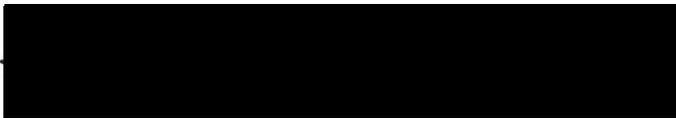


Committee on Energy and Commerce
U.S. House of Representatives
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: <i>DR. ROBIN ROBINSON</i>		
2. Your Title: <i>DIRECTOR, BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY DEPUTY ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE</i>		
3. The Entity(ies) You are Representing: <i>U.S. Health and Human Services</i>		
4. Are you testifying on behalf of the Federal, or a State or local government entity? <i>- Federal</i>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2013. Only grants, contracts, or payments related to the subject matter of the hearing must be listed. <i>NONE</i>		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature



Date *NOV. 16, 2015*

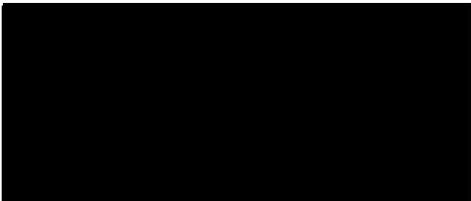
CURRICULUM VITAE

Robin A. Robinson, Ph.D.

BACKGROUND

Business Address:

U.S. Dept of Health & Human Services
Biomedical Advanced Research and Development Authority (BARDA)
Office of Preparedness and Response (ASPR)
Thomas O'Neil Bldg.
200 C Street, SW330
Washington, D.C. 20201



EDUCATION

Bachelor of Science, 1976, Biology, Millsaps College, Jackson, MS

Doctorate of Philosophy, 1981, Microbiology, University of Mississippi Medical School, Jackson, MS

Thesis: "Biological, Biochemical, and Molecular Characterization of Herpesvirus Oncogenes"

Advisor: Dr. Dennis J. O'Callaghan

Postdoctoral Fellowship:

1981-83, NIH Fellowship, Princeton University, Princeton, NJ and SUNY at Stony Brook, Stony Brook, NY

Cloning of human p53 gene and subtractive cDNA cloning of large T antigen-stimulated host genes in SV40 transformed cells

Advisor: Dr. Arnold J. Levine

1996-1999, Graduate School, Chemical Engineering, University of Maryland – Baltimore Campus, Biopharmaceutical Manufacturing & Regulations

PROFESSIONAL EXPERIENCE

4/08 – present: Director (SES), Biomedical Advanced Research and Development Authority (BARDA) and Deputy Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, Washington, D.C.

Functions:

- Lead and manage a U.S. federal agency whose sole mission is to support development and procurement of medical countermeasures for preparedness and response to chemical, biological, radiological, and nuclear (CBRN) threats (Project BioShield), pandemic influenza (Pandemic Influenza Program), and emerging infectious diseases for the entire U.S. civilian population
- Lead emergency activities for development, manufacturing, and testing of medical countermeasures to the above threats
- Make investments in the development, manufacturing, and innovation of drugs and vaccines, diagnostics, and medical devices (medical countermeasures) and related technologies towards FDA regulatory approval
- Make partnerships with domestic federal agencies, foreign governments, and industry as public-private partnerships towards this mission
- Establish and manage stockpiles of vaccines and drugs (medical countermeasures) for preparedness to these threats
- Establish drug and vaccine manufacturing facilities through cost-sharing with industry as public-private partnerships to produce vaccines and biological products for preparedness and emergency response to these threats
- Establish programs that provide core service assistance for nonclinical and clinical studies, product development and manufacturing, regulatory and quality affairs, and mathematical modeling for internal demands and developers of medical countermeasures on a routine basis
- Establish a National MCM Response Infrastructure using BARDA's core service assistance programs to respond rapidly and nimbly to pandemic influenza and emerging infectious diseases
- Brief the White House, Congress, Office of Management and Budget, other USG departments and agencies, and foreign nations and Non-Government Organizations (NGOs including WHO, BMGF, Wellcome Trust, GAVI, etc.) on all matters related to medical countermeasures that inform policy, budgets, legislation, initiatives, and directives
- Engage stakeholders on all matters related to medical countermeasures
- Prepare, defend, and execute multi-billion dollar budgets on five-year cycles for medical countermeasures before HHS Department, White House, OMB, and Congress

Accomplishments:

- Established BARDA as fully, comprehensive R&D organization with extramural and intramural preparedness and response capabilities as the first BARDA Director

- Built a development product pipeline of 162 medical countermeasures (vaccine, therapeutics, diagnostics, and medical devices) for chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases
- 21 MCMs approved, licensed, or cleared by the FDA since 2007 with 6-8 more expected by 2018
- 12 new MCMs delivered under Project BioShield with 12 more MCMs by 2018 that have multi-purpose indications including everyday healthcare applications
- Established a pre-pandemic influenza vaccine stockpile able to protect at least 200 million persons
- Established a domestic pandemic influenza vaccine manufacturing capacity able to meet U.S. demand in 6 months or less with modern manufacturing technologies
- Established the original influenza antiviral drug stockpile to protect at least 60 million persons
- Established five (5) core service programs that were transformed into the National MCM Response Infrastructure for the Ebola response
- Responded to the pandemic H1N1 and H5N1 (2004- 2009) and H7N9 (2013) threats with vaccine production
- Responded to MERS-CoV (2012-2015) and Ebola (2014-2015) epidemics with rapid development of new vaccines and drugs
- Testified before Congress on BARDA, pandemic influenza, and Ebola (2008-2015; N=6)
- CBS 60 Minutes interview on Ebola and BARDA (Feb. 2015)

5/04 to 4/08: Pandemic Influenza Director (SES), Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS), Washington, D.C.

- Leader of BARDA Influenza & Emerging Disease (IED) MCM R&D Program for advanced development, acquisition, and stockpiling of pandemic influenza vaccines, antiviral drugs, rapid diagnostics, and non-pharmaceutical countermeasures (mask/respirators/ventilators) for domestic infrastructure building of pandemic vaccines.
- Provide policy advice as subject matter expert on influenza to HHS Secretaries Thompson and Leavitt and Assistant Secretary Stewart Simonson of Public Health Emergency Preparedness
- Provide project management on all HHS/OS influenza and pandemic influenza projects, contracts, plans, budgets, and initiatives
- Provide briefings to HHS senior officials, the White House and Vice President's Office, and U.S. Congress on pandemic influenza
- Served as Technical Consultant to the 2005 CBC documentary entitled "The Next Pandemic"

2/05 to present: WHO influenza vaccine expert

- Served as expert panel member for field evaluation and guidance on H5N1 vaccine manufacturing in Vietnam
- Served as Team leader to review and revise WHO biosafety guidelines for avian influenza vaccine manufacturing
- Served as technical evaluation panelist for WHO on grant proposals to develop H5N1 vaccine in developing countries
- Ebola vaccines and therapeutics working group member

2000 to 2004: Director, Novavax Inc., Vaccine Division (formerly Biomedical Services Division) (Rockville, MD)

In addition to responsibilities held previously as Associate Director, the following duties are included:

- Managed 22 R&D and manufacturing personnel at vaccine facility
- Served as lab chief to six (6) senior scientists (Ph.D.) and seven (7) technicians in laboratory
- Served as principal investigator currently to the following:
 1. Principal Investigator on NIH contract N0 AI 30042 entitled "HIV Vaccine Design and Development - VLPs" - \$19.1 M over 5 years; contract awarded Sept. 26, 2003
 2. Principal Investigator of Core C (Vaccine Development and Manufacturing) on NIH grant U19 AI 28147 entitled "VLP-based Systemic and Mucosal HIV Vaccine" - Novavax share \$4.5 M of \$17 M grant to University of Alabama-Birmingham over 5 years; awarded August 1, 2003
 3. Co-Principal Investigator on NIH grant UC1 AI 49509 entitled "Avian Influenza Vaccine Development" - \$1.7 M over 3 years; awarded in 2001
 4. Principal Investigator on multiple NIH contracts [NCI N0 2RC17046 (melanoma vaccines), NIAID 263-MF-212310 (hepatitis E vaccine), NIAID 263-MF-312497 (hepatitis B virus mAb)]
 5. Principal Investigator on multiple internal vaccine projects [E-selectin, SARS, HCV, and Variola]
- Led development of pre-clinical through Phase III development of recombinant HPV-16 L1 VLP vaccine
- Led establishment of Novavax GMP bulk manufacturing facility of HPV VLP vaccines (Phase III) at Parkedale Pharmaceuticals (Rochester, MI)
- Directed R&D and clinical cGMP manufacturing activities of recombinant protein vaccines and therapeutics for Molecular Vaccine Laboratory at Rockville site
- Interfaced with corporate partners of Novavax on recombinant protein vaccine projects.
- Reported directly to Chief Scientific Officer, Dr. D. Craig Wright
- Represented the technical expertise of Novavax in corporate-sponsored meetings with outside concerns including investor analysts.
- Prepared IND application, clinical protocols, and CMC reports to FDA on Novavax vaccine and biological products
- Prepared and submitted contract and grant proposals, CRADAs, and supply, licensing, and manufacturing agreements between Novavax and other companies on projects

- Advised corporate management on technical aspects of projects and business acquisitions
- Served as technical advisor for new R&D and Bulk Manufacturing facilities for Novavax and Parkedale Pharmaceuticals
- Prepared patent applications as inventor on vaccine inventions.
- Prepared and/or reviewed facility, equipment and process SOPs, batch records, validation documents, and assay protocols.

1999 to 2000: Associate Director, Novavax Inc., Biomedical Services Division (Rockville, MD)

- Directed R&D and manufacturing activities of Molecular Virology Laboratory.
- Led development and GMP manufacturing of recombinant proteins as vaccine and/or therapeutic products using bacterial, baculovirus, CHO, and other gene expression systems.
- Presented technical interests of Novavax to investment and banking analysts.
- Developed manufacturing processes for recombinant proteins used as antigens to prevent or treat the following diseases:
 1. Hepatitis caused by hepatitis viruses A, B, and E
 2. Virus infection and cervical cancer caused by human papillomaviruses
 3. Infantile diarrhea caused by rotaviruses
 4. Adult gastroenteritis caused by caliciviruses
 5. Dengue fever caused by dengue virus
 6. Adult pneumonia caused by adenovirus
 7. Prostate cancer
 8. Colorectal cancer
 9. Malaria
- Developed proprietary baculovirus vectors and insect lines to express recombinant proteins.
- Developed platform technology of recombinant virus-like particles as vaccines
- Received patent for hepatitis E virus vaccine from USPTO.

1997 to 1999: Associate Director, DynCorp, Experimental Vaccine Facility (Rockville, MD) [DynCorp was purchased by Novavax, Inc., August 10, 1999]

- See above for Novavax, Inc.
- Managed government and pharmaceutical contracts to develop and produce recombinant proteins.
- Supervised Molecular Virology Laboratory to develop recombinant proteins and associated technologies including platform technology of virus-like particles.

1995 to 1997: Program Manager/Senior Scientist, DynCorp, Experimental Vaccine Facility (Rockville, MD)

- See above for Novavax, Inc.
- Managed government and pharmaceutical contracts to develop and produce recombinant proteins.

- Supervised Molecular Virology Laboratory to develop recombinant proteins and associated technologies including platform technology of virus-like particles.

1994 to 2004: Adjunct Professor, Johns Hopkins University
Graduate Program in Biotechnology (Baltimore, MD)

- Taught graduate courses on virology, medical microbiology, and emerging infectious diseases

1992 to 1995: Staff Scientist, Life Technologies Inc., (Gaithersburg, MD)

- Responsible for product discovery and development in the areas of DNA footprinting, cDNA cloning, and gene expression vectors.
- Responsible for the evaluation and development of the bacmid system for baculovirus expression and related cell culture products.
- Released the BAC-to-BAC baculovirus expression system as a multi-million dollar product in 1995.
- Refinement in screening recombinant baculoviruses by a Long PCR method
- Developed multi-gene baculovirus vectors, prokaryotic TAG vectors and the mammalian virus vector, Semliki Forest Virus.
- Taught these systems as well as yeast and developed into a one week workshop at LTI Training Center, Johns Hopkins University, and offsite locations in Mexico, Canada, and U.S.

1989 to 1992: Section Leader, Laboratory of Molecular Carcinogenesis,
National Cancer Institute, National Institutes of Health, (Frederick, MD)

- Directed R&D laboratory in the study of HIV post-transcriptional gene regulation by host proteins.
- Identified several sets of HIV RNA sequences, *crs*, in *gag-pol* and *env* viral mRNAs that bound specific host proteins.
- Demonstrated binding of viral mRNAs to these host ribonucleoproteins inhibited both splicing and mRNA export.
- Cloned several of host ribonucleoprotein genes from cDNA libraries derived from HIV-1 infected Jurkat cells.
- Demonstrated the efficacy of recombinant host proteins to inhibit viral replication in chronically HIV infected T4 helper cells.

1984 to 1988: Scientific Consultant, California Biotechnology Inc. (Nova Scios)
(Mountain View, CA)

- Consulted on herpesvirus and molecular biology projects

1983 to 89: Assistant Professor, Dept. of Microbiology and Immunology, Univ. of Texas Southwestern Medical Center (Dallas, TX)

- Directed laboratory research in the areas of herpesvirus pathogenesis and HIV gene regulation.

- Served as faculty and mentor to medical, graduate, and postdoctoral fellows in laboratory.
- Taught medical school and graduate school courses in medical microbiology, virology, immunology, and molecular biology.
- Key research findings included:
 1. Regulation of viral and host factors in herpesvirus acute infection and latency.
 2. Repression of several host genes modulated herpesvirus latency.
 3. Identification and cloning of host genes involved in herpesvirus latency by
 4. subtractive cDNA cloning.
 5. Identification of stress, UV-light, and glucocorticoid activation of host genes reactivated herpesvirus latency
 6. Mapping of binding sites in the promoters of host genes by herpesvirus transactivators.
 7. Concept of herpesviruses as cofactor for AIDS and demonstrated reactivation of latent herpesviruses including cytomegalovirus coupled to HIV activation in AIDS patients
 8. Transactivation of HIV LTR-directed gene expression by herpesvirus regulatory proteins ICP4, ICPO, and ICP22.
 9. Herpesvirus transactivators acted as coactivators through Sp1 and TFIID transcription factors or through NF-KB enhancer binding proteins.

Awards:

- HHS Secretary's Award for Distinguished Service for Medical Countermeasures s (2014)
- HHS Secretary's Award for Distinguished Service for Medical Countermeasures s (2013)
- Service to America Award Finalist for H5N1 vaccine development (2008)
- Clay Dalrymple Award from Department of Defense for Excellence in the development of H5N1 vaccines (2008)
- HHS Secretary's Award for Distinguished Service for Pandemic Influenza Preparedness (2006)
- HHS Secretary's Award for Distinguished Service for the 2004 Influenza Vaccine Shortage Response (2005)

Professional Societies

- American Association for the Advancement of Science
- American Society for Microbiology
- American Society for Virology
- International Society for Vaccines
- American Society for Tropical Medicine and Hygiene

Journal Editorial Boards

- Reviewer, Protein Expression and Purification
- Assoc. Editor, Bioprocessing
- Ad Hoc Reviewer, J. Virology and Virology

Consultant Experience

- California Biotech (NovaScios), Mountain View, CA - 1983-87: Herpesviruses
- Jenner Biotherapies, Inc., Tiburon, CA - 1996 – 99: Cancer Vaccine Development and Manufacturing
- SmithKline Beecham Biologics, Rixensart, Belgium – 1997-98: Hepatitis E Vaccine Development and Manufacturing
- BioConsul Drug Development Corp., Danville, CA – 2000 – 2001: PSA Vaccine Development and Manufacturing

Patents

- Emerson, S.U., Purcell, R.H., Tsarev, S., and Robinson, R.A. Recombinant Proteins of a Pakistani Strain of Hepatitis E and Their Use in Diagnostic Methods and Vaccines. April 25, 2000. U.S. Patent No. 6,054,567.
- Emerson, S.U., Purcell, R.H., Tsarev, S., and Robinson, R.A. Recombinant Proteins of a Pakistani Strain of Hepatitis E and Their Use in Diagnostic Methods and Vaccines. April 9, 2002. Australian Patent No. 739915 (72470/98)
- Robinson, R.A. Cell Line for Serum-free Growth and Recombinant Protein Secretion. U.S. Patent Application 60/356,119 filed February 14, 2002.
- Robinson, R.A. Optimization of Gene Sequences for Expression in Insect and Other Cells. U.S. Patent Application 60/356,161 filed February 14, 2002.
- Robinson, R.A. Production of Extracellular Virus-like Particles. U.S. Patent Application 60/356,118 filed February 14, 2002.
- Robinson, R.A. Production of Papillomavirus Chimeric Virus-like Particles. U.S. Patent Application 60/356,133 filed February 14, 2002.
- Robinson, R.A. Upstream Purification of Extracellular Virus-like Particles. U.S. Patent Application 60/356,157 filed February 14, 2002.
- Robinson, R.A. and Cioce, V. Upstream Purification of Intracellular Virus-like Particles. U.S. Patent Application 60/356,156 filed February 14, 2002.
- Robinson, R.A. and Cioce, V. Upstream Purification of Chimeric Virus-like Particles. U.S. Patent Application 60/356,123 filed February 14, 2002.
- Robinson, R.A. and Thompson, M. Downstream Chromatographic Purification of Papillomavirus Virus-like Particles. U.S. Patent Application 60/356,113 filed February 14, 2002.
- Robinson, R.A. and Donabedian, A. Downstream Purification of Papillomavirus Virus-like Particles Using Linear Sucrose Gradients. U.S. Patent Application 60/356,154 filed February 14, 2002.

- Robinson, R.A. Downstream Purification of Papillomavirus Virus-like Particles Using Sucrose Step Gradients. U.S. Patent Application 60/356,135 filed February 14, 2002.
- Robinson, R.A., Knell, J., and Graves, D. Methods of Inactivating Baculoviruses. U.S. Patent Application 60/356,126 filed February 14, 2002.
- Robinson, R.A. and Thompson, M. Methods of Analyzing Virus-like Particles. Patent Application 60/356,162 filed February 14, 2002.
- Robinson, R.A. and Donabedian, A. Recombinant Papillomavirus Virus-like Particle Therapeutic and Prophylactic Products and Methods. Patent Application 60/356,150 filed February 14, 2002.
- Robinson, R.A. Recombinant Papillomavirus Virus-like Particle Diagnostic Products and Methods. Patent Application 60/356,151 filed February 14, 2002.
- Robinson, R.A. Containers for Papillomavirus Virus-like Particle Products. Patent Application 60/356,152 filed February 14, 2002.
- Emerson, S.U., Purcell, R. H., Tsarev, S.A., and Robinson, R.A. Recombinant proteins of a Pakistani strain of hepatitis E and their use in diagnostic methods and vaccines U.S. Patent No. 6,458,562 issued October 1, 2002.
- Robinson, R.A., Novel Cell Line for Serum-Free Growth and Recombinant Protein Secretion. USPTO (10/367,043) and WCT (PCT/US03/04516) Patent Applications filed February 14, 2003. US Patent No 7,041,500 B2 issued May 9, 2006 as Insect Cell Line.
- Robinson, R.A. Insect cell line. US Patent No. 7,041,500, May 9, 2006
- Robinson, R.A. and Pushko, P. Functional Influenza Virus-like Particles. US Patent No. 8,592,197 issued November 26, 2013.
- Robinson, R.A. Optimization of Gene Sequences of Virus-Like Particles for Expression in Insect and Other Cells. USPTO and WCT (PCT/US03/04480) Patent Applications filed February 14, 2003.
- Robinson, R.A. and Cioce, V. Optimization of Gene Sequences of Chimeric Virus-Like Particles for Expression in Insect and Other Cells. USPTO (10/367,043) and WCT (PCT/US03/04473) Patent Applications filed February 14, 2003.
- Robinson, R.A. and Thompson, M.S. Method for Isolation and Purification of Expressed Gene Products In Vitro. USPTO and WCT (PCT/US03/04474) Patent Applications filed February 14, 2003.
- Robinson, R.A. and Cioce, V. Malaria Merozoite Specific Protein Type 1 Protein Purification and Vaccine Methods. USPTO Patent Application filed.
- Robinson, R.A. and Cioce, V. Recombinant E-selectin Proteins. Patent disclosure filed.
- Robinson, R.A. SARS VLP Vaccines.. Patent disclosure filed.
- Smith, G., Wu, V., Massare, M., Pushko, P., Nathan, M., Kort., T., and Robinson, R. Highly Efficient Influenza Matrix (M1) Proteins. USPTO Patent Application Filed Oct. 24, 2011. USP Application NO. 13/280,043.
- Robinson, R.A. Highly Efficient Influenza Matrix (M1) Proteins. Patent Issued March 31, 2015 USPTO No. 8,992,939

PUBLICATIONS

- Robinson, R.A., Henry, B.E., and O'Callaghan, D.J. 1979. Oncogenic transformation by equine herpesvirus (EHV). I. Properties of hamster embryo cells transformed by UV-irradiated EHV-1. *Virology* 101: 335-362.
- Robinson, R.A., Vance, R.B., and O'Callaghan, D.J. 1980. Oncogenic transformation of equine herpesvirus (EHV). II. Co-establishment of persistent infection and oncogenic transformation by preparations enriched for defective interfering particles of EHV-1. *J. Virol.* 36: 204-219.
- O'Callaghan, D.J., Henry, B.E., Wharton, J.H., Dauenhauer, S.A., Vance, R.B., Staczek, J., and Robinson, R.A. 1981. Equine herpesviruses: biochemical studies on genomic structure, DI particles, oncogenic transformation, and persistent infection. in Herpesvirus DNA Developments in Molecular Virology I. Herpesvirus DNA. Ed. Becker, Y., Martinus Publishers, The Hague, pp. 387-418.
- Robinson, R.A. and O'Callaghan, D.J. 1981. The organization of integrated herpesvirus DNA in equine herpesvirus type 1 transformed and tumor cell lines. in Herpesvirus DNA Developments in Molecular Virology I. Herpesvirus DNA. Ed. Becker, Y., Martinus Publishers, The Hague, pp. 387-418.
- Robinson, R.A., Tucker, P.W., Dauenhauer, S.A., and O'Callaghan, D.J. 1981. Molecular cloning of equine herpesvirus type 1 DNA: analysis of standard and defective viral genomes and viral sequences in oncogenically transformed cells. *Proc. Natl. Acad. Sci. USA* 78: 6684-6688.
- Henry, B.E., Robinson, R.A., Dauenhauer, S.A., Atherton, S.S., Hayward, G.S., and O'Callaghan, D.J. 1981. Structure of the genome of equine herpesvirus type 1. *Virology* 155: 97-114.
- Dauenhauer, S.A., Robinson, R.A., and O'Callaghan, D.J. 1982. Chronic production of defective interfering particles by hamster embryo cultures of herpesvirus persistently infected and oncogenically transformed cells. *J. Gen. Virol.* 60: 1-14.
- Robinson, R.A., Schutzbank, T., Oren, M., and Levine, A.J. 1982. Large T Antigen regulates the levels of cellular transcripts. in Cell Proliferation, Cancer, and Cancer Therapy. Vol. 397, Ed. Baserga, R., N.Y. Acad. Sci. pp. 221-228.
- Schutzbank, T., Robinson, R., Oren, M., and Levine, A.J. 1982. The SV40 large tumor antigen can regulate some cellular transcripts in a positive fashion. *Cell* 30: 481-490.
- Robinson, R.A. and O'Callaghan, D.J. 1983. A specific viral DNA sequence is stably integrated in herpesvirus oncogenically transformed cells. *Cell* 32: 569-578.
- Levine, A.J., Schutzbank, T., and Robinson, R. 1983. Control of cellular transcripts in transformed cells. in Genes and Proteins in Oncogenesis, Ed. Vogel, G., Academic Press, NY, pp. 323-326.
- Kalyanaraman, S., Jannoun-Nasr, R., York, D., Luciw, P., Robinson, R., and Srinivasan, A. 1988. Homologous recombination between human immunodeficiency viral DNA in cultured human cells: analysis of the factors influencing recombination. *BBRC* 157: 1051-1060.

- Kettman, J., Robinson, R., Kuhn, L., and Lefkovits, I. 1988. HIV-1 isolates of varying cytopathogenicities alter the polypeptide expression in infected T lymphocytes. *Electrophoresis* **9**: 15-19.
- Bohan, C., Shiao, F.C.H., Yuan, R., Robinson, R., Kaplan, H.J., and Srinivasan, A. 1988. Interaction of human immunodeficiency virus and cytomegaloviruses. *UCLA Symposia* **88**: 145-150.
- Srinivasan, A., York, D., Jannoun-Nasr, R., Kalyanaraman, S., Dorsett, D., Bohan, C., Luciw, P., Schnoll, S., Butler, D., and Robinson, R. 1989. Generation of hybrid human immunodeficiency virus by homologous recombination. *Proc. Natl. Acad. Sci. USA* **86**: 6388-6392.
- Yuan, R., Bohan, C., Shiao, F.C.H., Robinson, R., Kaplan, H.J., and Srinivasan, A. 1989. Cofactor regulation of human immunodeficiency virus: pseudorabies virus immediate early gene transactivates HIV long terminal repeat. *Virology* **172**: 92-99.
- Bohan, C.A., Robinson, R.A., Luciw, P.A., and Srinivasan, A. 1989. Mutational analysis of sodium butyrate inducible elements in the human immunodeficiency virus type 1 long terminal repeat. *Virology* **172**: 573-583.
- Benko, D.M., Robinson, R., Solomin, L., Mellini, M., Felber, B., and Pavlakis, G. 1990. Binding of *trans*-dominant mutant *Rev* protein of human immunodeficiency virus type 1 to the *cis*-acting *rev*-responsive element does not affect the fate of viral mRNA. *New Biologist* **2**: 1111-1122.
- Pavlakis, G.N., Schwartz, S., Benko, D.M., Drysdale, C.M., Solomin, L., Ciminale, V., Robinson, R., Harrison, J., Campbell, M., and Felber, B. 1991. Genomic organization and regulation of HIV-1 expression. in Genetic Structure and Regulation of HIV. Eds. Haseltine, W.A. and Wong-Staal, F., Raven Press, NY. pp. 234-245.
- Kettman, J., Robinson, R., Kuhn, L., and Lefkovits, I. 1991. Global analysis of lymphocyte gene expression: perturbation of H9 cells by infection of distinct Isolates of human immunodeficiency virus - an exposition by multivariate analysis of a host parasite interaction. *Electrophoresis* **13**: 535-553.
- Nathan, M. and Robinson, R. 1995. Optimization of immunoscreening cDNA libraries. *Focus* **17**: 49-52.
- Tsarev, S.A., Tsareva, T.S., Emerson, S.U., Govindarajan, S., Sharp, M., Gerin, J.L., Robinson, R., Gorbalenya, A.E., and Purcell, R. 1996. Prospects for prevention of hepatitis E. in Enterically Transmitted Hepatitis Viruses. Eds. Y. Buisson, P. Coursagei, and M. Kane, pp.373-383.
- Tsarev, S.A., Tsareva, T.S., Emerson, S.U., Govindarajan, S., Sharp, M., Gerin, J.L., Robinson, R., and Purcell, R. 1997. Recombinant vaccine against hepatitis E. in Viral Hepatitis and Liver Disease. Eds. M. Rizzeto, R. H. Purcell, J.L. Gerin, and G. Verme. pp. 648-649.
- Robinson, R.A., Burgess, W.H., Emerson, S.U., Leibowitz, R.S., Sosnovtseva, S.A., Tsarev, S., and Purcell, R.H. 1998. Structural characterization of recombinant hepatitis E virus ORF2 proteins in baculovirus-infected insect cells. *Protein Expression and Purification* **12**: 75-84.
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- alternate vaccines based on *Plasmodium falciparum* merozoite surface protein 1 in an *Aotus* challenge trial. *Infect. Immunity* **69**: 1536-1546.
- Harro, C.D., Pang, Y.-Y.S., Roden, R.B.S., Hildesheim, A., Wang, Z., Reynolds, M.J., Mast, T.C., Robinson, R., Murphy, B.R., Karron, R.A., Dillner, J., Schiller, J.T., and Lowy, D.R. (2001) Safety and immunogenicity trial in adult volunteers of a human papillomavirus 16 L1 virus-like particle vaccine. *J. Natl. Cancer Inst.* **93**: 284-292.
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 - Pushko, P., Tumpey, T.M., Bu, F., Knell, J., Robinson, R., and Smith, G. (2005). Influenza virus-like particles comprised of the HA, NA, and M1 Proteins of H9N2 influenza virus induce protective immune responses in Balb/c mice. *Vaccine* **23**:5751-5759.
 - Pushko, P., Tumpey, T.M., Van Hoeven, N., Robinson, R., Nathan, M., Smith, G., Wright, D.C., and Bright, R.A. Evaluation of influenza virus-like particles and novasome adjuvant as candidate vaccine for avian influenza. Submitted for publication.
 - Shimabukuro, T.T., Beets, C., Wilson, F., Keeler, M., Meese, S., Stanley, T., Dickinson, K., Huebner, R., Donabedian, A., and Robinson, R., Exercising Pre-Pandemic Influenza Vaccine Distribution: United States. Submitted for publication.

Recombinant Protein and Vaccine List

The following recombinant genes were designed as biological and vaccine candidates, and their recombinant proteins manufactured as pre-clinical, clinical and/or research products in the Molecular Vaccine Laboratory of Novavax, Inc. under the direction of Dr. Robinson for Novavax alone or in collaboration with government, institutional, or other commercial entities since 1995:

Human Clinical Trials

1. Human Chorioembryonic Antigen (CEA), truncated - Baculovirus, *E. coli* & Vaccinia (Phase I)
2. Human CEA fusion protein with immunoglobulin and cholera toxin gene partners - Baculovirus & *E. coli* (Phase I)
3. Human Prostate Specific Antigen (PSA), truncated - Baculovirus & *E. coli* (Phase I - II)
4. Human KSA, truncated protein - Baculovirus, *E. coli*, & SFV (Phase I - II)
5. Human, simian, and bovine rotavirus chimeric virus-like particles (VLPs), VP2, VP4, VP6, & VP7 (multimeric, triple-shell) - Baculovirus & *E. coli* (Phase I)
6. Norwalk virus VLPs, ORF2 - Baculovirus & *E. coli* (Phase I)

7. Human hepatitis E virus ORF2 capsid antigen, full-length, 5' truncated, and 5'-3" truncated, Pakistani and Mexican strains - Baculovirus & *E. coli* (Phase I-II)
8. Human papillomavirus type 16 L1 VLPs - Baculovirus (Phase I - III)
9. Human papillomavirus type 16 chimeric VLPs (L1, L2-E2-E7) - Baculovirus (Phase I)
10. Human E-selectin protein tolerogen - Baculovirus (Phase I/II)
11. Bovine E-selectin protein tolerogen - Baculovirus (Phase I)
12. Human melanoma NYESO1 proteins - *E. coli* (Phase I/II)
13. Human melanoma GP100 proteins - *E. coli* (Phase I/II)

Research Products

1. Human Adenovirus type 2 fiber protein - Baculovirus
2. Norwalk calicivirus ORF1 protease - Baculovirus & *E. coli*
3. Norwalk calicivirus ORF1 polymerase - Baculovirus & *E. coli*
4. Hawaii calicivirus VLPs, ORF2 - Baculovirus
5. Toronto calicivirus VLPs, ORF2 - Baculovirus
6. Desert Shield calicivirus VLPs, ORF2 - Baculovirus & *E. coli*
7. Snow Mountain calicivirus VLPs, ORF2 + 3 - Baculovirus
8. MD145 calicivirus ORF2 VLPs - Baculovirus
9. Human hepatitis A polymerase - Baculovirus & *E. coli*
10. Human hepatitis E ORF3 antigen, Pakistani strain - Baculovirus & *E. coli*
11. Swine hepatitis E virus ORF2 capsid antigen, full-length and 5' truncated - Baculovirus & *E. coli*
12. Swine hepatitis E ORF3 antigen - Baculovirus & *E. coli*
13. Circle virus capsid antigen - Baculovirus & *E. coli*
14. Bovine papillomavirus L1 VLPs - Baculovirus
15. Dengue virus type 2 envelope protein (PreS + E) - Baculovirus
16. Dengue virus type 4 envelope protein (PreS + E) - Baculovirus
17. Malaria erythrocyte binding antigen (EBA), *P. falciparum*,
 - a. Fusion protein + (HIS) tag + gp67 secretory peptide,
 - b. Malaria codon or insect codon usage clones - Baculovirus
 - c. & *E. coli*
18. Malaria TRAP-1 (SSP1) protein - Baculovirus
19. Human IDDM protein (auto-immune) fusion protein + (HIS) Tag - Baculovirus cloned but not purified

The following recombinant genes were cloned individually or as tandem expression constructs under the direction of Dr. Robinson and the recombinant proteins were produced as soluble proteins or virus-like particles in the Molecular Vaccine Laboratory of Novavax, Inc. as company projects:

1. Dengue virus type 3 envelope protein (PreS + E)- Baculovirus & *E. coli*
2. Human PSA, full-length & truncated - Baculovirus, *E. coli*, & SFV
3. Human KSA, full-length & truncated - Baculovirus, *E. coli*, & SFV
4. Bacterial Chloramphenicol Acetyl Transferase - Baculovirus & *E. coli*

5. Avian, Porcine, and Human Hepatitis E Virus ORF2 wt and mutants - Baculovirus & E. coli
6. HIV_{SF162} env full length and truncated (codon-optimized) - Baculovirus and CHO
7. HIV_{SF162} gag full length (codon-optimized) - Baculovirus and CHO
8. HIV_{ConB} env full length and truncated (codon-optimized) - Baculovirus and CHO
9. HIV_{ConB} gag full length (codon-optimized) - Baculovirus and CHO
10. SHIV_{SF162P.3} env full length and truncated (codon-optimized) - Baculovirus and CHO
11. SIV_{mac239} env full length and truncated (codon-optimized) - Baculovirus
12. SIV_{mac239} gag full length (codon-optimized) - Baculovirus
13. SARS S (codon-optimized) - Baculovirus
14. SARS E (codon-optimized) - Baculovirus
15. SARS M (codon-optimized) - Baculovirus
16. Influenza Type A/H9 - Baculovirus
17. Influenza Type A/H5 - Baculovirus
18. Influenza Type A/H3 - Baculovirus
19. Influenza Type A/N2 - Baculovirus
20. Influenza Type A/M₁ - Baculovirus
21. Influenza Type A/M₂ - Baculovirus
22. Influenza Type A/NC - Baculovirus
23. Human monoclonal antibody (IgG^{H+L}) to hepatitis B virus - CHO