

**CURRICULUM VITAE**  
**LISA GEORGIANNE RIDER, M.D.**

**March 2009**

**PRESENT POSITION**

Deputy Unit Chief, Environmental Autoimmunity Group, Office of Clinical Research,  
National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH)  
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**EDUCATION**

1983-87           **M.D.**, Duke University School of Medicine, Durham, N.C.

1979-83           **A.B.**, Duke University, Durham, N.C.  
                          Chemistry with Biochemical Specialization

1979               **High School Diploma**, Ridge High School, Basking Ridge, NJ

**POST-GRADUATE TRAINING**

July 1991-       **Pediatric Rheumatology Fellow** (clinics), Children's Hospital National  
June 1993        Medical Center, Washington, DC

March 1991-     **Clinical Associate**, Laboratory of Chemical Immunology (Dr. Henry Metzger),  
July 1993        Arthritis and Rheumatism Branch, National Institute of Arthritis and Musculoskeletal  
                          and Skin Diseases, National Institutes of Health, Bethesda, Maryland

Aug 1990-       **Pediatric Rheumatology Fellow**, University of Washington/Children's  
Feb 1991        Hospital and Medical Center, Seattle, WA

July 1987-       **Internship/Residency in Pediatrics**, University of Washington/Children's  
July 1990        Hospital and Medical Center, Seattle, WA

**PROFESSIONAL POSITIONS**

Sept 2003-      **Deputy Unit Chief**, Environmental Autoimmunity Group (EAG), Office of Clinical  
Present            Research, National Institute of Environmental Health Sciences, National  
                          Institutes of Health, Bethesda, MD

**Duties/Accomplishments:**

- Supervisory and management responsibilities for administration of the clinical research unit together with the unit chief. Serve as acting unit chief 60 - 75 days per year, while he is on travel or leave. Duties include unit operations, research directions and communications with collaborators within and outside NIH, budget management, personnel issues, patient care administration, ongoing work on development and management of 2 large Oracle databases for clinical research data, and planning of duties for other unit personnel. Plan and execute all research for the unit together with the team.
- Principal investigator of myositis studies. Lead investigator in study of calcinosis. Associate investigator in studies of environmental factors associated with etiology and pathogenesis of systemic rheumatic diseases and in infliximab clinical trial for myositis. Steering Committee member of clinical trial of rituximab for adult and juvenile myositis.
- Precept research fellows and instruct 8 Unit personnel concerning ongoing basic and clinical research. Directly supervising:

- Mona Shah- PhD candidate student, George Washington University Department of Epidemiology (2008 – present)
  - Leora Vegosen – PhD Student (2008 – present) and Master’s of Environmental Science student (2004-05), Johns Hopkins University School of Public Health; NIEHS 2004 Summers of Discovery student; Recipient of 2005-06 ACR Research and Education Foundation Medical/Graduate Student Achievement Award
  - Michael Harris-Love PT PhD (2005- present): faculty member, DC VA Medical Center; studies on muscle strength and function
  - Lan Wu: 2007 -09: Johns Hopkins University college student, volunteer
  - Gulnara Mamyrova, MD PhD – Clinical Research Fellow (2003 – 2008); recipient DC Rheumatism Society Fellows Research Award (2005-2007); currently Research Associate, George Washington University Department of Medicine
  - Jonathan Chipman- NIEHS 2007 Summers of Discovery Student, completing PhD in statistics at Boston University
  - Kim Nguyen (2008-09), Amy Li (2007 -08): student volunteers, Montgomery Blair Math Science high school magnet student- senior research project
  - Jason Monroe – NIEHS 2005 Summers of Discovery student, PhD student in Statistics, UCLA
  - Melvina Evereklian – Summer student, RN student, Univ. Maryland
  - Ellen Caruso and Vanessa Voss, RN – Database managers of NIEHS myositis and IMACS studies
- Attending physician for all of the unit’s pediatric patients, including clinical evaluation, treatment and communications with referring physicians. NIEHS has been one of the five most active pediatric institutes at the NIH Clinical Center.
  - Co-chair of International Myositis Assessment and Clinical Studies (IMACS) Group. Developed group’s web site to provide public access to outcome measures, assessment tools and related educational materials. Building a database repository of myositis clinical trials and natural history studies, including an on-line Oracle database of outcome measures and study demographics. Organize group’s annual meeting and direct all correspondence to members.
  - NIEHS representative to NIH Clinical Center committees, particularly on pediatric care issues. NIH moved the hospital to the new Clinical Research Center and opened a NIH-wide multidisciplinary pediatric clinic in 2005.
  - Advisory board and executive section member of national advisory boards, including ACR Pediatric Executive Section, pediatric rheumatology collaborative trials groups, and The Myositis Association.
  - Recent research findings have included development of definitions of improvement as a primary composite endpoint for myositis clinical trials, discovery of a novel autoantibody that is the most frequent antibody present in juvenile dermatomyositis patients, development and validation of novel outcome measures for juvenile myositis, and discovery of new immunogenetic risk factors for juvenile myositis.
  - Senior editor of a book on juvenile myositis involving more than 70 health professionals.
  - Invited for multiple national and international lectureships at meetings and prominent medical schools.
  - Frequent advisor to NIH and other physicians and patients throughout the world, patient support groups, DHHS agencies, and colleagues at medical schools in the evaluation and care of challenging patients with pediatric rheumatic diseases, and in review of scientific activities related to autoimmunity in children.

January 2001–            **Senior Clinical Investigator and Medical Officer**, Environmental Autoimmunity Group (EAG), Office of Clinical Research, National Institute of  
 September 2003        Environmental Health Sciences, National Institutes of Health, Bethesda, MD

Duties/Accomplishments:

- Design and execute clinical research, assist Unit Chief in administration of EAG, supervise and mentor personnel within the group.
- Principal investigator of myositis study and lead investigator of calcinosis study. Co-investigator of research protocols examining environmental risk factors for autoimmune diseases and novel therapeutic agent for myositis. Contributed to study design and questionnaire development, design of Oracle databases for the studies.
- Attending physician for all pediatric patients admitted to EAG research protocols, plan research and clinical studies for patients, and communicate results to referring physicians.
- Attending physician and consultant in pediatric rheumatology clinic at Walter Reed Army Medical Center (until Aug 2004).
- Co-chair and co-founder of International Myositis Assessment and Clinical Studies (IMACS) Group, which has developed new instruments to assess myositis. Led 3 international workshops on outcome measures for myositis, which resulted in new standards for conduct and reporting of clinical trials in myositis, and will establish new clinical practice standards. Developed internet site for IMACS to house member applications, public use of validated tools and training materials, meeting presentations, ongoing studies.
- Invited for multiple national and international lectureships at meetings and prominent medical schools.
- Supervisor and mentor to:
  - Gulnara Mamyrova MD PhD – Clinical Research Fellow
  - April Bingham MD- Visiting pediatric rheumatology fellow, Columbia University
  - Melvina Evereklian- RN student; volunteer. 2005 Beacon conference award recipient.
  - Lauren Komarow – NIEHS 2003 Summers of Discovery student, MS in biostatistics, Univ. Michigan; currently employed at Harvard School of Public Health
  - Adam Schiffenbauer – NIEHS 2002 Summers of Discovery student, BA Univ. Chicago; currently MD PhD student at Penn State University
  - Tina Sanghvi – NIEHS 2002 Summers of Discovery student and 2003 summer student, BA, Duke Univ.; currently MD student at Univ. Iowa
  - Ellen Caruso- part-time volunteer for data management of myositis study.

Projects have included validation of clinical outcome measures and surrogate laboratory measures to assess disease activity in myositis, new autoantibodies in myositis, features of lipodystrophy associated with juvenile myositis, immunogenetic loci as risk factors for myositis, HLA typing of juvenile myositis patients.
- Teach NIAMS and NIEHS adult rheumatology fellows, students, post-docs in patient conferences, patient presentations, and quarterly lectures on juvenile dermatomyositis. Instruct EAG staff, including other researchers, clinicians, nurse and support staff concerning ongoing research and clinical studies of patients.
- Assist the Unit Chief in administration of unit, including serving as Acting Chief up to 30 days per year while he is on travel or leave. Developed all SOPs and procedures for pediatric patients enrolled in unit's research studies. Assisted the chief in establishing a new clinical research unit on the NIH campus in Bethesda, MD, with our institute in North Carolina, including defining space for offices and clinics, hiring of unit personnel, developing SOPs.
- NIEHS representative to NIH Clinical Center, IRB and data safety monitoring board committees; advisor to DHHS Children's Longitudinal Environmental Health Study (National Children's Study) and Immunity, Infections and Vaccines Working Group; advisory board and executive section member of national pediatric rheumatology and patient support groups, and the FDA.
- Senior editor of a book on juvenile myositis involving more than 70 health professionals.
- Frequent advisor to NIH and other physicians and patients throughout the world, patient

support groups, DHHS agencies, and colleagues at medical schools in the evaluation and care of challenging patients with pediatric rheumatic diseases, and in review of scientific activities related to autoimmunity in children.

September 1996 – **Medical Officer and Staff Scientist**, Division of Monoclonal Antibodies, December 2000 Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), Bethesda, MD

Duties/Accomplishments:

- Lead investigator of 2 large multi-center nationwide studies of the juvenile myositis syndromes, including data collection and analysis. Principal investigator of NIH research protocol. Discovered microchimerism is frequently present in children with myositis and potentially important in pathogenesis. Developed novel instruments to assess myositis outcomes. Identified a number of immunogenetic polymorphisms, as risk factors for myositis in adults and children. Defined a number of clinical, immunologic and environmental subsets of juvenile myositis.
- Supervised and mentored 4 students (Abhijit Pal and Adam Schiffenbauer – International Baccalaureate Program, Richard Montgomery High School; Ben Laskin, BA, Duke Univ., currently MD student Univ. Maryland; Elizabeth Zachariah, BA, Univ. Maryland) and 1 volunteer (Ellen Caruso) who participated in data management and analysis of clinical studies, or HLA typing of juvenile myositis patients and processing tissue samples from patients.
- Invited lectureships at national meetings and medical schools.
- Chaired licensure committee for Etanercept for juvenile rheumatoid arthritis, and served on other licensure committees for anti-TNF $\alpha$  therapies for rheumatoid arthritis. Involved in policy making for rheumatic diseases and pediatrics at the FDA. Authored Rheumatoid Arthritis, Systemic Lupus Erythematosus, and Pediatric Clinical Trials Guidance Documents; participated in drafts of 1998 Pediatric Regulation. Policies developed to apply pediatric use labeling regulation to juvenile rheumatoid arthritis resulted in a large number of IND and NDA submissions for this orphan pediatric population. Consultant reviewer for licensure of several drugs for juvenile rheumatoid arthritis, vaccine adverse events, blood product labeling for pediatric use, and silicone implant adverse events. Represented FDA on Pediatric Rheumatology Collaborative Study Group Advisory Council. Presentations to Arthritis Advisory Committee. Regulatory review of product and INDs.
- Attending physician and consultant in pediatric rheumatology clinic at Walter Reed Army Medical Center.
- Frequent Advisor to physicians and patients throughout the world, patient support groups, DHHS agencies, and colleagues at medical schools in the evaluation and care of challenging patients with pediatric rheumatic diseases, and in review of scientific activities related to autoimmunity in children.

September 1993 - **Medical Officer**, Division of Cellular and Gene Therapies, CBER, FDA, Bethesda, MD

Sept 1996

Duties/Accomplishments:

- Planned and initiated two large nationwide studies of juvenile myositis.
- Principal investigator of NIH juvenile myositis research protocol.
- Saw complex patients in research study and communicated results to referring physicians. Attending physician and consultant in pediatric rheumatology clinic at Walter Reed Army Medical Center.
- Participated in laboratory research studies of autoantibodies and immunogenetics of adult and juvenile myositis.
- Supervised and mentored three students, including Dr. Ejaz Shamim, who received the American College of Rheumatology Medical Student Research Fellowship Award (1995).
- Product and clinical reviewer of biologic therapeutic agents. FDA Rheumatology Working Group and Pediatric Use Working Group. Consultant to Agency on pediatric rheumatic

disease issues. Co-chair of FDA workshop on juvenile rheumatoid arthritis (1996).

### **CLINICAL RESPONSIBILITIES AND HOSPITAL APPOINTMENTS**

2001 – present: Senior Clinical Staff, NIEHS, National Institutes of Health, Bethesda, MD  
April 2008 – present: Attending Physician, Myositis Clinic, Division of Rheumatology, George Washington University (2 days/month)  
Dec 2005 – June 2007: Visiting Consultant and Attending Physician, Rheumatology, Children's National Medical Center (1 day/month)  
1994 -August 2005: Attending Physician, Pediatric Rheumatology, Walter Reed Army Medical Center, Washington, DC (1 – 2 days/month)  
Oct 1993 – 2001: Junior Clinical Staff, NIAMS, National Institutes of Health, Bethesda, MD (varying: 1 day/month – 1 day/week)

### **ACADEMIC APPOINTMENTS**

Sept 2008 - June 30, 2009 **Clinical Professor**, Department of Medicine, George Washington University, Washington, DC

#### Duties/Accomplishments:

Attending physician and consultant in George Washington University Myositis Center, Division of Rheumatology, Department of Medicine, which receives regional and nationwide referrals of patients with refractory juvenile myositis and other myopathies. Supervise, teach and lecture adult rheumatology fellows, medical residents, GWU medical students. Assist in establishing a clinical research program for the center.

Nov 2002 – present **Adjunct Associate Professor**, Department of Pediatrics, Uniformed Services University of Health Sciences (USUHS), Bethesda, MD

March 1994 - **Assistant Professor**, Department of Pediatrics, Uniformed Services University of Health Sciences, Bethesda, MD  
Nov 2002

#### Duties/Accomplishments:

Attending physician and consultant in Pediatric Rheumatology Clinic at Walter Reed Army Medical Center, which receives nationwide and worldwide referrals for military personnel. Supervise, teach and lecture adult rheumatology fellows, pediatric residents, USUHS medical students rotating through clinic. Consult with military physicians in US and worldwide (esp. Germany) on issues of care of complex patients with pediatric rheumatic diseases.

July - Aug 1993 **Acting Instructor**, Div of Immunology/Rheumatology, Department of Pediatrics, Univ. Washington/Children's Hospital and Medical Center, Seattle, WA

### **US PUBLIC HEALTH SERVICE APPOINTMENTS AND ACTIVITIES**

Captain (7/05 – present); Permanent Captain (7/07 – present)

Permanent Commander (9/03 – 7/05)

Assimilation into Regular Corps: Permanent Lieutenant Commander (4/12/02 – 9/03)

Commander (7/98 – 4/02)

Lieutenant Commander (10/91 – 6/93, 9/93 – 7/98)

Senior Assistant Surgeon (2/28/91 – 10/91)

Commissioned as a Corps Officer 2/28/91.

Commissioned Corps Readiness Force (December 2003 – present)

Status: Active; Roster: Fully Deployable; Primary Role: NIH Research Roster

Training/Skills: Completed 14 basic readiness level core training modules and 6 FEMA modules  
BLS certified. President's Fitness Challenge (completed August, 2004 and Dec 2006)

Deployments: President Ronald Reagan State Funeral (June 2004)

Mentor to Medical Officers, Physician's Professional Advisory Committee (2004)

Physician's Professional Advisory Committee Subcommittee on Mentoring (2004)

Public Health Service Medical Review Board member (June 2002, December 2003)

Commissioned Officers Association (2003 – present)

## **CERTIFICATION**

Pediatric Advanced Life Support (2007 - present)

Basic Life Support, American Heart Association (2003 – present)

American Board of Pediatrics, Certification in Pediatric Rheumatology (1994 - 2001, recertified for 2002 – 2008, Certificate No 000113; recertified 2009 – 2013, certificate No. 00113)

American Board of Pediatrics (1990, re-certified for 1998 - 2004, Certificate No. 045457)

FLEX (1987)

## **PROFESSIONAL LICENSE**

Maryland, #D46950, 12/30/94 - present (expires 9/30/09)

District of Columbia, #MD19164, 1991 - April, 1997; # MD035811, 10/27/2005 - present

Virginia, #0101052145, 3/1/95 - 6/30/96

Washington, #MD00027469, 06/90 - 2/14/94

Federal DEA Registration Number, #BR5314543

## **HONORS AND AWARDS**

2008	America's Top Pediatricians (Consumer's Research Council of America)
2007	Hero Certificate, Cure JM Foundation ("For dedication to finding a cure for juvenile myositis")
2006	Elected member of the Henry Kunkel Society
2006	Certificate of Appreciation, US Public Health Service ("For exceptional performance in response to the USPHS Transformation objectives and mission by developing resources to mentor the professional development of Commissioned Corps physicians")
2005 – 2008	Who's Who in America
2005, 2006	Who's Who of American Women
2004	Commendation Medal, US Public Health Service ("For superior service in identifying the presence of microchimerism in juvenile-onset myositis")
2004 – 2007	Who's Who in Medicine and Healthcare
2004	National Register's Who's Who, Executive and Professionals 2004 – 2005 edition
2002	Regular Corps Ribbon, US Public Health Service
2001	National Registry of Who's Who, Published 2001 edition
2000	Commendation Medal, US Public Health Service ("For exemplary performance of duty" in clinical review and policy development)
1999	Outstanding Unit Citation, US Public Health Service ("For innovative collaboration with academia, industry and the public in the development of programs for the treatment of rheumatoid arthritis")
1999	Unit Commendation, US Public Health Service ("For significant and exceptional performance in the review and licensing of new anti-TNF therapies for autoimmune disease")
1998	Achievement Medal, US Public Health Service ("For validating the usefulness of clinical tools to assess disease activity in juvenile myositis with implications for many other pediatric and orphan diseases")
1998	Bicentennial Unit Commendation, US Public Health Service
1985-86	Eugene Stead Research Fellowship, Duke University School of Medicine
1983	Phi Beta Kappa, Summa cum laude, Duke University

## **PROFESSIONAL ORGANIZATIONS**

Henry Kunkel Society (2006 – present)

Clinical Immunology Society (2006 – present)

Section on Environmental Health, American Academy of Pediatrics (2004 - present)

Section on Uniformed Services, American Academy of Pediatrics (2000 - present)

American Medical Association (1996 - present)

Pediatric Rheumatology Subsection, American College of Rheumatology (1994 - present)

Section on Pediatric Rheumatology, American Academy of Pediatrics (1994 - present)  
Washington DC Rheumatism Society (1991 – 1994, 2003 - present)  
American College of Rheumatology (1990 - present)  
American Academy of Pediatrics, Pediatric Rheumatology Section (1990 - present)

### **PROTOCOL INVESTIGATIONS**

Principal Investigator, Studies in the Natural History and Pathogenesis of the Idiopathic Inflammatory Myopathies of Childhood, NIEHS, National Institutes of Health, Bethesda, MD (NIEHS 94-E-0165) (1994 – 2001 as NIAMS protocol, 2001 – present as NIEHS protocol)  
Co-Investigator, “Rituximab in the Treatment of Refractory Adult and Juvenile Dermatomyositis and Adult Polymyositis” (NIEHS 07-E-0012) (2006 – present)  
Co-Investigator, “Studies in the Natural History and Pathogenesis of Adult Myositis” (NIAMS 91-AR-0196), (2005 – present)  
Co-Investigator, “Pathogenic Studies in Families with Twins or Siblings Discordant for Systemic Rheumatic Disorders” (NIEHS 03-E-0099) (2003 – present)  
Co-Investigator, “Studies on Tissues from Patients with Fibrous Dysplasia of Bone/McCune Albright Syndrome and Other Disorders of Calcified Tissues” (NIDR 97-D-0055) (2002 – 2008)  
Co-Investigator, “A Randomized, Double-Blind, Placebo-Controlled Trial of Infliximab in Patients with Dermatomyositis and Polymyositis” (NIAMS 02-AR-0156) (2002 – 2008)  
Co-Investigator, “Studies in the Natural History and Pathogenesis of Autoimmune/Connective Tissue Diseases” (FDA RIHSC CBER #121; NIEHS 05-E-N200) (1994 – present); Protocol includes Principal Investigator, Childhood Myositis Heterogeneity Collaborative Study, a registry of over 400 juvenile idiopathic inflammatory myopathy patients with clinical information, cell and serum bank, limited biopsy specimens.

### **GRANT SUPPORT**

2006 - present Inter-agency agreement, NIAMS, Rituximab Therapy in Refractory Adult and Juvenile Idiopathic Inflammatory Myopathies (NIEHS as enrollment site, \$515,586)  
2005 - present American College of Rheumatology, Development of Outcome Measures for Myositis (\$15,000 to support database development and management)  
2004 – 2007 Supervisor for Research Fellowship of Dr. Gulnara Mamyrova, Cure JM Foundation (salary support for 3 years; no funds being received by me or NIEHS)  
2002 – 2004 Supervisor for Research Fellowship of Dr. Gulnara Mamyrova, The Myositis Association (salary support for 2 years; no funds being received by me or NIEHS)  
2001, 2002 Co-Principal Investigator, NIH Office of Rare Diseases and NINDS funding for 2 workshops on Outcome Assessment and Clinical Trial Design in the Idiopathic Inflammatory Myopathies (\$25,000 each year).  
2001 – 2002 Co-Investigator, NIAMS R21 grant to Dr. Ann Reed, “Finalization of Outcomes and Design Issues for Myositis Trials” (\$83,000; no funds being received by me or NIEHS)  
1985-86 Pharmaceutical Manufacturer’s Medical Student Research Fellowship in Pharmacology - Clinical Pharmacology

### **COMMITTEES AND ADMINISTRATIVE EXPERIENCE**

Resource Committee, NIH Clinical Center Barriers to Clinical Research Working Group (2008 - )  
Pediatric Rheumatology Study Section Chair, American College of Rheumatology (2006 – 2009)  
Communications Committee, Clinical Immunology Society (2006 – 2009)  
Editorial Board, Table of Biologic Therapies, Clinical Immunology Society (2008 – 2009)  
Member and lead investigator of pediatric studies, International Myositis Genetics Consortium (MyoGen) (2006 – present)  
Steering Committee, ACR-EULAR International Myositis Classification Criteria Project for the Idiopathic Inflammatory Myopathies (2004 – present)  
The Myositis Association: Vice Chair of Medical Advisory Board (2005 –2007), Chair, Research Committee (2008); Chair, Nominating Committee (2001 –2006), Research Committee (2006 - 2008), Medical Advisory Board Member (1996 - present)  
Executive Council, Pediatric Subsection, American College of Rheumatology (2003 – 2007); Vice Chair

(2006 – 2008)

Consultant, NIH Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease (2004 – 2007)

NIEHS representative, NIH Clinical Research Center Pediatric Partners Care Team (2003 – present)

NIEHS representative to NIH Pediatric Care Committee (2002 – present); Subcommittee on Normal Childhood Laboratory Values (2003- 2008); Subcommittee on Infection Control Policies at Children's Inn (2004 – 2005)

NIEHS Code Red Team member for NIH Clinical Center; Designated evacuation safety leader for EAG, organizing annual safety and evacuation training (2003 – present)

Steering Committee, Trial of Rituximab in Adult and Juvenile Idiopathic Inflammatory Myopathies (2002 – present)

Children's Longitudinal Environmental Health Study (National Children's Study), Immunity, Infections and Vaccines Working Group (2002 – 2005)

Childhood Arthritis and Rheumatology Research Alliance (CARRA), Member: Juvenile Dermatomyositis Scientific Group, Translational Research Working Group (2002 – present); Disease registry working group (2008- present)

Member and NIH Representative, Advisory Council, Pediatric Rheumatology Collaborative Study Group (2001 – present)

Member, NIH Pediatric Consortium (2001 – present), NIH Muscle Interest Group (2001 – present)

Member, Search Committee for NIEHS Staff Clinician (2001 – 2002)

Co-Chair and Co-Founder, International Myositis Assessment and Clinical Studies (IMACS) Collaborative Study Group (2000 - present). Organizer of 3 international IMACS Workshops (2001-2003) and annual meetings. Developed IMACS internet site to make publicly available IMACS outcome measures, training modules and a database repository of myositis clinical trials.

Abstract Selection Committee, Pediatric Rheumatology (1998), Myositis/Myopathies (2002, 2004), American College of Rheumatology

Meeting Organizer and Co-Chair, FDA Juvenile Rheumatoid Arthritis Workshop, Bethesda, MD (July 23, 1996)

Advisor, the National Dermatomyositis Support Group, 1994-1996

Juvenile Dermatomyositis American College of Rheumatology Working Group (founding chair) (1993 - present)

### **FDA Regulatory Activities**

Special Government Employee Consultant to FDA, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), Bethesda, MD (2003 –2005): consultant on INDs for biologic therapies in children with pediatric rheumatic diseases

Guest Worker (Special Government Employee Consultant to FDA under Inter-Agency Agreement), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), Bethesda, MD (2001 - 2002): consultation on INDs for biologic and drug therapies in children with pediatric rheumatic diseases and consultation on immune-mediated adverse events to biologic therapies and vaccines.

Product Reviewer, Division Monoclonal Antibodies (1996 – 2001) and Division of Cellular and Gene Therapies (1993 – 1996), Office of Therapeutics Research and Review (OTRR), CBER, FDA

Adjunct Clinical Reviewer, Division of Clinical Trial Design and Analysis, OTRR, CBER, FDA (1994 – 2001), including chair of licensure committee for Etanercept in JRA, IND reviewer or consultant for multiple INDs of biologic therapies for patients with pediatric and adult rheumatic diseases; development of phase 4 studies for juvenile rheumatoid arthritis (JRA); and post-marketing adverse event review for biologic therapies and vaccines

Consulting Clinical Reviewer for CBER, Center for Drugs (CDER) and Center for Devices (CDRH), FDA (1994 – 2001): Division of Anti-Inflammatory Drugs, CDER (clinical trials of drugs for JRA, licensure applications and labeling issues for licensure of methotrexate, sulfasalazine and cyclosporine for JRA); vaccine-associated immunologic adverse events; pediatric labeling for blood products; pediatric rheumatic diseases associated with silicone implants

Pediatric Clinical Trial Guidance Document (1999): Authored section on adverse event assessment and clinical trial outcome measures.

FDA Representative, Advisory Council, Pediatric Rheumatology Collaborative Study Group (1998- 2000)



CBER Rheumatology Focus Group, Food and Drug Administration (1996 - 2001)  
Rheumatology Working Group, Food and Drug Administration (1995 - 2001) - author of Rheumatoid Arthritis and Systemic Lupus Erythematosus Guidance Documents, particularly pediatric policies. Co-chaired and organized workshop on juvenile rheumatoid arthritis (1996)  
Pediatric Use Working Group, Food and Drug Administration (1995 – 1998). Participated in drafting revisions of 1998 Pediatric Regulation.

### **EDITORIAL AND REVIEW BOARD ACTIVITIES**

Editorial Board, *The Open Rheumatology Journal* (2007 - present)

Ad hoc reviewer: *Arthritis and Rheumatism, Lancet, Arthritis Care and Research, Rheumatology, Journal of Neuroimmunology, Journal of Molecular Diagnostics, Journal of Rheumatology, Clinical and Experimental Rheumatology, Journal of Pediatric Rheumatology, Seminars in Arthritis and Rheumatism, Scandanavian Journal of Rheumatology, Journal of Pediatrics, Journal of Clinical Rheumatology, Archives of Dermatology, Pediatric Dermatology, Expert Opinion on Drug Safety*

Grant reviews:

American College of Rheumatology Research and Education Fund (2008)

Prinses Beatrix Fonds (2008)

The Myositis Association (2002 – 2008; Chair, Research Review committee 2008)

NIAMS RO1 applications (2004)

NIAMS PO1 Program Project Grant Applications (2002)

Univ Pittsburgh NIAMS Multipurpose Arthritis Center Development and Feasibility grants (2000)

Data Safety Monitoring Board, Ingested Interferon Alpha: Prolongation of Permanence of the “Honeymoon” Phase in Newly Diagnosed Diabetes Mellitus (01-DK-0249) (2002 – 2006)

Consulting reviewer, NIAMS/NIDDK/NIEHS Institutional Review Board (2001 - present)

Advisory Committee, NIH/Hospital for Joint Diseases Registry for Neonatal Lupus (1994 - present)

### **PUBLICATIONS**

#### **Publications in Refereed Journals:**

1. Abramson, S., H. Korchak, R. Ludewig, H. Edelson, K. Haines, R.I. Levin, **L. Rider**, and G. Weissmann. Modes of action of aspirin-like drugs. *Advances in Inflammation Research* 1985; 10: 31-35.
2. Abramson, S., H. Korchak, R. Ludewig, H. Edelson, K. Haines, R.I. Levin, R. Herman, **L. Rider**, S. Kimmel and G. Weissmann. Modes of action of aspirin-like drugs. *Proc. Natl. Acad. Sci.* 1985; 82: 7227-7231.
3. **Rider, L.G.** and J.E. Niedel. Diacylglycerol accumulation and superoxide anion production in stimulated human neutrophils. *J. Biol. Chem.* 1986; 262:5603-5608.
4. **Rider, L.G.**, R.W. Dougherty, and J.E. Niedel. Phorbol diesters and d-octanoylglycerol stimulate accumulation of both diacylglycerols and alkylacylglycerols in human neutrophils. *J. Immunol.* 1988; 140:200-207.
5. **Rider, L.G.**, D.D. Sherry, and S.T. Glass. Neonatal lupus erythematosus simulating transient myasthenia gravis at presentation. *J. Pediatr.* 1991; 118:417-419.
6. **Rider, L.G.**, W.R. Clarke, and J. Rutledge. Clinicopathologic conference: Pulmonary hypertension in a seventeen-year-old boy. *J. Pediatr.* 1992; 120:149-159.
7. **Rider, L.G.**, Buyon, J.P., Rutledge, J., and D.D. Sherry. Treatment of neonatal lupus: Case report and review of the literature. *J. Rheumatol.* 1993; 20:1208-1211.
8. **Rider, L.G.**, M.H. Wener, J. French, D.D. Sherry and P.M. Mendelman. Autoantibody production in Kawasaki syndrome. *Clin Exp Rheumatol.* 1993; 11:445-449.
9. **Rider, L.G.**, N. Raben, L. Miller, and C.L. Jelsema. The cDNAs for two forms of the *lyn* tyrosine kinase are expressed in rat mast cells and human myeloid cells. *Gene.* 1994; 138: 219-222.
10. **Rider, L.G.**, F.W. Miller, I.N. Targoff, D.D. Sherry, E. Samayoa, M. Lindahl, M.H. Wener, L.M. Pachman, and P.H. Plotz. Myositis-specific autoantibodies in children: A broadened spectrum of juvenile myositis. *Arthritis Rheumatism.* 1994; 37:1534-1538.
11. **Rider, L.G.**, P. Thapa, M. DelBecarro, and P.M. Mendelman. Cerebrospinal fluid analysis in children with seizures. *Pediatr. Emerg. Care.* 1995; 11:226-229.

12. **Rider, L.G.\***, N. Hirasawa\*, F. Santini, and M.A. Beaven. Activation of Mitogen Activated Protein Kinase cascade is suppressed by low concentrations of dexamethasone in mast cells. *J. Immunol.* 1996; 157:2374-2380. \* These authors contributed equally.
13. **Rider, L.G.**, B.M. Feldman, M.D. Perez, R.M. Rennebohm, C.B. Lindsley, L.S. Zemel, C.A. Wallace, S.H. Ballinger, S.L. Bowyer, A.M. Reed, M.H. Passo, I.M. Katona, F.W. Miller, and P.A. Lachenbruch, for the Juvenile Dermatomyositis Disease Activity Collaborative Study Group. Development of Validated Disease Activity and Disease Damage Indices for the Juvenile Idiopathic Inflammatory Myopathies: I. Physician and Parent/Patient Global Assessments. *Arthritis Rheumatism.* 1997; 40: 1976-1983.
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#### **Photographs/Slide Atlases:**

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  39. L Vegosen, C Weinberg, T O'Hanlon, I Targoff, B Koneru, G Mamyrova, F Miller, **L Rider**, and the Childhood Myositis Heterogeneity Study Group. Seasonal Birth Patterns in Subgroups of Myositis Suggest a Role for Perinatal Environmental Factors in Etiology. *Arthritis Rheum.* 2005; 52 (suppl): S228.
  40. G Mamyrova, D Carrick, T O'Hanlon, J Malley, A Reed, D Sherry, C Wallace, L James-Newton, L Zemel, M Perez, C Lindsley, F Miller, **L Rider**, and the Childhood Myositis Heterogeneity Study Group. Relative Importance of Immunogenetic Risk and Protective Factors for the Development of Juvenile Dermatomyositis (JDM) in European American (EA) Patients. *Arthritis Rheum.* 2005; 52 (suppl): S308-S309.
  41. G Mamyrova, T O'Hanlon, D Carrick, J Malley, F Miller, **L Rider**, and the Childhood Myositis Heterogeneity Study Group. DRB1\*0301 and the Second Hypervariable Region DRB1 Motif, <sup>70</sup>QKRGR<sup>74</sup> are HLA Risk Factors for Dermatomyositis (DM) in African-American (AA) Patients. *Arthritis Rheum.* 2005; 52 (suppl): S308.
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48. G. Mamyrova, CA. Bingham, EA Oral, K. Rother, E. Cochran, N. Sebring, J. Pandey, L. James-Newton, T. O'Hanlon, I. Targoff, F. Miller, **L. Rider**. Clinical and Metabolic Characteristics of Acquired Lipodystrophy in Juvenile Dermatomyositis Arthritis and Rheumatism 2007; 55 (suppl): S145.
49. **L. Rider**, P Lachenbruch, L James-Newton, I Cabalar, B Feldman, A Ravelli, B Myones, R Rennebohm, L Pachman, M Villalba, E Adams, C Lindsley, C Wallace, L Zemel, A Reed, F Miller, for the IMACS Group Predictors of Calcinosis in Juvenile and Adult Myositis. Arthritis and Rheumatism. 2008; 58 (S): **S230**.
50. **L. Rider**, P. Lachenbruch, L. James-Newton, I. Cabalar, B.M. Feldman, A. Ravelli, B. Myones, R. Rennebohm, L. Pachman, M. Villalba, E. Adams, C. Lindsley, C. Wallace, S. Ballinger, L. Zemel, A. Reed, F. Miller, IMACS Group Effects of Treatment on Disease Damage in Juvenile and Adult Myositis . Arthritis and Rheumatism, 2008; 58S, S229.

#### **Government Publications:**

Guidance for Industry: Clinical Development Programs of Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis. Food and Drug Administration February 1999.

<http://www.fda.gov/cder/guidance/1208fnl.htm>.

#### **Internet Sites:**

<https://dir-apps.niehs.nih.gov/imacs/home.htm>

#### **INVITED LECTURES AND SELECTED PRESENTATIONS**

- “Juvenile myositis: A research update”. Cure JM 5<sup>th</sup> anniversary meeting, January 25, 2008, Carlsbad, CA.
- “Clinical Databases: Setup and Maintenance for Clinical Data Sharing”, NIAMS Conference on SAPHO/Bechet’s, Bethesda, MD, September 4, 2008
- “Adult and Juvenile Myositis”, George Washington University Rheumatology lecture series, July 18, 2008
- Participant, Career as a Pediatric Rheumatologist and Clinical Researcher, Lucy Barnsley Elementary School Career Day, Rockville, MD, May 2007 and May 30, 2008
- “Components and Predictors of Damage in Juvenile Myositis Using the Myositis Damage Index”, American College of Rheumatology Pediatric Rheumatology Meeting, Keystone, CO, March 4, 2008
- “Ask the Expert: Online Chat on Juvenile Myositis”, The Myositis Association, February 22, 2008
- Invited Participant, CARRA Consensus Conference to Develop Treatment Protocols for Juvenile Dermatomyositis, November 30 – December 2, 2007, Toronto, Canada
- Department of Pediatrics Grand Rounds, Children’s Memorial Hospital, Northwestern University School of Medicine, “Juvenile Myositis: A Research Perspective”, Chicago, IL, November 16, 2007
- “Rheumatic Disease Update: Adult and Juvenile Dermatomyositis/Polymyositis”, American Rheumatology Health Professionals, Boston, MA, November 10, 2007
- Cure JM Foundation Educational Forum and Panel Discussion, “Juvenile Myositis: Assessing Outcomes and Potential New Therapies”, Arlington, VA, October 27, 2007
- Department of Pediatrics Grand Rounds, Georgetown University School of Medicine, “Juvenile Myositis: A Clinical Update”, Washington DC, May 11, 2007
- Rheumatology Grand Rounds, George Washington University School of Medicine, “Juvenile Myositis”, Washington DC, March 29, 2007
- Clinical Immunology Society School for Autoimmune Diseases, “Immunogenetic and Environmental Risk Factors for Juvenile Myositis”. Faculty, March 14 -18, 2007, Santa Fe, New Mexico.
- “IMACS Clinical Data Repository” and Chair, IMACS/JDM Working Group Breakfast Meeting, November 14, 2006, Washington, DC
- American College of Rheumatology, Pediatric Study Section, “Immunogenetic and Environmental Risk Factors for Juvenile Myositis”, Washington DC, November 13, 2006
- Rheumatology Grand Rounds, Georgetown University School of Medicine, “Juvenile Myositis”, Washington DC, October 25, 2006
- Ann Hengel Lecture in Pediatric Rheumatology. “Juvenile Dermatomyositis” Medical College of Wisconsin, Milwaukee, Wisconsin. April 28, 2006.
- Clinical Immunology Society School for Autoimmune Diseases, “Juvenile Myositis”. Faculty, March 15 - 18, 2006, Santa Fe, New Mexico.

Invited Alumni Panelist, "Medicine and Research", Duke University Career Week, January 28, 2006, Durham, NC.

American Academy of Pediatrics Workshop, "Juvenile Dermatomyositis Dilemmas: A Case of Flare Following Remission". November 15, 2005, San Diego, CA.

Meeting co-organizer and presentation of "IMACS Internet Site" and "IMACS Outcomes Repository", November 13, 2005, San Diego, CA.

Rituximab in Myositis Investigator's Meeting, "Core Set Measures, including the MMT8, and the Definition of Improvement", and "Rituximab in Myositis Study Protocol" October 29, 2005 and February 6, 2006, Bethesda, MD.

The Myositis Association Annual Conference. Medical Panel: "TMA's Research Program and Funded Research on Juvenile Myositis" and Workshop on "Juvenile Myositis", October 8, 2005, Cleveland, OH.

American Juvenile Arthritis Organization National Conference. "Juvenile Dermatomyositis" Workshop and Roundtable Discussion, July 29, 2005, Providence, RI.

Rheumatology Grand Rounds, University of Pittsburgh, Pittsburgh, PA. November 12, 2004.

"Classification of Juvenile Myositis", Working Group meeting on the Classification of Idiopathic Inflammatory Myopathies, October 26, 2004, Bethesda, MD; Meeting co-organizer for Working Committee meeting, November 11, 2005, Dulles Airport, VA.

"IMACS Internet Site and Clinical Data Repository" and Chair, IMACS Breakfast Meeting, October 18, 2004, San Antonio, TX

"Juvenile Myositis Handbook", The Myositis Association, Conference on Juvenile Myositis, May 9, 2004, Bethesda, MD.

Rheumatology Grand Rounds, Hospital for Special Surgery, Cornell Medical College, NY, NY, February 11, 2004

Invited Alumni Panelist, Duke University Career Week, Durham, NC, January 31, 2004 (sessions on Science and Research, Women and Leadership).

"Meet the Professor: Juvenile Dermatomyositis", American College of Rheumatology meeting, November 12/13, 2001, San Francisco, CA; October 26/27, 2002, New Orleans, LA; October 27-29, 2003; Orlando, FL; October 25/27, 2003, Orlando, FL.

American College of Rheumatology meeting, October 28, 2003, Orlando, FL: Presentation of paper, "Preliminary Definitions of Improvement for Juvenile Myositis"

Meeting Co-Organizer and Presentation of several papers ("Summary of IMACS Definitions of Improvement", "Future Plans for IMACS" Workshop), IMACS Meeting, October 27, 2003, Orlando, FL.

Invited Participant and Speaker, Pediatric Rheumatology International Trials Organization (PRINTO) International Consensus Conference on Defining Improvement in Juvenile Dermatomyositis. "IMACS Preliminary Definitions of Improvement for Juvenile and Adult Myositis". September 29 – 30, 2003, Camogli, Italy.

European League Against Rheumatism (EULAR) meeting, "Preliminary Definitions of Improvement for Adult and Juvenile Myositis" and moderated session on Difficult Cases of Myositis/Myopathies, June 20, 2003, Lisbon, Portugal

Invited Participant, Consensus Conference to Develop Criteria for Inactive Disease in Juvenile Rheumatoid Arthritis, May 3- 4, 2003 Marco Island, FL

Schlager Family Visiting Professor Lectureship in Juvenile Dermatomyositis April 30, 2003, Children's Hospital, Boston, MA: "Juvenile Idiopathic Inflammatory Myopathies: Lessons from the Children".

Rheumatology Grand Rounds, Brigham and Women's Hospital: Evaluation and Treatment of the Juvenile Idiopathic Inflammatory Myopathies, April 29, 2003, Boston, MA.

American Academy of Pediatrics Pediatric Rheumatology 2003: Park City and Beyond: General Session, "Preliminary Definitions of Improvement for Juvenile and Adult Myositis" (March 26, 2003); Meet the Expert, "Juvenile Dermatomyositis" (March 23, 2003); Concurrent Session, "The Development of Outcome Measures for Juvenile Dermatomyositis" (March 23, 2003), Snowmass, CO.

American College of Rheumatology meeting, Clinical Symposium, "Treatment of Refractory Juvenile Dermatomyositis", October 26, 2002, New Orleans, LA.

American College of Rheumatology meeting, October 29, 2002, New Orleans, LA: Presentation of 2 papers, "Extra muscular disease activity is frequent in adult and juvenile idiopathic inflammatory myopathies (IIM) and does not correlate with other myositis activity measures" and "Defining clinically

relevant change in core set activity measures for adult and juvenile idiopathic inflammatory myopathies”

Meeting Co-Organizer and Presentation of several papers (“Summary of the First Workshop”, “Top Candidate Definitions of Improvement for Adult and Juvenile Myositis”, “Clinical Trial Design Issues”, “Preliminary Study of Disease Damage in Adult and Juvenile Myositis using the Myositis Damage Index”),

2<sup>nd</sup> Workshop, Developing Consensus on Outcomes and Clinical Trial Design Issues in Adult and Juvenile Myositis, October 22 – 23, 2002, New Orleans, LA.

The Myositis Association Annual Conference. Medical Panel: “Similarities and Differences between Adult and Juvenile Idiopathic Inflammatory Myopathies” and Workshop on “Juvenile Myositis”, September 28, 2002, Atlanta, GA.

“Scoring of the Cutaneous Manifestations of the MITAX and Myositis Damage Index”; Presentation of Sample Cases of Global Activity and Damage Ratings, and Myositis Workshop Participant in two Myositis Outcome Measure Workshops, London, England (May 2002, March 2001).

“New Developments in the Juvenile Idiopathic Inflammatory Myopathies”, Grand Rounds, Department of Pediatrics, Stanford University, Palo Alto, CA, November 16, 2001.

American College of Rheumatology meeting, November 13, 2001, San Francisco, CA: Presentation of paper, “Lipodystrophy in juvenile dermatomyositis is associated with calcinosis, but not with adipocyte differentiation factor *dllk* levels

Meeting Organizer and Presentation of several papers on Core Set Outcome Measures in Adult and Juvenile Myositis, for International Workshop on Myositis Outcome Measures and Clinical Trial Design Issues: Defining Improvement in Adult and Juvenile Myositis. November 9-10, 2001, Palace Hotel, San Francisco, CA.

“Assessment of Disease Activity and Damage in Juvenile Dermatomyositis (JDM)”, and Invited Participant, International Consensus Conference to Define Core Sets of Outcome Measures for Juvenile Systemic Lupus Erythematosus and Juvenile Dermatomyositis, March 30 – April 4, 2001, Pavia, Italy

“Acquired Lipodystrophy associated with Autoimmune Diseases”, First International Workshop on Lipoatrophic Diabetes and other syndromes of Lipodystrophy, March 23, 2001, Bethesda, MD.

NIAMS Intramural Research Program Workshop on Pediatric Rheumatic Diseases, “Juvenile Dermatomyositis: Future Research Needs”, February 16, 2001, Bethesda, MD.

Joseph L Hollander Lectureship, Division of Rheumatology, “Pathogenesis of Dermatomyositis and Polymyositis” and “Myositis-specific and Myositis-associated Autoantibodies in the Juvenile Idiopathic Inflammatory Myopathies”, The Children’s Hospital of Philadelphia and University of Pennsylvania, January 17, 2001, Philadelphia, PA.

American College of Rheumatology Pediatric Subsection Meeting. “Clinical and Serologic Classification of Juvenile Myositis”, October 30, 2000, Philadelphia, PA.

Myositis Association of America Annual Conference. Workshop on Juvenile Myositis. October 14, 2000, Fairfax, VA.

FDA Arthritis Advisory Committee Presentation, Closed Session, Gaithersburg, MD, April 11, 2000.

NIAMS Workshop on Inflammatory Myopathies, April 5-6, 2000, Bethesda, MD: “Juvenile Myositis: Clinical Overview”.

Workshop: Hands on Approach to the Diagnosis and Management of the Child with Rheumatic Disease: Juvenile Dermatomyositis. American Academy of Pediatrics meeting, Washington DC, October 10, 1999.

VI Pediatric Rheumatology European Congress/EULAR, Glasgow, Scotland, June 6, 1999: “Classification and epidemiology of the juvenile idiopathic inflammatory myopathies”.

National Institutes of Health Clinical Center Grand Rounds, Bethesda, MD, May 27, 1999: “Lipodystrophy in Association with Autoimmune Disease” as part of Clinical Staff Conference: “The importance of Fat: Lipoatrophy, Insulin Resistance and Diabetes”, S. Taylor, moderator.

Moderator of Concurrent Session, Immunogenetics and Autoantibodies in Pediatric Rheumatologic Diseases, American College of Rheumatology meeting, San Diego CA, November 11, 1998

American Juvenile Arthritis Organization National Conference, July 24, 1998, Arlington, VA: Medical Understanding: Juvenile Dermatomyositis and Mixed Connective Tissue Disease

Park City IV International Pediatric Rheumatology Meeting, Allied Health Professionals section, March 18,

1998, Park City, Utah, "Clinical Evaluation and Management of Childhood Myositis"  
American Academy of Pediatrics, Rheumatology Subsection, November 2, 1997, New Orleans, LA: "The Spectrum of Childhood Inflammatory Myopathies"  
Myositis Association of America Conference, October 4, 1997: "Workshop for parents of children with myositis".  
FDA Arthritis Advisory Committee Meeting, February 4/5, 1997: "Juvenile Rheumatoid Arthritis and the Proposed Application of the Pediatric Use Regulation".  
American College of Rheumatology Meeting, October 21, 1996, Orlando Florida: Presentation of paper, "Immunogenetic risk factors for juvenile idiopathic inflammatory myopathy"  
Meeting Co-Chair, FDA Juvenile Rheumatoid Arthritis Workshop, July 23, 1996, Bethesda, MD  
Grand Rounds, Dept of Rehabilitation Medicine, National Institutes of Health, May 19, 1995: "Juvenile dermatomyositis"  
National Institutes of Health Clinical Center Grand Rounds, September 29, 1993; "Juvenile idiopathic inflammatory myopathies" as part of Clinical staff conference "Myositis: Immunologic contributions to understanding causes, therapy", P.H. Plotz, moderator.