



The Children's Hospital

www.thechildrenshospital.org  
Approved

OCT 30 2009

COMIRB

**Autism Spectrum Research Study Announcement**  
(COMIRB Protocol Number: 07-0362)

Dear Caregiver:

We are conducting a research study to evaluate ways to improve medical examinations with children diagnosed with autism or Asperger's.

**What is the purpose of study?**

Routine medical visits can be difficult, even traumatic, for children with an autism spectrum disorder. Children with autism spectrum disorders have unique social, communication and sensory issues that interfere with a successful doctor visit. The purpose of this study is to find ways to make doctor visits less stressful for children with autism and to enable a more thorough exam by the doctor.

**Who can participate in this study?**

This study is for children ages **5-10 years** who have been diagnosed with autism or Asperger's.

**What is involved?**

The first step is to answer a few screening questions over the phone. Following this, our study requires you and your child to come in to The Children's Hospital for two visits. During the initial three hour visit, we will review the study consent, conduct up to three screening assessments (diagnostic, adaptive, and intelligence) with your child, and you will be asked to fill out questionnaires regarding your child's behaviors. If your child meets study criteria, you will be asked to come in to The Children's Hospital for a second visit during which time your child will have a routine physical exam with a nurse and pediatrician. Before and after the physical exam, you will be asked to fill out a few additional questionnaires about your child's sleep habits and behaviors.

**What are the benefits to being involved in this study?**

There may be some benefit to you and your child which could include the following:

- As part of this study, your child will receive one free medical examination by a nurse and resident.
- You will also receive a summary of any intelligence and adaptive assessment results administered as part of the study.
- If you ask for it, you can receive a summary of the findings that will be submitted for publication.

We thank you for your time in reading this letter and hope that you will be interested in learning more about our studies and possibly participating. With your help, we can learn more about the treatments that may better assist individuals with autism or Asperger's. **If you are interested in participating in the study, please contact the study coordinator: Kate Holt (720) 273-7688 to complete a screening over the phone.**

Sincerely,

Robin Gabriels, Psy.D.  
Primary Investigator

Consent Form Approval  
Approved

OCT 30 2009

Date: \_\_\_\_\_  
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Valid For Use Through: 11-29-10

**COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD**

*Evaluating the Effects of a Visual Pedagogy and Structure on the Successful Completion of the Medical Office Visit and Physical Examination with Pre-pubescent Children with Autism*

**Principal Investigator: Robin Gabriels, Psy.D.**

**Co Investigators: Jane Gralla, Ph.D., Edward Goldson, M.D., John Agnew Ph.D.**

**SUBJECT CONSENT FORM**

**6 October, 2009 Version 3/COMIRB Protocol Number 07-0362**

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**Project Description**

You ("you" equals you/your child) are being asked to take part in a research study to evaluate how to make normal visits to the doctor easier and less stressful for children with autism and more useful for the doctor. Many children with autism are unable to cooperate with their doctors because they feel stressed and uncomfortable in the unfamiliar doctor's office. This study involves having your child participate in one physical examination by a nurse and a doctor to assess different methods to reduce your anxiety during the exam.

You are being asked to be in this study because of your diagnosis of an Autism Spectrum Disorder. Up to 50 local subjects will be enrolled in this research study and will have a physical exam.

**Procedures**

If you agree to take part in this study, we will ask you to do the following things...

- If your child has never had autism diagnostic testing or has not had a nonverbal IQ assessment completed with the past year, then these assessments will be completed with your child. This should take approximately two hours.
- Complete questionnaires regarding your (child's) sleep habits and behaviors before the physical exam and rating how cooperative your child usually is when visiting the doctor. These questionnaires will take less than 30 minutes to complete.
- Answer interview questions to identify your child's current adaptive ability. This should take approximately one hour.
- The child will have a routine physical exam with a nurse and pediatrician familiar with autism.
- Complete questionnaires regarding your (child's) behaviors immediately following the physical examination and rate how cooperative your child was during this examination visit with the nurse and doctor.
- Your child's participation in this study ends at the completion of the physical exam.
- Your child will be receiving a free medical examination by a nurse and resident. Additionally, you (the caregiver) will be informed of any abnormal examination findings of your child and consent will be obtained from you to report these findings to your child's primary care physician.

Initials: \_\_\_\_\_

- I (the caregiver), will also receive a summary of any cognitive and adaptive assessment results administered as part of this study with my child. This information can be useful to school districts to ensure appropriate educational placements and services for your child.

**Discomforts and Risks**

The discomfort of participating in a medical examination is a risk for your child. These discomforts may be considerable. The nurse and/or doctor will be instructed to end the examination if my child objects, but this does not eliminate the risks and discomforts associated with the examination, which may include your child being fearful of the exam setting including the nurse, doctor, or routine physical exam procedures. Other risks would involve discomfort for you as a caregiver associated with answering questions about your child's difficulties and results from diagnostic or cognitive assessment of your child, conducted as part of this study; however, we will discuss these results with you.

**Benefits**

This study is designed for the researcher to learn more about the process of doing physical exams in children with autism. This study is not designed to treat any illness or to improve your health.

**Study Sponsor**

This research is funded by The Children's Hospital Research Institute

**Cost to Subject**

There is no cost to you for participating in this study. There will be no charge for any procedures or drugs required by the study.

**Subject Payment**

You will not be paid for participation in this study.

**Study Withdrawal**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, your doctor will still take care of you. You will not lose any benefits or medical care to which you are entitled. The study doctor or nurse may choose to discontinue the physical exam with your child if they judge your child's behaviors to be aggressive in nature such that they are a danger to themselves or others.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, or for any other reason.

**Invitation for Questions**

The researchers carrying out this study are Dr. Robin Gabriels, Dr. Jane Gralla, Dr. Edward Goldson and Dr. John Agnew. You may ask any questions you have now. If you have questions later, you may call Dr. Gabriels at 720-777-3404. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, please call the Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055.

Initials: \_\_\_\_\_

**Confidentiality**

We will try to keep your research records confidential, but it cannot be guaranteed. Records that identify you (including your medical records) and the consent form signed by you, may be looked at by the following people:

- Colorado Multiple Institutional Review Board
- The investigator and research team for this study
- The sponsor or an agent for the sponsor
- Regulatory officials from the institution where the research is being conducted, to ensure compliance with policies or monitor the safety of the study
- Federal agencies that oversee human subject research

I also understand that my child's physical examination findings will be recorded in The Children's Hospital electronic medical records. Additionally, you (the caregiver) will be informed of any abnormal examination findings of my child and consent will be obtained from you to report these findings to your child's primary care physician.

The results of this research may be presented at meetings or in published articles. However, your name will be kept private. You will also be asked to sign a separate authorization form. This form will explain who will have access to your protected health information.

**Mandated Reporting of Child Abuse, Neglect, Suicide, or Threatened Violence**

Some things we cannot keep private. If you give us any information about concerning suicide, threatened violence, child abuse or neglect we have to report that to the proper authorities. If you tell us you are going to physically hurt someone, we have to report that to the police. Also, if we get a court order or subpoena to turn over your study records, we will have to do that.

**Injury and Compensation**

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about injury related to the research, you may call Dr. Robin Gabriels at 303-869-3404 and/or your private physician. Dr. Gabriels should be informed about any injury you experience while you take part in this study.

If you are hurt by this research, we will give you medical care if you want it, but you will have to pay for the care that is needed.

**AUTHORIZATION:**

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study. I know I can stop being in this study and I will still get the usual medical care. I will get a copy of this consent form.

Signature of legal representative: \_\_\_\_\_

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_

Consent form explained by (Signature): \_\_\_\_\_

Print Name: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of witness \_\_\_\_\_ Date: \_\_\_\_\_

Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Initials: \_\_\_\_\_