

Message from the Research Director

Dear Community Partners,

Welcome to another edition of the Developmental Pediatrics/JFK Partners Research Newsletter! We have been working on a number of exciting projects over this past year and are excited to share them with you in this newsletter.

Spotlight!

In this issue, we are highlighting the Facing Your Fears (FYF) program. We have been studying the clinic-based FYF for a number of years, but as we have reported in previous newsletters, our research group has recently partnered with Cherry Creek Schools, Denver Public Schools, Littleton Public Schools and The Joshua School to adapt FYF for school settings. Interdisciplinary teams of school providers have now been trained to deliver FYF to students with ASD in school and are well positioned to train/coach their colleagues as part of a train-the-trainer model. In the spotlight section we have provided the most up to date information on the progress of this innovative project. A special “shout out” to Aubyn Stahmer (one of our speakers for the JFK Annual ASD Conference) as she has been our consultant on the project since its inception!

Research Updates

Check out the research update section for current updates on the research projects that are ongoing or recently completed within Developmental Pediatrics/JFK Partners.

Recent Publications

We have included a list of recent publications at the end of this newsletter.

Study Recruitment

Don't miss our Recruitment Section where we list research projects that are actively recruiting individuals for participation.

Feedback

We would appreciate any feedback you have for us about this newsletter, as well as topics you are interested in hearing about in future editions. Please share your thoughts with us here: <https://www.surveymonkey.com/r/2019FallNews>.

Warmly,



Judy Reaven, PhD
Associate Professor of
Pediatrics and Psychiatry
Director of Research
Associate Director, JFK Partners

We greatly value and seek out opportunities to partner with parents and communities, working together to find relevant, innovative, and creative ways to address the needs and improve outcomes for individuals with autism and other developmental disabilities and their families.

Sandra L. Friedman, MD, MPH
Section Head, Developmental Pediatrics
Director, JFK Partners

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Spotlight!

Facing Your Fears in Schools: An Implementation Study to Manage Anxiety in Underserved Students with ASD or other Social/Communication Challenges

(COMIRB Protocol #17-0114), PI: Judy Reaven

Who is on the project?

JFK/Developmental Pediatrics Faculty and Staff: Judy Reaven (PI), Audrey Blakeley-Smith, Richard Boles, Erin Engstrom, Lisa Hayutin, Allison Meyer, Megan Morris, Katherine Pickard, Nuri Reyes, Tanea Tanda, and Caitlin Walsh

Consultants:

- Aubyn Stahmer, PhD, Professor of Clinical Psychiatry and Behavioral Sciences, UC Davis Health MIND Institute
- Connor Kerns, PhD, Assistant Professor of Psychology, University of British Columbia

What was the goal of the study?

This study has several main aims:

1. To adapt the clinic-based Facing Your Fears program for school settings by obtaining input from school professionals and parents of students with ASD and anxiety.
2. To train cross-disciplinary teams of school providers to deliver the school-based FYF in public schools.
3. To team with school providers to train other teams of school providers in their districts to deliver FYF-SB using a Train-the-Trainer approach.

We have been particularly interested in working with students from low income and/or traditionally underserved racial/ethnic minority families in efforts to increase access to care.

Three school districts in Colorado:

- Cherry Creek School District Leads: Connie Egleston, Cindy Maas
- Denver Public Schools District Lead: Sheri Katzman
- Littleton Public Schools District Leads: Michelle Butler, Carla Burnell

And one additional school:

- The Joshua School School Lead: Nicole Pearson, PhD



Key Words & Definitions

Cognitive behavior therapy (CBT): A therapeutic approach used to treat many different mental health symptoms, most commonly anxiety and depression.

CBT for anxiety includes:

- identifying anxious symptoms and/or triggering events,
- increasing awareness about thoughts and the body's physiological reaction to anxiety, and
- encouraging individuals to use graded exposure (facing fears a little at a time).

This intervention approach is empirically supported and is considered best practice for anxiety treatment.

For more information about Facing Your Fears, check out our website at:

<http://www.FacingFears.org>

What is Facing Your Fears?

An evidence-based group CBT program for children 8-14 with ASD and anxiety. The purpose of the intervention is to help parents and their children manage anxious symptoms and improve emotion regulation so that these symptoms do not interfere with their ability to have fun with friends, family or in school. The school-based version of FYF (FYF-SB) is a 12 week, 40 minute/ week curriculum delivered by cross-disciplinary school teams to students with ASD or other social/communication challenges and anxiety during the school day.

What have we found so far?

Parents and school professionals provided excellent input during the first part of the project, which allowed us to create a feasible school-based intervention program that could be delivered by cross-disciplinary school teams. Across the three districts, eight schools and 24 students completed FYF-SB. School teams were able to deliver FYF-SB with very good treatment fidelity, meaning that they delivered FYF-SB as it was intended to be delivered. In addition, both parent report and student self-report indicated that significant reductions in anxiety occurred following participation in FYF-SB.

Why is this study important?

This study is important because it demonstrates that interdisciplinary school providers can deliver a group CBT program to students with ASD or other social/communication challenges and anxiety in school settings. Preliminary results also indicated that significant reductions in anxiety may occur following participation in FYF-SB for these students. The results are very promising and suggest that training school providers to deliver FYF-SB can potentially increase access to much needed mental health care for many students with ASD or other social/communication challenges who otherwise would not have access to treatment.

What's next?

In the 2019-2020 academic year, our group is using a hybrid train-the-trainer model to train additional school providers in more than 25 schools across the three districts. We hope to reach more than 60 students in the upcoming academic year. Successful completion of this project may result in a feasible and sustainable intervention program for students with ASD and anxiety in schools.

Research Updates

Virtual and Augmented Reality Treatment of Fear of Spiders and Insects in Children with Autism Spectrum Disorder

(COMIRB Protocol #: 18-1914) PI: Jack Dempsey

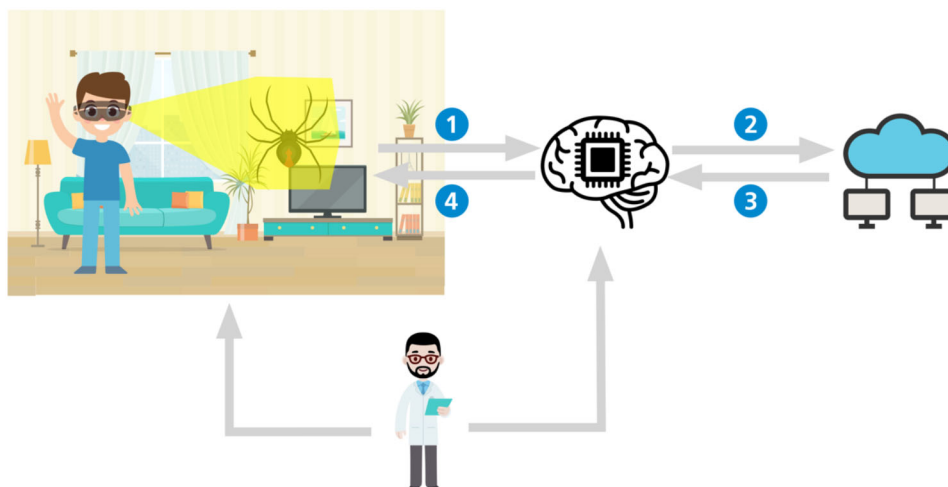
Children with Autism Spectrum Disorder (ASD) often suffer from debilitating fears or phobias which can substantially impact their own lives as well as the lives of family members. Prior research has demonstrated patients perceive virtual-and augmented-reality aided treatments as preferable (i.e., higher acceptance rates) to traditional forms of therapy for these issues.

This may be especially true in children with ASD who often demonstrate a high-level of interest in technology and videogames. The purpose of this study is to examine the use of an augmented-reality (e.g., Pokémon Go™, Snapchat™) therapy platform as a treatment for phobia of insects and/or spiders in children with ASD. Success will be defined as reducing the anxiety to the point of the child being able to tolerate the presence of the phobic stimuli as well as being able to progress to this treatment outcome quickly.

Enrollment in this protocol is open to families with children diagnosed with ASD between the ages of 7-13 who are able to communicate in complete sentences and have a fear of spiders or insects that causes significant anxiety. 10 families will be able to be enrolled in this protocol. Interested families will complete an initial screening questionnaire over the phone. Eligible families will visit the clinic on 3 occasions over the course of several weeks and will receive follow-up calls at 6 weeks and 6 months after the final session. The first clinic visit will consist of a 1-2 hour meeting describing the treatment in detail and teaching therapeutic techniques. Families will also fill out several measures at this time. The following 2 visits will each consist of two 20-30 minutes sessions using the augmented-reality platform (Delivered on the Microsoft Hololens™). Participants are offered gift cards (\$50) at completion of the third visit.

Clinicians are welcome to discuss the protocol with individuals they are working with. If the family or caretaker is interested it works best if you get their permission to refer and leave their information at 303-777-6632 someone will contact them about enrollment.

Contact Jenifer Sargent with any questions at Jenifer.Sargent@childrenscolorado.org



Research Updates

Parent Mediated Interventions in Autism: Search for Meaningful Outcomes

Elizabeth Griffith, PI

The goal of our research project, *Parent Mediated Interventions in Autism: Search for Meaningful Outcomes* - R40MC2773, was to partner with families to determine meaningful outcomes in parent mediated interventions with very young children with Autism Spectrum Disorder (ASD). The four project aims were accomplished through collaboration among the Research Team, Community Advisory Council, and Clinical Team.

The project began with phenomenological qualitative work with parents of children with ASD looking back at their 'lived experience' during parent mediated early interventions (Study 1). These English- and Spanish-speaking families' reflections on the outcomes of the interventions included positive changes in their child with ASD, their understanding of their child, their interactions with their child, and their family functioning, as well as discussion around the burden of intervention and the need for more intensive and on-going supports. These themes then guided the selection of measures for Study 2. While it seemed linear and logical to map reliable existing measures onto the themes from Study 1, it was not.

The collaboration with the Community Advisory Council highlighted several concerns: measures were often negative and highly intrusive; paper and pencil questionnaires were distasteful, lengthy, and burdensome; families wanted research to focus more on how they were coping, what they were learning, and how their child was growing.

Study 2 then utilized measures that best matched the themes from Study 1 and were acceptable to families, to examine changes prospectively in a longitudinal design with 40 parent-child dyads, as families participated in a parent mediated intervention (Strategies of Early Start Denver Model) with their young child with ASD.

Parents continued to report changes across all levels (child, parent, parent-child relationship, family functioning) during the semi-structured exit interviews, and statistically significant improvements across time were found on a quantitative measure of parents' perception of their ability to effect change in their child's skills, observations of parent-child interactions, and parent report of child communicative skills. These are the measures most closely related to the intervention itself and likely the outcomes that parents were seeking when they enrolled in the intervention.

Additional research will be needed to determine whether the other constructs (e.g., family quality of life and coping styles) were more stable and less amenable to change during this short-term intervention or whether parent mediated interventions do not have an impact on these outcomes. Of note, the results of all aspects of this project shaped changes in the clinical service offered at Children's Hospital Colorado.

Research Updates

Colorado Project LAUNCH (Linking Actions for Unmet Needs in Children's Health)

Lead Evaluator: Lorraine F. Kubicek, Ph.D., IMH-E® (IV-R/F)

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Colorado Project LAUNCH (COPL) is a five year federal initiative funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). This initiative is grounded in the public health approach, working toward coordinated programs that take a comprehensive view of health and are family-centered and culturally and linguistically competent. Collaborating partners include the Office of Early Childhood within the Colorado Department of Human Services, the Colorado Department of Public Health and Environment, the Early Childhood Partnership of Adams County, and JFK Partners.



Goals and objectives are to improve and strengthen Colorado's early childhood system by increasing: (1) coordination of key child-serving systems, (2) expertise of behavioral health providers in primary care and other local programs, and (3) access to and availability of evidence-based prevention and wellness promotion practices that support young children and their families.

One of the many successes of COPL has been to increase successful referrals for developmental delays through enhanced, family-centered approaches to care navigation. While increasing numbers of young children are now routinely screened for developmental delays during well child visits in primary care settings, research indicates that there is often a gap between the number of children who receive an abnormal screen and the number who successfully follow through with a referral for further evaluation.

With support from COPL, care navigation services in South Adams County evolved over the past four years to address these issues and successfully reduce the referral gap. Changes were made in data monitoring and reporting. As a result, the four participating agencies refined their practice and implemented new approaches for engaging families and increasing equity.

From Year 2 to Year 5, the percentage of children who had a successful follow through with an evaluation was 39.5%, 37.5%, 63.8%, and 80.4%, respectively. Results will be published in an upcoming issue of the ZERO TO THREE Journal.

Research Updates

A Retrospective Description of the Effectiveness and Adverse Effects of Stimulants and Alpha-2 Agonists Used by Developmental-Behavioral Pediatricians for the Treatment of ADHD in Preschool Age Children

PI: Sandra Friedman, MD, MPH / Sandra.Friedman@childrenscolorado.org

The primary objective of this study is to determine the percentage of preschool age children with ADHD who responded positively to stimulants and alpha-2-agonists (A2A) based on a review of data in the Electronic Health Record (EHR) and to determine if there is a difference in the positive response rate to these two classes of medication. Secondary objectives are to describe type and frequency of adverse effects to stimulants and A2A when prescribed for the treatment of preschool age children for ADHD.

To date, 261 patient records have been preliminarily evaluated. The mean age at initial treatment was 59.7 months. Stimulant medications were initial medication prescribed in 68.2% and alpha agonists in 31.8%. Those prescribed alpha agonists were younger (55.8 months vs. 61.5 months). There was a high rate of co-morbidities and the majority (65.4%) were receiving special education services. Patients with more comorbidities (sleep disorder, ASD, disruptive behavior disorder) were more apt to be prescribed alpha agonists vs. stimulants.

Most preschoolers treated with medication for ADHD had one or more comorbidity and were receiving special education services. While DBP-prescribed stimulants are more frequently as initial treatment than A2As, younger age and co-morbidities are associated with increased likelihood of using alpha-2-agonists (A2As).

The Role of ADOS in Diagnosis of Autism by Developmental Behavioral Pediatricians

PI: Sandra Friedman, MD, MPH / Sandra.Friedman@childrenscolorado.org

This is a prospective study to determine the frequency with which results of the ADOS-2 alters the diagnostic conclusion of developmental-behavioral pediatricians (DBPs) evaluating a child age 18 months to 5 years, 11 months for possible ASD. This study involves 8 of the 14 DBPNet sites.

It is anticipated that 350 children ages 18 months to 5 years, 11 months who are referred to a DBP clinic for possible ASD will be enrolled in the study to yield 300 evaluable cases. The study interventions and measures include diagnostic assessment for ASD, including routine clinical assessments of cognitive, language and behavioral characteristics. DBPs will make a diagnostic conclusion (ASD or not ASD) both before and after administration of the ADOS-2. The main study outcome measure is the frequency with which the results of an ADOS-2 alter the diagnostic conclusion of a DBP.

Secondary measures include child and characteristics of DBPs that are associated with the likelihood that the results of an ADOS-2 will alter a DBPs' diagnosis (ASD=yes versus ASD=no). DBPs' reported degree of certainty of an ASD diagnostic conclusion, both before and after administration of an ADOS-2, and child/characteristics of DBPs that correlate with self-reported degree of certainty of ASD diagnostic conclusion.

Research Updates

Sleep Problems in 2- to 5-Year-Olds With Autism Spectrum Disorder and Other Developmental Delays

CADDRE: STUDY TO EXPLORE EARLY DEVELOPMENT (COMIRB protocol 06-0066)
PI: Cordelia Robinson Rosenberg

Reynolds AM, Soke GN, Sabourin KR, Hepburn S, Katz T, Wiggins LD, Schieve LA, Levy SE. Pediatrics. 2019 Mar;143(3). <https://doi.org/10.1542/peds.2018-0492>

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Sleep problems can impact daytime behavior, quality of life, and overall health. We compared sleep habits in young children with autism spectrum disorder (ASD) and other developmental delays and disorders and in children from the general population (POP).

We included 2- to 5-year-old children whose parent completed all items on the Children's Sleep Habits Questionnaire (CSHQ) in a multisite case-control study: 522 children with ASD; 228 children with other developmental delays and disorders with autism spectrum disorder characteristics (DD w/ASD); 534 children with other developmental delays and disorders without autism spectrum disorder characteristics (DD w/o ASD); and 703 POP. Multivariable analysis of variance compared CSHQ mean total score (TS) and subscale scores between groups. Logistic regression analysis examined group differences by using TS cutoffs of 41 and 48. Analyses were adjusted for covariates.



Sleep problems are more than twice as common in young children with ASD and DD w/ASD. Screening for sleep problems is important in young children to facilitate provision of appropriate interventions. Contact Kristina Hightshoe with any questions at Kristina.Hightshoe@cuanschutz.edu.

Facing Your Fears Adapted for Adolescents with ASD and ID

Principal Investigator: Audrey Blakeley-Smith, PhD
Audrey.Blakeleymsmith@cuanschutz.edu

The JFK research team recently completed a treatment study on adolescents with ASD, intellectual disability, and anxiety. This project was funded by the Organization for Autism Research. Twenty-three families participated in our adapted Facing Your Fears program. Preliminary results suggest that the intervention may improve adolescent anxiety and mood concerns. The JFK team presented these results at the May 2019 International Meeting for Autism Research and are seeking additional grant funding to expand this line of work. The presentations are listed below:

Blakeley-Smith, A., Meyer, A., Boles, R., Hepburn, S., & Reaven, J. (May, 2019) *Group cognitive behavioral treatment for anxiety in adolescents with ASD And intellectual disability*. Oral presentation at the International Meeting for Autism Research (INSAR), Montreal, Quebec.

Meyer, A., Boles, R., Pickard, K., Reaven, J., & Blakeley-Smith, A. (May, 2019). *Examining use of CBT strategies for anxiety: a pilot study with adolescents with ASD and intellectual disability*. Poster presented to the International Meeting for Autism Research (INSAR), Montreal, Canada.

Research Updates

Hearing Assessment for Children with Developmental Disabilities

PI: Angela Yarnell Bonino, Ph.D., CCC-A, CU Boulder | CU Boulder IRB #: 16-0639
American Speech-Language-Hearing Foundation | Study Dates: 2019 – 2021

For children with developmental differences, audiologists often report that they have difficulty measuring behavioral thresholds. Thus, audiologists tend to rely on physiological tests to diagnosis and manage hearing loss in children with developmental disabilities. However, unlike behavioral assessments, these measures only provide partial information about the integrity of the auditory system. The current lack of behavioral procedures that are effective for evaluating hearing in children with developmental disabilities is a significant public health problem, resulting in delayed diagnosis and difficulty fitting amplification.

The objective of this research is to demonstrate that reliable behavioral thresholds can be measured from 2- to 5-year-old children with developmental disabilities. Our approach builds upon a recent procedure that we have developed (Bonino & Leibold, 2017; Bonino et al., 2019) in which a child is trained to perform a play-based, motor response to the target sound. The child's behavior is then judged to determine when a target sound was presented. For this project, we will begin the process of preparing our method for clinical use by evaluating strategies for teaching children the task, developing strategies to monitor for changes in performance, and evaluating the types of auditory behavior provided by children with developmental disabilities.

This research is significant because children with developmental disabilities are underrepresented in both basic and clinical hearing research, which has limited the evidence-base available to pediatric audiologists for the best assessment and management practices in this population. This work will pave the way for developing effective clinical tools and testing strategies for measuring behavioral thresholds in children with developmental disabilities. If you are interested in learning more, please email childhear@colorado.edu or call 303-735-6252.

Descriptive Prospective Pilot Study of Severely Obese Adolescents/Young Adults with Intellectual Disability Presenting for Bariatric Surgery Evaluation

This study aims to explore the presenting psychosocial and health characteristics of adolescents with intellectual and developmental disabilities (IDD) and severe obesity who present for consideration to receive metabolic and bariatric surgery (MBS).

Bariatric surgery may be an effective procedure to reduce obesity and related comorbidities, but patients with IDD are rarely included in adolescent MBS studies. Additionally, patients will be followed to see how well they complete pre- and post-operative clinical procedures compared to a matched control group.

Among severely obese adolescents and young adults with intellectual disability, there is a clear need for 1) a more comprehensive description of the safety and efficacy of bariatric surgery and 2) the identification of factors that may help predict durable weight loss, improvements in cardiometabolic health, and quality of life. Such information could directly inform standardized clinical guidelines for appropriate candidate selection for bariatric surgery among intellectually disabled severely obese adolescents and young adults. Patients and their families are being recruited during their attendance to the Children's Hospital Colorado Metabolic and Bariatric Surgery Center.

Please contact Dr. Richard Boles at Richard.Boles@CUAnschutz.edu or Dr. Jaime Moore at Jaime.Moore@CUAnschutz.edu for more information.

Research Updates

Efficacy of Crisis Plans for Individuals with Neurodevelopmental and Behavioral Dual Diagnosis

PI: Cordelia Rosenberg (COMIRB protocol 17-0845)

Approximately 30 to 35% of individuals with intellectual disabilities (ID) also have a co-occurring mental health condition, such as an anxiety disorder, or significant behavioral problems, such as aggression (1). For individuals with dual diagnosis, and their families, finding the correct services and supports remains a challenge (2); navigating one complex system is difficult, and navigating to simultaneously is nearly impossible. While Colorado has heavily invested in community mental health support in recent years, families continue to find navigating the framework surrounding the services to be complicated and daunting.

Enrollment in this protocol is open to families of children and adults and adults and primary caretakers, who have experienced behavioral crisis where it was necessary to call 911 or visit the ED. Enrollment in this protocol involves providing assistance in using a crisis plan template and offers a resource guide to the Colorado Crisis System. Participation includes completing brief follow-up questions regarding use of the plan at 1, 4, 8, 12 months post development of the plan. Participants are offered gift cards with initial compensation of the plan (\$40) and at each follow up point (\$20).

Clinicians are welcome to discuss the protocol with individuals they are working with. If the family or caretaker is interested it works best if you get their permission to refer and leave their information at 303-724-0473 someone will contact them about enrollment. Contact Cordelia Robinson Rosenberg with any questions at cordelia.rosenberg@CUAnschutz.

LEARN Trial: NeuroNext AFQ056 in Fragile X Study

Colorado is one of 14 sites currently conducting this unique and innovative study of children with Fragile X syndrome that is exploring a different way to examine efficacy of a drug targeting brain development (AFQ056, an mGluR5 receptor antagonist which can enhance neural plasticity).

The primary objective of the study is to evaluate if there is greater improvement in language, cognition, and behavior in young children with Fragile X when treated with AFQ056 in combination with an intensive language learning intervention compared to the language intervention/placebo group. The language learning intervention is guided remotely by a speech-language pathologist in real time for all participants. The intervention includes parent education sessions, clinician coaching, and clinician feedback delivered by distance video-conferencing. In addition, each family completes weekly homework in the form of videos that are reviewed by the speech-language pathologist and provided with written feedback. Each family is committed to 27 months of intensive participation involving periodic standardized testing and informal play samples in addition to weekly 16 coaching, feedback, and homework sessions followed by 11 monthly booster sessions.

The larger goal of this study is to recruit and to treat 100 subjects with Fragile X ages 32 months to 6 years of age at different sites across the US. Colorado has enrolled 7 subjects with 1 waiting to enter the study. Families enrolled are from the Denver metro area as well as out of state locations. Other objectives specifically involve monitoring medical and drug safety.

Members of the team include: Nicole Tartaglia, M.D., Developmental Behavioral Pediatrician and Director of eXtraordinary Kids Clinic/Fragile X Clinic, Terry Hall, M.A., CCC-SLP, Developmental Pediatrics/JFK Partners, Nana Welnick, Clinical Research Coordinator at CHCO, and Gina VanderVeen, Senior Professional Research Assistant at CHCO. The principal investigator of the study is Elizabeth Berry-Kravis, MD, PhD at Rush University in Chicago.

Research Updates

Understanding temperament and emotion regulation in young children with ASD:

Nuri Reyes, PhD

In addition to experiencing social-communication difficulties, children with Autism Spectrum Disorder (ASD) also tend to experience more temperament and emotion regulation difficulties when compared to their peers. Whereas temperament is often defined as children's individual differences in thinking, feeling, and behaving in their environment, emotion regulation is described as children's ability to manage and respond to an emotional provoking event.

In a recent study, we found that children with ASD showed different change patterns and more variability in their temperament development suggesting that it is easier to predict temperament development in children with typical development than children with ASD. This is important because we may need to take child's temperament into consideration when working, guiding, or teaching children with ASD.

Notably, we don't know why children with ASD may show less stability in their temperament development over time. In another study that focused on emotion regulation, we found that children with ASD with enhanced emotion regulation abilities also showed increased social skills, fewer peer problems, and increased social prosocial behaviors. Positively, emotion regulation may be amenable to treatment, that is, children with ASD are likely to improve their ability to regulate their emotions when they learn to identify and express their emotions and practice tools on how to manage those emotions.

1. Sanson, A., Putnam, S., & Rothbart, M. K. (2002). Child temperament and parenting. In Handbook of Parenting, Vol. 1: Children and Parenting. Lawrence Erlbaum Associates. 255-277.
2. Thompson, R. A. (1994). Emotion regulation: A theme in search of definition. Monographs of the society for research in child development, 59(23), 25-52. <https://doi.org/10.2307/1166137>
3. Reyes, N.M., Walsh, K., Soke, N., & Hepburn, S. (2019). Changes in temperament over time in young children with Autism Spectrum Disorder: A follow-up comparison study. Journal of Intellectual Disability Research, p.1-14. <https://doi.org/10.1111/jir.12648>
4. Reyes, N.M., Factor, R., & Scarpa-Friedman, A. (submitted). Emotion regulation, emotionality, and expression of emotions: A link between social skills, behavior, and emotion problems with ASD and their peers.
5. Reyes, N., Pickard, K., & Reaven, J. (2019). Emotion regulation: A treatment target for Autism Spectrum Disorder. The Bulletin of the Menninger Clinic, 83 (3), p. 299-329. <https://doi.org/10.1521/bumc.2019.83.3.205>

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Developmental Pediatrics / JFK Partners

Peer-refereed journal publications published 2018-19

1. Bellesheim, KR., Cole, L, Coury, DL, Yin, L, Levy, SE, Guinnee, MA, Klatka, K, Malow, BA, **Katz, T**, Taylor, J, & Sohl, K. (2018). Family-driven goals to improve care for children with autism spectrum disorder. *Pediatrics*, 142 (3). e20173225; <http://dx.DOI.org/10.1542/peds.2017-3225>.
2. Christensen DL, Maenner MJ, Bilder D, et al. Prevalence and Characteristics of Autism Spectrum Disorder Among Children Aged 4 Years Early Autism and Developmental Disabilities Monitoring Network, Seven Sites, United States, 2010, 2012, and 2014. *MMWR Surveill Summ* 2019;68(No. SS-2):119. DOI: <http://dx.doi.org/10.15585/mmwr.ss6802a1>.
3. **Katz, T**, Shui, AM, Johnson, CR, Richdale, AL, **Reynolds, AM**, Scahill, L, & Malow, BA. (2018). Modification of the childrens sleep habits questionnaire for children with autism spectrum disorder. *Journal of autism and developmental disorders*, 48(8), 2629-2641. <http://doi.org/10.1007/s10803-018-3520-2>
4. Keefer, A, White, SW, Vasa, RA & **Reaven, J**. (2018). Psychosocial interventions for internalizing disorders in youth and adults with ASD, *International Review of Psychiatry*, 30:1, 62-77, <https://DOI.org/10.1080/09540261.2018.1432575> .
5. Klepper S, Khan TT, Klotz R, Gregorek AO, Chan YC, **Sawade S**. Effects of Structured Exercise Training in Children and Adolescents With Juvenile Idiopathic Arthritis. *Pediatric Physical Therapy*. 2019 Jan 1;31(1):3-21. <https://doi.org/10.1097/PEP.0000000000000555>
6. Levy, SL, Rescorla, LA, Chittams, JL, Kral, TJ, Moody, EJ, Pandey, J, Pinto-Martin, JA, Pomykacz, AT, Ramirez, AJ, **Reyes, N**, **Robinson Rosenberg, C**, Schieve, L, Thompson, A, Young, L, Zhang, J, Wiggins, L. (2019). ASD Screening with the Child Behavior Checklist/1.5-5 in the Study to Explore Early Development. *Journal of Autism and Developmental Disorders*. <https://doi.org/10.1007/s10803-019-03895-4>
7. Moody, E, **Kaiser, K**, Sharp, D, Kubicek, LF, Ricles, B, Davis, J, **McSwegin, S**, D'Abreu, LC, **Robinson Rosenberg, C** (2019). Improving Family Functioning Following Diagnosis of ASD: A Randomized Trial of a Parent Mentorship Program. *Journal of Child and Family Studies*, 28(2), 424-435. <https://doi.org/10.1007/s10826-018-1293-z>
8. **Pickard, K**, **Reyes, N**, **Reaven, J** (2018). Examining the inclusion of diverse participants in cognitive behavior therapy research for youth with autism spectrum disorder and anxiety. *Journal of Autism*. <https://doi.org/10.1177/1362361318795678>
9. **Pickard, K**, **Reyes, N**, & **Reaven, J**. (2018). Short Report: Examining the Inclusion of Diverse Participants in CBT Research for Youth with ASD and Anxiety, *Autism: International Journal of Research and Practice*. <https://DOI.org/10.1177/1362361318795678>
10. **Reaven, J.**, Moody, E., Grofer Klinger, L., Keefer, A., Duncan, A., OKelley, S., **Meyer, A.**, Hepburn, S., & **Blakeley-Smith, A**. (2018). Training Clinicians to Deliver Group CBT to Manage Anxiety in Youth with ASD: Results of a Multi-Site Trial. *Journal of Consulting and Clinical Psychology*, 86(3):205-217. <https://DOI.org/10.1037/ccp0000285>
11. **Reyes, N**, Lindly, O., Chavez, A., Macias, K., **Folan, A.**, Smith, K., **Reynolds, A.**, & Zuckerman, K. A. (2018). Maternal beliefs about Autism: A link between intervention services and Autism severity in White and Latino mothers. *Research in Autism Spectrum Disorders*, 51, 38-48. <https://doi.org/10.1016/j.rasd.2018.04.00>.
12. **Postorino, V**, De Crescenzo, F, Siracusano, M, Riccioni, A, Armando, M, Curatolo, P, Mazzone, L. (2019) Autistic Symptoms in Schizophrenia Spectrum Disorders: A Systematic Review and Meta-Analysis. *Front Psychiatry*, 21;10:78. <https://doi.org/10.3389/fpsy.2019.00078>.
13. **Postorino, V**, Gillespie, S, Lecavalier, L, Smith, T, Swiezy, N, Aman, M, G, McDougale, C, J, Bearss, K, Andrige, R, R, Vitiello, B, Scahill, L (2019). Clinical correlates of Parenting Stress in children with Autism Spectrum disorder and serious behavioral problem. *Journal of Child and family Studies*. <https://DOI.org/10.1007/s10826-019->

Developmental Pediatrics / JFK Partners

Peer-refereed journal publications published 2018-19

14. **Reyes, N., Walsh, C.,** Soke, N., & Hepburn, S. (2019). Changes in temperament over time in young children with autism spectrum disorder and other developmental delays: a follow-up comparison study, 1-14. <https://doi.org/10.1111/jir.12648>.
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University of Colorado School of Medicine, Developmental Pediatrics/JFK Partners Research Studies
Recruitment Needed

Study	Purpose	Eligibility	Contact
<p>Autism and Perception Research Study</p> <p>DUIRB Protocol 938383 Principal Investigator: Tim Sweeny, PhD JFK Faculty: Nuri Reyes, PhD</p> <p>Funded by: National Institutes of Health and the National Science Foundation</p> <p>Study dates: 9/11/17-9/10/2020</p>	<p>This study examines how typically-developing children and those with ASD understand social information, like emotional expressions and eye gaze.</p>	<ul style="list-style-type: none"> Children between 7-17 years Have been diagnosed with high-functioning Autism, Pervasive Developmental Disorder-Not otherwise Specified (PDD-NOS) or Asperger's Syndrome Children that have not been diagnosed with ASD to serve as controls for the study <p><i>Some children may be eligible to participate in full ADOS-2 and WISC-V assessments and then receive feedback from a clinical psychologist</i></p>	<p>Tim Sweeny E-mail: roboassist@du.edu Phone number: 720-946-0855</p>
<p>Virtual and Augmented Reality Treatment of Fear of Spiders and Insects in Children with Autism Spectrum Disorder</p> <p>COMIRB#: 18-1914</p> <p>Funded By: National Science Foundation</p> <p>Site Principal Investigator: Jack Dempsey, Ph.D</p> <p>Study dates: 9/2019-12/01/2019</p>	<p>The purpose of this study is to pilot the use of an augmented-reality (e.g., Pokémon Go™, Snapchat™) system to treat fear of spiders and insects in children with Autism Spectrum Disorder as state-of-the art system will be an improvement an order virtual-reality based system currently in use for this purpose by the National Health Service of the United Kingdom.</p>	<p>Diagnosed with Autism Spectrum Disorder 2. Can communicate in complete sentences 3. Age 7-13 4. Has a fear of spiders or insects that causes significant anxiety</p> <p><i>10 participants will be enrolled</i></p>	<p>Jenifer Sargent e-mail: Jenifer.Sargent@childrenscolorado.org Phone number: 720-222-4719</p>
<p>Efficacy of Crisis Plans for Individuals with Neurodevelopmental and Behavioral Dual Diagnosis</p> <p>COMIRB #: 17-0845 Principal Investigator: Cordelia Robinson Rosenberg, PhD, RN</p> <p><i>Recruitment begun on June 2017 and will end once 200 participants will be enrolled.</i></p>	<p>The primary objective of this study is to determine if families will adhere to a Crisis Plan, and, if followed, if the Crisis Plan is effective in decreasing occurrence of crises, crisis severity, and emergency service utilization.</p>	<p>We are enrolling the parent of an individual with both a neurodevelopmental diagnosis AND a psychiatric or behavioral diagnosis, and adult individuals with a dual diagnosis.</p> <ol style="list-style-type: none"> Study partner or legal guardian of individual between 5 - 65 years of age who lives in Colorado and who has both a neurodevelopmental diagnosis AND a psychiatric diagnosis or history of severe challenging behaviors. Individual with a dual diagnosis between 18 - 65 years of age who lives in Colorado and enrolls with a study partner or legal guardian. Study partner, parent or caregiver of individual with a dual diagnosis must be willing/able to complete the Crisis Plan and follow up surveys. Individual with a dual diagnosis must have 	<p>Cordelia Robinson Rosenberg, PhD, RN E-mail: Cordelia.Rosenberg@cuanschutz.edu Phone: 303-724-0473</p>

Study	Purpose	Eligibility	Contact
		<p>experienced one or more of the following events:</p> <p>(a) 911 call; (b) Emergency Department admission for mental health reasons or challenging behavior; or (c) requires physical restraint or seclusion to manage challenging behaviors.</p>	
<p>FX-LEARN: AFQ056 for Language Learning in Children with FXS (also known as NeuroNext)</p> <p>COMIRB#: 17-1129</p> <p>Principal Investigator: Nicole Tartaglia, MD, MS</p> <p>Study dates: 8/17/17 – 7/1/20</p> <p>Study website: https://clinicaltrials.gov/ct2/show/NCT02920892</p>	<p>This study is designed to determine whether intensive parent implemented language intervention in combination with AFQ056, an mGluR5 antagonist medication, leads to improvements in language development in young children with Fragile X syndrome compared to those treated with language intervention and placebo. This study uses an innovative trial design to evaluate the combination of an intensive therapy intervention and medication to brain plasticity and language skill development.</p>	<ul style="list-style-type: none"> • Males or females with a confirmed diagnosis of FXS • Individuals ages 32 months to 6 years 11 months on enrollment • Speak English as primary language <p><i>There are additional inclusion criteria to be a part of this study. Please contact study staff for additional information.</i></p>	<p>Nana Welnick E-mail: Nanastasia.Welnick@childrenscolorado.org Phone: 720-777-8608</p>
<p>Study to Explore Early Development (SEED): Phase 3</p> <p>COMIRB #: 16-1985</p> <p>Principal Investigator: Cordelia Robinson Rosenberg, PhD, RN</p> <p>Study dates: 7/1/2016-6/30/2021</p>	<p>The Study to Explore Early Development (SEED III) is a multi-year study to help identify factors that may put children at risk for autism spectrum disorders (ASDs) and other developmental disabilities.</p>	<p>By invitation only, we are enrolling children:</p> <ol style="list-style-type: none"> 1. Born in and currently live in one of the eight SEED study counties. 2. Between the ages of 2-5. <p><i>Many different children are eligible to take part in SEED including:</i></p> <ul style="list-style-type: none"> • Children with ASDs • Children with other developmental disabilities • Children without developmental disabilities 	<p>Kristina Hightshoe, MSPH E-mail: Kristina.Hightshoe@ucdenver.edu Phone: 303-724-7672</p>
<p>The aViation Study: A Multicenter Randomized Double-Blind Placebo-Controlled Study to Investigate the Efficacy and Safety of RO5285119 (Balovaptan) in Children with Autism Spectrum Disorder</p> <p>COMIRB#16-2631; WIRB Protocol No. 20162516</p> <p>Principal Investigator: Nicole Tartaglia, MD, MS</p>	<p>This study is evaluating the effectiveness and safety of an investigational medication called balovaptan being developed as a possible treatment to improve social behavior and communication in people with autism spectrum disorder (ASD). Balovaptan is a medication that blocks a hormone receptor in the brain linked to the control of socialization, stress, anxiety and aggression.</p>	<p>Males and females age 5-12 with a diagnosis of autism spectrum disorder who have an IQ of 70 or above are eligible to participate. Participants first have a screening visit, and if eligible are then assigned randomly to receive either balovaptan or placebo medication for 24 weeks, with study visits approximately every 6 weeks. Following participation in the aViation study, participants are eligible for an optional follow-up "open-label" study where everyone is treated with the study medication.</p>	<p>Coordinators:</p> <p>Courtney Klein Courtney.klein@childrenscolorado.org 720-777-5385</p> <p>Or</p> <p>Estee Hamo Ester.Hamo@childrenscolorado.org (720) 777-3486</p>

Study	Purpose	Eligibility	Contact
<p>Co-Investigators: Ann Reynolds, MD; Rebecca Wilson, PsyD</p> <p>The study is sponsored by Roche Pharmaceuticals</p>			
<p>The eXtraordinary Babies Study: Researching the Natural History of Health and Neurodevelopment in Infants and Young Children with Sex Chromosome Trisomy</p> <p>COMIRB#: 17-0118</p> <p>Principal Investigator: Nicole Tartaglia, MD, MS</p> <p>Co-Investigators: Shanlee Davis, MD; Rebecca Wilson, PsyD, and Jen Janusz, PsyD</p> <p>Study dates: September 2017 – August 2022</p> <p>Study website: https://clinicaltrials.gov/ct2/show/NCT03396562</p>	<p>This study is designed to research the natural history of neurodevelopment, health and early hormonal function in infants with XXY/Klinefelter syndrome, XYY, XXX and other sex chromosome variations in an effort to identify early predictors of developmental and health outcomes. The Investigators will also evaluate different developmental screening tools in infants with sex chromosome variations so the investigators can develop recommendations for pediatrician caring for infants and young children with XXY/Klinefelter syndrome, XYY, XXX, and other sex chromosome variations.</p>	<ol style="list-style-type: none"> 1. Children must be between the ages of 6 weeks to 12 months old 2. Children must have a prenatally identified diagnosis of XXY, XYY, XXX, XYY or other sex chromosome variation 3. Additional screening criteria to discuss with staff 	<p>E-mail: extraordinarykids@ucdenver.edu Phone: 720-808-0873</p>
<p>A Phase 2a, Randomized, Double-Blind, Parallel-Group, Proof-of-Concept Study Evaluating the Safety, Tolerability, and Efficacy of OV101 in Fragile X Syndrome</p> <p>COMIRB#: 18-0718</p> <p>Principal Investigator: Nicole Tartaglia, MD, MS</p> <p>Funding Source: Ovid Therapeutics Inc.</p> <p>Study Dates: 2018 – 2019</p>	<p>The Rocket study is a clinical research study that will help determine if an investigational medicine, called OV101 or gaboxadol, is safe and effective in treating behavioral characteristics commonly present in people with Fragile X syndrome (FXS). The study will test three different doses of OV101. Participation in the Rocket study will last about 21 weeks and include six visits to Children's Colorado and four phone appointments.</p>	<ol style="list-style-type: none"> 1. Males between 13 to 22 years of age with a diagnosis of Fragile X Syndrome 2. IQ <75 3. Able to tolerate blood draws 4. Additional screening criteria to discuss with staff 	<p>Coordinators:</p> <p>Courtney Klein Courtney.klein@childrenscolorado.org 720-777-5385</p> <p>Or</p> <p>Nanastasia Welnick Nanastasia.welnick@childrenscolorado.org 720-777-8608</p>
<p>A Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome – CONNECT-FX</p> <p>COMIRB#: 18-1480</p> <p>Principal Investigator: Nicole Tartaglia, MD, MS</p> <p>Funding Source: Zynerba Pharmaceuticals, Inc.</p> <p>Study Dates: 2018 – 2019</p> <p>Study website: www.connectfxtrial.com/</p>	<p>The purpose of the CONNECT-FX study is to evaluate the efficacy and safety of an investigational CBD gel (ZYN002). This study is a clinical trial evaluating a novel transdermally delivered CBD (ZYN002) for some common and debilitating behaviors associated with FXS.</p>	<ol style="list-style-type: none"> 1. Males and females ages 3 to <18 years of age with a diagnosis of Fragile X Syndrome 2. Able to tolerate blood draws and ECGs 3. Additional screening criteria 	<p>Coordinators:</p> <p>Courtney Klein Courtney.klein@childrenscolorado.org 720-777-5385</p> <p>Or</p> <p>Nanastasia Welnick Nanastasia.welnick@childrenscolorado.org 720-777-8608</p>

Study	Purpose	Eligibility	Contact
<p>A Retrospective Description of the Effectiveness and Adverse Effects of Stimulants and Alpha-2 Agonists Used by Developmental-Behavioral Pediatricians for the Treatment of ADHD in Preschool Aged Children</p> <p>COMIRB#: 18-0353 Principal Investigator: Sandra Friedman, MD</p> <p>Study Dates: 2018-2019</p>	<p>Primary objective is to determine the percentage of preschool age children with ADHD who responded positively to stimulants and A2A based and to determine if there is a difference in the positive response rate to these two classes of medication.</p>	<ol style="list-style-type: none"> 1. Males or females age 0 to <72 months with an outpatient visit to a DBP clinician between 1/1/13 and 7/1/17. 2. Visit diagnoses include ADHD (ICD10 codes F90.0-F90.9) 3. Current or past history of DBP clinician prescribing a stimulant or alpha-2 agonist. <p><i>We are one of seven DBP sites; data collection currently continues at our site.</i></p>	<p>Sandra Friedman sandra.friedman@childrenscolorado.org 720-777-6636</p> <p>Coordinator: Gina VanderVeen gina.vanderveen@childrenscolorado.org 720-777-5514</p>
<p>The Role of the Autism Diagnostic Observation Schedule in the Diagnosis of Autism by Developmental-Behavioral Pediatricians</p> <p>COMIRB#: 19-0382 Principal Investigator: Sandra Friedman, MD</p> <p>Study Dates: 2019-2020</p>	<p>To determine the frequency with which the results of the ADOS-2 alter the diagnostic conclusions of DBPs evaluation a child for possible ASD.</p>	<ol style="list-style-type: none"> 1. Males or females referred for evaluation of possible ASD 2. Age 18 months to 5 years 11 months <p><i>We are one of eight DBPNet sites. Enrollment begins in September 2019; 50 children to be enrolled.</i></p>	<p>Sandra Friedman sandra.friedman@childrenscolorado.org 720-777-6636</p> <p>Research Coordinators: Sarah Temple Sarah.Temple@childrenscolorado.org 720-777-5287 Rajgor, Trusha Trusha.Rajgor@childrenscolorado.org 720-777-7285</p>
<p>Hearing Assessment for Children with Developmental Disabilities</p> <p>CU Boulder IRB #: 16-0639 Principal Investigator: Angela Yarnell Bonino, Ph.D., CCC-A Funding Source: American Speech-Language-Hearing Foundation</p> <p>Study Dates: 2019-2021</p>	<p>For children with developmental disabilities, audiologists often report that they have difficulty measuring behavioral hearing thresholds. The current lack of behavioral procedures that are effective for evaluating hearing in children with developmental disabilities is a significant public health problem, resulting in delayed diagnosis and difficulty fitting amplification in this population. The purpose of this project is to determine the feasibility and reliability of measuring behavioral hearing thresholds in children with developmental differences with an innovative, observer-based procedure.</p>	<ol style="list-style-type: none"> 1. 2 to 5 years of age 2. Diagnosed delay or disorder that impacts at least one area of development. 3. No known permanent hearing loss. 4. Negative history for placement of pressure equalization (PE) tubes or other ear surgery. 5. Not under treatment for otitis media within the prior month. 6. Additional screening criteria regarding child's development. 	<p>Email: childhear@colorado.edu Phone: 303-735-6252 Website: https://www.colorado.edu/lab/chapl/</p>
<p>Descriptive Prospective Pilot Study of Severely Obese Adolescents/Young Adults with Intellectual Disability Presenting for Bariatric Surgery Evaluation</p> <p>COMIRB#: 17-1919 Principal Investigator: Jaime Moore, MD</p> <p>Study Dates: 2018-2019</p>	<p>The purpose of the project is to determine the psychosocial and health characteristics of severely obese adolescents and young adults with intellectual disability, who present to Children's Hospital Colorado's Bariatric Surgery Center for weight loss surgery evaluation. Additionally, we aim to determine if these pre-operative characteristics are associated with a) completing vs. not completing the pre-operative process and b) for those who undergo surgery, post-operative psychosocial and health-related outcomes.</p>	<p>Patients between 10-25 years old who has a documented history of intellectual disability will be approached for study enrollment. If there is no previously documented history of intellectual disability, but during the routine evaluation of the patient in the bariatric surgery clinic, there is a clinical suspicion that the patient may have intellectual disability, the clinical psychologist will administer brief screens for intellectual and adaptive functioning.</p>	<p>Dr. Jaime Moore Phone: 303-724-8419 Email: Jaime.Moore@CUAnschutz.edu</p>

Study	Purpose	Eligibility	Contact
STUDIES COMING SOON!			
CASCADE Study: Cannabidiol (CBD) Study in Children with Autism Spectrum Disorder Principal Investigator: Nicole Tartaglia, MD Funding Source: Colorado Department of Health and Environment (CDPHE) Study Dates: 2019-2022	This study is a placebo-controlled clinical trial of CBD in children age 5-17 with autism spectrum disorder evaluating the effect of CBD on symptoms of irritability, aggression, anxiety and social behaviors.	Approvals for this study are currently underway.	Official recruitment has not yet begun. Interested parties should email: CBDiAutismStudy@childrenscolorado.org with their contact information. We will contact you once study approvals are completed.
A Non-Drug Study to Assess the Suitability of Scales for the Measurement of Behavior, Sleep, and Functioning in Individuals with Fragile X Syndrome Principal Investigator: Nicole Tartaglia, MD, MS Funding Source: OVID Therapeutics COMIRB#: 18-215	This study evaluates different measures and scales to determine if they are good measures to capture the behaviors and skills seen in males with FXS. There are many new medications being evaluated in FXS, and it is important that research studies use scales, questionnaires, and research tools that are able to capture the range of behaviors in FXS and that are able to identify change over time. This study is set up like a clinical trial with 4 visits over a 15 week period, however there are no medications, blood draws or medical procedures involved.	1. Males with Fragile X syndrome 2. 5-30 years of age	Lisa Cordeiro Email: Lisa.cordeiro@childrenscolorado.org



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Upcoming Opportunities

Please be on the lookout for our next Research Newsletter in Spring 2020. We aim to provide updates on current research and will highlight new ways to get involved. Please share your ideas for future newsletters with us here:

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This is a newsletter of the Colorado University Center of Excellence funded by ACL (99DDUC0014) and the Leadership Education in Neurodevelopmental Disabilities grant funded by MCHB (T73MC11044). The content of this newsletter was generated by program faculty, staff, and trainees at JFK Partners, University of Colorado School of Medicine.

Special thanks to Judy Reaven, PhD, Valentina Postorino, PhD and Dina Johnson, MA for their work to create and edit this newsletter.

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