STUDY TITLE: Feasibility of Inpatient and At-Home Use of Handheld Spirometry

NCT Number: NCT03284203

IRB Number: IRB17-0562

Date of the Document: April 8, 2018

The UNIVERSITY OF CHICAGO

The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB17-0562 Name of Subject: _____
Medical History Number: _____

STUDY TITLE: Feasibility of Inpatient and At-Home Use of Handheld Spirometry

Doctors Directing Research: Valerie Press, MD, MPH and Steven White, MD
Address: 5841 S. Maryland Avenue, MC 2007, Chicago, IL, 60637
Telephone Number: 773-702-5170

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to understand whether a handheld spirometry device is useful for patients and whether it provides measurements similar to the measurements that we can collect on large machines in the hospital or clinic. Spirometry is a measurement of your breathing and lung function. Currently, many patients with breathing problems do not receive spirometry to measure their breathing on a regular basis. We would like to determine if measuring breathing using spirometry at home will be useful for helping patients manage their breathing problems.

We will ask you to use a home spirometry device, SpiroPD, which allows you to measure your lung function and keep track of your medication at home. This device is handheld and small, only 8 inches wide by 4 inches tall. It weighs less than one pound. We will compare the measurements from this device to measurements we collect for research using a larger hospital machine, the Koko Spirometer. Both of these devices are approved by the FDA and we will use these for their approved purposes.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 150 people will take part in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?

There will be one visit in the hospital or clinic and one visit that will take place about 30 days later. Each visit will last about 1 hour. We would prefer that you come back in-person so that we can test your breathing again with spirometry in the clinic. However, if you are unable to come back in-person in 30 days, we will call you to ask you questions.

During your initial study visit, which will take place either in the hospital or the clinic, we will do the following:

- An interviewer will ask you a few questions about your health and complete a survey.
- An interviewer will ask you about the SpiroPD and your plans for using it at home.
- You will have spirometry performed. You will be asked to blow into a tube so that we can measure the severity of your lung disease.
- Your vision will be assessed using a standard assessment tool called a Snellen Card (eye chart).
- We will ask a few verbal questions and then use a brief reading test called a STOFHLA. This will help us get an understanding of how difficult it is for patients to read and understand medical information.
- You will be asked to take 2 puffs of albuterol, and then the spirometry will be repeated. The use of albuterol for the spirometry is part of the research study. It will help us measure the severity of your lung disease. Albuterol is used to prevent breathing difficulties by relaxing and opening air passages to the lungs to make breathing easier and spirometry is used to check lung function. Albuterol is approved by the Food and Drug Administration (FDA) for this purpose.

You will then be given the at-home spirometry device (SpiroPD) and you will be taught how to use it. You will also be given information about whom to call if you have any questions about the SpiroPD while you are at home.

We would like you to use the SpiroPD at home for 30 days. The device will collect information about how often you use the device, when you use the device, your lung function measurements from the device, and information on whether you are using your medications that you enter into the device as a tracking diary. This information is automatically shared over the internet with the research team and stored on the SpiroPD website.

After about 30 days, we will ask you to come to the clinic again to do the following:

- An interviewer will ask you a few questions about your health and complete a survey.
- An interviewer will ask you about the SpiroPD. We would like to know if you had any trouble using the device, if you liked to use it, and if you had any problems with it.
- You will have spirometry performed. You will be asked to blow into a tube so that we can measure the severity of your lung disease.
- You will be asked to take 2 puffs of albuterol, and then the spirometry will be repeated. The use of albuterol for the spirometry is part of the research study. It will help us measure the severity of your lung disease. Albuterol is used to prevent breathing difficulties by relaxing and opening air passages to the lungs to make breathing easier and spirometry is used to check lung function. Albuterol is approved by the Food and Drug Administration (FDA) for this purpose.

If you cannot come back to the clinic in-person, we will call you to ask you questions about your health and about the SpiroPD.

During this study, Dr. Press and her research team will collect information about you for the

purposes of this research. This includes the following information, some of which will be collected from your medical record:

- your name
- phone number
- address
- medical record number
- date of birth
- height
- weight
- ethnicity
- medical history
- pharmacy and hospital records
- the results of physical exams
- questionnaires
- date of study entry and dates of study procedures
- relative's names and addresses

We collect your relative's information to be better able to reach you. If you prefer, we do not need to obtain this from you.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for about 30 days.

Dr. Press may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study;
- Your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

You may be uncomfortable answering some questions about your health.

Spirometry can cause some chest soreness or dizziness.

There is a risk that information about you could become known to unauthorized persons, but we have safeguards in place to prevent this from happening. If you agree to participate, all information will be kept confidential and in password-protected computers accessible only by approved researchers. Any paper records will be kept in locked offices and cabinets accessible only by approved researchers.

Side effects of Albuterol can include:

- feeling nervous
- shakiness
- sore throat
- cough
- muscle pain
- upper respiratory tract infection, including viral infection
- your heart feels like it is pounding or racing (palpitations)
- chest pain
- fast heart rate
- dizziness

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you if using this

device at home helps you remember to use your medications and/or provides you with information about your lung function that you use to help manage your symptoms. These benefits are not guaranteed. We hope the information learned from this study will benefit other individuals with COPD self-manage their symptoms and medications in the future .

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate.

The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

There are no costs to participation in this study.

Clinical services provided during a clinical research study are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance.

The costs that are considered research-related for this study may include any additional laboratory tests, physician visits, imaging, procedures or other clinical services that are dictated by the research protocol and only required because you are part of this study.

Usual medical care costs include any and all services that are considered medically necessary for your disease and would be done even if you were not part of this research study. This may include laboratory tests, physician visits, imaging, procedures, and other clinical services that your physician orders for your routine care. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance, and may include deductibles and co-payments. Similarly, this care will be subject to all the same requirements and restrictions of your insurance.

If you have questions about whether specific clinical services are research related or usual medical care, please speak to your physician or research contact person.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Press as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance or the study sponsor in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Press know right away.

WILL I BE PAID FOR MY PARTICIPATION?

For participation in this study you will receive the SpiroPD device, which you may keep after the study is complete. You will receive this device at the time of your first study visit. At the end of the study, you will be allowed to keep the SpiroPD device. If you choose to continue using it, we

will not use any of your data for research purposes, but the device use information will continue to be stored on the SpiroPD website, which you will be able to access.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Data will be stored in a locked office, or in password protected computers. Only research staff involved in the study will have access to the data except as specified below. The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

We will share some information from this study with the company that makes SpiroPD. This information will not contain your name or any way to identify you. The information will include a summary of how well the SpiroPD compared to the machine used in hospitals/clinics, how often participants used the SpiroPD at home as directed, and information about whether participants used the medication adherence functions on the SpiroPD to keep track of their medicine, like a diary. The information about your device use and your diary are automatically shared over the internet with SpiroPD. At the end of the study, you will be allowed to keep the SpiroPD device. If you choose to continue using it, we will not use any of your data for research purposes, but the device use information will continue to be stored on the SpiroPD website, which you will be able to access.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Press is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Press in writing at the address on the first page. Dr. Press may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to _____ about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Press at 773-702-5170.

If you have a research related injury, you should immediately contact Dr. Press at 773-702-5170. In case of emergency call 773-702-6800 and ask for page # 2346.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing:

University of Chicago
Institutional Review Board
5841 S. Maryland Ave.
MC7132, I-625
Chicago, IL 60637

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____

Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:
Signature of Investigator/Physician _____
Date: _____ Time: _____ AM/PM (Circle)