

Spinal Bulbar Muscular Atrophy (aka Kennedy's Disease)

Tissue Donation Program

Facilitated by:

**Kennedy's Disease Association
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&

M MICHIGAN BRAIN BANK

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Pager: 734-936-6267 – pager # 9198
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Website: www.brainbank.umich.edu

Keep this booklet in a safe place known by several family members

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Kennedy's Disease Tissue Donation Program

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Kennedy's Disease Tissue Donation Program

About the Tissue Donation Program

Spinal Bulbar Muscular Atrophy, aka Kennedy's Disease, is considered a rare disorder. Less than 1-in-40,000 people have the defective gene. Most research is performed on fruit flies and mice models. Until recently, human tissue was not available for testing in research labs. Today, tissue donated from an individual with Kennedy's Disease is being used in several labs. This human tissue is very helpful in studying the biology as well as the effects of the disease. The KDA's Scientific Review Board feels that the availability of additional human tissue will benefit research and might help find a treatment for Kennedy's Disease.

About the KDA

The Kennedy's Disease Association is a non-profit California corporation. The KDA is recognized under United States of America Internal Revenue Code 501(c)3 as a publicly supported organization as described in sections 509(a)1 and 170(b)1(A)(vi).

The Kennedy's Disease Association was formed with the following objectives in mind:

1. To put those living with Kennedy's Disease in touch with others for support
2. To share information in regards to Kennedy's Disease for those who seek it
3. To raise awareness in both the medical and public communities
4. To raise funding for research and awareness campaigns

The KDA's Scientific Review Board

Kenneth Fischbeck, MD, PhD - [National Institute of Neurological Diseases and Stroke](#)

A leading researcher, professor, and educator on the subject of Kennedy's Disease; a co-discoverer of the Spinal Bulbar Muscular Atrophy gene.

Diane Merry, PhD - [Thomas Jefferson University](#)

Leads a dedicated research team focused on Kennedy's Disease.

Al La Spada, MD, PhD - [University of California, San Diego](#)

Co-discovered the Spinal Bulbar Muscular Atrophy gene and continues to research Kennedy's Disease.

J. Paul Taylor, MD, PhD - [St. Jude Children's Research Hospital](#)

Leads a team that studies neurodegenerative diseases including Kennedy's Disease.

Andrew P. Lieberman, MD, PhD - [University of Michigan Health System](#)

Leads a team that studies the pathogenesis of inherited neurodegenerative diseases including Kennedy's Disease.

Ed Meyertholen - *Research Liaison*

Assistant Dean and Director of Pre-Health Programs at Georgetown College, Georgetown University and an individual living with Kennedy's Disease.

Todd Allen - *Patient Liaison*

An individual living with Kennedy's Disease who supports Kennedy's Disease Research

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Note: Preplanning is required to minimize last minute decisions and possible delays. Finding a qualified pathologist ahead of time is especially important.

Questions about Donating Tissue

1. What research will be done on the collected tissue?

Tissue samples and results of clinical testing are made available to qualified scientists only after their research proposal is reviewed and approved by the Kennedy's Disease Associations (KDA) Scientific Review Board (SRB). These studies may lead to improved understanding and advances in the diagnosis and treatment of Kennedy's Disease and related disorders. Samples are provided for biochemical and genetic studies. The samples are labeled with numbers rather than names to keep information anonymous.

2. What tissue is collected?

Brain and spinal cord (with attached dorsal root ganglia) are the minimal tissues that will be collected from patients with Kennedy's Disease. Other tissues, such as testes and skeletal muscle, could also be useful to researchers and will be collected if permission is received from the next of kin.

3. Is patient confidentiality maintained?

Yes. Patient confidentiality is strictly maintained by the autopsy service, hospital and tissue bank. An autopsy number assigned at the time tissue is submitted to the tissue bank is the only identifier of tissues provided to researchers. This assigned number is devoid of all private information, such as name, address, or other personal identification numbers.

4. Will the funeral arrangements be delayed?

No, with preplanning and careful coordination, there should be no delays for typical funeral arrangements. The tissue collection procedure will be performed within the first 24 hours after death. A family member needs to be able to work with the hospital, nursing home, or funeral home to expedite the transportation from the place of death to the Medical Center or hospital, and after the collection then to the funeral home. Completion of Forms A (or B) and C located in the back of this booklet before the time of death and Form D at the time of death will assist in preventing any delays.

5. Can there still be an open casket?

Yes. The removal of tissue does not change the appearance of the body for the funeral service.

6. Do I have to tell my relatives that the tissue has been removed?

No, you do not have to tell anyone if you do not wish.

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7. Does donating tissue for research purposes interfere with religious beliefs?

No, tissue donation does not conflict with most religious beliefs. If you have any questions concerning this issue, please contact your priest, minister, imam, rabbi, or other religious leader.

8. Who can legally grant permission for the tissue to be removed?

Prior to death, an individual donor or family member can indicate their intent by signing the provisional consent. This permits your doctor to plan for the tissue collection. However, after death, the person's legal next-of-kin must authorize the tissue removal before it can be performed. The following persons, in order of priority, may provide such consent:

- 1) Spouse
- 2) An adult son or daughter (*)
- 3) Either parent
- 4) An adult brother or sister (*)
- 5) A guardian of the decedent at the time of death. (*)
- 6) Any other person legally authorized.

(*) Note: The person must be at least 18 years old

If there are several individuals in a category, they must all agree. For example, for priority level 2 above, all adult children have equal authority and must agree. Signing a provisional consent can help others by documenting a patient's wishes.

9. Will genetic analysis be performed?

Possibly, genetic tests may be performed on collected tissue at the discretion of the researcher. Since no patient identifiers are provided with the tissue, the results of these tests will remain anonymous.

10. If genetic analysis is performed, will anyone be informed of the results?

No, results of genetic tests, like other research results, are kept confidential to the full extent of the law. Genetic test results are shared with other researchers when appropriate. In these cases, since no patient identifiers are provided with the tissue, the results of these tests will remain anonymous.

11. Where is the tissue collection done?

The next of kin and family doctor determine this. It is most helpful for the donor and family to make pre-arrangements with a pathologist at a nearby medical center or university hospital to collect the tissue. Your family doctor should be able to recommend a facility in your area that can perform this service. Autopsies at community hospitals are not performed regularly, but academic medical centers are generally more receptive to the procedure. Once an autopsy is agreed to and arranged and upon the request of the donor or authorized family member, a member of the KDA's Scientific Review Board can become involved by speaking with the pathologist and advising what tissue should be harvested for banking.

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12. Are there any costs or fees involved?

Yes, the family will be responsible for any costs related to the actual tissue collection process as well as the transportation costs to and from the medical center or university hospital where the tissue is collected. There is no charge for the shipping of the tissue collected, the tissue storage, or for any of the research testing.

13. Will the Tissue Bank Coordinator help make the collection arrangements?

No, unfortunately the KDA and Tissue Bank Coordinator are not able to help the family locate a medical center and pathologist to perform the tissue collection. The coordinator, however, will work closely with you to facilitate arrangements to transfer the harvested tissue from the hospital or medical center to the tissue bank. A member of the KDA's Scientific Review Board could also be made available to help answer any questions that the pathologist may have providing that the KDA has advanced notice of an impending death and autopsy.

14. Where is the tissue stored?

The tissue will be stored at a tissue or organ storage facility. Currently, that location is at the University of Michigan Brain Bank.

15. When should pre-arrangements for a tissue donation be made?

Planning should begin as soon as your decision is reached. **Preferably, tissue donation preparations should be made before the time of death.** To indicate your intent for a tissue donation, you should complete and sign either Form A or B in this booklet and return it to the KDA and the University of Michigan Brain Bank.

Form A or B simply indicates your intent to make the tissue donation arrangements. The form itself is not legally binding. It only serves as notice to the KDA of your desire to donate tissue. The actual tissue collection consent must be given at the time of death by the legal next-of-kin. Upon completion of either Form A or B, a copy should be sent to your next of kin, your family doctor, the intended executor of the estate, the agent under Medical Power of Attorney, and the KDA.

Important: Your decision to donate tissue should be shared with the immediate family, the appointed legal guardian, medical caregivers, the intended executor of the estate, the agent under Medical Power of Attorney, and your funeral director to avoid last minute confusion.

16. What if a member of my family is opposed to the tissue donation?

The best way to ensure that your wishes are carried out is to tell your family how strongly you feel about being a tissue donor. You also should sign and carry a donor card and record your wishes in legal documents.

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17. What needs to be done when I have made a decision to become a donor?

- Discuss your decision with your family and agent with Medical Power of Attorney so they will understand and support your decision.
- Sign the tissue donor form included in this brochure.
- Send a copy to your next of kin, your family doctor, the intended executor of the estate, the agent under Medical Power of Attorney, the KDA and the University of Michigan Brain Bank at the address shown on the front of this brochure.
- Keep a copy of the document with your other legal documents.
- Sign the Tissue Donor Card included in this brochure and carry it in your wallet.
- Ask your family doctor to recommend a suitable hospital, medical center, or pathologist.

18. How do we minimize any last minute decisions or conflicts?

Preplanning is required. If the decision is made to donate tissue at the time of death, the process becomes impossible to have the collection performed in a timely manner.

- Discuss your decision with your family and agent with Medical Power of Attorney so they will understand and support your decision.
- Discuss your decision with your family doctor.
- Ask your doctor to recommend a suitable hospital, medical center, or local pathologist where the harvesting of the tissue can be performed.
- Contact the hospital, medical center, or pathologist ahead of time; review with them your decision, and determine what the institution requires to perform the collection.
- Finally, discuss transportation requirements with the funeral home director.

19. What tissue will be harvested?

Researchers recommend the following:

- The entire spinal cord
- Skeletal muscles
 - Upper arm – 2”
 - Upper leg – 2”

Other tissue that could also be useful for research:

- Brainstem
- Testes

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What Needs To Be Done At The Time Of Death?

The responsible family member or legal guardian should oversee the final arrangements of the deceased. The following checklist shows the steps to follow:

1. **Notify the donor's attending doctor.** If death occurs at home, the doctor, nurse, or funeral director can provide the phone numbers for the local agencies that need to be notified.
2. **Notify the pathologist, hospital or medical center** where the collection is to take place. After notification, the funeral director can make transportation arrangements from the place of death to the medical center or local pathologist.
3. **Call the Kennedy's Disease Tissue Bank Coordinator at 734-936-6267 Pager#9198.** If unavailable, leave your area code and phone number (and cell phone number, if available) where you can be reached. Have the following information available:
 - The name of the deceased as well as the date, time, and location of death.
 - The deceased's KDA registration number.
 - Most recent medical history.
 - Name and phone number of the funeral director.
 - A copy of form A or B.
4. **Contact the funeral director and hospital.** Arrangements must be made to transport the body to the hospital, medical center or to the local pathologist where the tissue will be harvested. Forms A (or B), C, D and E need to be given to the pathologist.
Important: The body should not be embalmed and must be kept cool (4° C) until after the pathologist has collected the tissue.
5. **Inform the pathologist of what tissue to harvest.** Researchers recommend the following:
 - The entire spinal cord
 - Skeletal muscles
 - Upper arm – 2"
 - Upper leg – 2"Other tissue that could be useful for research:
 - Brainstem
 - Testes
6. **Provide verbal or written consent.** The next of kin, agent with Medical Power of Attorney, or appointed legal guardian will receive a phone call from a medical center staff member asking for verbal consent to perform the tissue collection. This call will be placed and witnessed or recorded by a medical center operator. If you are present at the medical center, you will sign a written consent form. The tissue collection should be completed and the body will be returned to the funeral home normally within 24 hours.
7. Continue with your funeral arrangements

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The Forms You Need

- **Form A: Provisional Consent for Pre-Arrangements by a Legally Competent Adult**

This form states that it is the wish of the patient to donate tissue for research after death. It is not legally binding. A signed copy of this form should be placed in the Hospital, Doctor, and/or Nursing Home Medical Record.

- **Form B: Provisional Request For a Patient Who Is Unable to Give Consent**

This form allows a legal next-of-kin, the intended executor of the estate, or the agent under Medical Power of Attorney to give provisional consent for the tissue collection, if the donor is unable to communicate this decision. This form states the wishes of the next-of-kin, the intended executor of the estate, or the agent under Medical Power of Attorney only, and is not legally binding. A signed copy of this form should be placed in the donor's medical record at the Hospital, Doctor's office, and/or Nursing Home.

The KDA must receive a signed copy of Form A or B for enrollment in the Tissue Donation Program. When you send a signed copy to the KDA, we will acknowledge receipt of your request by sending you an enrollment letter. You should keep the forms with this booklet. **The legal next-of-kin, the intended executor of the estate, or the agent under Medical Power of Attorney will still need to give permission for the tissue collection at the time of death.** Depending on the circumstances, permission will be given verbally, as described on the previous page (step 4), or by completing a written form at the medical center.

- **Form C: Nursing Information on Postmortem Procedure**

This form describes the procedures for the nursing staff to follow after the patient has died. A copy of this form should be placed in the patient's chart along with Form E, every time the patient is admitted to a hospital or nursing care facility. It should be given to the funeral director to take with the body to the medical center, university, or local pathologist.

- **Form D Patient Medical History at Death**

This form is placed in the donor's chart along with Form C. It documents the date and time of the patient's death. The doctor or nursing staff should complete it. The form also records the donor's medical history. The donor's nurse and family should fill it out as completely as possible. It should be given to the funeral director to take with the body to the medical center, university, or the local pathologist.

- **Form E: Tissue Donor Card for your wallet**

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FORM A

**Provisional Consent for Tissue Collection Pre-Arrangements
by a Legally Competent Adult Donor**

Directions: This form is to be completed by a legally competent adult wishing to indicate a desire to set up pre-arrangements to donate the person's tissue to the Kennedy's Disease Tissue Donation Program for medical research.

Most likely, the patient's spouse or an adult son or daughter (18 years or older) will sign the tissue collection consent. The pathologist will determine who the appropriate legal next-of-kin is at that time and whether their consent for autopsy is valid.

In the hope that this authorization will further the understanding of neurological disease,

I, _____,
(Print Name)

authorize the pre-arrangements necessary for a postmortem collection of relevant tissue for research and clinical purposes in the interest of advancing medical knowledge in the area of Kennedy's Disease and related disorders. I relinquish all rights to the tissue and give sole responsibility to the Scientific Review Board of the KDA for determining where the tissue will be stored and how the tissue will be used for medical research.

Signature of Patient

Date

Signature of Witness

Date

Signature of Witness

Date

If your state requires a notarized document:

SUBSCRIBED AND SWORN TO before me by _____, Donor, and

by _____ and _____, Witnesses,

on _____, 20__.

Notary Public, State of _____

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FORM B

Provisional Request for Tissue Collection Pre-Arrangements For a Donor Who Is Unable to Give Consent

Directions: This form is to be completed by a legally competent adult (as listed below) on behalf of a donor who is unable to give consent. This completed form indicates a wish to have the donor enrolled to donate tissue to the Kennedy's Disease Tissue Donation Program for medical research.

Most likely, the patient's spouse or an adult son or daughter will sign the tissue collection consent. The pathologist will determine who the appropriate legal next-of kin at that time and whether their consent for tissue collection is valid.

The "tissue collection" consent form can only be signed by the legal next-of-kin after a person has passed away. However, any one of the following individuals can make a non-binding pre-arrangement for the tissue donation:

- a. Agent named in the Medical Power of Attorney
- b. Spouse
- c. An adult son or daughter (*)
- d. Either parent
- e. An adult brother or sister (*)
- f. Appointed guardian of the deceased at the time of death (*)
- g. Any person authorized or under obligation to dispose of the body

(*) Indicates the person must be at least 18 years old

I, being a legally authorized (spouse, agent, son, daughter, brother, sister, or guardian) representative of

_____,
(Print Name of Patient)

authorize the pre-arrangements necessary for the donation of tissue for research and clinical purposes in the interest of advancing medical knowledge in the area of Kennedy's Disease and related disorders. I understand that consent for legal tissue collection must be given after the patient has expired. I also relinquish all rights to the tissue and give sole responsibility to the Scientific Review Board of the KDA for determining where the tissue will be stored and how the tissue will be used for medical research.

Signature Relationship to Donor Date

Signature of Witness Relationship to Donor Date

Signature of Witness Relationship to Donor Date

If your state requires a notarized document:

SUBSCRIBED AND SWORN TO before me by _____, Donor, and

by _____ and _____, Witnesses,

on _____, 20__.

Notary Public, State of _____

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FORM C

Nursing Home Information on the Postmortem Procedure

Print Name of Donor

KDA Registration #

Name of Local Hospital / Nursing Home

Patient Registration #

This patient is participating in a tissue donation program for neurology research. Please keep a copy of this sheet with either Form A or B, and D on the inside front cover of the patient's hospital or nursing home medical record/chart. **The nursing staff is asked to follow this protocol when the patient dies:**

- 1) Call the doctor in charge of the patient. Have the doctor "pronounce" the patient as soon as possible. Ask if the cause of death warrants calling the Medical Examiner's Office.
- 2) Call the family, next of kin, agent under Medical Power of Attorney, and/or legal guardian.
- 3) Contact the Kennedy's Disease Tissue Bank Coordinator at **734-845-5244**. Also, call the local pathologist, medical center, or hospital (shown below).
- 4) Complete Form D describing the patient's medical history for the past two weeks.
- 5) Contact the funeral home. When the family is ready, **please move the body to a hospital morgue/mortuary COLD ROOM (4° C) within 2 hours**, if possible.

IMPORTANT: There must be no embalming until after the tissue is collected

- 6) A completed Form D (attached) must accompany the body to the pathologist.

Doctor in Charge of Case

Pre-arranged Local Pathologist or Hospital

Name (Please Print)

Name (Please Print)

Address

Address

City, State, Zip

City, State, Zip

(_____) _____
AC Number

(_____) _____
AC Number

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FORM D

Patient Medical History at Death

To be filled out by a doctor or nursing staff and sent with the body for the tissue collection

_____		_____
Print Name of Patient		KDA Registration #
_____	_____	_____
Date of Birth	Date of Death	Time of Death
Sex: _____	_____	
Male	Female	

Clinical diagnosis at time of death: *(attach additional information as needed)*

- Immediate cause of death and the events leading to death over the past 2 weeks: Describe any physical changes during this time:
- Medications received over the past week - Dosage & schedule:
- History of neurological illness: Include date of onset and nature of symptoms, the rate and progression of symptoms, any symptoms of motor dysfunction, sensory problems, or pain:
- Past Medical history, other diagnosed medical illnesses, recent surgery or traumatic injury:
- Family history, number of siblings: age and cause of death of parents, if known; any illness of family members resembling patient's?

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FORM E

Donor Card

Kennedy's Disease Tissue Donor Card	
I wish to donate my tissues to the Kennedy Disease Association (KDA). For questions, call the KDA Tissue Bank Coordinator at 734-936-6267 Pager#9198.	
I wish to give: <input type="checkbox"/> Any tissue requested <input type="checkbox"/> Only the following tissues:	
<hr/>	
<hr/>	<hr/>
Donor Signature	Date
<hr/>	
Witness Signature	
<hr/>	
Witness Signature	

Important: Please carry a copy of this card in your wallet

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Important Telephone Numbers

- **For Routine Questions**

Call the **Kennedy's Disease Association (KDA)** at **(559) 658-5950** weekdays from 8:00 am to 4:30 PM PST. Leave your name and phone number (with the area code and extension) where you can be reached. You can expect to receive a return call shortly.

- **At the Time of Death**

Call the Kennedy's Disease Tissue Bank Coordinator at **734-936-6267 Pager#9198**. If no one is available, leave a message with contact information.

- **Your Doctor**

Name: _____

Phone: _____

- **Funeral Home Information**

Name: _____

Address: _____

City/State/Zip: _____

Phone: _____

Contact: _____

- **Pathologist, Medical Center, or Hospital (Tissue Collection Location)**

Name: _____

Address: _____

City/State/Zip: _____

Phone: _____

Contact: _____