

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
CONSENT TO BE A RESEARCH SUBJECT**

*Disorders of Cerebral Development: A Phenotypic and Genetic Analysis*

**A. PURPOSE AND BACKGROUND**

Elliott H. Sherr M.D. Ph.D. and his colleagues, from the Departments of Neurology, Pediatrics, Neurosurgery, Radiology and Obstetrics and Gynecology, are conducting a study to learn about brain development and disorders that can occur in this process. They would like to understand problems and issues associated with having these conditions and they would like to investigate the potential genetic and environmental causes.

Your child is being asked to participate in this study because you/your child or a close relative has a disorder of brain development that is visible on an MRI (or other imaging study) and/or a disorder of brain development that has been clinically diagnosed, such as autism, epilepsy or cerebral palsy.

**B. PROCEDURES**

If you consent for your child to participate in this study, the following will happen:

1. Your child will have a physical examination, you and your child will be asked questions about her/his medical history, her/his photograph will be taken and her/his medical chart will be reviewed.
2. Her/his blood, saliva, and/or cheek cells will be collected for laboratory tests. You will be asked to review and complete a separate consent for tissue banking form for your child that will allow us to save his/her donated tissue specimens for future research. If you/your child are unable to visit UCSF to donate samples, we may provide you with a kit for collection of specimen and shipping materials for sending it back via PathTec, a company that specializes in secure and confidential passage of said materials.
3. We are also interested in studying tissue obtained during medical or research procedures, for example a skin or muscle biopsy. If the individual affected by a brain developmental disorder will be receiving a biopsy as part of their care, and only as part of their care, we would like to obtain any tissue that would otherwise be discarded from the medical or research procedure. Analysis of this tissue can often teach us important information about diseases that cannot be learned from studying blood or saliva alone. This will be covered in the tissue banking consent.
4. She/he may be asked to complete an evaluation with a developmental psychologist. For this she/he will be asked to answer standard questions that assess her/his thinking at the time of the test. She/he may be asked to complete additional questionnaires.

5. Once a year for an indefinite period or until the termination of the study, you will be contacted by Dr. Sherr or members of the research team. At that time you will be asked information about your child’s medical history and demographic information will be updated. Your child may be asked to undergo a physical examination, an evaluation by developmental psychologist or a MRI.
6. Study subjects who are quite young upon enrollment may be asked to return for a full physical examination and neuropsychological evaluation at one or two of the annual intervals.
7. The majority of the results of this research study will not be shared with study participants. However, if you would like to receive information an MRI interpretation or the neuropsychological tests, please inform our research team. We can provide participants with information about MRI scans as evaluated by a neuroradiologist on our research team. We can also provide the scaled scores from the standardized neuropsychological tests performed during the evaluation. In neither case should these substitute for standard medical care. However, if we identify important and treatable clinical information during our study, we will inform you in a timely manner and help you quickly identify medical assistance.
8. Your/your child’s photographs, radiographic data, and/or medical history may be used in published medical journal articles or scientific presentations for diagnostic, descriptive or educational purposes. Your/your child’s photographs or medical history will not be connected with your/your child’s name, your/your child’s date of birth, or any such identifying information. Your consent to publish unaltered photographs will be asked for at the end of this consent form.

Time to participate in this study will range from 4-16 hours for the initial evaluation and 1-3 hours for yearly assessments.

You may at any time contact the researchers at 415-502-8039 and ask that your child’s samples be withdrawn from research use, and any identifiable samples still in their possession will be destroyed.

### **C. MULTI-SITE COLLABORATION**

For this project we are collaborating with the Fuller Graduate School of Psychology (Drs. Warren Brown and Lynn Paul), California Institute of Technology (Drs. Ralph Adolphs and Lynn Paul) and the University of Washington (Dr. William Dobyms). We will ask for your consent to have your/your child’s personal health information shared between this study and the previously mentioned research programs at the end of this form.

### **D. RISKS/DISCOMFORTS**

1. Confidentiality
  - i) Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. If you sign this consent form, you are allowing the principal investigator and his research

- team to review the medical records that you provide us with. Your or your child's name will not be used in any published reports about this study.
- ii) This study involves an investigation into the genetic cause of brain malformations. All genetic information obtained in this study (including the possible determination of unsuspected paternity) will be handled with the utmost attention to confidentiality and will not be shared with study participants. If you have questions about the clinical genetic implications of brain malformations in your family, we will provide you with a referral to a medical genetics team for possible evaluation and counseling.
  - iii) There is a risk of insurance or employment discrimination on the basis of substantiating the diagnosis or of determining carrier status for an inherited disorder. However, no information obtained in this study will be placed in your child's medical records nor will it be provided to any insurance entity or place of employment, except in the situation described in the following section (iv).
  - iv) A UCSF medical record will be created if your child receives services from the Pediatric Clinical Research Center (PCRC) because of their participation in this study. Their consent form and some of his/her research test results will be included this record. Therefore, his/her other UCSF doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.
  - v) If you choose for your child to allow sharing of his/her personal health information with the studies mentioned in Section C: Multi-site Collaboration, it may involve a loss of privacy. Your child's information will be handled as confidentially as possible to minimize any risk to his/her privacy

**Treatment and Compensation for Injury:**

If your child is injured as a result of being in this study, treatment will be available. The cost of such treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at (415) 476-1814.

**E. CERTIFICATE OF CONFIDENTIALITY**

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. 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.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. For example, we will voluntarily disclose information about incidents such as child abuse, and intent to hurt yourself or others. In addition, 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. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

## **F. BENEFITS**

We are able to release a limited amount of data that we have collected to participants. If you are interested in receiving a copy of this data, please notify Dr. Sherr or a research coordinator and they can provide you with more information. Please remember that the information we collect is for research purposes only and is not meant to replace a diagnostic clinical report as would be provided by your personal physician. We cannot give recommendations or interpretation of the data.

There will be no direct benefit to your child (other than the data we mentioned above) from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like this and will help the researchers learn more about how the structure of the brain is formed.

## **G. ALTERNATIVES**

This study is strictly voluntary. You or your child may choose not to participate.

## **H. COSTS**

You will not be charged for any of the study procedures. The costs of MRI exams and all other tests associated with this study will be covered by the study.

## **I. PAYMENT**

You/your child will not be reimbursed for your/your child's time spent participating in this study. If you/your child come to UCSF for additional testing, you will be given a separate consent form which discusses payment options.

## **J. QUESTIONS**

This study has been explained to you by Dr. Elliott Sherr or the person who signed below and your questions were answered. If you have any other questions about the study, you may call Dr. Sherr at 415-514-9306, or his associate at 415-502-8039

## **K. CONSENT**

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about your child. **PARTICIPATION IN RESEARCH IS VOLUNTARY.** Your child has the right to decline to participate or to withdraw at any point from this study. You will be given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

## Multi-Site Collaboration

By initialing below, I allow the sharing of my personal health information between Dr. Sherr and his collaborators at Fuller Graduate School of Psychology (Dr. Warren Brown and Dr. Lynn Paul), the California Institute of Technology (Drs. Ralph Adolphs and Lynn Paul) and the University of Washington (Dr. William Doherty), as is outlined in Part C of this consent form.

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Initials

## Contact About Future Studies

There may be studies in the future in which your child may be eligible. Your child is under no obligation to participate in these studies and your decision will not affect your child's care. Please indicate your preference below by writing your initials next to the appropriate line:

\_\_\_\_\_ Yes, you may contact me in the future about other studies. I understand that my child is under no obligation to take part.

\_\_\_\_\_ No, I am only interested in taking part in this study.

## Publishing of Photographs in Scientific Journals and Presentations

Please initial next to the statement that you agree with. **Initial** next to **one statement only**.

\_\_\_\_\_ I allow unaltered photographs of my child to be published in scientific journals and presentations.

\_\_\_\_\_ I only allow altered photographs that will remove key identifying features (for example, a black bar over the eyes) to be published in scientific journals and presentations.

\_\_\_\_\_ I do not allow any photographs at all to be published in scientific journals and presentations.

## Study Participation

If you would like your child to participate, you should sign below.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent/Legal Guardian

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Relationship to Minor Subject

\_\_\_\_\_  
Name of Minor Subject

If your child is able to read and understand the procedures, risks, and benefits of the study, please have them indicate their willingness to participate by signing below, in addition to your signature above.

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Date	Signature of Minor	Print Name
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Date	Signature of Person Obtaining Consent	Print Name of Person Obtaining Consent
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