

### NATIONWIDE RECRUITMENT

#### CHILD & ADOLESCENTS WITH SEVERE MOOD DYSREGULATION: BRAIN IMAGING, NON-TREATMENT AND TREATMENT STUDIES

The NIMH is seeking boys and girls ages 7 to 17 with severe mood dysregulation to participate in research. Children and adolescents with mood and behavioral dysregulation display chronic anger, sadness, or irritability, as well as hyperarousal symptoms common in ADHD (such as insomnia, distractibility, hyperactivity) and extreme responses to frustration (such as frequent, severe temper tantrums). Sometimes, children with this pattern of severe, chronic irritability and outbursts are given the diagnosis of bipolar disorder. The non-treatment study involves visits to the NIH campus in Bethesda, MD and includes outpatient assessment, computer tasks, and fMRI scanning (a form of brain imaging).

A treatment study is also available for those who are not doing well on their current medication(s). The treatment study includes these outpatient assessments and research tasks, plus discontinuation of all current medications and starting new medications or a placebo. The discontinuation of current medication and starting of new medications occurs while the child is hospitalized or in day treatment at the NIH Clinical Center in Bethesda, MD. The remainder of the treatment trial can be completed in those settings or as an outpatient from home with the child coming to NIH only for clinic visits every other week. This study seeks to learn whether citalopram, a selective serotonin reuptake inhibitor (SSRI), added to methylphenidate (i.e., Ritalin®) is helpful for severe irritability. Eligible participants receive optimal doses of methylphenidate, and then are randomly assigned to receive citalopram or placebo, in addition to methylphenidate. While these medications are used commonly in the treatment of ADHD, depression, and anxiety, their use in very irritable children is experimental. All participants will receive a thorough clinical evaluation. All participants must be able to fill out daily self rating forms and cooperate with study procedures (including genetics study, MRI, neuropsychological, and behavioral testing). Participants in the treatment study also must be in treatment with a psychiatrist who agrees that it is appropriate for the child to participate in the study and not doing well on current medications.

There is no charge for participation in this study. Travel and lodging expenses paid for by NIMH.

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