

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Interactive Autism Network Research Database

Application No. : NA_00002750

Sponsors: Simons Foundation;
Patient-Centered Outcomes Research Institute (PCORI)

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1. What you should know about this study:

- You are being asked to join the Interactive Autism Network Research Database (IAN Research Database). This is similar to joining a research study. The IAN Research Database is a project of the Kennedy Krieger Institute, Baltimore, Maryland, USA. This consent form explains the research study, research database, and your part in the IAN Research Database. Please read it carefully and take as much time as you need. Please ask questions at any time about anything you do not understand. You can do this by contacting study staff at researchteam@ianproject.org or by calling 1-866-348-3440 (toll free in the U.S.) or +1-443-923-4140 (from outside of the U.S.).
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

- If children and adults can join this study, the word “you” in this consent form will refer to both you and your child.
- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

2. Why is this research being done?

The purpose of the IAN Research Database is to create an international online database to increase knowledge about Autism Spectrum Disorders (ASDs) and help find effective treatments for people affected by ASDs.

The IAN Research Database will help increase the understanding of ASDs by helping other researchers around the world to find the volunteers they need for research projects. Many research studies are difficult to do or take longer to complete because researchers have problems finding the volunteers they need.

The IAN Research Database researchers will also use the information you provide to better understand what causes ASDs, how it affects families, and what treatments are being used.

Anyone who has EVER been told by a professional - or if a professional, family member, or self suspects a diagnosis in the case of an adult - that they have any of the following, and their immediate family members* or Legally Authorized Representative (LAR), can participate in this study:

- Autism Spectrum Disorder (ASD)
- Autism
- Asperger Syndrome
- Autistic disorder
- Pervasive Developmental Disorder (PDD)
- Pervasive Developmental Disorder-Not Otherwise Specified (PDD-NOS)
- Childhood Disintegrative Disorder (CDD)

** By “immediate family members” we mean biological or adoptive parents or LARs and full or half siblings. LARs would only qualify for inclusion in the study if they register an adult under their guardianship who has one of the above listed diagnoses. Parents of independent adult children may join; however, they cannot consent for their adult child to join. Step siblings are not included in the IAN Research Database unless they qualify some other way.*

If you are concerned that your child under age 18 years has an ASD but has not yet received a diagnosis, you should not participate in the IAN Research Database. Instead you should seek advice from a local professional with expertise in developmental disorders.

If you have a diagnosis of Rett Syndrome, which is related to ASD, you should not participate in the IAN Research Database.

The ability to understand written English is necessary to complete the online IAN Research consent and study questionnaires.

How many people will be in this study?

We expect at least 100,000 individuals to participate in the IAN Research Database.

3. What will happen if you join this study?

If you are an adult **and/or** the parent or adult sibling of a child or an independent adult **and/or** you are the LAR of an dependent adult with any of these diagnoses (or suspected diagnosis in the case of an adult), and you agree to be a part of the IAN Research Database, we may ask you to provide information to us over a secure internet connection about:

- Medical history
- Residence
- Contact information
- Behavior and development of the affected individual
- Treatments and associated costs for you (if you are an affected adult), your affected child, or the affected adult under your guardianship
- The affected person's experience with doctors and other professionals, the school system, the work place, and social relationships, as age appropriate
- Your willingness to participate in the research studies that we tell you about
- Why you did or did not choose to participate in the research studies that we tell you about

You may also be asked to update treatment information for yourself, your child with ASD or the adult with ASD under your guardianship up to three times a year and complete a short autism checklist twice a year over the internet. It should take 10 minutes each time to update treatment information and 15 minutes to complete the checklist.

The questions that you will be asked will depend on your status and your relationship to other individuals.

Once a child participant reaches the age of 18, he/she will be able to participate in the IAN Research Database as an adult. In order to make this transition, they will need to provide their own consent or be consented through their LAR.

Data will cease to be collected from affected child participants once they reach the age of 18 unless they transition to consented adult participant status.

Data will cease to be collected from affected adult participants, who were consented by their LAR, if they gain the capacity to provide their own consent. The LAR should notify the study staff at researchteam@ianproject.org or by calling 1-866-348-3440 (toll free in the U.S.) or +1-443-923-4140 (from outside of the U.S.) in such an eventuality.

You may stop participating at any time or modify how often and in what ways you are willing to be contacted.

In addition to providing information, by joining the IAN Research Database we are asking you for authorization to be contacted about other research projects. We will work with researchers to find out what types of families and/or individuals they need as volunteers and we will contact you if you meet that profile. When eligible, we will send you information about specific research studies and how to join them. We will not provide the researchers with your contact information without your permission.

You can contact us if you decide that you no longer wish to be contacted about outside research projects. Note that you do not have to participate in any other research projects and your non-participation in any outside research project will neither affect the care you receive from any health provider nor your standing as a participant in IAN Research.

Before providing any of this information you will be asked to set up an account with your email address and a password. The email address you use should be private. You will be given the option to provide an alternate email address in addition to your primary address. This will enable you to stay connected with IAN if your primary email address changes.

When you are logged into the IAN Research Database you can view the data that you provided about yourself, and other members of your family. In addition, you can look at overall statistics from all participants in IAN. These overall statistics will never contain information that identifies specific people.

The time it takes to complete the initial registration process depends on the number of eligible participants in your family. If you are registering only for yourself, completion of the registration process and baseline forms will take approximately 30 minutes. If you are registering for a family of four, it should take approximately one and three-quarter hours to complete the entire initial registration process and the baseline forms. This will vary by the speed of your internet connection.

How long will you be in the study?

You will be asked to remain a participant in the IAN Research Database for as long as the study continues.

4. What are the risks or discomforts of the study?

There are no anticipated risks or discomforts associated with this study. To complete the basic amount of information for each child with ASD will take approximately 60 minutes; to complete information for each unaffected child will take approximately 45 minutes, parent forms will take no more than 15 minutes to complete; forms for adults with ASD will take approximately 15 minutes to complete. Updating information for each person with ASD will take approximately 60 minutes each year. You may pause at any time and come back to the IAN Research Database to continue completing information. If there are any questions that you are uncomfortable answering you may choose not to answer those questions.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer. The IAN Research Database was designed with input from many families and adults with ASD to make the experience as pleasant as possible. Also, the system allows you to sign out and come back to complete forms when it is convenient to you.

5. Are there benefits to being in the study?

There are no direct medical benefits of participating. By joining the IAN Research Database you will have the benefit of hearing about research studies that you qualify for in a more reliable and specific way. There are no other direct benefits of participating. The information you provide may help others with ASDs in the future.

In addition, the data you provide to the IAN Research Database will be available for you to download and view for your own interest. Also, you may view summary information on the internet based on the information you provide and what others provide. However, none of the information on the IAN Research Database is intended for medical decisions for you, your child, or any individual under your guardianship, as this is a research project.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

Incentives may be offered for participation in one-time questionnaires in the form of a drawing for up to ten (10) items (e.g., gift card or electronics item) to a maximum value of \$600 each item. The drawing would be held after the questionnaire has closed. Depending on sponsorship and the complexity of the study, gift cards up to the value of \$100 per participant may be used as compensation for time required.

Incentives may be offered for participation in ongoing questionnaire(s) in the form of a drawing for up to ten (10) items (e.g., gift card or electronics item) to a maximum value of \$600 each item. Drawings such as these would be held up to two times per year.

There may be occasion to send families a small thank-you gift valued at less than \$20 (e.g., t-shirt, puzzle, magnet, etc.)

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed \$600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later. However, any information you have provided to the IAN Research Database project prior to withdrawal will be kept so that research based on your information can be reproduced. If you decide to halt your participation in the IAN Research Database project, you will no longer be contacted by the IAN team, asked to fill out forms, or asked to participate in any other way. You can also change how often you are willing to be contacted by the IAN Research Database, or how often you are willing to update your information.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

10. Why might we take you out of the study early?

If the IAN Research Database staff discovers that you do not qualify for participation, then you might be removed from the IAN Research Database. Also, if there is a disagreement between parents about a child being part of the IAN Research Database then that child will be removed from the IAN Research Database.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study. If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator’s name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Use of Your Data by Researchers Outside of the Main Research Team

The IAN Research Database will give your data to other researchers who wish to use your data to better understand ASDs. Your name, contact information, and other information that can be used to identify you will not be given to researchers conducting any of these other studies outside of Kennedy Krieger Institute. Researchers wishing to use the IAN Research Database data may apply for access.

Researchers from other research institutions will be required to provide documents from their research review committees before they are given access to data in the IAN Research Database. These documents will include the following information:

- How the researcher plans to use the data.
- An approval document that states that their research has been submitted to a research review committee for review.
- A signed contract that states that the researcher will use the data responsibly, in accordance with IAN Research Database policies.

Kennedy Krieger Institute does not endorse any studies conducted by researchers outside of the main research team.

12. What if there is a Certificate of Confidentiality for this study?

The National Institutes of Health has given us a Certificate of Confidentiality for this study. This Certificate adds special protection for research information that identifies you and allows us, in some circumstances, to refuse to give out information that could identify you as a research subject without your consent, when such information is sought in a federal, state, or local court or public agency action. Still, we may disclose identifying information about you if, for example, you need medical help.

We may also disclose identifiable information about you as described in Section 11 of this form or in other cases. For example, the government may see your information if it audits us, and the research team will voluntarily comply with local disclosure laws and will tell the local or state authorities:

- if they suspect abuse, neglect or abandonment of a child or vulnerable or dependent adult;
- if certain diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

This Certificate does not mean the government approves or disapproves of this research project.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.
- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you otherwise have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

If you are a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-9302.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Paul H. Lipkin at 1-866-348-3440 (toll free). If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Paul H. Lipkin at 1-866-348-3440 during regular office hours.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

15. Assent Statement

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

16. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

**YOU WILL BE SIGNING THIS CONSENT FORM ELECTRONICALLY.
PLEASE PRINT OR DOWNLOAD THIS HARD COPY CONSENT FORM
FOR YOUR RECORDS.**

Signature of Adult Participant (Consenting for Self) Date/Time

Signature of Legally Authorized Representative (LAR) consenting for **ADULT NOT CAPABLE of GIVING CONSENT** (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative*) Date/Time

Relationship of LAR to Participant Date/Time

Signature of Biological/Adoptive Parent of Child Participant consenting for Child Date/Time

NOTE: A RECORD OF YOUR ELECTRONIC CONSENT IS KEPT BY THE PRINCIPAL INVESTIGATOR; PARTICIPANTS SHOULD PRINT OR DOWNLOAD A COPY OF THIS CONSENT FORM. IF YOU HAVE DIFFICULTY PRINTING OR DOWNLOADING A COPY OF THIS CONSENT FORM, PLEASE CONTACT THE STUDY TEAM AT 1-866-348-3440 SO THAT WE MAY PROVIDE YOU WITH A COPY.

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.