
**PARENTAL CONSENT FORM AND HIPAA AUTHORIZATION FOR A CHILD TO
PARTICIPATE IN A RESEARCH STUDY**

INVESTIGATOR'S NAME: CHRISTINA McCRAE, PhD

PROJECT IRB #: 2019182

Study Title: TARGETING INSOMNIA IN SCHOOL-AGED CHILDREN WITH
AUTISM SPECTRUM DISORDER

We ask you permission to allow your child to take part in this research study. This consent form tells you why we are doing the study, what will happen if you join the study, and other important information about the study.

Please take as much time as you need to read this consent form. You can discuss it with your family, friends, or child's doctor. If there is anything you do not understand, please ask us to explain. Then you can decide if you want your child to take part in the study or not.

The Principal Investigator (also called the study doctor) is **Christina S. McCrae**. The people working on this study are called the study team.

The United States Department of Defense (called the sponsor in this form) is paying for this study.

**WHAT SHOULD I KNOW BEFORE ALLOWING MY CHILD TO TAKE PART IN THIS
STUDY?**

Research studies help us to learn new things and test new ideas about treating certain conditions/diseases. Taking part in a research study is voluntary. You and your child decide if you want to take part, and you can stop taking part at any time.

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Your child's regular medical care at the University of Missouri Hospitals and Clinics will not be affected now or in the future if you or child decides they do not want to be in this study.

This is a clinical trial. Clinical Trials include only people who choose to participate. As a study participant you and your child have the right to know about the procedures that will be used in this research study so that you and your child can make the decision whether or not to participate. The information presented here is simply an effort to make you and your child better informed so that you and your child may give or withhold your consent to participate in this research study. Please take your time to make your decision and discuss it with your family and friends.

You and your child are being asked to take part in this study because your child is between the ages of 6-12 and has a diagnosis of autism spectrum disorder with chronic sleep problems.

In order to participate in this study, it will be necessary to give your written consent.

We adhere to the health safety guidelines and screening procedures of the Thompson Center and University of Missouri. This may include your and your child's temperature being taken, the use of facial masks, and maintaining 6-feet of distance as appropriate.

The purpose of this study is to test the effectiveness of a 4-session family-based cognitive behavioral therapy or behavioral therapy adapted for children with autism spectrum disorder.

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There are four phases of this study:

1. Screening and baseline assessments; this phase may include:

- Three visits to the Thompson Center and one videoconference visit

(through Zoom)

2. A 4-week treatment period; this phase may include:

- 4-weekly videoconference sessions or in person sessions with the sleep therapist

3. A two-week post-treatment period; this phase may include:

- Three visits to the Thompson Center

4. A two-week follow-up period 6 months after the post-treatment period; this phase may include:

- One videoconference visit and three visits to the Thompson Center

5. A two-week follow-up period 12 months after the post-treatment period; this phase may include:

- One videoconference visit and three visits to the Thompson Center

6. Four bi-monthly phone booster sessions that will last approximately 20 minutes.

- Two sessions between post-treatment and 6-month follow-up, two between the 6-month follow-up and 12-month follow-up.

About 180 people will take part in this study at this institution.

Taking part in this study may or may not make your child's health better. We hope that the information we learn from this study will help in the future treatment of children with insomnia in autism. **There is no guarantee that taking part in this research will result in any improvement in your child's condition.**

We will only include your child and you in this study if you give us your permission first by signing this consent form and your child agrees to take part and signs the assent form.

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What will happen if my child takes part in this study?

If you decide to take part in this study, you will have the following tests and procedures:

1. Screening and baseline assessments

1st visit (Thompson Center):

During phase one, if you agree to participate in this study and sign this consent form, your child will be asked to wear a Holter monitor for 8 minutes to collect information on heart rate variability. You will be asked to keep a record of their sleep each day for two weeks in daily diaries. You will also be asked to assist your child in maintaining a similar sleep diary. We will provide to you the daily diaries which ask you specific questions about your previous night's sleep. We will also provide you and your child with a special wrist watch, called an actiwatch, designed to detect your movement. This watch should be worn both day and night, except during strenuous physical activity where the device may be broken. In addition, the watch is not waterproof so you must take care to protect the watch from contacting water. You should take the watch off before swimming or taking a shower. We will use the information from your sleep diaries and the recordings from the watch to establish a baseline of your sleep behavior. The information will also help us figure out if your child's insomnia is severe enough to make you eligible to be in this study.

2nd visit (videoconference):

During this visit, you will be asked a few questions about your child's sleep history and other medical history. These questions will help us determine if your child's sleep problems might be insomnia. You will also be asked to provide basic

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information about yourself and your child's health history, such as age, race, and diagnoses. You do not have to answer any question you do not wish to answer.

If the screening test indicates that your child's sleep problem does not appear to be related to insomnia, you will be informed that you do not qualify for the study.

*If the screening test indicates that your child's sleep problem appears to be related to sleep apnea (this is where an individual periodically stops breathing during the night) your child will be referred to a physician for further evaluation. If during this physician visit it is determined that it is probable that your child may have sleep apnea, they will be referred for further screening using overnight at home polysomnography (PSG). The PSG will record your child's brain wave activity, body movements, and breathing. This will involve attachment of small cords to your child's scalp, chin, cheek, chest, legs, neck, and index finger. Also, breathing tubes will be placed in your child's nostrils to monitor their breathing. The recording will occur in your home. You will be required to return the equipment at the next visit. This single night sleep test will give us basic information about your child's sleep patterns and determine if they have sleep apnea or periodic limb movement disorder (this is where your legs periodically twitch while you are asleep). *If you have either of these problems you will be referred to a Sleep Disorder Center so you can get help for your sleep problem but you will not be able to continue your participation in the study.**

3rd visit (Thompson Center):

You will come to the Thompson Center to drop off the actiwatches. You will be given a charged actiwatch for the second week of sleep.

2. A 4-week treatment period

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4th –7th sessions:

Your family will bring the actiwatches to the Thompson Center. If you are randomized to the in-person condition, you will stay for your first treatment session. You will be randomly assigned (through a process similar to flipping a coin) to receive either the cognitive behavioral treatment or behavioral treatment program designed for children with ASD. These interventions involve helping you to learn a number of skills to manage your child's insomnia. These interventions have been shown in research to be helpful in improving symptoms of insomnia. However, there is no guarantee that your child's insomnia will improve. There are a total of 4 weekly sessions. You and your child will be required to meet with the sleep therapist once a week via either a videoconference at your home or in person (at the Thompson Center). Each session will last about 50-90 minutes. You will be given homework in each treatment session to practice the skills you learned from the session. During these 4 weeks, you and your child will be required to continue to complete the sleep diaries.

3. A two-week post-treatment period*8th visit (Thompson Center), 9th visit (Thompson Center), & 10th visit (Thompson Center):*

Following the 4-week treatment, you and your child will be asked to wear the watch and complete daily sleep diaries for another 2 weeks. You will come to the Thompson Center at the beginning of the first week to obtain the actigraph watches. During this visit your child will be asked to wear a Holter monitor for 8 minutes to collect information on heart rate variability. You will also fill out two weeks of sleep diaries during these two weeks. You will also be asked to complete fresh copies of the questionnaires about your child's behaviors, mood, and fatigue you completed before the treatment period. At the beginning of the second week, you will return to the Thompson Center to drop off the actiwatches and you will be

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given a charged actiwatch for the second week of sleep. At the end of the two weeks you will return to the Thompson Center to return the actiwatches.

4. Two phone booster sessions.

11th and 12th visits (phone):

Between posttreatment and 6-month follow-up, you will be asked to take part in two 20-minute booster sessions over the phone. During this session you and the therapist will review session content and troubleshoot any sleep difficulties. Prior to the phone sessions you will be asked to fill out 2 weeks of electronic sleep diaries.

5. A two-week follow-up period 6-months after the post-treatment period.

13th visit (Thompson Center), 14th visit (videoconference), 15th visit (Thompson Center), & 16th visit (Thompson Center):

The exact same procedures will occur in the 6-month follow-up period as in the post-treatment period. In addition, a videoconference visit will occur to touch base with study families.

6. Two phone booster sessions.

17th and 18th visits (phone):

Between 6-month follow-up and 12-month follow-up, you will be asked to take part in two 20-minute booster sessions over the phone. During this session you and the therapist will review session content and troubleshoot any sleep difficulties. Prior to the phone sessions you will be asked to fill out 2 weeks of electronic sleep diaries.

7. A two-week follow-up period 12-months after the post-treatment period.

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19th visit (Thompson Center), 20th visit (videoconference), 21st visit (Thompson Center), & 22nd visit (Thompson Center):

The exact same procedures will occur in the 12-month follow-up period as in the 6-month follow-up period. At the end of this period, you will also be offered to receive the other study treatment at no cost.

We will keep the information we collect from your child for this study to use in future research without asking for your or your child's consent again. Information that could identify your child will be removed from their research data so no one will know that it belongs to them.

How long will my child be in the study?

We think you will be in the study for 56 weeks.

The investigator and/or your doctor may decide to take you off this study if your child does not meet the diagnostic criteria for insomnia.

CAN MY CHILD STOP BEING IN THE STUDY?

Your child can stop being in the study at any time without giving a reason. If your child stops being in the study, their regular medical care will not change. Leaving the study will not affect your or your child's future medical care at the University of Missouri.

There is no penalty to you or your child if they do not join the study or if they leave it early. You and your child will not lose any benefits you and they are entitled to if they leave the study.

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If you and/or your child decide to stop participating in the study, you should discuss your decision with the study doctor.

The study doctor may decide to take your child off this study at any time, even if you and/or they want to stay in the study. The study doctor will tell you the reason why your child needs to stop being in the study. These reasons may be:

- If it is in your child's best medical interest
- Your child's condition gets worse
- You or child are unable or do not follow the study rules
- The whole study is stopped

What health risks or problems can my child expect from the study?

There are risks to taking part in any research study. While on the study, you are at risk for the side effects described below. You should discuss these with the investigator and/or your doctor. There may also be other side effects that we cannot predict. Many side effects go away shortly after the interventions stopped, but in some cases side effects can be serious or long-lasting or permanent.

Risks and side effects related to the procedures we are studying include:

The physical, psychological, and social risks associated with this study are minimal. However, some participants may experience very mild, temporary worsening of their insomnia as the sleep/wake cycle adjusts to changes in daily sleep habits and routines. When this occurs, it typically occurs early in the course of therapy and resolves within 1-2 weeks.

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The Holter monitor sensors and/or actiwatch may cause temporary redness/irritation of the skin.

Researchers will take appropriate steps to protect any information they collect about you and your child. However, there is a slight risk that information about you and your child could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform Dr. Christina McCrae or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call Dr. Christina McCrae or contact person listed on the front page of this form.

For the reasons stated above the investigator will observe your child closely while giving the treatment described and, if you have any worrisome symptoms or symptoms that the investigator or her associates have described to you, notify the investigator immediately. Dr. Christina McCrae's telephone number is (573) 884-7362. The Research Team telephone number is (573) 884-7362.

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Are there benefits to taking part in the study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will benefit other children with autism and insomnia in the future. There is no guarantee that taking part in this research will result in any improvement in your condition.

What other choices does my child have?

Your child does not have to take part in this study. You and your child are free to say yes or no. If you do not want your child to join this study or your child does not want to take part, your doctor will discuss other choices with you.

You may choose to receive treatment at a Sleep Disorder Center for your sleep problems. An alternative is to not participate in this research study.

Please discuss these and other options with the investigator and your doctor. The study doctor can discuss the possible benefits and risks of the other options available to your child.

What about privacy and confidentiality?

A copy of this consent will be placed in the medical record. Anyone accessing your record will be able to view the document and see that you have agreed to participate in the study. Medical information produced by this study will become part of your hospital medical record. Information that does not become part of your child's medical record will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the University of Missouri in
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a form that could identify you without your written consent, except as required by law. If the investigator conducting this study is not your primary, or regular doctor, the investigator must obtain your permission before contacting your regular doctor for information about your past medical history or to inform them that you are in this trial.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

To maintain the quality of the intervention delivered to you, we would like to videotape all the treatment sessions. The Principal Investigator will be reviewing the videotapes to ensure that the interventionist is administering the intervention correctly and effectively.

You will be given the opportunity to view or listen, as applicable, to the photographs, audiotapes or videotapes before you give your permission for their use if you so request.

HIPAA AUTHORIZATION

State and federal privacy laws (HIPAA) protect the use and release of private health information. If your child takes part in this study, you also give us your permission to use their private health information, including the health information in their medical records and information that can identify them.

You have the right to refuse to give us your permission for us to use your child's health information. However, doing so would mean that your child could not take part in this study.

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The following identifiers will be obtained from your child's health records:

- | | |
|---|--|
| <input checked="" type="checkbox"/> Name | <input checked="" type="checkbox"/> Address |
| <input checked="" type="checkbox"/> Dates related to your child | <input checked="" type="checkbox"/> Telephone number(s) |
| <input type="checkbox"/> Fax Number | <input checked="" type="checkbox"/> Email Address |
| <input checked="" type="checkbox"/> Social Security Number | <input checked="" type="checkbox"/> Medical Record Number |
| <input type="checkbox"/> Health Plan Beneficiary Number | <input type="checkbox"/> Account Numbers |
| <input type="checkbox"/> Certificate or License Numbers | <input type="checkbox"/> Any vehicle or device serial number |
| <input type="checkbox"/> Web Address (URL) (IP)Address(es) | <input type="checkbox"/> Internet Protocol |
| <input type="checkbox"/> Biometric Identifiers (finger/voice print) | <input type="checkbox"/> Photographic images |
| <input type="checkbox"/> Any other characteristic that could identify you | |

The following is the type of protected health information that will be used in the study:

- | | |
|--|--|
| <input type="checkbox"/> Radiology Images | <input type="checkbox"/> Discharge Summaries |
| <input type="checkbox"/> Radiology Reports | <input type="checkbox"/> Health Care Billing or Financial Records |
| <input type="checkbox"/> EKG Recordings/Reports | <input type="checkbox"/> Consultations |
| <input type="checkbox"/> Progress Notes | <input checked="" type="checkbox"/> Medications |
| <input checked="" type="checkbox"/> History and Physical Exams | <input type="checkbox"/> Emergency Medicine |
| <input type="checkbox"/> Operative Reports | <input type="checkbox"/> Dental Records |
| <input type="checkbox"/> Pathology Reports | <input checked="" type="checkbox"/> Demographics (age, race, etc.) |
| <input checked="" type="checkbox"/> Laboratory Reports | <input checked="" type="checkbox"/> Questionnaires, Surveys, |
| <input type="checkbox"/> Photographs/Video Recordings | <input type="checkbox"/> Audio Recordings |

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Social Security Number (This is only collected for billing/payment purposes and will not be shared with the study sponsor)

Other

Your permission for us to use and/or release your child's information will not expire unless you cancel your permission.

You can cancel your permission at any time by writing to:

Investigator's Name: Christina S. McCrae

Institution: University of Missouri, Columbia

Department: Psychiatry

Address: One Hospital Drive, Columbia, MO 65212

The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

You have the right to access your child's protected health information that is obtained or created during this research project until the end of study.

If you have not already received a copy of the University of Missouri Healthcare Privacy Notice, you may request one. If you have any questions or concerns about privacy rights, you may contact the Privacy Officer at 573-882-9054.

We will scan a copy of this consent form into your child's medical record. We may also record your child's research information, including the results of tests and procedures, in their medical record. The medical information produced by this study will become part of your child's hospital medical record, and people allowed to look at their medical records may see this research information.

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Information that does not become part of your child's medical record will be stored in the investigator's electronic/computer or paper files. Computer files are protected with a password and the computer is in a locked office that only study team members can open. Paper files are kept in a locked drawer in a locked office that only study team members can open.

Your child's records will be given a code number and will not contain their name or other information that could identify them. The code number that connects your child's name to their information will be kept in a separate, secure location.

Information that may identify your child may not be given to anyone who is not working on this study without your written consent, or if required by law.

The people who may use and/or release your child's research information include:

- Those working on the study team at the University of Missouri
- Study sponsor, the United States Department of Defense
- The members of the University of Missouri Institutional Review Board (IRB)
- Those who check on research activities to make sure it is being done correctly and safely
- Other government or inspection agencies

If the study investigator is not your child's regular doctor, he/she must ask your permission before contacting their regular doctor for their health history.

We may present the results of this study in public talks or written articles, but we will not use information that can identify your child.

You must give us permission to use the video recordings we take of your child during the study. You/child will be able look at/listen to/watch them before you
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give your permission for us to use them. Images/photographs/audio recordings/video recordings will not contain anything that might identify your child.

Are there any costs to being in the study?

The study will pay for all research tests and procedures. You and/or your/your child's health plan/insurance will not be billed for tests and procedures that are done in this research study.

Will i or my child be paid for taking part in this study?

You will receive compensation for your efforts. At the end of week two, you will receive \$100. At the end of week 8, you will receive another \$100 and at the end of the 6-month follow-up, you will receive \$100. At the end of the 12-month follow-up you will receive \$125. Your compensation will be paid in cash.

If your child leaves the study early, you will still receive a payment for each visit they completed.

We will need your social security number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

What happens if my child is injured during the study?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability

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insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff.

The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event your child has suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information.

This statement is not to be construed as an admission of liability.

What Are my child's Rights as a Study Participant?

Taking part in this study is voluntary. Your child does not have to take part.

Your and your child's present or future medical care will not be affected if your child does not take part.

If your child does take part, you and they can change your mind and drop out of the study at any time. This will not affect your or your child's current or future care at the University of Missouri Hospitals and Clinics. There is no penalty for leaving the study and you and your child will not lose any benefits that you or they are entitled to receive.

If the study investigator decides to take your child off the study, she will explain the reasons and help arrange for your child's continued care by their own doctor, if needed.

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A Data Safety and Monitoring Board, an independent group of experts, will review the data collected during this study. We will tell you about any new information discovered during this study that might affect your child's health, welfare, or change your/your child's mind about taking part.

Where can i get more information about this study?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about the study?

If you have more questions about this study at any time, you can call Dr. Christina McCrae at 573-882-0982 or the Research team at 573-882-3806.

You may also contact the University of Missouri Institutional Review Board (IRB) if you:

- Have any questions about your child's rights as a study participant;
- Want to report any problems or complaints; or
- Feel under any pressure to have your child take part or stay in this study.

The IRB is a group of people who review research studies to make sure the rights of participants are protected. Their phone number is 573-882-3181.

If you want to talk privately about your child's rights or any issues related to their participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing MUResearchRPA@missouri.edu.

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We will give you a copy of this consent form. Please keep it where you can find it easily. It will help you to remember what we discussed today.

Consent to Participate in Research

By signing my name below, I confirm the following:

- I have read/had read to me this entire consent form.
- All of my questions were answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits were explained to me.
- I voluntarily agree to allow my child to take part in this research study. I have been told that my child can stop taking part at any time.
- I voluntarily agree to participate in this research study with my child.

Parent/Guardian's Signature	Relationship to Child	Date

Parent/Guardian's Signature	Relationship to Child	Date

Signature of Witness (if applicable)*	Date

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**A witness is required when a participant is competent to provide consent but is blind, or cannot read or write.*

SIGNATURE OF PERSON AUTHORIZED TO OBTAIN CONSENT*

I have explained the purpose of the research, the study procedures (identifying those that are investigational), the possible risks and discomforts and potential benefits of the study, and have answered questions regarding the study to the best of my ability.

Signature of Person Authorized to Obtain Consent	Date

**This signature is required for FDA regulated research and/or research that involves any medical procedure or surgical treatment.*

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