

FACT SHEET



<p>WHAT IS THIS STUDY ABOUT?</p>	<p>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, experts will test the plan by gathering specimens from at least 300 interested PALS. Once the testing is done, ATSDR will decide if a National ALS Biorepository is practical.</p>
<p>WHAT IS A BIOREPOSITORY?</p>	<p>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.</p>
<p>WHY IS THIS STUDY BEING DONE?</p>	<p>This study is being done to find out whether it is practical to establish a Biorepository as part of the National ALS Registry.</p>
<p>WHO IS CONDUCTING THIS STUDY?</p>	<p>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.</p>
<p>WHY IS THIS BIOREPOSITORY IMPORTANT?</p>	<p>The specimens in this biorepository will complement the registry's epidemiologic data and will also add to the total numbers of biological specimens available for research on ALS. The National ALS Biorepository will differ from others already in existence because its scope is comprehensive rather than defined by geographic area, exposure, or clinical characteristics.</p>
<p>WHO CAN TAKE PART IN THIS STUDY?</p>	<p>PALS enrolled in the National ALS Registry.</p>
<p>WHAT INFORMATION ABOUT ME WILL BE COLLECTED IN THIS STUDY?</p>	<p>You will be asked to sign a consent form and answer a few brief questions. Then the nurse will draw blood, clip hair and nail specimens, and you will provide a urine specimen. The samples will be stored for future research on ALS. No specimens will be tested for this study.</p>
<p>WHERE WILL THE STUDY BE CONDUCTED?</p>	<p>We will contact you to set up a time for a trained professional to come to your home and draw your blood and collect the other specimens.</p>
<p>IS THERE ANY RISK TO ME?</p>	<p>Very little. We will try to make you as comfortable as possible but taking your blood may hurt a little. You will feel a slight "pinch" when the needle is put in. You may feel some discomfort or see a small bruise where the blood was drawn. There is no risk for the other specimens being collected.</p>
<p>IS THERE ANY BENEFIT TO ME?</p>	<p>There is no direct benefit to you, this study is being done to evaluate the effectiveness and cost-efficiency of the biospecimen sample collection, processing and long-term storage. However, your samples may help us to better understand ALS in the future.</p>



<p>WILL THE INFORMATION I TELL YOU BE KEPT PRIVATE?</p>	<p>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 employees 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.</p>
<p>WHAT WILL HAPPEN AT THE END OF THE STUDY?</p>	<p>The final results of the pilot study will be summarized in a written report and provided to all participants and other 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 specimens for future research.</p>
<p>IS THERE ANYTHING I NEED TO DO TO PREPARE FOR THE DAY I HAVE THE SPECIMENS TAKEN?</p>	<p>Yes.</p> <ul style="list-style-type: none"> • Do not cut your hair for at least 1 week before your appointment. • 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.
<p>IS THERE ANYTHING I NEED TO DO ON THE DAY I HAVE THE SPECIMENS TAKEN?</p>	<p>Yes.</p> <ul style="list-style-type: none"> • Drink plenty of water on the day of your blood draw. • You may want to provide your urine specimen collection the morning before your appointment to have specimens taken. • Please remove nail polish for the day of your appointment to have specimens taken.
<p>HOW LONG WILL IT TAKE?</p>	<p>We ask you to give specimens on two occasions, six months apart. Each specimen collection home visit should take less than one hour.</p>
<p>IS THERE ANY COST TO ME FOR THE SPECIMEN COLLECTION?</p>	<p>No. There is no charge for the specimens being collected.</p>
<p>DO I HAVE TO PARTICIPATE IN THIS STUDY?</p>	<p>No. Taking part in the study is completely voluntary. You can refuse to answer any question for any reason. You can also refuse to provide a blood sample. 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.</p>

FOR MORE INFORMATION ABOUT THE STUDY, CONTACT:

LAURIE WAGNER, MPH, Study Coordinator
 TOLL-FREE: 1-855-874-6912
 EMAIL: lwagner@mcking.com
 WEBSITE: <http://wwwn.cdc.gov/als/ALSBioRegistry.aspx>