

INFORMED CONSENT

THE SUDDEN DEATH IN THE YOUNG CASE REGISTRY: RESEARCH, DIAGNOSTIC TESTING AND DNA BANKING



PLEASE PRINT:

Child's

Name: _____

_____ Family

Member's

Name: _____

Phone: _____ Email: _____

Mailing Address: _____
Street, City

_____ State, Zip Code



DATA COORDINATING CENTER FOR THE
SUDDEN DEATH IN THE YOUNG
CASE REGISTRY

Version 2 - February 2016



We are very sorry for the loss of your child. This must be a very sad time for you and your family. We are asking you to consent to save your child's DNA and/or be re-contacted as part of the SDY Case Registry to help researchers and death investigators learn more about the reasons your child and other children died suddenly and unexpectedly.

Please read through this consent form. Ask questions if you do not understand something. We are asking you for three types of consent. The first allows us to link information about your child's death to his/her DNA sample, store your child's DNA for research, contact you for more information or to share findings with you, and store the DNA sample and findings for future studies. The second allows us to send your child's DNA to a lab for testing to help identify the cause of death. The third is to allow us to store your child's DNA so that your family can have a sample for your own testing now or in the future. This is called DNA Banking.

If you consent to save your child's DNA sample and/or to be re-contacted by the SDY Case Registry, check the boxes on pages 11, 13 and 17, and sign your name.

If you cannot decide right now, this form will be left with you. If at a later time you choose to participate, please call the person listed here:

Name _____ of _____ Your _____ Local _____ Contact: _____

Contact's Agency: _____

Phone: _____

Email: _____



DATA COORDINATING CENTER FOR THE
SUDDEN DEATH IN THE YOUNG
CASE REGISTRY

1. What is the “Sudden Death in the Young” Case Registry?

The Sudden Death in the Young (SDY) Case Registry gathers information to learn more about children who die suddenly and unexpectedly. Babies, children and young adults up to age 20 are included in the SDY Case Registry. The SDY Case Registry is funded by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). Your child lived in one of the locations that is receiving funding to gather information for the SDY Case Registry. The SDY Case Registry’s Data Coordinating Center, based at the Michigan Public Health Institute (MPHI), is helping your state gather and store information for the SDY Case Registry. The NIH is funding researchers to study the information in the SDY Case Registry. In some cases, genetic testing may be done to help identify a cause of the death.

2. What is the Purpose of the Sudden Death in the Young Case Registry?

It is hard for death investigators to find the causes for many sudden deaths in young people. It is also hard for public health agencies to count the true numbers of these deaths. This means that doctors, scientists and families really do not have a good understanding of these deaths, which makes it harder to prevent more deaths like these. The SDY Case Registry will gather and store information about sudden child deaths to help:

- Count the number and types of sudden deaths in babies, children and young adults up to age 20
- Try to understand the causes for the deaths
- Study the information to see if some children are more at risk of dying than others
- Study the information to find ways to prevent these deaths

3. What Kind of Information is the SDY Case Registry Collecting?

Four types of information will be collected, stored and studied in the SDY Case Registry: information from the death investigation records, your contact information, a DNA sample extracted from blood or liver tissue that was saved as part of the autopsy, and any genetic testing findings performed as part of the SDY Case Registry.

- a. Information from Death Investigation Records:** Sudden deaths in children are usually investigated by medical examiners, coroners or pathologists. Sometimes a hospital will conduct the investigation. The people who investigate sudden deaths collect information

from health records, family interviews, the autopsy, first responders or police, and other agencies (e.g., social services). The SDY Case Registry is gathering the death investigation information in one place at the SDY Case Registry's Data Coordinating Center. The information will be kept at the Data Coordinating Center for as long as the CDC and the NIH provide funding for the SDY Case Registry.

- b. Your contact information:** The Registry would like to collect your home address, phone number and email address to allow death investigators or the SDY Case Registry to contact you in the future if they have questions or would like to learn more information about your family member. If you agree to be contacted by the SDY Case Registry, we may have follow-up questions about your child's health history and information about the health of family members. The SDY Case Registry may have additional questions. We may also want to contact you if we find information that may put your family members at risk for sudden death or for treatable health problems. Consent is needed for your contact information to be stored in the SDY Case Registry.
- c. DNA sample:** The SDY Case Registry is attempting to collect and store a DNA sample from each child. DNA contains genes, the instructions for how bodies grow and develop. If DNA is collected, the DNA will be stored at the Registry's Biorepository, located at the University of Michigan Medical School. A biorepository is a lab that collects, processes, stores and distributes biospecimens and/or DNA to support research or genetic testing. We want to store the DNA so that we can test it now or in the future. There are diagnostic genetic tests that are available now that can find changes in the genes that may cause disease or sudden death. We expect that in the future there will be even more tests to help us understand the reasons for these types of deaths. Consent is needed to store your child's DNA sample in the SDY Case Registry.
- d. Genetic testing findings:** If persons investigating your child's death need help finding the cause of death, the Biorepository may send the DNA to a diagnostic testing lab. If researchers, who have been approved and funded specifically for the SDY Case Registry, want to know more information about the DNA, the Biorepository may also send the DNA to research testing labs. Consent is needed to send a portion of your child's DNA sample to a diagnostic testing and/or research lab.



4. What if a Genetic Change is Found by the DNA Testing?

If you consent for the SDY Case Registry to perform testing, the testing laboratory may study your child's DNA sample and a genetic change that causes disease may be found. These changes may also be present in other members of your child's family. If a genetic change is found in your child's DNA sample, and the death investigators or researchers believe that family members will 1) benefit from additional testing, or 2) are at risk for sudden death or treatable health problems, the SDY Case Registry will notify you.

If diagnostic testing is requested by the death investigators, the results will be sent directly to those persons legally responsible for investigating the cause of your child's death. This person is usually a medical examiner, coroner or pathologist. This person may contact you directly and connect you with a genetic counselor. A genetic counselor can then help you understand the results and what they mean for you and your family's health.

If you consent to research genetic testing, researchers will be looking at all of your child's genes, not just those related to your child's death. This means they could find changes in genes that have health implications for family members related to your child. If testing is done by researchers and they want to contact you with results, they will contact the Data Coordinating Center. If you agreed to be contacted (by choosing, "YES, you may contact me," on page 11), the Data Coordinating Center will match the unique number associated with your child's DNA sample to your contact information. The SDY Case Registry will then contact you. They will help connect you to a genetic counselor who will explain the results and assist you in getting them confirmed in a clinical laboratory.

If you allow the SDY Case Registry to study your child's DNA sample, it is possible that no genetic changes or cause of sudden death will be found.

5. Who Can Use the Information in the SDY Case Registry?

Medical examiners, coroners and pathologists participating in the SDY Case Registry may use information from the diagnostic genetic testing to help them identify your child's cause of death.

Researchers from federal agencies, universities and other scientific centers may submit proposals to the NIH to study the information and/or DNA samples stored in the SDY Case Registry. These proposals will be reviewed by the SDY Case Registry to make sure the research studies are high quality, will protect confidential information, and are safe and

ethical. Each researcher is required to obtain Institutional Review Board (IRB) approval from their own organization as well. An IRB is an expert panel that will make sure the study meets high standards for quality and confidentiality. Only approved researchers will be able to use the information and/or DNA stored by the Registry.

6. What About Confidentiality?

The DNA sample will be stored at the Biorepository. All of the information gathered will be confidential and private. DNA testing results linked to your child's information will be entered into a secure database managed by the Data Coordinating Center.

Some of the health information may be subject to the federal privacy rules known as HIPAA (Health Insurance Portability and Accountability Act). If you check the box next to, "Allow information from my child's death to be studied in combination with his/her DNA sample," on page 11, you are authorizing the use and disclosure to researchers of information about your child that would otherwise not be available because of HIPAA.

To monitor the quality of the information that is gathered, a small number of approved staff members at the NIH, the CDC, the Data Coordinating Center, the Biorepository, and the sites funded to collect information will be allowed to look at the information from the death investigations and the results of the DNA sample. These people will all sign confidentiality statements that they will not share any of this information with any other persons.

Only death investigators participating in the Registry and researchers approved by the NIH or the Data Coordinating Center will be able to access SDY Case Registry information and/or DNA. All shared information used in research will have personal identifying information removed, so that the researchers will not know the identity of your child.

Genomic Data Sharing Policy

The NIH has created a Genomic Data Sharing Policy. Genomic data refers to information and results from DNA testing. The purpose of sharing genetic data is to better understand results from research and diagnostic genetic testing. If you consent to allow research or diagnostic genetic testing to be done on your child's DNA sample, results may be included in



the NIH data bank and other publically available databases. This will help researchers learn through future studies how to improve health and develop treatments for disease. Future research may include creating cell lines that will keep reproducing and can be used for many purposes. Your child's sample may enable researchers to develop medical tests or treatments that have commercial value. You will not receive any financial benefit from these activities. Data entered into any genetic sharing databases will be de-identified and the link between the DNA, data, and your name and contact information will be broken before the data is entered into any database. This means that your child's name or any other information that could be used to identify them will not be stored in the data bank. Researchers using the data from the NIH data bank or other genetic data sharing databases will not be able to contact you. Even though the data will have the identifying information removed, it may still be possible in the future to identify your child from their DNA sample because some genetic changes are unique only to one person or one family. Because of this, it may still be possible to link a genetic finding back to a family. There may also be additional risks that are not known at this time. The NIH will take care to minimize these risks by limiting who has access to the DNA data and by keeping it secure. Information about the policy can be found online here: <https://gds.nih.gov/03policy2.html>.

SDY Case Registry staff will do the following to protect the privacy of your information:

- A unique number will be assigned to both your child's information and the DNA sample. Your child's name will be removed (de-identified), and this number will be used instead.
- When research data is shared, no contact information or other personal information on your case will be shared with researchers.
- The agency investigating the death will keep a log that links your personal contact information (such as address and telephone numbers) with the unique identification number. This log will be kept private and separate from the medical information.
- The Data Coordinating Center and the Biorepository have many layers of computer security to prevent hacking, mishandling, and unauthorized access to information.
- If you provide consent for researchers to access and use information on your child's death in combination with their DNA sample, the SDY Case Registry cannot guarantee that



this information will not be disclosed to others. But we will take many steps to protect your information. All researchers and their staff will agree to follow security and privacy rules for keeping all the collected information private.

- As discussed in Section 4, researchers may find genetic changes in the DNA that they want to contact you about. They will not give these results to anyone else. This includes any health care provider, insurance company, or any other organizations. The research results will not be put in any medical record. A federal law, called the Genetic Information Nondiscrimination Act (GINA), says it is illegal for health insurance companies, group health plans, and most employers to discriminate against you based on genetic information. This law will protect you in the following ways:
 - Health insurance companies and group health plans may not request the genetic information that is used in this research.
 - Health insurance companies and group health plans may not use genetic information when making decisions about your eligibility or premiums.
- Researchers will agree to only use the data for approved research.
- The SDY Case Registry has obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). This certificate will help to protect your privacy. The Certificate protects you by not allowing the Registry to release any information about your participation in the Registry. The researchers involved in this Registry cannot be forced by the courts to share information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. We will take the necessary action and report to authorities any indication of abuse of your rights to confidentiality.
- You can choose to voluntarily share information about yourself, your child, or your involvement in the SDY Case Registry. The Certificate does not protect against that voluntary disclosure. Researchers will not disclose voluntarily, or without your consent, information that would identify you or your child as a participant in this Registry.
- If an insurer or employer learns about your participation in the SDY Case Registry and obtains your consent to receive information about your participation in the Registry, we may not use the Certificate of Confidentiality to withhold this information.
- We will be required to disclose information about your participation in the Registry upon request of the Department of Health and Human Services (DHHS) only for the purpose of audit or evaluation, but access will be limited solely to DHHS employees involved in an evaluation of the Registry. DHHS will not be allowed to disclose information about your participation in the Registry to anyone else.

7. How Much will it Cost My Family to Join the SDY Case Registry?

There is no cost to you to be involved in the SDY Case Registry. Based on the sudden death of your child, it may be recommended you meet with a genetic counselor. The costs associated with genetic counseling are not paid for by the SDY Case Registry.

8. Will My Family be Paid to Join the SDY Case Registry?

No, your family will not receive any payments or compensation for participating in the SDY Case Registry.

9. Will My Family Get Any Benefits from Joining the SDY Case Registry?

There are no expected benefits to you or your family for participating in this Registry. There is also no guarantee the Registry will find a cause of death or that you will receive results about your child. In the rare event that testing finds a genetic change in your child's DNA, and you allow the death investigators or the SDY Case Registry to contact you, a benefit may be that you and other family members learn about an unknown health problem that was present in your child or in your family. Even if there is no benefit to you, the studies done on the information and DNA samples may help us to understand the causes of sudden death in the young and may help us to develop ways of preventing it from happening to others.

10. What Are the Risks to My Family of Joining the SDY Case Registry?

There are no risks of physical harm associated with participation in the SDY Case Registry. You may be asked to share some private personal information, if the the SDY Case Registry contact you. In this case there is a very small risk of loss of privacy. Protection of your privacy and confidentiality is discussed in Section 6.

The decision to sign this form is yours. You do not have to agree to become involved in this research. If you choose not to participate, there will be no loss of benefits or services available to you.



11. Will We Be Able to Get the Results from the Research Studies?

Results from the SDY Case Registry research will not likely be available for a number of years. The Data Coordinating Center and the NIH will establish a public web site to share the findings from published studies. If you agree to be contacted by Registry staff, we will attempt to inform you when study findings are published.

These study results will not have any information in them specific to your child. They will be general studies that include information on all of the sudden deaths within a particular time frame with no identifying information on any specific child.

12. How Long Will the DNA and Other Information be Kept in the Registry?

The Biorepository will keep the DNA samples until the end of the funding for the SDY Case Registry. After that, samples saved for family DNA banking will remain at the University of Michigan for continued family access and use. Research samples consented to be transferred to the NIH will be sent to the NIH. The Data Coordinating Center will keep information from the death investigation and testing results until the end of the funding for the SDY Case Registry. After funding ends, the DNA will be moved to the NIH for ongoing storage and use. Your child's name will not be stored there. The link between the DNA, data, and your contact information will be broken, and the SDY Case Registry will no longer be able to contact you to ask additional questions or report and discuss your child's DNA findings with you. Researchers will still be able to apply to NIH to access de-identified data and DNA samples to study the information for health research.

13. Can We Drop Out and/or Remove My Child's Information and DNA Sample from the SDY Case Registry?

If you consent to allow research on your child's DNA sample or consent to allow researchers to recontact you, you can withdraw that consent at any time. To withdraw consent, you will need to write a letter to the Data Coordinating Center at the address below asking to:

- Have your contact information for recontact removed
- And/or your child's DNA sample destroyed
- And/or the link between your child's DNA and death investigation information destroyed

Once the letter is received, action will be taken to remove them. If you make this request, no further research on the DNA sample will occur.

Any information about the sample or the linked information that researchers have already learned from research will not be destroyed. This information will remain part of the SDY Case Registry.

Once the funding for the SDY Case Registry ends, if you consent to sending your child's DNA sample to the NIH, you will not be able to ask that the sample or information learned from studying the sample be destroyed.

14. Important Contacts for You:

You may contact the Data Coordinating Center for the Sudden Death in the Young Case Registry for many reasons, including:

1. If you have any questions, concerns or complaints, or if you think this research has hurt you.
2. If you want your child's information and/or DNA sample removed from the SDY Case Registry.
3. If you want to obtain findings from the NIH-funded research studies.

Sudden Death in the Young
Case Registry Data Coordinating Center
c/o Michigan Public Health Institute
2455 Woodlake Circle
Okemos, MI 48864
Telephone: 800-656-2434
Email: info@SDYregistry.org
Fax: 844-816-9662

Contact the Michigan Public Health Institute Office of Research Integrity if you have concerns or issues related to this consent form.

Michigan Public Health Institute
Office of Research Integrity
2364 Woodlake Drive, Suite 180
Okemos, MI 48864
Telephone: 517-324-8313
Email: ORI@mphi.org



Part One: Your Signed Consent for Research

There are five different items for which you can give consent. You need to give consent for each item separately. You do not need to give consent for all five items. Please check the boxes YES or NO next to each of the five options:

I give my consent for the Sudden Death in the Young Case Registry to:

1. Store a DNA sample that was gathered during my child's autopsy and allow that sample to be studied for research purposes approved through the SDY Case Registry. yes no

2. Allow information from my child's death to be studied in combination with his/her DNA sample. Such information includes details about the death and information about medical problems my deceased family member or other members of my family may have had. I authorize the release of health information that may be subject to the Health Insurance Portability and Accountability Act (HIPAA). I understand this information may be used for research studies approved through the SDY Case Registry. Note: You must first agree to Number 1 (Store a DNA sample) to agree to Number 2. yes no

3. Allow the SDY Case Registry to re-contact me if in the future approved researchers have follow-up questions about my deceased child or family history. yes no

4. Allow the SDY Case Registry to contact me in the future if the research on the DNA sample finds information that may put my family members at risk for sudden death or for treatable health problems. Note: you must first agree to Number 1 (Store a DNA sample) to agree to Number 4. yes no

5. At the conclusion of funding for the SDY Case Registry, allow my child's DNA sample to be sent to the NIH and stored so that it can be available for researchers to study in the future. No identifiable information on my child or my family will be stored with this sample at the NIH. Note: you must first agree to number 1 (Store a DNA sample) to agree to Number 5. yes no

Child's Name: _____

_____ Your Name: _____

_____ Phone: _____

_____ Email: _____

Mailing Address: _____
Street City State Zip Code

Your Signature: _____ Date: _____

I am the child's: Parent Other Legally Authorized Representative (describe below): _____

Name of person who explained this form: _____

Agency and Contact Information: _____

Signature: _____ Date: _____

Please fax completed form to the SDY Case Registry Data Coordinating Center at 844-816-9662.

Part Two: Your Signed Consent for DNA Diagnostic Testing

Please read this information carefully. If you have any questions, please ask the person who is helping you with this form. After you read this information and if you agree, you will be asked to sign the DNA Diagnostic Testing informed consent section below. Please check the boxes YES or NO:

If (1) the individual performing my child's autopsy determines that diagnostic genetic testing could help to determine the cause of my child's sudden death and (2) there is enough DNA sample at the Sudden Death in the Young Case Registry Biorepository, **I give my consent for the SDY Case Registry to send a portion of my child's DNA sample to the commercial laboratory, for the purposes of diagnostic genetic testing.** Possible indications for this testing may be to determine if the cause of death was due to a heart condition, epilepsy or metabolic cause. I understand that results will be sent to the person performing my child's autopsy and that this individual will then provide a copy of these results to me. If I have not yet met with a genetics professional, when I receive a copy of the genetic test report, it will include a recommendation for genetic counseling and information about how to locate a genetic counselor near me. I understand that consenting to diagnostic testing does not guarantee my child's sample will undergo diagnostic testing.

yes **no**

Child's _____ Name: _____

_____ Your Name: _____

_____ Phone: _____

_____ Email: _____

Mailing Address: _____
Street City State Zip Code

Your Signature: _____ Date: _____

I am the child's: Parent Other Legally Authorized Representative (describe below):

Name of person who explained this form: _____

_____ Agency and

Contact Information: _____

Signature: _____ Date: _____

Please fax completed form to the SDY Case Registry Data Coordinating Center at 844-816-9662.

Part Three: Your signed consent for DNA Banking for Family Use

Please read this information carefully. If you have any questions, please ask the person who is helping you with this form. After you read this information and if you agree, you will be asked to sign the DNA Banking informed consent section below.

Why Should my Family Want to Save a DNA Sample?

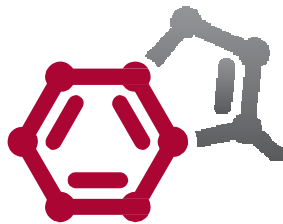
DNA is found in almost all the cells of the body. DNA is made up of many genes. Genes are the instructions that tell the body how to work. In some cases of sudden death, a change in a gene is the cause of death. There are genetic tests available to identify some of the known changes in the genes that can cause sudden death.

A sample of your child's DNA was saved at autopsy as part of the process of determining the cause of death. This sample of your child's DNA could be tested to look for changes in the genes that could have caused your child's sudden death.

By signing this consent form, you give permission for the Sudden Death in the Young Case Registry Biorepository to save a DNA sample that was gathered at the time of your child's autopsy for you or your family to access for potential future genetic testing. This "family sample" will be kept separate from the Sudden Death in the Young Case Registry and will not be used for research.

Is there a Cost to this DNA Banking?

There is no cost to you to have this DNA sample saved. However, if you decide to use the sample for genetic testing, you or your insurance company would need to pay for the shipping and the genetic testing.



How Do I Access My Child's Sample if I Decide to do Genetic Testing?

If you decide at some time in the future you want to have your child's DNA sample sent for genetic testing, you will need to contact the Sudden Death in the Young Case Registry Biorepository and send a letter requesting that the sample be sent to the genetic testing laboratory of your choosing. The Sudden Death in the Young Case Registry will not pay for the cost of shipping or clinical genetic testing of your child's DNA sample. The costs of shipping and testing the sample would have to be paid by you or your insurance company.

Can I Remove My Child's DNA Sample from the SDY Case Registry Biorepository or Have It Saved Somewhere Else?

Yes. You may also choose to have your child's DNA sample removed from the Biorepository permanently or sent to a DNA bank or genetic testing lab.

If you want to obtain your child's DNA Sample from the Biorepository or make other changes:

Contact: Mark Russell, M.D.
c/o MMGL Molecular Genetics Laboratory
University of Michigan Medical Center
3725 Med Sci II, 1150 West Medical Center Drive, SPC 5629
Ann Arbor, MI 48109-5629
Phone: 734-615-2429
Fax: 734-763-7610
Email: mruss@umich.edu

Part Three (continued): Your signed consent for DNA Banking for Family Use

Please check the box YES or NO for DNA Banking

I give my consent for the Sudden Death in the Young Case Registry Biorepository to:

Store a DNA sample that was gathered during my family member's autopsy as a "Family DNA Sample" so that my family will have a DNA sample to use for future genetic testing, as determined by my family.

yes **no**

Child's _____ Name: _____

_____ Your Name: _____

_____ Phone: _____

_____ Email: _____

Mailing Address: _____
Street City State Zip Code

Your Signature: _____ Date: _____

I am the child's: Parent Other Legally Authorized Representative (describe below):

Name of person who explained this form: _____
_____ Agency and

Contact Information: _____

Signature: _____ Date: _____

Please fax completed form to the SDY Case Registry Data Coordinating Center at 844-816-9662.



DATA COORDINATING CENTER FOR THE
SUDDEN DEATH IN THE YOUNG
CASE REGISTRY

Sudden Death in the Young Case Registry Data Coordinating Center
c/o Michigan Public Health Institute
2455 Woodlake Circle
Okemos, MI 48864
Telephone: 800-656-2434 Email: info@SDYregistry.org Fax: 844-816-9662
