DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
A Randomized, Sham-Controlled, Crossover Study to Evaluate the Effects of Noise Cancelling Headphones on Neurocognitive and Academic Outcomes in Children and Adolescents Diagnosed with Attention Deficit Hyperactivity Disorder (ADHD)

Protocol: Bose –ADHD POC-001

Sponsor: Bose Corporation

Principal Investigator: Scott H. Kolllins, PhD

Medical Oversight: Rachel E. Dew, MD

Research Site Address: Duke Child and Family Study Center
2608 Erwin Road, Pavilion East, Suite 300
Durham, NC 27705

Daytime Telephone Number: 919- 681-0014(Kollins) / 919-681-0031 (Dew)

24-hour Contact Number: 919- 970-9576 (Kollins) / 919-970-8541 (Dew)

Your child is being asked to take part in this research study because your child may have Attention Deficit Hyperactivity Disorder (ADHD). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your child's study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide for your child to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if your child is taking part in another research study.

Scott H. Kollins, PhD will conduct the study and it is funded by Bose. The sponsor of this study, Bose will pay Duke University to perform this research, and these funds may reimburse part of Dr. Kollins' salary and his research team.

WHO WILL BE MY CHILD'S DOCTOR ON THIS STUDY?
If you decide to have your child participate, Dr. Kollins will be your child's study psychologist and Dr. Rachel Dew will be the study physician. They will be in contact with your child's regular health care provider throughout the time that your child is in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to evaluate if there is a difference in the performance of children and adolescents when using a noise cancelling headphone versus a sham headphone while performing tasks

that involve working memory, inhibitory control, attention, math, and reading comprehension in the presence of standardized noise that simulates classroom noise.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 30 people will take part in this study at Duke University Medical Center. We may need to screen up to 60 participants in order to get 30 eligible. Duke is the only site for this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to allow your child to be in this study, you will be asked to sign and date this consent form. You and your child will be asked to come to the clinic 4 times (screening, baseline and two experimental sessions) over a period of 2-5 weeks.

Visit 1 -Screening: This visit will determine if your child is eligible to participate in the study. This visit will last for about 4 hours. The following will happen:

- You and your child (if 12 years old and above) will sign and date this consent form
- You will be asked about your child's medical and medication history
- You will be asked about your child's developmental history
- You will complete a diagnostic interview and assessment with one of our clinical psychologists in order to determine if your child meets the criteria for a diagnosis of ADHD or any other psychiatric condition.
- Your child will complete a brief Intelligence Quotient (IQ) screening
- If additional information is needed in order to determine your child's eligibility for the study, we may request additional materials from other sources (e.g., teacher forms or medical records). If this occurs, we will ask you to sign a release form for that information.

If your child qualifies to be in the study, you and your child will be asked to return to the clinic within 21 days after the screening visit.

Visit 2-Baseline: During this visit, the following will be completed:

- If your child is currently taking a stimulant medication for his/her ADHD, and he/she is eligible to be in the study, we will ask that your child not take his/her ADHD medication on the day of study visits 2, 3 and 4. Your child can resume taking his/her ADHD medication the same day after he/she completes the assessments for the study visit.
- You and your child will be asked if your child had any changes in his/her health since his/her last study visit.
- You will be asked for any medications that your child has taken since the last study visit.
- Your child will complete three computerized assessments about sustained attention, strategy, working memory and impulse control. This will take about 30 minutes to complete.

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- Your child will also complete math and reading comprehension activities.
- If your child continues to meet eligibility criteria to be in the study, he/she will be assigned to complete assessments in the next two visits using either the noise cancelling headphone first and then the sham headphone or the sham headphone first and then the noise cancelling headphone.
- Your child will be fitted for the proper earbud size for headphones and practice inserting the earbuds.
- This visit will last for about two hours.

Visits 3 and 4 – Experimental Sessions: Within 4 to 10 days since the last study visit, you and your child will be asked to come to the clinic to complete the following:

- You and your child will be asked if your child had any changes in his/her health since his/her last study visit.
- You will be asked for any medications that your child has taken since the last study visit.
- Your child will be asked to use a noise cancelling headphone first (Visit 3) and then the sham headphone (Visit 4) or the reverse order while he/she completes the following:
    1. Three computerized assessments about sustained attention, strategy, working memory and impulse control.
    2. Math and reading comprehension activities
- Your child will be asked to describe his/her experience after the assessments.
- The visits lasts approximately two hours each time
- At Visit 4, which is your child's last study visit, we will provide you with referrals for the continued care of your child's ADHD.

HOW LONG WILL MY CHILD BE IN THIS STUDY?
Your child will be in the study for up to 5 weeks
You and your child can choose to stop participating at any time without penalty or loss of any benefits to which your child is entitled. However, if you and your child decide to stop participating in the study, we encourage you to talk to your child's study doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your child's information confidential; however, this cannot be guaranteed. Some of the questions we will ask you and your child as part of this study may make you or your child feel uncomfortable. You and your child may refuse to answer any of the questions and you and your child may take a break at any time during the visits. You may stop your child's participation in this study at any time.

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Risks of Washout: During the washout period, your child's symptoms of ADHD may get worse. Washout is when your child stops taking his/her ADHD medication on the day of the study visits (Visits 2, 3, and 4). Please discuss the washout period with the study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to allow your child to take part in this study, there is no direct medical benefit to your child. We hope that in the future the information learned from this study will benefit other people with ADHD.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
You and your child do not have to participate in this study to get treatment for his/her ADHD. You can get treatment or care for your child's ADHD even if you are not in a research study. Your child could benefit from either FDA approved medication or behavior therapy, which have been proven to be helpful for treating ADHD.

Please talk to your child's primary care physician about these options before you decide for your child to take part in this study.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law or for your care, your child will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS (Bose Corporation, the study sponsor) your child will be assigned a unique code number. The key to the code will be kept securely at DUHS.

As part of the study, Dr. Kollins and his study team will report the results of your child's study-related assessments to the study sponsor Bose. Records may include your child's initials and/or your child's date of birth. In addition, your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of Bose and the Duke University Health System Institutional Review Board. If any of these groups review your child's research record, they may also need to review your child's entire medical record.

All of the study assessments are being done only because your child is in this study. The study results will not be given to you or be sent to your child's physician to include in your child's medical record.

The study results will be retained in your child's research record until your child reaches the age of 21. At that time either the research information not already in your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS. Any research information in your child's medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study, Bose .If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child's identity will not be revealed.

WHAT ARE THE COSTS TO YOU?
There will be no additional costs to you as a result of your child being in this study. You or your child's insurance provider will be responsible and billed for all costs related to your child's routine medical care, including copayments and deductibles. Routine medical care services are those that your child would have received for his/her condition if you they not participating in this research study. You may wish to contact your child's insurance company to discuss this further. In order to make sure that tests and studies done solely for research purposes are charged correctly, we will carefully monitor your child's Duke Hospital and Clinic charges as long as he/she is participating in this study. These tests and studies are not a part of routine care, and people who are not part of the study do not usually have them performed. Please ask Dr. Kollins if you would like to know more about which tests and studies are being done solely for research purposes.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $200 for your expenses related to your child's participation to cover your gas, and time. You will receive $50 for each completed visit. If your child does not complete the study, you will receive compensation for the parts of the study that he/she completed.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that your child is injured as a result of his/her participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., your Duke physicians, or the study supporter, Bose Corporation, to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Scott Kollins, PhD at 919-681-0014 or Dr. Rachel Dew, MD at 919-681-0031 during regular business hours and at 919-970-9576 (Kollins)/ 919-970-8541(Dew) after hours and on weekends and holidays.

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WHAT ABOUT MY CHILD'S RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to allow your child to be in the study, or, if you agree to allow your child to be in the study, you may withdraw from the study at any time. If you withdraw your child from the study, no new data about your child will be collected for study purposes other than data needed to keep track of your child's withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to allow your child to participate or to withdraw your child from the study will not involve any penalty or loss of benefits to which your child is entitled, and will not affect your child's access to health care at Duke. If you do decide to withdraw your child, we ask that you contact Dr. Kollins in writing and let him know that your child is withdrawing from the study. His mailing address is 2608 Erwin Road, Pavilion East, Suite 300, Durham, NC 27705.

We will tell you and your child about new information that may affect your child's health, welfare, or willingness to stay in this study.

Your child's doctor may decide to take your child off this study if your child's condition gets worse, if your child has serious side effects, or if your child's study doctor determines that it is no longer in your child's best interest to continue. The sponsor or regulatory agencies may stop this study at anytime without your consent. If this occurs, you will be notified and your child's study doctor will discuss other options with you and your child.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ct2/home as required by U.S. Law. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Rachel Dew, MD at 919-681-0031 or Dr. Kollins at 919-681-0014 during regular business hours and at 919-970-8451 (Dew) or 919-970-9576 (Kollins) after hours and on weekends and holidays.

For questions about your child's rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to my child and me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw my child at any time. We have discussed the study with my child, who agrees to be in the study. I have been told that I will be given a signed and dated copy of this consent form."

_____
Printed Name of Child

_____ _____ _____
Signature of Subject (if 12 years or older) Date Time

_____
Printed Name of Parent/Guardian

_____ _____ _____
Signature of Parent/Guardian Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time