

**University of North Carolina at Chapel Hill  
Adult Consent and Parental Permission for a Minor Child to Participate in a  
Research Study  
HR Subjects**

**Consent Form Version Date:** 6-19-2020

**IRB Study #** 17-1871

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

**Principal Investigator:** Joseph Piven

**Principal Investigator Department:** Psychiatry - General

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**University of Washington:** Steve Dager

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**Funding Source and/or Sponsor:** National Institutes of Health (NIH) , Foundation of Hope

**Study Contact Information:**

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**What are some general things you and you child should know about research studies?**

You are being asked to take part in and allow your child to take part in a research study. To join the study is voluntary.

You may decide to not allow your child to participate, or you may withdraw your permission for your child to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You and your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your or your child's relationship with the researcher, the health care provider, or any of the research sites listed above. If your child is a patient with an illness, your child does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study.

You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this 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.

You and your child are being asked to be in the study because they participated in our prior study “Brain Development in Infants at High Risk for Autism”.

**How many people will take part in this study?**

A total of approximately 400 children and their families at 4 institutions will take part in this study, including approximately 100 children at each data collection site (UNC, CHOP, UW and WU).

**How long will your child’s part in this study last?**

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 will happen if your child takes part in the study?**

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.

- a. 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.
- b. Sedation: If after we attempt the behavioral training plan your child is unable to successfully remain still for their scan, they may be sedated for their MRI scan. This option may require you to travel to a different study site so the MRI scan can take place in a hospital setting that uses the type of MRI machine needed in this study. A hospital consent for sedation will be obtained by the anesthesiologist or nurse working with your child prior to the procedure. Sedation is like being asleep so that your child is not aware of his/her surroundings. Medications are used to allow your child to sleep during the MRI procedure. After the MRI is completed we will keep your child in a supervised environment on a stretcher until fully awake. Vital signs, such as pulse and blood pressure, will be monitored before and after sedation. Your child will also be monitored continuously during the MRI.

*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 possible benefits from being in this study?**

Research is designed to benefit society by gaining new knowledge. There is little chance you or your child will benefit from being in this research study.

**What are the possible risks or discomforts involved from being in 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.

*Sedation:* The medications to be used for sedation during the MRI are commonly used for conscious sedation in children and adolescents. These may include propofol, pentobarbital, Chloral hydrate or versed. However, if clinically indicated, other medications may be used based on the anesthesiologist's judgment. These medications have been shown to be safe with few side effects and are recommended for use during MRI in individuals who have difficulty relaxing and lying still during the procedure. The anesthesiologist and nurse will discuss which specific medications will be used with your child prior to the procedure. Generally, the adverse effects of sedation medications may occasionally include hypotension (low blood pressure) and hypoventilation (shallow breathing) during the procedure and, nausea, vomiting, increased agitation (restlessness), headache, and sleepiness after the procedure. The anesthesiologist and nurse are skilled at dealing with all of these issues.

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

**What if we learn about new findings or information during the study?**

You and your child will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

**How will information about your child be protected?**

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, we will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Records of all participation in this research (including collected data as well as audio and video of behavioral measures) will be maintained indefinitely and kept confidential to the extent permitted by law. Only those working on our research team will have access to you and your child's file and the files will be coded with a unique numeric identifier without reference to the name of the child or family. We will keep confidential you and your child's name any other personal information we learn about you/them. This information will not be given out to the repository or to anyone else outside of our research group.

For data analysis and publications of our research results, you and your child will be identified only by this unique code number.

DNA and mental health information collected from you and your child will be stored. This will include information about your family structure and your child's age, sex, and psychological

symptoms. DNA and mental health information will be stored in a coded way to keep your child's identity a secret. Your child's DNA and mental health information will be stored as a national resource. NIMH will provide them to qualified scientists around the world to study genes associated with autism. These scientists may not be currently working on this research right now.

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.

Since funding for this study will come from the National Institutes of Health, they reserve the right to inspect and copy information directly related to this research as a way of monitoring our use of funds. Results of this study may also be reported to the NIH.

The results from the analysis of your family's information will not be released or shared in any way with your child's doctors, with insurance companies, or any third party not involved in research unless the you request that we do so. When results of this study are published, your family's name will not be used.

To help us protect your privacy, the National Institutes of Health has provided us with a Certificate of Confidentiality. 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 required by Federal or State law.

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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

#### 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

### **HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?**

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. An Institutional Review Board has reviewed and approved this study.
- The University of North Carolina IRB
- The research project data coordinating center at McGill University.

### **Are there additional protections for my health information?**

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and

shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

**If you decide not to sign this form, it will not affect**

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

**If you sign this form:**

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

**What will happen if your child is injured by this research?**

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 1-314-747-6759 and/or the Human Research Protection Office at 1-800-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.



**What if you or your child wants to stop before your child's part in the study is complete?**

You can withdraw or withdraw your child from this study at any time, without penalty. The investigators also have the right to stop you or your child's participation at any time. This could be because you or your child has had an unexpected reaction, or has failed to follow instructions, or because the entire study has been stopped.

**Will your child receive anything for being 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.

**Will it cost you anything for your child to be in this study?**

It will not cost anything to be in this study.

**Who is sponsoring this study?**

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you or your child has questions about this study?**

You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form.

**What if there are questions about your child's rights as a research participant?**

All research on human volunteers is reviewed by a committee that works to protect you and your child's rights and welfare. If there are questions or concerns about your or your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to [IRB\\_subjects@unc.edu](mailto:IRB_subjects@unc.edu). You may also contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email [hrpo@wustl.edu](mailto:hrpo@wustl.edu). General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

**Parent's Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to participate and allow my child to participate in this research study.

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Printed Name of Research Participant (child)

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Signature of Parent

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Date

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Printed Name of Parent

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Signature of Parent

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Date

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Printed Name of Parent

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Signature of Research Team Member Obtaining Permission

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Date

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Printed Name of Research Team Member Obtaining  
Permission