

**University of Oklahoma Health Sciences Center**  
**Oklahoma Project to Learn about ADHD in Youth (OK PLAY)**  
**ADHD School Based Prevalence**  
**Mark Wolraich, M.D., CMRI/Shawn Walters Professor of Pediatrics**

If you are a parent consenting for your minor child, all references to “you” are applicable to your minor child.

**Why Have I Been Asked To Participate In This Study?**

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. Discuss this with your family and friends. You are being asked to take part in this study because your family participated in the PLAY study interview.

**Why Is This Study Being Done?**

The purpose of this study is to follow up the information we got from the PLAY study. The PLAY study looked at rates of diagnosis and treatment of children with Attention Deficit Hyperactivity Disorder (ADHD) or co-occurring conditions like Tourette’s Disorder. Ultimately, we hope to improve how children with these conditions are diagnosed and treated. The questions we ask will help us determine if certain children are at risk of under-diagnosis or over-diagnosis and if proper treatments are being used. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241; Attachment A1).

**How Many People Will Take Part In The Study?**

About 600 families will take part in this study statewide. We selected every family who participated in the PLAY study interview. If you recall, we invited both children having or at risk of having ADHD and co-occurring disorders, and children who do not have ADHD or co-occurring disorders. Receiving this form does not mean that your child has any of these conditions.

**What Is Involved In The Study?**

As part of the study, you will answer written surveys and interviews once a year for up to 5 years. It will take approximately 3 hours to complete the annual interview. Part of the interview may be completed at home prior to the visit. We will contact you every 3 months to update contact information. It will take approximately 5 minutes to complete the questions for 3 and 9 month update. It will take approximately 30 minutes to complete the 6 month surveys. Once a year we will give parents forms to have your child’s teacher complete and return to us. This information will not be included in your child’s school record. Your child will also be asked to participate in the study and to provide the information we are requesting. The child interview (comprised of computer and paper-pencil questionnaires) will be done once a year and takes about 2 hours to complete. Altogether, the questions are intended to find out about the thoughts, feelings and behaviors of children their age. We believe it is important to respect the privacy of your child. For that reason, the annual interviews with you and your child will be conducted

separately, so neither of you can hear what the other says. We will assure your child that his/her answers will be treated in a confidential manner, and that we will not reveal those answers to you unless your child threatens to harm himself/herself or someone else or there is a serious problem that requires referral.

The surveys cover a range of topics about you and your family.

- 1) General questions about you (age, gender, ethnicity, number of children, etc.)
- 2) Symptoms and treatments
- 3) Health risk behaviors
  - a) All children will be asked sensitive questions about alcohol and tobacco use
  - b) Children 11 and older will be asked sensitive questions about drug use & delinquent behavior
  - c) Children 14 and older will be asked sensitive questions about sexual behavior
- 4) School performance
- 5) Social support
- 6) Family relationships

We will provide you with a summary of results of the annual interview.

### **How Long Will I Be In The Study?**

The study is planned for 3 years but may be extended to take 5 years. To participate in this study a you will complete annual interviews up to 5 years, quarterly parent surveys, and annual teacher surveys. Your participation in this study ends after you complete the 5th annual interview. Your participation is voluntary, and you may refuse to participate at any time.

### **What Are The Risks Of The Study?**

You may be asked questions that you are uncomfortable answering. You may refuse to answer any questions you choose.

### **Are There Benefits To Taking Part In The Study?**

Summaries from the interviews will be mailed to you. We can give you information about local resources for ADHD. We hope that the information learned from this study will benefit other children with this disorder in the future.

### **What Other Options Are There?**

This study will not interfere in nor try to change any of the services your child receives. Your doctors and teachers will be free to choose any care they feel will be beneficial. Instead of being in this study, you may choose not to participate.

### **What About Confidentiality?**

Efforts will be made to keep your personal information confidential. All your answers are stored without your name, under lock and key. Only code numbers are used on the forms or in the database. The key that links a name to a code number is stored in a separate, secured database.

Only the key researchers working with this project have access to your information. All reports will use summary data and you can not be identified by anyone outside the research team.

“All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it’s okay. But under the law, we must report suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.” Parents will not be told how a child answers questions unless the child tells us something that must be reported.

There are organizations that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the Centers for Disease Control and Prevention (CDC), the organization funding the project, and the OUHSC Institutional Review Board. Data will be reported to CDC without your name or other information that tells who you are.

### **What Are The Costs?**

There will be no costs to you because of your participation in this study. You will not receive any additional medical care because of this study.

### **Will I Be Reimbursed For Participating In This Study?**

Because we understand that these interviews take time, we will give you a \$50 dollar gift card at each annual interview. And, we will give you a \$25 dollar gift card for the semi-annual packet of questionnaires that are mailed back to us. With your permission, we will also give your child a \$20 gift card for participating in each annual interview.

### **What Are My Rights As A Participant?**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Leaving the study will not result in any penalty or loss of benefits that you would otherwise receive. We will tell you about any new information that may affect your health, welfare or willingness to stay in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. You may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

### **Will Other People Be Asked To Supply Information?**

In addition to the information gained from our interview, we would also ask you to give three short forms to the child’s teacher for us. We would also like you to bring in a copy of your child’s last report card. If your child is diagnosed as having ADHD and receives treatment from a health professional, we would like to know about the treatment your child receives. You can refuse your permission for any of these contacts if you choose and still participate in the rest of the study. You can choose to be interviewed if your child does not want to take part, and you can give permission for your child to participate if you do not want to complete the interview yourself.

Yes, I give permission for my child to participate in this study. \_\_\_\_ (initials)

- Yes, you may look at my child’s school report card to collect information on attendance, grades, test scores, and behavior. \_\_\_\_ (initials)
- Yes, I would be willing to hand a survey to my child’s teacher, ask them to fill it out and send it back to the OUHSC researchers. \_\_\_\_ (initials)

In case you move, we may want to contact your neighbors for updated contact information.

- Yes, you may contact my neighbors for updated contact information. \_\_\_\_ (initials)

**Whom Do I Call If I Have Questions Or Problems?**

If you have questions about this study, you can contact the **Principal Investigator, Dr. Mark Wolraich**, or his representative at one of the following phone numbers **405-271-3999 or 1-866-770-3859**. For questions about your rights as a research subject, or if you feel you have been harmed from the study, contact the Director, Human Research Participant Protection Office of Research Administration at 405-271-2045.

**What About Other ADHD Studies?**

Please mark the box below to indicate your interest to be included in other studies on ADHD. Would you like researchers at OUHSC to contact you to participate in other studies on ADHD?

- Yes, I am interested in participating in other ADHD studies.
- No, please to do not contact me for other ADHD studies.

**Signature:**

By signing this form, you agree to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or institution from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

- I agree to participate in this study
- I do not agree to participate but give permission for my child to participate.

\_\_\_\_\_  
Date                      Signature of Volunteer (Parent)

\_\_\_\_\_  
Printed Name of Volunteer (Parent)

\_\_\_\_\_  
Date                      Consent obtained by: