BIOGRAPHICAL SKETCH

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NAME: Yukiko Kimura, MD

eRA COMMONS USER NAME (credential, e.g., agency login): ykimura

POSITION TITLE: Professor of Pediatrics, Hackensack Meridian School of Medicine; Chief, Pediatric Rheumatology, Joseph M. Sanzari Children's Hospital, Hackensack University Medical Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
City College of New York	B.S.	01/1978	Biology
Albert Einstein College of Medicine	M.D.	06/1982	Medicine
Babies Hospital, Columbia University College of Physicians and Surgeons (P&S)	Residency	06/1985	Pediatrics
Babies Hospital, Columbia University P&S	Fellowship	12/1992	Pediatric Rheumatology

A. Personal Statement

I am a Professor Pediatrics, and my research efforts are directed toward improving the health, treatment and outcomes for patients with pediatric rheumatic diseases. I am a leader of the Childhood Arthritis and Rheumatology Research Alliance (CARRA) including having been President, Chair of the JIA Research Committee, and Co-Chair of the CARRA Research and Registry Oversight Committee, and current member of the CARRA Biobank and Registry Strategy Committee. I led the effort to launch the new CARRA Registry and to develop it into a consolidated disease registry for JIA for CARRA to understand adverse events and other outcomes in children with JIA, and have been the co-PI of the Registry, which has now enrolled almost 13,000 patients. This work has supported multiple research studies and data analyses, including the STOP-JIA study cited below. I have led efforts to demonstrate the utility of disease specific registries to be used for long-term pharmacosurveillance and for registration studies as well as to do comparative effectiveness research (CER).

I led the development of the CARRA consensus based standardized treatment plans (CTPs) for JIA to be used for comparative effectiveness research (NIH/NIAMS (Wallace, Ilowite MPI, 9/09-9/11: Comparative Effectiveness Research in Pediatric Rheumatic Diseases: Leveraging CARRA to Improve Child Health: Y Kimura JIA co-I). Initially, I led the development of CARRA CTPs for new onset systemic JIA, followed by polyarticular JIA (Y Kimura PI: ACR Research and Education Foundation Disease Targeted Research Grant, 7/1/12-6/30/13), both of which were published. In addition, I obtained funding and was the PI of the CARRA-wide implementation of these CTPs for CER. These include the PCORI-funded Start Time Optimization of biologics in Polyarticular JIA (STOP-JIA) study, which was successfully completed. It was the first successful large scale observational comparative effectiveness study of the CARRA CTPs for poly JIA, the largest prospectively enrolled study in poly JIA, and showed that starting biologics early (by 3 months after diagnosis) may lead to better outcomes in this disease.

I am also the co-PI of an NIH and CARRA funded Systemic-JIA Lung Disease cohort study along with Dr. Schulert, which enrolls patients to collect SJIA-LD specific data and biosamples through the CARRA Registry. I authored the first recent report of SJIA-LD patients that highlighted the increased incidence of this condition. With the NIH R01 award, continued enrollment of incident patients and longer term follow up including the collection of more detailed clinical and patient reported information, as well as analyses to detect biomarkers of disease activity and damage will be enabled.

I have a proven track record as a collaborative and productive researcher, having been the overall PI and/or site PI for many multi-center clinical trials, registry studies, studies collaborating with translational researchers, and many other research projects conducted through several research networks including CARRA over many years, and have the skills and experience needed for this research proposal.

Ongoing and recently completed projects that I would like to highlight include:

"Clinical disease progression and validation of surrogate biomarkers and patient-reported outcomes for SJIA-LD" (MPI: G. Schulert, Y Kimura)
NIH-NIAMS 1R01AR084717-01
Goal: To create a registry of SJIA-LD patients with accompanying biospecimens to establish a case definition, natural history and contemporary cohort of this disease and validate surrogate biomarkers of disease activity and damage
Total award: $726,002
Role: Co-Principal Investigator
8/15/24-6/30/28

"Trial of Sequential Medications AfteR TNF failure in JIA (SMART-JIA)" (PI: Schanberg)
Patient Centered Outcomes Research Institute Phased Large Awards for Comparative Effectiveness Research
Goal: Randomized trial of second TNF inhibitor vs other treatment in JIA patients who fail their first TNF inhibitor
Total award: $20M
Role: Co-Investigator
4/1/24-12/31/26

"Learning to predict longitudinal treatment effects in relapsing-remitting diseases" LEAP-JIA (MPI Ong, Kimura)
7/1/23-6/30/26
Patient Centered Outcomes Research Institute
Goal: To use advanced machine learning methods for evaluating and predicting the effects of therapies on disease course in JIA
Role: Co-Principal Investigator

"Comparative Effectiveness of CARRA Consensus Treatment Plans for Polyarticular JIA" (PI: Kimura)
PCORI CER-1408-20534
Total award: $2.6M
Role: Principal Investigator
11/2015-11/2020

Citations:

1. **Yukiko Kimura MD**, Laura E. Schanberg MD, George A. Tomlinson PhD, Mary Ellen Riordan BSN CCRC, Anne C. Dennos MSPH, Vincent Del Gaizo, Katherine L. Murphy MPH, Pamela F. Weiss MD MSCE, Marc D. Natter MD, Brian M. Feldman MD MSc, Sarah Ringold MD MS, and the CARRA STOP-JIA Investigators. The Childhood Arthritis & Rheumatology Research Alliance Start Time Optimization of Biologics in Polyarticular Juvenile Idiopathic Arthritis Study. Arthritis Rheumatol. 2021 Jun 8. doi: 10.1002/art.41888. Online ahead of print. PMID: 34105312
2. MS Ong, S Ringold, **Y Kimura**, LE. Schanberg, GA Tomlinson, MD Natter. Improved disease course associated with early initiation of biologics in new-onset polyarticular Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2021 PMID: 34105303

3. Beukelman T, Tomlinson G, Nigrovic PA, Dennos A, Del Gaizo V, Jelinek M, Riordan ME, Schanberg LE, Mohan S, Pfeifer E, **Kimura Y**; CARRA FROST Investigators. First-line options for systemic juvenile idiopathic arthritis treatment: an observational study of Childhood Arthritis and Rheumatology Research Alliance Consensus Treatment Plans. Pediatr Rheumatol Online J. 2022 Dec 8;20(1):113. doi: 10.1186/s12969-022-00768-6. PMID: 36482434; PMCID: PMC9730566.
4. **Y Kimura** et al: Pulmonary Hypertension and Other Potentially Fatal Pulmonary Complications in Systemic Juvenile Idiopathic Arthritis. Arthritis Care Res 2013 PMID 23139240

B. Positions, Scientific Appointments, and Honors

Position and Scientific Appointments

2024-present Research consultant, CARRA
2022-present Member, CARRA Biobank and Registry Strategy Committee
1991-present Chief, Pediatric Rheumatology Division, Hackensack University Medical Center
2019-2023 Co-Chair, CARRA Research and Registry Oversight Committee
2017-present Professor of Pediatrics, Hackensack Meridian School of Medicine
2017-present Member, International Scientific Advisory Board for UCAN-CAN Du
2008-present Member, CARRA Steering Committee
2020-2021 Member, ACR JIA Guidelines Expert Panel
2018-2020 Member, Board of Directors, CARRA, Inc.
2018-2020 Past President, CARRA, Inc.
2016-2018 President, CARRA, Inc.
2012-2019 CARRA Registry Executive Committee
2008-2018 Board of Directors, Arthritis Foundation of New Jersey
2006-2018 Chair, Juvenile Arthritis Committee, Arthritis Foundation of New Jersey
2013-2017 Professor of Pediatrics, Rutgers-NJMS
2013-2016 Vice Chair and Chair Elect, CARRA Steering Committee
2009-2014 Member, American Board of Pediatrics (ABP) Pediatric Rheumatology Sub-Board
2012-2013 Chair, Credentials Committee, sub-board of Pediatric Rheumatology, ABP
2010-2013 Expert reviewer, Agency for Healthcare Research and Quality (AHRQ) Effective Health Care
2002-2013 Associate Professor of Pediatrics, UMDNJ-NJMS
2008-2013 Chair, JIA Research Committee (CARRA)
2009-2012 Study Section, ACR Research & Education Foundation
2009-2012 Member, Committee on Finance, American College of Rheumatology
2008-2011 Co-Chair, ACR Pediatric Rheumatology Symposium
2009-2011 Pediatric Rheumatology Collaborative Study Group Advisory Board
2011 Invited Expert Participant, “Development of Best Care Standards for JIA-associated Uveitis”, UCLA Geffen School of Medicine, Los Angeles, CA
2007-2010 ACR-REF Clinician Scholar Educator Award
2008-2009 Member, ACR JIA Treatment Recommendations Core Expert Panel
2004-2006 Chair, Pediatric Rheumatology Scientific Abstract Selection Committee, ACR
1998-2001 Assistant Professor of Pediatrics, UMDNJ-NJMS
1991-1998 Assistant Professor of Clinical Pediatrics, University of Medicine and Dentistry of New Jersey-New Jersey Medical School (UMDNJ-NJMS)
1987-1991 Assistant in Clinical Pediatrics, Columbia University College of Physician and Surgeons
1985-1987 Instructor in Clinical Pediatrics, Columbia University College of Physicians and Surgeons

Honors:

2022 Lifetime Achievement Award, Arthritis Foundation
2021-present Master of the American College of Rheumatology (ACR)
2017 Hackensack University Medical Center Annual Scholarship Award Honoree
2015 Earl Brewer Award for Physician Leadership, Arthritis Foundation (National)
2006-2007 ACR-REF Pediatric Rheumatology Visiting Professorship Award

C. Contributions to Science

1. I led the development and launch of the CARRA Registry as a tool for pharmacosurveillance and to speed the approval of new treatments for pediatric rheumatic diseases. The Registry has become one of the world's largest prospective registries of pediatric rheumatic diseases, enabling multiple research studies involving large numbers of patients with these rare diseases. Studies using the Registry will further the understanding of medication effectiveness, as well as rare and long term adverse events that may be related to medication usage.
    a) Lionetti G, **Kimura Y,** Schanberg LE, Beukelman T, Wallace CA, et al. Using registries to identify adverse events in rheumatic diseases. Pediatrics 2013 Nov; 132(5):e1384-94. PMID: 24144710
    b) Beukelman T, **Kimura Y,** Ilowite NT, Mieszkalski K, Natter MD, Burrell G, Best B, Jones J, Schanberg LE; CARRA Registry Investigators. The new Childhood Arthritis and Rheumatology Research Alliance (CARRA) registry: design, rationale, and characteristics of patients enrolled in the first 12 months. Pediatr Rheumatol Online J. 2017 Apr 17;15(1):30. PMID: 28416023
    c) L Schanberg, AV Ramanan, F De Benedetti, T Beukelman…**Y Kimura**. Toward Improvement in the Timely Authorization and Availability of New Medicines for Juvenile Idiopathic Arthritis: Multi-Stakeholder Perspectives. Arthritis Rheumatol. 2019 Jul 16. doi: 10.1002/art.41043. [Epub ahead of print] PMID: 31313532
    d) Brunner HI, Schanberg LE, **Kimura Y**, Dennos A, Co DO, Colbert RA, Fuhlbrigge R, Goldmuntz E, Kingsbury DJ, Patty-Resk C, Mintz S, Onel K, Rider LG, Schneider R, Watts A, von Scheven E, Lovell DJ, Beukelman T; PRCSG Advisory Council, the CARRA Registry Investigators. New medications are needed for children with juvenile idiopathic arthritis. Arthritis Rheumatol. 2020 Jun 10. doi: 10.1002/art.41390. Arthritis Rheumatol. 2020. PMID: 32524767

2. I helped develop and utilize innovative approaches using observational approaches for comparative effectiveness research (CER), including the development of standardized consensus treatment plans (CTPs) for observational CER using the CARRA Registry. I led the developing of CTPs in both polyarticular and systemic JIA, and am the PI of the first two large-scale funded CARRA CTP CER projects (in polyarticular JIA and systemic JIA) which have resulted in improved understanding of optimal treatments for these diseases, and demonstrated the feasibility of using this approach for clinical trials in rare diseases. Long-term results from STOP-JIA are demonstrating that early use of combination biologic and methotrexate treatment lead to longer times in disease inactivity over 3 years. Other analyses using the registry have led to improved understanding of disease trajectories and whether disease inactivity can be recaptured after medication withdrawal.
    a) **Y Kimura** et al: "The Childhood Arthritis and Rheumatology Research Alliance Start Time Optimization of Biologic Therapy in Polyarticular JIA Study: Three Year Outcomes. Arthritis Rheumatol. Oral plenary abstract presentation, ACR Convergence Annual Scientific Meeting, Philadelphia PA 11/22
    b) Ringold S, Nigrovic PA, Feldman BM, Tomlinson GA, von Scheven E, Wallace CA, Huber AM, Schanberg LE, Li SC, Weiss PF, Fuhlbrigge RC, Morgan EM, **Kimura Y.** The Childhood Arthritis and Rheumatology Research Alliance Consensus Treatment Plans: Toward Comparative Effectiveness in the Pediatric Rheumatic Diseases. Arthritis Rheumatol. 2018 May;70(5):669-678. doi: 10.1002/art.40395. Epub 2018 Mar 31. PMID: 29333701
    c) E M Dewitt,* **Y Kimura,*** T Beukelman, P Nigrovic, K Onel, et al for CARRA. Consensus Treatment Plans for New-Onset Systemic Juvenile Idiopathic Arthritis (sJIA). Arthritis Care Res 2012; 74(7):1001-1 *Both authors contributed equally
    d) S Ringold, AC Dennos, **Y Kimura,** T Beukelman, P Shrader, TA Phillips, M Kohlheim, LE Schanberg, RSM Yeung, DB Horton. Disease Recapture Rates After Medication Discontinuation and Flare in Juvenile Idiopathic Arthritis. Arthritis Care Res (Hoboken). 2022 Aug 3. doi: 10.1002/acr.24994. Online ahead of print.PMID: 35921198

3. My collaborations led to contributions to important clinical trials in pediatric rheumatology: JIA, lupus and other pediatric rheumatic diseases, including to treatment guidelines for these diseases.
    - Peng J, Dönnes P, Ardoin SP, Schanberg LE, Lewandowski L; **APPLE trial investigators** and Childhood Rheumatology Research Alliance (CARRA); Robinson G, Jury EC, Ciurtin C. Atherosclerosis Progression in the APPLE Trial Can Be Predicted in Young People With Juvenile-Onset Systemic Lupus Erythematosus Using a Novel Lipid Metabolomic Signature.

Arthritis Rheumatol. 2024 Mar;76(3):455-468. doi: 10.1002/art.42722. Epub 2023 Dec 19. PMID: 37786302; PMCID: PMC10922368.

- Nigrovic PA, de Benedetti F, **Kimura Y,** Lovell DJ, Vastert SJ. The 4th NextGen Therapies for SJIA and MAS: part 1 the elephant in the room: diagnostic/classification criteria for systemic juvenile idiopathic arthritis and adult-onset still's disease. Pediatr Rheumatol Online J. 2024 Jan 5;21(Suppl 1):114. doi: 10.1186/s12969-023-00864-1. PMID: 38183114; PMCID: PMC10768075.
- KB Onel, DB Horton, DJ Lovell, S Shenoi, CA Cuelio, ST Angeles-Han, ML Becker, RQ Con, BM Feldman, PJ Ferguson, H Gewanter, J Guzman, **Y Kimura**, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol 2022. Epub ahead of print 3/1/22
- C Wallace, E Giannini, S Spalding., P Hashkes, K O'Neil, A Zeft, I Szer, S Ringold, H Brunner, L Schanberg, R Sundel, D Milojevic, M Punaro, P Chira, B Gottlieb, G Higgins, N Ilowite, **Y Kimura**, et al for the Childhood Arthritis and Rheumatology Research Alliance (CARRA). Trial of Early Aggressive Therapy in Polyarticular Juvenile Idiopathic Arthritis. Arthritis Rheum 2012; 64 (6): 2012–2021
- NT Ilowite, K Prather, Y Lokhnygina, LE Schanberg, M Elder, D Milojevic, JW Verbsky, SJ Spalding, **Y Kimura,** et al. The randomized placebo phase study of rilonacept in the treatment of systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2014 May 16. doi: 10.1002/art.38699. PMID: 24839206

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sitsses/myncbi/1FsdgYN5pKcAe/bibliography/public/