UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO DONATE SPECIMENS FOR FUTURE RESEARCH

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

This is a research study. The study doctor Elliott H. Sherr, M.D., Ph.D. from the Department of Neurology and/or a research coordinator will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about your child's participation in this study, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because:

1. You/your child 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 or you are a brother or sister of someone who has a disorder of brain development.

   OR

2. You/your child has a particular chromosomal change. A chromosomal change is a specific change inside the DNA of a person that may affect their development and/or health.

Why is this study being done?

The purpose of this study is to learn about brain development and disorders that occur in this process. We would like to understand problems and issues associated with having these conditions and they would like to investigate the potential genetic and environmental causes.
We are collecting blood samples from participants as well as certain family members as a part of the genetic analysis. In addition, we are collecting other tissue samples including those obtained during a medical or research procedure(s) performed by your personal physician or the principal investigator Dr. Elliott Sherr.

How many people will take part in this study?

About 900-1000 individuals with disorders of cerebral development, their parents and other significant relatives will take part in this research study.

What will happen if I agree to take part in this research study?

If you agree to be in this study, the following may happen:

1. You will be asked questions about your medical history, your photograph will be taken and your medical chart will be reviewed.
2. Blood, saliva, and/or cheek cells will be collected for laboratory tests. You will be asked to review and complete a separate consent form for tissue banking that will allow us to save your donated tissue specimens for future research. If you 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. 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. You may be asked to complete an evaluation with a developmental psychologist. For this your will be asked to answer standard questions that assess your thinking at the time of the test. You may be asked to complete additional questionnaires.
5. Once a year for an indefinite period or until the termination of the study, Dr. Sherr or members of the research team will contact you. At that time you will be asked for updated information about your medical history and demographic information will be updated.
6. The majority of the results of this research study will not be shared with study participants. However, if you would like to receive information regarding the MRI interpretation, please inform our research team. We can provide participants with information about MRI scans as evaluated by a neuroradiologist on our research team Please note that his report does not 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.
7. Your 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 photographs or medical history will not be connected with your name, your 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.

Can my child stop being in the study?

If you first agree to participate and then change your mind, you are free to withdraw from the study and discontinue your child's participation at any time. To do so, you can notify the investigator in writing at the address below and we will destroy any remaining identifiable sample and information if it is no longer needed for your care. However, if any research has already been done using portions of your specimens, the data will be kept and analyzed as part of those research studies. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. Your decision will not affect your ability to receive medical care and you will not lose any benefits to which you would otherwise be entitled.

Elliott H. Sherr M.D. Ph.D.

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Are there benefits to taking part in the study?

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 you (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.

What risks can I expect from being in the study?

Drawing blood may cause temporary discomfort from the needle stick. Other risks associated with having blood drawn are slight but may include fainting or feeling light-headed, bruising, and infection. There is also a small risk that your child might feel distressed or nervous about having blood drawn (venipuncture).

You might feel worried about the possibility of your personal information and/or participation in this study not being kept confidential. The risk of unwanted sharing of health information will be minimized by ensuring that all study records that identify you will be kept completely confidential. A unique study subject number will be used on sample tubes as well as databases containing your follow-up testing and questionnaire information. Only select members of the primary research team will have access to the original data. The information you provide will be stored in a locked file cabinet.

There may be risks that are unforeseen and no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about your participation in the study.

For more information about risks, ask one of the investigators or research staff.

What other choices do I have if I do not take part in this study?

You are free to choose not participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of his or her regular benefits. Your decision regarding participation, will not affect your enrollment in other research studies.

Will my medical information be kept private?

We will do our best to protect the information we collect about you. Information which identifies you will be kept secure and restricted. If information from this study is published or presented at scientific meetings, your name and other identifiers will not be used. Information which identifies your child will be destroyed when this research is complete. Your personal information may be given out if required by law. The following information about you in your research records may be requested by:

- UCSF's Committee on Human Research
- Government agencies involved in keeping research safe for people, such as the Food and Drug Administration (FDA).

Sensitive research information: Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. There is a risk that information about taking part in a study about ASD may influence insurance companies and/or employers regarding your health. However, no information obtained in this study will be placed in your medical records nor will it be provided to any insurance entity or place of employment.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Elliott Sherr, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him 415-502-8039.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, treatment will be available. The costs of the treatment may be covered by the University of California, depending on a number of factors. The University and the study sponsor do 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

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study by calling the research staff or Dr. Sherr at (415) 502-8039.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

What financial issues should I consider before donating?

You will not be charged for donating your specimen. You child will not be paid for donating your specimen. If any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. UCSF may receive payment from researchers requesting specimens in order to cover the costs of collecting and storing the specimens

What alternatives do I have?

You can choose not to donate your specimen and/or you can choose not be a part of the overall study on disorders of cerebral development.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. No matter what decision you make, there will be no penalty to you. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

You child have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. PARTICIPATION IN RESEARCH IS VOLUNTARY. You will be given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

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 Dobyns). 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.

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 Adophs and Lynn Paul) and the University of Washington (Dr. William Dobyns).

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Initials

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.

Contact About Future Studies

There may be studies in the future for which you may be eligible. You are under no obligation to participate in these studies and your decision will not affect your 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 I am 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 ofmuseIf 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.

When subject is an adult:

Please note that all individuals providing blood samples and/or medical records are considered subjects. Therefore, all participating relatives must sign a copy of this form.

Date	Subject's Signature for Consent	Print Name of Adult Subject

If the person being considered for this study is unable to consent himself/herself because he or she is cognitively impaired the legally authorized parent or legal guardian my sign here:

Date	Parent or Legal Guardian's Signature	Print Name

Relationship to Adult Subject

When subject is a minor:
If the subject being considered for the study is a minor, the parents or legal guardians may sign here:

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.

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