Welcome to the National Institute of Mental Health
Division of Intramural Research Programs (NIMH DIRP)

What is the NIMH Division of Intramural Research Programs?

The National Institute of Mental Health (NIMH) is one of the world's foremost mental health scientific organizations. The NIMH DIRP is the internal research division of NIMH, with most of the research conducted at the National Institutes of Health Clinical Center. The NIH Clinical Center is the world's largest research hospital, and is located in Bethesda, Maryland, just outside Washington, D.C. Leading physicians and scientists investigate the diagnosis, treatment and prevention of mental illness. The NIMH DIRP is made up of different departments, each of which specializes in specific areas such as schizophrenia, depression, bipolar disorder (manic-depression), anxiety disorders, post-traumatic stress disorder, hormone-related mood disorders, childhood psychiatric disorders, and others.

What do we do?

The NIMH DIRP consists of teams of physicians, nurses, social workers and other professionals who conduct both inpatient and outpatient clinical studies. Some studies focus on the physical and biochemical changes associated with mental disorders, while others test potential treatments. It is our hope that by better understanding how mental illnesses develop, we will be able to provide better treatment options for patients and reduce the stigma of mental illness in the eyes of the public.

Why participate in research?

There have been many significant advances in both the diagnosis and treatment of mental disorders in recent years. These advances could not have occurred without the participation of many patients and families, and we are indebted to those who have volunteered. Your participation can contribute to increased knowledge about mental illness in general and may also contribute to your own better understanding of your condition. All medical evaluations, consultations, procedures and medications related to the research studies are provided at no cost to you. Some studies provide travel costs or other reimbursement.

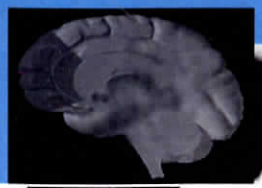
What are your rights?

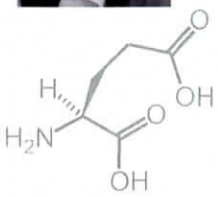
If you decide that you are interested in participating in a research study there are some things you should know. While we pride ourselves on the quality of the medical environment in which our studies are conducted, it is important to realize that the primary goal of clinical research is to answer a research question rather than to provide individual treatment. All studies are reviewed by an NIMH Institutional Review Board to ensure that studies are designed to minimize even minor risk to participants. All volunteers are told the details of the study and any potential risks, and your informed consent is needed to enroll in the research. You may withdraw from a research study at any time. As a safeguard to protect patients' rights, the DIRP's Clinical Director's Office also has a team of clinicians who follow participants' progress through our studies and are always available to answer questions. These clinicians are concerned that you understand the research and have the ability to give informed consent, as well as facilitate referrals to our other studies.

Thank you for your interest in **NIMH DIRP**.
We invite you to call us at **301-496-5645** or **1-800-411-1222** with any questions, or if you are interested in finding out more about our research studies.
Visit us at **http://patientinfo.nimh.nih.gov**
OR **http://www.clinicaltrials.gov**

Researchers at NIMH that specialize in Depression and Bipolar Disorders seek through **RESEARCH STUDIES** to:

- **DEVELOP** medications that rapidly decrease symptoms of depression
- Better **PREDICT** who might respond to medications and treatments
- **IDENTIFY** physical traits (biomarkers) that measure or indicate the depressive state
- **UNDERSTAND** the mechanisms in the brain that are causing depression





Participation in research studies helps transform the understanding and treatment of mental illnesses through basic science and clinical research.

For more information about Depression and Bipolar Disorder Research Studies conducted at the NIH Clinical Center in Bethesda, Maryland, visit our website: **http://patientinfo.nimh.nih.gov** or call toll free: **1-877-MIND-NIH (1-877-646-3644)**

What types of research studies are being conducted at NIMH?

Different types of Depression and Bipolar Disorder research studies are being conducted. Ongoing studies include evaluations, medication, brain imaging, sleep studies, genetics, and neuropsychological (memory, attention and concentration) testing.

What is the time commitment?

Time commitment varies with each research study. In general, outpatient studies enroll participants for a few day-visits up to 12 weeks. Inpatient studies enroll participants in stays at the NIH Clinical Center for a few days up to about 8 weeks.

What does it cost to participate?

There is no cost to participate in research studies. All treatment associated with research study participation is free of charge and transportation may be reimbursed. Standard treatment is provided to participants while transitioning back to the community.

Where are the studies conducted?

Our studies are conducted at the NIH Clinical Center in Bethesda, Maryland, the largest clinical research hospital in the world.

Can I participate if I do not live near NIH?

Yes, many of our studies enroll participants from across the United States and transportation may be provided or reimbursed.

Who conducts the research studies?

Depression and Bipolar Disorder research is led by Carlos A. Zarate, Jr., M.D., Chief of the Experimental Therapeutics and Pathophysiology Branch in the NIMH's Division of Intramural Research Programs. Inpatient and outpatient research study participants will work with an interdisciplinary team of research physicians, psychiatrists, psychologists, neuroscientists, clinicians, social workers, therapists, pharmacists, counselors, nutritionists and nurses.

For more information on Depression and Bipolar Disorder research studies, or to find out about participation:

Call toll free: 1-877-MIND-NIH

(1-877-646-3644) TTY: 1-866-411-1010

Email: moodresearch@mail.nih.gov

Participants from across the United States enroll in our studies.

Depression & Bipolar Disorder

Depression & Bipolar Disorder **RESEARCH STUDIES** Conducted at NIMH

Screening evaluations are conducted first to qualify a participants entry into a research study. These are outpatient and inpatient evaluations that include 1-4 visits, psychiatric interviews, medical history, physical exam, blood and other medical tests. Participants must be free of serious medical conditions.
[01-M-0254]

Depression with Anxiety Symptoms & AZD2327. Ages 18-65. This is a 12-week outpatient study, with 4 days as an inpatient, to evaluate the effectiveness and safety of the research study drug.
[08-M-0196]

Depression & Citalopram. Ages 18-65. This is a 10-to 12-week outpatient study. This is a comparative study of blood levels in depressed vs. non-depressed persons.
[08-M-0150]

Depression & Scopolamine: Ages 18-55. This is a 7-session outpatient imaging study of a currently FDA approved drug, Scopolamine, used for motion sickness, to ascertian rapid response of depression and its effects on memory and attention.
[03-M-0108]

Bipolar Disorder & Riluzole to treat Depression: Ages 18-70. This is an inpatient and outpatient study of Riluzole (an FDA approved drug for Lou Gehrig's disease, ALS) testing how this drug affects glutamate in the brain and improves treatment-resistant depressive symptoms (failure to reduce symptoms after taking two or more antidepressants.)
[03-M-0092]

Depression & Bipolar Disorder and the Rapid Antidepressant Effects of Ketamine: Ages 18-65. This is a 6-to 8-week inpatient study testing ketamine, a drug that affects glutamate in the brain, seeks to understand the causes of depression and whether a rapid reduction of antidepressant symptoms (within hours) can be achieved and sustained.
[04-M-0222]

Depression & NR2A/B: Ages 18-65. This 7-week inpatient or outpatient study, with 4 days as an inpatient, will investigate a medication's 'mechanism of action' and determine if the study drug can produce, through a single infusion, a same day reduction of symptoms in treatment-resistant depression.
[09-M-0240]

http://patientinfo.nimh.nih.gov/

DO YOU HAVE A CHILD WITH Bipolar Disorder or *Severe Irritability?*

At the NIH Clinical Center in Bethesda, Maryland, several research studies are being conducted into the **causes of bipolar disorder or severe irritability.**

These studies seek children and adolescent participants who have bipolar disorder or severe irritability.

All evaluations, research procedures, inpatient (day or full hospitalization) and outpatient visits are free of cost. Both parent and child must agree to the child's participation. Schooling is provided during inpatient visits.

Children and parents are compensated for participation. Travel and lodging expenses are paid by NIMH.

STUDIES OF BIPOLAR DISORDER

Those eligible to participate must be ages 6-17, have bipolar disorder and be able to perform research tasks including neuroimaging, computer tasks, and neuropsychological tasks.

A) Non-Treatment Study:

If stable on current medications research study participation includes a 5-day outpatient assessment and then annual, one-day research follow-up visits.

B) Treatment Studies:

If unstable on current medications participant receives day or full hospitalization to discontinue medication.

Parent and clinician together choose, either (1) or (2):

1) If between ages 6-17, participant will perform research tasks while medication-free for 2 weeks, followed by standard medication;

2) If between ages of 9-17, participate in a 12- to 15-week trial of riluzole vs. placebo, if participant has not done well on mood stabilizer and/or atypical antipsychotic drugs alone or in combination.

- At study end, those who receive placebo, have the opportunity to take the active medication.

Protocol #: 00-M-0198 & 09-M-0042

STUDIES OF SEVERE IRRITABILITY

Those eligible to participate must be:

- Ages 7-17.
- Displaying irritability symptoms that include: difficulty handling frustration (severe temper tantrums and rages) and "hyper" behavior (distractible, hyperactive, trouble sleeping).
- Able to perform research tasks that include neuroimaging, computer tasks and neuropsychological testing.

A) Non-Treatment Study:

Research study participation includes up to 5 outpatient visits of 2-4 hours each, followed by annual visits of 4 hours.

B) Treatment Studies:

If unstable on current medications participant receives day or full hospitalization to discontinue medication.

Parent and clinician together choose, either (1) or (2):

1) Perform research tasks while medication-free for 2-weeks, followed by standard medications;

2) Participate in a 12- to 15-week study of the efficacy of methylphenidate plus citalopram, vs methylphenidate plus placebo, for decreasing irritability in children with severe mood and behavioral problems.

- If clinically appropriate, participants who received methylphenidate plus placebo will be offered the opportunity to receive methylphenidate plus citalopram at the end of the study.

Protocol #: 02-M-0021 & 09-M-0034

FOR FURTHER INFORMATION CALL: **301-496-8381** TTY: 1-866-411-1010

Ellen Leibenluft, M.D. or Kenneth Towbin, M.D.

Email: bipolarkids@mail.nih.gov

BiPOLARKids

Intramural Research Studies at NIMH

NATIONAL INSTITUTE OF MENTAL HEALTH

NATIONAL INSTITUTES OF HEALTH | DEPARTMENT OF HEALTH & HUMAN SERVICES

http://patientinfo.nimh.nih.gov Pediatric Bipolar & Severe Mood Dysregulation Research

NIMH National Institute of Mental Health