CONSENT TO DONATE SPECIMENS FOR FUTURE RESEARCH

Disorders of Cerebral Development: A Phenotypic and Genetic Analysis

This is a request that you donate specimens from your child for medical research. The researchers, Dr. Sherr and his colleagues from the Departments of Neurology, Pediatrics, Neurosurgery, Radiology and Obstetrics and Gynecology from UCSF, will explain this research to you.

Medical research includes only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your healthcare team. If you have any questions you may ask the researchers.

You are being asked to participate because your child has been diagnosed with a disorder of brain development, and you have expressed an interest in donating your child’s tissue specimens in the event of their death.

Why is this research being done?
The purpose of the study, Disorders of Cerebral Development: A Phenotypic and Genetic Analysis, is to learn about brain development and disorders that arise in this process. This research program is being conducted by the University of California at San Francisco (UCSF), in collaboration with University of Washington, Fuller Graduate School of Psychology, and California Institute of Technology.

This study is being funded by the National Institute of Health. The scientific data collected may be shared with collaborating researchers at UCSF, University of Washington, Fuller Graduate School of Psychology, and California Institute of Technology. Investigators participating in this research have no financial interests in the study.

How many people will take part in this research?
About 900-1000 individuals with disorders of cerebral development, their parents and other significant relatives will take part in the study, while only a small number of interested individuals will take part in the tissue donation described in this consent form.

What will happen if I agree to donate my child’s specimens?
If you agree to let researchers collect and store your child’s specimens for future research, the following will happen:
• In the event of your child’s death, we will collect and store your child’s tissue specimens in a “tissue bank” for our research purposes as well as possible future research. In addition, we will collect and save information from your child’s medical records. We do not know for sure if your child’s specimens or information from the medical record will be used, but they might be used in research about the development of human nervous system.
• Depending on your wishes, either the entire brain or representative areas will be collected. The representative areas of the brain are selected based on our research interests and on the current scientific literature.
• We may collect a small section of your child’s liver, unless the child’s liver is viable and you have consented to donate the liver for organ transplant.
• We may collect a piece of skin (1 x 1 square cm) from the same place that an incision is made for the autopsy or any other type of postmortem procedure.
• We may draw a small amount of blood (approximately 2 tablespoons).
• We will work closely with your child’s physician and you to facilitate the collection and shipment of your child’s tissue specimen(s) to the tissue bank at UCSF.
• Your child’s tissue specimens will be kept indefinitely at our tissue bank at UCSF.

What risks are involved with donating my child’s specimens for research?
There are no risks to your child for donating tissue specimens once they have been declared dead. There may be some psychological risks associated with donating your child’s tissue specimens in the event of their death. These risks include anxiety and a sense of grief. You may also have concerns about how your child will look following the tissue collection. The procedure for postmortem tissue collection will not alter the appearance of your child’s face.

Confidentiality: Donating specimens may involve a loss of privacy, but all information will be handled as confidentially as possible. Names will not be used in any published reports from research performed using the specimens. The manager of tissue bank and select tissue bank staff members will have access to information about you but they will not release any identifying information about you to researchers using the specimens. The UCSF Committee on Human Research and other University of California personnel also may see subject information to check on the tissue bank.

If you first agree and then later decide that you do not want your child’s tissue specimens and information to be used for research, then you can tell us, and we will destroy any remaining identifiable specimens and
information. However, if any research has already been done using portions of your child’s specimens, the data will be kept and analyzed as part of those research studies.

Reports about any research using your child’s donated tissue will not be given to you or your child’s doctor. Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if we use the specimen for genetic research, we will not put the results in your or your child’s medical record. The research will not change the care your child or you receive. Your child’s specimens and any information about your child will be kept until it is used up or destroyed. Your child’s and your personal health information cannot be used for additional research without your approval. Standard precautionary measures to protect confidentiality will be taken. However, it is possible that a breach of confidentiality (i.e., a loss of privacy) could occur. Confidentiality will be protected to the extent provided by federal, state, and local law. Genetic information obtained from DNA analysis will not be added to your child’s medical records, nor will incidental genetic findings revealed in the autopsy be communicated to you or your child’s doctor.

**What are the benefits of donating specimens for research?**

There is no direct benefit to your child or you for agreeing to donate your child’s tissue specimens for research purposes. However, we hope to learn something that will advance medicine and help future patients.

**What financial issues should I consider?**

You will not be charged for donating your child’s specimens. You will not be paid for donating the specimens. If any new products, tests or discoveries come about because of this research and 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 may choose not to donate your child’s tissue specimens in the event of their death.

**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 your child or you, and you will not lose any of your regular benefits. Leaving the study will not affect your child’s or your medical care. Your child and you can still receive medical care from our institution.
Who can answer my questions about the study?
You can talk with the study researchers about any questions, concerns or complaints you have about this study. Contact the Principal Investigator, Dr. Elliott Sherr, at 415-502-8039 for any questions, concerns, or complaints.

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.

CONSENT
Please read each sentence below and think about your choice. After reading each sentence, put your initials in the "Yes" or "No" box. If you have any questions about this study, please talk to the study doctor or nurse. No matter what you decide to do, it will not affect your care.

1. My child’s tissue may be kept for use in research to learn about, prevent, or treat brain disorders.

   YES  NO

2. My child’s tissue may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

   YES  NO

3. Someone may contact me in the future to ask me to take part in more research.

   YES  NO
4. Additional tissue may be taken for this research, as described in the What Will Happen If I Agree… section above.

YES  NO

You have been given copies of this consent form and the Experimental Subject’s Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You 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.

If you wish for you and your child to participate in this study please sign below. You will be asked to sign a separate HIPAA form to authorize access, use, and disclosure of protected health information about your child and you. If you do not sign the HIPAA form, the researchers will not collect identifiable information about your child or you.

________________________________________________________________
Date Parent/Legal Guardian #1’s Signature for Consent

________________________________________________________________
Print Parent/Legal Guardian #1’s Name

________________________________________________________________
Date Parent/Legal Guardian #2’s Signature for Consent

________________________________________________________________
Print Parent/Legal Guardian #2’s Name

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