

UNIVERSITY OF PENNSYLVANIA

RESEARCH PARTICIPANT

INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: Mechanical Insufflation in the Philadelphia Amyotrophic Lateral Sclerosis Cohort (MI-PALS) Study Protocol

Principal Investigator: Jason Ackrivo, MD, MSCE
330 S. 9th Street
Room 310
Philadelphia, PA 19107
215-829-6529

Emergency Contact: Pulmonary Attending on call
215-662-4000

Research Study Summary for Potential Participants

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to test if using a mechanical insufflator-exsufflator (MI-E, also known as a “cough assist device”) in early ALS helps with breathing function.

If you agree to join the study, you will be asked to complete the following research procedures: training and daily use of a cough assist device, medical history, physical exam, vital signs, spirometry, peak cough flow, and other breathing tests.

Your participation will last for approximately 6 months. We may collect information from your medical chart or by telephone for up to 6 months after completing participation.

There is no direct benefit of your participation. We will provide compensation of \$50 for each study visit up to a maximum of \$200. However, the knowledge gained from your participation will be used to inform the general ALS community and future research studies.

The most common risks associated with cough assist use is chest wall discomfort, dizziness, or drop in blood pressure. However, risks of participation are expected to be minimized as we are using the cough assist device within its intended FDA-approved purpose. We also exclude certain medical conditions to lessen risks of cough assist use.

The alternatives to participation are not to participate. Refusing to participate will not impact your ALS clinical care.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because:

- x You have been told that you have a diagnosis of amyotrophic lateral sclerosis (ALS) and you are not yet on any respiratory treatments.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The main purpose of this study is to determine if regular use of a cough assist device in early ALS can slow the decline or even improve breathing function. The cough assist device is an FDA-approved device and this study involves using it for its intended purpose.

How long will I be in the study?

If you are eligible, the study will last for approximately 6 months.

This research study will be performed at the University of Pennsylvania ALS clinic with up to 25 people. Men and women aged 18 or older with ALS who are not yet on respiratory treatments will be included in this study.

We will enroll up to 25 people over 18 months at the University of Pennsylvania.

What am I being asked to do?

Before you can start the study, the study doctor or study staff will talk to you about the study. If you agree to participate in this study, you have to sign this form before the study doctor or study staff can do any procedures.

It is important for you to know that it is not necessary for you to change your current treatment prescribed by your doctor.

After you sign this form, the study doctor or study staff will do the tests and procedures listed below. Some of these tests, including questionnaires, vital signs, spirometry, and physical exam are considered the “standard of care” for patients with ALS. That means that these tests will be required even if you decide not to participate in this study. As part of this research study, we will get results and information from these tests from your medical record.

Some of the measurements and questionnaires will only be collected if you participate in this study. The study-related measurements include peak cough flow, maximal insufflation capacity, and maximal inspiratory pressure. The study-related questionnaires include the ALS Specific Quality of Life and global rate of change for peak cough flow.

You will be asked to come to the clinic for your regularly scheduled clinical visits. These tests and procedures will take approximately 1 hour of your time for each visit. A description of each procedure is provided below. You will be asked to not exercise or smoke before you come to the visit.

Clinical Visit

- x **Health and Medication Questions:** You will be asked about your health, your medical and surgical history, and the medications you take. You will be asked about your physical activity.
- x **Demographics (first visit only):** You will be asked about your age, gender, race, and ethnicity.
- x **Personal History (first visit only):** You will be asked questions about your lifestyle and background (such as education, smoking, insurance coverage, etc.).
- x **Contact information (at time of consent/first visit only):** You will complete the Contact Information Form which includes your contact information as well as the name and two phone numbers of relatives and/or friends that are willing to be contacted about the status of your health if we cannot reach you. You will also be asked to provide your primary care physician information.
- x **Physical Exam:** The study doctor will complete a physical exam. He/she will listen to your heart and lungs, and perform a complete neurologic exam.
- x **Blood Pressure and Heart Rate:** Your blood pressure will be checked by putting a band around your arm. This will squeeze your arm for about a minute. Your heart rate will be checked (how fast your heart is beating).
- x **Body Height and Weight:** Your height will be measured to see how tall you are and you will be weighed.
- x **Date of symptom onset (first visit only):** Your doctor will ask the approximate month and year that you first began to notice new neurological symptoms (for example, weakness or a fall).

- x **Site of symptom onset (first visit only):** Based on history and physical exam, your doctor will determine an approximate location in your body where your symptoms began.
- x **Spirometry:** A test that measures how much air you can inhale and exhale. You will be asked to take a deep breath and breathe out as hard as you can for several seconds into a tube that's attached to a machine. You will be asked to do this three (3) times to make sure the results are accurate. You will be asked to do this in an upright (sitting or standing) as well as lying down on your back.
- x **Peak cough flow:** A test that measures how forcefully you can cough. This test is measure with a small, lightweight, hand held device known as a "peak flow meter", which is attached to a disposable mouthpiece. You will be asked to take a deep breath and cough into the peak flow device as hard as you can. You will be asked to perform the maneuver in an upright (sitting or standing) position. We will record the highest value of three repeated attempts.
- x **Maximal insufflation capacity:** A test that measures how much air you can breathe out after your chest is inflated as much as possible using the cough assist device. After using the cough assist device to inflate your lungs with as much air as possible, research staff will have you exhale into a spirometer. We will record the highest value of three repeated attempts.
- x **Maximal insufflation capacity assisted peak cough flow:** Similar to maximal insufflation capacity above, except instead of breathing out into the spirometer you will be asked to cough as forcefully as possible into a peak flow meter. We will record the highest value of three repeated attempts.
- x **Maximal inspiratory pressure:** This is a breathing test that measures how strongly you can breathe in as forcefully as possible. We will use a hand-held device (a manometer) connected to a mouthpiece or mask. The test involves you first exhaling fully and then inhaling as forcefully as possible.
- x **Maximal expiratory pressure:** This is a breathing test that measures how strongly you can breathe out as forcefully as possible. We will use a hand-held device (a manometer) connected to a mouthpiece or mask. The test involves you first inhaling fully and then exhaling as forcefully as possible.
- x **Transcutaneous carbon dioxide and oxygen value:** These will be measured using a Sentec transcutaneous monitoring system. Use of this monitor is standard of care in the University of Pennsylvania ALS clinic. The monitor has a transcutaneous sensor that will be placed on your forehead, cheek, or earlobe. The sensor rests on your skin for a 15 minute recording. At the end of the recording the monitor will read an average carbon dioxide and oxygen value.
- x **ALS Functional Rating Scale – Revised Score:** Based on interview questions, your doctor or Research Coordinator will determine your strength to perform various tasks in 12 categories: eating by mouth or gastrostomy tube, speaking, swallowing, saliva control, developing shortness of breath, breathing while lying flat, rolling over in bed, walking, handwriting, and dressing.
- x **ALS Quality of Life Questionnaire – Short Form:** This is a for with 21 questions asking about your life over the last 7 days. It will ask you to rate various aspects of your life on a scale of 0 – 10. This form will be given to you to complete. A caregiver may help you answer the questions, if necessary. After completing the form you can return the form back to the research coordinator.

- x **Medical Record Review:** Information and results from the following will be collected from your medical records:
 - x Any of the above mentioned information from your clinical visit can be extracted from your medical record review, as necessary:
 - ☐ Contact information
 - ☐ Medical history
 - ☐ Physical exam and vital signs
 - ☐ Clinical tests, such as spirometry, peak cough flow, ALS Functional Rating Scale – Revised Score, carbon dioxide, etc.
 - x Blood tests
 - x Imaging (such as X-rays, CT scans, MRIs, etc)
 - x Electromyograph (EMG) - a test that measures your muscle reaction to minor electrical activity.
- x **Respiratory insufficiency criteria:** Your doctor will assess if you meet any one of the criteria which identify severe breathing complications of ALS: forced vital capacity from spirometry less than 50% of predicted normal; use of non-invasive ventilation (a machine attached to a tube and mask which delivers pressure to help you breathe); or tracheostomy placement.
- x **Cough assist device usage using ARC Connect:** This is an app that can be downloaded onto your smartphone which collects usage data from the cough assist device assigned to you. The reports will include the following related to device use: date/time of use, number of inhalation cycles, number of sets of inhalation cycles, and pressure used. You will be asked to bring in your smartphone with the ARC Connect app for data review at every visit.

The medical team and research staff will schedule clinical follow-up visits with you approximately every 3 months. We will continue to collect data at each study visit for up to 12 months. Follow-up appointments are activities necessary as part of routine ALS care.

Time permitting, research staff may call you within a few days before or after your visit to collect any information missing from the above list.

If you are unable to make an appointment, the research or clinic staff will call you to reschedule your appointment. If we are unable to reach you, we may have to call one of your designated alternative contacts (such as a friend or family member) to assist with rescheduling your appointment.

What are the possible risks or discomforts?

Some possible harmful risks that may be associated with participation in this study are specifically disclosed below; however, there may be additional harmful consequences that are not discussed below or not yet known.

Risks of performing maximal insufflation with a mechanical insufflator-exsufflator (MI-E, also known as a cough assist device): The most serious complication from using an MI-E device for applying positive pressure using to the lungs includes

pneumothorax, or collapsing of a lung. The chance of this occurring is felt to be extremely low, as the use of a cough assist device is widespread across the world in both the inpatient and outpatient setting, and the medical literature has very few descriptions of cases of pneumothorax. In many of the described cases, patients had a medical condition that increased the chance of pneumothorax (such as chronic obstructive pulmonary disease). Additional potential risks include: chest wall discomfort or soreness during insufflation; increasing the amount of air entering the chest can slow down blood flow to the heart and therefore may cause a brief drop in blood pressure or light-headedness; the long-term risks of mechanical insufflation of the chest are unknown. It is estimated that most of the risks are associated with device performance, and thus most risks would occur almost immediately. We hope to minimize risk by excluding patients who have a history of a medical condition (such as COPD) that may increase the risk of cough assist use.

Spirometry risks: Spirometry is part of routine clinical care for ALS, so you will be asked to perform spirometry regardless of your participation in the study. The spirometry test is very similar to peak cough flow, and therefore it has similar risks as described below under “Peak cough flow risks”.

Peak cough flow risks: Coughing as forcefully as possible may cause lightheadedness or mild soreness in your chest. There is a very small risk of collapsing a lung if you have a severe form of emphysema that causes large bullae (large air pockets) in your lungs. There is a risk of brief increase in pressure in your chest, abdomen, face, or eyes. There is a risk of mouth, face, or tooth pain if using a mask or mouthpiece would cause you pain. The test should also be avoided if you have any of the following: history of severe chronic obstructive pulmonary disease (COPD); you have a collapsed lung; coughing up blood; an aortic aneurysm in your chest, recent heart attack in the previous month; surgery on your chest, abdomen, face, or eyes in the previous 6 weeks; or use of a face mask or mouthpiece would cause you pain.

Risks associated with loss of confidentiality: Every effort will be made to protect your health information, including information that we collect from your medical records. However, there is also a small risk of loss of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn’t happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by keeping your information on a password-protected health system computer hosted at the University of Pennsylvania.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

Given that performing mechanical insufflation with a cough assist device is an exercise in inflating the lungs, the possible benefits include:

- x Opening areas of your lungs that are under-inflated due to weakened breathing (this may improve carbon dioxide and oxygen levels)
- x Improve range of motion of the chest wall (similar to how physical therapy improves joint range of motion)
- x Reducing stiffness of the chest wall over time

Specifically in ALS, prior research has shown that volume recruitment of the lungs through techniques such as mechanical insufflation has shown brief improvements in spirometry, peak cough flow, and ability to inflate the lungs.

In alternative neuromuscular diseases (such as Duchenne muscular dystrophy), volume recruitment, similar to mechanical insufflation, is believed to slow decline of breathing function over time and maintain coughing strength.

What other choices do I have if I do not participate?

If you decide not to participate in this study, it will not change the regular medical care you receive from your doctor.

Will I be paid for being in this study?

You will be reimbursed for your participation in the study per visit where you complete all study related procedures. Upon completion of the visit and all study procedures, you will be reimbursed \$50. Reimbursement will be issued each completed visit up to a maximum of \$200 in total reimbursement for the study.

You will be reimbursed after agreeing to participate in this study. You will be given a Greenphire ClinCard, which is a specially-made debit card for clinical research payments. It works like a bank debit card. We will add your reimbursement money to this card. The payment will be available immediately. It can be used wherever Visa cards are accepted.

You may use this card at any store that accepts credit cards or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, and date of birth. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or your participation in this study.

Lost or Stolen ClinCards:

You will be given this card only once while you are in the study. If your card is lost or damaged, please contact the study coordinator for assistance. The first lost card will be replaced at no charge to you. To replace an additional lost card, you will be charged \$7.00. The fee will be deducted from the balance available on the card when it was lost. Unused funds will be loaded onto a new card and the original card will be cancelled.

If the card is stolen, please call (866) 952-3795 for ClinCard's Customer Service and also notify our research team.

No other compensation is offered.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of \$600 in a calendar year.

Will I have to pay for anything?

There are no additional costs to you for taking part in this study. The cough assist device and supplies for it will be provided at the expense of the manufacturer of the cough assist device, ABM Respiratory Care, LLC.

You and/or your health insurance will be billed for the costs of medical care during this study since these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

What happens if I am injured from being in the study?

If you are injured during your clinic visit, we will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

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

You are encouraged to ask questions at any time during the study. In the event you have further questions about the study, please contact Dr. Ackrivo at 215-662-3202 during regular business hours, or the Hospital of the University of Pennsylvania pulmonary attending on call at 215-622-4000 after hours, on weekends, and on holidays.

When is the Study over? Can I leave the Study before it ends?

All participants will be followed for 6 months of regularly scheduled clinic appointments. For the subsequent six months, we may contact you or review your chart to obtain further medical information. This study may also be stopped at any time by your physician or the National Institute of Health without your consent because:

- x The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- x You have not followed study instructions.
- x The National Institute of Health or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

If you decide to stop participating in the study, we encourage you to call the Penn ALS clinic and talk to your doctor first. It is important to tell the doctor if you are thinking about stopping so any risks to you can be minimized. A final study visit may be requested to ensure your safety.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

You will be assigned a unique Participant number (PID) which is a unique sequence of numbers. All research information will be linked to these numbers so your research record will not have any of your personally identifying information, therefore the data will be coded by this PID.

Data sharing across sites will always be in the form of coded data. Only the research staff at the University of Pennsylvania will have access to your identifiable information. Any information with the code linking your record to your unique PID will be kept on an electronic spreadsheet on a password-protected health system computer hosted at the University of Pennsylvania.

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.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable health information and samples may be shared with that new institution and their oversight offices. Private health information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

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

Your privacy rights:

- x 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.
- x 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.
- x 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.
- x 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.

Adherence to MI therapy sessions will be recorded on the BiWaze Cough system in the subject's home. BiWaze Cough stores the data in an encrypted log file which can be sent via WiFi to an online, HIPPA complaint data repository platform called ARC Connect (ABM Respiratory Care, USA). The clinicians can access the usage data through a secure online ARC Connect portal and review the subject's compliance to the MI therapy.

Reports will include: date/time of use, number of inhalation/exhalation cycles, number of sets of insufflation/exhalation cycles, and pressure used.

ARC Connect's data privacy policy states that it does collect the following personal information:

- x Name
- x Email Address
- x Phone Number

To help protect subject privacy: we will create subject accounts with altered contact information for each subject's profile in ARC Connect as follows:

<u>Title</u>	<u>Will be changed to:</u>
x Name -----Æ	Subject ID number
x Email Address -----Æ	An @pennmedicine account for research staff
x Phone Number -----Æ	The Penn ALS clinic research staff mobile number

The confidentiality of your information will be protected in the following way during the study: While we cannot guarantee total confidentiality, we will do our best to make sure that your data are kept security. We will protect your confidentiality during storage and sharing by keeping your information on a password-protected health system computer hosted at the University of Pennsylvania. We will store your data on a secure online research database known as REDCap.

Only the research staff at the University of Pennsylvania will have access to your identifiable information. Any information with the code linking your record to your unique participant number will be kept on an electronic spreadsheet on a password-protected health system computer hosted at the University of Pennsylvania. Any presentation of the results of this study using your data will have all identifiers removed.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will information about this study be available to the public?

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

What may happen to my information collected on this study?

Future Use of Data

Your coded information may be stored and used for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law.

The following identifiers will be retained with your information at the University of Pennsylvania:

1. Linking ID code connecting your personal information to a unique participant identifier number
2. Names and/or initials
3. Geographic information, including street address, city, county, precinct, zip code, etc.
4. Important dates related to your health care, such as birth date, admission date, discharge date, date of death.
5. Phone numbers;
6. Electronic mail addresses;
7. Medical record numbers;
8. Records about your study visit;
9. Results from physical exams, tests, procedures, and surveys;
10. Results from using the monitor that measures your carbon dioxide, oxygen, and heart rate;
11. Any current and/or ongoing medications that you are taking;
12. All of your current and past medical history

Your information may be stored and used for future research purposes for an indefinite amount of time.

There are no plans to tell you about any of the specific research that will be done. Possible future research may include presentations and posters at academic conferences, or scientific manuscripts.

We may share your identifiable information with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. Information shared with institutions outside of the University of Pennsylvania will include the following identifiers:

1. Dates related to your healthcare, such as birth date, admission date, discharge date, date of death;
2. Results from physical exams, tests, procedures, and surveys;
3. Results from using the monitor that measures your carbon dioxide, oxygen, and heart rate;

4. Any current and/or ongoing medications that you are taking;
5. All of your current and past medical history

This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

We will not follow up with you to tell you about the specific research that will be done. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by keeping your information on a password-protected health system computer hosted at the University of Pennsylvania.

Only the research staff at the University of Pennsylvania will have access to your identifiable information. Any information with the code linking your record to your unique participant number will be kept on an electronic spreadsheet on a password-protected health system computer hosted at the University of Pennsylvania.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information, then you can contact Dr. Jason Ackrivo at 215-662-3202 during regular business hours, or the Hospital of the University of Pennsylvania pulmonary attending on call at 215-622-4000 after hours and on weekends and holidays.

Electronic Medical Record and Release of Study Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related

services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a participant, have access to research related information within the EMR?

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

Study tests performed as part of the study that are also part of routine clinical care (such as spirometry) will be made available to you in the EMR soon after your study visit. Any data that are specific to participation in the research study (such as a peak cough flow) will be made available to you at the conclusion of your participation in the study.

Will I receive the results of research testing that may be relevant to my health?

Since some study procedures (spirometry, maximal inspiratory pressure, transcutaneous carbon dioxide results) are part of routine care in our clinic, you will receive all results of your testing in this study. If standard of care testing indicates weakness of your breathing, then we will inform your doctor so that they can use this information to direct your care. Typically, the test results can be reviewed and communicated to you by the end of your visit.

Many of tests done in research studies are only for research and have no clear impact on your healthcare (such as the maximum insufflation capacity). Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?

If you choose to be in this study, the study doctor will get personal information from you. This may include information that might identify you. This information will only be shared with select research staff within participating research centers. This information may include:

- x Medical and Research Records
- x Name, address, telephone number, e-mail address, medical record number
- x Date of birth
- x Records about study-related phone calls
- x Records about your study visit
- x Results from physical exams, tests and procedures
- x Any current and/or ongoing medications that you are taking
- x All of your current and past medical history

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- x do the research
- x oversee the research
- x to see if the research was done right
- x to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Coded Information related to your participation in clinical research will be contained in a secure medical research database known as REDCap.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- x The investigator for the study and the study team
- x Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- x Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

Participating research staff at other institutions participating in this research project, which include:

- x The funding sponsor agency, which includes the National Institutes of Health

Oversight organizations

- x The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- x You have given written authorization
- x The University of Pennsylvania's Institutional Review Board grants permission
- x As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study listed on page one of this form. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at (215) 898-2614 for assistance.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Participant [print]	Signature of Participant	Date
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Name of Person Obtaining Consent [print]	Signature	Date
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For use with Non-English Speaking participants / LARs utilizing a short-form process:

Name of Witness (Please Print)	Signature of Witness	Date
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Name of Interpreter (Please Print) (When available)	Signature of Interpreter	Date
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