Reach Out and Read from Cradle to Clinic:

A novel Reach Out and Read Intervention in the Newborn Nursery







#### **Participation Statement**

If funded, I agree to participate in any conference calls and/or in-person grantee meetings

### **Project Description**

Reach Out and Read (ROR) increases early childhood vocabulary,<sup>1-5</sup> enhances brain development,<sup>6,7</sup> and predicts future school success.<sup>1,5,8-16</sup> Historically, ROR begins at 6 months, but recent studies show that language exposure beginning at birth may influence literacy outcomes for children<sup>10,17-21</sup> and new neuroimaging technology reveals that learning and language development begins during this period.<sup>22-27</sup> Currently, early literacy interventions are not fully integrated into newborn care, though they are being piloted in some early well child visits. While clinic interventions continue to represent the core of Reach Out and Read, the newborn nursery represents a high yield population with a reach of over 3 million eligible children per year.<sup>28</sup> The immediate postnatal time is a unique and understudied<sup>29-31</sup> window of learning for families to gain knowledge about the impact of early shared reading.

We propose to test the feasibility, acceptability, and early impacts of an adaptation of the Reach Out and Read (ROR) model in the newborn nursery. We will utilize a randomized, controlled, clinical trial design to compare a ROR-based intervention with usual newborn care. Our intervention will include education about the potential impact of early literacy activities and providing two books appropriate for shared reading with newborns. Our primary outcome will be to assess acceptability and feasibility of this program to both new parents receiving the intervention and the physicians providing it in order to better understand the unique timing of this intervention for the family and the busy clinician in the nursery setting. Additionally, we will assess the effectiveness of the program by measuring the impact on the home literacy environment. Our team is highly qualified to carry out the proposed work. Dr. (PI) is the , overseeing a cohort of 3500 deliveries per year, and directs the Reach Out and Read program at Primary Care. The mentorship brings significant clinical trial and content expertise. We team ( hypothesize that the ROR-nursery intervention will be feasible to deliver as part of newborn care in an academic medical center and engaging to parents of newborns. We will test this hypothesis through the following aims:

**Aim 1:** To evaluate the feasibility of delivering a novel ROR intervention in the newborn nursery. **Aim 2:** To describe the acceptability of a ROR-nursery intervention among new parents and pediatricians working in the newborn nursery in an academic hospital using a structured benefits and barriers assessment tool and a subset of key informant interviews.

**Aim 3:** To describe the effectiveness of the ROR-nursery intervention on parent attitudes toward shared reading, the home literacy environment, and parental feelings of self-efficacy in newborn care.

An early literacy program that effectively engages parents of newborns has the potential to engage families in the early development of their newborns and to cultivate the habit of reading in parents. The intervention is both novel and has direct relevance to child developmental outcomes and the Reach Out and Read evidence base and will form a critical platform for my future research.

### Methods

<u>Study Design</u>: We will conduct a mixed-methods study to understand feasibility, acceptability and effectiveness of delivering ROR in the nursery. We will conduct a randomized controlled pilot trial to evaluate the effect of our newborn-ROR intervention versus usual care on parent attitudes toward reading, the home literacy environment and parental self-efficacy. We will use structured interview guides and recorded transcribed interviews with parents and providers to understand their perspectives on literacy education in the newborn setting. <u>Intervention</u>: Families will be provided with a board book of age appropriate high contrast images at the time of their discharge from the nursery. In addition, parents will receive education from nursery providers about the importance of early shared reading in the newborn period.

<u>Methods</u>: We will identify qualifying families during the newborn hospital stay and consent them to be enrolled. Once enrolled, families will be randomized using a random number generator to either the control or intervention arm. At the time of enrollment, families will complete baseline assessments of their attitude toward reading, the home literacy environment and parenting self-efficacy. These will be measured by the Parents Reading Belief Inventory<sup>32,33</sup>, age appropriate items adapted from the StimQ<sub>2</sub>-Infant READ subscale (developed by Co-Mentor Mendelsohn) and the Parenting Sense of Competence Scale (PSOC)<sup>34-37</sup> respectively. The intervention and control teaching will then be carried out by residents on their newborn nursery rotation, who will receive training in the Reach Out and Read model by the PI

<u>Selection of Subjects</u>: We plan to enroll 150 families (75 per arm) using consecutive sampling of families with newborns delivering at the newborn nursery at **Selection**. A sample size of 75 per group will provide >80% power to detect a difference of at least 2 in StimQ-READ score between groups using repeated measure ANOVA, assuming a 10% drop-out rate and an alpha level of 5%. To be enrolled, families must speak Spanish or English, have a well infant >36 weeks gestational age, and plan to continue pediatric care with **Selection** Primary Care.

| Task | Description                                       | Month |   |   |   |   |   |   |   |   |    |    |   |
|------|---|-------|---|---|---|---|---|---|---|---|----|----|---|
|      |   | 1     | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |   |
| 1    | Refine Study Design and<br>Prepare Materials, IRB |       |   |   |   |   |   |   |   |   |    |    |   |
| 2    | Enrollment and Randomization                      |       |   |   |   |   |   |   |   |   |    |    |   |
| 3    | Patient Follow Up                                 |       |   |   |   |   |   |   |   |   |    |    | ] |
| 4    | Data Analysis<br>PAS abstract preparation         |       |   |   |   |   |   |   |   |   |    |    |   |
| 5    | Manuscript Preparation                            |       |   |   |   |   |   |   |   |   |    |    |   |

# Timeline: March 2018 – February 2019

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# Budget

| Item                  | Detail                                    | Requested | Total   | Justification             |
|-----------------------|---|-----------|---------|---------------------------|
| Books                 | Educational intervention book 75 x \$3.33 | \$250     | \$250   | Intervention<br>materials |
| Research<br>Assistant | Data collection/management                | \$13000   | \$13000 | 13 hr/wk                  |
| Patient compensation  | \$10 participant compensation             | \$750     | \$1000  |                           |
| Travel to PAS         |   | \$1000    | \$1000  | Per RFP                   |
| Total                 |   | \$15000   | \$15000 |                           |

#### NAME:

POSITION TITLE: Assistant Professor of Pediatrics

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.)



# A. PERSONAL STATEMENT

Throughout my training I have been dedicated to primary care and the importance of education for patients and families. In my roles as a primary care pediatrician and full term nursery attending, I have the opportunity to impact children starting at the very beginning of their lives. Reach Out and Read has been a passion of mine from the beginning of residency training and I have been excited to work with this program and its coordination at for the last 7 years. As we learn more about the neurological impact and sociodemographic effects of early childhood experiences, we have a responsibility to our patients to promote and encourage healthy home environments that foster positive development. This project represents a full integration of my passion for Reach Out and Read and my clinical experience as a nursery director for the last three years. As a former chief resident and current clinical attending, I am dedicated to resident education and anticipate that resident involvement in this project will foster a dedication to the Reach Out and Read program for children of all ages. In addition, my participation in the Research Scholars program through the Academic Pediatric Association, has allowed me to gain experience in design and execution of clinical research that I can apply to the successful completion of the project.

# B. POSITIONS AND HONORS

### **Positions and Employment**



Other Experience and Professional Memberships

2013- Member, Academic Pediatric Association

2014- Research Scholar's Program participant, APA







# **C. PUBLICATIONS**



### **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:

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

POSITION TITLE: Associate Professor of Pediatrics, and of Community and Family Medicine

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.)



#### A. Personal Statement

The first 13 years of my career in pediatric medicine was clinical, and focused on the treatment of children and adolescents with obesity both in primary and tertiary care settings. I developed and direct comprehensive pediatric weight management clinic, comprehensive pediatric weight management with healthcare to drive effective and associated at the pediatric weight management with high-quality nutrition and physical activity. My focus is on low-income and racially-diverse populations. My research spans a range of methodologies; currently I serve as principal investigator on three trials, including an NIH-funded clinical and basic science trial (NIDDK), an implementation trial (Duke En

#### B. Positions and Honors Positions and Employment





### **C.** Contributions to Science

 My most significant contribution is in the field of CLINICAL TREATMENT OF CHILDREN AND ADOLESCENTS WITH OBESITY. I developed the clinic in 2006, and I oversee a cohort of over 15,000 pediatric patients with obesity. I also co-direct research for a national pediatric obesity registry, inclusive of 32 pediatric weight management programs. I serve on the American Academy of Pediatrics Executive committee, and have co-authored policy statements to guide policy related to obesity treatment. My publications reflect a tertiary-care obesity treatment settings, primary care, community settings, and collaborative work with other centers to develop national guidelines for clinical care of obese youth in outpatient settings.



2. I have contributed significantly in DEVELOPING INNOVATIVE TREATMENT OPTIONS FOR YOUTH WITH OBESITY. I have completed three prospective trials to test (1) children's literature (2) an innovative "preceptor" model of MI training, (3) a community partnerships as innovative strategies to augment effectiveness of outpatient obesity treatment.



3. I conduct ongoing work TO ELUCIDATE THE BIOLOGIC AND BEHAVIORAL MECHANISMS that cause and potentiate obesity among children. This includes basic science mechanisms including hormonal metabolites, metabolomics, and the fecal microbiome; and behavioral science mechanisms including weight bias, cultural influences, and stigma. This work also includes investigation into policy influences impacting access to care for children with obesity:



A list of additional publications may be found in MyBibliography in MyNCBI/Pubmed:

### C. Research Support

### Ongoing Research Support





# **Completed Research Support**

September 6, 2018

Academic Pediatric Association Young Investigator Award Reach Out and Read

Dear Selection Committee,

I am writing to support Dr. and the support of the APA's Research Scholars Program (RSP), and have now joined the serving as Dr. and the support of the APA's Research Scholars Program (RSP), and have now joined the serving as Dr. and the support of the APA's Research Scholars Program (RSP), and have currently serving as Dr. and the serving serving as RSP local mentor. We have established a mentorship team for the present proposal that includes myself as the Primary Mentor, and the serving and the serving as co-Mentors. The purpose of this structure is to allow me to have experience mentoring, under the guidance of more senior researchers. In addition, both co-Mentors will add significant content expertise and clinical trials experience to support Dr.

Dr. **Dr. Dr. <b>Dr. Dr. Dr. Dr. Dr. Dr. Dr. Dr. <b>Dr. <b>Dr. Dr.** 

For the present proposal, the highly qualified RSP mentorship team, including myself, and Drs. , will be advising directly. I will serve as her main contact, and meet with her weekly to monitor her progress. Drs. **Serve and the serve as her main contact**, and meet ensure overall study quality and to advise on content. Given the strong teaching and mentorship team she has assembled for this project, the urgency and importance of the topic, and her well-thought out study design, I am very confident that this project will not only add important information to our understanding of early childhood literacy interventions, but will launch her academic career in this field.

Sincerely,

