Children's Hospital of Orange County
INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT AGREEMENT

National Human Neural Stem Cell Resource
(Post-Mortem Specimen Consent)

*Name of Child:*_____

You are being asked to donate your child's, ward's, or next-of-kin's (hereinafter "child's") tissues for research. Before you give your consent, it is important that you read the following information and ask as many questions as necessary to be sure that you understand what you are being asked to do. If you don't understand something in this consent form, please be sure to ask your study doctor to explain.

TITLE

National Human Neural Stem Cell Resource

PRINCIPAL INVESTIGATOR

Philip H. Schwartz, PhD (714) 516-4310

PURPOSE

You are being asked to allow your child to participate in the program described below because it is believed that your child may have a developmental disorder or can act as a donor who did not suffer from a neurodevelopmental disease. The developmental disorders are problems in cell function and/or metabolism that affect the normal fetal and childhood development of the human being. These problems are being studied by many techniques, including the tissue culture technique and genetic research, and you are being asked to donate samples of your child's tissues during a post-mortem examination. By signing this consent you agree to allow the National Human Neural Stem Cell Resource (the RESOURCE) to have these tissues, to grow cells from some of these tissues using the tissue culture technique, to store these tissues and cells for many years, to make these tissues and cells available to qualified researchers as explained below and/or to transfer some or all of these tissues/cells to another tissue repository(s). The tissue may be used to derive human pluripotent stem cells for research. These cells will be derived and used following National Institutes of Health (NIH) guidelines and may be used, at some future time, for transplantation research.

The RESOURCE is collecting human tissues/cells from patients with disorders such as Down's Syndrome, Sudden Infant Death Syndrome, various types of encephalopathies, aminoacidopathies, leukodystrophies, and lysosomal disorders, autism, Alzheimer's disease, Parkinson's disease, and other disorders of development as well as tissues/cells from normal

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v. 11/8/2000

individuals. The RESOURCE stores these tissues/cells according to rigid scientific criteria and make catalogs of tissues/cells available to qualified researchers across the United States and around the world. Specimens of the tissues/cells are released to specific researchers after they have demonstrated scientific competence to the Resource in the research that they intend to use the specimens for and have signed a Tissue Transfer Agreement with the RESOURCE that, among other things, protect privacy and confidentiality. Specimens are only released for the purpose of conducting meaningful research on the causes and treatments of developmental disorders or on understanding normal human development.

PROCEDURE

Unless constrained by the restrictions listed below, the RESOURCE will remove the entire brain and varying size samples of almost every other organ in the body. A complete list of the organs/tissues to be removed is listed on the signature page of this consent. In addition, the RESOURCE will grow cells from skin, muscle, blood, brain and/or other organs. The tissues/cells will be stored for many years or decades. The tissue and cells will be handled respectfully, as is appropriate for all human tissue used in research. We will also ask you to sign a release that permits review of your child's medical records. The RESOURCE may also transfer some or all of these tissues or cells to another tissue repository(s).

RISKS

There are no immediate risks posed by this donation. A breach of confidentiality, however, could affect your insurability or employability. The results of this study could provide information about the risk of future development of developmental disorder in you, in your relatives including any offspring, or in future offspring. This may be very upsetting because there may be no therapy for this developmental disorder or the results may show that the developmental disorder may be passed on to any other children you may have.

BENEFITS

Although there is no direct personal benefit to you or your child for participation in this donation, there may be a benefit to society and medical knowledge by allowing investigators to study cell function and metabolism.

SUBJECT ACCESS TO INFORMATION

You will not receive any information regarding subsequent testing on this tissue that is derived from researchers using this tissue unless that information is confirmed and is clinically significant or scientifically relevant and a course of action or treatment is readily available.

If we discover new information that is clinically relevant to you, you may be asked to have the test repeated in a clinical laboratory. The results from the clinical laboratory will be forwarded to your primary care giver.

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COSTS AND COMPENSATION

You understand there will be no costs to you for any test performed by the RESOURCE or by researchers supplied by the RESOURCE. The only costs to you will be those directly attributable to any procedures ordered by your physician. There is no compensation available for your participation. There is a possibility that the donated tissue may have commercial potential, subject to the laws of the Federal Government; however, you will not receive financial or any other benefits from such future commercial development.

COMMERCIAL DEVELOPMENT

Under federal law, the cell lines and purified DNA derived from your child's blood or tissue samples are yours to do with as you determine. By consenting to participate, you authorize the use of your child's samples for the research described in the PURPOSE and PROCEDURES sections of this document. In addition, you acknowledge that the RESOURCE may make any lawful use of your child's samples, including, but not limited to, future research studies, destroying them, or transferring them to a public or private entity.

Samples obtained from your child in this research may be used to make a discovery that could be patented or licensed to a company. There are no plans to provide financial compensation to you should this occur. However, should the RESOURCE ever provide your child's samples to anyone else for research or commercial use, it will do so in such a way as to protect your privacy and confidentiality as stated in the CONFIDENTIALITY section of this document. Further, you will have no responsibility or liability for any use that may be made of your samples.

CONFIDENTIALITY

Case histories, the results of treatment, laboratory and pathologic data, photographs and x-rays may be released to researchers or be published for scientific purposes, but your child's identity will not be disclosed without your expressed permission. Confidentiality will be maintained to the extent permitted by law. A code number will be assigned to your child's samples/information. Only the investigators named on this consent form, or their designees, will be authorized to link the code number to your child. Other investigators who may receive a sample of your child's tissue or DNA or cells for research will be given only the code number which will not identify your child. The Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and/or their designee(s) or members of the CHOC Institutional Review Board may inspect the records relating to the RESOURCE. All other parties including employers, insurance companies, personal physicians, and relatives will be refused access to the information or to the samples, unless you provide written permission, or unless we are required by law to do so. If the plan or use of the information is to be changed, you will be so informed.

VOLUNTARY PARTICIPATION

_____
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This program has been reviewed and this consent form has been approved by the CHOC Institutional Review Board (IRB). The approval of this Board does not alter the fact that the final decision to enter yourself in the program is yours; you may choose not to participate in this study. You understand that you have the right to remove yourself from the program at any time. The RESOURCE Principal Investigator will answer any questions you may have regarding the program. Subsequent medical care at the medical institution where your child was treated in no way depends upon participation in this study program.

If in the future you decide you no longer want to participate in this research, we will destroy all your child's blood/tissue samples/genetic or other information. However, if your samples are already being used in an on-going research project and if their withdrawal jeopardizes the success of the entire project, we may continue to use them until the project is completed.

HOW TO OBTAIN INFORMATION

Daytime, Monday through Friday, 8:00 a.m. to 4:30 p.m., you may call (714) 516-4310. You may leave a message with a secretary/voice-mail and your call will be returned as soon as possible.

If you have any questions about your child’s rights as a participant in a research study, please contact the CHOC Institutional Review Board for the protection of research participants through:

Research Subjects Manager
Office of Research Administration
(714) 516-4341

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SIGNATURE AND CONSENT

Your signature below indicates that you have read this document, understand its meaning, have had a chance to ask questions, have had these questions answered to your satisfaction, and consent to your participation in this program. You give your consent to have your child's tissue collected according to this program; however, you reserve the right to withdraw your child's samples in the future. You will be given a signed copy of this consent form and a copy of your bill of rights.

I, belonging to one of the following classes of persons authorized to make an Anatomical Gift of the tissues of the above-named decedent at the time of his/her death,

_____ the attorney-in-fact under valid durable power of attorney that expressly authorizes the attorney-in-fact to make an anatomical gift
_____ the spouse
_____ an adult son or daughter
_____ a parent
_____ an adult brother or sister
_____ a grandparent
_____ a guardian or conservator

hereby donate to the National Human Neural Stem Cell Resource for purposes of research studies/education the following:

The following organs or parts will be taken in the following amounts:

_____

_____

(If no restrictions, please write "No Restrictions")

I have no knowledge of any objection by the decedent or objection of an adult son or daughter of the decedent to this donation. I also have no knowledge that the making of this Anatomical Gift is opposed by a member of a higher class of persons, authorized to make an Anatomical Gift, than mine (See the list above for a description of classes, in order of authority.)

_____ _____
Signature Date

May we contact you in the future? Yes_____ No_____

_____ _____
Witness Signature Date

_____
Person Obtaining Consent (Principal Investigator)

Obtained via telephone

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DONOR ADDRESS

_____ _____
Phone No.

_____ _____
Alternate Phone No.

DECEDENT INFORMATION

Name _____Age _____ Sex _____ Race _____

Date of Birth__ Date of Death_____ Time of Death_____

Known Medical History:

_____

_____

_____

Last Treating Physician_____

Phone _____ Address_____

Last Treating Institution_____

Physician and/or institution where diagnosis of developmental disorder (if any) was made_____

_____

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Human Research Participant's Bill of Rights
(For Medical Experiments)

Pursuant to the California Protection of Human Subjects in Medical Experimentation Act, any person who is asked to consent to become a participant in a research study involving a medical experiment or any person who is asked to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedure to be followed in the medical experiment and any drug or devices to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the participant reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the participant, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the participant after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the participant may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the participant's decision.

Date:_____ Signed:_____
Participant

_____
Parent/Guardian/Conservator

_____
Indicate Relationship

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INFORMED CONSENT FORM FOR THE
RELEASE OF MEDICAL RECORDS

Name of donor:_____

The above named individual has endowed his/her tissues to the National Human Neural Stem Cell Resource. As a part of our research program, we routinely request all medical records from attending physicians, hospitals, or other health care providers. The clinical histories and medical records are an important part of the research protocols.

Please be advised that the signature below (patient or legal guardian) authorizes the release of all medical records of _____ to the National Human Neural Stem Cell Resource.

PLEASE RELEASE RECORDS TO:

CHILDREN'S HOSPITAL OF ORANGE COUNTY
NATIONAL HUMAN NEURAL STEM CELL RESOURCE
455 SOUTH MAIN STREET, ORANGE, CA 92868

_____ _____
Signature of person authorizing release of Medical Records Date

_____ _____
Witness Witness

IDENTIFYING INFORMATION:

_____ _____
Other surnames using during lifetime Date of Birth

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CHILDREN'S HOSPITAL OF ORANGE COUNTY
INSTITUTIONAL REVIEW BOARD

Authorization To Use, Create and Disclose Health Information for Research

Study Title: National Human Neural Stem Cell Resource

Research Participant: _____ Age: _____

In this form, the word "you" means both the person who takes part in the research and the person who gives permission to be in the research.

Purpose of this Authorization
We are asking you to take part in the research described in the consent form for the study whose title is identified above. To do the research described, the research staff at CHOC needs to use, create and/or disclose your health information during the course of this study. By law, we have to tell you how we do this and get your permission. This form describes what we will do with your information. Please read it carefully. If you agree with it, please sign your name at the bottom. You will get a copy of this form after you have signed it.

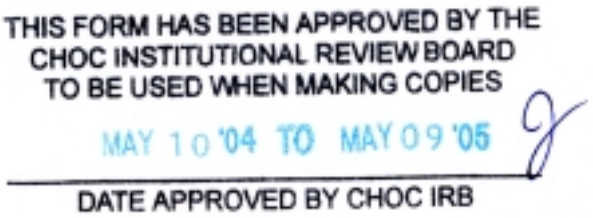
Description of Health Information that will be Used/Disclosed
With your permission, the health information that will be used, created and shared includes:

- All information about you that is collected during the research study. This might include the results of tests or exams that become part of the study records; diaries and questionnaires that you might be asked to fill out as part of the study and other records from the study.
- All health information in your medical records that is needed for this research study. These might include the results of physical exams, blood tests, x-rays, diagnostic and medical procedures and your medical history.

Person/Organization Authorized to Receive Your Health Information
We may share your health information with people at CHOC who help with the research. We may also share your health information with certain people and groups outside of CHOC. These may include:

- The sponsor of the study, National Human Neural Stem Cell Resource, and its representatives
- Government agencies of the United States and foreign countries, review boards, and others who watch over the safety, effectiveness, and conduct of the research
- Other researchers when a review board approves the sharing of the health information
- Your health insurer if they are paying for care provided as part of the research study
- Others, if the law requires

Duration of Authorization and Future Use of Health Information
This authorization will expire 50 years from the date you signed it unless you revoke (cancel or withdraw) it sooner. If you sign this form, we will use, create, and share your health information



until the end of the research or until the expiration date of your authorization, which ever comes first.
Your information may also be useful for other research studies. We can only use your information again if the CHOC Institutional Review Board gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information confidential.

The study Sponsor may use your health information to analyze and evaluate the results of the study. The Sponsor may also reanalyze the results of the study at a later date and combine them with results of other studies. However, your name will never appear on any sponsor forms, reports or publications or in any future disclosures by the Sponsor.

Your Privacy Rights in Research
You do not have to sign this authorization form. If you choose not to allow us to use your protected health information, you cannot participate in this research study. You will not be able to receive any research-related treatment described in the study consent form. We will discuss any non-research alternatives available to you. No matter what you decide you will still get your doctor's care and will not lose any of the benefits you have now.

You may revoke this authorization at any time by notifying the principal investigator in writing at the address below. If you do revoke your authorization, any information previously disclosed cannot be withdrawn. Once information about you is disclosed in accordance with this authorization, the recipient may redisclose it and the information may no longer be protected by federal privacy regulations. However, the recipient may be prohibited from disclosing substance abuse information under the Federal Substance Abuse Confidentiality Requirements.

If you do revoke your authorization, you may need to leave the research study if all the necessary information has not been collected. We will tell you if this is the case. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Access to Protected Health Information Collected, Used, or Disclosed Under this Authorization
You have the right to see and copy your Personal Health Information related to the Study, by contacting the study doctor for as long as this information is held by CHOC. However, to ensure the scientific integrity of the Study, you agree that you may not be able to review some of your records related to the Study until after the Study has been completed.

Questions About this Authorization
If you have any questions, please ask the researcher. You can also call the CHOC Privacy Officer at (714) 532-8466 with questions about the use of your health information.

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Signature and Date

I agree to the use, creation, and sharing of my/my child's health information for purposes of the research study described in this form and the study consent form.

Signature of Participant OR Participant's Legal Representative	Date
Printed Name of Participant's Representative	Relationship to the Participant

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