NEALS Northeast Amyotrophic Lateral Sclerosis Consortium

Subject Identification

Template Model ICF
Version Date: April 2015

Protocol Title:

Principal Investigator:

Site Principal Investigator:

NEALS study site:

Description of Subject Population:

INSTRUCTIONS: Many sections of this document include brief instructions to provide the user with a general overview of information required in the section. The instructions are shaded so that you can tell the difference between the instructions and required information. Some sections are password protected and cannot be edited.
Please delete all shaded instruction boxes prior to submitting this form to the NEALS Central Institutional Review Board (CIRB) for review. To delete, select a shaded box and click the cut button on the Word toolbar.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

[Name of site] is **[description of site]**. We are doing this research as part of the Northeast ALS (NEALS) Consortium.

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

Comment [PHS IS1]: Study specific info will be provided by the sponsor

The study will be conducted in about **x** sites around the United States. About **[insert number]** subjects will take part in the study at **[insert site name]**.

[Place any Conflict of Interest disclosures mandated by your institution or the Central IRB here.]

How long will I take part in this research study?

Comment [PHS IS2]: Study specific info will be provided by the sponsor

What will happen in this research study?

Comment [PHS IS3]: Study specific info will be provided by the sponsor

What are the risks and possible discomforts from being in this research study?

Comment [PHS IS4]: Study specific info will be provided by the sponsor

What are the possible benefits from being in this research study?

Comment [PHS IS5]: Study specific info will be provided by the sponsor

What other treatments or procedures are available for my condition?

Comment [PHS IS6]: Study specific info will be provided by the sponsor

Can I still get medical care within [NEALS site] if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within [NEALS site] now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

Comment [PHS IS7]: Study specific info will be provided by the sponsor

What will I have to pay for if I take part in this research study?

Comment [PHS IS8]: This info will be provided by the sponsor.

You may add further language to describe specific items/services/amounts that will be the subject's responsibility, but you may not delete any portion of the standard language.

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs."

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you

may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

Insert any site-specific injury statement or compensation here.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[Insert name and academic degrees] is the person in charge of this research study. You can call him/her at [Insert phone number] [insert when person is available M-F 9-5 or 24/7]. You can also call [Insert name(s)] at [Insert phone number(s)] [insert when each person is available M-F 9-5 or 24/7] with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call [Insert name(s)] at [Insert phone number(s)].

If you want to speak with someone **not** directly involved in this research study, please contact the NEALS Central IRB. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

INSTRUCTIONS: Below is HIPAA authorization language. Sites can use this language, or use their own language, or a separate authorization form.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Research staff involved in this study
- Non-research staff within the institution who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this NEALS clinical study and their ethics boards
- Other researchers and medical centers that are not part of this NEALS clinical study but are part of the NEALS consortium
- Partners HealthCare System, Inc. ("Partners"), Brigham and Women's Hospital and Massachusetts General Hospital ("MGH") and their ethics boards (the NEALS Central IRB)
- MGH (the NEALS Coordinating Center and Data Coordinating Center)
- A group that oversees the data (study information) and safety of this research
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers

- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney

☐ Family Member/Next-of-Kin

Signature _____ Date _____ Time (optional) _____

Relationship to Subject:_____

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent _____ Date _____ Time (optional) _____