

INSTITUTE: National Institute of Mental Health

STUDY NUMBER: PRINCIPAL INVESTIGATOR: Deleted: Judith L. Rapoport, M.D

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 for Healthy Subjects

You have been selected to participate in this study because you are healthy, and so by being in this study you can help us better understand some children with behavior and attention problems. There is no direct benefit to you from being in the study. This study will examine the brain patterns of healthy children and hyperactive children. We also want to see how a single low-dose of a stimulant medicine, dextroamphetamine, changes these brain patterns.

During this study, you need to come in to the NIH four times, with the last two times for the brain imaging tests. During the first two visits you will have some interviews where we will ask you some questions. You will also practice doing some tasks to become comfortable with the fMRI machine and used to the tasks that we will use during your last two visits. . If you are a twin, we may make sure if you are an identical twin by examining DNA from a cheek swab.

At the beginning of each of the last two visits, we will give you a pill. One time, this pill will just have sugar in it and it will not affect you (it is called a placebo). The other time we will give you dextroamphetamine, a stimulant medicine that helps ADHD. Each time, after you take the pill, 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 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 answer some questions about

how you felt while you were completing the tasks in the scanner. These questions will ask you to rate your feelings about the task (like boring, interesting, tiring, and difficult) on a scale from 1 to 10.

During this study, you will be given a pill before each imaging session. You may be given the placebo first, or you may be given the dextroamphetamine first. Neither you nor your doctors will know which one you took during either of your visits until the study is over. This is done so the study can better compare the effects of the two pills. If either one makes you feel bad, tell the doctor.

The dextroamphetamine we will give you might make you feel a little different afterwards. 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 a few hours before they go away. 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 stop being in 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. We are careful to keep private any information that you give us. The only time that we would break this rule would be if you tell us information that we think your parents need to know to be able to keep you or other people safe. For example, if you have been having serious thoughts about hurting yourself in some way, we would inform your parents.

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.

MEDICAL RECORD**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY**• Adult Patient or • Parent, for Minor Patient

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: _____

PATIENT IDENTIFICATION**CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet)**

Adult Patient or • Parent, for Minor Patient

P.A.: 09-25-0099

File in Section 4: Protocol Consent