<UNIVERSITY NAME> v 9-13-12
CONSENT TO BE PART OF A RESEARCH STUDY
INFORMATION ABOUT THIS FORM

You and your family members may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose, risks, and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Simons Variation in Individuals Project (Simons VIP)

1.2 Company or agency sponsoring the study: The Simons Foundation

1.3 Names, degrees, and affiliations of the researchers conducting the study:
<Researcher Information>

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The *<Site Name>* conducts clinical research seeking to advance understanding of autism spectrum disorders (ASD) and other developmental disorders. For this study, we are collecting developmental, behavioral and medical information about you and/or your children. We are also collecting blood samples (DNA) from all participating family members and the option to provide skin sample in willing participants. MRIs of the brain will be offered to participants who have not previously had a MRI of the brain. Developmental, behavioral, and structural brain imaging information will be stored in a central databank with Prometheus Research. DNA and skin cells will be stored in a central repository. Qualified researchers will access the databank and repository to look at how specific genetic factors may be linked to characteristics of ASD and other developmental disorders. In the event that researchers need additional information to further analyze findings, we will re-contact you and your family.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to.

3.1 Who can take part in this study?

All individuals with specified genetic variations thought to be associated with ASD and other developmental disorders will be eligible to participate in this study. In Phase I of this study, all individuals with deletions and duplications of 16p11.2 within 28.5 Mb-31.2 Mb are eligible for inclusion in this study, regardless of age, diagnosis, or other medical conditions. Phase II, which will take place simultneoulsy with the completion of Phase I, will enroll individuals with 1q21.1 abnormalities. The only other criterion for inclusion is a requirement for blood from both biological parents. The family members (parents and siblings) of the study participant in the

family with the 16p11.2 or 1q21.1 deletion/duplication (del/dup) will also be invited to participate. Participants with other known genetic conditions that affect brain function or participants who do not speak English well enough to answer the questions in the study and perform the study tasks will be excluded from the study.

3.2 How many people (subjects) are expected to take part in this study?

This research study is being conducted at several different universities throughout North America. The number of families recruited at all of the sites combined will total at least 200. At <*site name*>, we plan to recruit about <*number*> families into this study over the next two years.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

To confirm eligibility for the study, we will review the genetic test result that documents the 16p11.2 del/dup. For other family members willing to participate in the study, we will review the results of their genetic tests to determine if they also carry the 16p11.2 or 1q21.1 del/dup. If such genetic tests have not yet been performed, we will assist you in arranging for these tests to be performed in a clinical genetic laboratory. If you would like to know the results of your test, a genetic counselor will speak with you. Genetic counselors have experience in the areas of medical genetics and counseling, and they provide support to families undergoing genetic testing. More information on genetic counseling is provided later in this document.

Parents/participants will complete standardized questionnaires, interviews and forms about their own and their child's behavior, development, medical history, and daily interactions. The first interviews, about medical and family histories, will be performed by phone by a genetic counselor from Emory University. For participants who have a history of seizures, study investigators from Harvard University will conduct a seizure-specific interview over the phone with either the participants or their parents. There will be additional interviews at the time of the study visit. One of the interviews (the Autism Diagnostic Interview-Revised; ADI-R) will be videotaped so that the clinician and another person can verify the assessment of the participant**.** Parents will also complete standardized questionnaires about each other's behavior; feedback about these questionnaires will not be provided. Parents and siblings will also complete a battery of standardized tests to measure their verbal and non-verbal skills.

There is a possibility that we may want to use the videotape of your family's ADI-R for training and reliability purposes only. The videotape will include full facial features and voice recording. These clinicians will not receive information about your last names, addresses, or dates of birth. If you agree to this, the ADI-R videotape may be viewed by clinicians who conduct this research study at different universities. These videotapes will be stored in locked cabinets and will be kept indefinitely. Your decision regarding outside use of your family's ADI-R videotape will not affect your family's participation in this research study. You will not receive any additional compensation for these tapes.

Please sign and check the appropriate box below to indicate your preference.

__ I allow the videotape of the ADI-R. It will be used for training, reliability, and additional analysis purposes.

__ I do NOT allow the videotape of the ADI-R.

Signed:_____Date:_____

Participants with specified genetic variations will complete a battery of age-appropriate standardized tests to measure verbal, nonverbal, social-communication and motor development skills. One of the tests (the Autism Diagnostic Observation Schedule; ADOS) will be videotaped so that the clinician and another person can verify the assessment of the participant with Autistic Spectrum Disorder (ASD). These videos will also be used to document early behavior and communication for very young children and as baseline information for possible longitudinal or other studies or analyses. Parents will receive a brief written report summarizing the results of this session. Some participants with Autistic Spectrum Disorder may have previously completed some or all of these tests; however these tests may need to be redone for this study.

Siblings of those participants having specific genetic variations will complete a similar battery of age-appropriate standardized tests to measure verbal, nonverbal, social-communication and motor development skills. One of the tests that may be administered (the Autism Diagnostic Observation Schedule; ADOS) will be videotaped so that the clinician and another person can verify the assessment of the participant with Autistic Spectrum Disorder. These videos will also be used to document early behavior and communication for very young children. Parents will receive a brief written report summarizing the results of this session. Some participants may have previously completed some or all of these tests; however these tests may need to be redone for this study**.**

There is a possibility that we may want to use the videotape of your family's ADOS for training and reliability purposes only. The videotape will include full facial features and voice recording. These clinicians will not receive information about your last names, addresses, or dates of birth. If you agree to this, the ADOS videotape may be viewed by clinicians who conduct this research study at different universities. These videotapes will be stored in locked cabinets and will be kept indefinitely. Your decision regarding outside use of your family's ADOS videotape will not affect your family's participation in this research study. You will not receive any additional compensation for these tapes. Please sign and check the appropriate box below to indicate your preference.

__ I allow the videotape of the ADOS. It will be used for training, reliability, or additional analysis purposes.

__ I do NOT allow the videotape of the ADOS.

Signed:_____ Date:_____

All participants will have height, weight and head circumference measured. Head and face 3D digital scans and/or regular 2D photographs will be taken to allow researchers to look at how facial/head features may be related to the genetics of autism. The pictures will include full facial features. These researchers will not receive information about your last names, addresses, or dates of birth. These photo files will be stored on password protected computers in locked offices and will be kept indefinitely. You will not receive any additional compensation for these photos.

All participants will have a standard neurological exam appropriate to the age of the participant.

All participants will have blood drawn. About three tablespoons or 40 cc of blood will be collected for research genetic analyses. In rare instances, if the amount of blood recovered is not sufficient to enable completion of the protocol or in case of laboratory error, it may be necessary to contact the participant again for a blood redraw.

There are methods currently available to take skin cells and convert them into other cells type by reprogramming the cells into immature embryonic stems cells and then making those cells mature into brain cells (neurons) and other cells. In the future it may be possible to convert blood cells into other cell types as well through the same technology. The ability to study neurons from patients is extremely powerful because it is otherwise extremely difficult to understand how the brain works since we cannot study the tissue directly since you need your brain cells. These types of studies may help us understand better how brains cells from patients with 16p11.2 deletions and duplications work differently than other individuals.

_____ I give my permission to have induced pluripotent stem cells (iPS) generated from my or my child's donated blood if and when that technology becomes feasible.

_____ I do not give permission to have induced pluripotent stem cells (iPS) generated from my or my child's donated blood if and when that technology becomes feasible.

For some participants we may ask to collect fibroblasts (skin cells) to from an incision site with routine surgery (done for other reasons) or a skin biopsy. If a skin biopsy is necessary, Dr. ___ will perform this procedure after injecting numbing medicine to minimize the pain. A 3 mm biopsy will be performed on the inner arm or outer thigh under sterile conditions to prevent infection. This tissue may allow us to create models of brain cells to better study the properties of brain cells in patients with autistic features.

____ I consent to skin biopsy at the incision site at the time of surgery.
____ I consent to a skin biopsy outside of surgery.
____ I do not consent to a skin biopsy.

After blood and skin (if provided) have been collected from participating family members, it will be sent to Rutgers University Cell and DNA Repository (RUCDR). RUCDR collects, maintains and distributes all specimens associated with this study. DNA will be extracted from specimens and stored indefinitely at RUCDR.

De-identified information will be stored in a central databank associated with this study at Prometheus Research. This de-identified information may include demographic, medical, developmental, brain imaging, and behavioral information collected at <*site name*>. Digital photographs will be analyzed for facial features associated with the deletion/duplication of 16p11 or 1q21.1 at Columbia University, and the images will be stored there. Data obtained from the 3D digital scan will be sent to the Eunice Shriver Kennedy Center at the University of Massachusetts for analysis. These data may be sent to and stored in the central databank at Prometheus Research. Qualified researchers will access the DNA at RUCDR and the de-identified information in the central databank to look at how specific genetic factors may be linked to characteristics of Autistic Spectrum Disorder and other developmental disorders.

If consent to storage of the tissue sample is withdrawn at any time, Rutgers University Cell and DNA Repository shall promptly destroy the sample or portions thereof that have not already been used for research purposes. In no event shall family members of an individual who provided a stored tissue sample be contacted for clinical, research, or other purposes without consent from the individual who provided the tissue sample with respect to the specific family members who will be contacted and the specific purpose of the contact. In no event shall any information about an individual derived from genetic tests performed on stored human tissue or information linking an individual with specific results of genetic tests be released to any organization or person without the explicit written consent of the individual who donated the stored tissue to release of the information for the purposes set forth in the written consent document.

All participants over age 6 with the specified genetic variation (del or dup 16p11.2 or 1q21.1) will have a structural MRI performed without sedation and without contrast. If a previously administered MRI of the brain is deemed adequate for these research purposes by the study neuroradiologist, then a brain MRI may not be necessary. Data from the MRI studies will be sent to the University of California, San Francisco for analysis and storage. Additional imaging protocols may be instituted for selected individuals. Separate consent will be obtained for these studies.

One of the forms completed as part of this research study is associated with the National Database for Autism Research (NDAR). NDAR is a program created by the National Institutes of Health (NIH). The information collected from this form allows NDAR to create a unique subject number that will allow researchers to see if your family has been involved in more than one autism research study. If your family has participated in more than one autism research study, this unique subject number may prevent any incorrect duplication of findings. This subject number will also allow your de-identified data to be combined via NDAR with data from other research studies to increase the likelihood of meaningful analysis findings. Only this subject number and not your personal identifiable information will be accessible to NDAR.

All procedures completed as part of this research study are paid for through the study sponsor (The Simons Foundation). At no time will you or your insurance be billed for these research procedures. Some of the research procedures are similar to those provided by the <*site name*> clinic. If your family wants to pursue additional services through the <*site name*> clinic, we will refer you to our clinic office. Any additional clinic services are not part of this research study and would be billed to your family or your family's insurance.

It is possible that researchers will need additional information to further analyze or extend findings from some of the procedures in this study. If this occurs, we will re-contact you for follow-up information or to ask if you are willing to participate in additional studies. If you are not comfortable with this, you should not provide consent. We may also give you the opportunity to participate in an annual meeting for the purpose of conveying information on the progress of the study and to provide an informal setting for interacting with other participating families. Participation in this annual meeting would be entirely voluntary. In the box below, please provide alternate contact information in case we cannot contact you using your current contact information.

Alternate Contact Information for Possible Follow-Up:

Name: _____
Relationship: _____

Address:_____

Phone Number: _____
Alternate Phone Number: _____

E-mail (optional): _____

For children under 60 months of age, we have a unique opportunity to study how different behavioral patterns emerge and change over time. A longitudinal portion of our study involves in-person follow-up visits for your child at 6 and/or 12 month intervals, with phone calls between visits to check in. These in-person follow-up visits would be less time intensive than your initial visit, and would take 1 day.

Please check and initial the appropriate box below to indicate your preference.
____ I wish to enroll in the longitudinal portion of the study.
____ I do NOT wish to enroll in the longitudinal portion of the study.
____ N/A (i.e., child out of age range).

4.2 How much of my time will be needed to take part in this study?

The behavioral and cognitive evaluation part of the study requires about 11-14 hours of combined parental time (to be split between parents), 2.5 to 4 hours for your child with del or dup 16p11.2 or 1q21.1, and 2 hours for the sibling. The blood draw requires about 20 minutes for each family member to complete. The MRI evaluation will require approximately 60 minutes. The neurological exam will take approximately 30 minutes. All study procedures will generally be scheduled at one time and will take place over 2 days. It is possible that researchers will need additional information to further analyze study findings. If this occurs, we will re-contact you for follow-up information.

4.3 Will there be any therapy provided as part of this study?

There will be no therapy associated with this research. However, the molecular investigations performed in the course of this study will sometimes provide more precise diagnostic information to participants, their families and their physicians, which may significantly affect genetic counseling, prognosis, management, and decisions related to reproductive options. Frequently, molecular investigations will demonstrate that the genetic abnormality present in an affected individual is sporadic with no increased recurrence risk for parents or other relatives in future pregnancies. Project staff includes trained genetic counselors who will be available to discuss genetic test results with you. Participants will be referred back to their medical home for additional genetic counseling if indicated.

4.4 When will my participation in the study be over?

In addition to the time above, qualified researchers who have permission to access the central databank and repository will access your information (i.e., de-identified data, DNA, skin cells) to analyze the genetics of Autistic Spectrum Disorder or other developmental disorders. The central databank and repository will be available for researchers indefinitely. If researchers need additional information to further analyze or extend any findings, we will contact you for follow-up information. If you are not comfortable with this, you should not provide consent to participate in this study.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Since the evaluation portion of this study takes between 2.5 and 4 hours of your child/children's time, there is a risk that he/she may become bored or tired. This amount of time is typical for an evaluation so we minimize this risk by allowing breaks and snacks as needed. We will take breaks and can reschedule as necessary.

You and/or your child/children may experience mild discomfort when blood is collected. After the blood draw, you may feel soreness or tingling in your arm. Some participants may experience bleeding, a small bruise, clot, or infection at the site of the blood draw. In rare situations, the blood draw may cause you to feel tired (fatigue), and lightheadedness and/or fainting may occur. A minority of participants may feel nauseous and or vomit during or after the blood draw. Care will be taken to avoid all complications.

Standard structural MRI evaluation involves the following risks: Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during the examination. Precautions will be taken to insure that no loose metal objects are in the room. Participants who have any pieces of metal in their bodies will not be allowed in the MRI room and will not receive an MRI evaluation. There may be some discomfort associated with the MRI procedure, in particular, feelings of claustrophobia and discomfort from the loud banging noise during the study. Participants will be asked to wear earplugs to prevent temporary hearing loss that has occasionally been reported from the loud noise.

Genetic testing of family members as part of this study may reveal a previously undetected chromosomal abnormality. If that occurs, you will be informed of this finding. This is because it may explain why the person has a developmental disability, and/or pregnancy loss. It also provides the information needed for thorough genetic counseling. But, sometimes learning that a person has a genetic abnormality can cause emotional problems or a disruption in family relationships. In order to lessen these risks, results are given to you through doctors and genetic counselors who have experience in helping people and families understand the results and implications of genetic testing. The doctors and genetic counselors associated with our study can provide support, information, and referrals to other medical or counseling specialists in order to help people and families adjust to results of genetic testing in a healthy manner.

Regarding action in the event that information of medical significance is found during the course of this study:

At this early stage of genetic research in autism and other developmental disorders, we do not anticipate finding meaningful genetic information of use to you. However, if we do find any information of use to you, we will inform you of this information and may refer your family for further clinical evaluation. You are given the option of not being contacted in the event that we find meaningful genetic information.

Please sign and check the appropriate box below to indicate your preference.

_____ I would like to be contacted to discuss medically significant findings.

_____ I would NOT like to be contacted to discuss medically significant findings.

Signed:_____ Date:_____

During the genetic analysis of your DNA, there is a possibility that researchers may reveal that you are not biologically related to your other family members who participated in this study. If this occurs, at no time will this information be disclosed.

Your child's brain MRI will be reviewed by a board certified neuroradiologist at <*study site*>. Whenever an MRI of the brain is conducted, there is a chance that the neuroradiologist will observe an Incidental Finding (IF). An IF is a finding of potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study.

There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as anxiety over a finding for which no treatment is required or appropriate). We will describe three different types of IFs and explain the way that our study manages each type below. All participants will receive a CD/DVD of MRI images to keep. For some participants, a copy of the radiology report prepared by the neuroradiologist reviewing your scan will be included with your CD/DVD. In some cases, you will need to opt-in or opt-out of receiving information about your scan by writing your initials in the appropriate space below. You can change your preferences by contacting the research coordinator.

Please remember that the information we collect is for research purposes only and is not meant to replace a diagnostic clinical report as would be provided by your personal physician. We cannot give recommendations except to refer you to your child's personal clinician (or make a referral if you do not currently have one) so that they can make a more complete assessment.

1. Incidental Finding of Strong Net Benefit

You will be informed of all findings of strong net benefit that may be revealed during the imaging procedure. Findings of strong net benefit are likely to uncover a problem that is serious and that may be treatable. For example, if we suspect a condition such as a brain tumor or an aneurysm, the study's neurologist will communicate these findings to you in person. If returning to <*study site*> for a findings review is not possible, these results will be communicated using a video and phone conference with the study neurologist. After this conference, you will be advised to follow up with your child's primary care physician if you still have further questions and/or if clinical care is needed to address these findings.

You may choose to have your child's physician informed of IFs of strong net benefit by writing your initials below. Please note, however, that if you choose to have your physician informed of any findings of clinical significance, that report will likely be placed in your medical record. Please indicate your preference by writing your initials on the appropriate line:

_____ Please inform my child's doctor of findings that are likely to be related to a serious health condition

OR

_____ Please do not inform my child's doctor of findings that are likely to be related to a serious health condition

If you **do** wish us to report any findings to your physician, you must provide us with the name and
location of your primary physician, prior to your MRI.

Name of primary physician_____
Contact information

2. Incidental Finding of Possible Net Benefit
There is a chance that the MRI will reveal an IF of possible net benefit. This type of IF may or may or may not uncover a problem that is real and possibly treatable. An example of this type of IF in a brain MRI is an increase in the number of white matter spots which may have been caused by brain injury, is static and does not require treatment. However, the white matter spots may reveal a treatable condition such as hypertension or type 2 diabetes. Because these findings are of uncertain origin and they may not be treatable, there may be little benefit to learning such results.

You can choose to learn about IFs of possible net benefit that we observe on your MRI OR you can
choose not to receive such results. Please indicate your preference by writing your initials next to the appropriate statement below.

_____ I choose to opt-in and receive an MRI report about IFs of possible net benefit.

_____ I choose to opt-out of receiving an MRI report about IFs of possible net benefit.

If you chose to opt-in and receive an MRI report about IFs of possible net benefit, the study's neurologist will communicate these findings to you in person. If returning to <*study site*> is not possible,
these results will be communicated using a video and phone conference with the study neurologist. After the conference, you will be advised to follow up with your primary care physician if you still have further questions and/or if clinical care is needed to address these findings.

3. Incidental Finding of Unlikely Net Benefit
Some brain MRIs may reveal a condition that is not likely to be of serious health importance or whose health importance is unknown at this time. An example of this type of finding is an arachnoid cyst, or a fluid filled sac located inside the brain or spine. Usually, arachnoid cysts do not have symptoms and do not require treatment. Because arachnoid cysts and other findings of unlikely net benefit are of unknown significance or are known to have no health significance, there may be little to no benefit to learning such results. If the IF is determined to be of unlikely net benefit we will NOT provide you with a report of your MRI results.

4. No Findings
Sometimes brain MRIs will not have IFs. If this is the case we will NOT provide you with an MRI report.

We will take standard precautionary measures to protect confidentiality. However, it is possible that a breach of confidentiality (i.e., a loss of privacy) could occur and insurance companies or current or potential employers would acquire the genetic information obtained from this study. Currently, there are federal laws that protect against discrimination on the basis of genetic information in health insurance and employment. Your confidentiality will be protected to the extent provided by federal, state, and local law.

As with any research study, though, there may be additional risks of participating that are unforeseeable or hard to predict.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

You should discuss participation in more than one study with the researchers, since some types of studies (e.g., questionnaire style studies) may not pose any significant difficulties.

5.4 How could I benefit if I take part in this study? How could others benefit?

We cannot promise that you personally will receive any benefits from being in this study. This study may help us to understand better the genetics of Autistic Spectrum Disorder and the behavioral, cognitive, and structural brain consequences of specific genetic variations. However, this information may not directly benefit you. Individuals with specific genetic variations in the future, their family members and future generations may benefit if we can better understand the genes related to Autistic Spectrum Disorder and other developmental disorders. We do not expect to discover any information of direct clinical relevance to you in the near future.

You will be provided with some test results about your child and your family as part of this study. You will receive the results of the clinical genetic testing for the 16p11.2 or 1q21.1 del/dup if this has not already been performed for yourself, your partner, and your children. You will receive a report of your child's MRI if one is performed. You will also receive a summary of your child's neuropsychological testing scores.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Participation in this study is voluntary. You may refuse to participate or leave the study at any time. This will not affect the care you are currently receiving or the care you may receive in the future at <site name>.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no foreseeable harm if you should decide to leave this study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

The researcher believes that it is not in your best interest to stay in the study.
You or your family becomes ineligible to participate.
The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. Your family will be compensated for any parking or other travel costs associated with this study. If you receive a bill for any procedures completed as part of this study, please call the researchers' number listed in section 10.1.

If complications occur as a result of this study, the researchers or the <site name> will help arrange for medical treatment, including, if necessary, emergency treatment. This study does not, however, pay for these costs. They may be billed to your insurer. You may have to pay for these costs if you health insurance does not cover them.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

For completing the protocol of this study each member of your family who participates will receive a gift certificate for $100.00. Participants in the longitudinal part of the study will receive additional compensation.

8.3 Who could profit or financially benefit from the study results?

You will not be compensated for any commercially valuable products that may be developed or are discovered as a result of the research funded in this study.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

All information collected about you and your family members will be maintained in a manner specified by professional codes and ethics. Written records, videotapes, and photographs will be kept in locked cabinets in locked offices at <*site name*>.

If you consent to allow your family's videotaped ADI-R and/or ADOS to be used for training, reliability, and additional analysis purposes, it/they will only be watched by clinicians associated with this research study at different universities. No information will be provided to these clinicians that would directly identify your family (e.g.: last names, addresses, dates of birth, etc.).

All information will be maintained in a password-protected, electronic database on a firewall-protected server. We shall not allow anyone to see your record, other than people who have a right to see it. All research records will be kept indefinitely after the study ends.

All original 3D image data sent to the Eunice Shriver Kennedy Center at the University of Massachusetts for analysis will be labeled with a unique identification code and will not contain your name or any other personal information. Data and images will be kept secure, with computer information kept in a password-protected computer on a firewall-protected server. 3D images generated from the data cannot be seen without a password and proprietary software. 3D image print-outs will be kept in a locked file cabinet in a locked office. Only researchers at the Eunice Shriver Kennedy Center at the University of Massachusetts who are analyzing the 3D image data have access to the password and 3D image print-outs. After analysis is complete, all analysis data may be transferred to the central databank at Prometheus Research. All 3D images and original image data will be retained at the Eunice Shriver Kennedy Center at the University of Massachusetts under the secure conditions described above.

Your family's standard set of pictures, including 3D images, will be sent initially to Columbia University Medical School on a password protected CD. All pictures will be labeled with a unique identification code and will not contain your name or any other personal information. Any print outs of the pictures will be kept in a locked file cabinet in a locked office. Only researchers at the Columbia University Medical School who are analyzing these pictures will

have access to the CD password and print-outs. The pictures will be retained at the Columbia University Medical School under the secure conditions described above.

To help protect you and/or your child's privacy the investigators of this study have obtained a Certificate of Confidentiality from the National Institutes of Health, part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government.

With this Certificate, we, the investigators, cannot be forced (e.g., by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your familyfrom voluntarily releasing information about your child, yourself, or your involvement in this research. Note however, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

We are also asking your consent to provide research data and related findings to NDAR. NDAR is a biomedical informatics system and data repository, created by the National Institutes of Health to assist biomedical researchers working to develop a better understanding of autism and/or to develop more effective methods to diagnose, treat and prevent autism spectrum disorders.

The data from the form associated with NDAR will be entered into a local program that converts the data into strings, encrypts it and sends it to a server at NIH. The encrypted strings are stored in the NIH database and used to generate a unique identifier. No personal information will be shared with NIH. The encryption method is designed to be extremely secure, to prevent converting the string back to your original identifying information.

Data entered into NDAR will be kept confidential, with NDAR being designed for access by researchers only. Data provided to NDAR as part of you and/or your child's participation in this research study will be de-identified—i.e., you and/or your child's name will be separated from the data. However, since this institution and others submitting data to NDAR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" that will help NDAR and participating institutions avoid being forced to disclose information that may identify you as an NDAR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you, your child, or others such as in cases of child abuse or neglect. With respect to you and/or your child's participation in NDAR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

All information sent to the central databank at Prometheus Research, the Rutgers University Cell and DNA repository (RUCDR) and the <*local site genetics*> Department will be labeled with a unique identification code. This code does not contain your name or any other personal identifying information. All data stored in the central databank at Prometheus Research, RUCDR, and the <*local site genetics*> Department is de-identified. To link the data to your personal files, access to a coding sheet, or "key," is required. This sheet will contain your name and the unique code. It will be maintained electronically in a secure database and a hard copy will be kept in a locked file cabinet in a locked office at <*site name*>. Only <*site name*> research staff members will have access to this coding sheet.

In no event shall family members of an individual who provided a tissue sample be contacted for clinical, research, or other purposes without consent from the individual who provided the tissue sample with respect to the specific family members who will be contacted and the specific purpose of the contact. In no event shall any information about an individual derived from genetic tests performed on stored human tissue or information linking an individual with specific results of genetic tests be released to any organization or person without the explicit written consent of the individual who donated the stored tissue to release of the information for the purposes set forth in the written consent document.

Your privacy will be protected by federal, state, and local law.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may include information about your health and your medical care before, during, and after the study, even if that information wasn't collected as part of this research study. For example:

- Mental health care records (except psychotherapy notes not kept with your medical records)
- Medical history records
- All records relating to the treatment you have received at <*site name*>.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

This project is a multi-site, multi-disciplinary collaboration among investigators at several research institutions. For effective analysis of study data and coordination of scheduling among the various components of the study, personal identifying information may be shared among the recruitment core at Emory University, the clinical sites at Harvard University, Baylor College of Medicine, Emory University, and the University of Washington and the neuroimaging sites at the

University of California at San Francisco and Children's Hospital of Philadelphia. By initialing below you give your consent for your family's data, including personal health information, to be shared among the participating centers.

_____ I give my permission for my family's data and personal health information to be shared among the research centers listed above.

Although every effort will be made to protect the confidentiality of your records, absolute confidentiality cannot be guaranteed. By signing this document you grant permission for information about you obtained during the study to be made available to:

-The investigator, study staff and other health professionals who may be evaluating the study;

-Authorized representatives of the sponsor of this research (The Simons Foundation);

-Columbia University;

-New York Presbyterian Hospital;

-Authorized representatives of the Office of Human Research Protections ('OHRP') or other government regulatory agencies; and

-Applicable Institutional Review Boards ('IRBs') that independently review the study to assure adequate protection of research participants, as required by federal regulations.

The investigator, regulatory authorities, IRB and study sponsor may keep the research records indefinitely. If the results of the study are published or presented at a medical or scientific meeting, you will not be identified.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:
To avoid losing study results that have already included your information
To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the <*university name*>, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the <*university name*> Notice of Privacy Practices. This information is also available on the web at <*web link*>. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health

Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission will not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).
If you withdraw permission to store the tissue sample at any time, we will promptly destroy the sample or portions thereof that have not already been used for research purposes.

This is not a treatment study. The information being collected is for research purposes only. The alternative to participation is not to participate. Your medical care will not be jeopardized in any way if you choose not to participate. You are welcome to participate in other research studies and other Simons Foundation activities if you choose not to participate in this study.

You/your child is not waiving any of your/their legal rights by participating in this research.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:
Obtain more information about the study
Ask a question about the study procedures or treatments
Report an illness, injury, or other problem (you may also need to tell your regular doctors)
Leave the study before it is finished
Express a concern about the study

Principal Investigator:	*<Investigator name>*
Mailing Address:	*<Investigator address>*
Study Manager:	*<Study manager name>*
Mailing Address:	*<Study manager address>*

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the *<university name>* Compliance Help Line at *<phone number>*.

<University IRB name & contact information>

If you are concerned about a possible violation of your privacy, contact the *<university name>* Health System Privacy Officer at *<phone number>*.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRB number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following

documents:

This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular <university name> medical record).*

Other (specify): *<Site name>*

12. SIGNATURES

Research Subject

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request.

Signature of Subject (or parent if a minor): _____ Date: _____

Signature of Subject (or parent if a minor): _____ Date: _____

Name of Subject: _____ Date of Birth: _____

I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions about this aspect of the study have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request.

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____