INSTITUTE: National Institute of Mental Health

STUDY NUMBER: PRINCIPAL INVESTIGATOR:

STUDY TITLE: Effects of Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder: A functional magnetic resonance study

Latest IRB Review: New Protocol
Latest Amendment Approval: N/A

Standard Assent – Child with ADHD

We would like you to be in this study because you have been diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD). There are no direct benefits to you from being a subject. This study will help us understand what causes ADHD and how the medicine that helps ADHD works. During this study, you need to come in to the NIH three or four times, with the last two times for brain imaging tests. During the first two visits you will have some interviews where we will ask you a lot of questions. If you are a twin, we may check on whether or not you are an identical twin by measuring DNA from a cheek swab. You will also practice doing some tasks to become comfortable with the fMRI machine that we will use during your last two visits. At the beginning of the last two visits, we will give you a liquid medicine to drink. One time, this medicine will do nothing (it is a placebo). The other time we will give you dextroamphetamine, a stimulant medicine that helps ADHD. After you take this medicine, we will take pictures of your brain in the fMRI machine. This machine will make some loud pops while you are inside it. These sounds are perfectly normal and are made when the machine focuses on different parts of the brain. While we take these pictures, we will need you to complete some tasks inside of the machine. These will involve watching a screen in the machine and pushing a button with your finger. You will be in the scanner tube for about 60-90 minutes and we will ask you to lie still for short periods of time. If it is impossible for you to lie still, we will not do the scan. The scan does not hurt at all, although the scanner will make some loud noises. We can talk to you and you can talk to us during the scan and we will give you a picture of your brain after the scan is finished. After we finish the scans, we will ask you to fill out a survey about how you felt while you were completing the tasks in the scanner. This survey will ask you to rate your feelings about the task (like boring, interesting, tiring, and difficult) on a scale from 1 to 10.

Neither you nor we will know which medicine you take during either of your visits. This is done so we can better compare the effects of the two medicines. If either one makes you feel sick, the doctor can find out which one you have taken.

If you already take a stimulant drug for your ADHD (like methylphenidate or dextroamphetamine) we will need you to not take your medicine for at least 36 hours before you come to NIH for the screening interviews or the imaging sessions. During these times, the symptoms of your ADHD may feel stronger and you may be more hyperactive or it may be harder for you to pay attention to things.

The medicine we will give you might have some side effects. After you take this medicine, you might not feel hungry that day or it might be harder for you to fall asleep that night. If you feel these effects, they will only last for the rest of that day before they get better. You should not notice any other effects from this medicine. If, at any time during the study, you feel sick or bad from any part of the testing we will stop the study and a doctor will help you. You can decide to leave this study at any time.

Confidentiality:

The fact that you are participating in this study and all the information that we get from the study will be kept private. No one except our research team will know that you are in the study unless you and your parents decide to tell them.

If there is anything you don't like about being in this study, you should tell us and, if we can, we will try to change it for you. We will try to explain everything that is being done, and why. Please ask about anything that you want to know.

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions. I agree to take part in this study.

Signature of Minor Patient:_____ Date:_____

Signature of Investigator:_____ Date:_____