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Patient Consent – Part 1

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

Title of Project: The reliability of remote pulmonary function testing, performed via telemedicine, for monitoring respiratory function in patients with 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, PLS, or PMA.

This research is being done to evaluate the use of a guided assessment of breathing function. Participants will communicate through the telemedicine interface with a respiratory therapist of the Hershey ALS clinic, who will guide the administration of two pulmonary function tests.

Approximately 40 pairs of patients and caregivers will take part in this research study at the Hershey Medical Center and surrounding region. Approximately two respiratory therapists will also take part.

2. What will happen in this research study?

You and your caregiver (the participant team) will be situated in a research room in the Hershey ALS clinic just before or after your regular clinic appointment. You will use the telemedicine computer to videoconference with the respiratory therapist in another room. With guidance from the therapist, you will utilize two breathing assessment devices in order to acquire three valid measurements of forced vital capacity (FVC) and maximal inspiratory pressure (MIP).

Following the guided assessment of breathing function, you will report the results to the therapist and complete an online survey of your experience with the simulated home breathing assessment. For this survey, you are encouraged to answer as thoroughly as possible, but are free to skip any questions that you would prefer not to answer.

This procedure will be done in addition to the standard assessment of pulmonary function completed as part of regular clinical practice.

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

You may experience discomfort or fatigue while completing the tests for breathing function. We have a licensed respiratory therapist who will guide you through 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?

You will not benefit from this research study.

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 45 minutes to complete this research study. You will not be required to return to the research site for additional visits.

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, mailing address, date of birth, telephone number, email address, medical record number, 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 code and will be kept in a safe area Dr. Geronimo's research office.

- Results of some of the research-related tests (including but not limited to ALS – Functional Rating Scale, Forced Vital Capacity, and Maximal Inspiratory Pressure) 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

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.

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.

<u>HMC/PSU compensation for injury</u>

- 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?

You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?

This study is being funded by the National Institutes of Health as part of an institutional award to The Penn State College of Medicine.

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.

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 x 289123 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