The Children's Hospital *of* Philadelphia®

## Informed Consent Form and HIPAA Authorization

**Study Title:** Brain and Behavior Study of Autism from Infancy through School Age

Version Date: June 19, 2020

Consent Name: Low-Risk Group

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| **Principal Investigator:** | Robert Schultz, PhD | Telephone: (267) 426-7540 |
| **Emergency Contact:** | Juhi Pandey, PhD | Telephone: (267) 426-4911 |

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

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

### Why are you being asked to take part in this study?

You and your child are being asked to be in the study because they participated in the prior IBIS study "A Longitudinal MRI Study of Infants at Risk of Autism".

### What is the purpose of this research study?

The purpose of this research study is to investigate the brain development of school aged children who have been examined using detailed brain imaging and behavior assessments between 3 and 36 months of age. As part of this project, our research team will need to gather information about your child to help us understand important issues that may relate to the subject data we are collecting. It does not offer treatment, although one day the information learned from this study may be useful in the treatment of autism. We will also gather information about you and the rest of your family to help us understand important issues that may relate to the subject data we are collecting.

**How many people will take part?**

About 400 people will take part in the study, including approximately 100 participants from CHOP.

## What is involved in the study?

### How long will you be in this study?

You and your child's participation will be spread out over several days of time. The assessments include 14 to 15 hours (spread out over convenient and tolerable time blocks) for cognitive, behavioral, and physical assessments of your child and about 1 hour for the MRI scan (not including pre- and post-procedure preparation time).

Samples of you and your child's DNA will be stored indefinitely.

### What are the study procedures?

During the course of this study, the following will occur:

*Cognitive/Behavioral Assessment:* We will need to interview an informant (a parent) about your child's behavior, obtain some previous medical and/or school records, conduct some direct assessment of your child's skills and development, collect questionnaires, and make observations of your child's behavior. We will also ask questions about you and your child's environment. Some interviews and observations may be audio- and/or videotaped. Most interviews and the observations will be done in our research building, though some can be completed over the phone and online. You will receive a brief report of your child's test results.

*MRI Scan*: The MRI (or brain scan) will be done at our research scanning facilities. Your child will lie on a sliding table that will slowly move his or her body into a large cylinder which is inside a large magnet (the scanning machine). While the MRI scan is being performed a loud machine-like noise can be heard. Your child and any adult in the room will therefore be required to wear earplugs to avoid hearing damage. The MRI for this study involves lying motionless in the scanning machine for approximately 55 minutes. We will provide Behavioral Training to help your child remain still during this scan. We will provide Behavioral Training to help your child remain still during this scan.

> Behavioral Training: To ensure that children lie still for the MRI scan and that pictures of the brain are of high quality, children may undergo a behavior training. Our team will use a practice scanner, which resembles the real scanner, along with a training plan that will help them learn to remain as still as possible during their MRI scan. This practice will take place at our research location. We will also send you items before your visit to help your child get used to the scanning process.

*Future Use of Data:* As part of the study, we will collect information about you from the cognitive/behavioral assessment and the MRI scan. We may wish to use this information in a future study. This information will be given a unique code and will not include information that can identify you. Information that can identify you may be kept permanently in a computer database in the Center for Autism Research at CHOP. Only the study doctors and those working with them on this study will be able to see information that can identify you. If your information is shared outside of CHOP, no identifiable information will be included.

*Genetic Testing*: We will need to obtain a salivary DNA sample from you and/or your child during the assessments or scan. This sample will consist of a small amount of spit into a cup we will supply. You may have already provided this sample in the prior research study. In that case, you may not need to provide an additional sample. This sample will be used to test for genetic markers thought to be related to autism.

**What are Genome Wide Association Studies (GWAS)?**

Your child's saliva contains cells that contain genes that are made of DNA unique to them. The exact DNA blueprint of many genes varies between people. Genome-wide association studies (GWAS) are a relatively new way for scientists to study ways to prevent, diagnose, and treat disease. The National Institutes of Health (NIH) has established a national database that holds information from many individuals across the country, including medical and genetic information. If coded information about you and/or your child is sent to this database, access will be controlled and limited to other researchers.

**What are the risks of this study?**

This study might involve the following risks and/or discomforts to you or your child:

*Breach of Confidentiality:* There is a risk of breach of confidentiality. When data are stored electronically, there is a risk of breach of computer security. Since you and your relatives and other members of your ethnic group share some of the same genetic make-up, there is a small chance for breach of their privacy, as well.

*Clinical Evaluation*: There is no risk from the behavioral and cognitive assessments we plan to do with your child. As part of this evaluation we will be doing a physical exam and history. There is a chance that we will identify a previously unrecognized condition. If any other medical conditions are detected during the course of the evaluation or during the period of follow up in the study, you and your child will be referred to the appropriate care provider to properly address this issue.

*Genetic Testing:* No feedback regarding the DNA testing will be provided to you. There is some risk in collecting DNA since this information is personally sensitive and may create psychological stress in the family. All routine clinical protocols will be followed and results will therefore be confidential.

*GINA (Genetic Information Non-Discrimination Act):* A federal law, called GINA, generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance. GINA does not protect you against discrimination based on an already diagnosed genetic condition or disease.

*Genetics Registries:* The National Institutes of Health has established a central repository for genotype information (DNA sequences obtained from blood or other tissue) and phenotype information (information such as age, signs and symptoms of illness, response to therapy). You and your child's genotype and phenotype information will be included in these national databases and shared with many researchers. The idea is that the

greatest public benefit is served when this information is shared with a large number of researchers.

Many research groups include scientists from private companies. Scientists who get your DNA and mental health information may work with a private company. Such companies have a financial interest in using information found from studying DNA. This includes developing commercial products that may later help others by improving the diagnosis and treatment of various medical problems. These companies may patent products or sell discoveries based on this research. Some of the scientists who study your DNA and mental health information may get some financial benefit from this work. There are no plans to provide any compensation to you or your heirs should this occur.

*MRI Scan:* There is no known risk from MRI scans unless your child has certain existing conditions (such as metal clips from prior surgery). These will be explored fully prior to scanning on a separate MRI screening form.

There may also be uncommon or previously unknown risks. You should report any problems to the researcher.

## Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help doctors understand more about the causes of autism and potential therapies.

## Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

**What are your responsibilities?**

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

**What happens if you decide not to take part in this study?**

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

**Can you stop your participation in the study early?**

You can stop being in the study at any time. You do not have to give a reason.

**Can the study doctor take you out of the study early?**

The study doctor may take you off of the study because you or your child has had an unexpected reaction, or has failed to follow instructions, or because the entire study has been stopped.

**What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?**

As part of this research, health information about you will be collected. This will include information from the cognitive/behavioral assessment, the MRI scan, and genetic testing. Information related to your medical care at CHOP will go in your medical record. This could include physical exams, imaging studies (x-rays or MRI scans) or tests done in the clinical lab. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Laboratory test results will appear in your medical record with the exception of the genetic tests which are performed only for this research study. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- Investigators at the University of North Carolina at Chapel Hill and their IRB;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The Data Coordinating Center;
- The National Institutes of Health who is sponsoring this research;
- If you agree, your data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you. You can tell us at the end of this form whether you will allow is to share your data in this way;
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information that they are required by law to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect and communicable diseases.

**Can you change your mind about the use of personal information?**

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Robert Schultz, PhD
The Children's Hospital of Philadelphia
Center for Autism Research
2716 South Street, 5th Floor
Philadelphia, PA 19146

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

## Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

**Will there be any additional costs?**

There will be no additional costs to you by taking part in this study.

**Will you be paid for taking part in this study**?

You will be receiving up to $150 for taking part in this study ($50 for the questionnaires, $50 for the testing and $50 for the MRI scan).

Travel related expenses related to your visit to our research site will be paid by the project.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

If your travel to CHOP (e.g. flight, hotel) is arranged and paid for by the study team, the agency making the reservations and their representatives will have access to identifiable information.

**Who is funding this research study?**

The National Institutes of Health is providing funding for this study.

## What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Schultz at 267-426-7540. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

## What happens if you are injured during the study?

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call Dr. Pandey at 267-426-4911. She can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

## Sharing Data with the National Institutes of Health (NIH)

### Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH's goal is to maximize the benefits that come from the research.

The NIH repository stores genetic information and phenotypic data from many studies. The NIH then shares that information with researchers. We will send the information about you and the other participants to a repository at the NIH. The information will be de-identified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual.

The NIH intends to share the collected information with other researchers. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

The goal of genetic studies is to look for genetic connections that may explain how to identify, prevent, and treat health problems. For example, genetic data may be used to find out:

- Who is more likely to develop a certain illness, such as asthma, cancer, or diabetes, or a condition like high blood pressure or obesity;
- What genes affect the progress of a certain disease or condition; and
- What genes may affect treatments which now may or may not work in certain people.

### Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it's possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.

### Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future.

### Controlled or Unrestricted Access

The data about you can either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access are publicly available to anyone (e.g., The 1000 Genomes Project).

## Consent to Share Data with the NIH

Please indicate whether you will allow us to share your information with the NIH by putting your initials next to one of the following choices:

Please check and initial one of the following statements:

___I want a sample of my child's DNA to be stored.

___I do NOT want a sample of my child's DNA to be stored.

## Audio/Visual Taping

Recordings will be used for this study only for the rating of behaviors by other members of the research team. These tapes will be maintained indefinitely as part of your child's research file in the same manner as all other information collected as part of this study (in secure network folders by code number). You may decline the audio/video taping if you wish. You can also request that these recordings be destroyed after the study has been completed. By initialing the space provided, you verify that you have been told that audio/visual material will be generated during the course of this study and indicate whether this material can be stored or destroyed.

Check the line that best matches your choice:

_____ OK to record my child during the study

_____ Not OK to record my child during the study

## Contact for Future Research Studies

Please let us know if we can contact you about future research studies. You will let us do that by putting your initials and date next to one of the following choices:

_____ I wish to be contacted about future studies.
(Initials/Date)

_____ I **DO NOT** wish to be contacted about future studies.

**Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research**

The research study and consent form have been explained to you by:

| Person Obtaining Consent | Signature of Person Obtaining Consent |
|---|---|
| | Date |

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study.

**NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject

| Name of Authorized Representative 1 | Relationship to subject:<br>Parent Legal Guardian |
|---|---|
| Signature of Authorized Representative #1 | Date |
| Name of Authorized Representative #2 | Relationship to subject:<br>Parent Legal Guardian |
| Signature of Authorized Representative #2 | Date |

If the second representative is unavailable, per §46.408(b) / §50.55(e)(2), explain the reason.

**Consent for Parents' participation**

Name of Mother

Signature of Mother | Date

Name of Father

Signature of Father | Date