

PROFESSIONAL EXPERIENCE

Dr. Malone is internationally recognized as one of the original inventors of “DNA Vaccination.” He holds numerous fundamental domestic and foreign patents in the fields of gene delivery, delivery formulations, and vaccines, has over fifty publications, has served as an invited speaker at over thirty conferences, has chaired numerous conferences, and has sat on numerous US Federal study sections.

Dr. Malone has extensive research and clinical development experience in the areas of clinical trials design and implementation, vaccines, gene therapy, biodefense, and immunology. He has over twenty years of management and leadership experience in academia, pharmaceuticals and biotechnology. His NGO, HHS, NIH, and DoD contract and grant knowledge is extensive, and he has helped many groups and companies to capture and manage multi-million dollar awards with these sponsors, including almost 10 billion dollars won in the last five years. Dr. Malone has superior leadership skills, and has often brought diverse teams together to tackle complex problems, and develop innovative solutions.

In 2014, Dr. Malone built and led the initial team, under NewLink Genetics, that took the Canadian rVSV-ZEBOV-G Ebola vaccine from an abandoned vaccine candidate to funding in the 100 million USD range. He led the team that implemented effective stockpiling strategies, project planning and clinical trials development for dosing strategies. He also set up the initial acquisition talks between Merck Vaccine and Newlink, which led to the sale, research collaboration, and successes of the development of the rVSV-ZEBOV-G Ebola vaccine.

In 2016, Dr. Malone started a new company: Atheric Pharmaceutical, LLC. Atheric™ Pharmaceutical LLC is a biopharmaceutical company focused on the rapid development and commercialization of re-purposed drugs to prevent and treat Zika and other Flavivirus disease. Atheric's lead drug products are reformulated broad spectrum antiviral drugs that inhibit autophagy-dependent viral replication as well as other virus-cell interactions. Atheric is committed to providing broad-spectrum medical countermeasures for Zika and other neglected tropical diseases. Provisional patents for these indications have been filed with the USPTO. The lead drug candidates are approved or allowed by FDA/EMA for use during pregnancy, and cross the placenta enabling clinically significant pharmacodistribution to both mother and fetus. While CEO of Atheric, Dr. Malone has led research teams that have conducted an extensive analysis of drug compounds –working closely with USARIID, published two papers in PLoS NTD, have three more papers on Zika in preparation, has filed nine patents with due diligence performed for field of use, conducted in-vitro screening of compounds, and has identified lead drug candidates for prophylactic and therapeutic indications.

Dr. Malone is licensed to practice medicine in the state of Maryland, USA and holds a Doctorate of Medicine from Northwestern University Medical School.

He graduated from Harvard Medical School, Global Clinical Scholars Research Training Program in 2016. His pathology internship was completed at UC Davis. Dr. Malone has served as Adjunct Associate Professor of Biotechnology at Kennesaw State University, as faculty (Associate Professor) at the Uniformed Services University of the Health Sciences, as faculty at the University of Maryland, Medical School and at UC Davis. He holds a MS from UC San Diego in Biology and a BS in Biochemistry from UC Davis.

SUMMARY OF ACCOMPLISHMENTS / SKILLS

- A senior executive and scientist with a highly successful track record of leading bench and discovery research through FDA Phase I, II, and III clinical trials, protocol development and submission, and related regulatory submissions including pIND and IND.
- Significant expertise in drug development and delivery.
- Experienced capturing and managing large federal contracts (including BARDA) with over 9 billion in ID/IQ awards and 562 million government contracts won and/or managed in the last five years.
- Domestically trained, Maryland Licensed Physician/Scientist.
- Expertise in pathology, infectious disease, pandemic clinical trials, influenza, regulatory affairs, project management, biodefense, HIV and Ebola.
- Significant expertise with federal contracting, grants, international NGO health related research and development coupled with professional relationships at CDC, DoD, HHS (BARDA, CDC, FDA and NIAID).
- Prior and current service on many federal study sections and oversight boards involving infectious disease, vaccine, and biodefense.
- Experienced Business Development Professional, project manager, capture/proposal manager, color team reviewer and editor for projects valued from 10M\$ up to 1B\$ US, with experience managing processes and teams in a wide variety of non-profit and for-profit corporate cultures including both matrix and traditional environments.
- Highly skilled in fostering a culture of innovative problem solving within project teams.
- DoD Secret Clearance authorized.
- Graduated from the Harvard Medical School Global Clinical Scholars Research Training Program, a year-long program focused on international clinical research. This program combines on-site (London & Boston) as well as distance learning, with an average of 15h per week lecture and practicum exercises. The 2016 class included approximately 150 other MD and PhD-level participants from around the world.

WORK EXPERIENCE

Atheric Pharmaceutical, LLC.

CEO, and Co-founder.

Feb 2016-present. Atheric™ Pharmaceutical LLC is a biopharmaceutical company focused on the rapid development and commercialization of re-purposed drugs to prevent and treat Zika and other Flavivirus disease.

RW Malone MD, LLC

CEO and Consultant 2001-Present

Proposal development, strategic leadership, partnership development, Consulting services in Government Contracting Consulting services in Commercial Intelligence and due diligence, FDA Phase I, II, and III clinical trials, protocol development and submission, and related regulatory submissions including pIND and IND. Provided business development, proposal management, clinical development and medical affairs support for vaccines-related business operations

Projects include:

- Ebola vaccine project for NewLink/Bioprotection Systems (rVSVdG ZEBOV vaccine project), resulting in well over 100M USD non-dilutive capital to NL/BPS. This also included working with the

World Health Organization as well as initial set up of the licensing deal to Merck Vaccines of the rVSVdG ZEBOV vaccine.

- Served as Medical Director, Beardsworth, half time position on retainer (2010 – 2013)
- Service on federal biotechnology/vaccines proposal study sections
- Served as Editor-In-Chief of Journal of Immune Based Therapies and Vaccines 2007-2012
- Service on Safety Monitoring Committee, Phase 1 safety/immunogenicity of novel Influenza vaccine
- Consulting support for multiple vaccine-focused clinical sites in US and Latin America
- Served as Medical Director, Vaccines with Accelovance, Inc. (2008 – 2009)
- Served as medical monitor for multiple seasonal and pandemic (H1N1) studies
- Reviewed and edited clinical protocols
- Examples of multi-year contract clients include Accelovance, Avancer, Beardsworth, Chesapeake Perl, Corium, ITS, ITT-Exelis, EpiVax, Jean Brown Research, Quest Diagnostics (Focus), PaxVax, SAI, Soligenix, TASC, Univ of MA.
- Commercial intelligence work for two of the largest pharmaceutical companies in the world (sub-contractor).
- Partnering with Galloway and Associates (Darrell Galloway) 2012-2014
- Acting as *Managing Director, Clinical Development and Government Affairs* for the Avancer Group. April 2012 – 2016.
- Proposal development (patch-based vaccine delivery, Tularemia vaccine, CDC contract for clinical trials site development, international government and NGO contract and grant solicitations) – Aeras Global TB Vaccine Foundation 2003-2005
- Proposal development (plague vaccine- HHS), Technical diligence – VaxGen Corporation
- Consulting services for EpiVax, 2005-present (member, Scientific Advisory Board)
- Consulting services for Aldevron, LLC 2001-2005 (operating as Gene Delivery Alliance)
- Business and proposal development in the areas of Bioinformatics and Life Sciences (including telemedicine) and research at the University of Bern, Switzerland
- Consulting services for Molecular Histology, Inc. with the title of Medical Director
- Consulting services for MSD, Inc. for business/ technology development planning

Kennesaw State University

Adjunct Associate Professor 2009-2013

Beardsworth Consulting Group, Inc

Medical Director, Vaccines (RW Malone MD, LLC under contract to Beardsworth)

2010-2013

Dr. Malone functioned as the in-house medical vaccine expert for medical monitoring and Scientific Liaison

- Medical liaison to investigator sites including oversight of clinical monitoring
- Provided medical monitoring input including CRF review, 24x7 accessibility to site personnel, assess enrollment waiver requests, SAE review, etc.
- Safety Officer and Medical Representative on project teams
- Medical consultant to clients
- Business development/proposal writing/government contracting

Solvay Pharmaceuticals, Inc (currently Abbvie)

Director, Clinical Development/Medical Affairs, Influenza 2006-2007

Led an extended clinical team (both internal and CRO components), providing project and clinical trials management oversight, serving as primary author on clinical protocols, strategic documents including clinical development plans, DSMB/SMC charters, and all clinical documents required to support IND filing Support and review of outcomes including safety data assessment

Generated and managed cost projections and budgetary oversight, providing strategic management and serving as a communication hub for clinical aspects of a \$300 million USD federal contract to develop and license a cell-based influenza vaccine

Solvay's US Government contract for cell-based influenza vaccine was terminated around the end of 2007. At which point the cell-based influenza vaccine project was dissolved.

Summit Drug Development Services

Senior Medical Director 2005-2006

Directed due diligence assessments and strategic drug development planning and prepared regulatory submissions and implemented, monitored, and analyzed clinical trials for clients (oncology, vaccines, biologicals, cell/stem cell therapies)

Primary author of three pIND, two IND, an Appendix M submission

Served as proposal manager and primary author for a 129M USD federal contract submission focused on pandemic influenza.

AERAS Global TB Vaccine Foundation

Director, Business Development and Program Management 2004-2005

Initially serving as consultant, provided leadership primarily focused on tuberculosis vaccine development and proposal development to NGO (B&M Gates), USG (CDC, NIH, DoD).

Dynport Vaccine Company, LLC

Associate Director, Clinical Research 2002-2003

- Served as liaison between product development teams and clinical research support groups
- Prepared planning documents and product development plans
- Participated in and supported safety review and assessment of smallpox vaccine product.
- Identified new technologies relevant to product development teams, facilitating integration of same in product development plans
- Created documents for clinical trials including investigator brochures. Prepared proposal solicitations, technical review of subcontractor proposals. Performed technical review of potential subcontractors, new technologies
- Assisted business development group in strategic evaluation and planning concerning new business opportunities and managed in-house Publication

Intradigm, Corp

Co-Founder (one of three co-founders), CSO, Board of Director Member 2000-2001

- Helped to secure \$2.3 million in V.C. funding, including monies from the Novartis Venture Fund, ETP Venture Capital Fund and the State of Maryland
- Performed facilities set-up, infrastructure set-up and Intellectual Property Development
- Business and technology development planning, including in-depth business and scientific plan

USUHS

Dept of Surgery, Clinical Breast Care Program (CBCP) through the Henry M. Jackson Foundation

Chief of Laboratory Science and Director of Tissue Banking 2000-2001

- Worked closely with architect firm to design space, set-up laboratory facilities for the Clinical Breast Care Project, including new facilities design (tissue banking facilities, laboratory, animal rooms, animal surgical suite, office suites) at USUHS and Windber Medical Center, PA
- Hired faculty, technicians, staff for CBCP at both sites, including writing and initiating job descriptions, job interviews, hiring decisions, set-up for re-locations
- Laboratory Supervisor: Tissue banking immunology, cell culture, gene transfer, genetic vaccination research, animal research
- Set-up equipment and laboratory purchases, including vendor price quotes, equipment specs
- Wrote initial budgets and supervised equipment purchases; wrote animal protocols and grants

University of Maryland, Baltimore School of Medicine, Dept. of Pathology

Assistant Professor 1997-2000

Set-up and ran successful research laboratory in immunology (genetic vaccination) and gene transfer.

University of California, Davis Department of Medical Pathology

Assistant Professor 1993-1997

Director and Founder, Gene Therapy Program (pulmonary, dermal, heart, liver, mucosal and parenteral vaccines)

Medical Pathology, UC Davis Medical

Research Fellow, Pathology Resident 1991-1993

Vical, Inc

Research Scientist 1989

- Set up Vical's molecular biology laboratory
- Initiated and carried out research in non-viral gene therapy and DNA vaccination
- Inventor of "naked DNA" gene therapy. (see issued patents for details)
- Inventor of DNA vaccination (see issued patents for details)

TEACHING EXPERIENCE

Kennesaw State University

Associate Professor:

BTEC 4490 Experimental Design and Analysis (2009): Survey course focused on advanced product development and regulatory aspects of biotechnology and vaccines products.

University of Maryland, Medical School

Assistant Professor:

Fundamentals of Molecular Biology (Graduate Course, Winter 2000)

Host defenses and Infectious Diseases, small group instructor Year 2 Medical School core curriculum. 1998, 1999

University of California, Davis

Assistant Professor:

MD 410A/410B. General Systemic Pathology (1992, 1993, 1994, 1995, 1996)

PTX 202. Principles of Pharmacology and Toxicology-Lecturer (1995, 1996)

BCM 214-414. Molecular Medicine-Lecturer (1995, 1996)

IM 295 Cytokines-Lecturer (1996)

IDI 280. Molecular Basis of Disease-Lecturer (1996)

University of California, San Diego

Biology 111. Cell Biology (Fall 1988). Teaching Assistant under Dr. M. Montal

Biology 123. Embryology laboratory (Spring 1988). Teaching Assistant under Dr. C.Holt

Santa Barbara City College

Computer Laboratory (Spring 1981) Teaching Assistant

PROFESSIONAL OFFICES AND MEMBERSHIPS

- American Society of Tropical Medicine and Hygiene Member (ASTMH): 2016-present
- Harvard Medical School Alumni
- Virginia Bio: 2016-present
- IEEE Genomics and Bioinformatics Working Group Member: 2002
- Northern Virginia Technology Council BioMedTech Committee: Co-chair: 2002 – 2003
- Intradigm, Corp. – a new start-up from Novartis, Inc.: Scientific Advisory Board: 2000 – 2001
- Novartis, Inc. (GTI/Systemix & Pharmacokinetics): Scientific Advisory Board and External Portfolio Reviewer: 1999 – 2001
- University of Maryland, Medical School: Pathology Education Policy Committee: 1999 – 2000
- UC Davis:
 - Education Policy Committee Graduate Group in Comparative Pathology: 1996 – 1/1997
 - Member, Biochemistry and Molecular Biology Graduate Group: 1993 – 1/1997
 - Member, Comparative Pathology Graduate Group: 1995 – 1/1997
- Boehringer Mannheim: Scientific Advisory Board: 1992 – 1993

EDUCATION

- HARVARD MEDICAL SCHOOL *Global Clinical Scholars Research Training Program*
A year-long comprehensive program that combines on-site (London, Boston) and distance learning, with an average of 15h per week lecture and practicum exercises. 2015-2016.
- UC DAVIS, RESEARCH FELLOWSHIP, funded by Bank of America- Giannini Foundation Medical Research: 1992 – 1993
Postgraduate Fellowship Award
- UNIVERSITY OF CALIFORNIA, DAVIS, MEDICAL CENTER: 1992
Clinical Pathology Internship

- NORTHWESTERN UNIVERSITY MEDICAL SCHOOL: 1991
Doctor of Medicine
- UNIVERSITY OF CALIFORNIA, SAN DIEGO: 1988
Master of Science, Biology
- UNIVERSITY OF CALIFORNIA, DAVIS: 1984
Bachelor of Science, Biochemistry

LICENSURE / CERTIFICATIONS

Physician and Surgeon, State of Maryland License 1997-present. #DOO55466

SPECIALTY POSTGRADUATE COURSEWORK

- Walter Reed Healthcare System, Department of Clinical Investigation: Research Course: 2000
- USUHS: Rodent Handling and Techniques Laboratory: 2000
- USUHS: Animal Protocol Writing Workshop: 2000
- University of Maryland: CIPP 909 Research Ethics: 1999
- University of Maryland: Primate Handling Course: 1999
- University of Maryland: Biohazard US Training Course: 1999
- University of Maryland: Chemical Training Course: 1999
- University of Maryland: Radiation Training Course: 1999
- Anne Arundel Community College: Computer Programming in C: 1999
- Bowdoin College: Annual Course in Flow Cytometry: 1998
- University of Maryland Office of Human Resource Services: "The Magic of Conflict" Conflict Management Workshop: 1998
- University of California, Davis: Laboratory Animal Handling Course: 1994 – 1997
- University of California, Davis: Biohazard US Training Courses: 1994 – 1997
- University of California, Davis: Chemical Training Courses: 1994 – 1997
- University of California, Davis: Radiation Training Courses: 1994 – 1997

EDITORIAL BOARDS

- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, for "Congressionally Directed Medical Research Programs (DMRDP). 2012
- Editor-In-Chief, Journal of Immune Based Therapies and Vaccines. 2009 – 2012, Editor: 2012-present
- Committee member and reviewer for NIH/NAIAD Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines. 2011
- Chair and reviewer for NIH/NAIAD: Partnerships in Biodefense Immunotherapeutics. 2011
- NIH/NAIAD Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel. 2010
- Gene Therapy/Molecular Biology International Society. 1997 – 2014

Reviewer for:

- Numerous peer-reviewed journals on infectious disease, public health 2016

- Nucleic Acids Research: 2001 – 2002
- Molecular Therapy: 1999 – 2001
- NIH Study Section K01 Breast Cancer Study Section: July 1997
- NIDDK Special Emphasis Panel Review Committee for Competing Continuation Program Project: April 1999 and April 1998
- NIAID Study Section “Innovative Grant Program for Approaches in HIV Vaccine Research”: June 1998

ACADEMIC HONORS

- DNA Vaccine Recognizes Robert W. Malone, MD, MS, 2013
- Trainee Investigator Award, American Federation for Clinical Research: 1993
- Bank of America – Giannini Foundation Medical Research Fellow: 1992 – 1993
- Henry Christian Award for Excellence in Research, American Federation for Clinical Research: 1992
- UCDCM Medical Scholars Grant: 1992 – 1993
- First Place, Northwestern AOA Research Symposium Competition for Medical Students: 1989
- USPHS Pre-Doctoral Fellowship: 1986 – 1988
- San Diego Supercomputer Grant for RNA Structure Modeling: 1988
- Northwestern University MD/ PhD Scholarship: 1984 – 1986
- Dean's List, UC Davis: 1982 – 1984
- President's Undergraduate Fellowship Grant for Investigation of Oncogene Expression in Breast Tumor Tissue: 1983 – 1984
- Edmonson Summer Fellowship, Department of Pathology, UC Davis Medical School: 1984

PATENTS SUBMITTED:

Application No.	Filing Date	Title	MLB Docket No.
62/289,214	1/30/16	“Use of Anti-Malarial Compounds for Prevention or Treatment of ZIKV Infection and Disease”	11985-5003
62/292,296	2/6/16	“Use of Anti-Malarial Compounds for prevention or Treatment of ZIKV Infection”	11985-5004
62/294,355	2/12/16	“Methods for Preventing Guillain-Barre Syndrome and/or Microcephaly”	115985-5001
62/301,147	2/29/16	“Methods for Preventing Diseases of the Central Nervous System”	115985-5002
62/304,211	3/5/16	“Methods for Preventing Diseases of the Central Nervous System”	11985-5005
62/304,214	3/5/16	“Methods for Preventing Diseases of the Central Nervous System”	11985-5006
62/330,142	4/30/16	“Compositions of Matter and Methods for Preventing Infection and Disease Caused by Arbovirus”	11985-5007

Application No.	Filing Date	Title	MLB Docket No.
62/357,923	7/1/16	“Methods of Use of Piperaquine Metabolites”	115985-5009

PATENTS ISSUED:

1. Lipid-mediated polynucleotide administration to deliver a biologically active peptide and to induce a cellular immune response. Felgner P, Wolff J, Rhodes GH, Malone RW, Carson D. US Pat. Ser. No. 7,250,404. issued 7/31/07
2. Lipid-mediated polynucleotide administration to reduce likelihood of subject's becoming infected. Felgner P, Wolff J, Rhodes, Malone RW, Carson D. US Pat. Ser. No. 6,867,195. issued 3/15/05
3. Generation of an immune response to a pathogen. Felgner P, Wolff J, Rhodes GH, Malone RW, Carson D. US Pat. Ser. No. 6,710,035. issued 3/23/04
4. Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human Felgner P, Wolff J, Rhodes GH, Malone RW, Carson D. US Pat. Ser. No. 6,673,776. issued 1/6/04
5. Methods of delivering a physiologically active polypeptide to a mammal. Felgner P, Wolff J, Rhodes GH, Malone RW, Carson D. US Pat. Ser. No. 6.413.942 issued 7/2/02
6. Induction of a protective immune response in a mammal by injecting a DNA sequence. Felgner P, Wolff J, Rhodes GH, Malone RW, Carson, DA. US Pat. Ser. No. 6,214,804 issued 4/10/01
7. DNA vaccines for eliciting a mucosal immune response. Malone, RW. and Malone, JG US Pat. Ser. No. 6,110,898 issued 8/29/00
8. Formulations and methods for generating active cytofectin: polynucleotide transfection complexes Nantz M, Bennett M, Balasubramaniam RP, Aberle AM, Malone RW. US Pat. Ser. No. 5,925,623 7/20/99
9. Cationic Transport Reagents. Bennett M, Nantz M, and Malone RW. US Pat. Ser. No. 5,892,071 issued 4/06/99
10. Polyfunctional cationic cytofectins, formulations and methods for generating active cytofectin: polynucleotide transfection complexes. Nantz M, Bennett M, Balasubramaniam RP, Aberle AM, Malone RW. US Pat. Ser. No. 5,824,812 issued 10/20/98
11. Cationic Transport Reagents. Bennett M, Nantz M, and Malone RW. US Pat. Ser. No. 5,744,625 issued 4/28/98
12. Generation of antibodies through lipid mediated DNA delivery. Felgner P, Wolff J, Rhodes GH, Malone RW, Carson, DA. US Pat. Ser. No. 5,703,055. issued 12/30/97
13. Induction of a protective immune response in a mammal by injecting a DNA sequence. Felgner P, Wolff J, Rhodes GH, Malone RW, Carson, DA. US Pat. Ser. No. 5,589,466. issued 12/31/96
14. Delivery of exogenous DNA sequences in a mammal . Felgner P, Wolff J, Rhodes GH, Malone RW, Carson, DA. US Pat. Ser. No. 5,580,859. issued 12/3/96
15. Cationic Transport Reagents. Bennett M, Nantz M, and Malone RW. US Pat. Ser. No. 5,527,928. issued 6/18/96

PUBLICATIONS

1. Malone RW, Soloveva V, Bulitta JB, Jiao Y, Glasspool-Malone J, Dean N, et al. Accelerated Discovery and Development of Re-purposed Licensed Drugs for Zika Virus Prophylaxis and Therapy Science Translational Medicine. 2016; In Preparation.

2. Schneider AB, Malone RW, Guo J, Homan J, Linchangco G, Witter Z, et al. Molecular evolution of Zika virus as it crossed the Pacific to the Americas. *Cladistics*. 2016; 12: 10.1111/cla.12178
3. Malone RW, Homan J, Callahan MV, Glasspool-Malone J, Damodaran L, Schneider Ade B, et al. Zika Virus: Medical Countermeasure Development Challenges. *PLoS Negl Trop Dis*. 2016;10(3):e0004530.
4. Klase ZA, Khakhina S, Schneider Ade B, Callahan MV, Glasspool-Malone J, Malone R. Zika Fetal Neuropathogenesis: Etiology of a Viral Syndrome. *PLoS Negl Trop Dis*. 2016;10(8):e0004877.
5. Homan J, Malone RW, Darnell SJ, Bremel RD. Antibody mediated epitope mimicry in the pathogenesis of Zika virus related disease. *PLoS Negl Trop Dis*, submitted to (preprint in bioRxiv). 2016.
6. De Groot AS, Einck L, Moise L, Chambers M, Ballantyne J, Malone RW, et al. Making vaccines "on demand": a potential solution for emerging pathogens and biodefense? *Hum Vaccin Immunother*. 2013;9(9):1877-84.
7. Byrnes CK, Malone RW, Akhter N, Nass PH, Wetterwald A, Cecchini MG, et al. Electroporation enhances transfection efficiency in murine cutaneous wounds. *Wound Repair Regen*. 2004;12(4):397-403.
8. Glasspool-Malone J, Steenland PR, McDonald RJ, Sanchez RA, Watts TL, Zabner J, et al. DNA transfection of macaque and murine respiratory tissue is greatly enhanced by use of a nuclease inhibitor. *J Gene Med*. 2002;4(3):323-2.
9. Glasspool-Malone J, Steenland P, McDonald RJ, Sanchez RA, Watts TL, Zabner J, et al. Marked enhancement of macaque respiratory tissue transfection by aurointricarboxylic acid. *J Gene Med*. 2002;4(3):323-2.
10. Glasspool-Malone J, Malone RW. Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields. *Methods Enzymol*. 2002;346:72-91.
11. Drabick JJ, Glasspool-Malone J, King A, Malone RW. Cutaneous transfection and immune responses to intradermal nucleic acid vaccination are significantly enhanced by in vivo electropermeabilization. *Mol Ther*. 2001;3(2):249-55.
12. Somiari S, Glasspool-Malone J, Drabick JJ, Gilbert RA, Heller R, Jaroszeski MJ, et al. Theory and in vivo application of electroporative gene delivery. *Mol Ther*. 2000;2(3):178-87.
13. Glasspool-Malone J, Somiari S, Drabick JJ, Malone RW. Efficient nonviral cutaneous transfection. *Mol Ther*. 2000;2(2):140-6.
14. Colosimo A, Goncz KK, Holmes AR, Kunzelmann K, Novelli G, Malone RW, et al. Transfer and expression of foreign genes in mammalian cells. *Biotechniques*. 2000;29(2):314-8, 20-2, 24 passim.
15. Kisich KO, Malone RW, Feldstein PA, Erickson KL. Specific inhibition of macrophage TNF-alpha expression by in vivo ribozyme treatment. *J Immunol*. 1999;163(4):2008-16.
16. Glasspool-Malone J, Malone RW. Marked enhancement of direct respiratory tissue transfection by aurointricarboxylic acid. *Hum Gene Ther*. 1999;10(10):1703-13.
17. Berlyn KA, Ponniah S, Stass SA, Malone JG, Hamlin-Green G, Lim JK, et al. Developing dendritic cell polynucleotide vaccination for prostate cancer immunotherapy. *J Biotechnol*. 1999;73(2-3):155-79.
18. Ahearn A, Malone RW. Models of Cationic Liposome Mediated Transfection. *Gene Therapy and Molecular Biology* (Dec., 1999) Vol 4. *Gene Therapy and Molecular Biology* 1999;4.
19. Malone JG, Bergland PJ, Liljestrom P, Rhodes GH, Malone RW. Mucosal immune responses associated with polynucleotide vaccination. *Behring Inst Mitt*. 1997(98):63-72.
20. Bennett MJ, Aberle AM, Balasubramaniam RP, Malone JG, Malone RW, Nantz MH. Cationic lipid-mediated gene delivery to murine lung: correlation of lipid hydration with in vivo transfection activity. *J Med Chem*. 1997;40(25):4069-78.
21. Montbriand PM, Malone RW. Improved method for the removal of endotoxin from DNA. *J Biotechnol*. 1996;44(1-3):43-6.

22. Freedland SJ, Malone RW, Borchers HM, Zadourian Z, Malone JG, Bennett MJ, et al. Toxicity of cationic lipid-ribozyme complexes in human prostate tumor cells can mimic ribozyme activity. *Biochem Mol Med.* 1996;59(2):144-53.
23. Bennett MJ, Aberle AM, Balasubramaniam R, P., Malone JG, Nantz MH, Malone RW. Considerations for the design of improved cationic amphiphile-based transfection reagents. *Journal of Liposome Research* 1996;6(3):545-65.
24. Balasubramaniam RP, Bennett MJ, Aberle AM, Malone JG, Nantz MH, Malone RW. Structural and functional analysis of cationic transfection lipids: the hydrophobic domain. *Gene Ther.* 1996;3(2):163-72.
25. Aberle AM, Bennett MJ, Malone RW, Nantz MH. The counterion influence on cationic lipid-mediated transfection of plasmid DNA. *Biochim Biophys Acta.* 1996;1299(3):281-3.
26. Schenborn E, Oler J, Goiffon V, Balasubramaniam R, Bennett M, Aberle A, et al. Tfx-50 Reagent, a new transfection reagent for eukaryotic cells. 1995.
27. Hickman MA, Malone RW, Sih TR, Akitad GY, Carlsson DM, Powelle JS. Hepatic gene expression after direct DNA injection. *Advanced Drug Delivery Reviews.* 1995;17(3):265-71.
28. Bennett MJ, Malone RW, Nantz MH. A flexible approach to synthetic lipid ammonium salts for polynucleotide transfection. *Tetrahedron Letters.* 1995;36(13):2207-10.
29. Bennett MJ, Nantz MH, Balasubramaniam RP, Gruenert DC, Malone RW. Cholesterol enhances cationic liposome-mediated DNA transfection of human respiratory epithelial cells. *Biosci Rep.* 1995;15(1):47-53.
30. Malone RW, Hickman MA, Lehmann-Bruinsma K, Sih TR, Walzem R, Carlson DM, et al. Dexamethasone enhancement of gene expression after direct hepatic DNA injection. *J Biol Chem.* 1994;269(47):29903-7.
31. Hickman MA, Malone RW, Lehmann-Bruinsma K, Sih TR, Knoell D, Szoka FC, et al. Gene expression following direct injection of DNA into liver. *Hum Gene Ther.* 1994;5(12):1477-83.
32. Dwarki VJ, Malone RW, Verma IM. Cationic liposome-mediated RNA transfection. *Methods Enzymol.* 1993;217:644-54.
33. Wolff JA, Malone RW, Williams P, Chong W, Acsadi G, Jani A, et al. Direct gene transfer into mouse muscle in vivo. *Science.* 1990;247(4949 Pt 1):1465-8.
34. Malone RW, Felgner PL, Verma IM. Cationic liposome-mediated RNA transfection. *Proc Natl Acad Sci U S A.* 1989;86(16):6077-81.
35. Malone RW. mRNA Transfection of cultured eukaryotic cells and embryos using cationic liposomes. *Focus.* 1989;11:61-8.
36. Gardner MB, Malone RW, Morris DW, Young LJ, Strange R, Cardiff RD, et al. Mammary tumors in feral mice lacking MuMTV DNA. *J Exp Pathol.* 1985;2(2):93-8.
37. Faulkin LJ, Mitchell DJ, Young LJ, Morris DW, Malone RW, Cardiff RD, et al. Hyperplastic and neoplastic changes in the mammary glands of feral mice free of endogenous mouse mammary tumor virus provirus. *J Natl Cancer Inst.* 1984;73(4):971-82.

PUBLISHED ABSTRACTS: Over 40 published

CHAIRPERSON/ORAL PRESENTATIONS BY INVITATION: Over 40 Invitations
(Only the most recent events listed)

- Chairperson, Repurposing drugs. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017.

- Accelerated Discovery and Development of re-purposed licensed drugs for Zika virus outbreak antiviral prophylaxis and therapy. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017.
- Bridging the Sciences: Zika Virus. Speaker. Zika Virus: Accelerating Development of Medical Countermeasures by Re-purposing Licensed Drugs, Emery, Atlanta, GA 1-3 May, 2016
- World Vaccine Conference. Speaker/Round table- Zika virus: Challenges for Medical Countermeasure Development Washington, DC. 29-31 March, 2016
- The World Health Organization (WHO) Consultation for Zika Virus: Research and Development. Presentation of Drug Development TPP. Geneva, Switzerland. 12-14 March, 2016
- Vaccines R&D, Keynote Speaker: Ebola Vaccine in 12 months, Global Village, and the Need for Speed. Baltimore, MD. 2-4 November, 2015
- World Vaccine Conference Speaker. Current USG contracting Opportunities and Initiatives from the point of View of Vaccine Developers. Washington, DC. 24-26 March, 2014
- World Vaccine Conference Session Chair, Washington, DC. 24-26 March, 2014
Preclinical and Clinical Vaccine Research.
- Conference Organizer and Coordinator: MODELING WORKSHOP, 2013
- The World Health Organization (WHO) Global Action Plan for Influenza Vaccines. Robert W Malone, MD, MS "Vaccine Production Strategies: Ensuring Alignment and Sustainability" Geneva, Switzerland. 12-14 July 2011 Invited speaker

RECENT STUDY SECTIONS:

- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, for “Congressionally Directed Medical Research Programs (CDMRP), Defense Medical Research And Development Program (DMRDP), 2012
- Chairperson and reviewer for NIH/NAIAD Committee on Partnerships in Biodefense Immunotherapeutics, Fall 2011.
- Committee member and reviewer for NIH/NAIAD Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines, Fall 2011.
- NIH/NAIAD Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines,” Special Emphasis panel, 2010

BOOK CHAPTERS

- Malone RW. "Present and Future Status of Gene Therapy.' Intro Chapter in Advanced Gene Delivery: From Concepts to Pharmaceutical Products. Editor: Allain Rolland. Harwood Academic Pub. 1998.
- Malone RW. Toxicology of non-viral gene transfer. Editor, Walsh B. In: Non Viral Therapeutics: Advances, Challenges and Applications for Self-Assembling Systems. Boston: IBC's Biomedical Library Series. (1996) 4.1

Robert W Malone, MD, MS Five Year Performance: Grants and Contracts	Role	Year Awarded	Amount
Awarded to What a Smoke: Development of a Standardized Electronic Cigarette for Clinical Research	Capture manager, Proposal manager and Technical Proposal lead author	2016	In Negotiation
IDIQ Award to TASC by U.S. Army for Medical Product Research and Development. (W81XWH-15-D-0042)	Capture manager, lead author.	2016	\$5 Billion
Awarded to BioProtection Systems (New Link Genetics): DTRA Contract for Ebola Medical Countermeasure.	Capture manager, Proposal manager lead author.	2015	\$8 Million base, \$5.2 M option
Awarded to What a Smoke: Development of a Standardized Electronic Cigarette for Clinical Research	Proposal manager and Technical Proposal lead author.	2015	\$350,000
Award to BioProtection Systems (Newlink): contract to support the development and manufacturing of its VSV-EBOV (Ebola) vaccine candidate, including a new 330-subject Phase 1b study. Options for base grant.	Capture Manager, Proposal manager and Technical Proposal lead author.	2015	\$18 Million
Award to BioProtection Systems (Newlink): contract to support the development and manufacturing of its VSV-EBOV (Ebola) vaccine candidate, including a new 330-subject Phase 1b study.	Capture Manager, Proposal manager and Technical Proposal lead author.	2014	\$30 Million
Award to Soligenix: NIAID contract for "Development of Vaccine Formulations Effective against NIAID Priority Pathogens." (HHSN272201400039C)	Proposal manager and Technical Proposal lead author.	2014	\$24.7 Million
Awarded to Kai Research and Benchmark Research: contract for Support Annual Influenza Vaccine Serology Testing - for the CDC.	Developed the plan, assembled the team, formulated the contract and helped produce the final product.	2013	\$2.8 million base period, 5 total renewable years
IDIQ Award to Excelis: Combating Weapons of Mass Destruction Research and Technology Development from Defense Threat Reduction Agency. (HDTRA1-14-D-0005)	Capture manager, lead author for CBRN section.	2013	\$4 Billion
Awarded to Nanotherapeutics: Defense Department contract for Medical Countermeasures Advanced Development.	Original thought leader, Pre-Proposal manager and Technical Proposal lead author.	2013	\$427 million
Awarded to Soligenix: BARDA Contract (Advanced Development of OrbeShield in GI ARS)	Tech Watch: proposal development. Proposal manager and Technical Proposal lead author.	2013	\$26 million
Awarded to Vaxin: Contract by BARDA to develop next generation Anthrax Vaccine.	Proposal manager and principal scientific author.	2011	\$21 million
TOTAL Flexible IDIQ Awards		2011-2016	9 Billion
TOTAL Award Amounts (excluding IDIQ awards)		2011-2016	562 Million