Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

CREATE GUID

GUID ID Information Sheet – Collect at Screening Visit only AFTER the participant has signed the ICF. Information collected on this page will be utilized to generate the subject's GUID. Note that dates for date of birth should be entered as 1-31 for day, 1-12 for month, and 4 digits (YYYY) for year.

Complete Legal Name at Birth (as it appears on birth certificate)		
Legal, Given First **[REQUIRED]**	Legal, Given Middle **[REQUIRED]**	Legal, Given Last **[REQUIRED]**
Any Additional MIDDLE name(s) given at birth? **[OPTIONAL]**		
DOB		
Day of Birth[1-31] **[REQUIRED]**	Month of Birth[1-12] **[REQUIRED]**	Year of Birth[YYYY] **[REQUIRED]**

Name of City/municipality at birth (as it appears on birth certificate) [REQUIRED]	
Country of Birth [REQUIRED]	
Physical Gender at birth [REQUIRED]	○ Male ○ Female
Gov't Issued or National ID [OPTIONAL]	Not needed for this study
Country issuing Gov't issued or National ID [OPTONAL]	Not needed for this study

Please follow your institutional SOP regarding storing confidential patient data. Do not retain this form in the subject's binder.

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E_ _U ___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

In addition to the subject ID, a patient Global Unique Identifier (GUID) will be used as the identifier for individuals participating in the study in NeuroBANK™. The GUID is an 11-character string that is generated using encryption technology and algorithms licensed by the NCRI from the National Institutes of Health (NIH).

The GUID is generated on a secure website that utilizes 128-bit Secure Socket Layer (SSL). Of note, this website is not linked to NeuroBANK™. The GUID is generated using an irreversible encryption algorithm – it accepts twelve identifying data elements, (e.g. last name at birth, first name at birth, gender at birth, day, month and year of birth, city and country of birth, etc.), and produces a unique random-generated character string, or GUID. No identifying information is stored in the system; it is simply used to generate the GUID. If the same information is entered again, the same GUID will be returned.

The GUID is entered into NeuroBANK™ when the patient is being created in the system. As the same patient may participate in multiple studies, NeuroBANK™ will also allow capturing a study-specific ID for the patient.

The Subject's 11-character GUID is

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

SCREENING VISIT CHECKLIST

Informed Consent:

- Was informed consent obtained from the subject?* ☒ Yes ☐ No
  (Written/verbal consent must be obtained **prior** to the start of any screening procedures)
- The consent form, version date __2/16/2017_____, for the Answer ALS study was thoroughly explained to the subject. The subject had adequate time to review the consent form and consider participation, and all questions regarding this study were answered. ☒ Yes ☐ No
- The subject was given a signed copy of the informed consent form. ☐ Yes ☐ No

Consenting process completed by Site Investigator or delegated study staff member per the delegation log of responsibilities: ☒ Yes ☐ No

Inclusion/Exclusion Review

☒ Inclusion/Exclusion Criteria Verification – *Complete Worksheet*

Screen Failure? ☐ Yes ☒ No (if yes complete worksheet)

Visit Procedures (***** = Complete corresponding source worksheet and EDC)

☐ Collect Demographic Information*
☐ Measure Weight and Height*
☐ ALS History*
☐ Key Study Event Review*
☐ ALS Gene Mutations*
☐ Environmental/Social History*
☐ ALS Diagnosis / El Escorial Criteria*
☐ Risk Factor Assessment*
☐ Medical History*
☐ Create GUID
☐ Vital Signs*

Assessments & Outcomes

☐ ALSFRS-R*
☐ Slow Vital Capacity (SVC)*
☐ Ashworth Spasticity Scale*
☐ Hand Held Dynamometry*
☐ ALS Cognitive Behavioral Screen (ALS-CBS)*

Optional Procedures

☐ Lumbar Puncture for CSF Collection*
☐ Blood draw for Additional Blood samples (Uric Acid, Creatinine, Phosphorus, and Creatine Kinase (CK))*

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Biomarker Studies

☐ Blood for PBMC* ☐ Plasma*

☐ Serum* ☐ DNA*

Protocol Deviation Review

Have there been any protocol deviations noted at this visit? ☐ Yes ☐ No

If **yes**, specify, and update the Protocol Deviation Log.

_____
_____
_____
_____

Concomitant Medication Review

Have there been any concomitant medications noted at this visit? ☐ Yes ☐ No

If **yes**, specify, and update the Con-Med Log.

_____
_____
_____

Adverse Events (only Adverse Events that occur AFTER signing informed consent and are directly related to study procedures will be recorded)

Have there been any adverse events noted at this visit? ☐ Yes ☐ No

If **yes**, specify, and update the Adverse Event Log.

_____
_____
_____

Visit Comments/Notes:

Signature of person obtaining information **Date**

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

INFORMED CONSENT FORM		
Instructions: Complete this form each time a subject signs a new version of the consent form.	**Yes**	**No**
1. Confirmed subject name, second identifier, and valid consent form.	☐	☐
2. Discussed, explained, and reviewed the consent form with the participant.	☐	☐
3. All of the participant's questions were answered and/or concerns were addressed	☐	☐
4. The participant agreed to participate in the study and signed/dated a valid consent form prior to the start of any study procedures.	☐	☐
5. Caregiver/surrogate consent was obtained.	☐	☐
6. A copy of the signed and dated consent form was given to the participant.	☐	☐
7. A copy of the signed and dated consent form was placed in the subject's binder.	☐	☐

Protocol Version: _____4_____

ICF Version/Date: ____2/16/2017_____

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

INCLUSION/EXCLUSION CRITERIA REVIEW			
All subjects enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the application and approved by the IRB.			
Inclusion Criteria **[NOTE: The answer to question 2, 3, or 4 must be "Yes" for the subject to be eligible.]**	**Yes**	**No**	**N/A**
1. The subject is male or female, aged 18 to 100, inclusive.	☐	☐	
2. The subject has been diagnosed with possible, laboratory-supported probable, probable or definite (according to the WFN El Escorial criteria) familial or sporadic ALS.	☐	☐	
3. The subject has a clinically diagnosed motor neuron disorder (MND), including primary lateral sclerosis (PLS), flail arm ALS, progressive muscular atrophy (PMA), monomelic amyotrophy, or another clinical variant of neurodegenerative MND (See Appendix 1 of Study Protocol).	☐	☐	
4. If the subject is an asymptomatic participant, he/she has documentation of the presence of a gene known to cause ALS.	☐	☐	☐
Exclusion Criteria **[NOTE: If the answer to question 1 or 2 below is "Yes," then the patient is ineligible.]**	**Yes**	**No**	**N/A**
1. The participant has Spinal-Bulbar Muscular Atrophy.	☐	☐	
2. The participant has a known diagnosis of HIV/AIDS, Hepatitis B, or Hepatitis C.	☐	☐	

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

ELIGIBILITY CONFIRMATION			
	Yes	**No**	**N/A**
Did the subject read, understand, and provide informed consent for this study?	☐	☐	
Date consent was received: ___ ___/___ ___/___ ___ ___ ___ (MM/DD/YYYY) Person who Obtained Consent: _____			
Consent Version:___4____ Is this a re-consent? ☐ Yes ☒ No			
Does the subject satisfy all inclusion and exclusion criteria for this study?	☐	☐	

Consent Process Description:	Explained study and procedures. Went through consent with participant.
	Explained risks and that they may withdraw at any time. Answered
	questions. Had participant sign consent.

STATEMENT OF ELIGIBILITY	
This subject is [☐ **eligible** / ☐ **ineligible**] for participation in the study.	
Principal Investigator Signature:	Date:
Printed Name:	

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

SCREEN FAILURE

Instructions: Please complete this form if the subject was considered ineligible and a protocol waiver(s) was not granted, if the subject decided to withdraw consent during the screening process, or for any other reason.

Please specify reason for screen failure:

☐ Subject did not meet inclusion criteria (Select all that apply):

☐ Failed inclusion criteria (list):

_____

_____

☐ Subject did not meet exclusion criteria (Select all that apply):

☐ Failed exclusion criteria (list):

_____

_____

☐ Subject withdrew consent during the screening process

☐ Other (specify): _____

_____

_____

_____

_____

_____

_____

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

ALS History
Where was the ALS diagnosis made: ☐ Outside center ☐ ALS center
Date of symptom onset: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)
Date of diagnosis: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)
Site of onset – check all that apply ☐ Bulbar ☐ Speech ☐ Swallowing ☐ Axial ☐ Neck ☐ Trunk ☐ Respiratory ☐ Limb ☐ Upper ☐ Left ☐ Right ☐ Hand/fingers ☐ Arm ☐ Lower ☐ Left ☐ Right ☐ Ankle/foot/toes ☐ Leg ☐ Other, specify: _____ _____ _____

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

ALS Gene Mutation			
Not Tested	**Mutation**	**Result**	**Laboratory**
☐	ANG	☐ Positive ☐ Negative	
☐	C9ORF72	☐ Positive ☐ Negative	
☐	FUS	☐ Positive ☐ Negative	
☐	PROGRANULIN	☐ Positive ☐ Negative	
☐	SETX	☐ Positive ☐ Negative	
☐	SOD1	☐ Positive ☐ Negative	
☐	TAU	☐ Positive ☐ Negative	
☐	TDP-43	☐ Positive ☐ Negative	
☐	VAPB	☐ Positive ☐ Negative	
☐	VCP	☐ Positive ☐ Negative	
☐	Other, specify:	☐ Positive ☐ Negative	

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

ALS DIAGNOSIS			
Does the subject have:	**Yes**	**No**	**Not Done**
1. Topographical location and pattern of progression of UMN and LMN signs, including signs of spread within a region or to other regions, consistent with ALS?	☐	☐	
2. Exclusion by electrophysiological testing of all other processes including conduction block that might explain the underlying signs and symptoms?	☐	☐	☐
3. Exclusion by neuroimaging of other disease processes such as myelopathy or radiculopathy that might explain observed clinical and electrophysiological signs?	☐	☐	☐

Please check YES or NO if signs are present.

	CLINICAL						**EMG**		
	UMN			**LMN**			**LMN**		
	Yes	**No**	**Not Done**	**Yes**	**No**	**Not Done**	**Yes**	**No**	**Not Done**
BULBAR	☐	☐	☐	☐	☐	☐	☐	☐	☐
LUE	☐	☐	☐	☐	☐	☐	☐	☐	☐
RUE	☐	☐	☐	☐	☐	☐	☐	☐	☐
TRUNK	☐	☐	☐	☐	☐	☐	☐	☐	☐
LLE	☐	☐	☐	☐	☐	☐	☐	☐	☐
RLE	☐	☐	☐	☐	☐	☐	☐	☐	☐

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

ALS DIAGNOSIS
El Escorial criteria for ALS (select one):
☐ Suspected
☐ Possible
☐ Probable laboratory supported
☐ Probable
☐ Definite

Site Investigator Signature **Date** (MM/DD/YYYY)

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__ _E_ _U ___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Family History

Instructions: Enter one relative per line. Make as many copies of this form as necessary to record all family history.

Relative (enter code or specify)	**Hereditary**	**Gender**	**Medical Condition** (enter code(s))	**Genetic Testing Performed?**	**Known Mutation** (enter code)
	☐ Paternal ☐ Maternal	☐ Male ☐ Female		☐ Yes ☐ No	
	☐ Paternal ☐ Maternal	☐ Male ☐ Female		☐ Yes ☐ No	
	☐ Paternal ☐ Maternal	☐ Male ☐ Female		☐ Yes ☐ No	
	☐ Paternal ☐ Maternal	☐ Male ☐ Female		☐ Yes ☐ No	
	☐ Paternal ☐ Maternal	☐ Male ☐ Female		☐ Yes ☐ No	
	☐ Paternal ☐ Maternal	☐ Male ☐ Female		☐ Yes ☐ No	
	☐ Paternal ☐ Maternal	☐ Male ☐ Female		☐ Yes ☐ No	

Relative:	**Medical Condition – select all that apply:**	**Known Mutations:**
1=Mother 2=Father 3=Sister 4=Brother 5=Half-sister 6=Half Brother 7=Daughter 8=Son 9=Grandmother 10=Grandfather 11=Aunt 12=Uncle 13=Cousin 14=OTHER, Specify:	1=Alzheimer's disease 2=ALS 3=Dementia 4=Down's syndrome 5=Frontotemporal Dementia 6=Huntington's disease 7=Parkinson's disease 8=Psychiatric disorder, specify: 9=Arthritis 10=Asthma 11=Cancer 12=Circulation problems 13=Diabetes 14=Heart Disease 15=Lung disease 16=Stroke 17=OTHER, Specify:	1=ANG 2=C9ORF72 3=FUS 4=SETX 5=SOD1 6=TDP-43 7=VAPB 8=VCP 9= OTHER, Specify:

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E_ _U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

MEDICAL HISTORY

Instructions: Please enter any and all medical history the patient may have experienced in their lifetime. Make as many copies of this form as necessary to record all relevant past medical history.

Description	Year of Diagnosis (YYYY)	Still Present? (Yes/No)
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E_ _U ___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

DEMOGRAPHICS
Date of Birth: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)
Age: _____
Gender: ☐ Male ☐ Female
*Ethnic Category (Select **one**): ☐ Non-Hispanic or Latino ☐ Hispanic or Latino
*Racial Categories (Select **all that apply**): ☐ White ☐ Black/African American ☐ Asian ☐ Native Hawaiian/Pacific Islander ☐ American Indian/Alaska Native
***PLEASE NOTE: Ethnic and Racial categories collected via subject self-report**

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

CNS-LABILITY SCALE

Date Performed: _____ _____ / _____ _____ / _____ _____ _____ _____

Evaluator's Initials: _____

INSTRUCTIONS FOR SUBJECT

Please select the number that describes the degree to which each item has applied to you DURING THE PAST WEEK.

	Does not Apply	Rarely Applies	Occasionally Applies	Frequently Applies	Applies Most of the Time
1. There are times when I feel fine 1 minute, and then I'll become tearful the next over something small or for no reason at all.	1	2	3	4	5
2. Others have told me that I seem to become amused very easily or that I seem to become amused about things that aren't funny.	1	2	3	4	5
3. I find myself crying very easily.	1	2	3	4	5
4. I find that even when I try to control my laughter, I am often unable to do so.	1	2	3	4	5
5. There are times when I won't be thinking of anything happy or funny at all, but then I'll suddenly be overcome by funny or happy thoughts.	1	2	3	4	5
6. I find that even when I try to control my crying, I am often unable to do so.	1	2	3	4	5
7. I find that I am easily overcome by laughter.	1	2	3	4	5

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

VITAL SIGNS				
Not Done	**Test**	**Measurement**	**Unit**	**Measurement Specification**
☐	Temperature	_____.____	☐ ◦F ☒ ◦C	Method (Select One): ☐ Axillary ☐ Oral ☐ Rectal ☐ Tympanic ☒ Other (specify):__temporal_____
☐	Blood Pressure	Systolic: _____ Diastolic: _____	mmHg	Position (Select One): ☐ Standing ☐ Left Arm ☒ Sitting ☐ Right Arm ☐ Supine
☐	Heart Rate	_____	beats/min	
☐	Respiratory Rate	_____	breaths/min	
☐	Weight	_____	☒ pounds ☐ kilograms	
☐	Height *(Screening Only)*	_____	☒ inches ☐ centimeters	
☐	BMI	_____		

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__ _E_ _U __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

VITAL CAPACITY

Instructions: A printout from the spirometer of all Slow Vital Capacity (SVC) or Forced Vital Capacity (FVC) trials will be retained. Three VC trials are required for each testing session, however up to 5 trials may be performed if the variability between the highest and second highest VC is 10% or greater for the first 3 trials. Up to three of the best trials are recorded on the CRF in the EDC.

Type of Vital Capacity Collected:

☐ SVC
☐ FVC

Position:

☐ Supine
☐ Upright
☐ Unknown

PLACE SPIROMETER PRINTOUT HERE

****Must be signed and dated by the Evaluator****

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

ALSFRS-R	
Was the ALSFRS-R Performed? ☐ Yes ☐ No	
Responded by: ☐ Patient ☐ Patient via Caregiver	
Mode of Administration: ☐ In person ☐ Telephone ☐ Other:_____	
QUESTIONS:	SCORE
1. Speech 4 = Normal speech processes 3 = Detectable speech disturbances 2 = Intelligible with repeating 1 = Speech combined with non-vocal communication 0 = Loss of useful speech	
2. Salivation 4 = Normal 3 = Slight but definite excess of saliva in mouth; may have nighttime drooling 2 = Moderately excessive saliva; may have minimal drooling 1 = Marked excess of saliva with some drooling 0 = Marked drooling; requires constant tissue or handkerchief	
3. Swallowing 4 = Normal eating habits 3 = Early eating problems – occasional choking 2 = Dietary consistency changes 1 = Needs supplemental tube feeding 0 = NPO (exclusively parenteral or enteral feeding)	
4. Handwriting 4 = Normal 3 = Slow or sloppy; all words are legible 2 = Not all words are legible 1 = No words are legible but can still grip a pen 0 = Unable to grip pen	
5a. Cutting Food and Handling Utensils (patients without gastrostomy) 4 = Normal 3 = Somewhat slow and clumsy, but no help needed 2 = Can cut most foods, although clumsy and slow; some help needed 1 = Food must be cut by someone, but can still feed slowly 0 = Needs to be fed	
5b. Cutting Food and Handling Utensils (alternate scale for patients with gastrostomy) 4 = Normal 3 = Clumsy, but able to perform all manipulations independently 2 = Some help needed with closures and fasteners 1 = Provides minimal assistance to caregivers 0 = Unable to perform any aspect of task	

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E_ _U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

6. Dressing and Hygiene 4 = Normal function 3 = Independent, can complete self-care with effort or decreased efficiency 2 = Intermittent assistance or substitute methods 1 = Needs attendant for self-care 0 = Total dependence	
7. Turning in Bed and Adjusting Bed Clothes 4 = Normal function 3 = Somewhat slow and clumsy, but no help needed 2 = Can turn alone, or adjust sheets, but with great difficulty 1 = Can initiate, but not turn or adjust sheets alone 0 = Helpless	
8. Walking 4 = Normal 3 = Early ambulation difficulties 2 = Walks with assistance 1 = Nonambulatory functional movement only 0 = No purposeful leg movement	
9. Climbing Stairs 4 = Normal 3 = Slow 2 = Mild unsteadiness or fatigue 1 = Needs assistance 0 = Cannot do	
R-1. Dyspnea 4 = None 3 = Occurs when walking 2 = Occurs with one or more of the following: eating, bathing, dressing 1 = Occurs at rest, difficulty breathing when either sitting or lying 0 = Significant difficulty, considering using mechanical respiratory support	
R-2 Orthopnea 4 = None 3 = Some difficulty sleeping at night due to shortness of breath, does not routinely use more than two pillows 2 = Needs extra pillow in order to sleep (more than two) 1 = Can only sleep sitting up 0 = Unable to sleep without mechanical assistance	
R-3 Respiratory Insufficiency 4 = None 3 = Intermittent use of NIPPV 2 = Continuous use of NIPPV during the night 1 = Continuous use of NIPPV during the night and day 0 = Invasive mechanical ventilation by intubation or tracheostomy	

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Hand page 2 to caregiver **ALS Cognitive Behavioral Screen (CBS)™**

Attention

a. Commands: *I am going to say some commands. Please listen carefully and then do what I say. (If patient is unable to indicate with finger, movement can be substituted with eyes, arm or other means).*

1. Point/indicate (with your finger) to the ceiling and then make a fist.
2. Touch your shoulder, point to the floor, and then make a fist.

#errors	0	1+
Score	1	0

b. Mental Addition/Language: I am going to say some phrases. I want you to tell me the number of syllables in each phrase. For example, "the table" has 3 syllables. (Repetition of each phrase is allowed once)

1. The weather is nice (correct response: 5) answer ___
2. Tomorrow will be sunny (correct response: 7) answer ___

#errors	0	1+
Score	1	0

(score 0 if >20 sec on either)

c. Eye movements: Saccades and Antisaccades

# of correct saccades out of 8: ___/8 Score: 8/8 = 1 point, ≤7/8 = 0 points

# of correct antisaccades out of 8: ___/8 Score: 8/8 = 2 points, ≤7/8 = 1 point, ≤6/8=0 points

/5

Concentration

I am going to say some numbers. After I say them, I want you to say them to me backwards, or in reverse order. For example, if I say 3-6, you would say 6-3. (If written, do not allow pt to write forward span. Discontinue after failure on 2 consecutive trials).

	Correct	Incorrect		Correct	Incorrect
2-9 (9-2)	_____	____	7-8-6-4 (4-6-8-7)	____	____
6-4 (4-6)	_____	____	5-4-1-9 (9-1-4-5)	____	____
3-7-2 (2-7-3)	_____	_____	8-2-5-9-3 (3-9-5-2-8)	____	_____
5-8-1 (1-8-5)	_____	_____	5-7-6-3-9 (9-3-6-7-5)	____	_____

Maximum Span Correct:

/5

Tracking/Monitoring

a. Months: *Please say the months of the year backwards, starting with Dec.*

Dec Nov Oct Sept Aug Jul June May Apr Mar Feb Jan

#errors	0	1	2+
Score	2	1	0

b. Alphabet: *Please say/write the alphabet*

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

#errors	0	1+
Score	1	0

c. Alternation Task*: I want you to alternate between numbers and letters, starting with 1-A, 2-B, 3-C, and so on. Please continue from there, alternating between # and letter, in order, until I tell you to stop.*

(Errors: any mistake in sequencing, i.e. 7-H or 8-9)

4-D 5-E 6-F 7-G 8-H 9-I 10-J 11-K 12-L 13-M

#errors	0	1	2
Score	2	1	0

/5

Initiation and Retrieval *Say/write as many words as you can think of starting with the letter F, as quickly as you can, in 1 min. You can't say/write the names of people, places or numbers. Please don't say/write the same word with a different ending, like truck and trucks. (S words can be substituted for F words). Errors: repetitions, rule violations.*

1. _____ 9. _____ 17. _____
2. _____ 10. _____ 18. _____
3. _____ 11. _____ 19. _____
4. _____ 12. _____ 20. _____
5. _____ 13. _____
6. _____ 14. _____
7. _____ 15. _____
8. _____ 16. _____

#correct words	>12	12-8	<8	≤4
Score:	3	2	1	0*

plus

#errors	0	1	2+
Score	2	1	0

*if ≤4 words, total verbal fluency score = 0 regardless of # of errors

/5

TOTAL SCORE

/20

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E_ _U ___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__ _E_ _U ___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Caregiver Initials: __ __ __ relationship:_____

ALS CBS™ ALS Cognitive Behavioral Screen Caregiver Questionnaire

These questions pertain to possible changes that you have noticed since the onset of ALS symptoms. As best you can, consider changes that are unrelated to physical weakness. For example, question #1 asks about interest in activities. If the person can no longer play tennis but still seems interested in it (i.e. talks about it, watches it on t.v.), then you would circle 3 for no change in level of interest.

If the person has always had the trait in question, please respond No Change, since there has been no change over time.

Compared to before ALS, does he/she: *Please circle a number*	**No Change**	**Small Change**	**Medium Change**	**Large Change**
1. Have less interest in topics/events that used to be important to them?	3	2	1	0
2. Show little emotion, or seem less responsive emotionally?	3	2	1	0
3. Seem more agreeable or pleasant than in the past with fewer worries?	3	2	1	0
4. Fail to think things through before acting?	3	2	1	0
5. Seem more withdrawn from others but not sad?	3	2	1	0
6. Get confused or distracted more easily?	3	2	1	0
7. Have less ability to deal with frustration or stress?	3	2	1	0
8. Seem less concerned about the feelings or concerns of others than before:	3	2	1	0
9. Get angry or irritable more easily than before?	3	2	1	0
10. Seem more sarcastic or childlike than before?	3	2	1	0
11. Eat more or have a new preference for particular foods (i.e. sweets)?	3	2	1	0
12. Have more trouble changing opinions or adapting to new situations?	3	2	1	0
13. Show less judgment or more problems making good decisions (i.e. regarding safety, finances, etc)	3	2	1	0
14. Have less awareness of obvious problems or changes, or deny them?	3	2	1	0
15. Have new problems with language, such as saying the wrong word more often, making up new words, or declines in spelling ability?	3	2	1	0

TOTAL SCORE: ____ / 45

The following questions relate to current symptoms, not changes over time:

Do you think your loved one:	**YES**	**NO**
• Seems depressed on most days?	**[ ]**	**[ ]**
• Seems anxious on most days?	**[ ]**	**[ ]**
• Seems extremely fatigued on most days?	**[ ]**	**[ ]**
• Suffers from unexpected crying or laughing spells?	**[ ]**	**[ ]**

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E_ _U __ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

ASHWORTH SPASTICITY SCALE
Date Performed: _____ _____ / _____ _____ / _____ _____ _____ _____
Evaluator's Initials: _____
*Key: 1 No increase in muscle tone 2 Slight increase in tone giving a "catch" when affected part is moved in flexion or extension 3 More marked increase in tone but affected part is easily flexed. 4 Considerable increase in tone; passive movement difficult. 5 Affected part is rigid in flexion or extension. 6 Not Tested 7 Not Tested (subject unable to perform task)

Not Done	**Limb**	**Score***
☐	Right Arm	
☐	Left Arm	
☐	Right Leg	
☐	Left Leg	

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

REFLEXES
Date Performed: _____ _____ / _____ _____ / _____ _____ _____ _____
Evaluator's Initials: _____

Instructions:
If the reflex was a **1+ or 2+,** was the reflex ABNORMALLY retained in a weak/wasted limb suggesting hyperreflexia? Please answer by checking the appropriate box as indicated below. 0 = Absent 1+ = Present

Not Done	Cranial	Absent	Present
❑	Jaw Jerk	❍	❍
❑	Facial Reflex	❍	❍
❑	Palmomental Sign	❍	❍

Not Done	Right Cervical	0 (Absent)	1+ (Present)	2+	3+	4+	Retained in Weak Limb?
❑	Triceps Reflex	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Biceps Reflex	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Brachioradialis	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Finger Flexors	❍	❍				
❑	Clonus	❍	❍				
❑	Hoffman's Sign	❍	❍				

Not Done	Left Cervical	0 (Absent)	1+ (Present)	2+	3+	4+	Retained in Weak Limb?
❑	Triceps Reflex	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Biceps Reflex	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Brachioradialis	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Finger Flexors	❍	❍				
❑	Clonus	❍	❍				
❑	Hoffman's Sign	❍	❍				

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E_ _U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Not Done	Right Lumbosacral	0 (Absent)	1+ (Present)	2+	3+	4+	Retained in Weak Limb?
❑	Patellar	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Ankle	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Crossed Adduction	❍	❍				
❑	Clonus	❍	❍				
❑	Babinski Sign	❍	❍				

Not Done	Left Lumbosacral	0 (Absent)	1+ (Present)	2+	3+	4+	Retained in Weak Limb?
❑	Patellar	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Ankle	❍	❍	❍	❍	❍	❍Yes ❍No ❍N/A
❑	Crossed Adduction	❍	❍				
❑	Clonus	❍	❍				
❑	Babinski Sign	❍	❍				

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

HAND HELD DYNAMOMETRY (HHD)

Date Performed: __ __ /__ __/ __ __ __ __

Evaluator's Initials:

Not Tested	Muscle	Check if Not Done	Trial 1 (lbs)	Trial 2 (lbs)	Trial 3 (lbs) (if needed)	Able to Break		Not Done Reason
						Y	N	
	LEFT SHOULDER FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT SHOULDER FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT ELBOW FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT ELBOW FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT ELBOW EXTENSION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT ELBOW EXTENSION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT WRIST EXTENSION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT WRIST EXTENSION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT HIP FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT HIP FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT KNEE FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT KNEE FLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT KNEE EXTENSION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT KNEE EXTENSION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT ANKLE DORSIFLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT ANKLE DORSIFLEXION	❑				❑	❑	❑ Too weak ❑ Other:
	LEFT FIRST DORSAL INTEROSSEOUS	❑				❑	❑	❑ Too weak ❑ Other:
	RIGHT FIRST DORSAL INTEROSSEOUS	❑				❑	❑	❑ Too weak ❑ Other:

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

GRIP STRENGTH TESTING
Date Performed: __ __ / __ __ / __ __
Evaluator's Initials:

Not Tested		Trial 1 (pounds)	Trial 2 (pounds)	If "Not Tested", explain
	LEFT GRIP **Setting:**			○ **Too weak** ○ **Other:**
	RIGHT GRIP **Setting:**			○ **Too weak** ○ **Other:**

Brief Environmental Questionnaire

Geography:

In what city/state do you live? _____

In the time prior to your diagnosis, in what city/state did you live? _____

Toxin Exposure:

Have you used any of the following products more than twice per month for at least 6 months (check all that apply)?

- ☐ Insecticide sprays inside your home
- ☐ Insecticide sprays outside your home
- ☐ Herbicides

Head injury (more than one year prior to symptom onset):

Have you ever been admitted to the hospital for a head injury? ○ Yes ○ No

Have you ever been seen in the ED for a head injury? ○ Yes ○ No

Have you had any concussions? ○ Yes ○ No

If so, how many? _____

Habits:

Have you ever been a smoker? ○ Yes ○ No

Are you an active smoker? ○ Yes ○ No

If so, for how many years? _____

How many packs per day (on average)? _____

How much alcohol do you drink per week, if any? _____ (drinks per week)

In the 10 years prior to your diagnosis, approximately how much alcohol did you drink (on average per week), if any? _____ (drinks per week)

Prior to your symptom onset:

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

How many marathons have you run? _____
How many days per week do you exercise at least moderately (break a sweat)? _____

Military:
Were you in the military? ○ Yes ○ No
How many years? _____
Were you deployed outside the US? _____
If so, what years? _____
To where? _____

Work History:
Which of the following occupations have you had for at least 1 year (check all that apply)?
- ❑ Management Occupations
- ❑ Business and Financial Operations Occupations
- ❑ Computer and Mathematical Occupations
- ❑ Architecture and Engineering Occupations
- ❑ Life, Physical, and Social Science Occupations
- ❑ Community and Social Service Occupations
- ❑ Legal Occupations
- ❑ Education, Training, and Library Occupations
- ❑ Arts, Design, Entertainment, Sports, and Media Occupations
- ❑ Healthcare Practitioners and Technical Occupations
- ❑ Healthcare Support Occupations
- ❑ Protective Service Occupations
- ❑ Food Preparation and Serving Related Occupations
- ❑ Building and Grounds Cleaning and Maintenance Occupations
- ❑ Personal Care and Service Occupations
- ❑ Sales and Related Occupations
- ❑ Office and Administrative Support Occupations
- ❑ Farming, Fishing, and Forestry Occupations
- ❑ Construction and Extraction Occupations
- ❑ Installation, Maintenance, and Repair Occupations
- ❑ Production Occupations
- ❑ Transportation and Material Moving Occupations
- ❑ Military Specific Occupations

Sports History:

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Sport (Circle One)	Level (High School, College, Amateur, Recreational, Professional)	Number of Years
Soccer Football Baseball Hockey (ice/field) Lacrosse Track & Field/Distance Running Swimming Tennis Golf Other:		

PBMC COLLECTION (Cedars)
Instructions: Sites are to follow the Cedars SOP titled "Peripheral Blood Collection and Processing for Reprogramming to iPSCs" or "Peripheral Blood Collection and Processing for Cryopreservation." Please refer to section H of the site MOP for complete collection, processing, and shipping details.
Date Collected: _____ _____ / _____ _____ / _____ _____ _____ _____
Collector's Initials: _____
Number of Tubes Collected: _____
Date Tubes Shipped to Cedars-Sinai: _____ _____ / _____ _____ / _____ _____ _____ _____

DNA – WHOLE BLOOD COLLECTION (NYGC)

Answer ALS

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

Instructions: All samples will be collected in accordance with the policies and guidelines of the site's institution. Please refer to section H of the site MOP for complete collection, processing, and shipping details.
Date Collected: _____ _____ / _____ _____ / _____ _____ _____ _____
Collector's Initials: _____
Time Collected: ____ ____ : ____ ____ (24-Hr Clock)
Number of tubes collected: _____
Date Tubes Shipped to the NYGC: _____ _____ / _____ _____ / _____ _____ _____ _____

DNA – ALIQUOT COLLECTION (MGH Biorepository)
Instructions: All samples will be collected in accordance with the policies and guidelines of the site's institution. Please refer to section H of the site MOP for complete collection, processing, and shipping details.
Date Collected: _____ _____ / _____ _____ / _____ _____ _____ _____
Collector's Initials: _____
Collection Number:
Time Collected: ____ ____ : ____ ____ (24-Hr Clock)
Time of aliquot: ____ ____ : ____ ____ (24-Hr Clock)
Number of 1.0mL aliquots:
Volume of LAST aliquot if less than 1.0mL:
Time aliquots put on dry ice: ____ ____ : ____ ____ (24-Hr Clock)
Time aliquots put in -70ºC or -80ºC freezer: ____ ____ : ____ ____ (24-Hr Clock)

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

PLASMA COLLECTION (MGH Biorepository) **Instructions:** Blood samples will be collected in accordance with the policies and guidelines of the site's institution. Please refer to section H of the site MOP for complete collection, processing, and shipping details.	
Date Plasma Samples Collected: _____ _____ / _____ _____ / _____ _____ _____ _____	
Collector's Initials: _____	
_____ Collection Number: Place Sample Label Here	
Time Collected:	____ ____ : ____ ____ (24-Hr Clock)
Time centrifugation started:	____ ____ : ____ ____ (24-Hr Clock)
Speed of centrifugation:	__1750__ x gravity (g)
Duration of centrifugation:	___10____ minutes
Time aliquoted:	____ ____ : ____ ____ (24-Hr Clock)
Time aliquots put on dry ice:	____ ____ : ____ ____ (24-Hr Clock)
Time aliquots put in -70ºC or -80ºC freezer:	____ ____ : ____ ____ (24-Hr Clock)
Did plasma remain pink after centrifugation, indicating hemolysis?	❍ Yes ❍ No

Number of full (0.5mL) aliquots: _____

Volume of aliquots: **0.5mL**

Volume of LAST aliquot if less than 0.5mL: _____

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

SERUM COLLECTION (MGH Biorepository) **Instructions:** Blood samples will be collected in accordance with the policies and guidelines of the site's institution. Please refer to section H of the site MOP for complete collection, processing, and shipping details.
Date Serum Samples Collected: _____ _____ / _____ _____ / _____ _____ _____ _____
Collector's Initials: _____
Collection Number
Time Collected: ____ ____ : ____ ____ (24-Hr Clock)
Time centrifugation started: : ____ ____ : ____ ____ (24-Hr Clock)
Speed of centrifugation: _1300__ x gravity (g)
Duration of centrifugation: ___10____ minutes
Time aliquoted: ____ ____ : ____ ____ (24-Hr Clock)
Time aliquots put on dry ice: ____ ____ : ____ ____ (24-Hr Clock
Time aliquots put in -70ºC or -80ºC freezer: ____ ____ : ____ ____ (24-Hr Clock
Did serum remain pink after centrifugation, indicating hemolysis? ❍ Yes ❍ No

Number of full (0.5mL) aliquots: _____

Volume of aliquots: **0.5mL**

Volume of LAST aliquot if less than 0.5mL: _____

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

PERMANENT ASSISTED VENTILATION (PAV)
Did the subject reach permanent assisted ventilation (PAV)* during the study? ☐ Yes ☐ No If yes, start date: ___ ___ / ___ ___ / ___ ___ ___ ___ Comments: *Assisted ventilation is defined as permanent when BiPAP or invasive ventilation is used for > 22 hours in a 24 hour period for 7 consecutive days. Date started is the FIRST day of the 7 day period.
NON-INVASIVE VENTILATION (NIVV)
☐ Subject has not used non-invasive ventilation (NIV) during the study period. ☐ Non-invasive ventilation (NIV) use is continuing at the end of the study.

NIV Usage (Hours/Day)	Start Date	Stop Date

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

FEEDING TUBE

Date recommended: ___ ___/___ ___/___ ___ ___ ___

Date accepted: ___ ___/___ ___/___ ___ ___ ___

Admission date: ___ ___/___ ___/___ ___ ___ ___

Discharge date: ___ ___/___ ___/___ ___ ___ ___

Type of Feeding Tube: ○ Nasogastric ○ Gastrostomy

Placement Method:

○ General surgery ○ Interventional radiology

○ Microscopic Laparotomy ○ Percutaneous Endoscopic Gastrostomy

○ Other, specify: _____

Feeding tube was: ○ Prophylactic/Elective ○ Emergent

Morbidity/mortality related to feeding tube:

☐ Aspiration

☐ Death (please complete the Mortality Form)

☐ Excessive Pain

☐ Hemorrhage

☐ Local Infection

☐ Nausea/vomiting

☐ Oxygen desaturation/inadequate ventilation during procedure

☐ Peritonitis

☐ Procedure aborted secondary to anatomy

☐ Other, specify: _____

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

TRACHEOSTOMY

Did the subject require a tracheostomy during the study?

☐ Yes

☐ No

Date recommended: ___ ___/___ ___/___ ___ ___ ___

Date of tracheotomy: ___ ___/___ ___/___ ___ ___ ___

Admission date: ___ ___/___ ___/___ ___ ___ ___

Discharge date: ___ ___/___ ___/___ ___ ___ ___

Reason for tracheotomy:

○ Respiratory Failure

○ Secretion Control

○ Other, specify: _____

DIAPHRAGM PACING SYSTEM (DPS)

Did the subject have a diaphragm pacing system placed during the study?

☐ Yes ☐ No ☐ NA (placed prior to enrollment)

Admission Date: ____ ____/____ ____/____ ____ ____ ____ (MM/DD/YYYY)

Date of Placement: ____ ____/____ ____/____ ____ ____ ____ (MM/DD/YYYY)

Discharge Date: ____ ____/____ ____/____ ____ ____ ____ (MM/DD/YYYY)

Comments:

_____
_____
_____
_____

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U__ __ __ __ __ __ __ __
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

PREGNANCY
(To be completed for female subjects only)

Did the subject become pregnant during the study?: ☐ Yes ☐ No

Date reported:	____ ____/____ ____/____ ____ ____ ____
Start date of last menses:	____ ____/____ ____/____ ____ ____ ____
Date pregnancy confirmed:	____ ____/____ ____/____ ____ ____ ____
Anticipated date of childbirth:	____ ____/____ ____/____ ____ ____ ____

Pregnancy History:

	0	**1**	**2**	**3**	**4**	**5**	**6**	**> 6**
Number of Pregnancies	☐	☐	☐	☐	☐	☐	☐	☐
Number of Normal Deliveries	☐	☐	☐	☐	☐	☐	☐	☐
Spontaneous Miscarriage	☐	☐	☐	☐	☐	☐	☐	☐

Other (please specify):

Pregnancy Outcome:

☐ Not known at this date
☐ Still Birth
☐ Uneventful (normal/healthy baby)
☐ Neonatal death
☐ Induced Abortion
☐ Spontaneous Abortion
☐ Birth defects

Comments:_____

Date of outcome: ___ ___/___ ___/___ ___ ___ ___

Pregnancy reported by (study staff name): _____

Subject Number: _7_ 1_ _3__ - ___ ___ ___	Subject GUID: _N__E__U___ ___ ___ ___ ___ ___ ___ ___
Date: ___ ___/ ___ ___/ _2_ _0_ _1_ _8_	Evaluator Initials: ___ ___ ___
Study Visit: **x** Screening Visit	

SUBJECT FINAL DISPOSITION	
Subject's participation in this study has ended. ☐ Yes ☐ No If **Yes**, please select **one** of the following options:	
☐ Subject was a Screen Failure	Date of Screen Failure: Reason:
☐ Subject died (Please complete Mortality Form)	
☐ Discontinued Participation If Discontinued Participation, Date Last Known Alive: ___ ___ / ___ ___ / ___ ___ ___ ___	
☐ Other (Specify): _____ If Other, Date Last Known Alive: ___ ___ / ___ ___ / ___ ___ ___ ___	

MORTALITY FORM
Did the subject die? ☐ Yes ☐ No
If **Yes**: Date of death: ____ ____/____ ____/____ ____ ____ ____ (MM/DD/YYYY) Cause of death: _____ ICD-10 CM Code for cause of death: _____ Was a general autopsy performed? ☐ Yes ☐ No If **Yes**, Date of Autopsy: ____ ____/____ ____/____ ____ ____ ____ (MM/DD/YYYY) If **YES**, location of autopsy: _____ If **Yes,** has a copy of the autopsy report been obtained? ☐ Yes ☐ No