IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

I TE KŌTI MATUA O AOTEAROA
TE WHANGANUI-A-TARA ROHE

CIV-2022-485-013

IN THE MATTER	of an application under the Judicial Review Procedure Act 2016
BETWEEN	**DCB**
	First to Eighth Applicants
AND	**THE MINISTER OF HEALTH**
	First Respondent
AND	**THE GROUP MANAGER OF THE NEW ZEALAND MEDICAL DEVICES SAFETY AUTHORITY (MEDSAFE)**
	Second Respondent
AND	**THE COVID-19 RESPONSE MINISTER**
	Third Respondent

AFFIDAVIT OF DR ROBERT W MALONE

Dated 22 June 2022

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Solicitor acting:
Shelley Eden

I, **ROBERT WALLACE MALONE**, Medical Doctor of Charlottesville, Virginia, United States of America, swear/affirm:

1. I am a scientist and physician and the original inventor of mRNA vaccination as a technology, DNA vaccination, and multiple non-viral DNA and RNA/mRNA platform delivery technologies.

2. I have been asked to provide my expert opinion in respect to the COVID-19 vaccine for children aged 5-11 years of age, specifically the Pfizer mRNA vaccine.

3. I have read and understood the High Court Rules Code of Conduct for Expert witnesses (schedule 4).

4. A copy of my report is annexed hereto **marked "A"**.

Sworn/Affirmed at Madison, Va)
this 21 day of June 2022)
before me: Peter Dean)

PETER DEAN
NOTARY PUBLIC
REG. 7741372
COMMONWEALTH OF VIRGINIA
MY COMMISSION EXPIRES JANUARY 31, 2025

[Person of appropriate office or occupation that is able to take oaths or affirmations in the jurisdiction that you are in at the time of swearing/affirming this affidavit]

Exhibit "A"

"A"

Robert W Malone, MD, MS

January, 2022

You have asked me to provide my expert opinion in respect to the COVID-19 vaccine for children aged 5-11 years of age, specifically the Pfizer Comirnaty mRNA vaccine.

Background and Expertise

1. I am a scientist and physician and the original inventor of mRNA vaccination as a technology, DNA vaccination, and multiple non-viral DNA and RNA/mRNA platform delivery technologies. I hold numerous fundamental domestic and foreign patents in the fields of gene delivery, delivery formulations, and vaccines: including for fundamental DNA and RNA/mRNA vaccine technologies.

2. I have approximately 100 scientific peer- reviewed publications with over 12,000 citations of my work (per Google Scholar with an "outstanding" impact factor rating)[1].

3. I have been an invited speaker at over 50 conferences, have chaired numerous conferences and have sat on and served as chairperson on the U.S. Department of Health & Human Services and U.S. Department of Defence committees.

4. I currently sit as a non-voting member on the U.S National Institute of Health Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) committee[2], which is tasked with managing clinical research for a variety of drug and antibody treatments for COVID-19.

5. I received my medical degree from the Northwestern Feinberg School of Medicine. I completed the Harvard Medical School fellowship as a global clinical research scholar in 2016 and was scientifically trained at the University of California at Davis, the University of California at San Diego, and at the Salk Institute Molecular Biology and Virology laboratories.

6. I have served as an assistant and associate professor of pathology and surgery at the University of California at Davis, the University of Maryland, and the Armed Forces University of the Health Sciences.

[1] https://scholar.google.com/citations?user=Jf1bApYAAAAJ&hl=en and General 4 — Robert W Malone MD (rwmalonemd.com)

[2] ACTIV | National Institutes of Health (NIH)

7. Since January 2020, I have been leading a large team focussed on clinical research design, drug development, computer modelling and mechanisms of action of repurposed drugs for the treatment of COVID-19.

8. I am a Medical Director of The Unity Project, a group of 300 organisations across the US standing against mandated COVID-19 vaccines for children and President of the Global Covid Summit, an organisation of over 16,000 doctors and scientists committed toCOVID-19 pandemic research and treatment.

9. For many years, my wife and I have built and run a consultancy and analytics firm, RW Malone MD, LLC: Consultancy Group[3], specializing in biotechnology and clinical trials development.

10. More recently, I have been much more public facing by hosting daily podcasts, interviews, op-eds, advocacy with legislators and until recently building a twitter feed of almost a half million people. This is in response to my concerns regarding the safety and bioethics of how the COVID-19 genetic vaccines were developed and prescribed around the world. I have now done hundreds of podcasts and interviews. I am a regular guest on many shows and have written many editorials that have been published in mainstream newspapers. Along with many other physicians and scientists advocating early treatment of COVID-19, I have toured globally to help educate physicians and the public about early treatment options while also opposing the unethical mandates.

11. On Christmas Eve I was interviewed by renowned American commentator and podcaster Joe Rogan on his show The Joe Rogan Experience which was published on 1 January 2022 https://open.spotify.com/episode/3SCsueX2bZdbFzRtKQCEyT. At the time of preparing this report, that podcast has had in excess of 52 million views.

12. I am a vaccinologist. I invented the core mRNA vaccine technology platform. I have spent much of my career working on vaccine development. I have also had extensive experience in drug repurposing for infectious disease outbreaks. I am not an antivaxxer in any way, shape or form. But I do believe that the short cuts that the United States Government have taken in bringing the mRNA and the adenovirus vaccines to market for this pandemic have been detrimental and contrary to globally accepted standards for developing and regulating safe and effective licensed products.

[3] https://www.researchgate.net/lab/RW-Malone-MD-LLC-Consultancy-Group-Robert-Malone

13. I hold the nine original mRNA vaccine patents which were originally filed in 1989 and have been deeply involved in the development of mRNA vaccines (including both the idea of mRNA vaccines and the original proof of principle experiments) and RNA transfection). However, I believe I may be the only inventor and developer that does not have a financial stake in their development and distribution.

14. I have had a career dedicated to vaccine research and development. I'm vaccinated for COVID-19 and I am generally pro-vaccination. I have devoted my entire career to developing safe and effective ways to prevent and treat infectious diseases.

15. A copy of my current CV is **Attachment 1** to this Report.

16. I confirm that I have read, understood and will comply with the expert code of conduct of the High Court of New Zealand[4].

Expert Opinion

17. I have been asked to give my expert opinion on vaccinating the 5-11 year old age group with the Pfizer mRNA vaccine technology.

18. The mRNA COVID-19 vaccines are genetic vaccines, which are based on mRNA gene therapy technology that I created.

19. Not listed in my above qualifications but important to that which I have been asked to opine upon is that I am also a father and grandfather. I would not and could not recommend that my children, or my grandchildren receive a novel mRNA vaccine for COVID-19 at this time.

20. Vaccination with the Pfizer mRNA vaccine is irreversible and potentially permanently damaging, and is something to be cautiously considered by any parent or guardian when vaccinating a child, children or adolescent/s.

21. I strongly believe that healthy children should not be vaccinated for COVID-19 and this is a view shared by more than 15,000 physicians and medical scientists around the world who have signed a declaration publicly declaring the same https://gbdeclaration.org/.

Children are not at risk from COVID-19

22. The risk of death associated with COVID-19 in healthy children is virtually non-existent, as children have significant immunologic advantages relative

[4] https://www.legislation.govt.nz/regulation/public/2016/0225/latest/DLM6953324.html

to the older adult population (> 65 years) which comprises the high risk cohort for COVID-19[5].

23. While there have been virtually no healthy children die from COVID-19 in the U.S., the 700+/- children that have died *with* COVID-19 over the last two years have all had significant pre-existing health issues. They died *with* COVID-19 not *from* COVD-19.[6]

24. New data shows that, compared with adults, children infected by SARS-CoV-2 preferentially activate pre-existing immunity to endemic common-cold coronaviruses that are cross-reactive with SARS-CoV-2[7].

25. Further, the new COVID-19 variant Omicron (discussed further below), the risk of death and disease in children of COVID-19 has become even more rare.[8]

26. Healthy children are not at risk of COVID 19.

Risk / Benefit Ratio

27. The risk benefit ratio to vaccinating children is upside down compared with adults. The risk of death from COVID-19 decreases as age decreases, such that the risk/benefit analysis is not even close with this vaccine for children.

[5] Viner, R. M. et al. Susceptibility to SARS-CoV-2 infection among children and adolescents compared with adults: a systematic review and meta-analysis. *JAMA Pediatr.* **175**, 143–156 (2021) https://jamanetwork.com/journals/jamapediatrics/fullarticle/2771181, https://rwmalonemd.substack.com/p/covid-19-today, https://www.sciencedirect.com/science/article/pii/S221475002100161X?via%3Dihub#sec0175

[6] https://rwmalonemd.substack.com/p/covid-19-today

[7] As of 22 December 2021, https://www.nature.com/articles/s41590-021-01089-8

[8] https://rwmalonemd.substack.com/p/covid-19-today

Table 3. Model-estimated deaths attributed to COVID vaccination for each age group and month using US CDC data. Significant beta weight coefficients ($^{\beta}$) in Table 2 surviving p<0.05 FDR corrected were used to estimate VFR and total deaths for each age group and month. If a model using same (not previous) month vaccinations was significant and the equivalent models using previous month was not, then death estimates from those models were used instead (light gray boxes). Similarly, if a model using age-specific vaccination (i.e. doses administered to people >65 yrs) was significant and the equivalent model using all vaccine doses administered was not, then death estimates from those models were used instead (dark gray boxes). See methods for VFR and aVFR definitions and calculations. ns=not significant at p<0.05 FDR corrected. NA=Not available.

Model-estimated deaths

Ages	Jan	Feb	March	April	May	June	July	Aug	Totals	aVFR (%)
0-17	NA	ns	ns	ns	ns	ns	648	1,227	1,875	0.004
18-29	NA	ns	ns	ns	1,355	861	2,139	ns	4,355	0.005
30-39	NA	ns	ns	ns	ns	1,101	2,422	2,567	6,090	0.009
40-49	NA	ns	ns	ns	ns	ns	3,067	3,979	7,046	0.017
50-64	NA	ns	ns	ns	ns	ns	ns	ns	0	0.016*
65-74	NA	ns	ns	ns	ns	ns	ns	ns	0	0.036*
75-84	NA	ns	ns	41,316	ns	ns	ns	ns	41,316	0.060
85-plus	NA	11,613	13,181	48,186	13,326	ns	ns	ns	86,306	0.055
								Total	146,988	

 # Vaccine dose administered

Vax all ages	2.65E+07	4.60E+07	7.63E+07	8.04E+07	5.25E+07	3.15E+07	1.82E+07	2.46E+07	364,881,407
Vax >65 yrs	NA	NA	NA	1.49E+07	4.83E+06	3.05E+06	1.90E+06	2.83E+06	26,594,886
Vax <65 yrs	NA	NA	NA	7.54E+07	4.77E+07	2.84E+07	1.63E+07	2.17E+07	189,569,231
								VFR	0.04%

Light gray indicates models estimated using same, not previous, month vaccinations

Dark gray indicates models estimated using vaccines administered > ages 65

Light blue indicates significant results when predicting deaths in ages <1 years. Model estimated 867 infant deaths (see Supplementary Results).

*Robust regression did not yield significant results in these age groups. Thus these estimates were derived from results of standard least-squares regression.

[9]

28. Prior to the advent of Omicron, a peer reviewed study clearly demonstrated (using safety data accumulated during past variant circulation) that the genetic COVID-19 vaccines carry a risk/benefit ratio of five deaths in the older, high risk cohort for every one life saved from COVID-19 (and that data did not account for the reporting bias inherent in U.S. deaths due to COVID-19 consequent to inappropriate use of PCR tests).[10] The authors go on to say:

> *"Thus, our extremely conservative estimate for risk-benefit ratio is about 5/1. In plain English, people in the 65+ demographic are five times as likely to die from the inoculation as from COVID-19 under the most favorable assumptions! This demographic is the most vulnerable to adverse effects from COVID-19. As the age demographics go below about 35 years old, the chances of death from COVID-19 become very small, and when they go below 18, become negligible."*

[9] https://www.researchgate.net/publication/355581860_COVID_vaccination_and_age-stratified_all-cause_mortality_risk

[10] See "Why are we vaccinating children against COVID-19?" Toxicology Reports, Volume 8, 2021, Pages 1665-1684 - https://www.sciencedirect.com/science/article/pii/S221475002100161X?via%3Dihub#sec0175

29. There is no benefit for either children, or their families, for children to be vaccinated against the small risks of the COVID-19 virus.

30. Governments and health organisations worldwide are sending the same message; children need to be vaccinated to protect their parents and grandparents. In fact the opposite is true, children represent no danger to their parents or grandparents as children's innate immunity is very effective, it confers immunity after infection such that it acts as a buffer against continued transmission of COVID-19. Their immunity, after getting COVID-19, is critical to save their family if not the world from this disease.

Natural and Herd Immunity

31. The new variant of COVID-19, Omicron, has exploded in the U.S and around the world. What was already an inverted risk benefit ratio for genetic vaccination in children and adults (greater risk of death from vaccine than from COVID-19) will become even more inverted since the risks of COVID-19 are further reduced with Omicron. The Omicron variant is different in five essential ways, it is:

a. more infectious and will soon be the dominant variant in the USA and I believe worldwide;

b. less pathogenic;

c. poorly matched to currently available vaccines;

d. natural immunity is providing good protection against Omicron;

e. disease symptoms are more similar to the common cold.

32. Furthermore, I consider that Omicron will likely be an end to the pandemic as COVID-19 becomes endemic.

33. Taking from the comments of my colleagues at the Great Barrington declaration:

> *"The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk. We call this Focused Protection."*[11]

34. It is paramount that we let those that can develop a natural immunity to COVID-19 do so naturally as herd immunity will not be achieved with mRNA vaccines.

[11] https://gbdeclaration.org/

mRNA vaccines in human trials are new and the trials are inadequate

35. The mRNA vaccines are novel technology that have not been adequately tested.

36. In order for them to be properly tested, at least 5 years of testing and research is needed before we can really understand the risks associated with this new technology – the harms and risks from new medicines often only become revealed many years later.

37. The clinical trials for these vaccines were a few months, which is very short-term and were not a representative sample of the total population which means poor predicative power because of their small sample size. The clinical trials also failed to address biomarkers that could serve as early learning indicators of elevated disposition to serious disease.[12]

38. No long term effects are addressed in the trials and this is key – as any serious long term effects suffered by a child or adolescent would be borne by them for decades if not a lifetime.[13] Decreasing further their benefit in any risk/benefit analysis.

39. The issue of COVID-19 gene therapy technology-based vaccine mandates for children is a pressing issue confronting parents, grandparents, and public health officials throughout the world. Unfortunately, the topic has become highly politicized, and active censorship by legacy media outlets has made it difficult for parents and stakeholders to obtain access to the actual data required for the full informed consent prior to acceptance of a medical procedure required by law.[14] I have established a web resource containing multiple reference articles for parents, grandparents and families to review with respect to the use of mRNA vaccines in children[15], these canvass:

    a. Risk/Benefit: What is the ratio of COVID damage/risk of vaccine damage for children[16]

    b. Death Reports: Reports of vaccine-associated deaths and disability in children and young adults[17]

[12] https://www.sciencedirect.com/science/article/pii/S221475002100161X?via%3Dihub#sec0175
[13] Ibid.
[14] For example see https://odysee.com/@VSRF:d/Vaccine-Safety-Research-Foundation-TN:e
[15] https://www.rwmalonemd.com/mrna-vaccination-in-children
[16] https://www.rwmalonemd.com/risk-benefit
[17] https://www.rwmalonemd.com/deathreports

c. VAERS and Yellow Card: Safe and effective in children? National database information[18]

d. Myocarditis consequences: Is there evidence that the vaccine-associated myocarditis in children is not going to lead to long term damage?[19]

e. Applicable standards: Have normal standards for vaccine safety, quality and effectiveness in children been met?[20]

f. COVID-19 in children: What is the evidence of long term damage in children from COVID-19?[21]

g. Illegal mandates: U.S. Federal Mandate law[22]

h. References on Adverse Events[23]

i. Reuters fact-checking[24]

The potential risks of mRNA vaccines in children (adolescents and adults)

40. The very nature of an mRNA vaccine means that a viral gene will be injected into a child's cells. That gene forces the child's body to make toxic spike proteins. These proteins can cause permanent damage in critical organs, including, the:

a. brain and nervous system[25];

b. heart and blood vessels, which could cause inflammation of the heart including blood clots[26];

c. reproductive systems in both boys and girls, but predominantly girls[27].

41. The most alarming point about this is that once these damages have occurred, they are irreparable and cannot be reversed, the:

a. lesions within the brain cannot be fixed;

[18] https://www.rwmalonemd.com/vaers-and-yellow-card
[19] https://www.rwmalonemd.com/heart-blood-clotting
[20] https://www.rwmalonemd.com/standards
[21] https://www.rwmalonemd.com/long-term-damage
[22] https://www.rwmalonemd.com/illegal-mandates
[23] https://www.rwmalonemd.com/references
[24] https://www.rwmalonemd.com/reuters-factcheckers
[25] https://www.sciencedirect.com/science/article/pii/S221475002100161X?via%3Dihub
[26] https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf;
https://www.rwmalonemd.com/heart-blood-clotting
[27] https://ashmedai.substack.com/p/is-there-plausible-basis-for-fertility

b. heart tissue scarring cannot be repaired;

c. the reproductive damage could affect future generations to come.

42. Further, the mRNA vaccine can also trigger fundamental changes to children's immune systems – a genetically reset immune system cannot be repaired[28].

Mandates and COVID-19 Social Policies

43. I am against the very concept of vaccination mandates in the context of COVID-19 for all but especially for children.

Conclusion

44. There is no benefit for children or their families to vaccinate healthy children against the small risks of the virus, given the known health risks of the vaccine - as a parent, you and your children may have to live with for the rest of their lives.

45. The risk/benefit analysis for vaccination of otherwise healthy 5-11 year children with the Pfizer Comirnaty mRNA vaccine technology is not even close.

PETER DEAN
NOTARY PUBLIC
REG. 7741372
COMMONWEALTH OF VIRGINIA
MY COMMISSION EXPIRES JANUARY 31, 2025

Dr RW Malone

6/22/2022

28 https://childrenshealthdefense.org/defender/leslie-rose-mma-covid-vaccines-innate-immunity/

Attachment 1 – curriculum vitae

Robert W. Malone, MD, MS

PROFESSIONAL EXPERIENCE

Dr. Malone is a specialist in clinical research, medical affairs, regulatory affairs, project management, proposal management (large grants and contracts), vaccines and biodefense. This includes writing, developing, reviewing and managing vaccine, bio-threat and biologics clinical trials and clinical development strategies. He has been involved in developing, designing, and providing oversight of approximately forty phase 1 clinical trials and twenty phase 2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on approximately forty phase 1 clinical trials, and on twenty phase 2 clinical trials, including those run at vaccine-focused Clinical Research Organizations. He has served as principal investigator on some of these. Examples of his infectious disease pathogen advanced (clinical phase) development oversight experience include HIV, Influenza (seasonal and pandemic), Plague, Anthrax, VEE/EEE/WEE, Tularemia, Tuberculosis, Ebola, Zika, Ricin toxin, Botulinum toxin, and Engineered pathogens. In many cases, this experience has included vaccine product development, manufacturing, regulatory compliance, and testing (manufacturing release and clinical) aspects. In most cases, his oversight responsibilities have included clinical trial design, regulatory and ethical compliance, and laboratory assay strategy, design, testing and performance.

Dr. Malone has a history of assembling and managing expert teams that focus on solving complicated biodefense challenges to meet US Government requirements. He was instrumental in enabling the PHAC/rVSV ZEBOV ("Merck Ebola") vaccine to move forward quickly towards BLA and (now recently granted) licensure. Dr. Malone got the project on track in support of DoD/DTRA and NewLink Genetics, recruited organizations to team with USAMRIID/WRAIR to develop the immunoassays, put WHO and Norwegian government philanthropic leadership in touch with Pentagon leadership to expedite the initial WRAIR clinical and ring vaccination trials, recruited a management team, recruited Merck vaccines to purchase the product candidate from NewLink, helped write and edit the clinical trials developed by the World Health Organization and lead the development of the BARDA and DTRA contracts - yielding over 200M$ in resources. Dr. Malone's early involvement in this project allowed for the Merck vaccine to be developed very rapidly.

Currently, Dr. Malone is leading a large team since January 10, 2020, focused on clinical research design, drug development, computer modeling and mechanisms of action for COVID-19 treatment. This work has included multiple manuscripts summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease, and others focused on Celecoxib and Famotidine are being reviewed for publication. He has developed and wrote the initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults. Another project he has been involved with is a DTRA/DOMANE-funded development and performance of a virtual outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example. He has helped open an IND for famotidine use for treatment and

prevention of COVID19 disease including an associated drug master file, and has enabled teaming/pharmaceutical supply arrangements with two major pharmaceutical firms.

Dr. Malone has extensive research and development experience (bench to bedside) in the areas of pre-clinical discovery research, clinical trials, vaccines, gene therapy, bio-defense, repurposing drugs for infectious diseases, high throughput screening and immunology. He has over twenty years of management and leadership experience in academia, pharmaceutical and biotechnology industries, as well as in governmental and non-governmental organizations. He often serves as study section chairperson for NIAID contract study sections relating to biodefense medical product development. He is currently a topic editor for the journal Frontiers in Pharmacology, in the area of "Treating COVID-19 With Currently Available Drugs."

Scientifically trained at UC Davis, UC San Diego, and at the Salk Institute Molecular Biology and Virology laboratories, Dr. Malone is an internationally recognized scientist (virology, immunology, molecular biology) and is the original inventor of mRNA Vaccination, DNA Vaccination, and multiple non-viral DNA and RNA/mRNA delivery technologies. Dr. Malone holds numerous fundamental domestic and foreign patents in the fields of gene delivery, delivery formulations, and vaccines: including DNA and RNA/mRNA vaccines.

Dr. Malone received his medical training at Northwestern University (MD) and Harvard University (Clinical Research Post Graduate) medical schools, and in Pathology at UC Davis. Dr. Malone is currently finishing up his board certification in medical affairs (BCMAS).

Dr. Malone has approximately 100 peer-reviewed publications and published abstracts and has about 12,000 citations of his peer reviewed publications, as verified by Google Scholar. His google scholar ranking is "outstanding" for impact factors. He has been an invited speaker at over 50 conferences, has chaired numerous conferences and he has sat on or served as chairperson on numerous NIAID and DoD study sections.

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.
- Specialist in Medical Affairs.
- Special in Regulatory Affairs.
- Domestically trained, Maryland Licensed Physician/Scientist.
- Experienced capturing and managing large federal contracts (including BARDA) with over 9 billion in ID/IQ awards and almost a billion USD in government contracts won and/or managed in the last decade.
- Expertise in pathology, infectious disease, pandemic clinical trials, influenza, regulatory affairs, project management, biodefense, HIV and Ebola. A verified list of capture is available upon request.
- 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 and formally trained as a 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.
- Expert witness experience, with extensive training from some of the top attorneys/law firms in the USA.
- Graduated from the Harvard Medical School Global Clinical Scholars Research Training Program with distinction, 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.
- Dr. Malone will be board certified in medical affairs (BCMAS) by April, 2021. The BCMAS program is the certification program developed by the Accreditation Council for Medical Affairs (ACMA).
- Inventor of mRNA vaccination.

RW Malone MD, LLC
CEO and Principal Consultant: 2001-Present

Dr. Malone has been involved in developing, designing, and providing oversight of approximately forty phase-1 clinical trials and twenty phase-2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on approximately forty phase-1 clinical trials, and on twenty phase-2 clinical trials, including those run at vaccine-focused Clinical Research Organizations. He has served as principal investigator on some of these. Providing business development, proposal management, clinical trials development, expert witness, regulatory and medical affairs support for pharmaceutical, vaccines-related and biologics companies as well as related regulatory submissions including pIND and IND.

Projects include:

- Led a large team since January 10, 2020, focused on drug development, computer modeling and mechanisms of action for COVID-19 and is now preparing a manuscript summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease.
- Clinical trials protocol development: Developed and wrote initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults.
- Proposed is a DOMANE/WRAIR joint development and performance of outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example.
- Opening IND for famotidine use for treatment and prevention of COVID19 disease with associated drug master file.
- Principal Regulatory Consultant, Clinical Network Services (CNS)/Novotech, 2018-2019. Regulatory, clinical and business development support.
- Served as an expert witness with specialized training, 2017 - present.
- Ebola vaccine project for NewLink/Bioprotection Systems (rVSVdG ZEBOV Ebola 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 Ebola vaccine.
- Served as Medical Director, Beardsworth, half time position on retainer, 2010 – 2013.
- Service on federal biotechnology/vaccines proposal study sections (multiple).
- 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.
- Review and edit clinical protocols.
- Examples of multi-year contract clients include Accelovance, Alchem Laboratories, Avancer, Beardsworth, Chesapeake Perl, Corium, DOAR, ITS, ITT-Exelis, EpiVax, Jean Brown Research, Opgen, 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, 2005-2018 (member, Scientific Advisory Board), 2020.
- 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.
- Collaboration with Inovio, including incorporation of company in the USA.
- Consulting services for MSD, Inc. for business/ technology development planning.

Alchem Laboratories
Chief Medical Officer

This position was as a consultant, but then full time FTE. Consulting for Alchem and/or its CEO: 2012 – 2019. CMO 11/2019 to 4/2020.

- Led a high through-put screening and research team for drug development 2019-2020.
- Dr. Malone began modeling and focusing on the Plpro (papain-like protease) and Mpro (main protease) of then novel coronavirus (now SARS-CoV-2) using computational tools including Modeller to generate homology-modeled crystal structures for the SARS-CoV-2 Plpro and Mpro. Which generated a candidate list for COVID-19, which was reduced to a few candidates, based on binding sites, safety, licensure, efficacy, bioavailability of drug candidates.
- Lead the discovery and development of famotidine for the Treatment of COVID-19.
- Technical Lead/writer for funded full proposal under BAA-18-100-SOL-00003 Amendment 15 entitled: "A Multi-site, Randomized, Double-Blind, Multi-Arm Historical Control, Comparative Trial of the Safety and Efficacy of Hydroxychloroquine, and the Combination of Hydroxychloroquine and Famotidine for the Treatment of COVID-19 in Hospitalized Adults."
- Developed and wrote initial clinical trial design for a comparative trial of the safety and efficacy of hydroxychloroquine, and the combination of hydroxychloroquine and famotidine for the treatment of COVID-19 in hospitalized adults.

Atheric Pharmaceutical, LLC
CEO, and Co-founder.
Feb 2016-Dec 2017. Atheric™ Pharmaceutical LLC was a biopharmaceutical company focused on the rapid development and commercialization of re-purposed drugs to prevent and treat Zika and other Flavivirus disease. Optimization of high through-put screening techniques for anti-viral drug development.

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 2006-2008
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

Intradigm was a biotechnology company that develops gene therapeutic technology based on RNA interference. Intradigm merged with Silence Technologies in 2009 and the merged company is now publicly traded. Silence Technologies is involved in developmental research of targeted RNAi therapeutics for the treatment of serious diseases.

Dr. Malone co-founded and 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.

Uniformed Services University of the Health Sciences

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

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.

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

1991-1997

Assistant Professor 1993-1997

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

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).

- Inventor of "mRNA" gene therapy. Salk institute.
- Inventor of mRNA vaccination. Salk institute.

LICENSURE / CERTIFICATIONS

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

BOARD OF DIRECTOR POSITIONS:

Discovery Cure, Inc. Founding Board of Director. 2018-2020
Epivax, Scientific Advisory Board, 2012-2019.

EDUCATION

- **HARVARD MEDICAL SCHOOL** *Global Clinical Scholars Research Training Program (fellowship)*
  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. Graduation with distinction (top 5% of graduating class).

- **UNIVERSITY OF CALIFORNIA, DAVIS:** RESEARCH FELLOWSHIP, 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

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

- Harvard Medical School Alumni, 2016- present.
- American Society of Tropical Medicine and Hygiene Member (ASTMH): 2016-2018.
- Virginia Bio: 2016-2018
- 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

EDITORIAL BOARDS

- Topic Editor, Frontiers in Pharmacology (Respiratory Pharmacology): "Treating COVID-19 with Currently Available Drugs," 2020-present.
- Editor-In-Chief, Journal of Immune Based Therapies and Vaccines. 2009 – 2012, Editor: 2012.
- Gene Therapy/Molecular Biology International Society. 1997 – 2014.
- Reviewer for: Numerous peer-reviewed journals on infectious disease, public health 2016 to present.
- Nucleic Acids Research: 2001 – 2002.
- Molecular Therapy: 1999 – 2001.

ACADEMIC HONORS

- Harvard Medical School, Global Clinical Scholar Post Graduate: graduation with distinction (top 5% of graduating class).
- "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.
- UCDMC 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 ISSUED:

1. Lipid-mediated polynucleotide administration to deliver a biologically active peptide and to induce a cellular immune response. Assigned to Vical, Inc and licensed to Merck. No. 7,250,404, date of issue: 7/31/07 **Cited in 105 articles.**
2. Lipid-mediated polynucleotide administration to reduce likelihood of subject's becoming infected. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,867,195 B1, date of issue: 3/15/05.
3. Generation of an immune response to a pathogen. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,710,035, date of issue: 3/23/04. **Citations: 37 articles.**
4. Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,673,776, date of issue: 1/6/04.
5. Methods of delivering a physiologically active polypeptide to a mammal. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6.413.942, date of issue: 7/2/02. **(cited in 150 articles).**
6. Induction of a protective immune response in a mammal by injecting a DNA sequence. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,214,804, date of issue: 4/10/01. **Cited in 359 articles.**
7. DNA vaccines for eliciting a mucosal immune response. US Pat. Ser. No. 6,110,898, date of issue: 8/29/00. **Cited in 40 articles.**
8. Formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,925,623 7/20/99.
9. Cationic Transport Reagents. 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. US Pat. Ser. No. 5,824,812 issued 10/20/98.
11. Cationic Transport Reagents. US Pat. Ser. No. 5,744,625 issued 4/28/98.
12. Generation of antibodies through lipid mediated DNA delivery. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,703,055, date of issue: 12/30/97. **Cited in 463 articles.**

13. Induction of a protective immune response in a mammal by injecting a DNA sequence. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,589,466, date of issue: 12/31/96. **Cited in 889 articles.**
14. Delivery of exogenous DNA sequences in a mammal. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,580,859, date of issue: 12/3/96. **Cited in 1234 articles.**
15. Cationic Transport Reagents. US Pat. Ser. No. 5,527,928, date of issue: 6/18/96.

PUBLICATIONS (selected)

More Than Just Heartburn: Does Famotidine Effectively Treat Patients with COVID-19? Malone RW. Dig Dis Sci. 2021 Feb 24:1–2. doi: 10.1007/s10620-021-06875-w. Epub ahead of print. PMID: 33625612; PMCID: PMC7903029.

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.
Malone RW, et al DO.Res Sq. 2020 Jun 22:rs.3 rs-30934. doi: 10.21203/rs.3.rs-30934/v2. Preprint.PMID: 32702719
Submitted to Frontiers in Pharmacology, ACCEPTED January 30, 2021

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.
Malone RW, et al DO.Res Sq. 2020 Jun 22:rs.3.rs-30934. doi: 10.21203/rs.3.rs-30934/v2. Preprint.PMID: 32702719 (cited in 12 articles, downloaded 1200 times). https://www.researchsquare.com/article/rs-30934/v2

Tomera, Kevin, Malone, Robert and kittah, Joseph, Hospitalized COVID-19 Patients Treated With Celecoxib and High Dose Famotidine Adjuvant Therapy Show Significant Clinical Responses (July 8, 2020).
Available at SSRN: https://ssrn.com/abstract=3646583 or http://dx.doi.org/10.2139/ssrn.3646583
Submitted to Frontiers in Pharmacology, Accepted with minor revisions/final review, February, 2021.

Ricke, D.O.; Malone, R.W. Medical Countermeasures Analysis of 2019-nCoV and Vaccine Risks for Antibody-Dependent Enhancement (ADE). Preprints 2020, 2020030138 (doi: 10.20944/preprints202003.0138.v1). May, 2020
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3646583

Molecular evolution of Zika virus as it crossed the Pacific to the Americas. Schneider AB, Malone RW, et al. Cladistics. 2017; 12: 10.1111/cla.12178

Zika Virus: Medical Countermeasure Development Challenges. Malone RW, et al. PLoS Negl Trop Dis. 2016;10(3):e0004530. **Cited in 70 articles, viewed over 54,000 times, full PDF downloaded over 11,000 times.**

Zika Fetal Neuropathogenesis: Etiology of a Viral Syndrome. Klase ZA, Khakhina S, Schneider Ade B, Callahan MV, Glasspool-Malone J, Malone R. PLoS Negl Trop Dis. 2016;10(8):e0004877. **Cited in 51 articles, viewed over 13,000 times**.

Antibody mediated epitope mimicry in the pathogenesis of Zika virus related disease. Homan J, Malone RW, et al. BioRxiv. 2016.

Making vaccines "on demand": a potential solution for emerging pathogens and biodefense? De Groot AS, Einck L, Moise L, Chambers M, Ballantyne J, Malone RW Hum Vaccin Immunother. 2013;9(9):1877-84.

Electroporation enhances transfection efficiency in murine cutaneous wounds. Byrnes CK, Malone RW, et al. Wound Repair Regen. 2004;12(4):397-403.

DNA transfection of macaque and murine respiratory tissue is greatly enhanced by use of a nuclease inhibitor. Glasspool-Malone J, ..., Malone RW. J Gene Med. 2002;4(3):323-2.

Marked enhancement of macaque respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, ..., Malone RW. Gene Med. 2002;4(3):323-2.

Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields. Glasspool-Malone J, Malone RW. In Gene Therapy Methods: Methods Enzymol. 2002;346:72-91

Cutaneous transfection and immune responses to intradermal nucleic acid vaccination are significantly enhanced by in vivo electropermeabilization. Drabick JJ, Glasspool-Malone J, ..., Malone RW. Mol Ther. 2001;3(2):249-55. Cited in 192 articles.

Theory and in vivo application of electroporative gene delivery. Somiari S, Glasspool-Malone J, ... Malone RW. Mol Ther. 2000;2(3):178-87. Cited in 345 articles.

Efficient nonviral cutaneous transfection. Glasspool-Malone J, ..., Malone RW. Mol Ther. 2000;2(2):140-6. Cited in 138 articles.

Transfer and expression of foreign genes in mammalian cells. Colosimo A, ..., Malone RW, et al. Biotechniques. 2000;29(2):314-8, 20-2, 24 passim. Cited in 188 articles.

Specific inhibition of macrophage TNF-alpha expression by in vivo ribozyme treatment. Kisich KO, Malone RW, ..., Erickson KL. J Immunol. 1999;163(4):2008-16. Cited in 131 Articles.

Marked enhancement of direct respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, Malone RW. Hum Gene Ther. 1999;10(10):1703-13

Developing dendritic cell polynucleotide vaccination for prostate cancer immunotherapy. Berlyn KA, ..., Malone RW J Biotechnol. 1999;73(2-3):155-79

Models of Cationic Liposome Mediated Transfection. Gene Therapy and Molecular Biology. Ahearn A, Malone RW. Vol 4. Gene Therapy and Molecular Biology 1999;4

Mucosal immune responses associated with polynucleotide vaccination. Malone JG, ..., Malone RW. Behring Inst Mitt. 1997(98):63-72

Delivery of exogenous DNA sequences in a mammal. P Felgner, ..., R Malone, D Carson. Biotechnology Advances. 1997 15 (3-4), 763-763

Cationic lipid-mediated gene delivery to murine lung: correlation of lipid hydration with in vivo transfection activity. Bennett MJ, ..., Malone RW, Nantz MH. J Med Chem. 1997;40(25):4069-78

Improved method for the removal of endotoxin from DNA. Montbriand PM, Malone RW. J Biotechnol. 1996;44(1-3):43-6. Cited in: 43 articles

Toxicity of cationic lipid-ribozyme complexes in human prostate tumor cells can mimic ribozyme activity.Freedland SJ, Malone RW, et al. Biochem Mol Med. 1996;59(2):144-53

Considerations for the design of improved cationic amphiphile-based transfection reagents. Bennett MJ, ..., Malone RW. Journal of Liposome Research 1996;6(3):545-65

Structural and functional analysis of cationic transfection lipids: the hydrophobic domain. Balasubramaniam RP, ..., Malone RW. Gene Ther. 1996;3(2):163-72. cited in 172 articles.

The counterion influence on cationic lipid-mediated transfection of plasmid DNA.Aberle AM, Bennett MJ, Malone RW, Nantz MH. Biochim Biophys Acta. 1996;1299(3):281-3

Direct gene tranfer into mouse muscle in vivo. N Shafee, ..., RW Malone, et al. International Journal of Virology 2 (1), 33-38

A flexible approach to synthetic lipid ammonium salts for polynucleotide transfection. MJ Bennett, RW Malone, MH Nantz. Tetrahedron letters 36 (13), 2207-2210

Tfx-50 Reagent, a new transfection reagent for eukaryotic cells. Schenborn E, ..., Malone RW, et al. 1995

Hepatic gene expression after direct DNA injection. Hickman MA, Malone RW, et al. Advanced Drug Delivery Reviews. 1995;17(3):265-71

Cholesterol enhances cationic liposome-mediated DNA transfection of human respiratory epithelial cells. Bennett MJ, ..., Malone RW. Biosci Rep. 1995;15(1):47-53

Dexamethasone enhancement of gene expression after direct hepatic DNA injection. Malone RW, et al. J Biol Chem. 1994;269(47):29903-7

Gene expression following direct injection of DNA into liver. Hickman MA, Malone RW, et al. Hum Gene Ther. 1994;5(12):1477-83. Cited in 306 articles.

Cationic liposome-mediated RNA transfection. Dwarki VJ, Malone RW, Verma IM. Methods Enzymol. 1993;217:644-54. Cited in: 88 articles.

Successful gene transfection fo respiratory epithelium invitro using polyamine containing cationic lipids. CB Robinson, RW Malone, J Jessee, G Gebeyehu, R Wu AMERICAN REVIEW OF RESPIRATORY DISEASE 147 (4), A546-A546

Direct gene transfer into mouse muscle in vivo. Wolff JA, Malone RW, et al. Science. 1990;247(4949 Pt 1):1465-8. **Cited in 4,695 articles.**

Cationic liposome-mediated RNA transfection. Malone RW, Felgner PL, Verma IM. Proc Natl Acad Sci U S A. 1989;86(16):6077-81. **Cited in 717 articles.**

mRNA Transfection of cultured eukaryotic cells and embryos using cationic liposomes. Malone RW. Focus. 1989;11:61-8

High levels of messenger RNA expression following cationic liposome mediated transfection tissue culture cells. Malone R, Kumar R, Felgner P. NIH Conference: "Self-Cleaving RNA as an Anti-HIV Agent" (Abstract). Washington, DC June 1989.

A novel approach to study packaging of retroviral RNA by RNA transfection (Abstract). RW Malone, P. Felgner, I. Verma. RNA Tumor Viruses, May 17-18, 1988. Cold Spring Harbor

Mammary tumors in feral mice lacking MuMTV DNA. Gardner MB, Malone RW, ..., Cardiff RD, et al. J Exp Pathol. 1985;2(2):93-8

Hyperplastic and neoplastic changes in the mammary glands of feral mice free of endogenous mouse mammary tumor virus provirus. Faulkin LJ, ..., Malone RW, et al. J Natl Cancer Inst. 1984;73(4):971-82.

PUBLISHED ABSTRACTS: **Over 50 published**

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

- Vaccines R&D, 2019. Keynote Speaker, Panel Moderator: Boston, MA. 18-20 November, 2019.
- Repurposing drugs for Infectious Disease Outbreaks. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017 (Chairperson)
- 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. (Oral Presentation)
- Zika Virus: Accelerating Development of Medical Countermeasures by Re-purposing Licensed Drugs. Bridging the Sciences: Zika Virus. Emery, Atlanta, GA 1-3 May, 2016. (Oral Presentation)

- Speaker/Round table- Zika virus: Challenges for Medical Countermeasure Development. World Vaccine Conference. 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. (Oral Presentation)

- Keynote Speaker: Ebola Vaccine in 12 months, Global Village, and the Need for Speed. Vaccines R&D, Baltimore, MD. 2-4 November, 2015. (Keynote Speaker)

- Current USG contracting Opportunities and Initiatives from the point of View of Vaccine Developers. World Vaccine Conference, Washington, DC. 24-26 March, 2014. (Oral Presentation)

- World Vaccine Conference, Washington, DC. 24-26 March, 2014 Preclinical and Clinical Vaccine Research. (Session Chair)

- PHEMCE Modeling Workshop "Operational Decision Making using Innovative Modeling, Analysis, and Visualization Tools", Sponsored by Deloitte. 2013 (Conference Co-Organizer and Coordinator/Oral Presentation)

- "Vaccine Production Strategies: Ensuring Alignment and Sustainability" The World Health Organization (WHO) Global Action Plan for Influenza Vaccines. Geneva, Switzerland. 12-14 July 2011 (Oral Presentation)

RECENT STUDY SECTIONS (selected):

- Chairperson, NIH/NIAID/DMID Special Emphasis Panel, Development of Vaccines to Combat Antibiotic Resistant Bacteria September 2019.
- Chairperson, NIH/NIAID Special Emphasis Panel, December 2018.
- Reviewer, NIH/NIAID Special Emphasis Panel, December 2017.
- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, for "Congressionally Directed Medical Research Programs (DMRDP), 2012.
- Committee member and reviewer for NIH/NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines. 2011
- Chair and reviewer for NIH/NIAID: Partnerships in Biodefense Immunotherapeutics. 2011
- NIH/NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel. 2010
- Chairperson and scientific reviewer for NIH/NIAID Omnibus BAA 2017-1: Research Area 5 (N01) ZAI1-KP- M-C6 (Topic 5: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases), September 2017.
- Scientific reviewer for NIH/NIAID Special Emphasis Panel/Scientific Review Group 2017/08 ZRG1 IMM-R (12) B (Non-HIV Microbial vaccines), June 2017.
- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, "CDMRP: Defense Medical Research & Development Program (DMRDP), 2012.

- Chairperson and scientific reviewer for NIH/NIAID Committee on Partnerships in Biodefense Immunotherapeutics, Fall 2011.
- Committee member and reviewer for NIH/ NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines, Fall 2011.
- NIH/ NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel, 2010.
- 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": 1998

BOOKS AND 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, republished 2014.

- *Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields.* Glasspool-Malone J, Malone RW. In *Gene Therapy Methods: Methods Enzymol.* 2002;346:72-91

- Malone RW. *"Toxicology of non-viral gene transfer"*. Editor, Walsh B. In: *"Non-Viral Therapeutics: Advances, Challenges and Applications for Self-Assembling Systems."* IBC's Biomedical Library Series. (1996) 4.1