BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Ramey, Sharon Landesman

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

POSITION TITLE: Professor and Distinguished Research Scholar

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
New College, Sarasota, FL	B.A.	05/68	Psychology and Comparative Physiology
Institute of Child Development, University of Minnesota		09/68-06/69	Developmental Psychology
University of Washington, Seattle, WA	Ph.D. with honors	12/74	Developmental Psychology

A. Personal Statement

For the proposed National Pediatric Rehabilitation Resource Center (PedRehab Ctr), I will serve as the PI/Director and work closely with team members to provide leadership for the planning, operating, and ongoing evaluation of this new national center. I will be the primary contact with NIH as well as with OSU and NCH regarding budgets, reporting, and adhering to regulations, I bring high interest and extensive experience to this central role: I currently am the lead Multiple PI for 3 ongoing NIH multisite Randomized Controlled Trials (RCTs) (2 Phase II and 1 Phase III) in pediatric rehabilitation. As a developmental scientist and methodologist, I bring 4+ decades of experience developing and rigorously testing new treatments for children with disabilities and those with risk conditions (total RCTs I have led or co-led = 20; 11 have been multisite). I also have been engaged for the past 20 years in conducting research related to pediatric Constraint-Induced Movement Therapy (P-CIMT), working especially closely with Stephanie DeLuca (a Co-I on this application). We wrote the first manualized P-CIMT protocol, known as ACQUIREc, informed by principles of learning theory and "active ingredients" of shaping by successive approximations, varied reinforcement schedules, learning in natural environments, and practice with timely feedback - treatment principles supported by major theories and emerging evidence from developmental neurobiology. I have designed and directed (often along with Craig Ramey or Michael Friedlander) multiple NIH interdisciplinary research centers (P50, P30) and Data Coordinating and Analysis Centers for many NIH multi-site studies. I am particularly interested in continuing to refine the methods available for designing clinical trials- including alternative, innovative, and adaptive designs - that are adequately powered, well-suited for multicenter clinical trials, and supported by strong coordinating centers to document fidelity of the treatments and standardization of assessment methods. I have helped to develop and publish new statistical approaches for multivariate longitudinal datasets, detecting interaction terms, novel approaches to longitudinal analyses and growth curve analyses, and small sample sizes. Similarly, I have developed and validated many assessment tools for young children, including children with disabilities, and for parents. In this application, we propose an ambitious program for engaging scientists in collaborative ways intended to achieve the stated goals of the P2C National Pediatric Rehabilitation Resource Center (PedRehab Ctr) – namely "to generate ...higher quality and more impactful studies that influence clinical practice and access to health-care resources." I have directed a new PhD concentration in Health Implementation Science. I have worked closely with all of the proposed team members in conducting clinical trial research; teaching and mentoring medical students and PhD students; planning and conducting observational and longitudinal studies of human development; and presenting at national meetings and workshops.

1. Ramey, S.L., DeLuca, S., Stevenson, R., Case-Smith, J., Darragh, A., & Conaway, M. (2018). Children with Hemiparesis Arm and Movement Project (CHAMP): Protocol for a multi-site comparative efficacy trial of

paediatric Constraint-Induced Movement Therapy (CIMT) testing effects of dosage and type of constraint for children with hemiparetic cerebral palsy. *BMJ Open, 9*, bmjopen-2018-023285.

doi: 10.1136/bmjopen-2018-023285

2. Ramey, S.L., Coker-Bolt, P., & DeLuca, S.C. (Eds.) (2013). Handbook of pediatric constraint-induced movement therapy (*CIMT*): A guide for occupational therapy and health care clinicians, researchers, and educators. Bethesda, MD: AOTA Press. (Peer-reviewed)

3. DeLuca, S.C., Echols, K., Law, C.R., & Ramey, S.L. (2006). Intensive pediatric constraint-induced therapy for children with cerebral palsy: A randomized, controlled, crossover trial. *Journal of Child Neurology*, *21*, 931-938. 4. DeLuca, S.C., Case-Smith, J., Stevenson, R., & Ramey, S.L. (2012). Constraint-Induced Movement Therapy (CIMT) for young children with cerebral palsy: Effects of therapeutic dosage. *Journal of Pediatric Rehabilitation Medicine*, *5*, 133-142. doi:10.3233/PRM-2012-0206

4.Taub, E., Ramey, S.L., DeLuca, S., & Echols, K. (2004). Efficacy of Constraint-Induced Movement Therapy for children with cerebral palsy with asymmetric motor impairment. *Pediatrics, 113,* 305-312. PMID: 14754942

B. Positions and Honors - Positions and Employment

- 1975-1987 Instructor to Professor, Department of Psychiatry & Behavioral Sciences, School of Medicine, U. of Washington
- 1987-1990Director, Frank Porter Graham Child Development Center, U. of North Carolina at Chapel Hill
(also Director, NICHD P50 NC Mental Retardation and Developmental Disabilities Center)
- 1987-1990 Professor of Psychiatry and Psychology, University of North Carolina at Chapel Hill
- 1990-2002 Founding Director, Civitan International Research Center, and Professor, Departments of Psychiatry & Behavioral Neurobiology, Psychology, Pediatrics, Sociology, Nursing, Maternal and Child Health, and Neurobiology, The University of Alabama at Birmingham (UAB) (also Director, NICHD P30 Center on Myelinization and Development; Co-Director, NICHD P50 UAB Center on Developmental Disabilities Research)
- 2002-2006 Appointed Member, Fogarty International Center Advisory Board, NIH
- 2002-2011 Susan H. Mayer Professor of Child and Family Studies and Founding Director, Georgetown University Center on Health and Education, Professor of Psychiatry, Georgetown University
- 2011-Present Professor and Distinguished Research Scholar, Fralin Biomedical Research Institute, Virginia Tech; Professor of Psychology, Neuroscience, and Human Development, Virginia Tech; Professor of Psychiatry and Behavioral Medicine, Virginia Tech Carilion School of Medicine

Honors (partial listing)

NIH Research Career Development Award, 1980-1985; Fellow, American Psychological Association, 1985; Fellow, American Association on Mental Retardation, 1990; Fellow, Association for Psychological Science, 1990; Fellow, International Association for Scientific Study of Intellectual Disabilities (IASSID), 1992; AAMR Outstanding Research Award, 1999; President, Division 33 (Mental Retardation) of APA (1998-1999); Heflin Award for Statesmanship in World Health and Education, 2000; Treasurer (1992-2000) and Vice President (2000-2004) IASSID; two Gold Awards, National Parenting Publications Award Council (1999-2000); Civitan Extraordinary Contributions in Leadership and Community Service (2001); Children's Advocate Award (2002); National Public Television Award Contributions to Early Literacy (2006); Society for Research in Child Development Distinguished Research Contributions to Public Policy (2007); University of Washington Distinguished Alumna Award, Natural Sciences (2007); Timeless Achievement Award for the University of Washington's 150th Anniversary, 2012; March of Dimes Award, 2014; upcoming Multiple Sclerosis Society (2019).

NIH Review Activities: I have served as member of 5 NIH standing review committees (total of 7 terms); a member of the NICHD Mental Retardation/Developmental Disabilities Review Committee; appointed Council member for the Fogarty International Center (2002-2007), member of multiple Special Emphasis Panels (in recent years: Contraception and Reproductive Health Research; Maternal and Child Health and Human Development Research; Minority and Health Disparities; and Medical Rehabilitation Research), Senior Editor for the ARRA grant awards, NIH Director's New Innovator Awards panel (2012 -2014, NIH Child Psychopathology and Developmental Disabilities study section, and NIH Community-Based Participatory Research awards. At this stage in my career as a scientist, I am both highly motivated and well-prepared to help lead this effort, along with critical insights and commitment from my colleagues, to advance the field of Pediatric Medical Rehabilitation Research.

C. Contribution to Science (250 publications, 7 books)

In the past 40 years I have had an exceptional opportunity to conduct major and sustained research programs in many divergent areas of human development across the lifespan and across generations – programs driven theoretically by basic questions about the origins of human health and competence, with a strong focus on factors that can alter outcomes for vulnerable populations (i.e., malleability, neuroplasticity). I have led or co-led >20 RCTs, many multi-site and large-scale, that have enrolled and treated >16,000 children and families. Here, I select some of the intervention areas most closely related to this application and also identify a few of my major methodological and clinical design contributions.

1. Design and testing of innovative treatments for children with developmental, neuromotor, and intellectual disabilities. Since 1974, I have developed and rigorously tested via RCTs many innovative treatments for children with major lifelong disabilities. The treatments include: systematically increasing sensory, social, and vestibular stimulation; altering daily environmental supports; applying basic principles of learning, motivation, and cognitive development; and changing the behavior of caregivers. My findings repeatedly have shown that many children have far greater potential for change than realized and, in turn, contributed to major reforms in the care and education for those with severe disabilities, including those once medically deemed "incapable of responding to any treatment." My findings have been used widely to support major national legislation (IDEA and ADA) and to transform the education (pre-service and continuing ed) of practitioners. My findings often contributed to major paradigm shifts, informed by scientific evidence, that the collective social environment can exert strong effects on multiple daily skills - both positive and negative - far greater than predicted by individual characteristics such as IQ scores and medical diagnoses. Throughout this research, I often detected and reported "spillover effects," that is, benefits that extended beyond the primary outcomes targeted by the treatments (e.g., lowering uncontrolled seizures, stabilizing diurnal and ultradian sleep-wake cycles, decreasing illnesses, improving levels of daily engagement). For citations, I include several integrative reviews and peer-reviewed NIH conference proceedings that include contributions from my own research and reflect my role in being invited to synthesize major bodies of work to inform future research, theory, and practice.

1. Landesman-Dwyer, S (*now Ramey*), & Vietze, P. (Eds.) (1987). *Living environments and mental retardation.* Washington, DC: American Association on Mental Retardation.(NICHD conference proceedings)

2. Ramey, C.T., & Ramey, S.L. (1998). Early intervention and early experience. *American Psychologist, 53,* 109-120. PMID: 9491742.

3. Borkowski, J.G., Ramey, S.L., & Bristol-Powers, M. (Eds.). (2002). *Parenting and the child's world: Influences on academic, intellectual, and social-emotional development.* Mahwah, NJ: Erlbaum Publishers. (Proceedings of an NIH conference, peer-reviewed)

4. Ramey, S.L., Coker-Bolt, P., & DeLuca, S.C. (Eds.) (2013). Handbook of pediatric Constraint-Induced Movement Therapy (CIMT): A guide for occupational therapy and health care clinicians, researchers, and educators. Bethesda, MD: AOTA Press. (Peer-reviewed)

2. Prospective study of effects of prenatal maternal conditions, delivery of prenatal care, and the preconception period on maternal and child outcomes. I have been engaged in the field of behavioral teratology since the early 1970s, when I was a junior member of the UW interdisciplinary team with David Smith and Ann Streissguth, just after the discovery of Fetal Alcohol Syndrome. We conducted one of the first prospective, large-scale studies of maternal ethanol consumption, including "social drinking," in combination with diet, caffeine, nicotine, narcotics, marijuana, and other drugs (later known as the Seattle 500). I received my own adjunctive funding to develop highly refined quantitative observational methods to study newborn behavior in real-time and sequence. Our team later conducted another firstever study of effects of cocaine and crack/cocaine. Later, I co-led and participated in several independent large-scale studies of pregnancy outcome at UAB that included detailed biomarkers for maternal and fetal nutriture and then we followed children for many years. This includes an RCT of maternal zinc supplements that reduced low birthweight and an RCT of culturally adapted, multipronged, high-intensity prenatal care for extremely high risk, inner city Medicaid women. More recently, I have been a founding PI in an NICHD 5-site research network known as the Child Community Health Network (CCHN) that developed a novel, integrated framework that builds on decades of findings about prenatal effects and is the firstever to prospectively study health and stress in mothers and fathers before a child is conceived. This strand of my research intersects with this proposal in 3 ways: many children with CP experienced prenatal or early neonatal trauma or infection, often being premature and very low birthweight; the data analyses are cutting-edge, building on work by many colleagues in the CCHN; and the findings are intended to help inform future clinical care and preventive trials and engage multiple disciplines.

1. Streissguth, A.P., Landesman-Dwyer, S. (now Ramey), Martin, J.C., & Smith, D.W. (1980). Teratogenic effects of alcohol in humans and laboratory animals. *Science*, *289*, 353-361.

2. Klerman, L.V., Ramey, S.L., Goldenberg, R.L., Marbury, S., Hou, J., & Cliver, S.P. (2001). A randomized trial of augmented prenatal services for multi-risk, Medicaid-eligible African-American women. *American Journal of Public Health*, *91*, 105–111. PMCID: PMC1446489

3. Tamura, T., Goldenberg, R.L., Chapman, V.R., Johnston, K.E., Ramey, S.L., & Nelson, K.G. (2005). Folate status of mothers during pregnancy and mental and psychomotor development of their children at five years of age. *Pediatrics, 116,* 703-708. PMID:16140711

4. Ramey, S.L., Schafer, P., DeClerque, J.L., Lanzi, R.G., Hobel, C., Shalowitz, M., Chinchilli, V., Raju, T.N.K, & Community Child Health Network (2014). The Preconception Stress and Resiliency Pathways Model: A multilevel framework on maternal, paternal, and child health disparities derived by community-based participatory research. *Maternal and Child Health Journal*. PMID:25070734

3. Development of new statistical methods and approaches, as well as new methods to assess child development and environments/settings. Longitudinal, large-scale research of children and families has generated some of the most complex, multivariate, and potentially informative databases for developmental science - not only testing original study hypotheses (often narrowly focused) but also stimulating conduct of alternative analyses and exploring new models to detect probable causality, individual differences, and continuities versus discontinuities in human development. With colleagues, I have proposed and co-led several NIH conferences on longitudinal data analyses, conducted trans-university intensive "data camps" and statistical courses for senior investigators, and co-authored methodological and statistical papers. I also have helped develop many new tools and have a longstanding interest in collecting valid, reliable data from children, patients, and parents. Closely related, I authored the first editorial (highly controversial at the time) in the 1970s on the topic of "quality of life" for individuals with developmental and intellectual disabilities.

1. Muller, K.E., LaVange, L.M., Ramey, S.L., & Ramey, C.T. (1992). Power calculations for general linear multivariate models including repeated measures applications. *Journal of the American Statistical Association*, *87*, 1209-1226.

2. Chan, D., Ramey, S.L., Ramey, C.T., & Schmitt, N. (2000). Modeling intraindividual changes in children's social skills at home and at school: A multivariate latent growth approach to understanding between-settings differences in children's social skill development. *Multivariate Behavioral Research*, *35*, 365-396.

3. Guttentag, C.L., Landry, S.H., Baggett, K.M., Noria, C.W., Borkowski, J.G., Swank, P.R., Farris, J.R., Crawford, A., Lanzi, R.G., Carta, J.J., Warren, S.F., & Ramey, S.L. (2014). "My Baby & Me": Effects of an early, comprehensive parenting intervention on at-risk mothers and their children. *Developmental Psychology*, 50, 1482 – 1496. doi: 10.1037/a0035682

4. Van Horn, L.M., Jaki, T., Masyn, K., Ramey, S.L., Smith, J.A., & Antaramian, S. (2009). Assessing differential effects: Applying regression mixture models to identify variations in the influence of family resources on academic achievement. *Developmental Psychology, 45*, 1298-1313. doi:10.1037/a0016427

Partial List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/sharon.ramey.1/bibliography/41162840/public/?sort=date&direction=d escending

D. Research Support Ongoing Research Support

1U01NS106655-01A1, S.L. Ramey (Lead PI) & Warren Lo (Multiple PI), 02/01/2019 – 01/31/2024, NINDS/NIH *Perinatal Arterial Stoke(PAS): A Multi-site RCT of Intensive Infant Rehabilitation (I-ACQUIRE)*

Perinatal arterial ischemic stroke (PAS) occurs in an estimated 1 in 1150 livebirths and often leads to serious lifelong neuromotor impairment. This StrokeNet Phase III trial will provide definitive efficacy data from 12 sites (N=240)about an intensive form of infant rehabilitation (Infant ACQUIRE) to transform rehabilitation and improve clinical outcomes.

Role: Lead Multiple PI (PRIME PI)

1R01HD074574-01A1, S.L. Ramey (Lead PI) & S.C. DeLuca (Multiple PI), 03/01/2014 - 02/28/2018, NICHD/NIH (Projected No Cost Extension through 02/28/2020) *Multisite RCT of 3 Neurorehabilitation Therapies for Infants with Asymmetrical CP* This multisite randomized controlled trial tests 3 highly-promising new therapies for infants with asymmetrical CP (N=72) and will yield much needed data about the differential impact of these therapies on neuromotor outcomes and brain development up to 12 months post-treatment. Role: Lead Multiple Principal Investigator

1R01HD068345-01A1, S. Ramey (Lead PI), S.C. DeLuca, R. Stevenson, 09/27/2012 – 07/30/2017, NICHD/NIH (Projected No Cost Extension through 07/30/2019)

Multi-site RCT of Pediatric Constraint-Induced Movement Therapy (CIMT)

This is the first multi-site, randomized controlled trial (RCT) that comprises a comparative efficacy trial of ACQUIREC, a manualized form of pediatric constraint-induced movement therapy (CIMT), for 3 – 6 yr old children with unilateral cerebral palsy. The RCT (N=144) tests the efficacy of 2 different dosage levels and 2 types of constraint compared to a control condition (usual treatment). The study findings are critically needed to establish evidence-based practice standards to improve lifelong neuromotor capacity for >229,000 affected individuals in the U.S. Role: Lead Multiple Principal Investigator

1UL1TR003015-01, K.C. Johnston & D.E. Brown (Multiple PI), 02/27/2019 – 01/31/2024, NCATS/NIH

The integrated Translational Health Research Institute of Virginia (iTHRIV): Using Data to Improve Health

iTHRIV is a collaboration of institutions across Virginia (University of Virginia, Virginia Tech/Carilion, Inova, Center for Open Science and License and Ventures Group) that brings team science, innovation, and commitment to train the next generation of clinical and translational researchers to a broad statewide community. iTHRIV will marry the expertise of our world class data science team with our outstanding clinical translational researchers to empower our researchers to use data centered approaches to uncover health care solutions. Role: Special Populations Site Leader (Research Capacity Core)

1DP7OD018428-01, M. Friedlander (PI), 09/20/2013 - 08/31/2018, NIH

(Projected No Cost Extension through 08/31/2019)

Mentorship and Development Program for Biomedical Trainees

This is a new NIH multidisciplinary program that provides early professional development and guidance, as well as networking experiences, for biomedical trainees, such that they may efficiently identify and succeed along directed career paths. Role: <u>Program Faculty</u>