



*Investigational Drug Study for Children, Adolescents, and Adults with **Autism Spectrum Disorders***

Docket 14230; 209AS208

The Child and Adolescent Neurodevelopment Initiative (CANDI) at the University of Massachusetts Medical School is conducting a research study for an investigational drug to treat symptoms associated with Fragile X Syndrome.

Purpose of the Study

This study is sponsored by *Seaside Therapeutics* and is being conducted by approximately twenty research centers in the U.S. The purpose of the study is to evaluate whether an investigational drug is safe and effective for the treatment of the symptoms of Autism Spectrum Disorders.

Eligible participants will be offered up to approximately 3 months of study treatment with investigational drug. During the treatment period, participants will be monitored for side effects and will meet with the study doctor every 2 to 4 weeks. Between office visits, caregivers, parents, or guardians will also receive phone calls from the study doctor. At the end of the study treatment period, the investigational drug will be gradually withdrawn over a 4-week period.

Participation in this study will last up to approximately 5 months and requires up to 7 visits to the **University of Massachusetts Medical School** and between 10 and 15 phone calls with the study doctor. For each visit to the office, a small payment will be offered to offset travel expenses. The investigational drug and all study-related evaluations are provided free of charge.

Eligibility

- Males or females between **5 and 21** years of age
- Diagnosis of Autism Spectrum Disorder
- Exhibits behaviors such as:
 - Being listless, sluggish, or inactive
 - Doing nothing but sitting and watches others
 - Isolating himself/herself from other children or adults
 - Being difficult to reach, contact, or get through to
 - Fixed facial expressions or lack of emotions

If you are interested in learning more about this study, please contact:

Child and Adolescent Neurodevelopment Initiative (CANDI)

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or

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