Subject Information Sheet, Informed Consent Form and Authorization to Disclose Health Information

Sponsor / Study Title:	**Pulmonary Research Institute of Southeast Michigan / "ProAir Digihaler in COPD Disease Management: A real world study to assess ProAir Digihaler inhalation parameters thresholds and their use to identify deterioration in clinical practice"**
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Subject identification/number:

1.0 Introduction

We invite you to take part in a clinical research trial which seeks to identify a more effective means of treating Chronic obstructive pulmonary disease (COPD).

To keep the information in this form simple we shall refer to this clinical research trial as a "Study". You are being asked if you would like to take part in this study because you have COPD. The study staff will explain the study to you.

This information sheet is provided to help you to make an informed decision on whether you would like to take part in the study. The information sheet describes the purpose of the study, what is required of you, and any potential risks or benefits of taking part in the study. Only you can decide if you want to take part in this study. You should only make your decision after reading all the information in this form. You are free to ask questions at any time and may talk to your family, friends and/or your family doctor to help make your decision. You can take as much time as you like to decide.

Your participation is voluntary. The study will only include people who choose to take part in the study. If you do not want to take part you do not need to do anything, and your study doctor will discuss what other treatments are available to you.

After you have read the entire form and all of your questions have been answered to your satisfaction, you may then decide if you would like to participate in this study. If you decide to take part, sign and date the page at the end of this form to show that you agree to be a part of the study. This is called "giving your consent". You will receive a copy of the signed and dated consent form.

Even after you have signed and dated this study consent form you can change your mind at any time and decide not to participate or continue participation in the study. You do not have to give a reason.

If you have a personal insurance policy, review its terms and restrictions carefully to confirm that study participation does not interfere with the policy you have.

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

2.0 Purpose

COPD is a chronic disease that affects the lungs, causing cough, sputum and shortness of breath with negative impacts on lung function, symptoms, quality of life and future exacerbations/flares and can increase mortality. While there is no cure for COPD, appropriate management can improve these outcomes for people with COPD.

However, day to day management of people with COPD can often be poor. Many people with COPD experience worsening symptoms over time yet delay or fail to report these changes. These changes can also be missed by primary physicians. Finding a way to assist people with COPD and their primary physicians to better identify deterioration in COPD and improve disease management is essential to overcoming these issues.

The Pulmonary Research Institute of Southeast Michigan is sponsoring this research study to test if using the Albuterol sulfate electronic multidose dry powder inhaler (eMDPI) digital system can identify COPD deterioration, inform primary physicians of these changes and help improve the management of people with COPD in clinical practice.

This study will investigate whether information from the Albuterol eMDPI digital system can provide specific measurements that can be used to identify subject worsening and risk for exacerbation/flares earlier. It will also determine if the Albuterol eMDPI digital system, when used with other COPD symptom questionnaires, can provide even better predictions of disease worsening.

The Albuterol eMDPI inhaler is a rescue treatment for COPD (approved by the United States Food and Drug Administration [FDA]) that includes a rescue inhaler with a digital data tracker and Bluetooth capability built in. It is an inhaler with a data logger capable of storing and transmitting timestamped inhalation data. As a subject using the eMDPI digital system in this study, you will place the inhaler in your mouth, as instructed by your study doctor, inhale from the study device, and that inhalation data will be transmitted wirelessly (Bluetooth) to an application on your smart device (App). From the App, data will be transmitted to a provider dashboard on which your study doctor will be able to view your inhalation data.

Research center personnel will load the App onto your smart device (for example, phone or tablet) for you during your Screening/Baseline Visit 1. After loading the App to your smart device, research center personnel will sign you up to be able to use the App to view your inhalation data. In order to use the App, you will be asked to agree to the Terms of Use and Privacy Notice which will appear on your mobile device's screen when you first start using the app. If you decide that you do not want to agree, then you cannot participate in this study. As a subject using the eMDPI digital system in this study, you will be required to use your smart device with internet access throughout the study.

Throughout the study, no personal data about you will be collected by the App. A study supplied identifier will be provided to you for the App (for example, username and password), that does not require any of your personal information, medical information, and other health information that you

provide during account registration or otherwise will be collected. The app will also automatically collect and store data about your use of products connected to the app, including but not limited to the frequency and duration of use, and certain quality measures, some of which may be sensitive health information. Note, any such usage and health information stored by the product prior to being connected to the app will be imported once the product is connected to the app (for example, as part of the pairing process) and the terms of the Privacy Notice will apply to all such imported information. The app may also collect certain other categories of information automatically, including internet and electronic network activity information, such as your device type, Internet protocol (IP) address, device and advertising identifiers, operating system, Internet service provider, the date and time of your app use, information about the links you click and your activity within the app, and other standard log information.

While the Terms of Use may include statements limiting your rights if you are harmed in this study, you do not release the study doctor, funding organization, institution, or agents from responsibility for mistakes in this research study. Upon study completion, the research center personnel will securely remove the App from your smart device.

The digital health platform is used to provide subject-specific data to the research study's doctor via the dashboard, a secure web interface.

The study will assess average weekly rescue inhaler usage, the number of rescue inhaler-free days, and specific data about how well you inhaled during each eMDPI digital system usage. Information about COPD management actions by your healthcare providers will also be assessed while you are using the eMDPI digital system. You will be contacted regularly to assess how you are doing throughout the study and will be asked to complete various questionnaires asking about your symptom, quality of life and healthcare utilization. Questionnaires that focus on subjects' beliefs and perceptions about their disease and inhaler satisfaction using the eMDPI digital system, as well as questionnaires on system usability will also be asked.

Teva Branded Pharmaceutical Products R&D, Inc. (Teva) is a company that discovers and makes medicines and other health products. Teva is paying the study doctor's institution to run this study.

A total of 20 subjects will participate in the study over a period of approximately 7 months.

3.0 Study Design

The study doctor will explain when, how often and how to take the study drug.

You will discontinue the use of your regular albuterol rescue inhaler during the course of this study.

You will receive Albuterol eMDPI study drug to use as your rescue inhaler instead of your physician prescribed albuterol rescue inhaler.

You will be encouraged to use the Albuterol eMDPI study drug for all rescue treatments and to minimize the use of albuterol nebulizer rescue treatments.

You will continue to use all other medications prescribed for you by your personal physician throughout the study (other than your albuterol rescue inhaler).

4.0 Study Activities and Time Commitment

Your expected participation in this study will last about 7 months. During this time, you will need to visit the clinic on schedule, do testing and tell the study staff about any changes to your health.

You will be scheduled to attend 4 clinic visits and will be contacted by telephone at 5 additional timepoints (monthly). All clinic visits will begin in the morning at about the same time of day.

At visit 1, after signing and dating the consent, you will be scheduled to visit with the study doctor for an initial visit called a "screening visit". Based on the results of tests and procedures performed during Visit 1, if you continue to qualify to participate in the study, you will be provided an Albuterol eMDPI study inhaler with instructions, have the App downloaded to your smart device and ensure device connectivity with the digital dashboard. You will then be scheduled for a return visit (Visit 2) approximately 2 weeks after Visit 1.

During the 2 weeks run-in period, your ability to use the Albuterol eMDPI study inhaler and App will be assessed and the stability of your COPD will be determined. If you have had a moderate or severe COPD exacerbation or other acute medical problem, or you have changes to your COPD medications during this period, you will not be able to take part in the study. After the run-in period, you will return to the clinic for Visit 2.

If at Visit 2 you continue to qualify for the study, you will complete several subject questionnaires, undergo multiple breathing tests, perform a walking test and receive additional study drug and instructions. You will be provided a folder to take home containing several copies of 3 short paper questionnaires to be completed and then mailed to the research center on a weekly basis (stamped addressed envelopes are included in the folder). You will then be scheduled for 2 telephone calls (TC 1 & 2) approximately 1 and 2 months after visit 2 and also scheduled for a return clinic visit 3 approximately 3 months after visit 2.

During the pre-arranged telephone calls (TC 1 & 2) your health status, complete verbal questionnaires and digital data will be reviewed to ensure that all devices, questionnaires and testing for the study are being performed as planned.

Upon return for visit 3, you will complete several patient questionnaires, undergo 2 breathing tests and receive additional study drug and instructions. You will be provided a new folder to take home containing several copies of 3 short paper questionnaires to be completed and then mailed to the research center (stamped, addressed envelopes are included in the folder) on a weekly basis. You will then be scheduled for 2 at-home telephone monitoring calls (TC 3 & 4) approximately 1 and 2 months after visit 3 and also scheduled for a return clinic visit 4 approximately 3 months after visit 3.

During the pre-arranged telephone calls (TC 3 & 4) your health status, complete verbal questionnaires and digital data will be reviewed to ensure that all devices, questionnaires and testing for the study are being performed as planned.

Upon return for clinic visit 4, you will complete several subject questionnaires and undergo 2 breathing tests. You will then be scheduled for 1 at home telephone monitoring call (TC 5) approximately 1 week after visit 4 as a final safety check.

Throughout the study, your Albuterol eMDPI study inhaler usage data and your linked digital desktop information will be monitored by study center staff for any significant changes in your inhaler information. In the event that a significant change in inhaler information is identified, you will be contacted by telephone and may be asked to answer additional questionnaires over the telephone. Based on your inhaler results and answers to questions during the telephone call, you may be advised to contact your primary physician to determine if any additional therapy may be required.

5.0 Responsibilities

Before you begin the study:

If you choose to participate in the study, you will need to read this form, ask any questions and sign and date this form. A paper worksheet will be given to you in order to note any medical problems you may have and you will be asked to sign a release of information to obtain outside medical records from your health care practitioner.

Tests and Procedures at the Screening Visit (Visit 1)

- **Demography and medical history**: You will be asked about your health, about exacerbations or flare-ups of your COPD, and any illnesses you may have or had in the past and any treatments you may have received. You will be asked about medicines you are taking (including over-the-counter medicine, vitamins or herbal treatments). Demography, including information such as age, weight, height, ethnicity, and gender will then be collected.
- **Physical examination**: You will receive a complete physical examination.
- **Smoking status and history:** You will be asked whether you are smoking or not and whether you have stopped or started recently. You will also be asked how much you have smoked in the past.
- **Smoking cessation counselling:** If you are a current smoker, you will be advised about the risks of continuing to smoke and the advantages if you stop smoking. If you wish, you will also be advised about therapies to help you to stop smoking.
- **Vital signs:** Your weight, height, body temperature, blood pressure and pulse will be checked.
- **Pregnancy test:** If you are a woman and can become pregnant, a urine test will be done to see if you are pregnant.
- **Questionnaires:** You will be asked to complete 4 health related questionnaires
    - **CAT questionnaire**: will be self-administered at home on a weekly basis and at all clinic visits.
    - **Anthonisen Exacerbation Criteria (AEC)**: will be self-administered at home on a weekly basis and at all clinic visits.
    - **BCSS questionnaire**: will be self-administered at home on a weekly basis and at all clinic visits.
    - **mMRC questionnaire**: will be self-administered at clinic visits 1 and 2.
- If you meet all eligibility criteria at this visit:
- **Study Rescue inhaler:**
    - You will be provided with an Albuterol eMDPI study inhaler (an acute bronchodilator drug that can quickly relax muscles around your air passages in your lungs, allowing them to open up) as your rescue inhaler. This can be used to **relieve symptoms** as needed throughout the study. This will be replaced as needed.
    - You will be instructed on the proper use of the Albuterol eMDPI study inhaler
    - You will be asked to discontinue your regular albuterol rescue inhaler and to minimize use of your albuterol rescue nebulizer
    - The Albuterol eMDPI App will be downloaded to your smart device and linked to your Albuterol eMDPI study inhaler. The App will be linked to the study dashboard portal and functionality of the system will be documented.
    - You will be instructed on how to access and use the Albuterol eMDPI App
    - You will **continue to use all other COPD medications**

- You will be provided with a folder containing paper copies of 3 short questionnaires to be completed at home on a weekly basis, along with instructions and stamped envelopes for questionnaire return upon completing each week
- You will be scheduled to return in 2 weeks (±3 days) days for visit 2
- You will be asked to withhold use of your albuterol rescue inhaler 6 hours prior to your scheduled next visit 2 and withhold use of all other COPD inhalers for 24 hours prior to your scheduled next visit 2

Tests and Procedures at the Run-in Study (Visit 2)

You will be expected to do the following things during the study:

- You will need to come to the clinic for scheduled visits.
- Tell the study staff about any changes to your health or changes in your medications.
- Tell the study staff if you want to stop being in the study at any time.
- **Medication Withhold**: Confirm you have withheld taking your COPD medications for 6-24 hours prior to the visit as instructed at visit 1
- **Albuterol eMDPI Study Inhaler Usage:** Results from usage of the Albuterol eMDPI study inhaler will be downloaded and analyzed
- **Questionnaires:** You will be asked to complete 3 health related questionnaires and COPD stability will be confirmed from the questionnaires
- If you meet the Study Drug and Medication Withhold , Albuterol eMDPI Study Inhaler Usage criteria and COPD stability criteria by Questionnaires, you will be asked to perform the following procedures:
    - **Pregnancy test:** If you are a woman and can become pregnant, a urine test will be done to see if you are pregnant.
    - **Vital signs:** will be performed while sitting/resting, including your oxygen level on room air
    - **Inhalation tests:** you will be tested to see how well you are able to inhale or breathe in. This will be done before and after receiving Albuterol eMDPI study medication
    - **Breathing tests:** you will be tested to see how your lungs are working. This will be done before and after receiving Albuterol eMDPI study drug. Spirometry or lung function tests check the severity of your COPD. This test measures the amount of air you have in your lungs and how hard you can blow it out through your mouth. You will be asked not to take any of your COPD medications on the day of your study visit until after the breathing tests. You will then be tested to see how your lungs are working before and up to 30 minutes after you use the Albuterol eMDPI study drug.
    - You will take all of your regularly scheduled maintenance COPD medications after the breathing tests are complete
    - **6-minute walk test:** 1 hour after your maintenance medication administration, you will undergo two 6-minute walk tests separated by a 15-minute rest measuring how far you can walk in 6 minutes
- You will be provided with a folder containing paper copies of 3 short questionnaires to be completed at home on a weekly basis, along with instructions and stamped envelopes for questionnaire return upon completing each week
- Return the Albuterol eMDPI Study Inhalers dispensed at visit 1

- 3 additional Albuterol eMDPI Study Inhalers will be linked to your App and smartphone connectivity and internet access to the Digihaler Dashboard will be established
- You will be re-instructed on how to access and use the Albuterol eMDPI study inhalers and App
- You will remain off of your regular albuterol rescue inhaler and minimize use of your albuterol rescue nebulizer
- You will **continue to use all of your other COPD medications**
- 2 telephone calls for follow-up visits will be scheduled approximately 1 and 2 months after visit 2
- You will be scheduled to return to the research center in approximately 3 months for visit 3

Tests and Procedures during the Study (Visit 3)

You will be expected to do the following things during the study:

- You will need to come to the clinic for scheduled visits.
- Tell the study staff about any changes to your health or changes in your medications.
- Tell the study staff if you want to stop being in the study at any time.
- **Pregnancy test:** If you are a woman and can become pregnant, a urine test will be done to see if you are pregnant.
- **Questionnaires:** You will be asked to complete 4 health related questionnaires
- **Vital signs:** will be performed while sitting/resting
- **Inhalation tests:** you will be tested to see how well you are able to inhale or breathe in. This will be done after receiving Albuterol eMDPI study drug
- **Breathing tests:** you will be tested to see how your lungs are working. This will be done after receiving Albuterol eMDPI study medication.
- You will take all of your regularly scheduled maintenance COPD medications after the breathing tests are complete
- You will be provided with a folder containing paper copies of 3 short questionnaires to be completed at home on a weekly basis, along with instructions and stamped envelopes for questionnaire return upon completing each week
- Return the 3 Albuterol eMDPI Study Inhalers dispensed at visit 2
- 3 additional Albuterol eMDPI Study Inhalers will be linked to your App and smartphone connectivity and internet access to the Digihaler Dashboard will be established
- You will be re-instructed on how to access and use the Albuterol eMDPI study inhalers and App
- You will remain off of your regular albuterol rescue inhaler and minimize use of your albuterol rescue nebulizer
- You will **continue to use all of your other COPD medications**
- 2 telephone calls for follow-up visits will be scheduled approximately 1 and 2 months after visit 3
- You will be scheduled to return to the research center in approximately 3 months for visit 4

Tests and Procedures during the Study (Visit 4)

You will be expected to do the following things during the study:

- You will need to come to the clinic for scheduled visits.
- Tell the study staff about any changes to your health or changes in your medications.
- Tell the study staff if you want to stop being in the study at any time.

- **Pregnancy test:** If you are a woman and can become pregnant, a urine test will be done to see if you are pregnant.
- **Questionnaires:** You will be asked to complete 3 health related questionnaires
- **Vital signs:** will be performed while sitting/resting
- **Inhalation tests:** you will be tested to see how well you are able to inhale or breathe in. This will be done after receiving Albuterol eMDPI study drug
- **Breathing tests:** you will be tested to see how your lungs are working. This will be done after receiving Albuterol eMDPI study medication.
- You will take all of your regularly scheduled maintenance COPD medications after the breathing tests are complete
- Return the 3 Albuterol eMDPI Study Inhalers dispensed at visit 2
- You will resume use of your regular albuterol rescue inhaler
- You will **continue to use all of your other COPD medications**
- A final telephone call for follow-up will be scheduled for approximately 1 week after visit 4

Telephone Contact Visits

- You will be contacted by telephone at scheduled intervals in between visits 2-4 at monthly intervals
- During each telephone call:
    - Any changes in health history, health care contacts, changes in medications, any healthcare utilization and any safety issues will be reviewed
    - Paper questionnaires submitted over the prior month will be reviewed
    - Reminders and instructions will be given

Worsening of your COPD: Throughout the study, you will be asked to contact the research center if you have had any flare-ups of your COPD (COPD exacerbation) or any changes in your COPD medications by your primary physician.

After the study:

One week after you have finished taking the study drug, you will be contacted by telephone and asked about any medical problems you may have experienced since stopping the study drug and any new medications you may have started.

How will being part of this study affect my lifestyle?

Please keep in mind how the study tests and visits described here will affect your work and family schedules. Consider if you need transportation to and from the clinic. You may find that these tests and visits need some planning. Some tests may be uncomfortable. Ask the study doctor or nurse if you have any questions about the tests and procedures for the study.

You will need to allow enough time for phone calls from study staff, approximately 30 minutes for each.

You will have to stop taking your routine rescue medications.

You must inform the study doctor as soon as possible when starting any new medications for the duration of the study. You should not take the following medicines during the study:

- Any rescue inhaler medications other than the study drug.
- Any other investigational drug

As part of this study **you should**:

- Follow the directions given to you by the study staff
- Tell (or call) study staff if the symptoms of your COPD get worse over a period of 1 day (24 hours)
- Tell the study staff about all of the medicines you are taking now
- Not allow anyone else to use your study drug
- Take your study drug as instructed
- Tell the study staff if you are taking any new medicines while you are in the study
- Bring with/return your study drug at each visit. The study staff will confirm that you have taken the study drug correctly. You will be asked about any missed doses by the study staff.
- Keep your scheduled appointments
- Ask the study doctor about taking any new medicine
- Not be part of any other research study while participating in this study
- Tell the study staff about any changes to your health and any visits to other doctor's office, emergency room or hospitals
- Tell the study doctor or study staff if you want to stop being in the study at any time

As part of the study and in order to perform the breathing tests at the study visits **you should not**:

- Smoke for 1 hour before each breathing tests
- Drink any beverage with a high caffeine content such as tea, coffee, or soda for 2 hours before your breathing tests
- Take your study medication the morning of your scheduled clinic visit until the study staff instructs you to
- Take the quick rescue medicine (albuterol) for 6 hours prior to each breathing test

Pregnancy: Women who can get pregnant will have a pregnancy test at study enrolment and will need to use birth control while in this study. Check with the study doctor about what kind of birth control methods to use and how long to use them.

6.0 Disallowed Medications

The following medications are disallowed throughout the study. Please ask your study doctor or the study staff if you have additional questions about this section:

- The use of other inhaled rescue medication products is prohibited during this study except for the use of nebulized albuterol, as needed, in a severe acute worsening of COPD unresponsive to Albuterol eMDPI study medication
- You may continue the use of other COPD and non-COPD medications as advised by your doctor. You should talk with the study doctor about these medications.

7.0 Risks

Unforeseen Risks: All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. Albuterol has been used for several decades with a very well-established safety profile, and Albuterol eMDPI is an approved product in the US, bearing the name ProAir Digihaler. For the proposed study, the App and Dashboard are used in conjunction with the approved product (ProAir Digihaler) and should present no additional risk to study subjects.

Pregnancy: There also may be other side effects or discomforts that we are not aware of, including to a developing baby in the womb (fetus or embryo) or nursing infant. Some drugs cause premature (early) birth or birth defects.

It is unknown whether exposure to Albuterol eMDPI has an effect on milk production or presents potential risks to the infant.

8.0 Possible Side Effects

We do not know all the possible side effects of the study drug. Like all drugs, the study drug can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some people may experience serious side effects and may require treatment.

The following side effects have been experienced by other people who have taken the study drug.

Side Effect	**Adverse (bad) Reactions experienced by Adults and Adolescent Subjects in the PROAIR RESPICLICK Group in three 12-Week Clinical Trials**
Back Pain	common
Pain	common
Viral Gastroenteritis (Stomach Flu)	common
Sinus headache	common
Urinary Tract Infection	common

The table above includes the following terms:

- Very common: may affect more than 1 in 10 people
- Common: may affect up to 1 in 10 people
- Uncommon: may affect up to 1 in 100 people
- Rare: may affect up to 1 in 1,000 people
- Very rare: may affect up to 1 in 10,000 people
- Not known: frequency cannot be estimated from the available data

You will be monitored for the duration of your time in the study and you should tell your study doctor about any changes in your health while taking part in the study.

Spirometry risks:

You may have some coughing or experience some shortness of breath after the spirometry test, but there is no pain associated directly with these tests.

Discomfort with questionnaires:

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

6 Minute Walking Test Risk

The object of this test is to walk as far as possible for 6 minutes. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. There is also a chance you could fall while performing this test.

9.0 Potential Benefits

The possible benefit you may experience from the study drug is that your COPD might be better controlled. There is no guarantee that you will benefit from being in this research. Your COPD might not

get better or may even get worse while you are in this study. However, by taking part in this study you may contribute to obtaining new information that may benefit other people with COPD in the future.

10.0 Compensation/Cost

The study drug will be provided to you at no charge and you will not be charged for any procedure performed for this study. The Funding Organization (Teva Branded Pharmaceutical Products R&D, Inc.) has a contract with the study doctor/study center who will receive payment for taking part in this study.

You will be paid up to a total of $300.00 if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $50.00 for Visit 1
- $100.00 for Visit 2
- $75.00 for Visit 3
- $75.00 for Visit 4

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid after completing each visit

If you have any questions regarding your compensation for participation, please contact the study staff.

11.0 Compensation for Injury

All therapies provided within this research study are fully approved commercial products available for the care of COPD in the United States. Pulmonary Research Institute of Southeast Michigan has no plans to pay for or compensate you for any illness or injury potentially associated with participation in this study. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

12.0 Voluntary Participation/Withdrawal

You can choose whether or not you want to take part in the study and you can change your mind at any time. If you decide not to take part or stop taking part after the study has started this will not affect your future treatment and care. Refusal to participate or discontinuation at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled. If you want to withdraw from the study, you should contact your study doctor or study center staff.

Your study doctor may also decide that you should no longer take part in the study if it is in your best interests or if you do not follow the instructions you receive for taking part in the study. The study doctor, Funding Organization, Ethics Committee (Advarra IRB) or Regulatory Authority may also decide to stop the study at any time for any reason.

If you decide to no longer take part in the study, or your study doctor decides you should no longer take part you will be asked to attend a last visit to ensure it is safe for you to no longer be monitored by the study doctor. You will not take part in the study after withdrawal. Your study data until withdrawal may be used for analysis.

If there is new information available on the study drug during the study, which might make you change your mind about taking part in the study, you will be informed of this new information without delay.

13.0 Procedures for Termination of Study Participation

Your study doctor or the Funding Organization can stop study treatment at any time, for any reason without your consent. Some reasons your treatment may be stopped are:

- You have worsening disease
- You are unable to tolerate the study treatment due to problems or side effects even though the

dose was decreased
- You experience a general serious decline in your overall health
- You choose not to continue with the study treatment for any reason
- You develop another illness that in the view of your study doctor prevents continuation of this study treatment
- New information about the treatment becomes available and this information suggests the treatment would not be effective or safe for you
- Funding Organization ends the study
- You become pregnant
- You do not consent to continue in the study after being told of changes in the study that may affect you

You will be told in a timely manner about new information from this study or other studies that may affect your health, welfare, or willingness to stay in this study. If you decide to stop participating in the study, we encourage you to talk to your study doctor first. Your study doctor will discuss further options for appropriate treatments with you and continue to treat you with the best means available. Even if you stop treatment early, we would like to continue to collect data concerning your disease progress and follow you for health status.

14.0 Alternative Treatments

Your study doctor will discuss with you other treatments, including the benefits and risks, which are available for COPD.

15.0 Whom to Contact About this Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Drive, Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050600.

16.0 Confidentiality and Data Protection

It is very important that your personal and medical information stay confidential and secure. PRISM and Teva will protect your information in accordance with current law.

- Your study information will be labeled with a code number (for example, 1234782). It will not include your name or address. The study doctor will have the link between your name and the code number.

- The link between your name and the code number will not be shared. Only a code number and coded information will be sent to Teva.

During the study, the study doctor will collect certain personal data about you on behalf of the study site and/or Teva Branded Pharmaceutical Products R&D, Inc. (the Funding Organization). This will include data about your health (for example, your medical history, test results, as well as other information about your physical and mental health condition), including data collected on your inhaler (inhalation data) along with other data relating to you, such as your name, date of birth, gender, height, weight and other categories of information pertinent to this study. Your inhalation data is transmitted from your inhaler to the App and further transferred to a data cloud solution. Your study doctor can view your inhalation data on the data cloud solution through a dashboard interface. The collection of all of this data/information is essential if you wish to participate in this study.

The study doctor and institution will process, use, and may disclose personal data about you, including personal health data, for the following purposes: (i) to enroll you in the study; (ii) to contact you and communicate with you as part of the study; (iii) to carry out the study and for such other purposes as set out in the study plan; (iv) for data aggregation and statistical reporting purposes; (v) to comply with all legal, administrative and regulatory requirements including reporting and submitting information to health and other regulatory, governmental, judicial and law enforcement authorities; and (vi) for other uses/disclosures required or permitted by applicable laws or regulations. Personal data about you will be kept confidentially by the study doctor and his/her medical institution.

Before the study doctor sends personal data about you outside of the hospital/clinic/research setting to any of the parties described above, your name and other information that can identify you will be replaced by a code (for example, your initials and a random alphanumeric code). This personal data is called coded personal data. Only the study site personnel (including the study doctor) will have access to the code that can be used to identify you.

By signing and dating this form, you consent to allow the study doctor (and institution) to process personal data about you (including the inhalation data) for purposes of the study, and to disclose personal data about you to the following parties, or otherwise allow them to access the study doctor's records, in order for those parties to verify the scientific integrity of this study and to ensure that it conforms to the study plan (as required or permitted by law):

- The Funding Organization (Teva Branded Pharmaceutical Products R&D, Inc.)
- Third parties with whom the Funding Organization may collaborate in the development and marketing of Albuterol eMDPI
- The institutional review board and/or independent ethics committee(s) overseeing this study
- Auditors
- Authorized regulatory or government authorities (such as the FDA)

The Funding Organization will use coded personal data about you:

- For the purpose of this study
- To meet the Funding Organization's obligations in relation to the conduct of this study, the safety of its products and other administrative, regulatory and legal obligations
- To support the Funding Organization's product registrations and approvals.

You may have certain rights under applicable law, for example, to request access to personal data being processed about you, including its purposes and any categories of third-party recipients. You may also request correction of any personal data about you which is wrong or incomplete. You may also have a right to restrict the use of information about you, to have it deleted, or to have certain data returned,

but these rights may be limited by the law. Please contact the study doctor to exercise your rights or if you have any questions regarding this (contact information found on page 1). However, note that your right to access personal data about you may be suspended until the conclusion of the study.

The Funding Organization will keep and process your coded personal data about you for a minimum period of fifteen years, unless a longer period is either necessary to achieve the purposes stated in this document or is prescribed by applicable law. For example, this period can be longer if coded personal data about you has been used in submissions to competent authorities to obtain a product approval.

In the event of any publication or presentation resulting from the study, no personal data about you will be disclosed (and your identity will remain confidential). The Funding Organization may completely anonymize personal data about you (for example, by deleting the code), in order to engage in further research, to enable required or requested publication of study records, and for other related purposes.

You understand that collection, use, and transfer of personal data about you as described in this form is based on your consent and that if you do not consent, you will not be permitted to participate in the study. You may withdraw your consent at any time by writing to the study doctor at the address listed on page one of this consent form. In this case, you will no longer be able to participate in this study. No additional personal data will be collected about you, but the personal data that was already collected may still be used by the Funding Organization to meet its legal and regulatory obligations. The Funding Organization's use of information about you prior to your withdrawal of consent remains lawful.

Your permission for the study doctor and the Funding Organization to use and disclose personal data about you will expire in 50 years unless you withdraw it. Once personal data about you is disclosed by the study doctor and the Funding Organization, it may no longer be protected by federal law and may be subject to redisclosure by the recipient.

Subject Informed Consent Form

Before making the decision regarding enrollment in this study you should have:

- Discussed this study with the study doctor
- Reviewed the information in this form
- Had the opportunity to ask any questions you may have.

Your signature and date below mean that you have received this information, have asked the questions you currently have about the study and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Study Subject (if subject is age of majority or older):

By signing and dating this consent form, you indicate that you are voluntarily choosing to take part in this study.

_____	_____	__ : ___	_____
Signature of Subject	Date	Time	Printed Name

Person Explaining the study: Your signature and date below means that you have explained the study to the study subject and have answered any questions he/she has about the study.

_____	_____	___ : ___	_____
Signature of person who explained this study	Date	Time	Printed Name

Authorization for Use or Disclosure of Health Information

It is very important that your personal and medical information stay confidential and secure. By signing and dating this document, you authorize the study doctor and staff to use this information in conducting the study, and to provide access to or copies of this information to the Funding Organization (Teva) and their representatives as described below.

PRISM will protect your information in accordance with current law.

The following sections provide a specific description of how your information will be used and disclosed if you participate in this research study. By signing and dating this consent form, you are authorizing such access.

Your study records may include personal information (such as name, address, etc.), which could be used to identify you. However, no PHI will be transferred to PRISM that could identify you is called "Protected Health Information" (or "PHI").

If you sign and date this form and participate in the study, the study personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- PRISM or Teva (funding organization) to collect or review study data for verification of study procedures and/or adverse event reporting
- Advarra IRB. The Institutional Review Board (IRB) that oversees the research study at your site
- Government regulatory agencies including the FDA

PRISM may:

- Keep your coded information electronically and analyze it by computer to find out what the study is telling us. This may be done by a third party, in which case PRISM will ensure that the third party is required to keep your data secure
- Share the information with regulatory agencies that approve new medicines
- Share the information with people who check that the study is done properly (like the institutional review board)

Personal and medical data collected during the study may be moved, stored and used in the USA or another country where Teva or those working with Teva work.

Use of this information may take place in countries with lower data protection rules than the USA. Teva will make sure that if your data are moved to another country, it will still be treated as stated in this form.

This authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You may withdraw your authorization at any time by sending a written request to the study doctor at the address listed on page one. If you withdraw your authorization for use of your personal information,

you will no longer be able to continue in the study. However, all the information collected before you left the study, or at any follow up visit, will still be used as set out in this form.

At any time, you may ask the study doctor to see your personal information and correct it, if necessary. In some circumstances, you may not be able to access your study information while the study is ongoing. However, the study doctor will share any important medical information if it is relevant to your health during the course of the study.

You should know that once identifiable medical information about you is given to someone that is not a health care provider, it is not protected by the US federal privacy rules called the HIPAA Privacy Regulations.

You will receive a copy of this Authorization after you have signed and dated it.

_____ _____ (dd/mmm/yyyy)
Signature of Subject Date

_____
Printed name of Subject

_____ _____ (dd/mmm/yyyy)
Signature of study staff obtaining authorization Date

_____
Printed name of study staff obtaining authorization