

National ALS Biorepository Consent Form (Postmortem)

Why am I being asked?

You are being asked to take part in the biorepository because you are enrolled in the National ALS Registry and have told us you are interested in learning more about the biorepository. We ask that you read this form and ask any questions you may have before agreeing to be in the biorepository. McKing is the company that was awarded a contract by the Agency for Toxic Substances and Disease Registry (ATSDR) to manage the biorepository. The biorepository Project Director is Dr. Wendy E. Kaye.

Taking part in this biorepository is voluntary. You should feel free to ask the researchers any questions you may have. Your decision whether or not to take part will not affect your current or future relations with the National ALS Registry. If you decide to take part, you are free to withdraw at any time without affecting that relationship.

What is the purpose of this biorepository?

This biorepository is being created to increase the number of specimens available for ALS researchers. The specimens in this Biorepository will complement the National Registry's epidemiologic data.

Approximately 40 people will take part in the collection of tissues after death part of the biorepository.

What are the procedures involved?

You will be asked to set up a call that includes a family member for us to discuss the biorepository. After you have consented to take part, the coordinator will work with you or your family to create a donation plan. This plan will include all logistics for donating tissues after your death. We will also ask one of your family members to sign an authorization form because it is important that your family agree with this donation after your death.

The tissues being collected include the brain, spinal cord, cerebral spinal fluid (CSF), muscle, and bone.

Making arrangements for the tissue donation prior to death

The National Disease Research Interchange (NDRI), a group dedicated to collecting specimens for research, will work with us to obtain your donation. Someone from NDRI will call you if you agree to take part and answer any questions you may have about the donation. They will find a person and facility where tissue removal will happen. This will happen after you agree to be a tissue donor and before your death. This facility will be as close to your home as possible. We will take care of the transportation of your body until you are at the funeral home selected by you and your family.

Tissue donation after death

Upon your death, the following steps will be taken to collect your donated tissue:

- We will ask your selected family member to verbally agree to go forward with the donation. The donation cannot occur if he/she does not agree.
- We will have your body transported to the facility where the tissue collection will happen.
- We will arrange for the tissue collection process to happen within 24-36 hours of death. The collection will take about two to three hours to complete.

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- Your donated tissue will be express shipped by a special courier to the approved storage facility.
- Your body will be returned to your family's funeral home or to whatever facility that your family has arranged within three days of your death.

The collection process should not delay any funeral plans or prevent an open-casket funeral service. The professionals who will do the tissue collection are trained to collect the tissues in such a way that they will not disfigure the body. The tissue or organs you have decided to donate will be collected using surgical incisions and closed with stitches. Regular clothing will cover the stitches on the body. We will do our best to make sure cuts on the head are on the back and cannot be seen from the front or side. However, in some cases stitches may be visible on the head area.

We will make a good faith effort to collect your tissues. However, there may be things beyond our control that may prevent collection of your samples.

Tissue Banking

The purpose of this biorepository is to collect specimens for future research related to ALS. Your specimens will be stored with a number. No private information will be on the specimen container.

Researchers can ask to use specimens from the biorepository for research related to ALS. We do not know what types of research will be done. These studies will likely examine the DNA and RNA (genetic material) and other material from cells in the tissues. Researchers must provide a detailed plan of the study. This plan must be approved by ATSDR and the ethics committees at the researchers' institutions. Your specimens along with others will be provided to approved researchers. These tissues will not have your name on them. The specimens will include information about you such as your age or city where you lived. They may also request other data you gave the National ALS Registry. We will limit the amount of information about you to reduce the chances that you will be identified.

Results of research using these tissues will be available on the National ALS Registry website.

What are some of the risks and discomforts that may happen to people who are in this biorepository?

- There is a slight risk that someone could get access to the data we have stored about you. If information about you does leak out, ATSDR will not be able to guarantee that it will be protected.
- There may be unforeseen problems that may delay the delivery of your body to the funeral home. We do not think this will happen but we cannot be sure.
- All tissue samples will be collected at the time of your death. This will be a sensitive time for your family members. Some members may not agree with you and your selected family member's choice to allow the donation. This may cause some discomfort among family members.
- Future research may show that you and/or your family are at increased risk of developing a disease or condition. We will not provide this information to your family members.
- If future research results show that certain groups (for example, racial, ethnic, or men/women) have genes that are associated with increased risk of a disease, then this information could make it harder for your family to obtain employment, adopt children, or get medical and life insurance. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small.
- Rare, unknown, or unanticipated risks also may occur.

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ATSDR will do all it can to protect your privacy and confidentiality (see below). Therefore, these risks of discrimination are very small. But the risk may grow in the future if people come up with new ways of tracing information.

Are there benefits to taking part in this biorepository?

You will not directly benefit from taking part in the biorepository. It is hoped that knowledge gained from this biorepository may benefit others with ALS in the future.

What other options are there?

You have the option to not to take part in this biorepository.

What about privacy and confidentiality?

If you take part, we will not have access to your private medical records. However, we will have to ask your doctor to share some information about you.

The people who will know that you take part in this biorepository are members of the biorepository team, individuals who may have access to your informed consent document due to their job function with the National ALS Biorepository, and people processing your tissues.

Information that identifies you and the consent form signed by you will be looked at by the ATSDR.

A possible risk of the biorepository is that people outside of the biorepository may find out you are taking part or learn information about you and your health. Your tissues will be stored with a code. Your name will not be on the container.

When the results are published or discussed at meetings, no information will be included that would reveal your identity

Will my family be told biorepository results?

Your family can get the results of the neuropathology review. When the review is complete, the neuropathologist will check with your family to see if they want the report and answer any questions. Your family will not be told of any new findings that come to light during the course of this biorepository. We will not tell you or your family any genetic testing results from research studies. ATSDR will post biorepository results on the National ALS Registry website.

What are the costs for participating in this biorepository?

There is no cost for participating in this biorepository. The costs of transporting your body to and from the facility and collection procedures for this biorepository will be the responsibility of the ATSDR. There will be no cost to you, your family, or estate.

Will I be reimbursed for any of my expenses or paid for my participation in this biorepository?

You will not be reimbursed for any expenses. You will not be paid to take part in this biorepository.

Will my cells, tissues, blood, or other biological materials be used to develop commercial products?

It is possible that a commercial product may be developed from the tissues collected as part of this biorepository. The nature of the research means that your sample is only one of many that will lead to this product and your sample will not have your name on it. You and your family will not profit financially from such a product. You will have no legal rights to any discovery or invention that either directly or indirectly results from the use of your specimens collected, individual information, or information from your samples.

Cells obtained from your body may be used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line is one which will grow indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

Can I withdraw or be removed from the biorepository?

Taking part in this biorepository is voluntary. If you choose not to take part or decide to withdraw your consent and stop taking part, this will not affect your relationship with National ALS Registry or other benefits to which you are otherwise entitled.

You have the right to leave a biorepository at any time without penalty. Your family can also refuse to have your tissues collected after your death. If you withdraw from the biorepository, we will destroy any of your remaining samples. However, we will not be able to remove your samples that have already been used or shared with researchers.

Who should I contact if I have questions regarding the biorepository? Who should I contact if I wish to voice concerns or complaints? Who can I talk to about my rights or if I want to withdraw my samples?

If you have questions, concerns, or complaints, think the biorepository has hurt you, or if you want to withdraw your samples, you can talk to Wendy E. Kaye, Ph.D., Project Director or Laurie Wagner, MPH, Biorepository Coordinator at 1-855-874-6912.

If you want to speak with someone who is not directly involved in this biorepository, or have questions about your rights, or wish to voice questions, concerns or complaints, you may contact the CDC Human Research Protection Office at 1-800-584-8814.

Remember

Taking part in this biorepository is voluntary. Your decision whether or not to participate will not affect your current or future relations with the National ALS Registry. If you decide to take part, you are free to withdraw at any time without affecting that relationship.

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Subjects' Rights:

I have read the above information. I have discussed this biorepository with the person obtaining consent, been given an opportunity to ask questions, and my questions have been answered to my satisfaction. I agree to the release of personally identifying information about me to the funeral home. My name, address, telephone number and date of birth are needed to provide transportation to the pathology service and my return to the funeral home selected by my family. I agree to take part in this biorepository. I will be given a copy of this signed and dated form.

Signature of Subject

Date

If participant is physically unable to sign the consent form, please complete the following

Witness Signature

Date

I, _____, witnessed that _____ was explained the consent form and has agreed to take part in this biorepository. Due to the progression of the disease, the participant is physically unable to sign the consent form.