



# Research Updates

[www.JFKPartners.org](http://www.JFKPartners.org)

Spring 2019

## Message from the Research Director



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

Dear Community Partners,

As you may know, for the last couple of years we have produced a comprehensive Developmental Pediatrics/JFK Partners Research Newsletter. The newsletter has been disseminated in October, timed to coincide with our JFK Partners Annual Autism Spectrum Disorder Conference. In the previous editions, the research newsletter has highlighted ongoing research projects, provided in-depth information about current research findings, as well as details about how to get

involved in ongoing research projects through Developmental Pediatrics/JFK Partners. We have even provided a section where a researcher was in the "spotlight", to allow our readers an inside look at the careers of some of our faculty.

Clinical research is ongoing in our department, and rather than only disseminate a research newsletter on a yearly basis, we thought we would provide our community partners with brief research updates in the spring. In this abbreviated newsletter, you will find results from recently completed research projects, details about how to get involved in ongoing research, as well as information about JFK Partners' 7th Annual ASD Conference on October 4, 2019.

As always, we would appreciate any feedback that you have for us about this brief research update, 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/2019JFKnews>.

Sincerely,

## Save the Date!

JFK Partners' 7th Annual  
Autism Spectrum Disorder  
Conference

### Speakers:

*Aubyn C. Stahmer, PhD &  
Amber Fitzgerald, MA, BCBA,*  
University of California, Davis

Friday, October 4, 2019  
8:00 AM - 4:30 PM

Anschutz Medical Campus

Registration will open May 1, 2019  
at [www.JFKPartners.org](http://www.JFKPartners.org)

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

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. We included 2- to 5-year-old children whose parent completed 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 general population. The results of this study show that 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.



Reynolds AM, Soke GN, Sabourin KR, Hepburn S, Katz T, Wiggins LD, Schieve LA, Levy SE. Sleep Problems in 2- to 5-Year-Olds With Autism Spectrum Disorder and Other Developmental Delays. *Pediatrics*. 2019 Feb 11. pii: e20180492. <https://doi.org/10.1542/peds.2018-0492> [Epub ahead of print]

## Facing Your Fears Adapted for Schools

Principal Investigator: Judy Reaven, PhD / [Judy.Reaven@ucdenver.edu](mailto:Judy.Reaven@ucdenver.edu)

Children with ASD are at high risk for developing clinically significant anxiety that interferes with peer relationships, family functioning and participation in academic programming.

Although research has demonstrated the positive impact of modified Cognitive Behavior Therapy (CBT) on anxious symptoms in youth with ASD, substantial disparities in access to psychiatric services exist, particularly for youth from diverse and/or low income families.

Schools are the ideal location to access these services. We are partnering with Cherry Creek School District, Denver Public Schools and Littleton Public Schools for this project. After spending the past year adapting the clinic-based Facing Your Fears (FYF) Program (Reaven et al. 2011) for school settings, we are now implementing the program in 9 schools across the three districts. Approximately 30 students with ASD and anxiety have participated in the school based FYF. We are collecting post-treatment data, including exit interviews with all of the school teams.

We will expand the program to 10 schools per district next fall, and look forward to sharing more formal results of this project. Many thanks to our fantastic school partners at each district, as well as the many families who have participated in this project.

JFK Partners/Developmental Pediatrics faculty and staff on this project: Judy Reaven, PhD, Audrey Blakeley-Smith, PhD, Nuri Reyes, PhD, Richard Boles, PhD, Lisa Hayutin, Ph.D., Caitlin Walsh, Ph.D. and Megan Morris, Ph.D.

Funding: HRSA R41MC31075 (2017-2020).

## Facing Your Fears Adapted for Adolescents with ASD and ID

Principal Investigator: Audrey Blakeley-Smith, PhD  
[Audrey.Blakeleysmith@ucdenver.edu](mailto:Audrey.Blakeleysmith@ucdenver.edu)

Our research team received two years of funding from the Organization of Autism Research (OAR) to explore the efficacy of an adapted version of Facing Your Fears (FYF) for adolescents with Autism Spectrum Disorder (ASD) and Intellectual Disabilities (ID).

Nineteen families completed the 14 week cognitive behavioral treatment (CBT) intervention and significant improvements were noted in mood and anxiety symptoms.

We have learned that the intervention may be effective in developing strategies to help teens with ASD/ID to be "brave", face fears, and gain the skills necessary to manage difficult and overwhelming activities. Teens with ASD and ID can change the way they talk to themselves through coping statements (e.g., "I can handle it"), practice ways to calm their bodies (i.e., deep breathing), and create goals that reflect what they want to achieve.

Family, school, and friends can then help support the achievement of these goals by identifying anxiety, supporting strategy use, and coaching brave behavior.

Next steps in this project are to apply for an additional grant to conduct a randomized control trial with a comparison group. In addition, we are interested in providing this treatment as a clinical service within Developmental Pediatrics.

JFK Partners/Developmental Pediatrics faculty and staff on this project: Judy Reaven, PhD, Audrey Blakeley-Smith, PhD, and Allison T. Meyer, PhD (Fellow)

Funding: Organization of Autism Research (OAR) Award 170464 (2016-2018).

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

<http://www.FacingFears.org>

### Participating Schools

#### Cherry Creek School District



Our Vision:  
Respecting our past, Valuing our present,  
Believing in our future.

#### Denver Public Schools



SABIN WORLD  
ELEMENTARY

FAIRVIEW  
ELEMENTARY



#### Littleton Public Schools



POWELL  
Pumas



Centennial  
Academy

Fine Arts Education

# Research Updates

## A study of Cannabidiol (CBD) for treatment of Irritability/Aggression and Anxiety in Children with Autism Spectrum Disorder

Principal Investigator: Nicole Tartaglia, MD, MS

Co-Investigators: Ann Reynolds, MD, Sandra Friedman, MD, Elise Sannar, MD, Emily Werner, PhD, Judy Reaven, PhD

This study is designed to evaluate the effects of Cannabidiol (CBD) in children age 5-17 with Autism Spectrum Disorder to determine if there are benefits or risks to symptoms of irritability, aggressive behavior, anxiety, social interactions, repetitive behaviors, and sleep. The study will also evaluate safety and side effects of CBD in children with ASD. CBD is a chemical from the Cannabis (marijuana) plant that acts on receptors in the brain and throughout the body, but does not cause the same psychoactive effects of THC. Study participants will have 6-8 visits over a 26-30 week period, and all participants will receive treatment with both CBD and placebo during this period, with at least 12 weeks of CBD treatment during the study period.

This three-year study is sponsored by the Colorado Department of Health and Environment. Approvals for this study are currently underway. If you are interested in more information in the future, please email your name and contact information to [CBDinAutismStudy@childrenscolorado.org](mailto:CBDinAutismStudy@childrenscolorado.org). We will contact you once study approvals are completed.

This research proposes to evaluate the safety and efficacy of CBD in youth ages 5 to 17 with ASD with high irritability and aggression. The funding of the study from the state's Medical Marijuana Research Grant Program has been recently highlighted in both [The Gazette](#) and [The Denver Post](#). See Study Recruitment Section about how to join this study.



## The aV1ation Study: A Multicenter Randomized Double-Blind Placebo-Controlled Study to Investigate the Efficacy and Safety of RO5285119 (Balovaptan) in Children with Autism Spectrum Disorder

Principal Investigator: Nicole Tartaglia, MD, MS

Co-Investigators: Ann Reynolds, MD and Rebecca Wilson, PsyD

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. 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 aV1ation study, participants are eligible for an optional follow-up "open-label" study where everyone is treated with the study medication. The study is sponsored by Roche Pharmaceuticals. COMIRB#16-2631; WIRB Protocol No. 20162516. See Study Recruitment Section about how to join this study.

# Research Updates

## The eXtraordinary Babies Study: Researching the Natural History of Health and Neurodevelopment in Infants and Young Children with Sex Chromosome Trisomy

Principal Investigator: Nicole Tartaglia, MD, MS

The eXtraordinary Babies Study evaluates the early health and development of infants and children with sex chromosome disorders. This study follows babies, who were diagnosed with a sex chromosome disorder before being born, from 2-3 months of age every 6-12 months as they grow up. This is an amazing opportunity to learn about the natural history of neurodevelopment, health and early hormonal function in infants with XXY/Klinefelter syndrome, XYY, XXX and other sex chromosome variations.

We hope to identify early predictors of developmental and health outcomes observed in the variability in these conditions from a young age that will allow us to counsel families and develop specific treatment programs for these eXtraordinary kids. In the study, we will closely evaluate and track developmental skills, medical problems, hormone levels, body composition, and other important factors such as family history, interventions, and family quality of life. Funded by an NIH grant awarded to Dr. Tartaglia. COMIRB#: 17-0118. See Study Recruitment Section about how to join this study.

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## A Phase 2a, Randomized, Double-Blind, Parallel-Group, Proof-of-Concept Study Evaluating the Safety, Tolerability, and Efficacy of OV101 in Fragile X Syndrome

Principal Investigator: Nicole Tartaglia, MD, MS

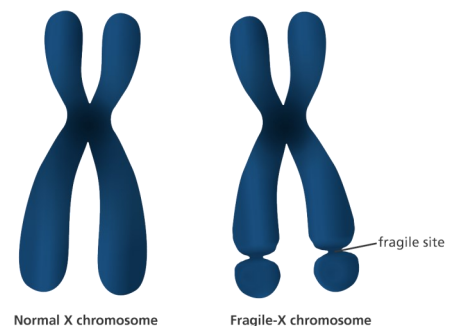
The Rocket study is a clinical research study that will help determine if an investigational medicine, called OV101 or gaboxadol, is safe and effective in treating behavioral characteristics commonly present in people with Fragile X syndrome (FXS). The study will test three different doses of OV101. Participation in the Rocket study will last about 21 weeks and include six visits to Children's Hospital Colorado and four phone appointments. COMIRB#: 18-0718. See Study Recruitment Section about how to join this study.

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## 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

Principal Investigator: Nicole Tartaglia, MD, MS

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 Fragile X. COMIRB#: 18-1480. See Study Recruitment Section about how to join this study.





# Research Updates



## DBPNet

Sandra L. Friedman, MD, MPH is the site lead for Colorado for the Developmental Behavioral Pediatrics Research Network (DBPNet). We are one of 14 sites of sites; other sites include Boston Children's; CHOP; Stanford; Cincinnati Children's; Einstein; Rainbow Babies; Yale; LA Children's; Boston Medical Center; Arkansas Children's; Hasboro Children's; UC Davis; Oklahoma.

There are two active studies:

### **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](mailto: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 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.

This study will involve review of EHR at 7 outpatient developmental and behavioral pediatrics practices and enroll up to 1700 children less than 72 months of age with a diagnosis of ADHD who are seen in the above practices. Approximately 850 charts of children treated with stimulants or A2A will be manually reviewed.

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

PI: Sandra Friedman, MD, MPH / [Sandra.Friedman@childrenscolorado.org](mailto: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 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 three hundred fifty 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.



## **Study to Explore Early Development (SEED 3)**

Principal Investigator: Cordelia Robinson Rosenberg, PhD, RN

[Colorado.SEED@ucdenver.edu](mailto:Colorado.SEED@ucdenver.edu)  
303-724-7638

JFK Partners is in the third phase of the national SEED study, which is funded by the Centers for Disease Control (CDC). SEED is one of the largest epidemiological studies to date that is designed to compare children with autism spectrum disorder (ASD) and other developmental disabilities to children without these conditions. SEED will help identify factors that might put children at risk for ASD and help improve services and treatments for children with ASD. SEED 3 is open to enrollment by invitation only. You can visit the Colorado SEED Study website at [www.coloradoseed.org](http://www.coloradoseed.org). Funding: CDC, National Center for Birth Defects and Developmental Disabilities, #5U01DD00120 (2016-2021).

**University of Colorado School of Medicine, Developmental Pediatrics/JFK Partners Research Studies**  
**Recruitment Needed**

Study	Purpose	Eligibility	Contact
<b>Autism and Perception Research Study</b>  <b>DUIRB</b> Protocol 938383 <b>Principal Investigator:</b> Tim Sweeny, PhD <b>JFK Faculty:</b> Nuri Reyes, PhD  <b>Funded by:</b> National Institutes of Health and the National Science Foundation  <b>Study dates:</b> 9/11/17-9/10/2020	This study examines how typically-developing children and those with ASD understand social information, like emotional expressions and eye gaze.	<ul style="list-style-type: none"> <li>Children between 7-17 years</li> <li>Have been diagnosed with high-functioning Autism, Pervasive Developmental Disorder-Not otherwise Specified (PDD-NOS) or Asperger's Syndrome</li> <li>Children that have not been diagnosed with ASD to serve as controls for the study</li> </ul> <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>	Dustin Weilbach E-mail: <a href="mailto:roboassist@du.edu">roboassist@du.edu</a> Phone number: 720-946-0855
<b>Efficacy of Crisis Plans for Individuals with Neurodevelopmental and Behavioral Dual Diagnosis</b>  <b>COMIRB #:</b> 17-0845 <b>Principal Investigator:</b> Cordelia Robinson Rosenberg, PhD, RN  <i>Recruitment begun on June 2017 and will end once 200 participants will be enrolled.</i>	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.	We are enrolling parents of an individual who has both a neurodevelopmental diagnosis AND a psychiatric or behavioral diagnosis. 1. Individual with dual diagnoses must be between 8-50 years of age 2. Individual must live in the state of Colorado 3. Individual with dual diagnoses must have experienced one or more of the following events: (a) 911 call; (b) Emergency Department admission for mental health reasons; or (c) other urgent mental health intervention. 4. Parent or caregiver must be willing/able to complete the Crisis Plan and follow up surveys.	Cordelia Robinson Rosenberg, PhD, RN E-mail: <a href="mailto:Cordelia.Rosenberg@ucdenver.edu">Cordelia.Rosenberg@ucdenver.edu</a> Phone: 303-724-7366
<b>Growing up with an extra X or Y: The TRIXY study</b>  <b>COMIRB#:</b> 16-1710 <b>Principal Investigator:</b> Nicole Tartaglia, MD, MS  Enrolling new participants through August 2019 Study ends August 2020	This study has been designed to learn more about young children who have an extra X or Y chromosome, also referred to as 'sex chromosome trisomies' (SCTs). We want to learn more about the early health and development in SCTs. This study includes tests of neurodevelopment, behavior and physiology in young children with a SCT. This study will help us find out if there are early predictors for future outcomes of learning, behavior, motor skills, social skills, and overall health. It will also help to develop recommendations for care of young children with SCT.	1. Children must be between the ages of 1 years and 5 years old at enrollment; 2. Confirmed diagnosis of 47,XXY, 47, XYY or 47, XXX or typically developing children; 3. Additional screening criteria to discuss with staff	Lisa Cordeiro, MS, CSP E-mail: <a href="mailto:trixy@ucdenver.edu">trixy@ucdenver.edu</a> Phone: 720-722-1515

Study	Purpose	Eligibility	Contact
<p><b>FX-LEARN: AFQ056 for Language Learning in Children with FXS (also known as NeuroNext)</b></p> <p><b>COMIRB#:</b> 17-1129  <b>Principal Investigator:</b> Nicole Tartaglia, MD, MS</p> <p><b>Study dates:</b> 8/17/17 – 7/1/20</p> <p><b>Study website:</b>  <a href="https://clinicaltrials.gov/ct2/show/NCT02920892">https://clinicaltrials.gov/ct2/show/NCT02920892</a></p>	<p>The overall goals are to change the paradigm for development of mechanism targeted pharmacotherapy in neurodevelopmental disorders and provide a definitive test of the mGluR theory in humans by determining whether AFQ056, an mGluR5 negative modulator, can enhance neural plasticity in the form of language learning during an intensive language intervention in very young children with fragile X syndrome. This trial therefore will use an innovative but exploratory new trial design to develop a different way to examine efficacy of an agent with substantial support as a drug targeting CNS plasticity in preclinical models of a developmental disorder. If the design is successful, this trial can serve as a model for future trials of mechanistically-targeted treatments operating on neural plasticity in other neurodevelopmental disorders.</p>	<ul style="list-style-type: none"> <li>• Males or females with a confirmed diagnosis of FXS</li> <li>• Individuals ages 32 months to 6 years 11 months on enrollment</li> <li>• Speak English as primary language</li> </ul> <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: <a href="mailto:Nanastasia.Welnick@childrenscolorado.org">Nanastasia.Welnick@childrenscolorado.org</a>  Phone: 720-777-8608</p>
<p><b>Study to Explore Early Development (SEED): Phase 3</b></p> <p><b>COMIRB #:</b> 16-1985  <b>Principal Investigator:</b> Cordelia Robinson Rosenberg, PhD, RN</p> <p><b>Study dates:</b> 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"> <li>1. Were born in and currently live in one of the eight SEED study counties.</li> <li>2. Are between the ages of 2-5.</li> </ol> <p><i>Many different children are eligible to take part in SEED including:</i></p> <ol style="list-style-type: none"> <li>3. Children with ASDs</li> <li>4. Children with other developmental disabilities</li> </ol>	<p>Kristina Hightshoe, MSPH  E-mail: <a href="mailto:Kristina.Hightshoe@ucdenver.edu">Kristina.Hightshoe@ucdenver.edu</a>  Phone: 303-724-7672</p>
<p><b>The GAIN Study</b></p> <p><b>COMIRB #:</b> 17-2308  <b>Principal Investigator:</b> Susan L. Johnson, PhD</p> <p><b>Study dates:</b> 09/01/2018-6/1/2019</p>	<p>Some foods are designed to support children's growth and development. The purpose of this research is to understand how children respond to one such food.</p>	<p><i>To participate your child must:</i></p> <ol style="list-style-type: none"> <li>1. Be between 7-24 months</li> <li>2. Have been born to term,</li> <li>3. NOT have any allergies or medical conditions.</li> </ol> <p><i>To participate you must:</i></p> <ol style="list-style-type: none"> <li>4. Be between 18 - 50 years old</li> <li>5. NOT have any nut allergies.</li> </ol>	<p>Abigail Flesher  E-mail: <a href="mailto:Abigail.Flesher@ucdenver.edu">Abigail.Flesher@ucdenver.edu</a>  Phone: 303-724-2922</p>

Study	Purpose	Eligibility	Contact
<p><b>The Infant Vegetable Study</b></p> <p><i>COMIRB #:</i> 18-0148  <i>Principal Investigator:</i> Kameron J. Moding, PhD</p> <p><i>Study dates:</i> 11/1/2018-7/31/19</p>	<p>This research will measure infants' responses to vegetables and caregivers' decisions about offering them to their child.</p>	<p><i>To participate you must:</i></p> <ol style="list-style-type: none"> <li>1. Live within 75 miles of Anschutz Medical Campus</li> <li>2. Be between 18 and 50 years of age</li> <li>3. Be responsible for feeding &gt; 50% of the time</li> </ol> <p><i>To participate your child must:</i></p> <ol style="list-style-type: none"> <li>1. Be between 6 months and 24 months</li> <li>2. Have been born at term (at least 37 weeks gestation)</li> <li>3. Must not have allergies or medical conditions</li> <li>4. Have experienced at least one complementary food (rice cereal or other solid food)</li> </ol>	<p>Kameron Moding  E-mail: <a href="mailto:kameron.moding@ucdenver.edu">kameron.moding@ucdenver.edu</a>  Phone: 303-724-2922</p>
<p><b>The aV1ation Study: A Multicenter Randomized Double-Blind Placebo-Controlled Study to Investigate the Efficacy and Safety of RO5285119 (Balovaptan) in Children with Autism Spectrum Disorder</b></p> <p>COMIRB#16-2631; WIRB Protocol No. 20162516</p> <p>Principal Investigator: Nicole Tartaglia, MD, MS</p> <p>Co-Investigators: Ann Reynolds, MD; Rebecca Wilson, PsyD</p> <p>The study is sponsored by Roche Pharmaceuticals</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 aV1ation 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  <a href="mailto:Courtney.klein@childrenscolorado.org">Courtney.klein@childrenscolorado.org</a>  720-777-5385</p> <p>Or</p> <p>Nanastasia Welnick  <a href="mailto:Nanastasia.welnick@childrenscolorado.org">Nanastasia.welnick@childrenscolorado.org</a>  720-777-8608</p>
<p><b>The eXtraordinary Babies Study: Researching the Natural History of Health and Neurodevelopment in Infants and Young Children with Sex Chromosome Trisomy</b></p> <p><i>COMIRB#:</i> 17-0118  <i>Principal Investigator:</i> Nicole Tartaglia, MD, MS</p> <p><i>Study dates:</i> September 2017 – August 2022</p> <p><i>Study website:</i>  <a href="https://clinicaltrials.gov/ct2/show/NCT03396562">https://clinicaltrials.gov/ct2/show/NCT03396562</a></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"> <li>1. Children must be between the ages of 6 weeks to 12 months old</li> <li>2. Children must have a prenatally identified diagnosis of XXY, XYY, XXX, XXYY or other sex chromosome variation</li> <li>3. Additional screening criteria to discuss with staff</li> </ol>	<p>E-mail: <a href="mailto:extraordinarykids@ucdenver.edu">extraordinarykids@ucdenver.edu</a>  Phone: 720-808-0873</p>



Study	Purpose	Eligibility	Contact
<b>A Phase 2a, Randomized, Double-Blind, Parallel-Group, Proof-of-Concept Study Evaluating the Safety, Tolerability, and Efficacy of OV101 in Fragile X Syndrome</b>  <b>COMIRB#:</b> 18-0718 <b>Principal Investigator:</b> Nicole Tartaglia, MD, MS <b>Funding Source:</b> Ovid Therapeutics Inc.  <b>Study Dates:</b> 2018 – 2019	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.	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	Coordinators:  Courtney Klein <a href="mailto:Courtney.klein@childrenscolorado.org">Courtney.klein@childrenscolorado.org</a> 720-777-5385 Or Nanastasia Welnick <a href="mailto:Nanastasia.welnick@childrenscolorado.org">Nanastasia.welnick@childrenscolorado.org</a> 720-777-8608
<b>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</b>  <b>COMIRB#:</b> 18-1480 <b>Principal Investigator:</b> Nicole Tartaglia, MD, MS <b>Funding Source:</b> Zynerva Pharmaceuticals, Inc.  <b>Study Dates:</b> 2018 – 2019 <b>Study website:</b> <a href="http://www.connectfxtrial.com/">www.connectfxtrial.com/</a>	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.	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	Coordinators:  Courtney Klein <a href="mailto:Courtney.klein@childrenscolorado.org">Courtney.klein@childrenscolorado.org</a> 720-777-5385 Or Nanastasia Welnick <a href="mailto:Nanastasia.welnick@childrenscolorado.org">Nanastasia.welnick@childrenscolorado.org</a> 720-777-8608
<b>STUDIES COMING SOON!</b>			
<b>A study of Cannabidiol (CBD) for treatment of Irritability/Aggression and Anxiety in Children with Autism Spectrum Disorder</b>  <b>Principal Investigator:</b> Nicole Tartaglia, MD <b>Funding Source:</b> Colorado Department of Health and Environment (CDPHE)  <b>Study Dates:</b> 2019-2022	This study is a placebo-controlled clinical trial of CBD in children age 5-17 with autism spectrum disorder.	Approvals for this study are currently underway.	Official recruitment has not yet begun.  Interested parties should email: <a href="mailto:CBDiAutismStudy@childrenscolorado.org">CBDiAutismStudy@childrenscolorado.org</a> with their contact information. We will contact you once study approvals are completed.
<b>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</b>  <b>COMIRB#:</b> 18-0353 <b>Principal Investigator:</b> Sandra Friedman, MD	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.	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.	Sandra Friedman <a href="mailto:sandra.friedman@childrenscolorado.org">sandra.friedman@childrenscolorado.org</a> 720-777-6636  Coordinator: Gina VanderVeen <a href="mailto:gina.vanderveen@childrenscolorado.org">gina.vanderveen@childrenscolorado.org</a> 720-777-5514

Study	Purpose	Eligibility	Contact
<p><i>Study Dates:</i> 2018-2019</p> <p><b>The Role of the Autism Diagnostic Observation Schedule in the Diagnosis of Autism by Developmental-Behavioral Pediatricians</b></p> <p><i>COMIRB#:</i> 19-0382  <i>Principal Investigator:</i> Sandra Friedman, MD</p> <p><i>Study Dates:</i> 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"> <li>1. Males or females referred for evaluation of possible ASD</li> <li>2. Age 18 months to 5 years 11 months</li> </ol>	<p>Sandra Friedman  <a href="mailto:sandra.friedman@childrenscolorado.org">sandra.friedman@childrenscolorado.org</a>  720-777-6636</p> <p><i>Coordinator:</i>  Roger Paxton  <a href="mailto:roger.paxton@childrenscolorado.org">roger.paxton@childrenscolorado.org</a>  720-777-5200</p>



# JFK Partners

UNIVERSITY OF COLORADO  
ANSCHUTZ MEDICAL CAMPUS

## Upcoming Opportunities

Please be on the lookout for our next Research Newsletter in October 2019. 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:

<https://www.surveymonkey.com/r/2019jfknews>

## Connect with Us

If you would like to hear about all of the ongoing opportunities at JFK Partners, please join our listserv by sending an email to: [Listserv@Lists.UCDenver.edu](mailto:Listserv@Lists.UCDenver.edu) with "Listserv Command" in the Subject Line and "SUBSCRIBE JFKPARTNERS" in the text of your email. If you have trouble, please email [Dina.Johnson@ucdenver.edu](mailto:Dina.Johnson@ucdenver.edu).



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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.

## Contact Us

Visit us online for more information about our programs at:

[www.JFKPartners.org](http://www.JFKPartners.org)

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