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Patient Consent – Part 2

CONSENT FOR RESEARCH
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Remote pulmonary function testing in amyotrophic lateral sclerosis (ALS)

Principal Investigator: Andrew Geronimo, PhD

Address: Penn State Hershey Medical Center, Department of Neurosurgery, Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-0003 x289123/
After hours call (717) 531-8521. Ask for the neurology doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

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

1. Why is this research study being done?

We are asking you to be in this research because you are a patient diagnosed with ALS.

This research is being done to determine the benefits of weekly breathing monitoring and nurse health coaching using the Hershey ALS Clinic telemedicine interface. Participants will be trained in the self-administration of two breathing tests. These remote breathing tests will occur weekly between regular clinic visits over the course of one year.

Approximately 60 pairs of patients and caregivers will take part in this research study at the Hershey Medical Center and surrounding region. You may be enrolled in the study without a caregiver if the investigator judges that you have the capacity to perform home PFTs unassisted.

2. What will happen in this research study?

Over the course of approximately one year, you will complete 5 study sessions occurring on the dates of ALS clinic appointments. Study sessions may be held in-person or via telehealth. On the day of the first session, a member of the research team will explain the study procedures to you and collect demographic and clinical information. The researcher will guide you through the completion of three forms:

- **Respiratory Health Questionnaire**, completed monthly, has you rate your quality of life, breathing symptoms, and quality of sleep. Questionnaires completed outside of study sessions will be administered a survey delivered via email.
- **Self-Efficacy Assessment**, completed during study sessions, has you rate your ability to manage your own symptoms, navigate social interactions, and manage medications and treatments.
- **ALS-Specific Quality of Life - Brief Form**, completed during study sessions, contains 20 questions in 5 domains encompassing quality of life. If completed as part of clinic procedures, this data may be accessed from your chart.

In addition to standard pulmonary function tests (PFTs) that occur as part of ALS clinic visits, you will have the additional task of completing approximately 47 weekly sessions of remote pulmonary function testing (rPFT) over the course of a year. You will receive a kit that contains: 1) spirometer and disposable turbines (used to measure forced vital capacity - FVC), 2) pressure meter and disposable mouthpieces (used to measure maximal inspiratory pressure - MIP), 3) face mask (if necessary), 4) nose clips (if necessary), and 5) instructions for kit setup and use. This kit will have enough supplies to perform the required assessments over the course of one year. If you do not have a device suitable for videoconferencing (a computer/laptop with a webcam) or a smartphone for downloading and using the spirometer application, you may be loaned a device for the duration of the study. You will email the results of the tests within the smartphone application.

For the first four weekly rPFTs (the training period), you will engage in a telemedicine videoconference with a member of the research team at the Hershey ALS clinic and record three valid measurements of FVC and MIP. During these assessments, the researcher will guide you through the procedures and make note of your ability to complete these assessments on your own. If by the fourth week of training, the researcher judges your ability to self-administer the rPFT to be adequate, you will be randomized into one of two arms at a ratio of 1:1. This means you are equally likely to be assigned to either group, and the research team has no control over that assignment. If the researcher determines self-administration is not feasible or accurate, study procedures will be ended. Refer to Figure 1 for a timeline of events.

rPFT arm: Subjects will continue to self-administer rPFTs every week until the 5th and final study session. A research team member will schedule rPFT training appointments at weeks 8 and 12 in order to confirm you are completing study assessments appropriately. rPFT procedures are not performed during weeks in which a study session occurs.

rPFT + Nurse Respiratory Health Coaching (NRHC) arm: In addition to the rPFT schedule described above, patients and caregivers randomized to the NRHC arm will begin monthly coaching sessions with an ALS nurse, with the first session scheduled as close as possible to the randomization date (week 4). These coaching sessions will take place over a videoconferencing interface and will last up to 30 minutes. A link to each videoconference will be sent via email. Coaching sessions will involve discussion of patient-driven goals for respiratory management, review of PFT results and answers to the respiratory questionnaire, identification of options and alternative strategies to meet goals, and a plan for implementation. Audio recordings of coaching sessions may be performed in order to assess the quality and consistency of the coaching protocol. Coaching sessions will end at the completion of the 5th study session, with approximately 12 coaching sessions total. Those randomized to the coaching arm also receive brief (15-30 minute) coaching checkups from another

nurse on the study team who is not the coach, during which you will be asked to reflect on the coaching process. These will occur during the 4th and 8th months after randomization, and at study exit. Coaching checkups will be by phone or via Penn State Health Zoom videoconferencing. Audio of these sessions may be recorded.

You may be enrolled without a caregiver available if the investigator determines that you are able to perform the home breathing tests without additional assistance. Your ability to perform these tests solo will be reviewed at least as often as each clinic visit. If you are no longer able to perform the home tests without additional assistance, a caregiver must be enrolled aid home PFT administration, or you will be exited from the rPFT portion of the study.

If during the course of the study you record an FVC or MIP value warranting intervention, the researcher will forward the test report to the ALS clinical team, including nurse, respiratory therapist, and neurologist. If the decision is made by the clinical team to initiate non-invasive breathing support (NIV), the ALS clinic physician will provide an order, and the ALS clinic nurse will arrange for initiation of in-home NIV via a third-party vendor according to usual standards of care. At the initiation of NIV, you will stop rPFT procedures and return the study equipment. The remaining procedures continue through the end of the study period. You can also opt to end the study at any time. Non-compliance with study procedures is defined as 30 days without submission of a breathing test if you are still eligible to report them, or 3 months without a nurse coaching session if you are in the nurse coaching arm.

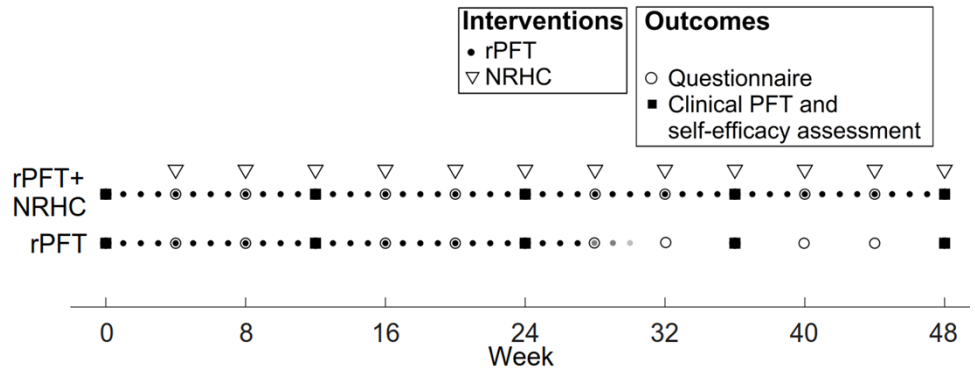

Figure 1: Timeline of study events. Randomization occurs around week 4. Square boxes denote approximate timing of study sessions.

Post-study focus group: Following completion of study procedures, you may be asked to participate in a focus group, where study participants will reflect on their experiences in the study regarding the use of technology, nurse coaching, and any behavioral changes observed. Focus groups will be conducted at the location of the Hershey ALS Clinic, with teleconferencing available. Audio recordings of the focus groups will be captured.

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

The risks associated with this study are the discomfort or fatigue associated with completing the tests for breathing function. A member of the research team will train you in the process of administering these tests so that discomfort may be avoided.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

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

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include the proactive initiation of breathing support for your ALS.

4b. What are the possible benefits to others?

The results of this study may guide the future development of tools for our ALS telemedicine program so that we may better serve patients who are unable to attend clinic.

5. What other options are available instead of being in this research study?

You may choose not to be in this research study.

6. How long will I take part in this research study?

If you agree to take part, it will take you about 12 months to complete this research study.

In addition to regular clinic activities, you will devote 19-26.5 hours of time to the procedures in this study.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include these identifiers: name, gender, date of birth, race, ethnicity, mailing address, telephone number, email address, medical record numbers, voice recordings, and study code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Geronimo's office.
- Your research records will be labeled with a unique REDCap code and will be kept in a safe area in Dr. Geronimo's research office.
- Results of some of the research-related tests (including but not limited to ALS-Functional Rating Scale, FVC, and MIP) will be kept in your HMC medical record.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. 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. We will use and disclose your information only as described in this form and in the HMC Privacy Notice.

The research team may use the following health information:

- Past, present, and future medical records
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- HMC/PSU research staff involved in this study
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office
- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- Organizations that provide independent accreditation and oversight of hospitals and research
- NuvoAir, the company who supplies the FVC equipment and online data portal for this study
- The sponsor of this study

These groups may also review and/or copy your original PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to 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 using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and 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. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?
There is no cost to you for participating in this study.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?
It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment.

HMC/PSU compensation for injury

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

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

The participant team (patient and caregiver together) will receive $10 per month for your participation in this research study for a total of $120. If you do not complete the study for any reason, you will be paid for the visits you have completed. The payment will be provided by Greenphire Clincard.

This reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.

When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, date of birth and Social Security Number.

You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your Mobile Phone Number and/or E-mail Address.

10. Who is paying for this research study?

The Penn State College of Medicine, the ALS Association, and gift funds for Dr. Simmons are paying for this study.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

Your research doctor may take you out of the research study without your permission.

- Some possible reasons for this are: continuing the research would be harmful, your condition has become worse, you did not follow the instructions of the study doctor, you experience serious side effects.
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Geronimo, at 717-531-0003 x289123 or the neurology doctor on 24-hour call at 717-531-8521 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and

- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

Subject's Legally Authorized Representative

By signing below, you indicate that you give permission for the subject to be in this research and agree to allow his/her information to be used and shared as described above.

_____	_____	_____	_____
Signature of Legally Authorized Representative	Date	Time	Printed Name

Check the applicable box below indicating authority to act for subject:

☐ Court-appointed legal guardian
☐ Health Care Power of Attorney
☐ Health Care Representative: _____
Relationship to Subject

Witness to Consent of Subjects Who Cannot Read or Write

Witness Statement: Your signature indicates that you were present during the informed consent discussion of this research for the above named subject, that the information in the consent form and any other written information was presented orally to the subject or subject representative, that the subject or subject representative was given the opportunity to ask questions, that the informed consent decision was freely made by the subject or subject representative who indicated consent and authorization for participation by (check the box as applicable):

☐ Making a mark
☐ Other means: _____
(fill in above)

_____	_____	_____	_____
Witness Signature	Date	Time	Printed Name