DETECTING ERRORS IN USING METERED DOSE INHALERS (MDI) AMONG ASTHMA AND COPD PATIENTS

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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

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Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study, participation in the study is completely voluntary. If you choose not to participate, it will not affect the medical care you would normally receive.

You are being asked because you are visiting the Smith clinic or the Pulmonary Function Laboratory for breathing-related problems. You have already been diagnosed with asthma or COPD or you may be scheduled for a breathing (pulmonary function test) today. The lung doctors at Baylor College of Medicine are asking you to take part in a research study to understand better how patients use their metered dose inhalers to take medication. A metered dose inhaler is used by millions of Asthma and COPD patients for managing their disease. However, using the inhaler correctly is important to get the most benefit from the medication.
This study will help doctors and researchers understand how you and other subjects use the inhaler.

We will record the way you use your inhaler using an electronic device. This device used to measure your inhaler usage is a flow meter developed by Rice University. Once all subjects have been enrolled, the study doctors and research staff will analyze the information to understand how the use of the inhaler may change the effect of the medication.

The results of the study may help the doctors learn how to help you and other patients improve the way inhalers are used so the patient may get more benefit out of the medication. Always using your inhalers regularly and correctly will help to keep your symptoms under control.

The information contained in this document will help you understand the research study.

This research study is sponsored by Baylor College of Medicine and Rice University

Purpose

The purpose of this study is to better understand the techniques used by Asthma and COPD patients when taking medication using a Metered Dose Inhaler. We will measure the MDI usage technique of patients, before and after coaching by a trained technician or physician.

Procedures

The research will be conducted at the following location(s): Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, Harris Health System- Smith Clinic.

You will be one of 120 subjects in this study. There is no preparation for doing the inhaler study but it is best that you are relaxed.

The technician will help you become familiar with the inhaler and the machine attached to it. Do not breathe into or blow into the inhaler. The inhaler does not contain real medicine and is called a placebo inhaler, you may take one or two puffs to practice. In some patients the placebo has

triggered bronchospasm so we want to limit how many times you use it.

Once you are ready to start, the technician will start the program to record your inhaler use. You will be told to do what you normally do when you use your inhaler. The machine will record the amount of air you breathe, how fast you breathe and when you press your inhaler.

You will then receive guidance and education on using an inhaler. You may ask as many questions as you like so you completely understand the procedure for using the inhaler. The technician will once again start the program to record your inhaler usage using the process you reviewed with the technician.

There is only this one visit for this study. Your participation will last only for this visit.

You can see and get a copy of your research related health information. Your research doctor may be able to provide you with part of your information while the study is in progress and the rest of your information at the end of the study.

Potential Risks and Discomforts
There are usually no side effects when using a placebo inhaler however there is a slight risk of bronchospasm (wheezing). The technician and physician are both aware of this, please tell the technician if you begin to feel tight or have trouble breathing. You will be given a short-acting bronchodilator if this occurs.

When the study is over, you can resume your normal activities. However, if, at any time, you feel you are unable to perform the test, feel uncomfortable or have trouble breathing, you may stop the test.

There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize the risks. The medical staff will know your name, it will not be entered into the study documents. You will be assigned a number; this number is specific to the study and to you. Your birthdate will not be recorded, only your age in years. Your height and weight will be recorded for the test. The severity of your disease will be recorded.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

Potential Benefits
The benefits of participating in this study may be: you may learn more about using your metered dose inhaler and this may help you get maximum benefit from your medication. Your participation may also help the doctors understand more about patient usage metered dose inhalers and how to better direct the education process. However, you may receive no benefit from participating.

Alternatives
You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

The investigator may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you, for example, if you have a serious reaction to the placebo inhaler. The sponsor, investigator, Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

Research Related Injury

All emergency equipment is available at both the Harris Health Smith Clinic and the Ben Taub Hospital Pulmonary Function Lab.

In the event of injury resulting from this research, Baylor College of Medicine, Harris Health Systems (Ben Taub General Hospital) are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Subject's Rights
Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Your Health Information

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We may be collecting health information that could be linked to you (protected health information). This protected health information might have your name, address, social security number or something else that identifies you attached to it. Federal law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law or as described in this form. Everyone working with your protected health information will work to keep this information private. The results of the data from the study may be published. However, you will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, agents of the Food and Drug Administration, and regulatory agencies such as the U.S. Department of Health and Human Services will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

The people listed above will be able to access your information for as long as they need to, even after the study is completed.

If you decide to stop taking part in the study or if you are removed from the study, you may decide that you no longer allow protected health information that identifies you to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your identifiable health information would affect the safety or quality of the research study.

The investigator, NICOLA ALEXANDER HANANIA, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: NICOLA ALEXANDER HANANIA at 713-873-2468 during the day and through the Ben Taub Hospital page operator 713-873-2010 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date

HARRISHEALTH SYSTEM

IRB Number: H-36079
Approval Date: 12/18/14
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