Curriculum Vitae

Mark McKinney Robinson, PhD, DVM Lecturer, Biology and Veterinary Technology Appalachian State University robinsonmm2@appstate.edu

Teaching Experience:

Forty years teaching through formal and informal courses, leading seminar series, mentoring, and
participating in the development of courses designed for undergraduates, graduates, professionals,
post-graduates, international trainees, and government officials, as well as developing and
delivering lectures and other public presentations for professional and lay audiences, both
nationally and internationally on a wide variety of subjects (see Subject Matter Expertise below)

Research and Research Administration Experience:

- Twenty years as a principal investigator, research coordinator, and research director for basic and translational research on sub-viral and viral pathogens, bacterial pathogens, development of infectious disease diagnostics, and epidemiology and control of viral and bacterial pathogens in developing countries (nineteen peer-reviewed publications, thirteen book chapters and other articles, ten invited presentations to regional, national, or international organizations)
- Ten years developing requests for applications (RFAs), evaluating grant proposals, managing the grant review peer review process, and providing post-award management of primary and translational research grants concerning animal health and disease

Regulatory Experience

- Six years as Director of Human Food Safety (FDA-CVM) directing the review and evaluation of primary research on human food safety for the regulatory approval of drugs
- FDA Advisor and Supervisor of JECFA and VICH experts
- Provided scientific and technical support to U.S. Trade Representative at the WTO
- Chair of FDA Technical Evaluation Committee which evaluated the competence of drug, biologic, device, and food additive reviewers throughout the FDA for promotion purposes

Leadership Experience:

- National Program Leader for Animal Health and Agrosecurity USDA National Institute of Food and Agriculture – July 2017 to February 2018
- National Program Leader for Animal Agrosecurity USDA National Institute of Food and Agriculture 2006 to 2015 (TS/SCI clearance held inactive)
- Director, Division of Human Food Safety US FDA Center for Veterinary Medicine 2000 to 2006
- Head, FAO/IAEA Animal Production and Health International Atomic Energy Agency 1996 to 2000
- Supervisory Research Microbiologist USDA Agricultural Research Service 1993 to 1996 (concurrently, Adjunct and Graduate Faculty, Washington State University)

Education:

- DVM, 1994, College of Veterinary Medicine Washington State University, Pullman, WA
- PhD Biological Structure, 1984, School of Medicine University of Washington, Seattle, WA
- BS Cum Laude, Biology/Genetics, 1977
 Washington State University, Pullman, WA

Formal Course Leadership (L) or Team Teaching (T):

- Cell and Molecular Biology (L)
- Genetics (T)
- Gross and Microanatomy (T)
- Physiology (L, T)
- Embryology (T)
- Microbiology (L, T)
- Diagnostic Assay Validation (L)
- Disaster preparedness (L)

- Diagnostic Laboratory Quality Assurance Systems (L)
- Molecular Disease Diagnostics (L)
- Program/Project Management (L, T)
- Systemic Pathology (T)
- Virology (L)
- Public Health (T)
- Inorganic Chemistry (T)

Subject Matter Expertise:

- Human, other animal, and public health
- Cell and molecular biology
- Infectious diseases of humans and other animals
- Epidemiology and disease control
- Development of disease diagnostics
- Gross anatomy, microanatomy, general physiology, general pathology
- Food security, safety, and quality
- Disaster preparedness
- Organizational change assessment, design, implementation, management
- Research regulatory compliance and ethics
- Quality assurance system development and implementation
- Regulatory policy development, implementation, and oversight
- Select agent, dual-use, and gain-of-function research regulations and policies
- Food additive and drug law (Federal Food, Drug, and Cosmetic Act FFDCA)
- INAD and IND (drug) approval processes (FFDCA)
- Discrete and probabilistic risk assessment and risk analysis
- Program and project management
- Federal research funding processes
- Personnel management

Employment History:

 Lecturer (January 2021 to present)
 Adjunct Instructor (August 2018 to December 2020)
 Department of Biology, Appalachian State University Boone, NC

I have been or am responsible for planning and delivering courses on Bacterial Pathogenesis and Infectious Diseases and Public Health for Senior and Graduate students (both dual-listed), Capstone courses on Microbial Diversity and Pandemics Through History for Senior students, and Human Physiology, Veterinary Physiology, General Biology, Career Explorations, and Microbiology for undergraduates.

 National Program Leader for Animal Health and Agrosecurity, July 2017 – Feb 2018 USDA National Institute of Food and Agriculture (NIFA)

I was responsible for the national leadership and management of the Veterinary Services Grant Program (VSGP), the Veterinary Medical Loan Repayment Program (VMLRP), and the National Animal Health Laboratory Network (NAHLN). The VSGP and VMLRP programs are intended to enhance the delivery of food animal veterinary services in underserved areas of the country through rural practice support and educational debt reduction, respectively. The NAHLN is a national network of animal disease diagnostic laboratories that provides early detection, quick response, and appropriate mitigation and recovery support for animal diseases of high consequence. Combined FY 2017 funding for these programs was \$13 million. I worked extensively with partner organizations in government and private sectors to develop a "community effort" to enhance each of these programs.

In addition, I was responsible as a team member for the animal care and use, dual-use research, and gain-of-function policy development and implementation for USDA.

- Retired March 2015 to July 2017
- National Program Leader for Animal Agrosecurity, 2006-2015 USDA National Institute of Food and Agriculture (NIFA) Washington, DC

I was responsible for national leadership and management in the area of animal agricultural security (TS/SCI Clearance) and USDA One Health (i.e., the integration of programs for human, public, animal, plant and environmental health). My work consisted of developing sustainable programs, processes, and educational and operational delivery systems to help all sectors of U.S. animal agriculture (i.e., small farmers, large producers, commodity groups, rural communities, other governmental agencies) understand the natures of, and prepare for and recover from disasters that will happen, whether they are intentional, accidental, or due to the effects of nature. The primary emphasis of these efforts was on prevention of disasters. However, for those that could not be prevented, the other program emphases included preparedness education, early detection and analysis of the problem, rapid response, and effective mitigation and recovery strategies, including the development of alternative business plans. My primary responsibilities included the development, leadership, and management of Federal/State partnerships (\$5-7 million annual funding), as exemplified by the National Animal Health Laboratory Network (NAHLN), the Extension Disaster Education Network (EDEN), and related research, education, and extension efforts. I provided leadership for the FY 2014 Agriculture and Food Research (AFRI) Food Security Challenge Area for Integrated Projects (\$6 million annual funding). During my tenure, I was responsible for awarding and managing over \$30 million in competitive grant funding and working extensively with other Executive Branch agencies and external organizations to ensure additive value in areas of program overlap. I provided support to other areas of agricultural security, food security, food safety, and other USDA-NIFA areas of extramural competitive grant evaluation and management, as well

as on-site and remote review and evaluation of animal science, animal health, and public health departments throughout the U.S. Land Grant University system and the Cooperative Extension Services.

Director, Division of Human Food Safety, 2000-2006
 Office of New Animal Drug Evaluation
 Center for Veterinary Medicine
 U.S. Food and Drug Administration
 Rockville, MD

I was responsible for ensuring the food safety and security of food animal commodities through the development, implementation, and management of outcomes of all aspects of the human food safety review of veterinary drugs in the United States. Every therapeutic and production animal drug that is proposed for use in food animals in the U.S. must pass this evaluation. My responsibilities included, among other things, policy development and implementation for the regulatory science and risk assessment of chemical residues, toxins, antimicrobials, and genetically engineered products; program and project development and management; review and approval of all drug evaluations performed by Division staff; personnel recruitment, development, and retention; management of supervisory and administrative issues; and participation in the Office and Center Management and Leadership Teams. I represented the Division to the Office and Center within FDA, and of FDA to the regulated industry, other U.S. government agencies and professional groups, international regulatory and standards setting bodies, and the general public. I provided and coordinated educational outreach regarding regulatory requirements for new animal drug approvals. Also, I supervised and provided policy oversight for staff who, in turn, provided scientific and technical expert representation to international food safety standards organizations (Codex, JECFA, and VICH). I was a member and chair of the FDA Technical Review Committee for agency-wide evaluations of proposed staff promotions for technical expertise or subject mastery, and a U.S. scientific representative in support of the U.S. Trade Representative during several World Trade Organization arbitrations.

 Head, Animal Production and Health Program, 1996-2000 (Concurrently)
 Head, FAO/IAEA Central Laboratory
 Head, OIE Collaborating Center
 Head, WHO Collaborating Center
 Standing Member, OIE Standards Commission
 FAO/IAEA Agriculture and Biotechnology Laboratory
 International Atomic Energy Agency
 Vienna, Austria

I was responsible as a co-manager of the FAO/IAEA Animal Production and Health program area of the FAO/IAEA Program in Food and Agriculture. One purpose of this international program is to provide sustainable assistance to developing countries through the improvement of epidemiology programs and diagnostic tools for the control of endemic and foreign animal diseases that affect livestock and humans. I participated in planning the strategic objectives and the Program of Work and Budget for the Program in Food and Agriculture, and was responsible for developing and implementing the same elements of the Animal Production and Health program. Concurrently, I was Head of the FAO/IAEA Central Laboratory, the OIE Collaborating Centre, and the WHO Collaborating Center, and represented the IEAE and FAO to each of these organizations. The primary focus of my work was on improvements to the scientific and technical aspects of animal production assays, disease diagnostic techniques, quality assurance programs, and the sustainable transfer of these technologies and programs to counterparts in Member States through technology transfer, educational, and training programs. I led or participated in basic and applied research, personnel recruitment, program management, the organization and conduct of regional and interregional workshops, and the performance of a wide variety of Agency missions in the field. Among other things, I was the Project Officer for an Interregional Project on the Implementation of Quality

Assurance Programs in Developing Country Research and Official Government laboratories. In addition, I was recruited by the Director General of the IAEA to help reform the program and project management practices within the Agency, and worked for nearly three years to develop and implement a successful training curriculum in Program and Project Management for nearly 3000 Professional Staff.

Supervisory Research Microbiologist, 1993-1996
 Adjunct Assistant Professor, Member of WSU Graduate Faculty USDA/ARS Animal Disease Research Unit College of Veterinary Medicine
 Washington State University, Pullman, Washington

I was the Project Leader for basic and applied research in the field of transmissible encephalopathies (e.g., sheep scrapie, BSE, etc.), and was responsible for developing a program of research, building research teams in three different locations in the U.S., leading and participating in the accomplishment of the research objectives by the teams, and reporting on the research results to the USDA, in peer-reviewed journals, professional meetings, and public venues. I also participated as a team member on herpes virus and lentivirus research. In this position, I represented the USDA in testimony before the U.S. Congress, as well as representing the U.S. government in numerous scientific meetings with scientists and government officials from Europe, Latin America, and Asia. As an Adjunct Assistant Professor in the Department of Microbiology and Pathology and WSU Graduate Faculty member, I taught segments of various courses in the DVM curriculum, presented multiple seminars, mentored undergraduate, graduate and professional students, and was a member of several graduate student committees.

 Research Microbiologist, 1988-1993 and ARS Research Fellow, 1986-1988 USDA/ARS Animal Disease Research Unit College of Veterinary Medicine Washington State University, Pullman WA

Refereed Publications:

- 1. Colling A, Jeggo M, Louvandini H, Lelenta M, Robinson M (2008). The establishment of quality systems in veterinary diagnostic testing laboratories in developing countries: experiences with the FAO/IAEA External Quality Assurance Programme. Accreditation and Quality Assurance: Journal for Quality, Comparability, and Reliability in Chemical Measurement 13: 33-45.
- 2. Cutlip RC, Miller JM, Hamir AN, Peters J, Robinson MM, Jenny AL, Lehmkuhl HD, Taylor WD, Bisplinghoff FD (2001). Resistance of cattle to scrapie by the oral route. Can J Vet Res 65:131-132.
- 3. Renukaradhya GJ, Isloor S, Crowther JR, Robinson MM, Rajasekhar M (2001). Development and field validation of an avidin-biotin enzyme-linked immunosorbent assay kit for bovine brucellosis. Rev Sci Tech 20: 749-756.
- 4. Khadra M, Richards JI, Robinson MM (2000). Development and evaluation of a micropipette tip washing system. J Immunol Meth 242:1-8.
- 5. Rebeski DE, Winger EM, Robinson MM, Gabler CMG, Dwinger RH, Crowther, JR (2000). Evaluation of antigen-coating procedures of enzyme-linked immunosorbent assay method for detection of trypanosomal antibodies. Vet Parisitol 90: 1-13.
- 6. Rebeski DE, Winger EM, Okoro H, Kowalik S, Burger HJ, Walters DE, Robinson MM, Dwinger RH, Crowther JR (2000). Detection of Trypanosoma congolense antibodies with indirect ELISAs using antigen-precoated microtitre plates. Vet Parisitol 89: 187-198.

- 7. Rebeski DE, Winger EM, Shin YK, Lelenta M, Robinson MM, Varecka R, Crowther JR (1999). Identification of unacceptable background caused by non-specific protein adsorption to the plastic surface of 96-well immunoassay plates using a standardized enzyme-lined immunosorbent assay procedure. J Immunol Meth 226: 85-92.
- 8. Rebeski DE, Winger EM, Rogovic B, Robinson MM, Crowther JR, Dwinger RH (1999). Improved methods for the diagnosis of African trypanosomosis. Mem Inst Oswaldo Cruz 94: 249-253.
- 9. Robinson MM, Jeggo MH (1998). Veterinary diagnostic laboratories in developing countries: the challenge of credibility. Rev Sci Tech 17: 454-458.
- 10. Robinson MM (1996). Transmissible encephalopathies and biopharmaceutical production. Dev Biol Stand 88: 237-241.
- 11. Robinson MM, Hadlow WJ, Knowles DP, Huff TP, Lacy PA, Marsh RF, Gorham JR (1995). Experimental infection of cattle with the agents of transmissible mink encephalopathy and scrapie. J Comp Pathol 113: 241-251/
- 12. Robinson MM, Hadlow WJ, Huff TP, Wells GAH, Dawson M, Marsh RF, Gorham JR (1994). Experimental infection of mink with bovine spongiform encephalopathy. J Gen Virol 75: 2151-2155.
- 13. O'Rourke KI, Huff TP, Leathers CW, Robinson MM, Gorham JR (1994). SCID mouse spleen does not support scrapie agent replication. J Gen Virol 75: 1511-1514.
- 14. Cutlip RC, Miller JM, Race RE, Jenny AL, Katz JB, Lehmkuhl HD, Debey BM, Robinson MM (1994). Intracerebral transmission of scrapie to cattle. J Infect Dis 169: 814-820.
- 15. Jackson MK, Knowles DP, Stem TA, Harwood WG, Robinson MM, Cheevers WP (1991). Genetic structure of the pol-env region of Caprine Arthritis-Encephalitis genome. Virolology 180: 389-394.
- 16. Robinson MM, Gorham JR (1990). Pathogenesis of hamster scrapie: adherent splenocytes are associated with high levels of infectivity. Arch Virol 112: 283-289.
- 17. Robinson MM, Cheevers WP, Berger D, Gorham JR (1990). Organ-specific modification of the dose-response relationship of scrapie infectivity. J Infect Dis 161: 783-786.
- 18. Robinson MM (1987). Fixation and immunofluorescent analysis of creatine kinase isozymes in embryonic skeletal muscle. J Histochem Cytochem 37: 717-722.
- 19. Robinson MM, Quinn LS, Nameroff M (1984). BB creatine kinase and myogenic differentiation: immunocytochemical identification of a distinct precursor compartment in the chicken skeletal myogenic lineage. Differentiation 26: 112-120.

Other Publications:

1. Burns K, Danesi PR, Donohue D, Fajgelj A, Markowicz A, Robinson MM. Nuclear Analytical Techniques at the IAEA's Seibersdorf Laboratory. In: ICARID – 98, Proceedings of the International Conference on Applications of Radioisotopes and Radiation in Industrial Development, Chembur, Mumbai, India, 1998.

- 2. Robinson MM. An assessment of transmissible mink encephalopathy as an indicator of bovine scrapie in U.S. cattle. In: (Gibbs CJ Jr, ed) Bovine Spongiform Encephalopathy The BSE Dilemma. Springer, New York, 1996, pp 97-107.
- 3. Robinson MM. Experimental infections of cattle and mink with the agents of transmissible mink encephalopathy, scrapie, and bovine spongiform encephalopathy. In: (Gibbs CJ Jr, ed) Bovine Spongiform Encephalopathy The BSE Dilemma. Springer, New York, 1996, pp 108-113.
- 4. Cutlip RC, Miller JM, Race RE, Jenny AL, Lehmkuhl HD, Robinson MM. Experimental transmission of scrapie to cattle. In: (Gibbs CJ Jr, ed) Bovine Spongiform Encephalopathy The BSE Dilemma. Springer, New York, 1996, pp 92-96.
- 5. Robinson MM. Transmissible encephalopathy research in the United States. In: Proceedings of a consultation on BSE with the Scientific Veterinary Committee of the EEC, 14-15 September 1993, Brussels.
- 6. Robinson MM, Gorham JR. Bovine Spongiform Encephalopathy. In: Foreign Animal Diseases. U.S. Animal Health Association, Richmond VA, 1992.
- 7. Gorham JR, Robinson MM, Knowles DP, O'Rourke KI. Transmissible spongiform encephalopathies Slow disease of animals and humans. In: Review of Science and Technology, Office of International Epizootics, Paris, 1992.
- 8. Robinson MM. Bovine spongiform encephalopathy Only a British concern? In: American Association of Bovine Practitioners Proceedings of the 1991 Annual Meeting.
- 9. Robinson MM. Hypotheses on the etiology and pathogenesis of BSE-like diseases. In: Toxicology Forum Proceedings of the 1991 Annual Summer Meeting.
- 10. Robinson MM. What are we learning about scrapie? And what do we need to know? In: Livestock Conservation Institute Proceedings of the 94th Annual Meeting (1989).
- 11. Robinson MM, Gorham JR, Glosser JW. Bovine Spongiform Encephalopathy. In: United States Animal Health Association Proceedings of the 94th Annual Meeting (1989).
- 12. Robinson MM. Skeletal Myogenesis: An immunocytochemical investigation of cell differentiation. Doctoral Dissertation, University of Washington (1984).
- 13. Robinson MM, Quinn LS, Nameroff M. Identification of a unique compartment in the chick embryo myogenic lineage. In: Myogenesis '83 The 3rd European Molecular Biology Organization (EMBO) Workshop on Molecular and Cellular Aspects of Myogenesis and Myofibrillogenesis in Cell Cultures of Normal and Diseased Muscle (1983).

Invited Abstracts:

- 1. Robinson MM. Human Food Safety and Antimicrobial Use in Animal Agriculture A Regulatory Perspective. In: Toxicology Forum Proceedings of the 2001 Winter Meeting.
- 2. Rebeski DE, Winger EM, Lelenta M, Colling A, Robinson MM, Ndamkou Ndamkou CH, Dwinger RH, Crowther JR. Comparison of precoated and freshly coated microtitre plates using denatured antigen for the detection of antibodies against Trypanosoma congolense by indirect enzyme-linked immunosorbent assay. In: 9th International Conference of the Association of Institutions of Tropical Veterinary Medicine, Harare, Zimbabwe, 1998.

- 3. Pearson JE, Robinson MM. Office International des Epizooties, Veterinary Laboratory Quality Assurance Standards. In: Proceedings of the 9th International Symposium of World Association of Veterinary Laboratory Diagnosticians, College Station, Texas, 1999.
- 4. Anderson J, Diallo A, Lubroth J, Robinson MM. Diagnostic tests for rinderpest. FAO/IAEA/WHO Annual Coordination Meeting, Rome, Italy, 1998.
- 5. Robinson MM. The FAO/IAEA External Quality Assurance Programme for Disease Diagnosis. In: Proceedings of the 4th Biennial Meeting of the Society for Tropical Veterinary Medicine, CIRAD-EMVT, Montpellier, France, 1997.
- 6. Van der Eerden BJM, Jeggo MH, Robinson MM. The FAO/IAEA external quality assurance programme for disease diagnosis. In: Proceedings of the 8th International Symposium of Veterinary Laboratory Diagnosticians. Jerusalem, Israel, 1996.
- 7. Robinson MM, Gorham JR. BSE surveillance in the United States. In: Proceedings of the 7th International Symposium of the World Association of Veterinary Laboratory Diagnosticians, Buenos Aires, Argentina, 1994.
- 8. Robinson MM. Transmission studies with transmissible mink encephalopathy and bovine spongiform encephalopathy and a survey of mink feeding practices. In: Symposium on risk assessment of the possible occurrence of bovine spongiform encephalopathy in the United States, JAVMA 204: 70-73, 1994.
- 9. Robinson MM, Cheevers WP, Gorham JR. Development of diagnostic reagents for preclinical scrapie infection. In: Food Animal Disease Research Proceedings of the 9th Annual Western Conference, Moscow, Idaho, 1988.
- 10. Robinson MM, Quinn LS, Nameroff M. Creatine Kinase and the Myogenic Lineage. In: Development and Cellular Biology of Excitable Tissues Proceedings of the First University of Washington Symposium in the Biomedical Sciences, Seattle, Washington, 1983.

Additional Information:

- Secured over \$8 million in competitive research funding (1986-2000)
- Provided leadership, planned, and managed the implementation and delivery of an international developmental aid budget of between \$4-\$6 million annually (1996-2000)
- Awarded and managed over \$45 million in competitive grant funding (2006-2018)
- Forty years of experience teaching at undergraduate, graduate, and professional degree levels, as well as organizing and conducting courses, seminars and workshops for international students, other trainees, and government officials in developed and developing countries

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U.S. Citizen - Born in Ann Arbor, Michigan