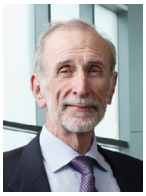
Pennsylvania Pediatric Medical Device Consortium

LEADERSHIP



Robert J. Levy, MD

Principal Investigator and Chair, Clinical and Scientific Advisory Committee

Robert Levy, MD, is the PPDC principal investigator and chair of the PPDC Clinical and Scientific Advisory Committee. He is the William J. Rashkind Endowed Chair in Pediatric Cardiology at Children's Hospital of Philadelphia. He has appointments as professor of Pharmacology and professor of Pediatrics at the Perelman School of Medicine of the University of Pennsylvania. Dr. Levy is also section chief for research in the Division of Cardiology at CHOP.

He has experience extending over three decades concerning device development, relating to both pediatric and adult clinical indications. His NIH-funded research has led to 46 issued U.S. patents. These patents have been the basis of extensive licensing activities, including four clinically used bioprosthetic heart valves developed by Abbott, Inc.

For the past 20 years, Dr. Levy has been the director of the NHLBI's Research Training Program in Pediatric Cardiology at CHOP, and he has completed a four year term as a standing member of the NHLBI Training Grant Study Section. Dr. Levy provides specific expertise concerning all aspects of pediatric medical device development, preclinical testing, and the regulatory approval process.

William R. Wagner, PhD

Principal Investigator, University of Pittsburgh
Co-Chair, Clinical and Scientific Advisory Committee

William Wagner, PhD is the co-chair of the PPDC Clinical and Scientific Advisory Committee. He is also the director of the McGowan Institute for Regenerative Medicine as well as a professor of Surgery, Chemical Engineering, and Bioengineering at the University of Pittsburgh. He serves as scientific director of the NSF Engineering Research Center on "Revolutionizing Metallic Biomaterials" and chief science officer for the Armed Forces Institute of Regenerative Medicine. He holds a BS from Johns Hopkins University and doctorate in Chemical Engineering from the University of Texas. Dr. Wagner is the founding editor and editor-in-chief of one of the leading biomaterials journals, Acta Biomaterialia, past-president of the American Society for Artificial Internal Organs, and past chairman and current council member of the Tissue Engineering and Regenerative Medicine International Society (TERMIS) Americas region.

He is a fellow and former vice president of the American Institute for Medical and Biological Engineering and has also been elected a fellow of the Biomedical Engineering Society, the International Union of Societies for Biomaterials Science and Engineering, TERMIS, and the American Heart Association.

In 2006 he was selected to the "Scientific American 50" annual list recognizing leaders in science and technology from the research, business and policy fields. His research has generated numerous patents and patent filings that have resulted in licensing activity, the formation of a company that began clinical trials in 2014, and University of Pittsburgh Innovator Awards 2007, 2008, 2009, 2010, and 2014. In recent years he has been awarded the Society for Biomaterials Clemson Award for Applied Research, the Chancellor's Distinguished Research Award by the University of Pittsburgh, and the Senior Investigator Award by TERMIS-Americas. In 2017 he was inducted into the National Academy of Inventors and in 2018 he was named Inventor of the Year by the Pittsburgh Intellectual Property Law Association.

His research interests are in cardiovascular engineering with projects that address medical device biocompatibility and design, biomaterial development, and tissue engineering.

Patrick Cantini

Project Manager, Pittsburgh

Mr. Cantini is the Project Manager at the PPDC's Pittsburgh office. As Strategy and Business Development Officer of the McGowan Insitute's Executive Management team, he focuses on conceptualizing and formulating strategic initiatives that result in short- and long-term growth of the Institute. This includes the development of innovative programs and activities to expedite technology translation; identifying and securing key community, government, and industry alliances on a regional, national, and global level; assessing the regenerative medicine field to identify emerging trends; improving project/program efficiencies; and recommending new initiatives to grow the McGowan Institute.

In a dual capacity, he serves as a Managing Principal for the Wound Research Alliance, a clinical accelerator moving wound healing research into clinical practice. Cantini is responsible for programmatically facilitating the end-to-end process for the Alliance's clinical research partnerships and programs, and serves on the Alliance's Executive Management Team providing strategic oversight for business development.
Prior to his appointment at the McGowan Institute, Cantini served as the Chief Business Officer for the Wake Forest Institute for Regenerative Medicine where he was responsible for all aspects of strategic planning, direction, and business development. In addition, he provided overall administrative direction and coordination in the formulation, interpretation, and implementation of current and long-range policies, procedures, and programs.

Before joining the Wake Forest Institute for Regenerative Medicine, Cantini served as the Associate Director for the Pittsburgh Tissue Engineering Initiative, a non-profit think tank for the advancement of regenerative medicine and tissue engineering. He joined the biotech industry in 2001 after a long, lustrous career in the automotive manufacturing industry where he held leadership positions at the Society of Automotive Engineers and the Society for Manufacturing Engineers.

Joshua Dienstman

Project Manager, Philadelphia

Mr. Dienstman is the PPDC's Philadelphia office project manager and a research engineer at Children's Hospital of Philadelphia. He holds a BS in Biomedical Engineering from Drexel University with a concentration in Biomechanics and is the first line of contact for intake of new projects and collaborators.

Prior to joining CHOP and the PPDC, Dienstman was a technical investment analyst for the University City Science Center, assisting with the management of the QED Proof-of-Concept Award. He also held positions as an operations quality engineer at Animas Corporation and as a clinical supply chain strategist at Janssen R&D. During his time at Drexel, he worked with a team of peers to develop a novel laryngoscope for pediatric patients, managing the team to reach project milestones while competing in the school's design competition. At the PPDC, Dienstman serves as a first line of contact for intake of new projects and collaborators, as well as a point of contact and resource manager for enrolled projects and consortium personnel.

Seth J. Goldenberg, PhD

Entrepreneur-in-Residence

Dr. Goldenberg provides commercialization support to innovators developing pediatric medical devices in his role as the PPDC's Entrepreneur-in-Residence. He is also principal at 2G Consulting and was previously the Director of Global Regulatory Strategy with NAMSA and a member of the U.S. FDA. He holds a doctorate in Pharmacology from the University of Washington and an MS from the School of Biomedical Engineering at Drexel University.

At NAMSA, Dr. Goldenberg worked with more 750 associates to develop global strategies for success taking into account regulatory, clinical, testing, and business considerations around the world. Prior to joining NAMSA Dr. Goldenberg founded a consulting company based in Shanghai supporting medical device market entry. He understands not only what it takes to carry out scientific study, but also the importance of communicating it with the global scientific community to foster partnerships and collaboration, demonstrated by his strong publication record in such journals as *Cell*, *Science*, and *Nature Cell Biology*.

Natalie Napolitano, MPH, RRT-NPS, FAARC

Clinical Advisor

Ms. Napolitano is a respiratory research clinical specialist at Children's Hospital of Philadelphia and is involved in research for novel pediatric respiratory devices as a project manager and research engineer. She assists the PPDC in its collaboration with the Children's Hospital Additive Manufacturing for Pediatrics (CHAMP) Lab. The CHAMP Lab is collaborating with the PPDC to use its resources to fill areas of need at CHOP.

Elizabeth Silvestro, MSE

Lead Engineer, Project Manager, and Research Engineer

Ms. Silvestro is the lead engineer at the Children's Hospital Additive Manufacturing for Pediatrics (CHAMP) Lab, promoting the discovery and use of 3D technology across Children's Hospital of Philadelphia by offering a broad range of expertise and services.

The CHAMP Lab is designed to give children and their families the best care and experience possible. 3D imaging and printing have seen rapid growth over the past few years with significant successes in the medical field. Applications such as surgical planning, virtual simulation, and custom biomedical devices are already improving outcomes and changing children's lives. The Lab aims to promote the discovery and use of 3D technology across the hospital by offering a broad range of expertise and services. The 3D Lab focuses on the digital side of these technologies by offering a variety of medical imaging processing for several departments. CHAMP works on the physical side, building models, devices and solutions CHOP clinicians and researchers can use to enhance care. The CHAMP Lab is collaborating with the PPDC to use its resources to fill areas of need at CHOP.

Stanley Stachelek, PhD

Co-Investigator

Dr. Stachelek has been involved in the reviews of more than 100 pediatric device ideas submitted to the PPDC for evaluation. He currently serves as a co-investigator for the Consortium as well as holding a faculty position as research associate professor. His areas of expertise are biomaterials, biocompatibility and the inflammatory response to medical devices.

Raymond Sze, MD, MAMS

Co-Investigator

Dr. Sze heads the Children's Hospital Additive Manufacturing for Pediatrics (CHAMP) Lab. CHAMP Lab is collaborating with the PPDC to use its resources to fill areas of need at CHOP.

His research interests lie in human factors engineering to improve patient quality and safety; additive manufacturing (3D printing) for procedural training, patient-specific simulation, and biomedical device design and prototyping; machine learning to augment radiologist interpretation and workflow; physician and staff wellness to reduce burnout; qualitative research to improve patient experience; and master coaching to achieve expertise, as opposed to post graduate training (residency and fellowship to achieve competency).