



Research Subject Informed Consent Form – Decedent Cohort

Title of Study: Risk Factors for Sudden Unexpected Death in Epilepsy (SUDEP)
Study 11-01664

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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. 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 find out more about the risk factors for sudden unexpected death in epilepsy (SUDEP). This in turn will help physicians and other caregivers to better identify and provide care for at-risk patients with epilepsy in the future. You are being asked to participate in this study because you have a relative with epilepsy who unexpectedly passed away or whose information can be used for a comparison group. We would like to collect information about your relative’s medical history and the circumstances around their death in order to contribute to research on achieving a better understanding of SUDEP.

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

Your participation in this study will last approximately an hour in order to conduct a telephone interview regarding your relative's medical history. At the end of this form, we ask you for your (optional) permission to contact you again in the future in the event that we require further information about your relative. If you choose to be re-contacted, this may extend your participation.

We estimate to enroll 1000 subjects in this study at NYU Langone Medical Center. The study will be open for approximately 6 years or until the estimated number of subjects are enrolled, and may be extended.

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

You will be asked to participate in an approximately 60 minute phone interview with a member of our study staff to discuss your relative's medical history, the circumstances surrounding their death and any other information about your relative that may be relevant to their epilepsy condition and/or their death. We will also collect your relative's medical records, MRI reports, EEG/videoEEG findings/reports, genetic testing reports, and medication records. We may ask you to mail any of your relative's medical records that you have in your possession and are willing to send. Participation in this study does not involve any office visits.

Option to donate your relative's bio-specimens:

As part of your participation in this study, there is also an option to donate your relatives' excess specimen (blood, saliva, and/or other biological material) to the study. The purpose of collecting bio-specimens in this study is to assess the biological mechanisms associated with SUDEP.

You may still participate in this study if you do not wish to donate your relative's specimens.

If you elect to donate your relatives' specimens, our study will handle arrangements for the collection of your relatives' specimens and they will be added to a bank of specimens for use in future research. This may include blood, saliva, and/or other biological materials. The specimens will be stored at the NYULMC Center for Bio-specimen Research and Development (CBRD), located in the Alexandria Center for Life Science.

Pathologists, medical examiners, geneticists, and other medical professionals use only a small portion of any specimen collected to conduct their tests and to make a diagnosis. The remainder of the specimen is usually stored for a variable amount of time before ultimately being discarded. It is this specimen that we plan to store and to make available for future for use by researchers.

If you elect to donate your relative's specimens, genetic testing will be conducted on these specimens. Genes determine things about a person like hair and eye color, but may also indicate risk for disease or how a person might respond to treatment. Your relatives' bio-specimens will be tested in research laboratories at Columbia University to look for genetic information related to epilepsy and/or SUDEP.

You will be asked at the end of this consent form whether you would like to donate your relative's bio-specimens. If you choose to donate your relatives' bio-specimens, you will also be asked to indicate which bio-specimens you wish to donate at the end of this this consent form. Please note that because the research laboratories that conduct these tests are not certified by law to share test results with individuals for official diagnosis or treatment, if the research testing indicates a result that could be of clinical significance to you, you will also have the option to be contacted by a physician if he or she believes that you could benefit from having the same test run in a laboratory that is certified to run the appropriate test. If this happens, the physician will also provide a referral to genetic counselors and laboratories where you can have this test done. You can choose whether or not to receive this information at the end of this consent form.

5. What are the possible risks or discomforts?

Participation in this study poses no more than minimal risk (no more risk than that expected in daily life). There are no physical risks and discomforts associated with your participation in this study as participation requires only a phone interview, however you may you may experience emotional distress as a result of discussing the death of your relative with study staff. The following is a list of other possible risks associated with participating in this study:

Risk of loss of confidentiality:

Although the health information that is collected from your relatives' medical record will be securely maintained, 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. All of your relatives' information we collect for research purposes (medical and family history, neurological exam results, EEG, MRI, genetic testing results and medication records) will be recorded in a NYU Langone Medical Center protected database. This information will not include yours or your relatives' name, date of birth or other personal information that would allow the data to be tracked back to you or your relative. Such identifying information from your relative's medical records and/or the interview will be stored in a locked filing cabinet, in a locked room only accessible by key study personnel. If you elect to donate your relatives' specimens, each stored specimen will be de-identified using a special coding system and will not contain yours or your relatives' identifiable information.

Specific risks associated with donating your relatives' bio-specimens:

Participation in this (optional) portion of the study poses no more than minimal risk.

Risk of damage to specimens

There is a risk of damage of your relatives' tissue or of the DNA samples through transportation. All precautions are being taken to minimize the occurrence of any damage to the samples through transportation.

Risks of Genetic Testing

Receiving genetic findings of any nature may generate information about your relative's personal health risks that can cause or increase anxiety, damage family relationships, and/or compromise insurability, employability and can even lead to discrimination. As explained above, the research tests performed in this study are conducted in research laboratories that are not certified by law to share test results with individuals for official diagnosis or treatment. These research tests may suggest genetic abnormalities in genes associated with SUDEP or other, unrelated medical conditions.

It is important to note that the absence of a reportable finding in any gene tested as part of these research tests does not necessarily mean that the individual tested has no disease-causing changes in these genes. Coverage of these genes through research Whole Exome Sequencing (WES - the type of testing being done in this study) may not be as comprehensive as in panels designed to investigate them, and only testing in a CLIA or CLEP certified laboratory can conclusively rule out or include abnormalities in genes. The research test results from this study cannot be relied upon for diagnosis or treatment of yourself or your family members. If, however, the research test indicates a result that could be of clinical significance to your relative's family members, whether these results are related to SUDEP or not, you will also have the option to be contacted by a physician if he or she believes that the relative's family members could benefit from having the same test run in a laboratory that is certified to run the appropriate test. If this happens, the physician will also provide a referral to genetic counselors and certified laboratories where this test can be done. You can choose whether or not to receive this information at the end of this consent form.

If you have any questions about giving your permission to have your relative's samples tested, about potentially receiving advice for additional testing in a certified laboratory, or about the results of the tests performed in a certified laboratory, you will be offered the opportunity to have a genetic counseling appointment with Dr. Heather Lau, a neurogeneticist, who is a doctor that specializes in the study of genetics of the brain. Dr. Lau will be able to discuss the implications of the genetic results may have for you, as well as provide information and referrals to geneticists (a doctor that specializes in the study of genes) in your area if you wish to discuss your results further.

You may choose not to be contacted with any information related to these genetic tests conducted in research laboratories. In addition, the decision whether or not to report this information to your healthcare providers or any other members of your family would be up to you.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

Unforeseeable Risks: This research study may also involve risks that are currently unforeseeable.

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?

There is no direct benefit to you or your relative expected from your participation in this study. It is hoped the knowledge gained in this study will be of benefit to others in the future. You will not benefit financially if discoveries are made using your relatives' specimens or health information.

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

You have the option to not participate in this study, which will bear no impact on yours or your relatives' clinical care.

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

You will not be paid for participating in this study.

10. Will I have to pay for anything?

All study-related costs associated with your participation in this study will be paid by the study. In the event that genetic research testing of your decedent's DNA produces findings believed to be of clinical significance by the study physicians and you elect to receive the results, we will recommend you get secondary testing done in a CLIA certified laboratory. Information on getting secondary CLIA laboratory testing will be provided to you, however whether you choose to get secondary CLIA laboratory testing done will be at your own discretion and cost. In addition, if you choose to see a genetic counselor outside of the services offered by Dr. Heather Lau, this will also be at your own discretion and cost.

Your relative's insurance company may still be charged or held responsible for the costs of your relative's routine clinical care (the care your relative would have received if you were not in this study).

This study is being sponsored by NYU FACES. Portions of Dr. Devinsky's and his research team's salaries are being paid from these funds.

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

It is very unlikely you will be injured as part of your participation in this study, as the study does not pose more than minimal risk of everyday activities. However, all forms of medical (or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study.

If you sustain any medical complications 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. You do not give up any rights to seek payment for personal injury by signing this form.

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

Your participation in the study will end after you have completed the phone interview, however if you give the study team permission to contact you again about the study, this participation may be extended. If you elect to provide your relative's bio-specimens and/or receive genetic results, your participation will end once the specimens are collected and genetic testing results are reported to you. The study will be open for approximately 6 years or until the estimated number of subjects are enrolled, although this may be extended.

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 the study to use or disclose your protected health information for the study. You may also withdraw your consent for the use of your loved one's specimen at anytime. If you choose to withdraw your consent for the use of your relatives' bio-specimens, any unused specimens that have not been provided to researchers will be destroyed and/or all identifying information will be removed that would link the sample to you. The samples that have already been analyzed may be used for other research, but no one will be able to relate those research results to you.

If you do decide to withdraw your consent or Authorization, 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. 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 and may be asked to return for a final check-up.

13. How will my and my relative'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 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 me or my relative may be used or shared with others?

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

- Information that you provide during the 45-60 minute telephonic interview
- Information in your relative's medical record and research record, for example, results from your relative's physical examinations, laboratory tests, procedures, questionnaires and diaries,
- Information from the results from biospecimen analyses (if elected), including genetic results.

If you are your relatives' next-of-kin, you have a right to access information in your relatives' 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 or my relative's information being used?

Your and your relative's 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 me or my relative?

The following individuals may use, share or receive your 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,
- Governmental agencies responsible for research oversight,
- Medical examiners or coroners who provided your relative's autopsy examination,
- The health care providers who provided services to your relative,
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol,
- 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.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

How long may my information be used or shared?

Your permission to use or share your relatives' 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 information?

Yes, you may withdraw or take back your permission to use and share your relatives' 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

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study. 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.

NYULMC 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 relative's health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. _____
Subject Initials

15. 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

16. 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.

I. Permission to collect, store and analyze your relative’s bio-specimens in this research study. You may still participate in this research if you do not give permission to collect your relatives’ bio-specimens.

Please select one:

- Checking this box indicates **I do not agree to donate** my relatives’ excess bio-specimen’s to be stored in the NYU Bio-repository bank
- Checking this box indicates **I agree to donate** my relatives’ excess bio-specimen’s to be stored in the NYU Bio-repository bank

This is a list of the types of biospecimens we wish to collect from your relative. Please check only the specimens you authorize to have collected and stored:

- **Brain (full or partial)
- *Blood spot card
- *Blood
- Heart
- Liver
- Buccal Swab (saliva swab)
- DNA
- Any other available tissue

*Most frequently requested tissue from scientists

**If full brain tissue is collected, a neuropathology report can be issued to you and/or the medical examiner. Do you wish to receive a copy of the neuropathology report? Yes No

II. Permission to be Contacted about Future Genetic Testing

As part of donating your relatives’ bio-specimens, genetic testing related to Epilepsy and/or SUDEP will be conducted on these specimens. This genetic testing is being done in research laboratories that are not certified to diagnose or treat conditions, and therefore is not information that can be shared with you. However, as explained above, you may choose to be contacted if a study physician would recommend retesting of you or your relative’s family members in a laboratory certified to return such results. It is optional to receive this information.

- Checking this box indicates **I want to be contacted if a study physician believes that genetic testing of me or my relative’s family members, in a laboratory certified to return such results for diagnosis and treatment,** is advisable based on research test results.
- Checking this box indicates **I do not want to be contacted about the above.**

III. Permission for re-contact

I **DO NOT consent to be re-contacted** after the interview by research staff to provide clarification or additional information regarding my relative.

I **DO consent to be re-contacted** after the interview by research staff to provide clarification or additional information regarding my relative.

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 as described in this consent form and according to your elected preferences marked in sections I and II.

Name of Decedent

Name of Subject/Next of Kin (Print)

Signature of Subject/Next of Kin

Date

Name of Person Obtaining Consent (Print)

Signature of Person Obtaining Consent

Date

*For subjects unable to give consent, the consent for study participation and authorization to collect and use protected health information is given by the following authorized subject representative:

Name of Authorized Subject Representative (Print)	Signature of Authorized Subject Representative	Date
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Select the category that best describes the above Authorized Subject Representative:

- Court-appointed guardian
- Health care proxy
- Durable power of attorney
- Family member/next of kin; for this category describe relationship below:

Signature of Parent(s)/Guardian for Child

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Name of Parent (Print)	Signature of Parent	Date
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Witness to Consent of Non-English Speaking Subjects Using the “Short Form” in Subject’s Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date
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