UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Digital Incentive Spirometer for Assessing Incentive Spirometry Adherence
Principal Investigator (and Emergency Contact):	Doraid Jarrar, MD Division of Thoracic Surgery, Hospital of the University of Pennsylvania 3400 Civic Center Blvd, Philadelphia PA 19104 215-662-7878 Doraid.Jarrar@pennmedicine.upenn.edu

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.

This study can take place at the Hospital of the University of Pennsylvania (HUP) and/or Penn Presbyterian Medical Center (PPMC).

The research study is being conducted to see if a digital incentive spirometer with progress tracking, progress sharing, real time exercise feedback/guidance, and exercise session reminders can improve spirometer use and lead to better exercise sessions.

If you agree to join the study, you will be asked to complete the following research procedures: complete incentive spirometry exercises with the Airalux incentive spirometer and companion app instead of a traditional mechanical incentive spirometer. An incentive spirometer is a tool that measures how much you can breathe in from it in one deep, slow breath. Spirometry is the practice of measuring breaths. An incentive spirometry exercise session is taking three deep, slow breaths in a row from the incentive spirometer. A digital incentive spirometer is different from a mechanical one in these ways: it records the exercise measurements automatically, it will guide (visual and audio) you on how to do the exercises, and it will remind you when to do the exercises.

Your participation will last for the length of your hospital stay. No follow up is required.

There are no direct benefits to this study beyond the known benefits of performing incentive spirometry exercises after surgeries that require general anesthesia,

independent of the type of incentive spirometer used. The exercise metrics collected with your use of the Airalux incentive spirometer will not be used to guide your clinical care or help make any diagnosis beyond that of a traditional mechanical incentive spirometer.

The most likely risks of participation are potential loss of confidentiality related to your incentive spirometry exercises and medical procedure. However, your name and identifiable information will not be linked to the exercise metrics nor procedure beyond the consent process and study administration. You may also find completing breathing exercises uncomfortable, in which case you should notify the providers on staff.

The alternative to participating is choosing not to participate. If you choose not to participate, you will be provided with the traditional mechanical incentive spirometer during your hospital stay as part of routine care.

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 to help us investigate a new device that may help patients adhere to incentive spirometry exercises.

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. You will receive a copy of this form if you agree to participate.

What is the purpose of this research study?

The goal of this study is to evaluate the ability of a digital incentive spirometer with progress tracking, progress sharing, real time exercise feedback/guidance, and exercise session reminders to facilitate incentive spirometry exercise adherence and exercise performance.

How long will I be in the study?

The consent process will take approximately 10 minutes. The use of the device will be throughout your hospital stay. An exit survey will take approximately 3-5 minutes.

What am I being asked to do?

You will receive a digital incentive spirometer. You will be asked to complete incentive spirometry exercises with your digital incentive spirometer throughout your hospital stay as you would with the traditional mechanical incentive spirometer. You will take three deep breaths from the digital incentive spirometer every 15 minutes to complete an exercise session. The device will buzz every 15 minutes to remind you when to do the exercises. During the night, the reminders will be turned off by a member of our clinical research team. At the end of your hospital stay, you will be asked to complete a short survey of your experience using the digital incentive spirometer.

Optionally, you may choose to download the Airalux companion app to your iPhone or iPad (IOS only at this time). If you choose to download the app, you will be asked to provide the email associated with your Apple ID in order for the Airalux app to be released free of charge to your App Store for you to download. You will be asked to create a profile in the app using your digital incentive spirometer's device identification key where you will be able to view your exercise progress. You will also be asked to create a password for your profile. The research team will be able to see that you have created an app profile, but will not be able to access your account or password, which will be encrypted. At the end of your hospital stay, you will be asked to complete a short survey of your experience using the app.

If you choose not to download the Airalux companion app, you will not be able to access your exercise progress graphs. You will be able to see your exercise measurements on your digital incentive spirometer device screen after the end of each exercise, but you will not be able to view measurements of past exercises.

Regardless of if you choose to use the app or not, your device will automatically record all your incentive spirometry exercise measurements, which our research team is collecting as data for this study.

What are the possible risks or discomforts?

There are no major risks associated with the device. There is a risk of loss of confidentiality with respect to your exercise metrics and medical procedure. You may also find completing breathing exercises uncomfortable, in which case you should notify the providers on staff.

If you choose to use the Airalux companion app, Apple may have access to certain types of data due to the nature of app distribution and operation on their platform. This might include metadata related to the app's performance and user activity, such as crash reports, usage analytics, and device-related information, which are part of Apple's standard practices for app management and improvement. Airalux is not using Apple services like iCloud or HealthKit, where users share their personal health data with Apple.

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?

You are not expected to get any benefit from being in this research study. In general, research shows that incentive spirometry exercises may reduce risk of lung complications after surgeries, similar in concept to how regular physical activity or exercise may reduce risk of heart disease. You will be contributing to the development of a new device that could help to improve how incentive spirometry is administered to patients.

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

Participation in this study is optional. You may choose not to participate.

Will I be paid for being in this study?

There is no monetary compensation for participation in this study.

Will I have to pay for anything?

You will not have to pay any fees relating to participation in this study.

You will still be responsible for any costs related to your care in the hospital. 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.

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

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician or the Food and Drug Administration (FDA) without your consent because:

- 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.
- You have not followed study instructions.
- The study Principal Investigator or the Food and Drug Administration (FDA) has

decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your future care.

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, the University of Pennsylvania, the Hospital of the University of Pennsylvania, Penn Presbyterian Medical Center, and Airalux Medical will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

The confidentiality of your information will be protected in the following way during the study:

1. Your name and study participation date will be stored on your consent form internally at Penn Medicine under lock and key and will not leave the facility; it will also be uploaded to your patient records.
2. Your name, birthdate, medical record number, medical procedure, SPO2 measurements, pulmonary function lab spirometry results, age, weight, height, sex at birth, and pain scores will be stored within the Penn Medicine EPIC database as part of routine care. A copy of your SPO2 measurements, pain scores, age, weight, height, sex at birth, and pulmonary function lab spirometry results will be used by the research team and be stored in PennBox with a study participant alphanumeric key. Your name will not be included in this.
3. Your mobile app profile anonymization ID (if you use app with your device), Airalux incentive spirometer device identification key, exercise metrics, exercise settings, exercise dates and time stamps will be stored with a study participant alphanumeric key in a secure cloud database. Your name will not be stored on this database at any point. Your name will not be used in conjunction with your exercise metrics, settings, dates, and times for any analysis or results.
4. Your paper survey responses will be stored at Penn Medicine under lock and key and a digitized version in PennBox. Your name will not be collected on this survey at any point.

Will information about this study be available to the public?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website 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.

The results of this study may be published or presented at scientific meetings. However, no identifying information will be made public.

What may happen to my information collected on this study?

There will be no biospecimen samples stored.

Collection of Identifiable Specimens

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Whole genome sequencing (WGS) will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code. WGS can be conducted to determine changes and mutations in DNA. The significance of these results may not be well defined. Not all genetic variations affect one's health.

Future Use of Data and/or Specimens

Your coded or identifiable information will be stored 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 future use of your information only applies to the information collected on this study.

The following identifiers will be retained with your information: Airalux incentive spirometer device identification key, study participant alphanumeric key, timestamps of your incentive spirometer exercises, age, weight, height, and sex at birth. We will not retain your name nor any other identifiers outside those listed except on consent forms.

We will store the following information: study participant alphanumeric key, mobile app profile anonymization ID (if applicable), incentive spirometer device identification key, exercise metrics, exercise settings, exercise dates and time stamps, SPO2 measurements, pulmonary function lab spirometry results, pain scores, age, weight, height, sex at birth, and survey responses.

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 studies about how incentive spirometry improves

patient vitals. We may share your identifiable information with other researchers within Penn, PPMC, or other research institutions, as well as pharmaceutical, device, or biotechnology companies.

We will not follow up with you to tell you about the specific research that will be done. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

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 name separate and by not sharing this with any other researchers.

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, or have changed your mind, you can contact Dr. Doraid Jarrar at 215-662-7878. If you change your mind, we will destroy all records of your participation, consent forms, and data.

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

Many of the analyses done in research studies are only for research and have no clear impact on your healthcare. 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?

We will store the following information: study participant alphanumeric key, mobile app profile anonymization ID (if applicable), incentive spirometer device identification key, exercise metrics, exercise settings, exercise dates and time stamps, SPO2 measurements, pulmonary function lab spirometry results, pain scores, age, weight, height, sex at birth, and survey responses.

The following identifiers will be retained with your information: Airalux incentive spirometer device identification key, study participant alphanumeric key, timestamps of your incentive spirometer exercises, age, weight, height, and sex at birth. We will not retain your name nor any other identifiers outside those listed except on consent forms.

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:

- do the research
- oversee the research
- to see if the research was done right
- 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.

Who may use and share information about me?

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

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- 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?

Airalux Medical may receive your information.

<u>Oversight organizations</u>

- 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:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- 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. If you withdraw your permission, you will not be able to stay in this study. Additionally, your Airalux app profile will be deleted, and you will not be able to access full functionality of the Airalux incentive spirometer. You will be issued a traditional mechanical incentive spirometer.

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.

Financial Interest Disclosure

This research study is designed to test a product made by Airalux Medical. The development and manufacturing of digital incentive spirometer devices used in this research study are supported in part by money from grants obtained by Airalux Medical and disbursed through the University of Pennsylvania. However, the University of Pennsylvania has no significant financial interest in the study product being evaluated in this study. Yi-An Hsieh, who is part of the research team, has taken part in inventing (patent pending) the digital incentive spirometers used in this research. Therefore, Yi-An could benefit financially from the results of this research study. In addition, Yi-An may receive financial compensation (in the form of a stipend, stock, or employment) from Airalux Medical, for work that is not a part of this study. These activities may include but are not limited to product development, mechanical engineering, and software engineering. The amount of money might be affected by the results of this study. This

means that Yi-An could gain or lose money depending on the results of this study. Yi-An is involved in study protocol drafting and data analysis for this study. If you would like more information, please ask the researchers or the study coordinator.

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 the number on page one of this form.

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
_____	_____	_____
Name of Person Obtaining Consent **[print]**	Signature	Date