

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Antonio Hardan, M.D.

Protocol Title: Pediatric Brain and Behavior Research Registry

STANFORD UNIVERSITY SCHOOL OF MEDICINE
**Consent to Act as a Participant in the Stanford University: Pediatric Brain
and Behavior Research Registry**

Principal Investigator: Antonio Y. Hardan, M.D.**Address:** Stanford University
401 Quarry Road
Stanford, CA 94305-5719**Telephone:** (650) 723-7845

If you do not understand this form or have questions please call (650) 723-7845.

DESCRIPTION: You are invited to participate in a research registry for children and adolescents diagnosed with brain disorders (neurological or psychiatric conditions).

From participation in the research registry, we hope to determine eligibility of participants in future studies concerned with understanding and evaluating brain conditions and their treatments. These studies would involve diseases, symptoms, or conditions for which your child is currently being treated for, are at risk for, or are suggested by information collected during routine clinical care or treatments. If eligible, each study's investigator would contact you and explain the specific nature of their study to you and your child.

Because your child has been diagnosed with a brain condition, we are asking for your permission to allow us to place your child's past, current, and future medical record information originally collected as part of your child's routine clinical care into the Research Registry. This will allow researchers to review and study the medical records of a large group of patients (approximately 5,000) across the age span that are being seen at Stanford Children's Health to answer questions regarding treatment outcome as well as the course of brain conditions.

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.

PROCEDURES: With your permission, we would like to be able to contact you to see if you are interested in future studies. Upon giving consent, you will be asked to complete a short research registry questionnaire online. Researchers will be able to access your medical records to answer questions regarding treatment outcomes as well as the course of brain conditions.

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RISKS AND BENEFITS: There are minimal anticipated risks associated with this study. The risks of participating include breach of confidentiality. If you are contacted to have your child participate in additional studies, those investigators will explain the risks and benefits of those studies. You and your child may choose to participate or not participate at that time. We cannot and do not guarantee or promise that you will receive any benefits from this Research Registry.

TIME INVOLVEMENT: Your participation in this study will take approximately 5 minutes to fill out a short online research registry questionnaire.

PAYMENTS: You will not be paid to participate in the research registry.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer particular questions. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

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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 select the agreement to be in this study, 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 giving authorization.

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

The purpose of this project 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 brain conditions and their treatment.

As part of this study, the study doctor and research staff will record health 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. 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 agreeing to be in this registry, 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, so risks are minimal.

Do I have to give my authorization?

You do not have to give authorization. But if you do not, you will not be able to participate in this research study.

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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 write to: Dr. Antonio Hardan, 401 Quarry Road, Stanford, CA 94305.

What Personal Information Will Be Used or Disclosed?

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 and/or medical records data collected as part of the research registry. More specifically, this includes information from participant's online registry questionnaire (ie: name, date of birth, email address, mailing address, and telephone number), research record, supporting information from 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 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 in connection with this research study:

- The Protocol Director
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Investigators conducting research at Stanford University and Research Staff

Who May Receive or 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

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Your 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 will end on December 31st, 2066 or when the research project ends, whichever is earlier.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Antonio Hardan, (650) 723-7845. You should also contact her at any time if you feel you have been hurt by being a part of this study.

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

Please print a copy or save this consent form for your records.

If you do not understand this form or have any questions about this form please call Dr. Hardan or his research staff at (650) 723-7845 before signing the following field.