

FACT SHEET: POSTMORTEM



WHAT IS THIS STUDY ABOUT?	This study will prepare a plan for the Agency for Toxic Substances and Disease Registry (ATSDR) to create a Biorepository. This plan will describe the best ways to collect, store, and share samples from participants in the National ALS Registry. When it is complete, we will test the plan by gathering tissue samples from up to 30 interested PALS. Once the testing is done, ATSDR will decide if a National ALS Biorepository is practical.
WHAT IS A BIOREPOSITORY?	A biorepository is a facility that collects and stores samples of biological material. This could include blood, urine, tissue, cells, DNA, and proteins. Some medical information may also be stored along with a written consent form. These samples may be used for future research.
WHAT TISSUES WILL BE COLLECTED IN THIS BIOREPOSITORY?	The tissues being collected after death include the brain, spinal cord, cerebral spinal fluid (CSF), muscle, and bone. The tissues will be stored for future research on ALS. No tissues will be tested for this study. Any future research will have to be approved by an ethics committee.
WHY IS THIS STUDY BEING DONE?	This study is being done to find out whether it is practical to establish a Biorepository as part of the National ALS Registry.
WHO IS CONDUCTING THIS STUDY?	This study is being funded by ATSDR. ATSDR is a federal public health agency located in Atlanta, Georgia. McKing Consulting Corporation (McKing) has been awarded a contract to conduct this study.
WHY IS THIS BIOREPOSITORY IMPORTANT?	The tissues in this biorepository will add to the Registry's data about ALS. It will also add to the total numbers of tissues available for research on ALS. The National ALS Biorepository will differ from others already in existence because its scope is broad and not limited by geographic area, exposure, or clinical characteristics.
WHO CAN TAKE PART IN THIS STUDY?	People that are enrolled in the National ALS Registry that meet the requirements of this study. We will contact your physicians for more information about your disease to see if you can take part.
WHERE WILL THE STUDY BE CONDUCTED?	McKing will transport your body to a local study collection facility and then to the funeral home of your choice within your local area.
IS THERE ANY RISK TO ME?	The only risk to you is the possible loss of confidentiality though we will protect this as much as possible. The funeral arrangements may be postponed but our goal is to return your body to the funeral home within three days. The health care workers who take your tissues and organs will treat your body like they would in surgery so that there are few marks and your body is not disfigured.
IS THERE ANY BENEFIT TO ME?	There is no direct benefit to you. This study is being done to evaluate the effectiveness and cost-efficiency of the postmortem sample collection, processing and long-term storage. However, your samples may help researchers better understand ALS in the future.



WILL THE INFORMATION I TELL YOU BE KEPT PRIVATE?	Yes. Just like when you talk to your doctor, everything you tell us will be kept private to the extent allowed by law. Any information with your name on it will be kept in a locked area. Only authorized staff will be able to look at this information. A summary of the study results will be printed in a report. Individuals will not be identified in the report.
WHAT WILL HAPPEN AT THE END OF THE STUDY?	The final results of the pilot study will be summarized in a written report. This report will be provided to interested persons. Individuals will not be identified in this report. At the end of this study, we will provide recommendations on the long-term implementation of a National ALS Biorepository. ATSDR will keep your tissues for future research.
HOW DO I ENROLL IN THIS STUDY?	First, we need to determine your eligibility to take part by speaking to your doctor about your health status and disease. We also need to review pertinent laws in your state related to organ donation. If you are eligible to take part, our staff will meet with you and a family member at your home. We will review the consent form and answer all questions you and your family may have about this study.
HOW LONG WILL THE IN-HOME CONSENT FORM APPOINTMENT TAKE?	We will contact you to set up a time for a trained professional to come to your home and speak with you and a family member. The review of the consent form and answering questions should take about one hour.
WHAT DO I NEED TO DO IN ORDER TO TAKE PART IN THIS STUDY?	Give McKing permission to speak with your physician. Have a family member present at the in-home consent form appointment who will also need to agree to the study in order for you to take part. Be prepared to make plans for your final arrangements. Agree to provide an update of your health status to McKing on a regular basis. Have a family member agree to notify McKing of your passing within 6-8 hours.
WHAT IF MY FAMILY DOES NOT AGREE WITH MY WISHES TO DONATE TISSUES AFTER MY DEATH?	It is important to make the decision to provide tissues after your death with your family. We will try to honor your request but if your family objects to donating tissues after your death, we will not be able to include you in this study.
IS THERE ANY COST TO ME FOR THE SPECIMEN COLLECTION?	No. There is no cost to you to donate tissues or to take part in this study.
DO I HAVE TO PARTICIPATE IN THIS STUDY?	No. Taking part in the study is completely voluntary. You may also refuse to answer any question for any reason and you may choose to leave the study at any time even after signing the consent form. There is no penalty for leaving the study. Your decision will have no impact on your medical care and other services provided by your neurologist.

FOR MORE INFORMATION ABOUT THE STUDY, CONTACT:

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