# ENROLLING CLINICAL TRIALS (03/2017)

## INSTITUTE *for* BEHAVIORAL MEDICINE

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(Now Soliciting Volunteers)

***IFBM** invites you to consider how clinical trials may provide alternatives to outpatient care. Please contact us about any of the following pediatric trials, which include the Clinical Trials NCT number for your reference. Visit clinicaltrials.gov to review details for these and other currently enrolling clinical trials. We welcome your general questions on these and other clinical trial opportunities for adults, adolescents and children that may not be included in the following summary.*
*The following clinical trials share general criteria as follows:*

**Benefits:** Focused, study-related psychiatric evaluation, study-related health exam procedures, close medical supervision, and study medication at no cost. Reimbursement for local travel may apply.

**Eligibility**: Inclusion criteria will be reviewed with potential candidates during a phone pre-screen interview. Candidates should be in good physical health. General exclusions include recent substance abuse, significant medical issues, significant history of suicidality, and current risk of self-harm.

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### Click for Adolescents with Bipolar I Disorder (Manic or Mixed) (NCT02075047)

**Population**: Ages 10-17 with current diagnosis or probable diagnosis of Bipolar I Disorder manic or mixed, most recent episode manic. Uses placebo or oral ziprasidone (20, 40, 60 and 80 mg), previously approved for this disorder in the adult population.

**Length**: Voluntary participation following screen spans up to 4 weeks in the double-blind study.

https://www.finishstudy.com/

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### Adolescents with Major Depressive Disorder (NCT02431806)

**Population**: Ages 12-17 with current or probable diagnosis of Major Depressive Disorder, who are willing to participate in placebo trial investigating dosing the efficacy, safety, and tolerability of levomilnacipran ER 40 or 80 mgs (SNRI) relative to placebo and a comparator, fluoxetine 20 mg. Study includes pharmacokinetics data to guide dose selection for future pediatric studies of levomilnacipran. The study medication is previously approved to treat depression in adults.

**Length**: Voluntary participation following screen spans up to 8 weeks in the double-blind study.

www.MDDEngageResearch.Com or 866-874-2523

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### Click for Juvenile Fibromyalgia (NCT01237587)

**Population**: Ages 13-17 with current or probable diagnosis of Juvenile Fibromyalgia Study , who are willing to participate in a placebo / open-label protocol. The purpose of this study is to determine whether duloxetine (SSNRI) is safe and effective in the treatment of adolescents with Juvenile Primary Fibromyalgia Syndrome (JPFS). This trial consists of two distinct study periods. A blinded treatment period of 13 weeks and an open label extension period of 26 weeks.of 30 or 60 mg duloxetine. The study medication is previously approved to treat major depressive disorder, neuropathic pain associated with diabetic peripheral neuropathy, generalized anxiety disorder, fibromyalgia and chronic musculoskeletal pain.in adults.

**Length**: Voluntary participation following screen spans up to 13 weeks in the double-blind study, and an optional 6 month open-label extension for those who qualify for and choose continuation.

https://www.ifbm.us/fibromyalgia

(See Additional Clinical Trials on Backside)

# ENROLLING CLINICAL TRIALS (continued)

**Click for Sertraline Pediatric Registry for the Evaluation of Safety** (NCT01302080)

**Population**: Ages 6-16. A Non-interventional, Longitudinal, Cohort Study to Evaluate the Effects of Long-term Sertraline Treatment in Children and Adolescents. Participants will be selected from those who have initiated Sertraline dosing within the last 45 days, or those who will be newly initiated on flexible dosing of Sertraline for symptoms of Depression, Anxiety or Obsessive Compulsive Disorder. This is a Phase IV trial; no placebo involved. No labs or ECGs.

**Length**: Voluntary participation following consent spans up to 3 years in an open-label study. Visits are once every three months.

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**Click for Adults with Major Depressive Disorder Taking ADT (RAP-MD-02)** (NCT02943564)

**Population**: Adults 18-65. A Randomized, Double-blind, Placebo-controlled, Multicenter Study of Rapastinel as Adjunctive Therapy in Major Depressive Disorder. A clinical research study is currently evaluating an investigational drug for its safety and effectiveness as an adjunctive antidepressant therapy for Major Depressive Disorder. Candidates must be in a depressed episode at least 8 months and less than 18 months, and taking an antidepressant medication at a therapeutic dose for at least 8 weeks with less than 50% improvement. Phase III trial uses placebo or Rapastinel infusion (450 mg or 225 mg).

**Length**: Voluntary participation following screen is for three treatment weeks. Completers are eligible to volunteer for RAP-MD-04, and receive open-label Rapastinel to stabilization prior to randomization into a double-blind relapse study. Responders in RAP-MD-04 who relapse, are eligible to volunteer for RAP-MD-06, an open-label, one-year extension.

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# PENDING CLINICAL TRIALS 2017-2018

Adult Males with Autism - Children with ADHD age 4-6

Adults with Bipolar Depression

Long-Term Antipsychotic Pediatric Safety Trial age 3-18

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# EDUCATION PRIOR TO PARTICIPATION

*Should I Participate?*

*Debunking Common Myths About Clinical Trials*

*What is a Placebo Controlled Clinical Trial?*

## IFBM CLINICAL RESEARCH DIVISION

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