Participating in a Research Study
You could learn more about your child’s condition by participating in a research study. Your child’s study team will want to know how he or she reacts to the medication administered and will closely monitor the overall health and well-being of your child. Participants in clinical research studies are typically required to undergo more tests and procedures than they would during routine medical care. Study doctors use physical exams, laboratory tests and other evaluations to monitor the effects of the study medication throughout the clinical research study.

Potential Benefits and Risks Associated With Clinical Research Studies
According to the National Institutes of Health (www.clinicaltrials.gov), there are multiple benefits and risks associated with participating in clinical trials.

Benefits
Well designed and well executed clinical trials are the best way for eligible participants to:
• Play an active role in their own healthcare
• Gain access to new research treatments before they are widely available
• Obtain expert medical care at leading healthcare facilities during the trial
• Help others by contributing to medical research

Risks
• There are also risks to clinical trials:
  • There may be unpleasant, serious or even life-threatening side effects to experimental treatment
  • The experimental treatment may not be effective for the participant
  • The protocol may require more time and attention than a non-protocol treatment, including trips to the study site, more treatment, hospital stays or complicated dosing requirements.

Questions You May Want to Ask
• What is the purpose of this research study?
• How long will this study last?
• How often will we need to go to the study site?
• How long will the visits last?
• What are the tests and procedures that are involved?
• Is there a chance my child will be on placebo?
• If the trial is not fitting in to my lifestyle can I back out?
• If I back out or discontinue participation, will I face any penalties or be denied medical treatment otherwise?
• Can I take my prescriptions or over the counter medications along with the study medication?
• Will there be any cost to me?
• Will I or my child receive any compensation for participating?
• How will my privacy be protected?
• What types of activities will I or my child be expected to do at home such as administering medication or keeping a journal?
• What are the potential side effects?
• If my child is ill, what might happen to the symptoms for their condition with or without this study medication?
• What are the potential risks?
• What are the potential side effects?
• How will my child’s safety be monitored?
• Whom do I contact with questions about my child’s rights?
• Who has reviewed and approved this study?
• Whom do I contact if my child experiences adverse effects?
• How experienced is this organization in conducting clinical trials?

Additional Resources
The Office of Human Research Protection - www.hhs.gov/ohrp
The Center for Information and Study on Clinical Research Participation - www.ciscrp.org
Clinical Research Studies: A Brief Description

Clinical research studies are scientific studies or investigations designed to test the safety and effectiveness of an investigational drug for a specific medical condition. You are reading this brochure because you are interested in having your child participate in a clinical research study to evaluate an investigational medication for the treatment of a particular mental health concern.

Why Clinical Research Studies are Important

Clinical research studies help determine the safety and effectiveness of an investigational medication. After all data are collected, researchers may gain a clearer picture of how an investigational medication behaves in the body, whether it is safe, and if it works in treating the medical condition for which it is being tested.

Informed Consent

Before taking part in any study activities, it is required by law for all clinical research study participants (or parents/caregivers) to read, understand, and sign an informed consent form. Signing this statement indicates that you clearly understand the goals of the clinical research study and any associated risks and discomforts, and that you voluntarily agree that your child can participate. This document also confirms that you are free to withdraw your child from the study at any time.

How Clinical Studies are Conducted

Health care professionals who conduct clinical research use a document called a protocol to guide their activities. The protocol is a detailed description of the clinical research study, including goals of the study, procedures involved, who is eligible to participate, and how effectiveness will be measured.

The Food and Drug Administration (FDA) regulates the management of clinical research studies by requiring that an Institutional Review Board (IRB) approve each informed consent form and study protocol. Doctors, scientists, allied health professionals, clergy, and other community representatives may sit on the IRB. They are responsible for ensuring that appropriate steps are taken to protect the rights, safety, and well-being of study participants.

For routine or non-study related health concerns please contact your child’s regular doctor, not the study doctor.

If the IRB approves the protocol and consent form, the study team can begin the clinical research study. The study team typically includes an investigator (usually a doctor, who conducts the study at the study site) and a study coordinator (a specially trained person who manages the data collection and paperwork for the study).

To participate in a clinical research study, an individual must meet the eligibility criteria described in the study protocol. These are the rules that determine who can be chosen to participate in the study. Inclusion criteria describe the factors the study team is looking for in study participants such as age and gender. Exclusion criteria are factors that will keep people from participating such as pregnancy and certain medical conditions.

Prescreening is done to help determine who might be eligible for the clinical research study. During prescreening you may be asked a series of questions. In this study, many of the questions are related to the health of your child.

If the potential study participant passes the prescreening process, signs the informed consent form (or has it signed by a parent/caregiver, if the participant is a minor), and meets the inclusion criteria, he or she can be enrolled in the study and take part in study tests, evaluations, procedures and visits.

Be sure to discuss any questions or concerns you have about clinical research studies with your child’s study team or your regular doctor. If your child does qualify, the actual decision about whether to participate is yours to make.

Phases of Clinical Research

Clinical research studies are divided into 4 phases:

- **Phase I:** Researchers test an investigational medication or treatment for the first time in people by giving it to a small number of healthy individuals to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The investigational medication or treatment is given to a larger number of people who have the disease or condition being studied evaluate its safety and efficacy.
- **Phase III:** The investigational medication or treatment is given to hundreds or even thousands of people with the disease or condition under study. Additional data are gathered on the safety and effectiveness of the investigational medication or treatment. The study team also keeps track of side effects and compares the investigational drug or treatment to commonly used treatments.
- **Phase IV:** After the investigational medication is approved by the FDA and available by prescription, information is gathered to further assess its risks, benefits and use.

Types of Study Designs

Several study design options are used in clinical research studies. One of the most highly regarded is the randomized, placebo-controlled, double-blind, Multicenter study. Here is what that means:

- **Randomized, placebo-controlled:** Participants are divided into groups randomly. One group receives a placebo – an inactive treatment (not the study medication) that looks just like the active medication. The other groups receive the active study medication, often in different doses. When the clinical research study is over the results from the various groups are compared.
- **Double-blind:** this means that neither the study participants nor the people conducting the research study know who is getting the active study medication and who is getting the placebo. After the study is completed and the data are collected and analyzed the study is “unblended.” At that time researchers can determine whether or not the study medication met the study’s objectives.
- **Multicenter:** this means that the study is taking place at numerous locations (sites).