

**University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
NDAR Participation**

Consent Form Version Date: 7-1-2019

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

Principal Investigator Phone number: (919) 843-8641

Principal Investigator Email Address: joe_piven@med.unc.edu

Co-Investigators:

Principal Investigators at Data Collections Sites:

University of North Carolina: Heather Hazlett

Children's Hospital of Philadelphia: Robert Shultz

University of Washington: Steve Dager

Washington University: Kelly Botteron

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

Study Contact Information:

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University of Washington: (206) 543-2125, mwendt11@uw.edu

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You are being given this consent form because your child is participating in a research study called "Brain and Behavior Study of Autism from Infancy Through School Age." This form is a supplement to the primary consent form you have already reviewed about this study.

As one of the Autism Centers of Excellence (ACE) funded by the National Institutes for Health (NIH), we are required to participate in the National Database for Autism Research (NDAR). This means that data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the NIH that allows researchers studying autism to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about autism more quickly than before.

With your permission, we will send data regarding the research subject (your child participating in the study), along with your family characteristics and medical history to NDAR.

During and after the study, the researchers will send information about you or your child's health and behavior and in some cases, you or your child's genetic information, to NDAR. This may also include the MRI data from the study. However, before they send it to NDAR, they will

remove information such as name, address, and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with the NIH to obtain access to your study data for research purposes. Experts at the NIH who know how to protect health and science information will look at every request carefully to minimize risks to you and your child's privacy.

You and your child may not benefit directly from allowing you or your child's information to be shared with NDAR. The information provided to NDAR might help researchers around the world treat future children and adults with autism spectrum disorders so that they have better outcomes. NDAR will report to Congress and on its website about the different studies that researchers are conducting using NDAR data; however, NDAR will not be able to contact you or your child individually about specific studies.

You may decide now or later that you do not want to share you and your child's information using NDAR. If so, contact the researchers who conducted this study, and they will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at <http://ndar.nih.gov>.

To help protect you and/or your child's privacy the investigators of this study will have a Certificate of Confidentiality from the NIH, 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.

We are also asking your consent to provide research data and related findings to the National Database for Autism Research (NDAR). 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 protected - 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. With respect to you and/or your child's participation in NDAR, we are not required to nor do we plan to make voluntary disclosures except if there were severe threats to the public health or safety.

What if you have questions about your rights as a research subject?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Principal Investigator: Joseph Piven, M.D.

UNC-CH Department: Psychiatry

Phone number: (919) 843-8641

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Consent Form Version Date: 2-1-2019

NDAR Participation

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Printed Name of Research Subject (Child #1)

Date of Birth

Printed Name of Research Subject (Child #2)

Date of Birth

Signature of Parent or Legally Authorized Representative

Date

Printed Name of Parent or Legally Authorized Representative

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent