

# SUDC Child Research Subject Informed Consent Form

**Title of Study:** The SUDC Registry and Research Collaborative  
# S14-01061

**Principal Investigator:** Orrin Devinsky MD  
Director, NYU and Saint Barnabas Epilepsy Centers  
Professor of Neurology, Neurosurgery & Psychiatry  
NYU School of Medicine  
223 E 34<sup>th</sup> Street  
NY, NY 10016  
Phone 646-558-0801  
[od4@nyu.edu](mailto:od4@nyu.edu)

**Emergency Contact:** Daniel Friedman MD  
646-558-0803

## 1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. As the legal next of kin for the child who died of SUDC, you are considered the “subject” throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

## 2. What is the purpose of this study?

The purpose of this study is to increase understanding of Sudden Unexplained Death in Childhood (SUDC). We would like to study the characteristics, circumstances surrounding death, medical histories and possible pertinent diseases of children age 1 month through 18 years who have died suddenly and unexpectedly, and in some instances, without explanation.

You are being asked to participate in this study because you are the parent/guardian of a child from 1 month through 18 years of age who has died suddenly and unexpectedly. The death may also turn out to be unexplained by a complete autopsy.

### **3. How long will I be in the study? How many other people will be in the study?**

We estimate that the following number of subjects will enroll in this study: At this site: 370 SUDC children; 30 SIDS infants, 800 Biological parents and 100 symptomatic siblings and/or second-degree relatives. Total at all sites: 1300 participants

Your participation will not involve any office visits. If you enroll, we would be requesting:

- your permission to review your child's medical records, MRI findings/reports, EEG/video, EEG findings/reports, genetic testing reports, medication records, reports/findings related to the death investigation of your child, a facial photograph of your child and any video that may be helpful in evaluating their cause of death.
- your permission to allow us to have your child's specimens analyzed and then banked at the NYU Biorepository
- your participation in a telephone interview

The total duration of the study will be 10 years.

### **4. What will I be asked to do in the study?**

Dr. Orrin Devinsky and collaborating investigators involved in this study will collect and review your child's medical record and information regarding your child's medical history, family history, imaging results, genetic testing, autopsy reports, medication records, reports/findings related to the death investigation of your child, biospecimens from your child and any other results that are important for understanding SUDC. If you agree to participate, you will be given a separate medical records release form to sign. After an in- depth investigation of all medical and autopsy records and biospecimen analysis, study investigators and Dr. Devinsky, will issue a case review report which can be sent to you.

You will also be asked to complete an interview about yourself, your family situation and your child via phone. The interview will take approximately 60 minutes. The content of the interview may be distressing because it may remind you about your child and their death. If at any time during the interview you feel upset or distressed you can decline to answer a question and/or stop the interview.

Biospecimens will also be collected, transferred and banked at the NYU Biorepository where they will be de- identified, coded and be analyzed by doctors within the SUDC Research and Registry Collaborative (SUDCRRC). Specimens banked at the NYU biorepository will be added to a bank of specimens for use in future research to pursue a greater understanding of sudden deaths in children and lead to their prevention. We will be banking biospecimens for 10 years with a potential to renew storage for another 5 years. We will work with your physicians and those involved in the investigation of your child's death to collect and bank the available biospecimens from your child.

Specimens and materials received at the study regarding your child will be analyzed by study team members to determine whether a possible, probable or definite cause of death can be identified and if additional studies were helpful in determining the cause of death they will be pursued if available. Case reviews that have appropriate specimens available will be sequenced and/or analyzed at Columbia University, NYU, or the NY Genome Center of the Children's Hospital of Philadelphia for genetic studies that involve testing DNA, the makeup of a person's genes or what makes them unique.

You may request transfer of your child’s specimens retained at the SUDCRRC to another research facility, funeral home, crematorium or DNA banking facility. Such requests will be reviewed by Dr Orrin Devinsky and approved if the removal of such specimens does not negatively impact the goals of the SUDCRRC. If you would like to request a transfer, ask Dr. Devinsky or study team members for the “SUDCRRC Biospecimen Transfer Request Form”.

### **Family Member Discrepancies**

Given that genetic analyses, including exome sequencing, are family-centered genetic testing, accurate interpretation of test results requires knowledge of true biological family relationships. There is a possibility that the family genetic relationships do not match what the family reported. This includes non-paternity (when the stated father is not the biological father), non-maternity (when the stated mother is not the biological mother), and consanguinity (when the parents are closely related by blood). It may be necessary to report these findings for accurate interpretation of test results.

Failure to disclose this information may result in incorrect interpretation of test results, incorrect recommendations for your ongoing clinical care and family planning.

Any discrepancies will be reported back to you and we will let you know what this information means for you as this information may be important for accurate interpretation of test results and ongoing clinical care recommendations.

Sometimes, whole organs are retained by the Medical Examiner or Coroner to thoroughly evaluate the causes as to why a person would die unexpectedly. When available and permitted by the Medical Examiner or Coroner investigating their death, the SUDCRRC will perform comprehensive brain and heart studies to better understand a potential cause for their death and to discover information to aide in the better understanding and improved investigations of SUDC. If brain studies are performed, they would be collected, studied and stored by doctors at the SUDCRRC through the Brain Donation Program at the Alzheimer’s Disease Center at the NYU Langone Health and the neuroimaging and neuropathology consultation reports from these studies will be provided to your child’s Medical Examiner or Coroner upon completion.

A case review synoptic report of your child’s review by the study doctors as well as their genetic analysis will be reviewed by Dr. Orrin Devinsky and coinvestigators, and if you agree, this report will be provided to you. The report will also be shared with the original medical examiner or coroner of record. You and your family may discuss any questions regarding the conclusions of the report with Dr. Orrin Devinsky, the collaborating doctors, or with Laura Gould, a co-investigator from the SUDC Foundation. After a report is generated and given to you, we will have SUDC Foundation or SUDCRRC mental health professionals follow-up with a phone call to ensure you aren’t suffering emotionally due to the report.

#### **Case Review Reports**

Checking this box indicates my written request to receive the case review report of my child.

\_\_\_\_\_  
Signature of Parent/LegalGuardianSubject

\_\_\_\_\_  
Date (mm-dd-yyyy)

Checking this box indicates I DO NOT want to receive the case review report of my child.

\_\_\_\_\_  
Signature of Parent/LegalGuardianSubject

\_\_\_\_\_  
Date (mm-dd-yyyy)

## SUDC Genetic Analysis Reports

- Checking this box indicates I DO want to receive the genetic analysis report that may be generated from this study from my child that may benefit family members in relation to choices regarding preventative or clinical care.

\_\_\_\_\_  
Signature of Parent/Legal Guardian Subject      Date (mm-dd-yyyy)

- Checking this box indicates I DO NOT want to receive the genetic analysis report that may be generated from this study from my child's blood even if results may be important to my/my surviving child's health or family's health.

\_\_\_\_\_  
Signature of Parent/Legal Guardian Subject      Date (mm-dd-yyyy)

Researchers will also need health information about the children enrolled, so we are also asking for your consent to place information from your child's medical records in a database to be used for research.

All your child's information collected for this study will be recorded in a computer database until the study is closed out. The computer database is protected by NYU firewall system and also the actual computer is in a locked room that is password protected. This information will not include your child's name, date of birth or other personal information that would allow these data to be tracked back to your child. Only

a few researchers from the study team will have access to the link between your child and his or her information. However, after study closeout, this link will be destroyed so that your child's information cannot be traced back to him or her. Once the link is destroyed, you will not be able to withdraw your child's information.

In order to communicate with you and return any results you have consented to receive, we will need your accurate contact information. We will attempt to contact you by email, phone and mail. If we are unable to contact you through your provided contact information, and have incomplete study participation from you or enrolled family members, we may not be able to complete our study investigation.

**Secondary/Unrelated Genetic Findings:** It is possible that this genetic study will identify information about your child that was previously unknown, such as disease status or risk. The American College of Medical Genetics and Genomics (ACMG) defines an secondary/unrelated finding as an abnormality that is discovered through a deliberate search for disease-causing or likely disease-causing genetic changes that are not relevant to the reason for testing and may not be included in genes of interest relative to the SUDCRRRC. We will look at a specific set of genes as currently recommended by ACMG; variants in these genes are known to be associated with human disease, and incidental/unrelated findings would have medical benefit for the patients and families of patients. These genes include some cancer or tumor syndromes, some connective tissue diseases, cardiomyopathies, and arrhythmias. Some of these conditions have onset in adulthood and an individual may not have recognizable features now. These disorders were selected because there may be changes in medical management for an individual if the individual is known to have a genetic susceptibility to one or more of these disorders. A complete list of diseases/disorders tested for is included in the Summary of Informed Consent Form, which you will be given.

Subjects may choose to be provided information on known, disease-causing genetic changes in these ACMG-specified genes as well as genetic changes that may be disease-causing. If a genetic change is identified in one of these ACMG-specified genes, further testing for that specific gene may be recommended. The absence of a reportable finding in these genes does not mean that an individual has no disease-causing changes in these genes. Coverage of these genes through whole exome sequencing may not be as comprehensive as in panels designed to investigate them.

It is possible that we may identify a genetic variant in a gene that is not included on the ACMG gene list. Most often we will not know with much certainty whether such variants have health implications. Rarely, we may believe the variant is of urgent medical importance; if that is the case, you will be informed of this information, regardless of your choice below.

If an incidental/unrelated result is found, we will attempt to notify you using the contact information you have provided, so that you can speak with Dr Orrin Devinsky, and/or a genetic counselor referral convenient to you.

Please initial below whether or not you would like to be notified of incidental/unrelated findings in the ACMG-specified genes identified in this research study:

\_\_\_\_\_ Please notify me of any incidental/unrelated findings in the ACMG-specified genes obtained from this research from my child.

\_\_\_\_\_ Please do NOT notify me of any incidental/unrelated findings in the ACMG-specified genes obtained from this research from my child.

\_\_\_\_\_ Please ask me if/when incidental/unrelated findings in the ACMG-specified genes are identified whether or not I want to receive this information from my child.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact us at the contact information listed on the first page of this consent form.

## **5. What are the possible risks or discomforts?**

### **Risk of Study**

Participation in this study poses no more than minimal risk (no more risk than expected in daily life). The following are risks and discomforts that you may experience during your participation in this research study. There are no physical risks and discomforts associated with your participation in this study, since there are no office visits required. We are asking for your permission to review your child's medical records, participate in phone interview and collect their available biospecimens for further study. There is the possibility that there may be damage of biospecimens through transportation.

However, all precautions are being taken to minimize any damage to the samples through transportation.

There are potential psychological risks that maybe associated with the investigative report generated. These include but are not limited to: survivor stress and guilt under circumstances where the cause of death was determined to have been preventable, survivor disappointment resulting from the lack of identifying a cause of death despite the research review done during this study, reactivation of painful.

emotions surrounding your child's death and hearing sensitive or graphic information about your child's death (i.e. autopsy information.)

There is also a legal risk. If your participation in the study brings out evidence that your child's death was due to circumstances related to abuse or neglect, the study team is obligated to report this information to legal authorities. There is also a risk of the loss of confidentiality of information provided to the study, but significant measures to prevent this have been addressed as above.

### **Genetic Testing:**

By donating your child's blood or tissue to a study in which we are going to try to discover more about the genetic risks of SUDC, you may be concerned about receiving or not receiving genetic results. It is optional to receive the genetic results to this study.

Genetic testing can generate information about subjects' personal health risks and can cause or increase anxiety, damage family relationships, and/or compromise insurability, employability and can even lead to discrimination. The "Genetic Information Nondiscrimination Act of 2008" is a Federal Law that prevents insurance companies from discriminating against genetic results (you may read more at the following website: <http://www.genome.gov/10002328>)

In order to protect against loss of confidentiality, sensitive information will be kept in locked file cabinets and in secured databases. The test results will not be released to insurance companies or any other third parties

Names of subjects and identifiers will not be mentioned in publications or reports; thereby greatly reducing the possibility of psychological or social risks that could arise from knowledge of this genetic information, such as risk for your employability or insurability or the risk of discrimination.

There are no risks to your health or possibility of physical discomfort involved in allowing your child's specimens to be stored in a bank. Although health information that is collected from your medical record will be kept in a secure database, there is always the risk that it may be accessed by individuals not associated with this study. Efforts will be made to protect your confidentiality as described in this form.

If you choose to obtain the genetic results from this study and clinically relevant findings related to your child's death are identified, we will have the results confirmed by a CLIA- certified genetic laboratory and offer genetic counseling by our genetic counselor at NYU Langone Health who can provide information and referrals to geneticists in your area.

### **6. What if new information becomes available?**

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

### **7. What are the possible benefits of the study?**

The only direct benefit to you from this study is that we will be able to provide you with a detailed analysis of your child's death. Also, it is hoped that the knowledge gained will be of benefit to others in the future in the understanding of SUDC and may help in developing prevention strategies.

## **8. What other choices do I have if I do not participate?**

Your alternative to participating is not to participate in this study.

## **9. Will I be paid for being in this study?**

There is no compensation for participating in the study.

## **10. Will I have to pay for anything?**

All study-related costs associated will be paid by NYU FACES (Finding A Cure for Epilepsy and Seizures), FACES is an organization dedicated to improving the lives of people with epilepsy, and their families, through research, education, and clinical and community support programs.

If the genetic report of your child identifies anything clinically relevant, the investigators would recommend to have the results confirmed by a CLIA-certified genetic laboratory. The investigators of this study would not be responsible for the costs of any CLIA- certified lab genetic testing, but would be willing to assist families, if they desire, with a letter of medical necessity for this testing.

NYU School of Medicine maintains a financial disclosure process, by which people who conduct research must disclose any financial investments (for example, stock shares or patent holdings), board and management positions, or payments (for example, for consulting or speaking engagements) that are related to the research. Persons involved in this research study have told us of an outside interest that may affect this research study.

Dr. Orrin Devinsky, the principal investigator of this study, is a scientific advisory board member and Ms. Laura Gould, a research study team member, is a board member of the SUDC Foundation. Ms. Gould receives travel reimbursements of less than \$5,000.

The NYU Grossman School of Medicine's Conflicts of Interest Management Unit has reviewed the potential conflict of interest arising from the researchers' board positions and Ms. Gould's receipt of travel reimbursements. After the review, they determined that these relationships and the receipt of payments is a potential conflict of interest and placed restrictions on the researchers' participation in the research study, including that you be informed before you enroll in this study. They further concluded that there is little increased risk to your health or to the scientific quality of the research study because of the receipt of payments. If you would like more information, please ask the researchers, the study coordinator or the Conflicts of Interest Management Unit at 212-263-4489.

## **11. What happens if I am injured from being in the study?**

For medical emergencies contact 911. If you think you have been injured or experience serious emotional distress as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

If you sustain any injury during the course of the research, please contact the Principal Investigator Dr. Orrin Devinsky at the following telephone number 646-558-0803. If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs.

There are resources available to you if you feel upset as a result of participating in this study. Dr. Orrin Devinsky and Laura Gould will be readily available if you have any concerns regarding the study. We also have Dr. Scott Hirsch, our in-house neuropsychiatrist and Dr. William MacAllister, a neuropsychologist, will both be available to speak to if you are under emotional stress due to this study. In addition, there are support services we would be able to help point you to the proper support group, if necessary.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

## **12. When is the study over? Can I leave the Study before it ends?**

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. You may also withdraw your Authorization for us to use or disclose your child's protected health information for the study.

If you do decide to withdraw your consent, we ask that you contact Dr. Orrin Devinsky and let him know that you are withdrawing from the study. His mailing address is 223 East 34th St., New York, NY 10016. If you wish to withdraw your Authorization as well you must contact Dr. Orrin Devinsky in writing, at the above mailing address. Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study.

If you agree to allow your child's information to be kept for research, you are free to change your mind at any time. We ask that you contact Dr. Orrin Devinsky in writing and let him know you are withdrawing your permission for your child's medical records to be used for research. His mailing address is 223 East 34th St., New York, NY 10016. Any medical records received will be destroyed.

This study is expected to end after all information has been collected. This study may also be stopped or your participation ended at any time by the principal investigator of this study (Dr. Orrin Devinsky) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

## **13. How will my child's information be protected?**

NYU Langone Medical Center, which includes NYU Hospitals Center and NYU School of Medicine, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your child's health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in



this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

### **What information about my child may be used or shared with others?**

The following information may be used or shared in connection with this research:

- Information in your child's medical record and research record, for example, results from your child's physical examinations, laboratory tests, procedures, questionnaires and diaries.
- Deidentified images may be used for educational purposes.

You have a right to access information in your child's medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Medical Center policies and applicable law.

### **Why is my child's information being used?**

Your child's health information will be used by the research team and others involved in the study to conduct and oversee the study.

### **Who may use and share information about my child?**

The following individuals may use, share or receive your child's information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- The study sponsor: FACES
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers and laboratories or other individuals who analyze your child's health information in connection with this study.
- Every research site for this study, including this hospital, and including each sites' research staff and medical staff
- Any laboratories and other individuals and organizations that analyze your child's health information in connection with this study in accordance with the study's protocol such as ExamOne
- The United States research regulatory agencies and other foreign regulatory agencies
- The members and staff of the hospital's affiliated Institutional Review Board
- The members and staff of the hospital's affiliated Privacy Board
- The Patient Advocate or Research Ombudsman (CTSI)
- Data Safety Monitoring Board/Clinical Events Committee
- Other study sites: Mayo Clinic, Columbia University, Children's Hospital of Philadelphia (as a research collaborators) and external study team members.

### **How long may my child's information be used or shared?**

Your permission to use or share your child's personal health information for this study will never expire unless you withdraw it.

### **Can I change my mind and withdraw permission to use or share my child's information?**

Yes, you may withdraw or take back your permission to use and share your child's health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the

principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

#### 14. Optional permission for future use

NYU Langone Health would like to store, use, and share your child’s health information from this study in research databases or registries for future research conducted by NYU Langone Health or its research partners. Identifiers will be removed from your identifiable data and specimens. After such removal, the data and specimens may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use these data and specimens as we have noted here.

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting information into one or more scientific electronic databases, where it is stored along with information from other studies. Researchers can then study the combined information with even more subjects to learn more about health and disease. For example, some of your child’s genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by NYU, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP” which is specific to genetic research. A researcher who wants to study the information must apply to the database and could use the data for any type of disease research. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your child’s name and other information that could directly identify your child (such as address or phone number) will never be placed into a scientific database. However, because your child’s genetic information is unique to them, there is a small chance that someone could trace it back to them. The risk of this happening is very small, but may grow in the future.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYU Langone Health will continue to protect the confidentiality and privacy of this information as required by law and our institutional policies. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

- Checking this box indicates my permission to store, use, and share my child’s health information and biospecimens from this study in research databases or registries for future research conducted by NYU Langone Health or its research partners as above. \_\_\_\_\_ Subject Initial
  
- Checking this box indicates I DO NOT provide consent for my child’s health information or biospecimens to be used for future research and therefore will be destroyed when the study is completed if they are not previously withdrawn and transferred. \_\_\_\_\_ Subject Initials
  
- Checking this box indicates I will transfer any unused study biospecimens from my child prior to completion of the study to a funeral home or crematorium for cremation, or to another authorized research facility for research with a materials transfer agreement with NYU. If I do not, they will be destroyed when the study is completed if they are not previously withdrawn and transferred. \_\_\_\_\_ Subject Initials

## 15. Permission to be contacted for future research studies

I authorize the principal investigator and his co-investigators to contact me about future research studies provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol. If I agree, then someone from Dr. Orrin Devinsky's research staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

Checking this box indicates my consent to be contacted in the future regarding research studies I may wish to join.

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Signature of Parent/Legal Guardian Subject

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Date (mm-dd-yyyy)

Checking this box indicates I DO NOT want to be contacted in the future regarding research studies.

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Signature of Parent/Legal Guardian Subject

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Date (mm-dd-yyyy)

## 16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible.

The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

## 17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

I/We, \_\_\_\_\_ the parent(s)/guardian(s)

of \_\_\_\_\_ (name of child who died) who was born on. \_\_\_\_\_

(mm/dd/yyyy) and died on \_\_\_\_\_ (mm/dd/yyyy), agree and consent to the research study as described in this form.

\_\_\_\_\_  
*Name of Parent/Legal Guardian Subject#1(Print).*

\_\_\_\_\_  
*Signature of Parent/Legal Guardian#1 Subject*

\_\_\_\_\_  
*Date (mm-dd- yyyy)*

\_\_\_\_\_  
*Name of Parent/Legal Guardian Subject#2(Print)*

\_\_\_\_\_  
*Signature of Parent/Legal Guardian#2 Subject.*

\_\_\_\_\_  
*Date (mm-dd- yyyy)*

\_\_\_\_\_  
*Name of Person Obtaining Consent (Print).*

\_\_\_\_\_  
*Signature of Person Obtaining Consent*

\_\_\_\_\_  
*Date (mm-dd- yyyy)*