

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Dr. Antonio Hardan

ep 9345

IRB USE ONLY

Approval Date: January 23, 2019

Expiration Date: (**Does Not**

Protocol Title: Autism and Developmental Disorders Research Registry

STANFORD UNIVERSITY SCHOOL OF MEDICINE
Consent to Act as a Participant in the Stanford University:
Autism and Developmental Disorders Research Registry

Please check one of the following:

 You are an adult participant in this study. You are the parent or guardian granting permission for a child in this study.

Print child's name here:

Principal Investigator: Dr. Antonio Y. Hardan**Address:** Stanford University
401 Quarry Road
Stanford, CA 94305-5719**Telephone:** (650) 736-1235

If you do not understand this form or have questions please call (650) 736-1235.

Why is this research being done?

Much advancement in medicine has resulted from research involving the collection and analysis of the medical record information of patients with a certain disease or condition. Because you or your son/daughter have been diagnosed with an Autism Spectrum Disorder (ASD) and/or intellectual disability (ID), we are asking for your permission to allow us to place you or your child's past, current, and future medical record information into a Research Registry. The Research Registry serves two purposes:

1. First, it will allow researchers to identify and recruit patients who might be eligible for participation in future research studies. For example, if faculty at the Autism and Developmental Disorders Clinic (ADDC) or Developmental and Behavioral Pediatrics (DBP) at Stanford University are involved in a study of how teenagers with ASD adjust to middle or high school, families of teenagers with ASD who have enrolled in the Research Registry would be contacted by email, letter, or telephone to invite them to participate in the study (participation in the study would be voluntary).
2. Second, it will allow researchers to review and study the medical records of many patients to answer questions about ASD and/or ID and its treatment. For example, if faculty at the ADDC or DBP wanted to see how their patients are responding to a new medication,



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faculty and their staff would be allowed to look at the medical charts of individuals enrolled in the Research Registry who had been prescribed this medication. The faculty would be able to publish their findings in a professional journal or present the results at a professional meeting. The names of patients and their families would not be used.

We want to collect information from a large group of patients (approximately 1,000) across the age span that are being seen in medical clinics such as the ADDC and DBP to answer questions regarding treatment outcome as well as the course of conditions such as ASD and ID. This will involve looking at and recording medical information that was originally collected as part of you/your child's routine clinical care, which may include information about you/your child's mental health and treatment, while you/your child are a patient. It does not involve any time commitment on your part, and no procedures will be performed beyond your usual clinical care. However, you will be asked to fill out an Online Research Registry Questionnaire about you/your child, which would take approximately 5 minutes to complete. Completion of this questionnaire is not required to participate in the Research Registry.

We also wish to identify individuals who would like to be notified about future research studies. These studies would involve diseases, symptoms, or conditions for which you/your child are currently being treated, are at risk for, or are suggested by you/your child's answers to questions collected during routine clinical care, or treatments you/your child are receiving. Each study's investigator would explain the specific nature of their study to you/your child.

We will continue to place you/your child's medical record information into the Research Registry until you/your child withdraws permission for participation in the Research Registry.

Your doctor or your child's doctor may be an investigator on one of these research studies. Before agreeing to participate in any study or at any time during the study, you may discuss your care with a doctor not associated with the research project. You are never obligated to participate in any study.

How will the privacy of my medical record information be protected?

Several procedures are in place to protect the privacy of you/your child's medical record information. All medical information will be stored in a secure password-protected database. All identifiable information, such as name, date of birth, and medical record number are stored in a separate password-protected database. These databases are maintained behind a firewall (a mechanism to prevent outside people from accessing the information) and are only accessible to Registry investigators and research staff.

The privacy of you/your child's information is very important to all of the researchers and everything possible will be done to keep the information private. However, just as with the use of your medical information for health care purposes, there is a risk that it will be accidentally disclosed.

We will keep your/your child's study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as suspected child abuse or neglect, suspected elder abuse or neglect, or intent to harm yourself or others.

Are there risks, benefits, or costs involved in participation in the Research Registry Project and Prospective Subject List?

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The risks of participating in the Research Registry include breach of confidentiality, as described above. If you/your child are contacted to participate in additional studies, those investigators will explain the risks and benefits of those studies. You/your child may choose to participate or not participate at that time.

There are no direct benefits to you or your son/daughter, nor are there any costs or payments to be in the Research Study. **WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

This is not a treatment study. Therefore, the alternative to participating is not to participate.

May I withdraw, at a future date, my consent for participation in this research study?

Yes, to do so you should contact the principal investigator at the address listed on the front page. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent will not be used and disclosed by the investigators for the purposes described above. However, any de-identified information will continue to be used.

Your participation in the research registry is completely voluntary and your decision whether to participate or not in this project, or later withdraw from it, will not affect your current or future medical care at the Stanford University Medical Center.



**Authorization To Use
Your Health Information For Research Purposes**

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to allow researchers to identify and recruit patients who might be eligible for participation in future research studies and to review and study the medical records of many patients to answer questions about ASD and/or ID and its treatment.

As part of this study, the study doctor and research staff will record health



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information about you or your child that contains your name or your child's name and other items that can be used to identify you or your child. The health information identifying you or your child will remain in the research records until December 31st, 2057. In addition, the records may be kept until December 31st, 2057. Authorized representatives of Stanford University will be given access to these records on request and may copy them. Copies of the study records that do not include your name or your child's name but may be traced back to you or your child may be given to Stanford University. By signing this form you are authorizing this use and disclosure.

Because of the need to release information to these and other parties, absolute confidentiality cannot be guaranteed. After its release, information that can identify you or your child may no longer be protected by federal privacy rules. However, information will be collected and shared following professional standards of confidentiality.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must contact Dr. Antonio Hardan, Division of Child and Adolescent Psychiatry, 401 Quarry Road, Stanford, CA 94305. Dr. Hardan's phone number is (650) 736-1235.

What Personal Information Will Be Used or Disclosed?

Your health information or your child's health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to information on the online research registry questionnaire, your research record or your child's research record, supporting information from your medical records or



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your child's medical records, results of laboratory, diagnostic or other tests, results of tests on samples (blood, urine or tissue) that have been stored, and clinical and research observations made during your participation or your child's participation in the research study.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information or your child's health information in connection with this research study:

- The Protocol Director Dr. Antonio Hardan and his research group.
- Investigators collaborating with Dr. Hardan on related research.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.

Who May Receive / Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information or your child's information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information or your child's health information will expire on December 31st, 2057.

Contact information: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, you should ask the Protocol Director, Dr. Antonio Hardan. You may contact him now or later at (650) 736-1235. You should also contact him at any time if you feel you have been hurt by being a part of this study

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Antonio Hardan, at (650) 736-1235.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can



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also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

VOLUNTARY CONSENT: Any questions I have about my rights as a research participant can be answered by Dr. Antonio Hardan or his research staff at (650) 736-1235 or the Stanford Institutional Review Board at (650) 723-5244 or toll free at 1-866-680-2906.

I agree to participate in the Stanford University Autism and Developmental Disorders Research Registry. This involves looking at the relationship among the presence or absence of medical conditions, quality of life, and use of health care resources and outcomes of medical conditions. I would like to know about research studies being done by Registry investigators and their collaborators that I may be eligible for.

If you agree to participate or have your child participate please sign in the following field. Your entered name serves as a signature. Please print a copy or save of this consent form for your records.

Please note, only parents, legal guardians and/or conservators are allowed to sign the following field on behalf of a research registry participant.

If you do not understand this form or have any questions about this form please call Dr. Hardan or his research staff at (650) 736-1235 before signing the following field.

