Fragile X Research and Treatment Center
Clinical Research Studies

A Controlled Double-Blind Cross-over Trial of Ganaxolone in Children with Fragile X Syndrome (Spring 2012-2015)
Coordinator: Erika Bickel 916-703-0281, erika.bickel@ucdmc.ucdavis.edu
This study assesses the safety, tolerability, and efficacy of ganaxolone, a GABAA agonist, for the treatment of behavioral problems including anxiety and inattention in children with FXS. The protocol involves 7 visits in 4 months with 6 blood draws, medical history exams, neuropsychological evaluation, behavioral testing, and psychophysiology evaluations.
We are recruiting males and females (ages 6-17 years) with the full mutation.

A Controlled Trial of Sertraline in Young Children with Fragile X Syndrome (January 2012-February 2015)
Coordinator: Salpi Siyahian 916-703-0391, salpi.siyahian@ucdmc.ucdavis.edu
This study investigates the efficacy of sertraline compared to placebo in children with fragile X syndrome. The protocol involves 2 visits in 6 months, 2 blood draws, medical history exams, neuropsychological evaluation, behavioral testing, and eye-tracking.
We are recruiting males and females (ages 24-60 months) with the full mutation.

A Controlled Trial of Sertraline in Young Children with Autism Spectrum Disorder (February 2015-December 2018)
Coordinator: Aisha Lott 916-703-0472, aisha.lott@ucdmc.ucdavis.edu
This study investigates the efficacy of sertraline compared to placebo in children with Autism Spectrum Disorder (ASD). The protocol involves 3 visits in 6 months, 2 blood draws, medical history exams, neuropsychological evaluation, behavioral testing, and eye-tracking.
We are recruiting males and females (ages 24-68 months) with Autism Spectrum Disorder (ASD).

Visual Processing and Later Cognitive Effects in Infants with Fragile X Syndrome (Fall 2007-Summer 2016)
Coordinator: Kim Gaul, 530-747-3808, kngaul@ucdavis.edu
This study examines low- and high-level visual processing differences in infants with fragile X syndrome, Down syndrome and typical development, in an attempt to elucidate where deficits do and do not exist in these disorders, and to guide new treatments. The protocol involves a developmental assessment, eye-tracking and blood draw. Participants are asked to return 1-2 years later for a Time 2 visit.
We are recruiting males and females (ages 10-48 months) with the full mutation or premutation.

Fragile X Clinical and Research Cooperative Consortium Registry and Repository (Fall 2009-2016)
Coordinator: Melanie Rothfuss, 916-704-1541, melanie.rothfuss@ucdmc.ucdavis.edu
This study aims to develop standards of care for diagnosis, evaluation and treatment (medical, psychological, educational and behavioral) for individuals with fragile X full mutation or premutation by collecting data from individuals who are seen at a Fragile X Clinic and Research Consortium Clinic. The protocol involves registering with the database and completing parent questionnaires.
We are recruiting males and females with the full mutation or premutation.

Genotype-Phenotype Relationships in Fragile X Families (Summer 2012-2017)
Coordinator: Laura Berkowitz-Sutherland, 916-703-0301, laura.berkowitz-sutherland@ucdmc.ucdavis.edu
This study aims to learn more about the fragile X premutation and develop an understanding as to how the problems seen in fragile X vary depending on the severity of the mutation. The protocol involves 3 days of testing consisting of a medical history exam, neuropsychological evaluation, behavioral testing, neurological evaluation, balance and tremor assessment, MRI and blood draw. We are recruiting males and females with and without the premutation (ages 8-65 years).

Longitudinal Study of Brain and Cognition in Fragile X Premutation Carriers (Summer 2013-2018)
Coordinator: Jessica Famula 916-703-0470, jessica.famula@ucdmc.ucdavis.edu
This study examines changes in the brain and cognition associated with aging, in males with and without the fragile X premutation. The study consists of three 2-day visits over the course of five years, to observe changes in the brain and cognition occurring over time. The protocol involves a medical history exam, neuropsychological evaluation, behavioral testing, MRI and blood draw.
We are recruiting males (ages 40-75 years) with and without the premutation.

Cognitive Training Program for Children and Adolescents with Fragile X Syndrome (Spring 2013-2017)
Coordinator: T-PAL Laboratory: 916-703-0461, T_PAL@ucdmc.ucdavis.edu
This study assesses the efficacy of a computerized cognitive training program to improve working memory, executive functioning, and attention in children and adolescents with FXS. The protocol requires adherence to an intensive home-based computerized program of 25 training sessions over a period of 5-6 weeks. Each training session is approximately 25-45 minutes and requires participation from the parent and the child. A staff member from the MIND Institute visits the home on three occasions in an 18 week period (~2-4hrs each visit) to conduct behavioral and cognitive assessments. We are recruiting males and females (ages 8-18 years) with the full mutation.

Updated 10-Feb-2015
Diaphragmatic Breathing and Heart Rate Variability Training for Improving Behavioral Self-Regulation in Fragile X Syndrome and Fragile X Associated Disorders (July 2013 – June 2015)
Coordinator: Patrick Adams, 916-703-0200, patrick.adams@ucdmc.ucdavis.edu
This study assesses the efficacy of a computerized biofeedback training program to improve the behavioral self-regulation for aggression and anxiety in children and adults with FXS and Fragile X Associated Disorders. The protocol includes home-based computer training for 20 sessions and three visits to the MIND Institute for baseline, and follow-up testing.
We are recruiting male and female individuals (ages 8-40 years) with fragile X associated disorders and healthy controls.

Extending Autism Behavioral Intervention to Young Children with Fragile X Syndrome (Fall 2012- 2015)
Coordinator: Melanie Rothfuss, 916-704-1541, melanie.rothfuss@ucdmc.ucdavis.edu
This study aims to develop and test the use of telemedicine technology to deliver a manualized, parent-implemented intervention for families of children with FXS. The intervention uses an Internet-based video conferencing program to teach families how to integrate the parent curriculum of the Early Start Denver Model into play activities and caretaking routines in their homes. The protocol involves a 2-day visit for behavioral assessments at the start and end of the study, and 12 weekly 1.5 hours of coaching sessions followed by 6 bimonthly 1.5 hour sessions. All intervention sessions will occur via secure video conferencing.
We are recruiting males and females (ages 18-48 months) with the full mutation.

A Cognitive Test Battery for Intellectual Disabilities (Summer 2014-2019)
Coordinator: Stephanie Sansone 916-703-0461, smsansone@ucdavis.edu
The purpose of this research is to explore whether certain types of intellectual or cognitive tests are reliable, valid and sensitive to improvement in evaluating treatment responses among individuals with intellectual disability. This newer cognitive test has been shown to accurately measure various cognitive skills across a wide age range, but has yet to be adapted and tested among individuals with intellectual disability. Participants include individuals between the ages of 6-25 years old with a confirmed diagnosis of intellectual disability caused by fragile X syndrome, Down syndrome, or another cause. This is a multi-site study with teams in Chicago and Denver also seeking participants.

Participation in the study involves two - three visits at the UC Davis MIND Institute. The first visit will last approximately 3.5 - 4 hours and is scheduled over a two day period. The second visit is scheduled approximately 4-weeks later and will be much shorter, only lasting about an hour. Some participants will be asked to return for a third visit. The schedule for the third visit is the same as the first visit and will take place approximately two years later. These visits will include cognitive testing for your son/daughter and parents/guardian will be asked to fill out questionnaires.