

## Clinical Trial Participation Update

### Find Clinical Trials by State:

<http://www.clinicaltrials.gov/ct2/results/map/click?term=Behaviors+and+Mental+Disorders%5BCONDITION-BROWSE-BRANCH%5D&recr=Open&fund=01&map.x=163&map.y=177>

### Nationwide Recruitment

Bipolar Disorder (Pediatric) Research Study

### Phenomenology and Neurophysiology of Pediatric Bipolar Disorder

This study seeks to learn more about bipolar disorder in children and adolescents. The objectives are to describe the course of moods and behaviors of children with bipolar disorder and to learn about changes in the brain that are associated with these symptoms.

There are three separate parts to the study. Patients may participate in one or more parts.

Part A is not a treatment study. In part A participants remain in treatment with their community psychiatrist. They do not receive any experimental treatment, but they do receive extensive testing and brain imaging.

In Part B children receive extensive testing and brain imaging off medications.

Part C (the high risk study) is a study of children and adolescents who have a parent, brother or sister with bipolar disorder. These children receive a clinical assessment and testing.

Families who are interested in participating are interviewed by telephone. Those who are judged to be likely to meet criteria for the study are invited to the NIMH.

In Part A, participants first come for one day of interviews to determine if they meet study criteria. Those patients who are accepted return for a 5-day baseline evaluation, including physiologic tests and procedures, neuropsychological testing, and questionnaires and interviews about mood and behavior. In addition, staff members obtain a medical and psychiatric history of the patient and extended family members, and a physical and neurological evaluation. Participants are asked to perform computer and written tests to assess intelligence, memory, learning, motor skills, reaction time, and planning skills. Psychophysiological measures (such as heart rate, skin conductance, and electroencephalogram) are obtained in response to emotions and while playing computer games. Participants are asked to give blood samples for blood count and thyroid levels, liver and kidney function and to check for other diseases. Structural magnetic resonance imaging (MRI) and functional MRI (fMRI) scans of the brain are obtained.

Participants and parents return to the NIH for repeat evaluations and physiologic tests after 2 months, and then every 3 months until 12 months have passed from the first visit. Thereafter, visits are every 6 months for 4 years, and then every year until the patient turns 25. Some visits will involve only interviews and questionnaires, some will also include a physical exam, behavioral tests, or repeat brain imaging. Patients, their parents and siblings will also be asked to have blood drawn to obtain a DNA sample for genetic studies.

In Part B, participants come into the NIH Clinical Center and are gradually removed from all their medications. While off medication, they receive up to two weeks of research studies, like those described above for Part A. Participants are then given appropriate medication and stabilized before returning home.

In the High Risk Study, children of parents with bipolar disorder, or parents and siblings of children with bipolar disorder come for 1-3 days of clinical interviews and assessment, as well as test procedures performed on computers.

All tests and procedures are provided free of charge, and travel expenses are paid by the NIMH.

To find out if you qualify or for more information, please call (301) 496-8381 or email us at [bipolarkids@mail.nih.gov](mailto:bipolarkids@mail.nih.gov).

National Institute of Mental Health, National Institutes of Health, Department of Health and Human Services.

For more information on research conducted by the National Institute of Mental Health in Bethesda, MD click here <http://patientinfo.nimh.nih.gov>.