ASSENT TO PARTICIPATE IN A RESEARCH STUDY (MINOR PARTICIPANTS 6-12 YEARS OF AGE)

TITLE OF STUDY: **L**ong-term **A**ntipsychotic **P**ediatric **S**afety Trial **(LAPS)**

STUDY #: NICHD-2016-LAP01

FUNDING SPONSOR: The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

STUDY MEDICAL CLINICIAN (SMC): (also called the study doctor) <<CF-Main Investigator Name>>

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BRIEF SUMMARY
For this form, the words “your parent” could also mean your guardian if you have one. The study doctor and his or her team are doing a research study to learn more about how two medicines called risperidone and aripiprazole affect changes in weight when they are used in children between the ages of 3 and 17. You are being asked if you want to be in this study because of your age and because you are taking one of these medicines.

To be in this study your parent needs to give their permission. You do not have to be in this study if you don’t want to, even if your parent has already said yes. Even if you say yes now and change your mind later, you can stop at any time, by telling the study staff. Your doctors will continue to take care of your health.

If you want to read more about the study, ask for a copy of the form that your parent will read and sign.

WHAT WILL HAPPEN DURING THIS STUDY?
If you decide you want to be in this study, you will be in the study for about 2 years. You may come to the clinic at least 2 times a year for 2 years. The study staff will tell you how long you will be in the study. You may only come one time. When you come to the clinic we will measure your weight and height and ask you and your parent about the medicines you are taking, how you are acting, and how you are feeling. The study doctor will examine you.

At least two times a year, during the in-clinic visits, we will collect about 2 teaspoons of blood from you. We will use the blood to check your health.

In between your clinic visits, you and your parent will answer some questions on the computer or phone, or on paper.

There are also optional parts of this study that the study staff will explain to you and your parent. Optional means it is not required for the study. You can still be in the main study even if you decide not to participate in the optional parts of the study. If you and your parent agree to be in any of the optional parts of the study, we will collect an additional small amount of blood from you. One of the optional parts includes a sub-study that includes collecting blood samples from you that will be used to learn more about how the medicine works in the bodies of children. Another optional part includes collecting a blood sample from you to use for unspecified studies in the future.

Another optional part is called the registry part. We will describe the registry part later and ask if you want to be part of it.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 700 children will take part in this study at about 60 locations.

WHO WILL BE IN CHARGE OF THE STUDY AT THIS LOCATION?
The study doctor named on the first page of this form will conduct the study at this location.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS STUDY?
People may have good things happen to them because they are in research studies. These are called “benefits”. We do not know if there will be a benefit to you for being in this study. We hope the information learned from this study will benefit children in the future. Since we will be sharing a lot of the study information with your doctor, it is possible that some of the tests and measures that we do will give your doctor important information about your health. Some of these tests and measures may only happen one time.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS STUDY?
Sometimes things happen to people in research studies that may make them feel bad. These are called “risks.” When we prick your skin to get blood you may feel a pinch. You may also have a bruise where the needle goes into your skin. There is a very small chance you could get an infection.

You may be asked to answer some questions that make you feel uncomfortable. If that happens, you can decide not to answer those questions.

If you feel any of these things, or other things, be sure to tell your parent or your study doctor. If you think something has happened to your body and you are going to have a baby, you will not be able to participate in this study. If you have these same feelings during the study, tell your parent right away. If you tell the study doctor that you think you are going to have a baby, we may have to tell your parents. We will ask you and your parent if we can see what happens to you and your baby, even if you are not in the study.

WHO WILL SEE THE INFORMATION COLLECTED ABOUT ME?
Some information may be shared with your regular doctor. Your information will be shared with the people working on the study including people from the National Institutes of Health (NIH) and other companies who are working with NIH. We will not share your information with anyone else unless we are required by the law to do so. The information we learn from you in this research study will be combined with information from other children in the study. In this case, your name and any personal information that could identify you will not be used.

WILL I GET ANY MONEY OR GIFTS FOR BEING IN THIS STUDY?
You/your parents will receive payment for time and travel in the form of a $ [X] debit card for each completed clinic visit.

<<CF-Main Payment for Part. Paragraph>>

WHO SHOULD I ASK IF I HAVE ANY QUESTIONS?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the study doctor or study staff at the phone number listed on the first page of this form.
This research is being overseen by WIRB-Copernicus Group IRB (IRB). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

STATEMENT OF ASSENT – Minor Participant	
By signing this form, I confirm that: • I have read this assent form and was given a chance to ask questions about things I didn't understand. • I have been told whom to contact if I have questions, to talk about problems, concerns, or suggestions related to this study. • I understand that being in this research study is voluntary and I can stop at any time • I have been told that I will be given a signed and dated copy of this assent form.	
Printed Name of Participant	
The information below can only be completed by a participant, capable of providing assent.	
Signature of Participant	Date: Time: ☐ AM / ☐ PM (check one)

MAIN STUDY STATEMENT OF PERSON OBTAINING MINOR ASSENT		
My signature below documents that: I have fully explained the study described by this form in a language the participant understood or via translation. I have answered the participant's questions and will answer any future questions to the best of my ability. I will tell the participant of any changes in procedures or in the possible harms/possible benefits of the study that may affect their willingness to stay in the study. Assent was freely given and I will provide the participant with a signed copy of this form.		
The information below can only be completed by the person obtaining assent		
Printed Name of Person Obtaining Assent	Signature of Person Obtaining Assent	Date
DOCUMENTED USE OF A TRANSLATOR OR IMPARTIAL WITNESS.		
If the consent/permission discussion has been conducted <u>in a language other than English</u>, and a qualified translator or impartial witness was required.		
Printed Name of Translator	Signature of Translator	Date