CONSENT FORM TO PARTICIPATE IN RESEARCH

Parent Consent Form for Children (Ages 5-8)

A Study of Children with Autism and How Their Brain Works

Subject's Name: ____________________________________________________

In the statements below, the word "you" refers to you or your child or ward.

You and your child are being asked to participate in a research study conducted by Kristi Clark, Ph.D., Jennifer Levitt, M.D. and Victoria Peccolo from the UCLA Departments of Neurology and Psychiatry. You are being asked to participate in this study because your child has shown symptoms of or has been diagnosed with autism or because your child does not have symptoms of autism. We anticipate that 50 children (boys only, ages 5-8) will participate in this study at UCLA. This study is funded by the National Alliance for Research on Schizophrenia and Depression (NARSAD). This study takes place over 1 visit, for a total of approximately 2 hours.

DISCLOSURE STATEMENT

Your child(ren)'s health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your child's clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your child(ren)'s care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your child's physician.

PURPOSE OF THE STUDY

The purpose of this study is to examine the relationship between brain structure and autism.

PROCEDURES

If you agree to participate in this study, and sign the consent form, you and your child will be asked to do the following things. It is possible that you may sign the consent form but not be able to participate in the study because you have been found ineligible by the study doctor. Study procedures will be conducted at UCLA. At the end of the consent form you will be asked to indicate whether you wish to be notified about future autism studies.

This research study involves a diagnostic interview with you and your child, where you will answer questions about your child's feelings and behavior and your child will answer about himself or herself. You will also be asked to complete a medical history questionnaire about your child and complete rating scales of your child's behavior. You have the right to refuse to answer any questions that you may not wish to answer. Your child will then take a test of intelligence and have MRI pictures of his or her brain taken. Participation in the study will take place over two hours. Testing and interview sessions may be broken up by breaks. You can stop participation in this study at any time. At the conclusion of this two-hour visit, you and your child's participation in the study will be complete.
At the end of the visit, your children will complete MRI testing. He or she will be asked to lie on a table that is moved into a large cylinder that is the MRI. Your child's head and shoulders lie in a plastic contoured tray that makes it more comfortable and easier to lie still. The MR scanner uses a magnet to make images (pictures) of the brain. No X-rays are involved. Except for a loud noise, there is no pain or physical discomfort of any kind, and there are no known harmful effects from the MR scanner. To reduce the noise, your child will be given earplugs and headphones. The actual MR scan takes approximately 30 minutes. Your child will be allowed to watch an age-appropriate movie during the scanning. The results of these scans show us the structure of your child's brain. The hardest part of the scan is the need to lie still for 30 minutes; however, he or she will be able to watch a movie while they are asked to lie still. You may stay with your child while the MR scan is being performed.

In addition, if your child is currently prescribed stimulant medication, he is asked to participate in this evaluation off of stimulant medication. Specifically, he is asked not to take his morning dosage of stimulant medication on the day of the MRI scan until after the tests are completed. You are encouraged to consult with your child(ren)'s physician to discuss this decision. If your child becomes disruptive or experiences unnecessary discomfort during the evaluation, he will be instructed to take his medication, so bring the medication with you on the day of your visit.

POTENTIAL RISKS AND DISCOMFORTS

The study involves the following potential risks and discomforts: embarrassment and/or anxiety due to the discussion of personal information.

The risks or discomforts associated with MRI scans may include anxiety from being in a tight, enclosed space, or discomfort from staying still for too long. Should your child become anxious or agitated during the MRI scan, this research study will be immediately discontinued. The sound of the MRI scanner can be loud. We will provide earplugs to minimize the noise, but some people find the noise annoying. The magnetism of the machine attracts certain metals; therefore, people with metals in them (specifically, pacemakers, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from the study. The metal in dental fillings is less susceptible to magnetism and is therefore allowed. Your child will be asked about any potential sources of metal, and their pockets will be emptied prior to the study.

There is a risk that skipping a single dose of stimulant medication may cause short term behavioral deterioration that should reverse when medication is resumed.

ANTICIPATED BENEFITS TO SUBJECTS

While this study is not designed to improve your child's condition or health, possible benefits of this study include an evaluation of his or her diagnosis and screening of academic and intellectual functioning, which could be useful for educational and treatment planning. The results of this evaluation will be provided in the form of written feedback letters following your participation in the study. If you would like additional information or have any questions regarding the research, Drs. Clark or Levitt, or one of the project's doctoral level research psychologists will have a direct meeting with you or a phone consultation (at your preference) to answer your questions. They may be reached at 310-825-6731. Additional benefits include information regarding resources for treatment for individuals diagnosed with autism.
ANTICIPATED BENEFITS TO SOCIETY

The results of this project may lead to increased understanding of how autism affects brain development, which may be useful in improving diagnosis and treatment of autism.

ALTERNATIVES TO PARTICIPATION

An alternative to participating in this research study is not to participate. You may receive psychological and educational tests through a private psychiatrist or psychologist as an alternative to participating in this research study. MRI is not a routine part of the evaluation for autism.

PAYMENT FOR PARTICIPATION

Your child will be compensated in the amount of $100 per participant after completion. You will also receive paid parking.

SAMPLE REMAINING AT THE END OF THE STUDY

Study investigators may use your brain structure data and your psychological information for future research. This is why the information obtained in this study will be stored for an indefinite period of time.

INFORMATION ABOUT THE STUDY

On the checklist at the end of the consent form you are asked to let us know if you would like to receive general information about what this study found. You may also choose not to receive any information. Research is a long and complicated process. Obtaining general information from a project may take years.

FINANCIAL OBLIGATION

Neither you nor your insurance company will be billed for your child's participation in this research. You will not be financially responsible for any of the procedures (e.g., MRI) conducted as part of the research protocol.

EMERGENCY CARE AND COMPENSATION FOR INJURY

If you are injured as a direct result of research procedures not done primarily for your child's benefit, he or she will receive treatment at no cost. The University of California does not normally provide any other form of compensation for injury.

RELEASE OF INFORMATION

If your child has participated in other studies of autism at UCLA and/or other evaluations, you may be asked to release information collected during that study. If this occurs, you will be asked to sign a separate release of information form. If you choose not to release this information, it will not affect your child's participation in this study.

PRIVACY AND CONFIDENTIALITY

We will do everything we can to keep others from learning about your participation in the research. You
will be assigned an ID number that will be used to protect your identity. Any data or information on you that is entered into a computer for analyses or in correspondence will be identified by ID number only. The information obtained from your clinical evaluations and family history interviews done in this study may be shared with other researchers conducting similar research. You and your family will be identified only by ID numbers and your names will not be revealed to these researchers.

The results of all analyses and all identifying information will remain confidential. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Finally, the researchers will disclose, without your consent, information that would identify you as a participant in the research project under the following circumstances: child abuse, elder abuse, danger to self or others.

Authorized representatives of the UCLA Office for Human Research Protection Program may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

PARTICIPATION AND WITHDRAWAL

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

Circumstances may arise which might cause the investigator to terminate a subject's participation before the completion of the study. If you must drop out because the investigator asks you to (rather than because you have decided on your own to withdraw), you will still receive payment and may receive the information gathered from tests already conducted.

NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS

If you have any questions about the research, or in the event of research related injury or if you experience an adverse reaction, please immediately contact Jennifer Levitt, M.D. or Kristi Clark, Ph.D., Co-Principal Investigators. Dr. Levitt, Dr. Clark and Victoria Peccolo can be reached at 310-206-2101. Their address is: UCLA School of Medicine 635 Charles Young Drive South, Suite 225 Los Angeles, CA 90095-7334.

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not
waiving any legal claims, rights or remedies because of your participation in this research study. If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please call the Office of the Human Research Protection Program at (310) 825-5344 or write to the Office of the Human Research Protection Program, UCLA, 11000 Kinross Avenue, Suite 211, Box 951694, Los Angeles, CA 90095-1694.
SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES

__________________________________________
Name of Subject

__________________________________________
Signature of Subject

INFORMATION ABOUT THE STUDY
Please indicate below if you want to receive general information about the study. It is your responsibility to let the investigator know if your address and/or telephone number changes. The contact information is in this informed consent form under "Identification of Investigators".

☐ _______________ I want to receive general information about what the study found.

☐ _______________ I do not want any information about the study.

FUTURE CONTACT
Please check the appropriate box below and initial:

☐ _____ I agree to be contacted by your group regarding participation in other autism research projects.

☐ _____ I do not agree to be contacted by your group regarding participation in other autism research projects.

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject or his/her legal representative, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

__________________________________________
Name of Investigator

__________________________________________
Signature of Investigator

Date (Same as subject's)