NEALS Northeast Amyotrophic Lateral Sclerosis Consortium

NEALS and NCRI Sample Repository Request Form Instructions & Descriptions

The sample repository consists of serum, plasma, cerebrospinal fluid (CSF), urine, extracted DNA and whole blood samples from NEALS and NCRI research studies of Amyotrophic Lateral Sclerosis.

The purpose, enrollment, and sample processing procedures are described below for each research study.

NEALS Clinical Trials *(Studies 1-5)*

1.) A Clinical Trial of Topiramate in ALS

This trial was a 12 month double-blind, placebo-controlled study of Topiramate in 296 people with ALS at 21 sites throughout the United States. Researchers collected blood from 198 subjects who received Topiramate and 98 subjects who received placebo. Maximum dose administration was 800 milligrams per day.

First Study Visit: June 1999
Last Study Visit: Dec 2001
Female: 84 Male: 150
Age at Enrollment Range: 32-81

Sample processing

Plasma – Blood was collected using sodium heparin vacutubes and centrifuged at 2500 rpm for at least 10 minutes. The supernatant was aliquoted into cryovials and frozen at -20 degrees Celsius. Cryovials were frozen at -80 degree Celsius upon study completion.

2.) A Clinical Trial of Celebrex in Subjects with ALS

This trial was a 12 month double-blind, placebo-controlled efficacy study in 300 people with ALS at 27 sites throughout the United States. Researchers collected longitudinal blood and CSF samples from 200 subjects who received 200 mg of Celebrex and 100 subjects who received placebo.

First Study Visit: Dec 2001
Last Study Visit: Oct 2004
Female: 104 Male: 192
Age at Enrollment Range: 22-83

Sample processing

Serum – Blood was collected using red top vacutubes and centrifuged at 1000-g for 10 minutes. The supernatant was aliquoted into screw cap cryovials and frozen at -80 degrees Celsius.

CSF – If site considered the lumbar puncture (LP) atraumatic, CSF was aliquoted into screw cap cryovials and frozen at -80 degrees Celsius. If site considered the LP traumatic, CSF was centrifuged at 1,000 cc for five minutes and frozen at -80 degrees Celsius.

3.) A Clinical Trial of Coenzyme Q10 in Patients with Amyotrophic Lateral Sclerosis

This trial was an eight month open-label, dose-escalation study designed to assess the safety and tolerability of high doses of Coenzyme Q10 in 31 subjects with ALS at four different sites. Researchers collected blood from 31 subjects who received up to 3,000 milligrams per day of CoQ10.

First Study Visit: Apr 2003
Last Study Visit: Dec 2004
Female: 15 Male: 16
Age at Enrollment Range: 39-72

Sample processing

Plasma – Blood was collected using sodium heparin vacutubes and centrifuged at 3000 rpm for 10 minutes. The supernatant was aliquoted into cryovials and frozen at -80 degrees Celsius.

4.) A Multicenter, Dose Ranging Safety and Pharmacokinetics Study of Arimoclomol in Amyotrophic Lateral Sclerosis – Phase IIa

This trial was a double-blind, placebo-controlled safety and tolerability study in 84 subjects with ALS at 10 sites throughout the United States. Researchers collected blood from 62 subjects who received Arimoclomol and 22 subjects who received placebo. Subjects were randomized to receive 75, 100, or 150 mg of Arimoclomol, or placebo, over a 12-week period with a 4-week post-treatment wash out period. Researchers also collected CSF from 44 subjects at their week four visit.

First Study Visit: Oct 2005
Last Study Visit: Apr 2007
Female: 20 Male: 24
Age at Enrollment Range: 27-77

Sample processing

Serum – Blood was collected using red-gray vacutubes. Between 30 and 80 minutes post draw, blood was centrifuged at 3100 rpm for 15 minutes, aliquoted into cryovials, and frozen at – 80 degrees Celsius.

CSF – CSF was collected by lumbar puncture, aliquoted into cryovials, and frozen at -80 degrees Celsius.

5.) A Multicenter Study for the Validation of ALS Biomarkers

This is a sample collection trial with a total of 650 volunteers across 30 sites in the US and Canada. Blood (plasma, serum and DNA) and CSF samples are collected from four groups: volunteers diagnosed with ALS or

suspected ALS (sALS and fALS), volunteers with neurological diseases that mimic ALS (i.e., MS, HSP) and healthy control volunteers. Longitudinal plasma samples are available from ALS and suspected ALS volunteers.

First Study Visit: May 19, 2008
Last Study Visit: N/A – Ongoing
Enrollment Age: 30-80

Sample processing

Plasma – Blood is collected using purple top K2EDTA vacutubes and centrifuged at 1750-g for 10 minutes. The supernatant is aliquoted into cryovials and frozen at -70 to -80 degrees Celsius.

Serum – Blood is collected using red top vacutubes and centrifuged at 1300-g for 10 minutes. The supernatant is aliquoted into cryovials and frozen at -70 to -80 degrees Celsius.

CSF - CSF is collected using polystyrene tubes and centrifuged at 1750-g for 10 minutes. CSF is aliquoted into cryovials and frozen at -70 to -80 degrees Celsius.

NCRI Biomarker Studies *(Studies 6-13)*

6.) Determination of Biological Markers in Cerebrospinal Fluid (CSF) of Subjects with Amyotrophic Lateral Sclerosis

Abbreviated Study Title: CSF Study

The study purpose was to determine unique and distinct biological markers for ALS subjects. Researchers collected CSF, blood, and urine from 348 subjects. There were 127 ALS subjects, 25 Healthy Control subjects, and 153 Disease Control subjects, including people with lower motor neuron disease, upper motor neuron disease, peripheral neuropathy, multiple sclerosis, and other neurological disorders.

First Study Visit: Mar 1997
Last Study Visit: Nov 2004
Female: 135 Male: 168
Age at Enrollment Range: 21-87

Sample Processing

Plasma – Blood was collected using green top sodium heparin vacutubes and centrifuged. The supernatant was aliquoted into screw cap vials and frozen at -80 degrees Celsius. Centrifuge speed and time unknown.

CSF – CSF was collected and placed immediately on wet ice and centrifuged at 5000 rpm for 5 minutes. The supernatant was aliquoted into screw cap vials and frozen at -80 degrees Celsius.

Urine – Urine was collected and aliquoted into screw cap vials and frozen at -80 degrees Celsius.

7.) Determinants of Disease Severity in Amyotrophic Lateral Sclerosis

Abbreviated Study Title: Disease Severity Study

The study aims were to examine possible risk factors for developing ALS and to compare biological markers in blood and urine of subjects with and without ALS. Blood and urine was collected from 327 subjects, including 161 ALS subjects and 166 Healthy Control subjects.

First Study Visit: Apr 1998
Last Study Visit: Apr 2005
Female: 127 Male: 157
Age at Enrollment Range: 22-82

Sample Processing

Plasma – Blood was collected using green top sodium heparin vacutubes, placed immediately on wet ice, and centrifuged at 5000 rpm for 5 minutes. The supernatant was aliquoted into vials and frozen at -70 degrees Celsius.

Serum – Blood was collected, placed immediately on wet ice, and centrifuged at 3000 rpm for 10 minutes. The supernatant was aliquoted into vials and frozen at -70 degrees Celsius. Collection tube type unknown.

Urine – Urine was collected and centrifuged at 5000 rpm for five minutes. The supernatant was aliquoted into vials and frozen at -70 degrees Celsius.

8.) Application of a product enhanced reverse transcriptase (PERT) assay to search for evidence of retroviral involvement in amyotrophic lateral sclerosis

Abbreviated Study Title: Retroviral Study

The study purpose was to look for evidence of retroviral involvement in ALS by measuring reverse transcriptase activity in blood from subjects with and without ALS. Researchers collected blood from 178 subjects, including 61 ALS subjects and 117 Healthy Control subjects.

First Study Visit: Oct 2002
Last Study Visit: June 2005
Female: 93 Male: 81
Age at Enrollment Range: 19-82

Sample Processing

Serum – Blood was collected using red top vacutubes and centrifuged between 1 and 2 hours post draw at 2000 rpm for 10 minutes. The supernatant was aliquoted into Nalgene cryovials and frozen at -80 degrees Celsius.

9.) Metabolomic Signatures in Amyotrophic Lateral Sclerosis

Abbreviated Study Title: NIH Study

The study purpose was to test the hypothesis that there are unique and distinct biological markers for people with ALS. Researchers collected blood from 285 subjects, including 88 ALS subjects, 95 Healthy Control subjects, and 102 Disease Control subjects, including people with myopathies and peripheral neuropathies.

First Study Visit: June 2004
Last Study Visit: Dec 2006
Female: 139 Male: 152
Age at Enrollment Range: 19-90

Sample Processing

Plasma – Blood from June 2004 through January 2006 was collected using green top sodium heparin vacutubes, placed on wet ice for 30 minutes, and centrifuged at 3000 rpm for 10 minutes. The supernatant was aliquoted into cryovials and frozen at -80 degrees Celsius.

Blood from February 2006 through December 2006 was collected using purple top K2EDTA vacutubes, placed on wet ice for 30 minutes, and centrifuged at 3000 rpm for 10 minutes. The supernatant was aliquoted into cryovials and frozen at -80 degrees Celsius.

Serum – Blood was collected using red top vacutubes, placed on wet ice for 30 minutes, and centrifuged at 3000 rpm for 10 minutes. The supernatant was aliquoted into cryovials and frozen at -80 degrees Celsius.

10.) Identification of Diagnostic Biomarkers and Therapeutic Targets for Amyotrophic Lateral Sclerosis
Abbreviated Study Title: ALSA Study

The study purpose was to determine unique and distinct biological markers for ALS subjects. Researchers collected blood and/or CSF from 119 subjects, including 42 ALS subjects, 46 Healthy Control subjects, and 31 Disease Control subjects. The disease control subjects include people with lower motor neuron disease, upper motor neuron disease, peripheral neuropathy, multiple sclerosis, and other neurological disorders.

First Study Visit: July 2004
Last Study Visit: May 2007
Female: 43 Male: 73
Age at Enrollment Range: 22-81

Sample Processing

Plasma – Blood from July 2004 through January 2006 was collected using green top sodium heparin vacutubes and centrifuged within 2 hours post draw at 3000 rpm for 10 minutes in a temperature of 4 degrees Celsius. The supernatant was aliquoted into polypropylene screw cap vials and frozen at -80 degrees Celsius.

Blood from February 2006 through May 2007 was collected using purple top K2EDTA vacutubes and centrifuged within 2 hours at 2500 rpm for 10 minutes in a temperature of 4 degrees Celsius. The supernatant was aliquoted into polypropylene screw cap vials and frozen at -80 degrees Celsius.

Serum – Blood was collected using red top vacutubes and centrifuged between 1 and 2 hours post draw at 2500 rpm for 10 minutes in a refrigerated centrifuge (4 degrees Celsius). The supernatant was aliquoted into polypropylene screw cap vials and frozen at -80 degrees Celsius.

CSF – CSF was collected and centrifuged within 15 minutes post draw at 3000 rpm for 5 minutes in a refrigerated centrifuge (4 degrees Celsius). The supernatant was aliquoted into polypropylene screw cap vials and frozen at -80 degrees Celsius.

11.) Validation of ALS Metabolomic Biomarkers and Development of ALS Diagnostics
Abbreviated Study Title: SBIR Study

The study purpose was to validate the sensitivity and specificity of metabolomic biomarkers. Blood was collected from 115 people, including 52 ALS subjects and 63 Healthy Control subjects.

First Study Visit: July 2006
Last Study Visit: July 2007
Female: 47 Male: 68
Age at Enrollment Range: 23-81

Sample Processing

Plasma – Blood was collected using purple top K2EDTA vacutubes and centrifuged within 2 hours post draw at 2500 rpm for 10 minutes in a refrigerated centrifuge (4 degrees Celsius). The supernatant was aliquoted into polypropylene screw cap vials and frozen at -80 degrees Celsius.

Serum – Blood was collected using red top vacutubes and centrifuged between 1 and 2 hours from draw at 2500 rpm for 10 minutes in a refrigerated centrifuge (4 degrees Celsius). The supernatant was aliquoted into polypropylene screw cap vials and frozen at -80 degrees Celsius.

12.) Clinical Trial of Ceftriaxone in Subjects with ALS
This study is a 52-week double-blind, placebo-controlled study of ceftriaxone in 600 people with ALS at 42 sites throughout the United States. Researchers collected blood from 34 subjects. Treatment distinctions are unknown at the current time as the study is ongoing. Maximum dose 4 grams daily.

First Study Visit: September 2006
Last Study Visit: N/A
Female: 11 Male: 23
Age at Enrollment Range: 27-77

Sample Processing

CSF – CSF will be collected in tubes from lumbar puncture kits and centrifuged at 1000 RPM for 5 minutes within one hour of collection. Supernatant was aliquoted into polypropylene screw cap cryovials and immediately frozen at –80 degrees Celsius.

13.) ALS Sample Repository
This is an open enrollment sample collection trial conducted at Massachusetts General Hospital. Blood (plasma, serum and whole blood) and optional CSF samples are collected from four groups: volunteers diagnosed with ALS or suspected ALS (sALS and fALS), volunteers with neurological diseases that mimic ALS (i.e., MS, HSP) and healthy control volunteers. Sample processing is consistent with the NEALS Multicenter Biomarker Study for the Validation of ALS Biomarkers.

First Study Visit: June 12, 2008
Last Study Visit: N/A – Ongoing
Enrollment Age: 20-80

Sample processing

Plasma – Blood is collected using purple top vacutubes containing K2EDTA and centrifuged at 1750-g for 10 minutes. The supernatant is aliquoted into cryovials and frozen at -70 to -80 degrees Celsius.

Serum – Blood is collected using red top vacutubes and centrifuged at 1300-g for 10 minutes. The supernatant is aliquoted into cryovials and frozen at -70 to -80 degrees Celsius.

CSF - CSF is collected using polystyrene tubes and centrifuged at 1750-g for 10 minutes. CSF is aliquoted into cryovials and frozen at -70 to -80 degrees Celsius.

Whole Blood – Blood is collected using purple top vacutubes containing K2EDTA and aliquoted into cryovials at the volume of 1 mL within 2 hours. Samples are frozen at -70 to -80 degrees Celsius immediately.

PLEASE NOTE:

- *Requests for samples from NCRI studies may be submitted at any time. These requests will undergo a review process by the NCRI.*
- *Requests for samples from NEALS studies will be solicited at predetermined times and reviewed by the NEALS Sample RepositoryCommittee. Samples will be distributed following committee approval.*

To request samples, please complete the NEALS and NCRI Sample Repository Request Form and submit by email to mghneuroclinicaltrialsunit@partners.org **cc:** tlincoln@partners.org**; or by fax at 617-643-3558; or by mail to:**

NEALS Program Manager
MGH Neurological Clinical Research Institute
50 Staniford St, Rm 401I
Boston, MA, 02114

Please note: When submitting request forms by e-mail, please enter the following into the subject line:

*"**Sample Repository Request Form**"*

Thank You.