and government. He organized the curriculum for the M.S. Biotechnology program at Georgetown that was shared with several other Universities ([www.biotechnology.georgetown.edu](http://www.biotechnology.georgetown.edu)). He also organized and offered summer 5-week courses for high school life science teachers on the basics of biochemistry and molecular biology.

Being trained as a science teacher and having taught in high school, he was aware of the many issues that deal with safety, cost and resources that are often barely sufficient to teachers for laboratory activities. His solution was to found Edvotek ([www.edvotek.com](http://www.edvotek.com)) to serve as the bridge between research and classroom education. He is also a founder of BRL/Life Technologies, Oncor and Trevigen. Life Technology and Oncor went public in 1986, while Trevigen and Edvotek are privately held Maryland companies.

Dr. Chirikjian earned a BA and MA in science education from the College of New Jersey, a MS and PhD in biochemistry from Rutgers University, and a PD in biochemistry/molecular biology from Princeton University.

***Melissa E. DeRosier, PhD, Founder & President, 3-C Institute for Social Development***

Dr. DeRosier is the Founder and President of the 3-C Institute for Social Development in Cary, NC. 3-C is a research and development company devoted to the promotion of social, emotional, and mental health on a broad scale. Schools and community agencies across the U.S. and abroad are currently using 3-C's research-based health promotion products with tens of thousands of children. 3-C also offers a wide range of web-based technologies to support the efforts of researchers and health-care providers, including online educational and training resources, networking and collaboration tools, and research implementation tools. 3-C ISD was recently awarded the *2011 Tibbett's Award* from the Small Business Association which recognizes small businesses that exemplify the mission and objectives of the SBIR program

Dr. DeRosier obtained her Master's degree in Child Developmental Psychology from the University of Virginia and received her Doctoral degree in Clinical Psychology from the University of North Carolina at Chapel Hill (UNC-CH). She completed her post-doctoral training in mental health services and systems research jointly through UNC-CH and the Duke University Medical Center. Dr. DeRosier is a licensed psychologist and health services provider specializing in the assessment and treatment of children and adolescents. More information can be found at [www.3CISD.com](http://www.3CISD.com).

***Connie Dresser, RDPH, LN, National Cancer Institute, NIH***

Ms. Dresser was the Director of the National Cancer Institute's Multimedia Technology Health Communication SBIR/STTR Grants Program for 16 years until the SBIR Development Center was formed in the Office of the NCI Director in 2008. Her program promoted science-based, theory driven, user-centered cancer communication research and the development of ehealth products across the cancer continuum. The program has produced five "Linking Science and Business SBIR Showcases" of award winning products and an up-to-date informative web site for new and experienced applicants. She is a recognized catalyst who has moved ehealth research forward.

***Lenka Fedorkova, PhD, SBIR/STTR Assistant Program Manager, NIH***

Dr. Fedorkova currently serves as the Assistant Program Manager for the SBIR/ STTR programs at the NIH. She has numerous responsibilities centered on providing resources and access to critical information to small business communities interested in obtaining Federal funding and manages NIH's commercialization assistance programs. Lenka has a long-standing interest in the biomedical innovation

enterprise and over the years worked to develop and expand her knowledge of core issues that small businesses face. Prior to joining the SBIR/STTR office, she was a congressional liaison in the NIH Office of Legislative Policy and Analysis for three years, most notably overseeing intellectual property, commercialization and small business innovation (SBIR/STTR programs) matters, and provided strategic intelligence and advice to NIH leadership.

Lenka was awarded the prestigious AAAS Science and Technology Policy Fellowship and worked in the NIH Office of Technology Transfer on international TT capacity building, R&D partnerships and negotiating license agreements. She also served as biotechnology special adviser to the Center for Strategic and International Studies, a think tank working with Central and Eastern European emerging economies. Before joining the NIH, she served at the American Association for the Advancement of Science (AAAS) as Program Director for Outreach and Marketing for the *Science Careers* division at AAAS. Lenka holds a doctorate from the Kent State University in neuroscience with a specialty in sleep research and plasticity of the mammalian biological clock.

***Steven M. Ferguson, CLP, Deputy Director, Licensing and Entrepreneurship,  
Office of Technology Transfer, NIH***

Steven M. Ferguson currently serves as a Deputy Director and senior licensing professional for the NIH Office of Technology Transfer, the patent & licensing office for technologies arising from the NIH and FDA research programs.

A former chemist at the National Cancer Institute, Mr. Ferguson holds Master's Degrees in Business Administration (George Washington University) and Chemistry (University of Cincinnati) as well as Bachelor's Degree in Chemistry (Case Western Reserve University).

A registered Patent Agent and a Certified Licensing Professional (CLP), Mr. Ferguson is the licensing instructor for both the USDA Graduate School and four NIH Foundation for Advanced Education in the Sciences (FAES) Graduate School courses on Technology Transfer and Biomedical Business Development, where he also serves as Technology Transfer Department Chair. Mr. Ferguson has published numerous articles on licensing and technology transfer and was also the Susan T. and Charles E. Harris Visiting Lecturer at the Watson School of Biological Sciences at the Cold Spring Harbor Laboratory.

He has received the AUTM President's Award, the NIH Director's Award, an FAES Instruction Award and twelve NIH Merit Awards in recognition of his service and activities in the area of technology transfer.

***Barbara Howard, MD, President, Total Child Health, Inc.***

Dr. Barbara Howard is Assistant Professor of Pediatrics at The Johns Hopkins University School of Medicine and co-creator of CHADIS. She is President of Total Child Health, distributor of CHADIS ([www.CHADIS.com](http://www.CHADIS.com)), a web-based system delivering previsit screening and diagnostic questionnaires linked to decision support and resources. After studying animal behavior at Cornell University, she received her MD from Johns Hopkins and completed pediatric residency training at Children's Hospital Medical Center in Boston. She had fellowship training at Harvard in Child Development and has been

faculty for residency training in developmental-behavioral pediatrics at Johns Hopkins, Sinai Hospital, University of Massachusetts Medical Center and Duke before returning to Baltimore. She co-founded the Center for Promotion of Child Development through Primary Care in 1996 with its clinical laboratory for research in applications to primary care. Dr. Howard is past president of the international Society for Developmental and Behavioral Pediatrics. She has served the American Academy of Pediatrics on the local and national level including on the Task Force on Mental Health and is a regular speaker at meetings around the country. Dr. Howard and the Total Child Health team have been awarded 5 SBIR grants for innovations in child health care projects.

***J.P. KIM, J.D., M.B.A., M.Sc., M.A.L.S, Director, Division of Extramural Inventions & Technology Resources, Office of Policy for Extramural Research Administration, NIH***

J.P. serves as Director & Policy Officer of the Division of Extramural Inventions & Technology Resources under the Office of Policy for Extramural Research Administration (OPERA) within the NIH Office of Extramural Research (OER), focusing on providing expert policy guidance and support to the extramural community on invention reporting, material and data resource sharing, and associated intellectual property (IP) matters. J.P. comes to OPERA with years of experience working with the extramural community and an extensive background in technology transfer and intellectual property. Prior to joining OPERA, J.P. worked for 10 years in the Office of Technology Transfer (OTT) under the NIH Office of Intramural Research (OIR), where he worked as a technology licensing specialist & patent advisor to market and further advance NIH inventions into commercial products. His past experience also includes over 10 years in the private sector at intellectual property law firms prior to coming to the NIH, which included work on domestic and international patent and trademark prosecution, litigation, and related work with the U.S. International Trade Commission (USITC). In addition to his IP work experience, J.P. also has academic research experience as a cancer researcher at the George Washington University School of Medicine and the Health Sciences, as well as commercial research experience at several biotechnology firms. J.P. has attended Georgetown University, American University, George Washington University, and Johns Hopkins University, where he earned degrees in the areas of law, international business, international marketing, biotechnology, zoology, chemistry, psychology, liberal studies, and social/public policy, as well as additional graduate work in genetics, international trade, international law, and European Union law. He is a registered U.S. Patent Attorney and is admitted to the Maryland courts and numerous Federal Courts, including the U.S. Court of International Trade, the Court of Appeals for the Federal Circuit, and the U.S. Supreme Court.

***Lisa M. Kurek, Managing Partner, Biotechnology Business Consultants***

Lisa is Managing Partner of Biotechnology Business Consultants (BBC) based in Ann Arbor Michigan. Lisa joined BBC as a partner in 1997 when its founder, Marilyn (Mickey) Katz-Pek, decided it was time to grow from a one person consulting practice to a two person consulting practice. In the ensuing years, BBC has expanded to a team of five full time consultants, recruited a stellar “bench” of ad hoc consulting partners and established a national reputation for assisting life science researchers and entrepreneurs. BBC works with universities, economic developers, large and small companies. The firms two primary areas of focus are in assisting university researchers and technology companies in securing NIH and other federal funding, and with commercialization and business planning for early stage life science companies.

In addition to overseeing all aspects of client relations at BBC, Lisa is nationally recognized as a trainer in grant-writing and commercialization for researchers and entrepreneurs. Her experience includes R&D and product development, sales and marketing, and business development and executive management. Trained in bioengineering, Lisa began her career at Baxter in Round Lake Illinois developing medical devices. She then moved to Boston and spent 13 years with Millipore Corporation where she morphed from an engineer into a sales and marketing person. It was during her tenure at Millipore that she relocated from the Boston area to Michigan. She has been involved with several early-stage entrepreneurial companies. She was Vice President of Sales and Marketing at BioImage, a biotechnology tools company, and held interim management positions at both Accumed Systems, a medical device company, and Thromgen, a developer of biopharmaceuticals.

Lisa earned two degrees in Biomedical Engineering, a Bachelor's from Brown University and a Masters degree from the University of Michigan.

***Renu Lal, PhD, Center for Drug Evaluation and Research***

Renu Lal joined the Food and Drug Administration in October 2002, where she has worked for the Division of Drug Information (DDI) in CDER's Office of Communications. In DDI, Renu is also part of the Small Business Assistance Program. She is responsible for answering questions from the public regarding a wide range of topics, from drug safety to drug development. She also is active in maintaining and developing the Small Business Assistance Program, along with increasing its visibility.

In addition to her time at FDA, Renu has spent time in industry, retail pharmacy, and hospital pharmacy.

Renu received her Doctor of Pharmacy from the Medical University of South Carolina, and her Bachelor's degree in Pharmacy from the University of Connecticut.

***John Lonsdale, PhD, Director of Research, National Disease Research Interchange***

Based in Philadelphia, John T. Lonsdale, Ph.D., is Research Director at NDRI (the National Disease Research Interchange), the leading NIH-funded provider of human tissues for research in the USA. NDRI provides a wide variety of high quality human tissues from normal donors, and those with common and rare diseases, to academic investigators, as well as those in the pharmaceutical and biotechnology industries. John joined NDRI after working as a drug discovery consultant providing R&D expertise to biotechnology and venture capital companies in the United States and Switzerland. He served as Director of Anti-Infectives Research in the Microbial, Musculoskeletal and Proliferative Diseases Center of Excellence in Drug Discovery at GlaxoSmithKline, where he directed the Center's Biochemistry Department and also gained an international reputation for drug discovery research in the search for new treatments for tuberculosis, through various NIH-funded initiatives. John played a major role in the transfer of Microbiology Research from the UK to the USA, helping to establish the business links necessary to succeed in a transnational R&D infrastructure. He holds a double Honors B.Sc. degree in Microbiology and Biochemistry, and a Ph.D. in Microbial Biochemistry, both from the University of Newcastle upon Tyne, UK.

***Carson R. Loomis, PhD, Program Director, National Human Genome Research Institute, NIH***

Carson R. Loomis has served as a Program Director in the National Human Genome Research Institute (NHGRI) since May 2005. Dr. Loomis is co-lead with Dr. Linda Brady in the program management of the NIH Common Fund Molecular Libraries Program (MLP). This Program provides a nationwide scientific resource for discovery of small molecule probes to explore the functions of genes and signaling pathways in health and disease, and to facilitate development of new therapeutics.

Dr. Loomis has over 30 years experience in both academia and the pharmaceutical industry. Before joining NIH, He was a founder and Vice President of Research of three successful startup companies. His last company, Norak Biosciences, developed proprietary imaging technology to study G protein-coupled receptors. The company's technology was sold to Molecular Devices Inc. in 2005. Dr. Loomis holds a Ph.D. in Biochemistry from Boston University Medical School and did his postdoctoral training at Duke University.

***John McKew, PhD, Branch Chief, Therapeutics for Rare and Neglected Diseases, Center for Translational Therapeutics***

Dr. McKew has been Branch Chief of the Therapeutics for Rare and Neglected Diseases program (TRND) program and is Director of Chemistry for the NIH Center for Translational Therapeutics (NCTT) since October, 2010. Prior to joining the NIH, Dr. McKew held a Director level position at Wyeth Research and began his career at Genetics Institute in Cambridge, Massachusetts where he spent a total of 17 years. At Wyeth he led a hit-to lead chemistry group supporting cardiovascular, musculoskeletal and metabolic diseases therapeutic areas. Prior to that Dr. McKew spent 10 years working in the inflammation therapeutic area resulting in multiple compounds entering clinical evaluation. Dr. McKew graduated from State University of New York at Stony Brook with degrees in Chemistry and Biochemistry. He completed his Ph.D. in Organic Chemistry at University of California, Davis and held post-doctoral research positions at the University of Geneva and Firmenich, SA. He is the immediate past chair of the Northeastern Section of the American Chemical Society and an Adjunct Associate Professor at Boston University School of Medicine, Department of Pharmacology and Experimental Therapeutics.

***Robbie Melton, Director, Entrepreneurial Innovation, Maryland Technology Development Corporation***

Ms. Melton is the Director, Entrepreneurial Innovation for the Maryland Technology Development Corporation (TEDCO). Ms. Melton manages the Rural Business Innovation Initiative that provides intensive business assistance to technology based companies in the rural regions of Maryland. She oversees the Incubator Business Assistance program and she serves on three incubator advisory boards. She manages the Working Capital Loan fund and is portfolio manager for 35 companies, Prior to her appointment, she served as Assistant Director of the Investment Financing Group of the Maryland Department of Business and Economic Development. Her career includes positions at the Maryland Industrial Partnerships program, the Center for Cancer & Transplantation Biology at Children's National Medical Center, the University of Hawaii, the National Science Foundation and the National Oceanic and Atmospheric Administration. She has over 20 years experience in managing technology development and commercialization projects, and 15 years working with early stage technology companies.

Ms. Melton is co-founder and past chairwoman and president of Women In Bio, a non-profit organization dedicated to helping women in life sciences industry create and build successful companies

and advance in their careers. In March 2010 the Robbie Melton Women In Bio Scholarship Fund was created to support students and entrepreneurs.

Ms. Melton holds a master's degree in Science, Technology and Public Policy from The George Washington University; and a bachelor's degree from Drake University in economics.

***Gregory Milman, PhD, Director, Office of Innovation & Special Programs, National Institute of Allergy and Infectious Diseases, NIH***

Gregory Milman, Ph.D., is Director of the Office for Innovation and Special Programs in the National Institute of Allergy and Infectious Diseases (NIAID). He manages the \$100 million NIAID small business programs and is acclaimed for his advice on NIH grant preparation and research funding.

Dr. Milman was Assistant Professor of Biochemistry at the University of California, Berkeley from 1970-1976, Associate Professor of Biochemistry and Immunology at Johns Hopkins University from 1976-1988, and visiting Professor in Honors at the University of Maryland College Park from 1997-2000. In 1985, he obtained NIH SBIR funding to start a biotechnology company focusing on viral diagnostics. From 1988-1999, Dr. Milman managed the NIAID \$70 million basic AIDS research program. He established the NIH Centers for AIDS Research (CFARs) and the NIH AIDS Reagent Program. From 1997 to 2000, Dr. Milman organized the NIH Bioengineering Consortium (BECON) and acted as its first Executive Secretary. In 2000, Dr. Milman was on the NIH staff in President Clinton's White House Office of Science Policy.

Dr. Milman has served on the Board of Directors of the Biotechnology Industry Organization Council of Biotechnology Centers, the Maryland Governor's Commission on the Development of Advanced Technology Business, and the Advisory Board for the National Institute of Science and Technology (NIST) Advanced Technology Program (ATP).

***Isai Peimer, Principal, MedImmune Ventures***

Isai Peimer is a Principal in MedImmune Ventures. He worked as a venture capitalist at Visium Asset Management, a large healthcare focused fund based in New York. Previously, Isai worked at JPMorgan Investment Bank and AllianceBernstein. Prior to Wall St., Isai was a management consultant and focused on corporate strategy for pharmaceutical and biotech sectors. Isai's career began at Merck & Co, Inc. Isai serves on the boards of Ambit Biosciences, Braincells, Corridor Pharmaceuticals, Inotek Pharmaceuticals, Synovex, and Xencor.

Isai is a graduate of Emory University where he earned a B.S. in Chemistry summa cum laude, and earned his M.B.A. from the Tuck School of Business at Dartmouth.

***Matthew Portnoy, PhD, SBIR/STTR Program Coordinator, NIH***

Dr. Matt Portnoy received his B.S. in molecular and cell biology from Penn State University. He received his Ph.D. in biochemistry and molecular biology from Johns Hopkins University School of Public Health. His graduate work focused on iron and copper metabolism in baker's yeast. Dr. Portnoy then joined the intramural program of National Human Genome Research Institute as a post-doctoral fellow in the

laboratory of Dr. Eric Green (current NHGRI Director). While at NHGRI, he conducted computational and bioinformatics research studying the evolution of vertebrate genomes and the consequences and regulatory implications of non-coding conserved DNA sequences. Dr. Portnoy made the leap to the extramural side of NIH in 2005 and joined the National Institute of General Medical Sciences as a program director. Over his time at NIGMS, he managed R01 grant portfolios in DNA repair, recombination and replication, SBIR/STTR grants, F32 post-doctoral fellowships, cooperative agreements, R25 education grants, and served as alternate project officer for the NIGMS Human Genetic Cell Repository contract at the Coriell Institute. Dr. Portnoy also served as SBIR/STTR lead for NIGMS for nearly 6 years. In 2011, he joined the Office of Extramural Research as Director, Division of Special Programs, OEP, OER and NIH SBIR/STTR Program Coordinator.

***Bruce Pratt, PhD, Former Vice President, Science Development, Genzyme Corp.***

*Dr. Bruce Pratt was most recently VP, Science Development for Genzyme Corporation, with responsibilities in the identification and evaluation of early stage therapeutic opportunities and proactive, selective outreach activities to the academic, biotechnology, and life science sectors. He worked for Genzyme for 22 years, initially in positions of increasing responsibility in Cell & Protein Therapeutics Research & Development, culminating as Sr. Director of Cell Biology. From 2002 through 2004, he was based in one of Genzyme's European offices, identifying early stage European research and product opportunities as well as developing relationships with biotechnology companies and academic centers of excellence. Following his return to the United States in July 2004, he continued his role in early stage opportunity identification and outreach to the biotechnology sector. He is currently engaged in consulting activities with early stage biotechnology companies on partnering and alliance strategies.*

*Prior to his work at Genzyme, Dr. Pratt worked at Collagen Corporation and Celtrix Pharmaceuticals in Palo Alto California. He earned his Ph.D. from Michigan State University and was a post-doctoral fellow at Yale University School of Medicine, Department of Pathology.*

***Rajesh Ranganathan, PhD, Senior Advisor to NIH Director for Translational Medicine***

Dr. Rajesh Ranganathan is the Senior Advisor to the NIH Director for Translational Medicine. He joined the NIH in November 2010 after spending 7+ years at the Novartis Institutes for BioMedical Research Inc. where he was a Director in the scientific strategy and portfolio management group and also founded and led the Global Office of Scientific Education for the Institutes. Dr. Ranganathan received his bachelor's degrees in Biology and Chemistry from Amherst College and performed his doctoral training with Dr. H. Robert Horvitz at MIT in *C. elegans* neurobiology. He completed his postdoctoral training with Dr. Linda Buck at Harvard Medical School and the Fred Hutchinson Cancer Research Center in the area of mammalian sensory regulation.

***Laura M. Roman, PhD, Associate Director, Division of Receipt and Referral, Center for Scientific Review, NIH***

Laura M. Roman is an Associate Director in the Division of Receipt and Referral at the Center for Scientific Review at the National Institutes of Health. Dr. Roman's responsibilities include the referral of

applications submitted to NIH from the extramural scientific community to the appropriate Integrated Review Groups, the assignment of applications to one or more of the Institutes and Centers at NIH for funding consideration and the development and application of NIH submission policies.

Prior to joining the federal government, Dr. Roman was a member of the Physiology Departments at Yale and then Johns Hopkins Medical Schools where her lab focused on the factors controlling neural crest development.

Education: B.A. Biology, Smith College, 1977; Ph D. Cell Biology, Yale University 1983; MBA Loyola College Maryland 2009

***Jody Sachs, PhD, National Center for Research Resources, NIH***

I have a doctorate in Podiatric Medicine, with 2 years of post-doctorate training, and 15 years of clinical hospital-related experience. In addition, I have had 15 years of administrative and managerial experience in biomedical research environments. I have also designed courses and programs in the drug development process for the pharmaceutical industry, and worked in a regulatory environment at the FDA, in the Center for Biologics Evaluation and Research, as a Health Science Administrator. Within the FDA, I oversaw and managed the Vaccine and Related Biological Products Advisory Committee (VRPAC) and worked as the CBER scientific liaison, with medical and scientific experts within FDA, CDC, NIH, DoD, industry, as well as representatives of the public, in areas of vaccine formulation, safety, and efficacy within the FDA approval process. This job involved summarizing policy and reporting to Congress. My past work has included administrative, management and policy development activities related to the implementation and coordination of NIH-supported biomedical research programs. I have served as the Acting Director, in the Division of Acquired Immunodeficiency Syndrome (DAIDS) Henry Jackson Foundation Liaison Office, and have participated in the development of all the international joint HIV vaccine protocols between CDC, DoD, and NIH. My work at The National Center for Research Resources (NCRR), NIH, includes directing and overseeing a NIH Roadmap Program to develop connections between many clinical research networks (NECTAR), and direct and manage the NIH Roadmap Inventory and Feasibility of Integrating and Expanding the Clinical Research Networks Initiative. I presently serve as a NIH Roadmap Scientific Project Officer managing large extramural academic research programs including [http://www.ncrr.nih.gov/clinical\\_research\\_resources/clinical\\_research\\_networks/index.asp](http://www.ncrr.nih.gov/clinical_research_resources/clinical_research_networks/index.asp) and <http://nihroadmap.nih.gov/clinicalresearch/overview-networks.asp> and the Clinical and Translational Science Awards: [www.ctsaweb.org](http://www.ctsaweb.org). I have developed strengths to cooperate with other Federal and non-Government organizations to coordinate program activities, as well as develop expertise in organizing and serving as an interface with Trans-NIH Institute staff and appropriate committees for the purpose of insuring coordination in systems planning, development and implementation. My plan for the future is to continue to work on strengthened collaborations, partnerships and cooperation of multiple NIH Institutes, industry, and the clinical research community in working together.

In my current job as a NIH SBIR Program Officer, I advise scientists on regulatory issues of drug, biologics, and product development. I bring a unique perspective to the extramural research investigators and small businesses given my experience with FDA federal regulations, when discussing IND/IDE concerns. I advise extramural investigators and small business owners of the process of product development of SBIR/STTR Phase 1 and 2, as well as the commercialization plan. I advise scientists how to develop mutually acceptable research and development plans to support federally funded research. In discussions with investigators, I advise which agreement types would be most suited to accomplish

the goals of the research plan, and discuss what other collaborative agreements would permit interchange of scientific and technical collaboration, as well as investigator /scientists' intellectual property (IP) and patents protections over long range planning up to five years. In addition, I have advised researchers and administrators on matters involving policies and procedures of clinical and translational science within the CTSA Program. I have provided advice and guidance in resolving collaborative issues in a variety of grants and contract initiatives, and have collaborated and engaged discussions with other agencies (DoD, CDC, HRSA, AHRQ, etc.) within the scientific community and professional organizations regarding translational science activities and development, and opportunities for scientific collaboration.

***Lisa Scott-Morring, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration***

Lisa Scott-Morring joined OER's Office of Policy for Extramural Research Administration, Division of Grants Compliance and Oversight as an Assistant Grants Compliance Officer in April 2010. She was most recently a Grants Management Officer for the National Institute of Allergy and Infectious Disease (NIAID) for six years. There, she managed a comprehensive grant portfolio and was the Grants Management Program coordinator for the NIAID Biosafety construction grant program and several other research RFA initiatives. Prior to joining NIH she was a college instructor at the University of Miami Ohio and an Army Sergeant.

She is an alumna of University of Maryland Eastern Shore where she received a B.S. in Human Ecology and Communications and also Miami Ohio University where she received her Master's Degree in Social Science.

***Shahid Shah, Chief Executive Officer, Netspective Communications***

Shahid N. Shah is an internationally recognized and influential healthcare IT thought leader who is known as "[The Healthcare IT Guy](#)" across the Internet. He is a consultant to various federal agencies on IT matters and winner of Federal Computer Week's coveted "Fed 100" award given to IT experts that have made a big impact in the government. Shahid has architected and built multiple clinical solutions over his almost 20 year career. He helped design and deploy the American Red Cross's electronic health record solution across thousands of sites; he's built two web-based EMRs now in use by hundreds of physicians; he's designed large groupware and collaboration sites in use by thousands; and, as an ex-CTO for a billion dollar division of CardinalHealth he helped design advanced clinical interfaces for medical devices and hospitals. Shahid also serves as a senior technology strategy advisor to NIH's SBIR/STTR program helping small businesses commercialize their healthcare applications.

Shahid runs three successful blogs. At <http://shahid.shah.org> he writes about architecture issues, at <http://www.healthcareguy.com> he provides valuable insights on how to apply technology in health care, at <http://www.federalarchitect.com> he advises senior federal technologists, and at <http://www.hitsphere.com> he gives a glimpse of the health-care IT blogosphere as an aggregator.

***Sam Smith, Project Manager Contractor, eRA, Division of Customer Support Services***

Sam has been with the eRA help desk since October of 2005, starting as a Help Desk Specialist just prior to the commencement of NIH's electronic submission transition. Just as the eSubmission process has matured through the years, so has Sam's help desk responsibilities, being promoted to eRA Commons Team Lead in May of 2006, Service Desk Manager in October 2008, and Project Manager in March of 2010, where he presently serves. As Project Manager, Sam is responsible for the overall operations of the User Support contract including the Service Desk, Training and Documentation, and Testing functional areas. Sam ensures that his 28-person team consistently "listens with focus, answers with accuracy, and helps with compassion". Sam has garnered numerous accolades from the grantee community and NIH community alike, receiving the 2008 Office of Extramural Programs (OER) Recognition Award for Outstanding Leadership. He has also earned the HDI professional certifications of Help Desk Analyst, Support Center Team Lead, and Support Center Manager. He is currently pursuing the Project Management Professional (PMP) designation. Sam holds a Master's degree in Special Education from Johns Hopkins University, and a Bachelor's degree in Communication from University of Maryland, College Park. A devoted husband of 7 years, Sam enjoys relaxing at home and spending time with his wife and 2-year-old daughter.

***Rohit Shukla, Founder and Chief Executive Officer, Larta Institute***

Mr. Shukla founded and is the CEO of Larta Institute ([www.larta.org](http://www.larta.org)). Apart from being an entrepreneur in his own right (he founded and ran two small technology-based companies early in his career), he also has been a guide and advisor to hundreds of businesses worldwide, and under his direction, Larta Institute has developed a solid reputation and expertise in commercialization of innovations emerging from the lab or spinning out from universities and larger companies.

Under his leadership, Larta Institute, which he founded in 1993, currently manages one of the nation's largest innovation pipelines of companies emerging from federally-funded research (including NIH, USDA, and NSF), 18 top research universities and from a network of global partner nations. He has designed and led dozens of well-regarded innovation programs, national commercialization assistance programs (under the "CAP" name) for NIH (the long-lived NIH CAP), USDA CAP and NSF CAP1, and most recently, TATRC CAP (Telemedicine Advanced Technology Research Center at Fort Detrick, Maryland). Larta under his leadership has also developed and conducted programs for the National Institute of Standards and Technology (NIST), the Defense Advanced Projects Agency (DARPA), the Department of Energy (DOE) and a number of countries, including New Zealand, Australia, Japan, Hong Kong, Taiwan, Canada, Sweden, Finland and Italy.

***Maria Stagnitto RN, MSN, Human Research Protection Officer, Office of Extramural Research***

Maria joined the Intramural Program of The National Institutes of Health (NIH) in 1987 as a Nurse Manager and Educator. In these roles she was directly involved in clinical research in a variety of settings. She moved to The National Heart, Lung, and Blood Institute (NHLBI) in 2000, and, as the Associate Director, established the Office of Clinical Affairs, which was responsible for the oversight of all the institute's intramural protocols. She also served as the Executive Secretary for the NHLBI Institutional Review Board, and three Data and Safety Monitoring Boards. She transitioned to the Extramural Program of NHLBI in 2005, and, as Director, established the Office of Clinical Research, which supported all of the institute's extramural programs. She recently joined the Office of Extramural Research as a Human Research Protection Officer. One of her main responsibilities in her current role is

to review all grant applications with human subjects concerns. Maria is also an Extramural Research Integrity Officer for NIH, with responsibility for the preliminary review of all allegations of research misconduct.

***Tony Stanco, Esq, Executive Director, National Council of Entrepreneurial Tech Transfer***

Tony Stanco, Esq. is the Executive Director of the National Council of Entrepreneurial Tech Transfer, and formerly the Director of the Council of Entrepreneurial Tech Transfer and Commercialization (CET2C) of The George Washington University. Mr. Stanco is a security attorney and was a senior attorney at the Securities and Exchange Commission (SEC), where he worked on over 200 IPOs. He also worked on innovation policy, including start-up creation and funding by angel investor and VCs. He has an LL.M. from Georgetown University Law Center in securities regulation and is licensed as a lawyer in New York state. At School of Engineering and Applied Science at The George Washington University, Tony worked on innovation policy, start-up finance policy, software policy, Open Source, cyber-security and eGovernment issues with universities and governments around the world. Tony has given presentations at the U.S. Congress, various U.S. defense and civilian agencies, the World Bank, the European Commission, United Nations, Inter-American Development Bank, Organization of American States, World Summit on Information Society, Advanced Computer and Internet Law Institute, and the International Computer Law Association, among others. Tony also teaches the "Lab to IPO" course dealing with start-up formation and funding.

***Lorraine Trexler, Director, Division of Financial Advisory Services, NIH***

Ms. Lorraine Trexler is the Director, Division of Financial Advisory Services (DFAS), OAMP, OALM, at the National Institutes of Health. The Division provides financial advice to the acquisition and grants community at NIH, including the negotiation of indirect cost rates for commercial organizations and the resolution of audit findings in audit reports related to contracts and grants awarded by NIH. The Division also performs financial capability and accounting system reviews of prospective awardees, and cost analyses of proposed contract awards. From 2005 through 2007, Ms. Trexler served as the Chief of the Special Reviews Branch in DFAS. Prior to this, she was a Senior Auditor in the Indirect Cost Branch. She previously worked for the Federal Home Loan Bank Board and a private CPA firm. Ms. Trexler is a Certified Public Accountant and a member of the American Institute of CPAs, the Association of Government Accountants and the Maryland Association of CPAs.

***Raphael Woodruff, Chief, Indirect Cost Branch, Division of Financial Advisory Services, NIH***

Raphael (Ray) Woodruff is currently the Chief of the Indirect Cost Branch in the Division of Financial Advisory Services (DFAS), Office of Acquisition Management and Policy (OAMP) of the National Institutes of Health (NIH). The Indirect Cost Branch is responsible for negotiating indirect cost rates for Commercial (For-Profit) Organizations performing under research grants and /or contracts with Department of Health and Human Services (DHHS).

Mr. Woodruff has been an auditor with NIH for 21 years and has over 30 years of service with the Federal Government. Prior to coming to NIH, Mr. Woodruff worked in various accounting and related areas with the Department of Navy and Department of Treasury, Financial Management Service. Mr. Woodruff is a graduate of the Catholic University of America with a Bachelor of Arts Degree in Accounting.

**Jerome R. Wujek, PhD, Research Resources Officer, National Eye Institute, NIH**

Jerome R. Wujek graduated with a BA *cum laude* in Biology from Saint Thomas College in Minnesota. He has a Ph. D. in Anatomy from the Case Western Reserve University School of Medicine, with a thesis on the role of axonally transported microtubules in determining the rate of nerve fiber regeneration in mammals. During post-doctoral research at the University of Maryland School of Medicine he investigated the use of embryonic nervous tissue as a means of repairing spinal cord injury and the neuroglial response to brain injury. As a Research Scholar at the Children's Hospital Medical Center (Division of Cell Biology) in Cincinnati, OH, he studied the ability of neuroglial extracellular matrix to stimulate nerve fiber outgrowth.

Following his training, Dr. Wujek joined the National Institute of Neurological and Communicative Diseases and Stroke (NIH) as a Senior Staff Fellow in the Laboratory of Molecular Biology, where he investigated the production of neurite growth-promoting factors by neuroglial cells during brain development. He next took a position as a Senior Scientist at a start-up biotechnology company, Gliatech, where he was instrumental in developing therapeutics for surgical adhesions and for Alzheimer's disease. Subsequently, he joined the Department of Neurosciences of the Cleveland Clinic Foundation as a staff scientist, to investigate the role of microglia, inflammation and nerve fiber pathology in Multiple Sclerosis.

In 2003, Dr. Wujek was recruited to the Center for Scientific Review, NIH in the Brain Disorders and Clinical Neuroscience group, as a Scientific Review Administrator. There he managed the Visual Systems Small Business study section and the Neuropharmacology Small Business study section. In the summer of 2006, he moved to National Eye Institute, Division of Extramural Research. He serves as the NEI's Research Resources Officer, managing grant portfolios in Small Business and in Myopia and Refractive Error. Dr. Wujek has been active within the NIH extramural research community, collaborating on several trans-NIH service committees.