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## **INFORMED CONSENT FORM**

**(For Parent/Guardian of 9-17 Year Old)**

### **WHY ARE YOU BEING INTERVIEWED?**

You are being asked to take part in this study because your family participated in the South Carolina Project to Learn about Attention Deficit Hyperactivity Disorder (ADHD) in Youth (SC PLAY). The purpose of this study (SC PLAY Follow-Up) is to learn about long-term outcomes and health status for children with and without ADHD. We want to better understand how ADHD or other problems are being diagnosed and treated in our community and what difference it makes for children's quality of life and their behavior. This is why we would like to continue to work with you and your child over the next couple of years. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241; Attachment A1).

### **WHAT WILL BE DONE?**

Just like the last time we worked together, we will collect information through both a computer based interview and some written questionnaires. Each year, we will meet for an in-person interview at our research office (at USC) or another convenient location and send you a packet of questionnaires in advance to fill out and bring with you. We expect the total time each year for these two activities (combined), will be about three hours. We will contact you every 3 months to ask for updated contact information and/or changes in treatment. It will take approximately 5 minutes to complete the questions for the 3 and 9 month update. It will take approximately 30 minutes to complete the 6 month surveys. Once a year, we will give you forms to have your child's teacher complete and return to us.

Our interview will include questions about your child's mental health and behavior. In addition to the interview questions involved with the evaluation for ADHD and other conditions, the questionnaires will ask you about your own health, including your emotional health, and about your child's medical history and general state of health. We will also ask about how you see your child's strengths and difficulties, your child's behavior, and your feelings about your relationship with your child. The questions also include potentially sensitive items such as tobacco use and alcohol. For children aged 11 and older we will ask some sensitive questions regarding drug use and delinquent behavior, and for children 14 and older we will also ask sensitive questions about fighting, driving, bullying, dating and sexual behavior.

Your child will also be asked to participate in this study. The child interview (made up of computer and paper-pencil questionnaires) takes about two hours to complete. Altogether, the questions are designed 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, we will work with you and your child separately during the annual interview, 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. 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. Our team includes a child psychiatrist who will review the interview results. If a problem is found, you will be informed of our concerns and you will be given information about where you can obtain help for you and your child. You should be aware, however, that we cannot provide a clinical diagnosis. We do not provide any money for services that may be needed for any problem identified by our study. We are required by law to report any instances of child abuse or neglect that come to our attention.

## **HOW WILL YOUR PRIVACY BE PROTECTED?**

Some of the questions may be of a sensitive nature, but we promise you that all information is being recorded without names. Only code numbers are used. We will make every effort to keep your and your child's identity and the information you give us confidential. The key that links a name to a code number is stored in a separate place, under lock and key. 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 USC Institutional Review Board. Data will be reported to CDC without your name or other information that tells who you are.

## **DO YOU HAVE A CHOICE ABOUT PARTICIPATING?**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. You may also say no to answering any questions or to doing any part of the interview. You can choose to withdraw for any reason at any time. We will tell you about any new information that may affect your health, welfare or willingness to stay in this study. You or your child will not be treated any differently if you choose not to participate.

## **WHAT ARE THE RISKS AND BENEFITS?**

There are no known risks for participating in this study. Your child may benefit from the evaluation, especially if we find a problem that was not known about before. You and your child are helping us learn information that will increase our understanding of ADHD and help children in the future.

**WHAT ARE THE COSTS?**

There will be no costs to you because of your participation in this study. Because we understand that these interviews take time, we will give you \$50 (\$75 if your child is 14 years old or older) 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 \$20 (\$50 if your child is 14 or older) for participating in each annual interview.

**WILL OTHER PEOPLE BE ASKED TO SUPPLY INFORMATION?**

In addition to the information gained from our interview, we would also like your permission to talk with your child’s school teachers and to have you give a survey to the child’s teacher for us. We would also like you to bring in a copy of your child’s last report card. You can refuse your permission for this part 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 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 send them back to the USC 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)

**PERMISSION FOR FOLLOW-UP:**

- Yes, you may contact me again for annual and semi-annual follow-up interviews. \_\_\_\_ (initials)

The Centers for Disease Control and Prevention (CDC) has funded this study from the beginning and they have been an active partner in the planning and implementation of the project. They are interested in continuing to follow the participants as they become adults. If you would be willing for us to share your contact information with CDC so they can contact you in the future, please check the box below.

- Yes, you may provide contact information for me to CDC for possible future data collection. \_\_\_\_ (initials)

## WHAT ABOUT OTHER ADHD STUDIES?

Please mark the box below to indicate your interest to learn about other studies on ADHD. Would you like researchers at USC to contact you with information about other studies on ADHD?

- Yes, I am interested in learning about ADHD studies.
- No, please do not contact me about other ADHD studies.

## CONTACT FOR QUESTIONS:

If you have any questions about the study or want to withdraw, you may contact the **ADHD Study office at 777-1124** and speak to the Project Director, Ms. Lorie James, or to the Principal Investigator, Robert McKeown, PhD. Or you may write to Dr. McKeown at:

SC PLAY, Department of Epidemiology and Biostatistics  
Arnold School of Public Health  
University of South Carolina  
Columbia, SC 29208

If you have questions about your rights as a research participant or feel you have been harmed from the study, please contact Thomas Coggins, Director of Research Compliance, at 803-777-4456.

A copy of this form is being provided for you to keep.

## CONSENT

“I have read and understand the above information. I have received a copy of this form.

- I agree to participate in this study and consent for my child to participate in this study with the understanding that I may withdraw at any time.
- I do not agree to participate but** consent for my child to participate in this study with the understanding that I may withdraw my child at any time.”

**Parent/Guardian's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Name of your child and his/her grade level:** \_\_\_\_\_

**ADHD Staff or Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_



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