Dignity Health.
St. Joseph's Hospital and Medical Center

# SUBJECT INFORMED CONSENT FORM

**Protocol No.:** BNI_ALS_001

**Funding:** ALS Finding a Cure®

**Title:** ALS Testing through Home-based Outcome Measures
**ALS AT HOME**

**Investigators:** Jeremy Shefner, MD, PhD
**Address:** St. Joseph's Hospital & Medical Center
Barrow Neurology Clinics
240 West Thomas Road, Suite 400
Phoenix, AZ 85013

**Telephone:** (602) 406-6262 (24-hour #)

**YOU WILL RECEIVE A SIGNED & DATED COPY OF THIS FORM FOR YOUR RECORDS**

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For the purpose of this form, the word "subject" means the individual that will be enrolled in this research study. If you are considering enrollment of an individual who lacks the capacity to consent, you must be the individual's legal representative and will be asked to provide documentation of your legal authority.

## WHY AM I BEING ASKED TO PARTICIPATE IN THIS STUDY?

You have been identified as a possible candidate for participation in the above referenced research study because you have been diagnosed with Amyotrophic Lateral Sclerosis (ALS) or are a healthy control (a person without neurological disorder).

Federal regulations state that no investigator may involve a human being as a subject in research unless the investigator has obtained the informed consent of the subject or the subject's legal representative. Informed consent contains three elements: information, understanding, and voluntariness. Adequate *information* is important to your decision to take part in research (or not). Prior to enrollment, you must *understand* the research, the nature of your participation, and the potential risks and benefits of the study. Finally, an agreement to take part in research is valid only if it is *voluntarily* given.

This document explains the purposes of the research, the procedures to be followed, and the potential risks and benefits of the study. You should read this document very carefully and ask as

many questions as you need to understand what your involvement in the study means. You should not sign the document until you have been given sufficient time to thoughtfully consider your participation in the study.

This research study is funded by ALS Finding a Cure®.

## HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 250 subjects will enroll in this research study through the coordinating center at Barrow Neurological Institute (BNI). Once the target number of subjects have been enrolled, all further enrollment will be closed.

## WHY IS THIS STUDY BEING DONE?

Outcomes measures are extremely important in ALS research. Outcomes measures are used to track disease progression and to determine if experimental treatments are effective. Commonly used outcomes measures in ALS research include breathing tests, muscle strength tests, and a questionnaire to determine function in daily activities.

One problem with outcomes measures is that study participants have to visit the clinical trial study center in order to obtain these measurements. This prevents many potential participants from taking part in a study if they live a great distance from a study center. Furthermore, it becomes increasingly difficult for participants to travel to the study center, and they may be forced to drop out of the study. One way to address these problems would be to provide the training and tools for the study participant to obtain their own measurements at home. This is what ALS AT HOME is designed to do.

This research study is being done to

- see how well ALS patients can take frequent measurements of breathing, muscle strength, activity and function at home,
- determine if the measurements are consistent, and
- compare these measurements with participants getting similar measurements in a research study where the measurements are done at the study site by trained study staff (the Answer ALS Study).

## WHAT IS INVOLVED IN THIS STUDY?

All of the activities for the study will take place at your home. Research study activities and communication will be done by phone, text, secure email, and the ALS AT HOME Study web site.

If you agree to participate, you will be emailed a link to electronically sign this consent form by typing your name. When signing the consent form electronically, you will also be asked to provide the month and day you were born. Your month and day of birth will be checked to ensure it matches the month and day of birth you used to sign up for the informed consent webinar. Once you have electronically signed this consent form, you will then be contacted by the Study Liaison to generate a globally unique identifier (GUID) and a Participant ID number. Only participants diagnosed with ALS will have a GUID generated. If you have acquired a GUID from NeuroBANK™ previously, this number will be used.

The Participant ID number will be your primary ID number for this study. You will be able to log on to the ALS AT HOME website using your Participant ID number and a personal password that will be given to you. After signing consent and obtaining a GUID, you will complete a demographic questionnaire. The demographic questionnaire will ask you about items such as your date of birth, gender, race, ethnic group, education, and ALS history (if applicable).

The study investigators wish to enroll participants with a wide range of demographics, (for example: location, ethnicity and education,) and will select participants based on the information provided in the demographic questionnaire from the pool of potential participants on a monthly basis. If selected, you will be re-contacted and asked to confirm that you are still interested in being part of the research study.

**Global Unique Identifier (GUID):** As part of your participation in the study, a unique subject number, called a "global unique identifier" (GUID) will be assigned to you that will allow researchers to see if you have been involved in more than one research study. If you have participated in more than one study or database, this unique subject number will help connect information across studies. This subject number will also allow your data to be combined with data from other research studies to increase the likelihood of meaningful analysis. This unique subject number can be shared with other investigators when your data is shared and may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you. However, because the GUID is generated randomly by a computer, anyone unfamiliar with your unique identifier will not be able to identify you by GUID alone.

## Study Procedures

If you are selected for the study, study equipment will be shipped directly to your home. You will receive the following four (4) devices:

- Respirometer: a device to measure your breathing function,
- Digital hand grip meter: a device to measure the strength of your hand grip,
- Skulpt Chisel: a device to measure your body fat and muscle quality, and
- Activity Band: a device that you wear on your wrist to measure and track movement.

In addition to these assessments, we will also be tracking your voice and speech. This will be done by having you speak into your smart phone. You will receive initial training on how to use each of the measurement devices and how to report your measurements via training videos accompanied by an instruction manual. The Study Liaison will be available to assist you with any questions you may have during training. After this initial training, you will take a test on-line. The test will have multiple choice questions about how to use the devices and how to report your measurements. Based on your test results, you may be asked to review the materials again, or you may receive extra one-on-one training from the Study Liaison via WebEx or phone and be asked to take the test again. At any time during the research study, you may view training videos and other helpful resources on the ALS AT HOME Study web site. The Study Liaison is also available to you for any questions or help you might need.

After receiving training and passing the test, you will begin collecting your own measurements. You will use your Participant ID and personal password to securely report your measurements on the ALS AT HOME study web site. You will collect and report your measurements using the devices or your smart phone EVERY DAY for the first three (3) months of the study. This will take approximately 45 minutes per day. We estimate that using the respirometer, speech tracking app, and dynamometer will take about 15 minutes in total with an additional 5 minutes to enter your measurements on the study web site. Using the Skulpt Chisel will take up to 25 minutes per day. The Activity Band will collect measurements for you when you wear it. The data collected by the Skulpt Chisel, Respirometer, and Activity Band will automatically be uploaded from a smartphone app to ALS AT HOME study web site. The study research team will assist you in setting this up.

Once a week, you will complete a questionnaire on the ALS AT HOME study web site called the Amyotrophic Lateral Sclerosis Functional Rating Scale - Revised (ALSFRS-R). The ALSFRS-R asks 12 questions about your ability to function in certain daily activities. Although we hope you will answer all questions, you can skip any questions that you do not want to answer. This questionnaire will take about 5 to 10 minutes to answer.

Once a month, you will complete a questionnaire on the ALS AT HOME study web site asking about adverse events you might have experienced from the study assessments.

After 3 months, you will begin taking and reporting measurements twice a week. You will continue to complete the ALSFRS-R once per week and complete the adverse events questionnaire monthly.

In addition, you will be asked to complete questionnaires called the Patient-Reported Experience Measures (PREMs). The PREMS will be completed on the study web site after one week, 3 months, 6 months, and 9 months or whenever you decide to withdraw from the study. The PREMS will take 5 to 10 minutes to complete on-line. It will ask you and/or your caregiver

about your perceptions of this research study. The questions will ask you, for example, about your experiences, comfort, and confidence in using the devices to take measurements.

If the study researchers do not receive your measurements, you will receive gentle reminders such as text messages, emails, and/or phone calls from the Study Liaison.

At the end of the study, you will keep all of the equipment provided during this study.

## HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this research study, your involvement will be for a total of 9 months.

You may stop taking part in this study at any time. If you stop taking part in the study, you will be asked to complete Patient-Reported Experience Measures (PREMs).

## WHAT ARE THE RISKS OF THIS STUDY?

The known risks and discomforts of this research study are listed below.

You may find it uncomfortable or upsetting to continuously perform these evaluations as you will likely have more difficulty taking the measurements over the weeks and months of the research study.

You and/or your caregiver(s) may find it upsetting to continue to take the measures since you will likely see worsening values over the course of the research study.

**ALSFRS-R:** The daily activity questionnaire (ALSFRS-R) may cause you to feel sad or upset about how ALS has changed how well you can perform daily activities, and how it has affected your quality of life. Although it is best for the study if you answer all of the questions, you may skip over any questions or entries that you do not wish to answer.

**Respirometer:** The risks and discomforts associated with testing of breathing function include feeling tired, light-headed, or short of breath. These symptoms will disappear with rest.

**Digital hand grip meter:** Strength testing can be fatiguing and can make your muscles feel sore, especially if you are already feeling weak.

**SKULPT Chisel**: This device uses electrical impedence myography. Electrical impedance methods have been used for various assessments of the human body for decades, and there is no known safety risk to the low levels of electrical current utilized here.

**Activity Band**: There are no known risks associated with this activity-tracking device.

**Voice/Speech Tracking:** The risks and discomforts associated with speech tracking include fatigue from the effort of speaking. This symptom will disappear with rest.

**OTHER RISKS**

Reviewing health related information might be stressful or make you feel uncomfortable. You do not have to answer any questions you do not want to, and you may stop the interview at any time if it is too uncomfortable.

**ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?**

You will not benefit directly by taking part in this research study. Knowledge gained from the study may benefit others in the future. Your participation may contribute valuable data to ALS research.

**WHAT OTHER OPTIONS ARE THERE?**

This is not a treatment study. Therefore, the alternative to taking part in the study is to not take part.

**HOW WILL I BE INFORMED OF ADDITIONAL INFORMATION OR NEW FINDINGS?**

The investigator will inform you of any significant new findings developed during the course of this study that may affect your continued willingness to take part in the study. This may include changes in the procedures or the potential risks or benefits.

**WHAT ABOUT CONFIDENTIALITY?**

Representatives from the Sponsor, St. Joseph's Hospital & Medical Center, and regulatory authorities in the United States (such as the U.S. Department of Health and Human Services [DHHS] and the U.S. Food and Drug Administration [FDA]) and other countries may inspect your medical and research records to check the progress of this study or to analyze study data. Additionally, the Institutional Review Board for Human Research (IRB) at St. Joseph's Hospital & Medical Center may inspect your medical and research records.

Although absolute confidentiality cannot be guaranteed, strict security will be in place to ensure that your information is kept private when it is shared with the persons or parties listed above. You will obtain a Participant ID number in addition to a GUID number via NeuroBANK$^{TM,}$ and these numbers, rather than your name or other direct identifiers, will be used to collect, store, and

report your information. However, in some cases it will not be possible for the investigator to withhold your identifying information. For example, a regulatory authority may require your name or date of birth.

The results of this research study may be published in scientific journals and/or may be presented at scientific meetings, but your identity will not be revealed.

## WHAT ARE THE COSTS?

There is no cost to you for participating in the study.

## IS THERE COMPENSATION FOR PARTICIPATING?

You will not be compensated (paid) for taking part in this study. You will keep all of the equipment provided at the end of the study.

## WHAT HAPPENS IF I AM INJURED WHILE PARTICIPATING IN THIS STUDY?

If you believe that you have suffered a research-related injury, notify Dr. Shefner at (602) 406-6262 immediately. St. Joseph's Hospital & Medical Center and/or the investigator will make available or arrange for appropriate care and treatment as needed. All related charges will, however, be billed to you or your insurance.

The investigator or St. Joseph's Hospital & Medical Center will not provide compensation (such as lost wages, lost time, or discomfort) to subjects who are injured as a result of participation in this study. This, however, does not waive your rights in the event of negligence.

## WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Taking part in this research study is voluntary, and refusal to take part will involve no penalty or loss of benefits to which you are otherwise entitled. You may stop taking part in the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, you must immediately notify the investigator of your decision in writing. Any data collected from you before the time of your withdrawal will remain the property of the Sponsor.

The investigator, the Sponsor, or regulatory authorities may stop your participation in this study at any time without regard to your consent. Some reasons your participation may be stopped are:

- if you do not follow the instructions of the investigator,
- if the investigator decides it is in the best interest of your health and welfare,
- if the study is stopped, and/or
- if other administrative reasons are cited.

## WHOM DO I CALL IF I HAVE QUESTIONS?

If you have any questions about this research study or your participation in it, please feel free to ask the questions now. If you think of questions later or have concerns about your participation, please call Dr. Jeremy Shefner, MD at (602) 406-6262 (24 hour #), or write to St. Joseph's Hospital & Medical Center, Barrow Neurology Clinics, 240 W. Thomas Rd., Ste. 400., Phoenix, AZ 85013.

If you have any questions about your rights as a research subject or about the Institutional Review Board for Human Research (IRB) at St. Joseph's Hospital & Medical Center which reviewed this Informed Consent document for compliance with federal guidelines, please call the IRB at (602) 406-3195 or write to: IRB Coordinator, Department of Research Administration, St. Joseph's Hospital & Medical Center, 350 W. Thomas Rd., Phoenix, AZ 85013.

## STATEMENT OF CONSENT

By typing in your name below, you are signing this electronic informed consent form. This electronic signature indicates that you understand what your involvement in this study means, and you are voluntarily agreeing to participate. You will receive copy of this form for your records.

## EXPERIMENTAL SUBJECTS
## BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Any person who is requested to consent to participate as a participant in a research study involving a medical experiment, or who is requested to consent on the behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment;

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;

3. Be given a description of any attendant discomforts and risks reasonably to be expected from your participation in the experiment;

4. Be given an explanation of any benefits reasonably to be expected from your participation in the experiment;

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to you, and their relative risks and benefits;

6. Be informed of the avenues of medical treatment, if any, available to you after the experimental procedure if complications should arise;

7. Be given an opportunity to ask any questions concerning the medical experiment or the procedures involved;

8. Be instructed that consent to participate in the experimental procedure may be withdrawn at any time and that you may discontinue participation in the medical experiment without prejudice;

9. Be given a copy of this form and the signed and dated written consent form;

10. Be given the opportunity to decide to consent or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on your decision.