



San Diego SIDS/SUDC Research Project Investigation into Sudden Unexplained Death in Childhood (SUDC) Informed Consent Form

This is a research study. Research studies include only subjects who choose to take part. You are being asked to participate in this study because you are a parent/guardian of a child from 1 through 16 years of age who has died suddenly and for unknown reasons. We will be asking you to share information about your child and provide permission for release of your child's records and materials for the purposes of learning more about SUDC. Please take your time to make your decision and discuss it with your family. Please be sure to ask any questions that you may have.

STUDY INVESTIGATOR AND SPONSOR:

Principal Investigator: Henry F. Krous, MD
Sponsor: CJ Foundation for SIDS and First Candle/SIDS Alliance
Research Associate: Elisabeth A. Haas, MPH

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to increase understanding of the characteristics, circumstances surrounding death, medical histories and pathology of children from ages 1 through 16 years who died suddenly and unexpectedly.

HOW MANY CHILDREN WILL BE IN THE STUDY?

At least 250 children from 1 through 16 years of age who have died suddenly and unexpectedly will be entered into this study.

HOW LONG WILL I BE INVOLVED IN THE STUDY?

Participation in the study will vary from 6 to 12 months or longer, depending on factors such as:

1. The length of time it takes to receive all of the requested materials,
2. The length of time required for our review and analyses,
3. Whether additional testing or evaluation will be performed after the Principal Investigator's initial review

You can stop your participation in this study at any time.

WHAT IS INVOLVED IN THE STUDY?

Your participation will involve:

1. Reviewing and signing this Informed Consent Form, a copy of which will be sent to your child's healthcare providers and pathologist who performed your child's autopsy, authorizing the release of his/her records, microscopic slides, and tissues/fluids, if available.
2. Reviewing and signing the Authorization for Use or Disclosure of Protected Health Information for Research Purposes.
3. Communicating information about your child to the Principal Investigator and/or research staff.
4. Completing a family survey (**OPTIONAL**) to collect information on your child's general history, medical history, maternal pregnancy history, sibling and family medical history, parental medication use, and the circumstances surrounding your child's death.

What the study will involve

1. Following receipt of a copy of this signed Informed Consent Form, your child's healthcare providers and pathologist will send his/her records and microscopic slide duplicates (and in some cases selected tissues or fluids) directly to the study site. NOTE: Some physicians or hospitals may require that you fill out an additional consent form for the release of your child's medical records to the principal investigator and research staff.
2. The Principal Investigator and research staff will review the microscopic slides, records, and any other information provided by you, whether from a written personal account, interview, or the family survey.
3. At this point, the Principal Investigator will either:
 - Confirm your child's original diagnosis,
 - Provide an alternative diagnosis, or
 - Delay diagnosis assignment until further testing or evaluation is complete.
4. Dr. Marjorie Grafe, Pediatric Neuropathologist at Oregon Health and Science University, will perform neuropathological evaluation on every case with available brain or brainstem microscopic slides and/or formalin-fixed tissue.
5. If considered necessary by the PI, further testing and evaluation may be done by the following research staff:
 - Dr. Roger Byard, Forensic Pathologist at the Forensic Science Centre, Adelaide SA, for clinicopathology and diagnostic support
 - Dr. Thomas Keens, Pediatric Pulmonologist at the Children's Hospital-Los Angeles, for clinical (health history) evaluation
 - Dr. Piero Rinaldo, Pediatric Metabolism Expert at the Mayo Clinic, for metabolic (chemical processes in body) evaluation
 - Dr. Michael Ackerman, Pediatric Cardiologist at the Mayo Clinic, for long QT (heart rhythm abnormality) evaluation
 - Dr. Hannah Kinney, Pediatric Neuropathologist, Boston Children's Hospital, for neuropathological (brain and brainstem abnormalities) evaluation
 - Dr. Ingrid Holm, Medical Geneticist, Boston Children's Hospital, for genetic evaluation and analyses.

Additional evaluation by these research staff may include record review, microscopic slide review, and/or additional testing on your child's available tissues or fluids.

6. After all appropriate testing and review has been completed, the Principal Investigator will assign a diagnosis and write a research report summarizing your child's history and describing his findings and his opinion about your child's diagnosis. You will be given the opportunity to review this report and ask the PI



any questions you have about your child's case. You may email him directly or request a telephone appointment.

7. **(Optional)** Genetic analyses: If you agree, postmortem specimens from your child will be used for this optional research to include an effort to determine genetic factors in SUDC. With this in mind, your child's identity will be kept confidential in all genetic research. Participation in the genetic portion of this study is completely voluntary. You should not feel any pressure to participate in this portion of the study. If you choose to not participate in the genetic portion of the study, it will not interfere with the resulting diagnosis assigned by the principal investigator. Results from research genetic testing may take months or years to complete and will not interfere with the report generated to the medical examiner pathologist who performed your child's postmortem examination.

Under the guidelines of the Human Research Protection Program at the University of California, San Diego, Dr. Henry Krous, Principal Investigator, will be responsible for deciding how the postmortem specimens will be used. The postmortem specimens collected from your child and the DNA they may contain would be used for genetic research conducted by investigators who collaborate with the San Diego SUDC Research Project with the University of California. These postmortem specimens, DNA and their derivatives (cell cultures), may have significant therapeutic or commercial value.

8. The research report will be sent to the medical examiner pathologist who performed your child's postmortem examination and copies will be sent to you, Dr. Marjorie Grafe, the neuropathologist who reviewed your child's microscopic slides of the central nervous system, Laura Crandall, SUDC Program Liaison, and Dr. Hannah Kinney, neuropathologist.
9. When the study period is complete, data from all SUDC cases will be analyzed and the results will be reported through abstracts, presentations, and manuscripts at medical and scientific meetings and medical journals.
10. Your child's information may be shared with researchers from other institutions for education and training purposes; no identifiable information will be released.
11. At your request, you will be provided with a bibliography listing these presentations and publications.

The use of your child's tissues or fluids

As stated in the previous section, in order to reassess your child's cause of death, it may be necessary to obtain selected tissues or fluids collected from your child by the medical examiner pathologist. Ultimately, these tissues and fluids may only be used for:

1. Diagnostic purposes and reassessment of your child's cause of death,
2. Research involving SUDC and SIDS,
3. Teaching and education regarding SUDC and SIDS,
4. Presentation or publication of findings,
5. Strict confidentiality will be maintained,
6. (Optional) Genetic analyses for research purposes only in an effort to determine which genes, if any, are involved in the development of SUDC. Only after we receive your permission will we use postmortem specimens from your child for this research. Your child's identity will be kept confidential in this genetic research.

NOTE: Any remaining samples will be retained indefinitely in our locked offices. The samples will be labeled with your child's name and study number. None of the specimens from your child will be used for any commercial purposes.



We will let you know if there are any changes to the study or any new information that may change your mind about participating in this study. If you decide that you do not want the specimens collected from your child to be used for future research, you may tell this to Dr. Henry Krous, the Principal Investigator who will use his best efforts to stop any additional studies. However, in some cases, such as if your child's cells are grown and are found to be generally useful, it may be impossible to locate and stop such future research once the materials have been widely shared with other researchers.

Information sharing with the Medical Examiner or Coroner's pathologist who performed your child's autopsy

Upon completion of his review, the Principal Investigator will send a research report to the pathologist who performed your child's postmortem examination. Information in this report may include a description of 1) what materials he received for the study, 2) his findings after review of all the materials, 3) any additional studies or review that were performed, 4) circumstances surrounding your child's death, 4) your child's medical history, including prenatal history and 5) relevant family medical history. By signing this form you authorize that any additional information you have provided to us may be shared with the medical examiner pathologist.

You will receive a copy of the Principal Investigator's research report that he sends to the pathologist that performed the postmortem examination on your child.

You will not receive any report relating to the genetic analyses of this study, should you choose to participate.

WHAT ARE THE RISKS OF MY PARTICIPATION IN THIS STUDY?

Potential psychological risks:

1. Reactivation of painful emotions surrounding your child's death
2. Stress and guilt if the cause of death is determined to have been preventable,
3. Disappointment in cases where no additional findings are identified and the diagnosis remains unchanged, or
4. Emotional difficulty in hearing about or discussing unpleasant details surrounding your child's death and/or postmortem examination.

Please remember that at any time you may contact the SUDC Program at 1-800-620-SUDC, run by parents like yourself who are suffering from the loss of their child. The SUDC Program is designed to provide you with emotional support when you need it.

Potential legal risks:

1. If there is any new evidence revealed by the Principal Investigator's review (evidence not recognized by the medical examiner or new evidence provided) that your child died as a result of some form of abuse, the Principal Investigator is legally required to report this to the proper authorities, including law enforcement.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Potential benefits of your participation in this study:

- 1) Possible determination or validation of your child's cause of death,
- 2) Potential recognition of a genetic disorder, such as long QT syndrome (heart rhythm problem) or metabolic diseases (problem with chemical processes that take place in body), that are important for your child's existing siblings, and for your future pregnancy planning,



- 3) Comfort from having a “second opinion” by a pediatric pathologist,
- 4) Comfort in knowing that your child’s participation in this study could lead to knowledge that reduces the risk of, or prevents future occurrences of SUDC in other families, and
- 5) Therapeutic benefit of taking an active part in the investigation of your child’s death

Potential benefits to others who have experienced SUDC in their families:

- 1) Generation of greater public awareness of SUDC,
- 2) Increased development of SUDC family resources

Potential benefits to science, society and humanity in general:

- 1) A basis for medical and other professional societies to encourage and support standards for standardized scene investigations and postmortem examinations,
- 2) Motivation for other researchers to investigate such cases,
- 3) Determination of possible cause(s) of SUDC and if there is a distinct connection to SIDS,
- 4) Publication of findings in peer reviewed medical journals and presentation of findings at scientific meetings,
- 5) Recommendations for medical examiners of tissue selection for microscopic examination and additional testing, and
- 6) Scientific basis for developing laws designed to help determine causes of death in cases of SUDC with endorsement of investigative protocols by professional societies.

WHAT OTHER OPTIONS ARE THERE?

At this time, there are no other formalized studies on SUDC of which the Principal Investigator is aware. However, if you feel your child died of something specific (i.e. obstructive apnea, breath-holding spells, etc.), you can contact an expert in this particular field on your own or enter into a study on this particular disorder, if desired. You may also choose to not participate in this study. Your decision not to participate is confidential and will not be communicated to any authorities.

WHAT ABOUT CONFIDENTIALITY?

All information regarding you and your child will be maintained in strict confidence. All of the information will be entered into a password-protected database. All case materials (microscopic slides, blood/tissue specimens, clinical and postmortem records) will be kept in locked offices when not under active review. Neither your name nor your child’s name will be used in any publications or presentations unless you indicate in writing that you wish us to disclose that information. While you are in this study, related information may be made available to the University of California, San Diego Human Research Protections Program and/or other regulatory entities to ensure your safety and protect your welfare.

No information regarding you or your child will be released without your consent to the extent the law allows.

WHAT ARE THE COSTS?

There is no cost to you. The costs of duplication of records and microscopic slides will be covered by research grant funds. In the event that you are accidentally billed for testing, please forward the invoices to the Principal Investigator who will send payment directly to the agency.



WILL I GET PAID TO BE IN THE STUDY?

You will not be paid for your participation in this study.

WHO DO I CALL IF WE HAVE QUESTIONS OR PROBLEMS?

For questions about the study, you may contact any of the following researchers:

Dr. Henry Krous, Principal Investigator, 858-966-5944, hkrous@rchsd.org
Elisabeth Haas, Research Associate, 858-576-1700 x5138, ehaas@rchsd.org
Laura Crandall, Parent Liaison, 1-800-620-SUDC, Laura.Crandall@sudc.org

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Since your participation in this study is voluntary, you may discontinue at any time.

If you have questions about your rights you may call University of California, San Diego Human Research Protections Program (HRPP) at 858-455-5050. The HRPP is a group of individuals who have reviewed and approved this proposal and who have no vested interest in this research other than protecting your rights.

If it becomes necessary, we will tell you about new information that may affect your willingness to continue your participation in this study.



SUBJECT'S BILL OF RIGHTS

It is important that the purpose and procedures of the research study are fully understood and that consent is offered willingly. A subject in a research study, or someone who is asked to give consent on behalf of another person for such participation, has the right to:

1. Be informed of the nature and purpose of the research.
2. Be given an explanation of all procedures to be followed and of any drug or device to be used.
3. Be given a description of any risks or discomforts, which can be reasonably expected to result from this research study.
4. Be given an explanation of any benefits, which can be reasonably expected to the subject as a result of this research study.
5. Be informed of any appropriate alternative procedures, drugs, or devices that may be advantageous and of their relative risks and discomforts.
6. Be informed of any medical treatment, which will be made available to the subject if complications should arise from this research.
7. Be given an opportunity and encouraged to ask any questions concerning the study or the procedures involved in this research.
8. Be made aware that consent to participate in the research may be withdrawn and that participation may be discontinued at any time without affecting continuity or quality of medical care.
9. Be given a copy of the signed and dated written consent form.
10. Not be subjected to any element of force, fraud, deceit, duress, coercion, or any influence in reaching the decision to consent or to not consent to participate in the research.

If you have any further questions or concerns about your rights as a research subject, please contact the researcher or the UCSD Human Research Protections Program (HRPP) at 858-455-5050.

