

National ALS Biorepository Consent Form (Biospecimens)

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. The biorepository is a new part of the National ALS Registry maintained by the Agency for Toxic Substances and Disease Registry (ATSDR). 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 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.

Up to 325 people will be asked to contribute specimens to the biorepository each year.

What are the procedures involved?

You will be asked to have specimens collected from you at your home. This should take no more than 1 hour.

You are being asked to donate specimens. We will make an appointment for a phlebotomist to come to your home to collect specimens at a time convenient for you. We will ask you to donate the specimen types checked below.

- A urine specimen collection kit with directions will be sent to your home before your appointment. You will be asked to provide a urine specimen (9 ml) before the end of your appointment. The best time to give a urine specimen is when you first get up in the morning on the day of your appointment.
- A blood sample will be drawn from your arm with a needle by a trained phlebotomist. There will be 5 tubes of blood taken (about 40 ml or 2.5 tablespoons).
- Fingernail clippings will be collected by the phlebotomist from all ten (10) fingers using a stainless steel nail clipper.
- Hair clippings will be collected by the phlebotomist on the day of your appointment. The hair specimen collection will be about 120 strands. These will be clipped from the back of your head, near your neck, and under your other hair.
- Saliva samples (2 ml) will be taken only if you are unable to give blood or if there is a problem with the blood. A saliva sample kit with directions will be mailed to your home and you will be asked to collect the saliva sample yourself.

Additional Instructions:

- Drink plenty of water on the day of your blood draw.
- You will be sent a cup to collect a urine specimen. We ask that you collect this the morning before your appointment.

Attachment 8B.

- Do not cut your hair for at least 1 week before your appointment, if we are collecting hair.
 - Hair should be free of all gels, oils and hair creams or sprays prior to sample collection. The hair to be collected should be untreated (not permed, dyed or bleached).
- Do not cut your fingernails for at least 1 week before your appointment. Please remove nail polish for the day of your appointment, if we are collecting fingernails.

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 specimens 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 specimens 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?

You will feel a slight "pinch" when the needle is put in to draw your blood. You may feel some pain or see a small bruise where the blood was drawn. There is little risk for the other specimens being collected.

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 is a very small chance that genetic research in the future could give genetic information that could be used to identify you.

Are there benefits to taking part in this biorepository?

You will not directly benefit from taking part. It is hoped that knowledge gained from this research 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 in the biorepository, we will not have access to your private medical records.

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 specimens.

Attachment 8B.

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 find out you are taking part in the biorepository or learn information about you and your health. Your specimens will be stored with a code. Your name will not be on the container.

When the results of the biorepository 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 will not be told of any new findings that come to light during the course of using your specimens. We will not tell you or your family any genetic testing results from research studies. ATSDR will post study 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. You will not be charged for any lab tests.

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

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 tissue or blood samples 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, 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 the biorepository at any time without penalty. 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 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. MPH, Biorepository Coordinator at 1-855-
Kaye, Ph.D., Project Director or Laurie Wagner, MPH, Biorepository Coordinator at 1-855-
874-6912.

Attachment 8B.

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 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.

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 participate in this biorepository. I will be given a copy of this signed and dated consent form.

Print Subject name

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.