Subject Information

Protocol Title: PeRson EmPowered Asthma REief Study (PREPARE)

Principal Investigator: **Elliot Israel, MD**

Site Principal Investigator:

PREPARE Clinical Study Site:

Description of Subject Population: Black and Hispanic adults ages 18-75 years old who have asthma

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

[Name of site] is **[description of site]**. We are doing this research as part of the Patient Empowered Asthma Relief Study (PREPARE), which is supported by the Patient Centered Outcomes Research Institute (PCORI).

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

A description of this study will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. We will never include any information on this Web site that can identify you. The Web site will include information on how the study is to be done and at the end, a summary of the results. You can look at this website at any time.

Why is this research study being done?

This study tests different ways to deal with asthma symptoms and to see the best way to prevent people with asthma from going to an emergency room or hospital, or needing to use oral steroids for an asthma attack.

We are asking you to be in the study because you have asthma, take daily asthma medicines and are either African American/Black (AA) or Hispanic or Latino (H/L) adults. Researchers have found that African Americans (AA) and Hispanic/Latino adults are impacted more often by

symptoms of asthma than other groups. We want to see if the methods used in this study are able to help reduce your asthma symptoms over time.

We will enroll 1200 people from up to 20 sites around the country.

The Patient Centered Outcomes Research Institute (PCORI) is paying for this study to be done.

How long will I take part in this research study?

Your participation in the study will last about 15 months.

During that time you will make only one study visit to **insert SITE NAME** when you sign up for the study. That visit will be with a research staff person, not a doctor or nurse. You will watch a video explaining what this study is about, and you will also be asked to complete some questions. This visit may take about 60 to 90 minutes.

For 15 months after your initial visit, we will ask you to answer questions about your asthma, asthma medicines and how your asthma is affecting you each month. These can be answered on your smart phone, or if you prefer you can also complete these questions online with a computer, or you can be sent the questions on paper by mail.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do anything else.

During the study, researchers will also be looking at your medical records, to find out about your visits to your clinic, urgent care, emergency room, or hospital for your asthma. The research team will also look at prescriptions for oral steroids for your asthma, so that we can better understand how your asthma is affecting you and your health.

There is one in-person study visit with the research staff person. At the visit, you will be told about the study and asked to sign this consent form. Before you sign the consent form, you will watch a short video (about 7 minutes) about the study to help you decide if you want to join.

If you decide to take part in the study and you have signed the consent form, we will assign you by chance (like a coin toss) to the PARTICS group or the usual standard of care group. You will have a 1 in 2 chance of being assigned to the intervention group PARTICS. You will have a 1 in 2 chance of being assigned to the control group usual standard of care.

The PARTICS group will learn to take an extra medicine whenever they need their quick reliever or “rescue” medicines. The usual standard of care group will continue using their rescue medicine as instructed by their doctor or nurse. In addition, both groups will get more education about asthma that you may not get from your regular doctor/nurse.

After you are put into one of the groups you will be asked to answer some questions. This may take up to 60 minutes to finish. The questions ask about you, about your asthma, and about your asthma medicines.

Regardless of the study group you are put into, we will also collect a gas in your breath for analysis, called nitric oxide. This collection will involve taking a deep breath and exhaling slowly into a machine which will measure the amount of the gas.

When you complete the questions, you will watch another 10-minute video that talks about what you will be asked to do in this study. This video is specific to the group you are assigned. After that the research staff person will answer your questions, give you a pouch for your inhaler (s), a money card, and watch you use your asthma inhalers to see if you are having any problems.

If you are in the group that gets the extra medicine, it will be given to you for free. You will be able to get free refills of that extra medicine for the next 15 months, while you are in the study.

After you enroll, you will receive a phone call from a study staff member within a month to ask you a few questions about getting the first survey and filling it out.

Each month for the next 15 months, you will be asked to answer a short set of questions (that are different from the surveys during the first visit). This monthly survey will take about 10 minutes and can be done on your smart phone or a computer. If you don't want to do the survey on a smart phone or computer, you can choose to have someone call you to ask you the questions over the phone, or we can mail the questions to you on paper with a postage paid return envelope. You can choose the way that works best for you. If you choose to fill out your survey by smart phone or computer, you will receive an email with a link to click on that will take you to the survey. The questions ask about any problems you had that month with your asthma. They will ask if you had to take extra asthma medicine or visit your clinic, urgent care, an emergency room, or hospital for your asthma.

If you tell us you had problems with your asthma during the monthly survey, we will review your medical records to get more information about your asthma problem. We may also call your doctor/nurse, or you, to ask more about the asthma problems.

For each monthly survey, you will receive text reminders if you choose to receive them. Leading up to the day that your survey is due, we will text you on day 26, 28, and 30 to remind you to fill out your short monthly survey.

At the end of the 15-month study, we will get information from your medical record that tells us about all of your asthma visits, any changes in asthma medicines, and how often you refilled all of your asthma medicines.

What are the risks and possible discomforts from being in this research study?

Adding a medicine. If you are in the group with the extra medicine, you will be shown how to use 2 medicines whenever you would usually take your 1 quick relief or rescue medicine. During the study, people in this group will use 2 medicines every time they need a quick relief medicine. The additional medicine is **not** experimental. It is a commonly used asthma medicine called beclomethasone dipropionate, or QVAR®. Beclomethasone dipropionate is a FDA-approved inhaled corticosteroid.

Inhaled corticosteroids are the most commonly used medications for asthma. You are part of this study because you already have been regularly taking an inhaled corticosteroid to control your asthma, even if that inhaled corticosteroid was not necessarily Beclomethasone dipropionate/QVAR®. QVAR is not currently used when quick relief is needed. You will continue to take all of the other medicines your usual doctor/nurse has given you and you will go to them for all your asthma care.

Inhaled corticosteroids generally involve very little risk especially as compared to steroids taken by mouth or injections such as prednisone or Medrol. The most common side effects of an inhaled corticosteroids such as QVAR are throat irritation, hoarseness, and/or yeast infection of the mouth or throat (known as thrush).

In some patients, taking very high doses of QVAR has a small risk of thinning your bones (osteoporosis), increasing the chances of developing glaucoma or cataracts, or weakening your body's ability to handle stress due to other medical conditions like infections. These side effects are usually seen when corticosteroids are taken by mouth, not inhaled, as you will use it in this study, and have been mostly reported in children.

If you are using more than 2 canisters a month of QVAR that we provide, we will notify your provider and ask them to be in touch with you.

You and your doctor or nurse will make all other decisions about asthma care and medicines. If you think you may be experiencing any effects due to using inhaled corticosteroids (like QVAR), you should discuss it with your doctor/nurse.

If you are in the usual standard of care group, you will be shown a new way to help keep your rescue or quick relief medicine, like Albuterol, with you all of the time. This will not involve any increased risk. You will continue to take all of the medicines your doctor/nurse has given you. You will continue to see your doctor/nurse for all your asthma care. You and your doctor or nurse will make all other decisions about asthma care and medicines.

Risks for study activities: During this study, you will be answering questions and letting us look at your medical records to review your asthma care. There is a small risk of loss of privacy about your asthma care. However, we have very strict ways to collect data and keep it stored in a safe place using only a study number and not your name. Your name will never be used in any reports or publications from this study. There are no known risks associated to collecting gas in your breath (nitric oxide gas).

When you click on the email link to bring you to your survey, you have the option of either having to enter a login and password, or being taken directly to the survey. If you want to directly link to the survey, you will need to check a box after you create an account in the survey system. If you choose to be taken directly to the survey, the email is "unencrypted" or not secure, and could result in the unauthorized use or disclosure of your information or that you have asthma. No other personal information will be available on this survey. If you want to receive communications by unencrypted email despite these risks, HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to this research study only.

Pregnancy and fetus: There is no foreseeable impact of this research on the fetus. To be in this study you must already be taking the same type of asthma maintenance medicine.

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or serious, and can even result in death in some cases. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call 911 immediately.

We will try to keep sensitive information related to the study out of your hospital electronic health record. However, information about serious side effects, serious allergic reactions, or important, unexpected results might become part of your records at **insert HOSPITAL**. The central pharmacy we use for this study, Shared Solutions Pharmacy, keeps copies of all drug dispensing information as required by law.

What are the possible benefits from being in this research study?

People in both groups may have some benefit from being in this study. Learning more about your asthma and how to keep your rescue medicine in a pouch to take everywhere with you may be helpful.

People in the group that learn to use 2 medicines when they need rescue or quick relief may have fewer asthma attacks. They may not need as many extra visits to the clinic, urgent care, emergency room, or hospital or need to take oral steroids for the asthma attack.

If the pouch and extra rescue medicine help, the results will be shared widely. This may help improve care and reduce asthma problems for all Black or African American and Hispanic/Latino adults with asthma.

What other treatments are available for my condition?

Usual asthma standard of care will be available to you. Usual standard of care includes using your asthma medicines as instructed by your doctor/nurse. This may include taking your

"maintenance" or daily medicine inhaler every day and using your "rescue" or quick relief inhaler when you are having an asthma attack.

You will continue with your usual asthma care from your usual doctor or nurse. You will be able to continue getting any type of care that is currently available to you. You and your doctor or nurse can make any changes to any of your current asthma medicines or add any new ones that you need.

Can I still get medical care within insert SITE NAME if I don't take part in this research study, or if I stop taking part?

You will still be able to get medical care with your usual doctors or nurses whether or not you decide to be part of this study. Your decision won't change the medical care you get from your usual doctor/nurse now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn any new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you decide to join this research study, but then want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also tell your usual doctor/nurse and help arrange for you to see them, if needed.

Will I be paid to take part in this research study?

You will be paid $50 for completing the enrollment visit and $20 for answering each monthly questionnaire for 15 months. If you have to pay extra to answer the monthly questions on your smart phone or a computer, we will pay $5 per month for answering those questions about asthma problems. If you choose to receive the monthly questionnaires by mail, a return postage paid envelope will be provided. The total you will be paid is $425 if you enroll, complete 15 monthly questionnaires, and are charged extra to use your smart phone or computer to answer the monthly questionnaires.

In addition, if you fill out your survey within 6 days of receiving your first reminder, you will be entered into a monthly lottery for a chance to win one of three $100 prizes. The winners will be alerted by phone and everyone in the study will be told which states had the patients that won.

You will be paid through a money card called a"ClinCard." This ClinCard works like a gift card. The money on the card can be spent at any store that takes credit or debit cards. If you complete the enrollment visit, you will receive the ClinCard and $50 will be put on the card within 2 days. For each monthly survey you complete, $20 will be added to the card within a few days. It is important to keep the card as long as you participate in the study.

What will I have to pay for if I take part in this research study?

There is no cost to you for any of the study activities or for the extra rescue medicine if you are in that group. You will continue to be responsible for all of your usual asthma and other care including visits to the clinic, urgent care, emergency room or hospital and all of your usual asthma medicines through your usual insurance or by self-pay as you have always done.

TEVA Pharmaceutical company is providing the extra medicine for the PARTICS/intervention group at no cost.

Charges for any ongoing or routine medical care you receive outside this study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study staff.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

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

If I have questions or concerns about this research study, who can I call?

You can call us with questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[Insert Name and academic degrees] is the person in charge of this research study. You can call him/her at **[Insert phone number] [insert when person is available M-F 9-5 or 24/7]**. You can also call **[Insert name(s) of local IRB or institutional contact]** at **[Insert phone number(s)] [insert when each person is available M-F 9-5 or 24/7]** with questions, concerns or complaints about this research study.

If you have questions about the scheduling of appointments or study visits, call **[Insert Name(s)]** at **[Insert phone number(s)]**.

If you would like to speak to the research staff at the Coordinating Center for this PREPARE study at the Brigham and Women's Hospital in Boston Massachusetts, please contact Dr. Elliot Israel, the Principal Investigator at 617-732-8110 and/or Nancy Maher, Project Director, at 857-307-3892.

If you want to speak with someone **not** directly involved in this research study, please contact the PREPARE Central IRB (the Partners HealthCare System Human Research office) in Boston Massachusetts. The Central IRB is the ethics board that oversees the research conducted by PREPARE. You can call them at **857-282-1900.**

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this study, we will collect information that could identify you such as your name and that you have asthma. This will only be used for purposes of this study and never given to anyone who is not part of this study except those required by law to be able to see this information. Your name will never be part of any report or published

In this study, we may collect health information about you from:

- Past, present, and future medical records through the end of the study (16 months)
- Study questions or phone calls to you.

Who may see, use, and share your identifiable health information and why they may need to do so:

- Investigators and other research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research

- Other researchers and medical centers that are part of this PREPARE study (PREPARE Study Sites) and their ethics boards
- Partners HealthCare System, Inc. ("Partners"), Brigham and Women's Hospital and Massachusetts General Hospital ("MGH") ethics boards (the PREPARE Central IRB)
- BWH (the PREPARE Coordinating Center)
- American Academy of Family Physicians National Research Network staff (the PREPARE Data Coordinating Center and Site Coordination Center)
- Duke Clinical Research Institute study staff who oversees the data analysis
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other: Shared Solutions and other study pharmacies that will be dispensing the asthma drug to you as part of this PREPARE study.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside our institution, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

Subject Information

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form, or had this consent form ready to me.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Person Obtaining Consent:

Statement of Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Person obtaining consent	Date	Time (optional)

Consent Form Version: **09/08/2017**