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This brochure presents information designed to help you decide about your child’s participation in the Children’s Health Care Study at Washington University School of Medicine. It contains detailed information about the study, its staff and our interests in providing quality care for children through careful research.

Parents: The research described in this brochure may be of interest IF you and/or your family, your child’s doctor or teachers are concerned about your child’s aggressive or irritable behavior, and current medication or behavioral therapy don’t seem to help. Specifically, this brochure may be of interest if your child’s doctor, therapist or counselor has suggested that your child might benefit from taking one of the newer antipsychotic medications.

Second-generation antipsychotic medications are most often used in adults to treat certain emotional and mental problems. They’re called atypical because they cause less of the “typical” nervous system side effects of the older, first-generation antipsychotic medications. These medications are being used more and more often in children to treat emotional and mental problems, although these uses are not currently approved by the FDA. Doctors and scientists want to learn more about the use of these medications in children, including how children’s bodies respond to them. For this study we are interested in learning how these medications might affect three things: weight gain, risk for diabetes, and cholesterol problems. The specific antipsychotic medications we are studying are Abilify (aripiprazole), Zyprexa (olanzapine), and Risperdal (risperidone).

Our study includes children ages 7-17 who have been diagnosed by their doctor with various problems that can result in increased aggressiveness. Your child’s doctor may have suggested that your child start on one of these medications. Joining our study will mean that your child will take one of these medications and receive extra medical care and attention for at least three months. Your child will be cared for and monitored by a team of doctors, therapists, and nurses who will stay in close contact with your child’s doctor. This study’s goal is not only to learn new information but to care for your child while doing so.

You will be paid up to $780 in gift certificates to stores and local attractions, depending upon how much of the study you complete. Naturally, we hope you complete the entire study because that will provide us with the best information.

Visit Three

On the next visit, about halfway through the study, (six weeks after beginning the new medication), we will ask your child to return to the GCRC to repeat the OGTT test, and DEXA scan.

Visits Four and Five

After your child has been on the medication for about 12 weeks, your child will return to repeat all the tests: the OGTT, the DEXA scan, the MRI, the EKG, and the insulin sensitivity test.

Our Research Facilities

The Washington University School of Medicine General Clinical Research Center at St. Louis Children's Hospital

Medical testing for this study will be done at The Washington University School of Medicine General Clinical Research Center (GCRC). This federally supported research resource, now in its 45th year, is made of an Adult and Pediatric Unit. Both are capable of providing care for children and both units are available for our use in this study. Making both units available gives us greater flexibility in scheduling a convenient time for you and your child. Both units are specialized areas available only to research participants.

The Adult Unit is located on the 4th and 5th floors of Barnard Hospital. The Pediatric Unit is located on the 11th floor of St. Louis Children's Hospital.

Washington University School of Medicine, including the pediatric, psychiatric and endocrinology contributions to this project, is a consistent leader in National Institutes of Health (NIH) funding. Washington University School of Medicine ranks 4th nationally in National Institutes of Health grant funding.
VISIT TWO

On the next visit, your child will come back to the General Clinical Research Center (GCRC) where he/she will lie in a reclining chair or bed, and a nurse will start two IV lines, one in each arm. This test is called an insulin sensitivity test. Just like the first visit, your child will not be able to eat or drink anything but tap water the night before and up until the test begins. This means no food after bedtime the night before, including no gum, candy, and breath mints like Tic Tacs. Again, it’s okay for your child to take his/her regular medications with plain water.

During this visit, an IV will be placed in one arm to give your child insulin (a naturally occurring hormone produced in the body to control blood sugar) and glucose (a type of sugar found in many foods and drinks), to put your child’s blood sugar into the normal range. The other arm will have an IV that will be used to take very small blood samples at various times to understand how your child’s body responds to sugar. This part of the visit-a very important part of our study- takes about six hours, plus two hours for preparation and discharge from the GCRC. Cable TV, videos, video games, and music will be available to keep your child occupied during this test. Your child will be provided with a late lunch before he/she goes home. This session will last about 8 hours total.

During this visit your child will have a different kind of imaging scan or picture taken to measure body fat, focusing on the abdomen (tummy). This is called an MRI (Magnetic Resonance Imaging). Your child will lie on a table which is then placed in a tube to have his/her tummy scanned. He/She will need to lie still during this test to get the best picture. The entire MRI process lasts about 20 minutes. The scan does not hurt and your child can wear earphones and listen to music during the scan.

At the end of this visit, we’ll work with your child’s doctor to start your child on an antipsychotic medication. As noted above, these medications have been FDA-approved for adults. While their prescription by doctors for children with various mental condition is now common and growing, this use is considered “off-label” or not FDA approved.

We will monitor your child closely during study visits, study doctor and therapist visits and by telephone while he/she is taking the new medication. In addition you will have phone and beeper numbers to call the study staff and doctors with any concerns or questions. Your child will receive extra care and attention with regular visits with the study doctor and child therapist, who will maintain close communication with your regular doctor.

Does my child have to participate?
This study is totally voluntary and your decision will not affect the health care your child receives from his/her doctor. You always have the right to say "no" to a research study. If you do say "yes," you may take your child out of the study at any time. However, you should discuss this with the research team first, so your child can be withdrawn in the safest way possible.

Why Include Children in Research?
You may wonder why children are included in research at all. After all, research involves some uncertainty and some risks. Why not do research only on adults, who can decide for themselves if they want to participate? In fact, when possible, research IS usually done first on adults. However, this also means that many medicines and treatments have only been carefully studied in adults and remain less studied in children. Children often don’t respond to medicines the same way adults do, so research in children is very important.

Sometimes children need treatment for a condition where the most promising and doctor-recommended medications have mostly been studied in adults. Those medications can also be given during a study that carefully measures benefits and side effects. When medicines are given in the setting of a study, scientists and doctors can learn more about them. At the same time, children, their families, and personal physicians can benefit from the close supervision provided by the study and information collected about an individual child’s response to their medication can be used to guide future treatment decisions by families and physicians.

In addition to any personal benefit that may come from a study medication, or any benefit that comes from the careful monitoring involved in a research study, participation in research can also benefit others. Many children today are benefiting from research that was done on children in the past. For example, the current treatments for many childhood cancers and for cystic fibrosis are based on past research. Hopefully, the research done on children today will help children in the future in a similar way.

What will my child be asked to do?
We are interested in how these medications might affect weight gain, risk for diabetes, and problems with cholesterol. To measure these things we will ask your child to do two kinds of blood tests and two kinds of scanning tests. We’ll do these tests before s/he starts medication, again about halfway through the study, and again when the study is over, about 12 weeks after the start of the medication. You will have between five and six study-related visits plus medication check-ups with the study doctor over the telephone or in person. You can be with your child during all of the testing.

All of these visits and tests are scheduled at the convenience of you and your child. We are able to work around school, work, sports, and other activity schedules as needed. If you need it, we can also arrange for a cab ride to and from your home for any part of the study.

Please read on for more information about each phone call, visit, and test.
**GETTING STARTED**

**The first contact you will have with the study staff will be a phone call.**

During this call we will tell you about the study and ask a few general questions about your child’s health to make sure it’s okay for him/her to participate. (This takes about 20-30 minutes.) You can ask any questions you want at this time, in fact, we encourage you to do so. If the study sounds like something you’re interested in we will send out some consent forms to you and your child. Consent forms are similar to permission forms. They tell you about a study in writing and in great detail so you and your child know what is involved before you begin and asks for your permission to be included in the study. This process is designed to help parents understand the study before they decide whether or not their child should participate.

**One week before the testing begins**

Diane Dubois, a pediatric nurse, will go over the study consent forms with you on the phone. Again, we encourage families to ask questions. To continue with the study you and your child will both be asked to sign these forms and return them to our office. We will also send you an extra copy for you to keep for your records.

**Telephone Interview**

Next, one of our study coordinators (Meghan Campbell, or Kathryn Salmo) will call to schedule a convenient time for you to answer more questions about your child over the phone. These questions take a bit longer, about an hour and a half, and ask more about your child’s health, behavior and emotions. First, we will talk to you and ask questions about your child. Then we will call at another time to talk to your child and ask most of the same questions.

If your child is 11 years old or younger, we may ask your child to come into our offices and answer these questions in person with one of our trained child interviewers. In our ten years of interviewing over 10,000 research participants we have learned that sometimes it’s easier for younger kids to talk to us in person, rather than on the telephone.

This combined length of time for both you and your child to answer these questions is about 3 to 4 hours.

**VISIT ONE**

Approximately one week after the phone questions are finished, your child will be asked to come to the General Clinical Research Center (GCRC), and have an Oral Glucose Tolerance Test (OGTT). With this test, your child will be given a sweet drink and will have some blood tests to see how his/her body handles sugar (glucose). The night before you come in, your child will not be able to eat or drink anything after bedtime except tap water before arriving at the hospital. This includes no breakfast, gum, candy, chewable vitamins or breath mints. It is okay to take your regular medication with water.

When your child comes in, he/she will lie in a reclining chair or bed, and a nurse will place a plastic tube (IV catheter) into a vein in one arm. This feels a little like getting a shot, but we use a special cream to numb the skin first to help it hurt less. Once the IV is in, it shouldn’t hurt at all. Your child will then drink a very sweet orange or lemon flavored drink, and we’ll use the IV to get very small blood samples during the next two hours. The blood samples check blood sugar and some other routine blood tests. Your child can watch cable TV or videos, play video games, or listen to music during this test, and we’ll give him/her lunch when he/she is finished, after about 2 to 3 hours.

On the same day, when this test is over your child will also have a DEXA (Dual Energy X-Ray Absorptiometry) scan and ECG (Electrocardiogram) done. The DEXA scan uses an extremely small amount of x-ray energy, (so much less than a dental x-ray that no shield or apron is required for your child or even the operator who uses the machine every day), in order to measure total body fat. Your child will lie flat while the machine takes pictures. This does not hurt and you cannot feel the machine taking the pictures. Your child will wear his/her own clothes or a hospital gown for the test. This takes about 10 minutes.

For the ECG, soft sticky pads will be placed on your child’s chest and a machine will record how your child’s heart is working. The ECG is a standard test that many parents have had. It produces a printout of how the build-in electrical activity of your child’s heart is performing. This is a very short test, lasting 10 to 15 minutes.