CONSENT FORM

IRB Protocol Title: Motor Assessment in Children with Autism Spectrum Disorders (ASD) - Simons VIP Family Meeting July 24-26, 2015

Participation Duration: 1 Hour

Anticipated Number of Subjects: 30

Contact	Title	Contact Type	Numbers
Sylvie Goldman	assistant professor of neuropsychology	Principal Investigator	Tel: 212-342-3079
Greysi Sherwood	Clinical Research Coordinator	Study Coordinator	Tel: 212-305-4630

Research purpose:
The purpose of this study is to improve our knowledge regarding motor functions in children diagnosed with neurodevelopmental disorders caused by a genetic mutation such as 16q11.1 or 1q21.1 deletion. During this meeting we will measure and study children's gait. We will also evaluate the gait of non-affected siblings enrolled in the main *Simons Variation in Individuals Project* (Simons VIP).

Information on Research:
This consent form is written to address a research subject. If, however, you will be providing permission as the parent or legal guardian of a minor, the words 'you' and 'your' should be read as 'your child'.

You or your child is being invited to participate in this part of the project because you or your child have enrolled in the main Simons VIP study and has been diagnosed with a 16q11.1 or 1q21.1 mutation or a genetic neurodevelopmental disorder or is a healthy sibling volunteer.

The Simons VIP is a research initiative that aims at study children with genetic variation that increase the risk of developing autism spectrum disorder and developmental delays such as communication and social skills. Overall, there is no particular pattern of physical abnormalities that accompany the 16q11.1 or 1q21.1 deletion syndromes. Their prevalence are estimated at approximately 3 in 10,000 individuals. Researchers are studying how the missing genes contribute to the features of this syndromes.

Study Procedures:
During the Simons VIP Family Meeting, we will administer the gait analysis task using the *GaitRite* to children carrying these genetic variation and their control healthy siblings who have enrolled in the main project.

The *GaitRite* is as commercialized electronic walkway system that is approximately 4.25 meters long and equipped with 16,128 sensors encapsulated in a roll up carpet to produce an active area

of 24 inches wide and 168 inches long. The walkway will be easily installed in one of the hallway, it does not require any devices placed on the child's body and be used while wearing shoes. As the child walks naturally for a total of 10-15 minutes including different trials on the computerized *GaitRite*, the system generates accurate gait analysis by computing temporal and spatial parameter including step and stride length velocity and cadence.

The *GaitRite* analysis requires videotaping of the children's body movements for later scoring. All videos will be returned to Columbia University stored and saved by a coded patient identifier. Only individuals who are on the study protocol will have access to these recordings. These recordings will be stored for 5 years, and then will be deleted. These recordings will be used for data analysis of motion as well as for presentations at educational conferences.

Please initial your choice below:
_____ (initial) Yes, I agree to recording as described above.

_____ (initial) No, I do not want to be recorded

Parents will complete the *Pediatric Evaluation of Disability Inventory* (PEDI) questionnaire. This questionnaire measures abilities in three functional domains: Daily Activities, Mobility and Social/Cognitive. It takes about 30 minutes to complete, and is designed for use with children and youth (birth through 20 years of age) with a variety of physical and/or behavioral conditions.

Risks:
There are no more than minimal risks (those encountered in everyday life) involved in this study.

Completion of the study questionnaire may cause families to identify problems in family functioning that they may have been previously unaware of however, the study is not designed to provide diagnostic information for anxiety or other psychological conditions.

Reviewing developmental histories and adaptive functioning may cause mild emotional distress. The motor evaluation may cause some fatigue. You or your child may become somewhat bored or irritated with the repetitiveness of the task.

Benefits:
There is no direct benefit to you or your child for participating in this project. It is hoped that the gait measure being kept in the data base will contribute to our understanding and enhance the clinical care of children affected by the disorder.

Alternative Procedures:
You or your child may choose not to participate in this study.

Confidentiality of Study Data for Simons VIP Meeting July 24-26, 2015
Any information obtained in connection with this study and that can be linked to you or your child will remain confidential and will be disclosed only with your permission or as required by law.

You have the right to stop your authorization at any time. You may not stop your authorization for uses or sharing of information that has already happened, or if sharing of that information is still needed to complete analyses or de-identified report results from the research study.

If you or a member of your family has participated in the *Simons Variation in Individuals Project* (Simons VIP), your information from the Simons VIP (including medical diagnoses and other personal medical and demographic information) will be released to the study staff of this project. This information will be kept within the Goldman lab, linked only to a code name. Your actual name will be linked to these data only by a decoding key kept in a locked place in the Goldman lab. After you complete the current project, your new study information will then be shared back with the larger Simons VIP study.

Dr. Goldman will be responsible for all the study related materials while off-site at this meeting. All study related data will be collected and stored on a Columbia University encrypted, password protected lap top, and USB drive. All data collected is stored with a unique study ID with no personal, identifying information. It will be encrypted and transmitted to the Simons VIP central data base as well as in the protected study database at Columbia University. All paper materials collected (consent forms, and de-identified study forms) will return to our offices at Columbia University. Only the study coordinator has access to link your data to your personal information.

Compensation:
There will be no compensation for this part of the project.

Additional Costs:
There are no costs to you for taking part in this study.

Voluntary Participation:
You or your child's participation in this study is voluntary. You or your child may decide not to participate in the study. If you decide to participate, you or your child is free to withdraw from this individual part of the project at any time. Your refusal to participate or your early withdrawal will not affect your or your child's participation in the main Simons VIP project.

You or your child has the right to refuse to sign this form. If you or your child does not sign the form you or your child will not be enrolled in this gait research study. Refusing to sign will not affect your health care outside the study. Once you do sign this form, the authorization to use your health information will be in place unless you say, in writing to the research staff, that you no longer want it to be in place.

Additional Information:
If you have any questions about your role in this research, please contact Dr. Sylvie Goldman at Columbia University at 212-342-3079. For questions about your rights as a research participant please contact the Institutional Review Board (IRB) at Columbia University at 212-305-5883.

By signing this consent form, you allow the use and sharing of your previous study records and research records in the Simons VIP database for this study. In addition, you allow the

information from the current project to be subsequently shared back with the larger Simons VIP study.

I voluntarily consent to participate in the study. I have thoroughly read (or it has been read to me) this consent form and understand the nature and the purpose of the study. I have fully discussed the study with the investigator or study staff, have had the opportunity to ask questions and have received satisfactory answers. The explanation I have been given has mentioned both the possible risks and benefits to participating in the study and the alternatives to participation.

I am not waving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signature

Parent/Guardian
Print Name_____Signature_____Date_____

Person Obtaining Consent
Print Name_____Signature_____Date_____

Child
Print Name_____