RESEARCH CONSENT/PARENTAL PERMISSION/AUTHORIZATION FORM

PROJECT # 2011-0320

STUDY TITLE: SIMONS VARIATION IN INDIVIDUALS PROJECT RECRUITMENT, INTAKE AND RETENTION (SIMONS VIP)

GEISINGER PRINCIPAL INVESTIGATOR: Cora Taylor, PhD
COLUMBIA UNIVERSITY PRINCIPAL INVESTIGATOR: Wendy K. Chung, MD, PhD
SITE(S): Telephone and Geisinger Clinic
PHONE NUMBER: 570-522-9430 (855-329-5638)
24-HOUR PHONE NUMBER: 570-271-6211 (HOSPITAL SWITCHBOARD)

In this consent form "you" always refers to the person taking part in the research study. If you are a parent or guardian, please remember that "you" refers to the person taking part in the research study.

You are being asked to take part in this research study because you or someone in your family has a genetic change that has been associated with autism spectrum disorders. This is a research study. Research studies include only participants who choose to take part. Please take your time to make your decision and ask questions of the study team.

This form serves two purposes: 1) It provides information about the research study and the possible benefits and risks involved; 2) It describes the protected health information (PHI) that will be obtained during the research study--how the PHI will be used and with whom it will be shared.

Geisinger Clinic is being reimbursed by the Simons Foundation for expenses related to conducting this study.

As part of the online consent process, you will be required to indicate that you understand the study at several points. If you do not understand any section, you will have the option to contact the Simons VIP Coordinator by email or phone for assistance.

You will be able to review, download and/or print a complete copy of this consent form upon completion.

Next

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to recruit individuals and families with changes in their chromosomes (copy-number-variations) or genes that may be associated with autism spectrum disorders (ASD) and other developmental disorders. For this study we are collecting developmental, behavioral and medical information about you and your children. You will have one or more telephone interviews to discuss the study and verify that you are eligible to participate. If you meet all the study qualifications, you will complete further evaluations to better understand your health, development and behavior, as described below. In the event that researchers need additional information, we will re-contact you and your family.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 5000 people will take part in this research study online and at several medical centers in the United States. Around 4000 people will be enrolled by the study coordinator at Geisinger Clinic. Less than 50 participants will be Geisinger Medical Center patients.

I understand that this study is being done to learn more about genetic changes that may be associated with autism spectrum disorders and other developmental disorders.

☐ I understand
➔ If online, will take to next page
☐ I have a question
➔ If online, will pause consent process and pop-up "Questions" page, see page 20
➔ If written consent, will provide coordinator contact info here

WHAT IS INVOLVED IN THE STUDY?

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

Initial intake and evaluation (performed for all study participants):

- You will be contacted by the study coordinator and a copy of the laboratory report confirming the genetic results will be requested. The study coordinator will be available to assist you in obtaining a copy of the report.
- The laboratory report will be reviewed and you will be informed if you qualify for the study.
- If available, both biological parents are strongly encouraged to participate.
- It is important to confirm if the genetics change is inherited from one of the parents or if it is a new change. If parents have been tested, copies of their laboratory reports will be required.
- If parents have not been tested, genetic testing for the parents will be arranged at no cost. This can be done either through the parents' healthcare provider, or through a blood-drawing service that can come to you at a time and place you determine.
    - In the future, the option for genetic testing by saliva sample, cheek swab, or blood spot (similar to heel-prick testing done for newborns or finger-prick done by individuals with diabetes) may be available. The study team will let you know if this is an option at the time that you join the study.
- Masters-level trained genetic counselors will be available to provide genetic counseling regarding your test results performed as part of this study or previously performed. Please note that family members may be informed of, or may be able to infer, your genetic testing results as needed for explanation and planning purposes.
- A study coordinator, or a medical records retrieval company called MediConnect, will assist you in requesting copies of other medical records as needed. If a clinical MRI has been previously performed, a copy of the data files from the MRI will be requested.
- If you participated in the Simons Simplex Collection project, the information gathered may also be used in this project.
- One or more telephone interviews to review the Medical History Form and discuss the family history information. These telephone interviews will be at your convenience and evening and weekend options will be available.

Phase 1:

Initially, this study was coordinating in-person clinical site evaluation visits for families at Baylor College of Medicine in Houston, TX; Harvard University in Boston, MA; University of Washington in Seattle, WA; Children's Hospital of Philadelphia in Philadelphia, PA; and University of California, San Francisco in San Francisco, CA. Families enrolled in this phase of the study would travel for 2-3 days of neuropsychological, behavioral and cognitive testing and MRI evaluations.

Phase 2:

In Phase 2, this study is performing remote (online, phone, mail) assessments by having you complete standardized surveys, interviews and forms about the development, medical history, and daily interactions of **each** family member of interest to the study.

The type of online research surveys a participant will be asked to complete will **depend on multiple factors,** such as the individual's age, relationship in the family (parent, sibling, etc.) and whether they have the genetic change being studied.

Individuals enrolled in Phase 2 will complete (or have completed for them, depending on their age and abilities) multiple online research surveys to measure behavior and verbal, nonverbal, social-communication and motor development skills. Individuals who have participated in Phase 1 or the MHI (Medical History Interview)-only protocol will also complete online research surveys. However, some surveys will not need to be repeated if they were completed in the past. Some participants may have previously completed some or all of these surveys either clinical or as part of a research study; however, these surveys may need to be redone for this study.

At the beginning of each online research survey you will see a brief description and will have the option to choose whether or not to complete the survey. You can view a current list of online research surveys on the Simons VIP Connect website.

For participants who have a history of seizures, study investigators from Harvard University may conduct a seizure-specific interview over the phone with either the participants or their parents.

The intent of the project is to share information with participants. This means that for some surveys you will not receive feedback, for some surveys you may receive personal results, and for others we may only be able to provide study population (group) results.

Adult participants will be asked to answer questions about their spouse/partner or to have their spouse/partner answer questions about them; individual results from these questionnaires will not be provided.

We may also ask **your child's teacher** to complete research surveys about your child's behavior in the classroom; feedback about these surveys will not be provided. Your child's teacher will be instructed to discuss any concerns with you directly.

At this time, recruitment is focused on enrolling participants for Phase 2 of the study.

If my family is found to be eligible for this study based on a review of my/my child's genetic lab report, we will be offered genetic testing for any family members who have an increased chance to carry the specified genetic variation and have not already been tested. We will also complete remote (online, mail, phone) assessments regarding behavior, development and medical history. These assessments will vary depending on the age of the person and whether they carry the genetic difference being studied.

By completing this online consent, I will be enrolling in Phase 2 of the Simons VIP study.

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HOW LONG WILL I BE IN THE STUDY?

While each online research survey will vary in length, most of the online research surveys are estimated to take between 5-30 minutes to complete; the medical history interview (MHI) may take up to 60 minutes to complete and is completed both online and by phone. The online and paper questions in Phase 2 are expected to take a total of about 2-4 hours to complete for each family member. If you become tired while completing the measures, you may take a break at any time. Online assessments may be saved and completed at a later time.

Some of the same online and paper research surveys will be repeated over time to see if anything is changing. You will be notified to repeat these surveys on an annual basis. You can choose not to provide additional follow-up information by not completing the research surveys, but will continue to receive reminders unless you withdraw from the study.

It is possible that additional online questions will be added in the future, and you will be invited to complete those questions as well.

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.

You will be in the research study indefinitely, unless you choose to withdraw. There is no expiration date for the use and disclosure of your protected health information.

Once a child participant reaches the age of 18, he/she will be able to participate in the Simons VIP Phase 2 study as an adult. In order to make this transition, they will need to provide their own consent by independently signing the informed consent, or be consented through their legally appointed representative (LAR).

I understand that each research survey will take between 5-60 minutes to complete and I will be asked to take surveys again in the future. I can choose not to provide follow-up information at any point. Until I withdraw from the study I will continue to receive notifications regarding follow-up research surveys.

My study data will be kept indefinitely

If my child turns 18 and still wants to participate in the study, he/she will need to complete a separate consent as an adult.

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WHAT ARE THE RISKS OF THE STUDY?

Drawing blood from your arm may cause pain, bruising, lightheadedness, and on rare occasions, infection. Care will be taken to avoid all complications.

If saliva and/or cheek swab and/or blood spot samples become method(s) of sample collection in this study, the following statement(s)* apply:

* There are no increased risks related to providing a sample by saliva or cheek swab.
* Providing a sample by blood spot may cause a small amount of pain and bruising, and the site may bleed slightly for a time after the blood is collected. There is also a very rare chance that the site could become infected.

Genetic testing of family members as part of this study may reveal a previously undetected genetic change. If that occurs, you will be informed of this finding. Most families find this information helpful. 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 genetic counselors who have experience in helping people and families understand the results and implications of genetic testing. The 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.

During the genetic analysis of your DNA, there is a possibility that clinical testing 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 to you or anyone else.

Phase 2 remote assessments are not expected to add any additional risks to you. Sometimes these types of assessments can bring up feelings of distress (for example, if results reveal an unexpected finding). If at any time you feel uncomfortable or have any concerns while completing the Phase 2 online research surveys please contact the study coordinator (coordinator@simonsvipconnect.org)(855-329-5638).

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. A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Your confidentiality will be protected to the extent provided by federal, state, and local law. For more information about confidentiality, please see below.

I understand that the risks of this study include:
Blood draw risks
Genetic testing risks
Confidentiality risks
Chance for unexpected findings

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ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There will be no direct benefit to you for being in this research study. This study may help us to understand better the genetics of ASD and the behavioral, cognitive, and structural brain consequences of specific genetic variations. Individuals with specific genetic variations, their family members, and future generations may benefit if we can better understand the genes related to ASD 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 specific genetic variation in your family if this has not already been performed. You may also receive feedback on some individual tests that were part of the online study. You will receive combined, group information from all participants on other tests and questionnaires.

I understand that there may be no direct benefit to me for participating in this research study, but information learned may help others in the future.

I will receive the results of any clinical genetic testing performed.

I may receive feedback on some individual Phase 2 assessments and on some group results on others.

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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 check the appropriate box below to indicate your preference.

I understand that while it is unlikely that this study will identify any medically significant findings that will be useful to be, I may decide whether I want to be contacted to discuss this information.

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

WHAT OTHER OPTIONS ARE THERE?

You have the option to not take part in this study.

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WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access.

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 family from 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.

If you agree to participate, you will also be allowing Simons VIP to provide research data and related findings to NDAR (National Database for Autism Research). 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.

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 or risk of imminent harm to self or others. 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.

Information from the research study will not be used to target you for marketing or sales communications.

Geisinger Clinic has several departments that are responsible for making sure research is performed according to federal and state regulations. The staff members of these departments may review your medical record and research data for this study. In the case of an onsite audit, as the sponsor, the Simons Foundation may also review your research records and data to make sure the study is performed appropriately. This review will be administrative in nature and no PHI will be sent outside Geisinger Clinic.

The study results will be retained in your research record for data analysis or required governmental review indefinitely. Any research information in your medical record will be kept indefinitely.

If data or information from the research study is submitted for publication in a medical journal or is presented at a medical meeting, your identity as a research participant will not be revealed.

I understand that my data and private information will be kept as securely as possible. This study has a Certificate of Confidentiality to further protect my information.

My de-identified data will be entered into NDAR for future researchers interested in studying autism to access.

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WHAT INFORMATION ABOUT ME WILL BE SHARED AND WHY?

This project is a multi-site, multi-disciplinary collaboration among investigators at several research institutions. To conduct this research project, to assure quality of the data, and for effective analysis of study data and coordination of scheduling among the various components of the study, all information collected during the study, including personal health information, will be shared across all sites that are involved in either phase of the study. The sites include: Baylor College of Medicine in Houston, TX; Data Coordinating Center (Prometheus Research) and Clinical Research Associates, LLC at Simons Foundation; Geisinger Health System in Danville, PA; Harvard University in Boston, MA; University of Washington in Seattle, WA; Children's Hospital of Philadelphia in Philadelphia, PA; University of California, San Francisco in San Francisco, CA and Columbia University in New York, NY. Personal information may be shared with external research study services in order to send items for participation such as study newsletters and surveys. This information may include your name and email address.

After data is collected, it is stored with a unique study ID with no personal, identifying information. It will be encrypted and transmitted electronically to a central database. Only the study coordinator has access to link your data to your personal information.

I understand that information collected during the study will be shared across all participating study sites. After collection, my personal identifying information will be removed from my data before it is securely sent to a central database.

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WHAT ARE THE COSTS?

There will be no costs to you for participating in this study, other than basic expenses like telephone and internet service. You will not be charged for any of the research activities.

While there is no foreseeable harm associated with participating in this study, if any results of the remote assessments lead to you seeking outside medical care, you or your insurance company will be charged or held responsible for these costs.

WILL I BE PAID OR GIVEN ANYTHING FOR TAKING PART IN THIS STUDY?

We have grouped the surveys by similarities and the order in which they should be completed. For each group of surveys completed the participant will receive a gift card for $25.00. Depending on the number of participants in your family, you may reach the limit at which these gift cards must be reported to the Internal Revenue Service (IRS) as income. If you reach this amount in one year, we will notify you and you will have the option to keep earning gift cards by sharing your social security number (SSN) with the study team to allow this income to be reported to the IRS **OR** you may stop earning gift cards at $500 per year and not need to share your SSN or have this income reported to the IRS. If at any time you feel uncomfortable while completing the research surveys and wish to stop, you may do so. However, in order to receive compensation, you will need to submit the information you are comfortable providing to indicate that you have finished the survey.

I understand that it does not cost anything to participate in this study. I will be awarded gift cards based on my participation in this study.

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WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this research study is voluntary. You may choose not to be in the study or withdraw from the study at any time. You may also withdraw your authorization for us to use your data/samples.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits. It will not affect your access to health care at Geisinger Clinic or any of the other institutions collaborating in this study or your participation in the online Simons VIP Connect community. If you do decide to withdraw, we ask that you contact the study PI in writing to state that you are withdrawing from the study.

Please contact: Cora Taylor, 120 Hamm Drive, Lewisburg, PA 17837 or coordinator@simonsvipconnect.org.

If you decide to stop participating in the research study, we encourage you to talk to the PI and your regular doctor first.

We will also inform you of information that may affect your health or welfare during your participation in this research study.

The study PI may decide to take you off this research study if

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- Or for any other reason.

I understand that participating in this study is my choice and I can withdraw at any time and will not be penalized. I will be informed of any changes to the study that would affect my desire to participate.

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the research study, contact the study PI Cora Taylor at 570-522-9430 or Dr. Wendy Chung at 212-851-5313.

For questions about your rights as a research participant, contact the Human Research Protection Program staff of the Geisinger Institutional Review Board (which is a group of people who review the research to protect your rights) at (570) 271-8663.

WHERE CAN I GET MORE INFORMATION?

You will be able to review, download and/or print a complete copy of this consent form upon completion. Upon your request the Simons VIP study coordinator or another member of the study team can discuss the entire study plan with you and provide more information. You may contact them at coordinator@simonsvipconnet.org or 855-329-5638.

ADULT CONSENT

I agree to take part in this research study. By completing this consent form, you have not given up any of your legal rights.

_____ _____

Research Participant's Signature Today's Date

_____ _____

Please Print Name (First, Last) Date of birth

CONSENT FOR CHILDREN

_____ _____

Child 1 Name (First, Last) Child 1 Date of birth

Please review and answer the following:

If the child is between the ages of 10 and 17, please explain the study and ask their permission to participate in the study – Please select one of the following:

- ☐ Not applicable; this child is under age 10.
- ☐ I explained the study to my child. My child has indicated their agreement to participate in this study.
- ☐ In my opinion, this child is not capable of agreeing to participate in this study.

_____ _____

Parent's/Legal Guardian's Signature Today's Date

_____ _____

Please Print Parent's/Legal Guardian's Name (First, Last) Parent's/Legal Guardian's Date of birth

Child 2 Name (First, Last) _____ Child 2 Date of birth _____

Please review and answer the following:

If the child is between the ages of 10 and 17, please explain the study and ask their permission to participate in the study – Please select one of the following:

- ☐ Not applicable; this child is under age 10.
- ☐ I explained the study to my child. My child has indicated their agreement to participate in this study.
- ☐ In my opinion, this child is not capable of agreeing to participate in this study.

Parent's/Legal Guardian's Signature _____ Today's Date _____

Please Print Parent's/Legal Guardian's Name (First, Last) _____ Parent's/Legal Guardian's Date of birth _____

Child 3 Name (First, Last) _____ Child 3 Date of birth _____

Please review and answer the following:

If the child is between the ages of 10 and 17, please explain the study and ask their permission to participate in the study – Please select one of the following:

- ☐ Not applicable; this child is under age 10.
- ☐ I explained the study to my child. My child has indicated their agreement to participate in this study.
- ☐ In my opinion, this child is not capable of agreeing to participate in this study.

Parent's/Legal Guardian's Signature _____ Today's Date _____

Please Print Parent's/Legal Guardian's Name (First, Last) _____ Parent's/Legal Guardian's Date of birth _____

CONSENT FOR OPTIONAL SAMPLE COLLECTION AND STORAGE

OVERVIEW

You are being asked to let some of your blood, saliva, and/or cheek cells ("your sample(s)") be stored for use in future research in order to learn about, prevent, or treat health problems. Your sample(s) will be stored at the Rutgers University Cell and DNA Repository (RUCDR). Your sample(s) and information will be kept along with those from other individuals who decide to take part. There is no limit on the length of time we will keep your sample(s). We will keep it as long as it is useful, unless you decide that you no longer want to take part or we choose to destroy the samples.

PROCEDURES

Blood draw:

The blood draw can be done either through the parents' or child's' healthcare provider, or through a blood-drawing service that can come to your house at a time and place you determine. Four tubes (40 mL, or less than 3 tablespoons) of blood will be collected during the blood draw. The blood will be used for research that could include creating cells that can grow indefinitely (cell line).

Saliva sample:

If the option for saliva collection becomes available, you may be asked to provide a sample by spitting into a collection tube.

Cheek cell sample (buccal swab):
If the option for cheek cell collection becomes available, you may be asked to use a buccal swab (a cotton-tipped stick, similar to a Q-tip but with a longer handle) to gently collect cheek cells from the inside of your mouth.

Blood spot:
If the option for blood spot collection becomes available, you may be asked to have a finger stick to collect a blood sample (similar to the way an individual with diabetes would check blood sugar). Your finger would be cleansed and then stuck with a sterile, single-use lancet (a very small device with a sharp point). The drops of your blood would then be collected on a paper card.

FUTURE USE

The information that is found from the analysis of your sample(s) may be used scientifically and may be used in other research. By agreeing to have your sample(s) stored, you do not give up ownership of your sample, but you do give up ownership of any technology that may be developed from it.

There is a chance that your sample(s) and/or genetic information may be shared with other researchers in the future. If this happens, only your sample(s) and none of your personal medical information or

any other information that could possibly identify you will be provided.

The researchers in this study and other individuals who may have access to your sample(s) are not authorized to ever use this material to attempt to clone a human.

I understand that I am being asked to provide an optional blood, saliva and/or cheek cell sample for storage and use in future research. If my sample(s) are shared with other researchers, no identifying or personal medical information will be shared.

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RISKS AND DISCOMFORTS

Potential risks and discomforts are the same as those listed in the main consent.

BENEFITS

You will not benefit from giving your sample(s) to be stored for future research. We do not expect to discover any information important to your health anytime soon. The main reason you may want to take part is to help researchers learn new things that will help people in the future. You should not expect to get any personal results from research done with your sample(s).

COMPENSATION

You will not be offered payment for agreeing to have your sample(s) stored. Your sample(s) will be used only for research and will not be sold. You should know that research sometimes results in discoveries. These may one day have marketable value. For example, discoveries could eventually lead to new tests, drugs, or other products. There are no plans to share any financial benefits with you. You may not get any health related benefits either.

COSTS

There will be no costs to you for having your blood, saliva and/or cheek cell sample(s) stored. Your sample(s) will be collected free of charge.

I understand the risks associated with drawing blood and providing saliva, cheek cell and/or blood spot samples. I will not receive direct benefit from providing a sample for research storage but may help to benefit others in the future. The sample collection is performed free of charge and I will not be paid for providing a sample(s).

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CONFIDENTIALITY

For coordination of scheduling, your personal identifying information will be shared between the recruitment site at Geisinger and the blood-drawing/sample collection team. However, none of your personal medical information will be shared with the Rutgers laboratory. The sample(s) that are collected will not be directly linked to any of your personal medical information, but rather will be coded. A unique code will be created for each individual who provides their sample(s) to be stored. This code is the only information that will be sent to Rutgers along with your sample(s). The key to the code will be linked to your personal medical information, and this information will be kept by Geisinger Medical Center and Simons VIP in a secure database. Qualified researchers can access the DNA at RUCDR; if these researchers need additional information, we will contact you for follow –up.

WITHDRAWING YOUR Sample FROM RESEARCH

You can change your mind at any time about having your sample(s) stored for research. Contact Cora Taylor at 570-522-9430 or Dr. Wendy Chung at 212-851-5313 if you no longer wish to have your sample(s) stored. If some of your sample(s) have already been used for research, it cannot be retrieved. Also, knowledge already gained from research using your sample(s) cannot be destroyed. However, any remaining, unused sample(s) will be destroyed and not used for future research.

I understand that my personal identifying information may be shared between the study team and the blood draw/sample collection team. My stored sample(s) will only be identified by a unique code number and will not be linked to any personal information.

I can choose to no longer have my sample(s) stored at any time. If part of my sample has already been used, this cannot be retrieved but any remaining sample can be destroyed.

☐ I understand
➔ If online, will take to next page
☐ I have a question
➔ If online, will pause consent process and pop-up "Questions" page, see page 20
➔ If written consent, will provide coordinator contact info here

You will be able to review, download and/or print a complete copy of this consent form upon completion. If you have any questions or would like more information, please contact the study team at coordinator@simonsvipconnet.org or 855-329-5638

PARENT CONSENT: OPTIONAL SAMPLE COLLECTION AND STORAGE

Please type your name below to indicate that you have reviewed this document of informed consent for the optional research blood or saliva sample. Please indicate your participation decision below. By completing this consent form, you have not given up any of your legal rights.

- ☐ I voluntarily agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.
- ☐ I do not agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.

Induced pluripotent stem cells (iPS) cells are a kind of immature cell that can be made into different cell types. It is possible that in the future, your sample will be used to make iPS cells into brain-like cells to study if and how brain cells work differently in people with genetic changes related to autism and their family members. You can agree to the storage and research testing without agreeing to allow your sample(s)to be made into iPS cells.

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

_____	_____
Research Participant's Signature	Today's Date
_____	_____
Please Print Name (First, Last)	Date of birth

CONSENT FOR CHILDREN: OPTIONAL SAMPLE COLLECTION AND STORAGE → Please type each of your participating children's names and dates of birth below and indicate a participation decision for them below.

_____ _____
Child 1 Name (First, Last) Child 1 Date of birth

- ☐ I voluntarily agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.
- ☐ I do not agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.

iPS cells:

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

Please review and answer the following:

If the child is between the ages of 10 and 17, please explain the study and ask their permission to participate in the study – Please select one of the following:

- ☐ Not applicable; this child is under age 10.
- ☐ I explained the study to my child. My child has indicated their agreement to participate in this study.
- ☐ In my opinion, this child is not capable of agreeing to participate in this study.

_____ _____
Parent's/Legal Guardian's Signature Today's Date

_____ _____
Please Print Parent's/Legal Guardian's Name (First, Last) Parent's/Legal Guardian's Date of birth

Child 2 Name (First, Last) _____ Child 2 Date of birth _____

- ☐ I voluntarily agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.
- ☐ I do not agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.

iPS cells:

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

Please review and answer the following:

If the child is between the ages of 10 and 17, please explain the study and ask their permission to participate in the study – Please select one of the following:

- ☐ Not applicable; this child is under age 10.
- ☐ I explained the study to my child. My child has indicated their agreement to participate in this study.
- ☐ In my opinion, this child is not capable of agreeing to participate in this study.

Parent's/Legal Guardian's Signature _____ Today's Date _____

Please Print Parent's/Legal Guardian's Name (First, Last) _____ Parent's/Legal Guardian's Date of birth _____

Child 3 Name (First, Last) _____ Child 3 Date of birth _____

- ☐ I voluntarily agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.
- ☐ I do not agree to allow my or my child's samples to be stored for use in future research, including DNA tests, in order to learn about, prevent, or treat health problems.

iPS cells:

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

Please review and answer the following:

If the child is between the ages of 10 and 17, please explain the study and ask their permission to participate in the study – Please select one of the following:

- ☐ Not applicable; this child is under age 10.
- ☐ I explained the study to my child. My child has indicated their agreement to participate in this study.
- ☐ In my opinion, this child is not capable of agreeing to participate in this study.

Parent's/Legal Guardian's Signature _____ Today's Date _____

Please Print Parent's/Legal Guardian's Name (First, Last) _____ Parent's/Legal Guardian's Date of birth _____

QUESTIONS

Please contact the Simons VIP study coordinator or the Principal Investigator (PI) of the study regarding any questions or concerns you may have.

Study Coordinator	coordinator@simonsvipconnect.org	855-329-5638
Geisinger PI Cora Taylor	cmtaylor1@geisinger.edu	570-522-9430
Columbia PI Wendy Chung	wkc15@columbia.edu	212-851-5313