Michael B. Wolfson, Ph.D.

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	LinkedIn	https://www.linkedin.com/in/mwolfson	
	Publications	https://www.novelsemi.com/~mw	
QUALIFICATIONS	Biotech entrepr Specializes in de commercial, sma budget and sch industrial applic such as bio-, m balanced portfol path to market. risk environment	reneur with substantial experience managing high-risk R&D portfolios. eveloping and managing complex biomedical initiatives within government, all business, and academic R&D environments. Assess scientific merit, risk, edule realism, and suitability for transition to clinical, government, and ations. Expertise spans multiple disciplines and covers emerging domains, nicro-, and nano-system technologies. Develops strategic plans to yield a lio of investments and project a clear vision to the public, accelerating the Creative at generating disruptive solutions on a shoestring budget in high- ts. Fosters a harmonious environment and encourages individual growth.	
	 Co-leads \$1.5B <u>RADx Tech</u>: brought > 10B over-the-counter COVID diagnostics to market Oversight of \$900M R&D projects: 26 programs over \$10M, hundreds of smaller grants Funds the best R&D: performed strategic analysis, secured funding, led 20 solicitations 		
	• Managed nine-person R&D Division: \$150M annual budget, reported to Institute Director		
	• Lead or co-le	ad: five major trans-NIH initiatives	
	• Builds partne	rships: coordinated across 14 US Government agencies for pandemic response	
	• Negotiated \$	48M cost sharing with industry: saved US Government funds	
	• \$28M for ear	ly-stage innovators: first-of-its-kind US Government neurotech incubator	
	• Inventor: two	new transducer technologies ($7,425,749$, $6,529,654$, and two other patents)	
	• Entrepreneur	: founded two startups; consultant to industry, government, and non-profits	
	Highly recogn	nized: ten awards from HHS Secretary and NIH Directors over eight years	
	• Board Memb	er: preschool, condo association, and ten academic centers	
EDUCATION	Cornell Universit	ty. Ithaca NY	
	Ph.D. in Electrical Engineering, January 2001		
	Specialization: N	AicroElectroMechanical Systems (MEMS)	
	Advisor: Noel C	MacDonald	
	Dissertation: <u>Or</u>	a MEMS-Based Parametrically Amplified Atomic Force Sensor	
	Brown University, Providence RI		
	Sc.B. in Electri	ical Engineering, Magna cum Laude, with Honors, May 1995	
	Specializations: Computer Engineering and Control Systems		
	Thesis: The Mic	cro-Kernel and Software for the HMA Microphone Module Board	
RECENT	National Institu	utes of Health (NIH) 2024 Director's Award	
HONORS	For building a highly innovative trans-NIH program to accelerate the translation of		
	technologies to	diagnose and treat disorders of the nervous system	

National Institutes of Health (NIH) 2024 Director's Award

For launching the Home Test to Treat program to provide underserved communities with antiviral treatments and demonstrating the efficacy of innovative technologies in facilitating healthcare

National Institutes of Health (NIH) 2024 Director's Award

For leveraging the RADx Tech Initiative to rapidly deliver point-of-care mpox diagnostics to address the mpox public health emergency

NIBIB Director's Award for Collaboration Achievement, 2024

In recognition of the Team's developing the Medical Imaging and Data Resource Center (MIDRC) into the National AI Ecosystem Initiatives

NIBIB Director's Award for Collaboration Achievement, 2024

In recognition of the successful obligation, execution, and reporting of NIBIB's \$274M supplemental COVID-19 funding, which was highly visible to NIH and HHS leadership and contributed to significant programmatic achievements

Going the Extra Mile (GEM) Award, 2022

NIH/NIBIB award, for "service on the Bioengineering Research Partnership workgroup [which] culminated in the recent publication of a new Bioengineering Partnership with Industry Funding Opportunity Announcement (PAR-22-123)"

HHS Secretary's Award for Distinguished Service, 2021

Rapid Acceleration of Diagnostics (RADx) Initiative (NIH) Recognizes extraordinary contributions or outstanding achievements above and beyond normal requirements that lead to the improvement of operational or program effectiveness such a, improving the efficiency or productivity in accomplishing the missions and goals of HHS

National Institutes of Health (NIH) 2021 Director's Award

As a member of the NIH RADx program, in response to the COVID-19 pandemic

Going the Extra Mile (GEM) Award, 2021

NIH/NIBIB award, for "RADx Tech & ATP Team: For exceptional dedication and innovation in advancing COVID-19 testing and diagnostics efforts"

National Institutes of Health (NIH) 2019 Director's Award

As a member of the NIH HEAL Team, in response to the opioid crisis

National Institute of Neurological Disorders and Stroke (NINDS) 2019 Director's Award

For outstanding effort under condensed timelines for the FY20 funding plan for the Devices to Treat Pain HEAL program

National Institutes of Health (NIH) 2018 Director's Award

As a member of the NIH Biomedical Engineering Day Team

Going the Extra Mile (GEM) Award, 2018

NIH/NIBIB award, given due to role on a team charged to "examine and develop strategies to address organizational culture and morale"

Salute to Excellence 2011: Technical Support Nominee

System Planning Corporation annual award: "The individual who in the past year has demonstrated outstanding team spirit and a willingness to 'go the extra mile'"

Salute to Excellence 2010: Technical Support Nominee

AFFILIATIONS	IEEE, Senior Member	1992 – present
	IEEE Electron Devices Society Membership	1995 – present
	IEEE Photonics Society Membership (formerly IEEE LEOS)	2004 – present
	IEEE Engineering in Medicine & Biology Society	2011 – present
	Society for Neuroscience, Regular Member	2014 – present
	Tau Beta Pi, The Engineering Honor Society, Member	1995 – present
	Sigma Xi, The Scientific Research Society, Member	1995 – present
	The NetBSD Project (open source operating system), Developer	1998 - 2009
	Westbard Mews Condominium Council, Vice President	2016 - 2017
	Rock Spring Children's Center, Board Member	2021 – present

LEADERSHIPSpecial Advisor, Director's Office, ARPA-H, Arlington, VA2022 – presentEXPERIENCEOne of earliest staffers helping to build a new US Government agency. Responsible for
identifying, recruiting, and preparing Program Manager candidates. Provides strategic
advice on funding announcements (including its first Open BAA, <u>75N99223S0001</u>),
coordination with other components of the US Department of Health and Human Services,
and building internal processes. Developing infrastructure resources via ARPANET-H such
as Advancing Clinical Trial Readiness (ACTR), Biomedical Data Fabric Toolbox (BDF),
and hub-and-spoke CORE infrastructure. Judge for high-profile Sprint for Women's
Health.

Co-lead, Rapid Acceleration of Diagnostics (RADx®) Tech2020 – presentNational Institute for Biomedical Imaging and Bioengineering (NIBIB)National Institutes of Health, Bethesda, MD

As part of Operation Warp Speed, the US Government's response to the COVID-19 pandemic, helped launch and run the National Institutes of Health's Rapid Acceleration of Diagnostics (RADx[®]) initiative. RADx Tech was created in April 2020 as a \$1.5B "lean startup" to speed the development, validation, and commercialization of innovative point-of-care and home-based tests. RADx Tech brought the first FDA authorized over-the-counter (OTC) diagnostic to market for home use, scaled up production of OTC diagnostic tests to nearly one billion per month, supported over fifty new Emergency Use Authorizations (EUA) from the FDA, and first three 510(k) cleared products.

As co-lead, primary responsibility is to manage RADx Tech operations and resources needed to support government investments in over 250 companies. Personally responsible for managing \$310M in emergency contracts, leading the deployment team, supervising 17 "special volunteer" NIH employees, and interagency coordination between NIH and other components of HHS and the DOD. Developed presentation material for NIH leadership to present to White House and Congress, including weekly briefings for Operation Warp Speed. Direct oversight of contracts with over 500 technical experts (including about 50

entrepreneurs in residence), 27 EUA-enabling clinical trials, and other critical pieces of infrastructure necessary to help startups mature into sustainable manufacturers (e.g., quality management systems, logistics, informatics, on-demand staffing). Defines policy and procedures for the consultant network and all RADx contractors regarding conflict of interest, information security, access to sensitive business information, and training. Liaison with HHS OGC to develop MOUs and letter contract templates, and with HHS CIO to support FedRAMP authorization of an HHS-wide informatics platform. Primary consultant for NHLBI Director of Acquisitions on all new contracts for RADx-Tech and unusual post-award contracting challenges. Assisted with \$3B acquisition of 500M tests for distribution via covid.gov.

Co-lead of RADx Home Test To Treat program, the first at-home testing, telehealth and treatment program for both Covid-19 and influenza at a national scale. Assisting with RADx business development. Met with NIAAA Director, NIA Director, and CDC HBV team to discuss potential new funnels. Assisted in finalizing arrangements with CDC and launch of the HBV funnel. Working with NIH's SEED Office to support future incarnations of I-Corps through RADx.

Collaborated with ASPR to ensure that individuals with accessibility needs had a more usable option when ordering from covidtests.gov. Managed a team of consultants to work with OraSure to improve the labeling, instructions, and videos to enhance usability. Coordinated release of these products with ASPR and ACL through the covidtests.gov website.

Responsible for launching the first RADx Tech scale-up contract in July 2020 for the first RT-PCR POC diagnostic product authorized by the FDA, shepherded the start-up through acquisition by Thermo-Fisher for \$450M, and sustained warm base manufacturing when demand is low. Negotiated risk management instruments with two manufacturers to incentivize at-risk pre-EUA production of product worth \$40M. Negotiated cost-sharing agreement with 16 manufacturers, saving the US Government approximately \$48M. Launched the nation's first "digital" test-to-treat trial using telehealth providers and overthe-counter diagnostics to prescribe antiviral treatments. Attained Defense Production Act rating for four contracts, in coordination with the NIH Principal Deputy Director and ASPR. Led record-breaking contract negotiation and awards in five business days. During 2022, transitioned RADx Tech from emergency policies to non-emergency contracts. Expanded the RADx Tech model to support mpox and high pathogenicity avian influenza (H5N1) on short notice, as well as diagnostics programs for maternal health, HIV, hepatitis C, and neurotechnology.

Acting Director, Division of Discovery Science & Technology 2017 - 2018

National Institute for Biomedical Imaging and Bioengineering (NIBIB) National Institutes of Health, Bethesda, MD

Responsible for managing the "bioengineering" division in NIBIB, which oversees about 40% of the Institute's \$390M annual budget. Set strategic direction for the Institute through membership on strategic planning committee, Extramural Program Executive Committee (EPEC), Extramural Training Committee, and as a member of senior staff. Led change by developing frameworks to clarify the role of NIBIB within NIH, setting vision for the future, and partnering with other Institutes and federal agencies. Through EPEC, made final programmatic recommendations to the Institute Director on grant funding, approvals for new concepts and funding announcements, and recommendations on Institute-wide portfolio balance.

Acting supervisor for seven program officers and one analyst. Responsible for annual <u>Performance Management Appraisal Program</u> ratings and contractor performance reviews. Applied federal, agency, and Institute policy to ensure staff met all necessary ethical, professional, and training requirements. In addition to providing career guidance to supervised staff, mentored two junior staff in other divisions.

Participated in an Action Learning Process to develop a new corporate culture for the Institute, with a focus on transparency, career progression fairness, and accountability. Formed the "leading from below" initiative to simplify and optimize internal processes and approvals. Completed the 2017 NIH Senior Leadership Program and 2018 NIH New Supervisor Essentials training.

PROGRAMProgram Director, NIBIB, NIH, Bethesda, MD2016 – presentMANAGEMENTProgram Officer for R&D grants, cooperative agreements, and contracts, Emphasis is on

EXPERIENCE

Program Officer for R&D grants, cooperative agreements, and contracts. Emphasis is on engineering non-imaging devices, components, and control systems for *in vivo* diagnostic and therapeutic interventions directed toward overcoming a technological challenge that limits translation into practice. Developed and manages "incubator hubs," based on the Coulter Commercialization Process, which provides financial support and in-kind support to help innovators begin formulating their commercialization plans through first-in-human demonstration of safety and effectiveness. To date, the hubs have received over 800 preproposals, spanning more than 37 kinds of technology across 35 distinct clinical conditions. Almost proposed to NIH, demonstrating that the program is tapping into a new field of innovators. Funded over a quarter of the full proposals. Funding to support these innovators exceeds \$28M.

Manages two U54 MedTech Incubator Hubs, six P41 National Centers for Biomedical Imaging and Bioengineering, six >\$1M per year U01 cooperative agreements (Research Project), 18 U18 cooperative agreements (Research Demonstration), six R44 Phase II Small Business Innovative Research (SBIR) and dozens of R01 (Research Project), R21 (Exploratory/Developmental Research), and R43 Phase I SBIR awards. Some of these awards are within the <u>Stimulating Peripheral Activity to Relieve Conditions (SPARC)</u> Common Fund activity, the National Robotics Initiative (NRI), Smart and Connected Health (SCH), Cyber-Physical Systems (CPS), BRAIN Initiative, and HEAL Initiative. Science Officer for cooperative agreements, training grants, and small business awards. *Ex officio* advisory board member for ten academic centers. Managed the entire lifecycle of five Request for Application (RFA) funding announcements: drafted, pitched, posted, hosted a webinar, responded to hundreds of applicant inquiries, trained reviewers, reviewed over 100 applications, made funding decisions, authored summary statements, negotiated milestones, and actively managed six Other Transaction awardees. Co-authored SPARC

Material Sharing Policy, which is required of all awardees.

Serves as the NIBIB representative to the NIH BRAIN Initiative Coordinating Team, overseeing all program activities within a \$500M/year activity. As a member of the Coordinating Team, participates in multiple working groups (Neural Recording and Modulation, Noninvasive or Minimally Invasive Technologies in Humans, Training and Dissemination, Neuroethics) and makes recommendations to Agency leadership on new funding announcements, new grants to be funded, and on strategic plans. Project team lead of one of four major SPARC components, "Next Generation Tools and Technologies", regularly interacting with the NIH executive oversight committee. Chair of the NIH National Robotics Initiative, representing nine NIH institutes to a trans-government team at NITRD/IRAS. Co-chair of the trans-NIH Neural Prosthesis Working Group. Chair of the trans-agency collaborative Spinal Stimulation Research Group involving four NIH institutes and two other federal agencies (VA and DOD/CDRMP). Co-chair of Finance Workstream for the FNIH-sponsored Pediatric Medical Devices consortium. Member of trans-NIH Medical Rehabilitation Coordination Committee, HEAL Initiative Preclinical & Translational Working Group, trans-agency (NIH-FDA) Medical Devices Research Interest Group, NIBIB Pediatric Research using Integrated Sensor Monitoring Systems (PRISMS) consortium, and unofficial NIH battery working group. Represents NIBIB to the trans-NIH Clinical Trials Operations Workgroup overseeing agency-wide clinical trials policy.

Led a crisis response team after news reports alleged an awardee was violating human subjects protections. Coordinated activities with NIH Office of Extramural Policy, NIBIB Institute Director, Chief Grants Management Officer, Director Extramural Science Programs, Communications Director, and with other funding agencies that had supported the awardee. Led one chapter of the 2020 NIBIB Strategic Plan: Advanced Therapies and Cures.

Subject Matter Expert for HEAL and BRAIN Initiative grants and for DARPA on the NESD, HAPTIX, and ElectRx programs. Scientific reviewer for the NIBIB DEBUT challenge award and for other agencies' programs: FDA opioid Innovation Challenge, HHS KidneyX, IARPA MOSAIC, DHA SBIR 2017-02, BARDA Accelerator Network 2.0, DARPA NESD, DARPA TNT, DARPA N3, DARPA BETR, DARPA BG+, DARPA PPB, NSF ERC site CSNE, NSF CBET Career Awards (NSF 17-537), and multiple ARPA-H programs (Open BAA/ISO, NITRO, PARADIGM, PSI, Sprint for Women's Health).

Represents NIBIB to other federal funding agencies (NSF, DARPA, IARPA, NITRD, Manufacturing Institutes, MRMC, CDMRP, VA, NIDILRR, DTRA), universities, private foundations (AAAS, Howard Hughes Medical Institute, C. H. Nielsen, C. Reeve, M. J. Fox, Wyss), industry research funders (Medtronic, GlaxoSmithKline, Rainbow Medical), patient advocacy groups, and other relevant bodies (FDA, NIST, DOE/Office of Science, MDIC, AdvaMed, editors of AAAS Science journals).

Independent Consultant, Arlington VA2013–2016Senior Scientist, System Planning Corporation, Arlington VA2009 – 2013Provided Subject Matter Expertise (SME) and Scientific, Engineering, and Technical

Assistance (SETA) to DARPA's Biological Technologies Office (BTO), Microsystems Technology Office (MTO), and IARPA's Office of Safe & Secure Operations (SSO). Successfully developed the Reliable Neural-Interface Technologies (RE-NET) program through all project stages: strategic vision, concept initiation, literature research, workshop with leading researchers, new-start pitch, funding authorization, Broad Agency Announcement (solicitation) development, SME proposal assessment, portfolio assessment and budget analysis, statement of work negotiation, day-to-day monitoring of ongoing awards' commitment, obligation, and execution of funds, responses to data calls, evaluation of performers' milestones and deliverables, transition through subsequent phases of the program, and composition of the final report.

Composed seven Broad Agency Announcements, four Research Announcements, and four Small Business Innovation Research (SBIR) topics. Served on 15 source selection review panels.

Liaison for program coordination with other funding organizations, including IARPA, ARPA-E, ONR, ARO, AFOSR, NIH/NINDS, NSF, industry, and venture firms. Worked with government and industrial transition partners to transfer technology from the RE-NET, Chip-Scale Vacuum Micro Pumps (HiVAC), Microtechnology for Positioning, Navigation, and Timing (micro-PNT), and Nano Electro Mechanical Computers (NEMS) programs to other organizations. Maintained performer compliance with relevant animal and clinical trial regulations for several neural interface programs. In conjunction with colleagues at the FDA, facilitated development of Device Evaluation Strategies and Q-submission procedures for Early Feasibility Study (EFS) Investigational Device Exemption (IDE) for BRAIN Initiative programs.

Applied technical expertise and program administration skills through work in the IARPA SSO office and on the following DARPA BTO and MTO programs: Neural Engineering System Design (NESD), micro-PNT, RE-NET, Hand Proprioception & Touch Interfaces (HAPTIX), Electrical Prescriptions (ElectRx), HiVAC, NEMS, N/MEMS Science & Technology Fundamentals, Hybrid Insect MEMS (HI-MEMS), Tip-Based Nanofabrication (TBN), and Chip-Scale Signal Analyzers (CSSA). Involved in a number of feasibility studies: hot fusion, magnetic MEMS, biodegradable neural probes, ultrasound-powered and -telemetered neural interfaces, electrocortiographic (ECoG) stent, surface charge effects on semiconductors, high-energy-density DC-DC power converters, micro-electrical discharge micromachining, and atomic-layer deposited hermetic and biocompatible coatings. Developed and hosted workshops on NESD, HAPTIX, RE-NET, High-Density Energy-Conversion Microsystems (Hi-DEC), and Extensible X-Ray Systems and Algorithms for Computed Tomography (EXACT).

Provided mentorship to over a dozen recipients of the DARPA Young Faculty Award. Developed and oversaw SBIR topics on Extensible Hermetic Neural Interface Microsystems, Cortical Modem Systems Integration and Packaging, Soft Bio-Interfaces for Physiological Sensing and Modulation, and Miniaturized Wireless Microscope and Tissue Diagnostics. **Consultant**, GlaxoSmithKline R&D Ltd, Middlesex, UK 2014 – 2016 Provided reviewing expertise for the GlaxoSmithKline Innovation Challenge Fund, which aims to develop neurotechnology solutions to peripheral nervous system interfaces for multiple organs and disease targets. Selected ten teams from 25 applications for the first round of funding. The second round of applications will be down-selected to the top three teams, awarded up to \$1M to solve the Innovation Challenge.

Developed program objectives and review criteria for both rounds of funding. Reviewed proposals and selected awardees. Evaluated progress of the ten funded and two unfunded teams towards the objectives of the Fund. Provided guidance to proposers on how reviewers evaluate proposals. Facilitated teaming among the Innovation Challenge teams and industrial translation and manufacturing partners.

Senior MEMS Engineer, MEMS and Nanotechnology Exchange, Reston VA 2013 As Principal Investigator, managed an effort to research the mechanical loss mechanisms in low-defect materials to provide new insight into fabrication of high quality-factor resonator systems. Extended techniques developed for silicon, a well-characterized material, to fused silica to take advantage of the superior thermo-mechanical properties for inertial and other sensor applications. Modeled, designed, and analyzed MEMS resonator devices to demonstrate that low-loss resonators are extensible to RF filters and high-value military systems.

ENGINEERING EXPERIENCE

Consultant, NovelSemi Solutions, LLC, Somerville MA 2007 – 2009 Enabled the transition of research innovations to robust implementation by developing and optimizing technical solutions, evaluating device designs and fabrication processes, and characterization of device behavior. Built instruments to provide rapid design turnaround and integration of novel devices with conventional systems.

Device Integration Engineer, RedShift Systems, Burlington MA 2006 – 2007 Acted as technical expert for OpTIC RS1080[™] product line, using practical experience to serve as top-to-bottom tactical sleuth. Solved problems in microfabrication, laser qualification, CMOS imager characterization, low-level instrument control, noise analysis, optical filter characterization, and development of custom instrumentation. Resolved unexpected and unusual problems encountered during product development. Successfully demonstrated 120 mK NETD thermal imaging using RS1080 prototype system and custom analysis algorithms.

Senior Researcher, Sharp Laboratories of America, Camas WA2005 – 2006Contractor, Sharp Laboratories of America2004 – 2005Demonstrated feasibility of integrating sensors into Sharp Electronics Corporation'sproduct lines. Developed and patented novel "Piezo-TFT" displacement sensor compatiblewith LCD thin-film transistor (TFT) process flow, facilitating cost efficiencies by utilizingfilms previously deemed unsuitable for MEMS. Successfully demonstrated functioningacoustic and biochemical sensor prototypes using Piezo-TFT technology fabricated onglass panels.

Director of MEMS Technology, Exajoule LLC, Palo Alto CA2002 - 2004Consultant, Exajoule LLC2002Responsible for all MEMS components of the Exajoule ELP1™ and ELP2™ product lines:
micromirrors for display and advanced optic devices. Developed the ELP process flows and
successfully fabricated device prototypes at the Stanford Nanofabrication Facility using
standard thin film deposition, patterning, and etching techniques. Simulated micro-

electromechanical system properties with MATLAB. Co-authored several white papers and

Member of Technical Staff, Nayna Networks Inc., Milpitas CA 2000 – 2002 Performed test, analysis, and integration of high-density next-generation MEMS-based photonic switches. Developed automated characterization and yield analysis tools for system boards containing 1024 two-axis mirrors using integrated capacitive sensors, laser Doppler vibrometry, stroboscopic and continuous interferometry, and white-light interferometry. Developed mirror-control algorithms for prototype subsystems using optic, digital firmware, analog, and mechanical properties. Patented mirror active feedback system. Developed automated test suite to measure static and dynamic behavior, optical quality, device repeatability, lifetime, and performance with an accuracy of 0.02°. Successfully demonstrated repeatable and real-time switching between multiple OC–3 data streams.

Engineering Aid, Manufacturing Engineering Laboratory, NIST, Gaithersburg MD1991 – 1994 Compliance testing of block point releases of the PDES (Product Data Exchange using STEP) toolkit in support of the Standard for the Exchange of Product Model Data (STEP, ISO 10303), an international standard for the interchange of product data between various vendors' CAD/CAM systems and other manufacturing-related software. As the sole internal alpha-tester of PDES, worked directly with developers to fix bugs in software and documentation in a cross-platform environment to ensure that the PDES consortium had a functional product to evaluate. To facilitate cross-platform use, developed a generic user environment to be delivered with the PDES toolkit. Developed process to automatically parse WordPerfect documents to generate SGML (a predecessor of XML) tags.

RESEARCHResearch Assistant, Cornell University, Ithaca NY1995 – 2001EXPERIENCEInvestigated atomic-scale forces using microscale parametric resonator. Designed, con-
structed, and characterized integrated system for measuring sub-nm mechanical dis-
placements in vacuum ambient using simultaneous optical interferometry and ca-pacitive
measurements. Additional projects included vacuum microelectronics and MEMS design
automation suite. Fabricated devices at Cornell Nanofabrication Facility using standard
microfabrication tools, such as CAD, photolithography, thin film deposition, DRIE, thin
film etching, and packaging. Analyzed failed devices using standard microanalysis
techniques, such as SEM, SAM, FIB, and optical microscopy.

 PATENTS
 US Patent Number 7,785,912

 C. Zhan, M. B. Wolfson, J. W. Hartzell

 "Piezo-TFT cantilever MEMS fabrication"

the corporate business plan.

US Patent Number 7,425,749 J. W. Hartzell , C. Zhan, M. B. Wolfson "MEMS pixel sensor"

US Patent Number 7,253,488 C. Zhan, M. B. Wolfson, J. W. Hartzell "Piezo-TFT Cantilever MEMS"

<u>US Patent Number 6,529,654</u> <u>R. K. Wong, E. D. Sheh, J. Chen, X. Yang, M. B. Wolfson</u> "Method for transparent switching and controlling optical signals using mirror designs"

PUBLICATIONS C. T. Gilliland, W. Heetderks, K. Juluru, A. Kirilusha, T. B. Lash, T. Merchak, F. Qashu, D. M. Sheeley, M. Snyder, A. Weitz, M. B. Wolfson, B. J. Tromberg (2024). Accelerating Diagnostic Innovation for Pandemic Control. In: Sorenson, R.A. (eds) Principles and Practice of Emergency Research Response. Pages 245-271. Springer, Cham. https://doi.org/10.1007/978-3-031-48408-7_13

E. J. Wolf, T. H. Cruz, A. A. Emondi, N. B. Langhals, S. Naufel, G. C. Y. Peng, B. W. Schulz,
M. B. Wolfson, "Advanced Technologies for Intuitive Control and Sensation of Prosthetics"
Biomedical Engineering Letters 10, 119–128 (2020)
https://doi.org/10.1007/s13534-019-00127-7

K. Hansen, H. Orser, J. Rey, **M. B. Wolfson**, Chapter 4 "Modeling and Simulation", In 2018 BioElectronic Medicine Roadmap, Edited by R. St Amant, V. Zhirnov, K. Hansen, D. Rašić, SRC Press, 2018, Pages 25-28 https://www.src.org/program/bem/

R. Bashirullah, Q. Lin, R. Raedt, K. Vonck, J. Weiland, A. Weitz, **M. B. Wolfson**, V. Zhirnov, Chapter 5 "Neural Interfaces", In 2018 BioElectronic Medicine Roadmap, Edited by R. St Amant, R. St Amant, V. Zhirnov, K. Hansen, D. Rašić, SRC Press, 2018, Pages 29-34 https://www.src.org/program/bem/

H. Deligianni, M. Bayachou, N. Langhals, **M. B. Wolfson**, and J. Mauzeroll, "Preface—JES Focus Issue on the Brain and Electrochemistry Honoring R. Mark Wightman and Christian Amatore" Journal of The Electrochemical Society 165.12 (2018): Y13-Y13 https://doi.org/10.1149/2.0211812jes

E. Mosier, **M. B. Wolfson**, E. Ross, J. Harris, D. Weber, K. Ludwig, Chapter 5 "The Brain Initiative—Implications for a Revolutionary Change in Clinical Medicine via Neuromodulation Technology", In *Neuromodulation (Second Edition)*, edited by E. Krames, P. H. Peckham, A. Rezai, Academic Press, 2018, Pages 55-68, ISBN 9780128053539 <u>https://doi.org/10.1016/B978-0-12-805353-9.00005-X</u> V. Zhirnov, **M. B. Wolfson**, et al. "Summary Report," SRC/NSF Workshop on Microsystems for Bioelectronic Medicine, Organizing Committee, (Washington, DC, April 12 – 13 2017) https://www.src.org/program/grc/semisynbio/semisynbio-consortium-roadmap/e006247-biomedicine-final-report-integrated.pdf

D. L. Polla, **M. B. Wolfson** "Intelligent Nanosystems," IEEE Nanoelectronics Conference (INEC) 2013, Keynote speech, (Singapore, January 2 – 4 2013) https://doi.org/10.1109/INEC.2013.6465935

D. L. Polla, **M. B. Wolfson** "N/MEMS: small components enable powerful microsystems," SPIE Defense, Security, and Sensing, 7679-49, Session 10, (Orlando, FL, April 5 – 9 2010) https://doi.org/10.1117/12.867394

D. L. Polla, **M. B. Wolfson** "Piezoelectric MEMS for Defense Applications," 35th Annual GOMACTech Conference, Session 18.1, (Reno, NV, March 22 – 25 2010) http://www.novelsemi.com/~mw/Publications/091025GOMAC.pdf

D. L. Polla, **M. B. Wolfson** "RF MEMS integration present & future trends," IEEE Int. Symp. on Radio-Frequency Integration Tech. 2009, pp.5 – 7, (Singapore, Dec 9 – 11 2009) https://doi.org/10.1109/RFIT.2009.5383747

M. B. Wolfson, N. C. MacDonald "On a MEMS-based parametrically amplified atomic force sensor," Transducers 2001/Eurosensors XV. 11th Int. Conf. on Solid-State Sensors and Actuators. 3C1.07P, pp 1082 - 1085 (Munich, Germany, June 10 – 14 2001) https://doi.org/10.1007/978-3-642-59497-7 http://www.novelsemi.com/~mw/Publications/010613Abstract3C107P.pdf

NIBIB Innovation Funnel 75N92022R0114, 75N92022R0113, 75N92022R0117, 75N92023R0158

SELECTED PROGRAMS

NIH RFA-EB-22-002 (2022) HEAL Initiative: Translational Development of Diagnostic and Therapeutic Devices (R18)

NIH Blueprint MedTech <u>PAR-21-314</u> (2021) https://neuroscienceblueprint.nih.gov/blueprint-medtech

NIH RADx Tech co-lead (2020-present) https://www.embs.org/ojemb/special-issue-radx-tech

NIH RFA-EB-18-003 (2018) HEAL Initiative: Translational Development of Devices to Treat Pain (U18)

<u>NIH RFA-RM-17-009 (2017)</u> SPARC Technologies to Understand the Control of Organ Function by the Peripheral Nervous System (OT1) NIH RFA-RM-17-010 (2017) SPARC Technologies to Understand the Control of Organ Function by the Peripheral Nervous System (OT2)

<u>NIH RFA-RM-16-003 (2016)</u> SPARC Technologies to Understand the Control of Organ Function by the Peripheral Nervous System (OT2)

DARPA-BAA-16-09 (January 21, 2016) Neural Engineering System Design (NESD)

DARPA SB161 (December 11, 2015) Miniaturized Wireless Microscope and Tissue Diagnostics

DARPA SB153-001 (August 27, 2015) Soft Bio-Interfaces for Physiological Sensing and Modulation

DARPA SB152-002 (April 24, 2015) Cortical Modem Systems Integration and Packaging

DARPA-BAA-15-06 (December 11, 2014) Electrical Prescriptions (ElectRx)

DARPA-BAA-14-30 (April 24, 2014) Hand Proprioception & Touch Interfaces (HAPTIX)

DARPA SB142-006 (April 23, 2014) Extensible Hermetic Neural Interface Microsystems

DARPA-BAA-11-37 (March 30, 2011) Reliable Central-Nervous-System Interfaces (RCI)

DARPA-BAA-11-08 (October 25, 2010) Reliable Peripheral Interfaces (RPI)

DARPA-SN-10-42 (May 27, 2010) Universal Batteries (UNIBAT)

DARPA-BAA-10-32 (March 3, 2010) Histology for Interface Stability over Time (HIST) Michael B. Wolfson, Ph.D.

INVITED SPEAKING ENGAGEMENTS	Blueprint MedTech Annual Meeting Boston, MA, December 10, 2024 "Blueprint Program: Proof of Principle"
	BMES Annual Meeting Baltimore, MD, October 24, 2024 "NIH-Sponsored Incubator-Style Programs" https://www.bmes.org/bmes2024
	2024 NIH Pain Consortium Quarterly Symposium virtual, September 25, 2024 "NIBIB Pain Activities" https://www.painconsortium.nih.gov/meetings-events/quarterly-meetings
	Medical Wearables virtual, October 8, 2024 "Funding Opportunities for Medical Wearables and Diagnostic Devices" https://www.medwearablesconference.com/agenda.html
	MTEC Annual Meeting Baltimore, MD, May 22, 2024 "Partnership Opportunities"
	Maryland MedTech Summit College Park, MD, April 11, 2024 "Blueprint MedTech" https://fischellinstitute.umd.edu/event/19207/2024-maryland-medtech-summit
	REACH Investigators' Annual Meeting Bethesda, MD, January 30, 2024 "NIH Programs to Leverage for Funding Projects Post-REACH" https://seed.nih.gov/portfolio/reach
	64th Meeting of the National Advisory Council for Biomedical Imaging and Bioengineering virtual, January 23, 2024 "Blueprint MedTech Update" <u>https://videocast.nih.gov/watch=52762&start=3065</u>
	SPARC Phase 2 PI Meeting Bethesda, MD, June 14, 2023 "What Comes Next?"
	Ninth Annual BRAIN Initiative Investigators Meeting Bethesda, MD, June 13, 2023 "Meet the Funders" "Impedance Matching With the U.S. National Institutes of Health"

https://www.braininitiative.org/achievements/the-9th-annual-brain-initiative-meeting

2022 Hamlyn Symposium on Medical Robotics London, UK / virtual, July 27, 2022 "Funders Forum" https://www.hamlynsymposium.org/wp-content/uploads/2022/08/HSMR22-Proceedings-FINAL.pdf

2021 Blueprint MedTech webinar virtual, August 20, 2021 "Blueprint MedTech: Incubator Hubs" https://www.youtube.com/watch?v=WIP7jwqp__xo

2021 North American Neuromodulation Society Mid-Year Meeting Orlando, FL / virtual, July 15, 2021 "Blueprint MedTech Program Launch"

Neural Interfaces 2021: The NANS-NIC Joint Meeting virtual, June 25, 2021 "Blueprint MedTech Program Launch"

Sybert, S. (Staff Writer/Researcher), Harris, M. (Staff Writer/Researcher). (June 14, 2021). The Rapid Acceleration of Diagnostics program, or RADx, brought scalability and advancements to COVID-19 testing [Audio Podcast]. On *GovernmentCIO Media & Research Healthcast* https://governmentciomedia.com/listen-inside-program-accelerated-covid-19-testing-and-diagnostics

Temin, T. (Host and Producer). (June 9, 2020). NIH Wants to Rapidly Accelerate Diagnostic Testing for Coronavirus [Radio program]. In *Federal Drive with Tom Temin*. Washington, DC: WFED https://federalnewsnetwork.com/technology-main/2020/06/nih-wants-help-taking-a-biomedical-approach-to-coronavirus-pandemic/

2020 NIH Pain Consortium Symposium on Advances in Pain Research: Technologies for Improved Understanding and Management of Pain virtual, June 3, 2020 "Engineering the Future of Pain Treatments" https://videocast.nih.gov/watch=36039&start=8116

53rd Meeting of the National Advisory Council for Biomedical Imaging and Bioengineering virtual, May 20, 2020 "Concept Clearance: Blueprint Neurotherapeutics Program for Medical Devices" https://videocast.nih.gov/watch=36367&start=6611

2019 Cyber-Physical Systems Principal Investigators' Meeting Crystal City, VA, November 21, 2019 "Medical Cyber Physical Systems: Current Research and Future Visions" 51st Meeting of the National Advisory Council for Biomedical Imaging and Bioengineering Potomac, MD, September 11, 2019 "Concept Clearance: Translational Development and Demonstration of Devices to Prevent and Treat Opioid Misuse and Addiction"

Fifth Annual BRAIN Initiative Investigators Meeting Washington, DC, April 13, 2019 "Opportunities through the HEAL Initiative for BRAIN Investigators"

Informational Webinar for RFA-EB-18-003 Bethesda, MD, December 10, 2018 "Developing Medical Devices to Treat Pain"

2018 National Robotics Initiative (NRI) Principal Investigators' Meeting Arlington, VA, October 29, 2018 "Robotics at NIH"

2018 Project Management Symposium Silver Spring, MD, October 10, 2018 "Tolerating Risk: A Federal Research Grant Perspective"

48th Meeting of the National Advisory Council for Biomedical Imaging and Bioengineering Potomac, MD, September 13, 2018 "Concept Clearance: Affordable and Accessible Monitoring of Physiological Systems (AAMPS)"

Engineering in Medicine and Biology Conference Honolulu, HI, July 18, 2018 "SPARC Program: Mapping Autonomic Targets for Neuromodulation Therapies"

Fourth Annual BRAIN Initiative Investigators Meeting Bethesda, MD, April 9, 2018 "Getting Technologies to Researchers: How to Commercialize Research Tools"

Establishing a Research Career in Benign Urologic Conditions Bethesda, MD, February 1, 2018 "Research Opportunities at the NIBIB"

Training in Grantsmanship for Rehabilitation Research Workshop Isle of Palms, SC, January 11, 2018 "Research Opportunities at the NIBIB"

Spreading the [infrared] Light: Infrared Neuromodulation Workshop Cleveland, OH, November 30, 2017 "National Infrared Happenings (NIH)" Medical MEMS and Sensors Santa Clara, CA, November 9, 2017 "MEMS and sensor grants at NIH: a how-to guide"

American Society of Neurorehabilitation Baltimore, MD, November 8, 2017 "Grantsmanship at the NIH and the Device Research Landscape"

The Electrochemical Society Fall Meeting National Harbor, MD, October 3, 2017 Chair: "The Brain and Electrochemistry" "The Biotic/Abiotic Interface Between Neuromodulation Electrodes and the PNS"

SRC/NSF Workshop on Microsystems for Bioelectronic Medicine Washington, DC, April 12, 2017 Keynote: "100 microns: Neurons and Semiconductors"

NIH Science Day | Mentoring in Medicine Bethesda, MD, April 7, 2017 "Medical Devices"

Informational Webinar for RFA-RM-17-009 Bethesda, MD, March 27, 2017 "Stimulating Peripheral Activity to Relieve Conditions (SPARC): Technologies to Understand the Control of Organ Function by the Peripheral Nervous System"

American Society for Experimental Neurotherapeutics, Annual Meeting Rockville, MD, March 17, 2017 Chair: "Implantable Devices to Treat Disease/Disorders of the Central and Autonomic Nervous Systems" "Neuromodulation Programs at NIH"

Third Annual BRAIN Initiative Investigators Meeting Bethesda, MD, December 14, 2016 "Federal Agency Panel: Synergy of BRAIN Initiative Efforts"

National Robotics Initiative, Annual PI Meeting Crystal City, VA, November 30, 2016 "Robotics and NIH"

Working 2 Walk Symposium | Unite 2 Fight Paralysis Minneapolis, MN, October 28, 2016 Keynote: <u>"New Approaches to Restore Lost Function"</u>

Biomedical Engineering Society, Annual Meeting Minneapolis, MN, October 6, 2016 Panel: "Meet the Experts: NIH Funding" Panel: "NIH Small Business Programs" "DEBUT Awards Ceremony / NIBIB Lecture Introduction"

Bioelectronics Approaches to Personalized Medicine Cleveland, OH, September 6, 2016 "SPARC: Current and Future Directions"

NIH Training Grantees Meeting Bethesda, MD, July 11, 2016 "Implantable and Assistive Medical Devices"

NIH BCI Standards Workshop Bethesda, MD, June 30, 2016 "Doesn't Everyone Love Legos?"

Bionics Institute, Organizational Review Melbourne, VIC, Australia, April 22, 2016 "Analysis of the Bionics Institute and Recommendations to the Board of Directors"

Mayo Clinic, Brain Initiative Symposium Rochester, MN, October 10, 2015 "DARPA Biological Technologies Office Neurotechnology Portfolio"

GlaxoSmithKline, Innovation Challenge Partnering Meeting 2015 Los Angeles, CA, May 13, 2015 <u>"How Proposals Are Reviewed"</u>

Integrated Photonics Institute for Manufacturing Innovation, Reviewer Meeting Arlington, VA, March 10, 2015 "Beyond Prosthetics"

Flexible Hybrid Electronics Manufacturing Innovation Institute, Proposers Day Arlington, VA, February 19, 2015 "Peripheral Nerve Interface Technology Programs"

Hand Proprioception & Touch Interfaces (HAPTIX), Proposers Day Arlington, VA, April 30, 2014 "System Integration"

SPIE Defense, Security, and Sensing 2010 Orlando, FL, April 6, 2010 "N/MEMS: small components enable powerful microsystems"

Biomedical engineer, point of care diagnostics, over the counter diagnostics, bioinformatics, in **KEYWORDS** vitro diagnostics, IVD, sars-cov-2, covid-19, neural engineer, neuroengineer, neurotechnology, neuromodulation therapy, brain machine interfaces, BCI, brain computer interface, BMI, neural interface, medical devices, reliable neural interfaces, biotic/abiotic transducers, optical, microscale, fabrication, acoustic, microphone, audio, biosensor, sensor, transducer, mechanical, transistor, TFT, thin film, LCD, display, micromirror, thermal imager, lwir, etch, silicon, glass, LabVIEW, MATLAB, surface, bulk, micromachining, analysis, novel, systems, subsystems, integration, network, multiple disciplines, multidisciplinary, DARPA, actuator, solid-state sensors, optical devices, actuators, acoustic and biosensing transducers, thin-film transistors, micromirror displays, thermal imagers, microscale fabrication, surface and bulk micromachining, device analysis, component integration, micro gas analyzer, in-vivo biosensors, MEMS, microelectromechanical, wireless telemetry, central nervous system (CNS), peripheral nervous system (PNS), autonomous nervous system (ANS), Multidisciplinary systems engineer, Scientific and technical leader, Programmatic risk management, Wrangles complexity, Strategic & tactical landscape analysis, Change management, R&D portfolio manager, Sought-after mentor, Published author, Persuasive public speaker, Wearables, In vitro diagnostics, Solid state sensors and actuators, Atomic-scale devices, nanotech, Photonic devices, Bioinformatics, AI/ML, Display technology, Surgical tools

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