H-34115- THE HOUSTON HOME-BASED INTEGRATED INTERVENTION TARGETING BETTER ASTHMA CONTROL (HIIT-BAC) FOR AFRICAN AMERICANS

Background
In this form the term "you" means you and the term "we" means the investigators.

You are invited to take part in a research study because you are an African-American adult who has poorly controlled asthma. Please read this information and feel free to ask any questions before you agree to take part in the study.

This research will be conducted through Baylor College of Medicine and affiliated hospitals. All research projects that are carried out in this institution are governed by the rules of Baylor College of Medicine, each affiliated hospital, and the Federal Government. Please ask the study investigator to explain any words or information that is not clear to you.

Before you learn about the study, it is important that you know the following:
1) Whether or not you will take part in this study is entirely up to you.
2) Even if you agree to take part, you may withdraw from the study at any time.
3) If you decide not to be in the study, or if you decide to withdraw from the study at any time, you will not lose any of your benefits (like, for instance, routine medical care).

Once you understand the study, and if you agree to take part in it, you will be asked to sign this consent form, and you will be given a copy of the form.

This research study is sponsored by Patient-Centered Outcomes Research Institute.

Purpose
The purpose of this research study is to improve the health of African-American adults who have poorly controlled asthma.

Procedures
The research will be conducted at the following location(s):
Baylor College of Medicine and HCHD: Harris County Hospital District.

We expect about 300 adults who live in Houston to take part in the study. The study will last one year.

The study will compare home visits to usual care. Participants in the usual-care group will receive the usual kind of instructions, appointments, and information that a person gets from their healthcare provider, along with improved asthma education in the clinic. The home-visit group will get usual care plus home visits by an environmental hygienist and a community health worker or nurse (the home-visit team). During these visits, the team will come to your home to show you how to monitor and control your asthma symptoms. They will help you identify things that may make your asthma worse, and teach you ways to reduce these "asthma triggers." They may also work with you to make your home safer.

You will be assigned by chance (like the flip of a coin) to see which group you will be in.

Study staff has confirmed that you have asthma and are eligible to take part in this study. You will be

asked questions about your home life and medical condition. You may refuse to answer any questions or items in any test, questionnaire, inventory, or interview. This will not keep you from taking part in the study.

You will first be asked to complete a baseline visit in the Environmental Health Clinic.

ENVIRONMENTAL HEALTH CLINIC: BASELINE VISIT
The visit will last about 2.5 hours. At this visit, we will ask you questions about environmental exposures in your home. We will ask whether you have pets; what types of appliances, heating and cooling systems your home has; and if anyone smokes in the home. We also want to know about your diet, lifestyle, hobbies, and occupation. Everyone will receive improved asthma education during their visit to the Environmental Health Clinic.

GROUP A: ENHANCED USUAL CARE
If you are in this group, you will receive usual care in the asthma clinic, plus enhanced asthma education. You will also receive phone calls at months 3, 6, and 9 to assess your asthma control, see how you are feeling, verify your contact information, and answer any questions you might have. At the end of the year, you will have the option to receive additional study services from an environmental hygienist and community health worker or nurse (home-visit team). The services include a home environmental assessment and up to two follow-up home visits. During the home visit(s), the team will work with you to develop a plan to control your asthma better. You will receive special tools and services that may make your home healthier. The home assessment and home visit(s) will each take up to 2 hours.

GROUP B: ENHANCED USUAL CARE PLUS HOME VISITS
If you are in this group, you will receive usual care in the asthma clinic, plus enhanced asthma education. You will also receive a home environmental assessment at the beginning of the study. Then there will be up to four follow-up home visits (at months 2, 5, 9, and 12) from an community health worker and environmental hygienist or nurse. At the fifth and final home visit, we will repeat the home environmental assessment.

The home visit team will walk around your home with you to look for things such as mold or pests that may make your asthma worse. They will ask you about things you might do to get rid of things that can set off asthma. During the home walk around, staff may take pictures to document housing conditions (these will not include people). Pictures will be used for training purposes, to help evelop a plan for you, and to describe the project. If you do not want pictures to be taken, you are free to say so and we will NOT take pictures.

While at your home, the community health worker or nurse may ask you to do a breathing test. This requires you to blow out as hard and as long as you can into a small machine (spirometer) to measure your breathing. The results of this test will be placed in your medical record and will be given to your asthma healthcare provider.

The study team will work with you to develop a plan to help you control your asthma better and to

encourage you to actively carry out the plan. Following this plan may take a couple of hours or more of your time each week. The home-visit team will bring you information and tools to help you with your plan. The home-assessment visits will each take about two hours. The other home visits will last about an hour.

You will receive a phone call at month 6 to assess your asthma control, see how you are feeling, and answer any questions you might have.

ENVIRONMENTAL HEALTH CLINIC: FOLLOW-UP VISIT, EXIT INTERVIEW
At the end of one year, everyone will return to the Environmental Health Clinic for a follow up and exit interview. The research project will be over after you complete this exit visit. You will be asked to do a breathing test. This requires you to blow out as hard and as long as you can into a small machine (spirometer) to measure your breathing. The results of this test will be placed in your medical record and will be given to your asthma healthcare provider. This visit will take about 1.5 hours.

Taking part in research is voluntary. You may choose not to take part. You may withdraw from the study at any time, without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect the care that you receive. All the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Participation will be kept confidential, within the limits of the law. A copy of this signed consent form will be put into your file. Your name will be separated from any information collected about you and your house. No names or other identifying information will be used in any publications or presentations that may result from this study. Access to study data that identify subjects will be limited to the project, your medical provider, and the funding agency (the Patient-Centered Outcomes Research Institute (PCORI)). Information from subjects (such as questionnaires) will be kept until February 2022.

OPTION TO CONSENT TO BLOOD SAMPLE COLLECTION

If you agree to take part in this research study and sign the consent form, we would like to collect about two teaspoons of blood from you. This is optional. If you are having other blood work done at the same time, we will collect the sample when they draw blood for your routine tests.

The purpose of collecting this blood sample is to create a bank of blood samples for future researchers whose studies are approved by our research review committees. These studies can help develop new knowledge about asthma in African Americans and how to treat it more effectively. The blood we take might be stored for a long period of time or indefinitely, in a laboratory at Baylor College of Medicine. Your samples will be kept until they are used up or until you withdraw your consent. If you withdraw your consent, we will destroy your remaining samples. Samples will not be sold.

We might use your sample to help develop new ways to treat asthma. Researchers may study the amount of certain proteins in your blood or they may look at the sequence of your genes to find genes linked with disease. Researchers could find changes in genes that make disease worse or better. The

results of research, including gene sequences, may be stored in a way that the public can access. Some limited health information may also be stored with the results, like your age or gender. This may help researchers all over the world find genes or changes in genes related to asthma and learn why people respond to treatment differently. No identifying personal information (like your name or address) will be stored with the results. It is also possible that your sample will not be used in any research.

Your participation is voluntary and you may refuse to participate or may discontinue your participation AT ANY TIME, without penalty, loss of benefits, or change in your present or future care. If you decide now that your blood may be kept for research, you can change your mind in the future. All you have to do is tell us (preferably in writing), and any of your blood that remains will be discarded. You may contact the Principal Investigator in writing with this request (One Baylor Plaza, Suite 011D; MS: BCM296; Houston, TX 77030-3411 or e-mail environmentalhealth@bcm.edu).

Everyone's genes are a little different. This means that there is a very small chance that someone could trace the genetic information back to you. This chance could grow as genetic technology grows. Researchers who use your blood samples must protect your privacy. We will tell you if we learn anything that may affect your willingness to stay in the study.

While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. There are both state and federal laws that protect against genetic discrimination by employers or insurance companies, but potential risks may remain.

The decision of whether or not to allow this blood to be drawn and allow genetic and clinical information about you to be gathered and released to scientific information sources is completely up to you. There will be no penalty to you if you decide not to allow your information to be used. Your decision will in no way affect your taking part in this research.

Please indicate by initialing below whether or not you agree to allow us to collect the blood sample and to release the de-identified genetic and clinical information into scientific information sources:

Yes_____ I consent

No_____ I do not consent

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and HCHD: Harris County Hospital District to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, HCHD: Harris County Hospital District, and PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI) and their representatives.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine and HCHD: Harris County Hospital District are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and HCHD: Harris County Hospital District to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine and HCHD: Harris County Hospital District maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine and HCHD: Harris County Hospital District to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine and HCHD: Harris County Hospital District.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI) and their representatives, regulatory agencies such as the U.S. Department of Health and Human

Services, Baylor College of Medicine, and HCHD: Harris County Hospital District may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Winifred J. Hamilton, PhD
Environmental Health Service
Baylor College of Medicine
One Baylor Plaza, Suite 011DV
Houston, TX 77030-3411

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

INTERVIEWS

You may find some of the questions asked during the interview to be embarrassing. For example we will ask you how often you clean your home and whether you had any problems with cockroaches. You are free to not answer any of these questions.

VISITING YOUR HOME

You may be uncomfortable having us in your home or inspecting your home for factors potentially related to your asthma or safety. We understand that we are guests in your home. If you are uncomfortable, please let the home-visit team know or, if you prefer, contact the Principal Investigator directly.

PEST CONTROL

If you have problems with roaches, the community health worker or another member of our home-visit team may suggest that we place a small bait station in places where roaches might be found but where children and pets can't get to it. The bait station contains a gel containing a chemical (pesticide) that kills roaches. It can harm people if they eat large amounts of it or get it on the skin or eyes. If you don't want to use the bait stations, you don't have to and can still take part in the study.

SPIROMETRY

This is a test of your breathing and requires you to blow hard. It may cause you to briefly feel dizzy or light headed or may cause you to cough. Very rarely it may cause fainting.

LANDLORDS

If you rent, we may suggest that you or we contact your landlord to make your home safer. Your landlord might not respond well to a request to make changes in your home. We will help you if this should happen. It is possible the landlord could take action against you. If this occurs, project staff (including

staff from the City of Houston) will be available to assist you. Note: in similar studies in other cities, there have been very few cases of landlords taking actions against subjects.

OTHER CONSIDERATIONS
If project staff sees clear signs of child abuse or neglect and/or vulnerable adult abuse or neglect, they are required by law to report this to Child Protective Services or Adult Protective Service.

BLOOD COLLECTION
The stick from the needle used to collect your blood may hurt a little bit. You could develop a bruise at the place where the blood was drawn, but this should go away by itself in a few days. Infection of the place where the blood was drawn is very rare.

CONFIDENTIALITY
The greatest risk to you is the possibility of release of information from your health records. We will make every effort to protect your records so that your information will be kept private. The chance that this information will be learned by a person who should not know it is extremely small.

If you provide a blood sample and allow for it to be banked for other scientists to use, there is a very small chance that someone could trace the genetic information back to you. This chance could grow as genetic technology grows. Researchers who use your blood samples must protect your privacy.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits
The benefits of participating in this study may be: improved asthma self-management skills, asthma control support, and supplies that may make your home healthier. Both groups will receive these benefits.

If this project shows that home visits improve asthma control, this project can be used to help community healthcare providers and other asthma programs promote access to home visits for all adults with asthma. Society will benefit from improved health of its members and potentially decreased costs for caring for people with asthma. However, you may receive no benefit from participating.

Alternatives
The following alternative procedures or treatments are available if you choose not to participate in this study: to not take part.

Subject Costs and Payments
You will not be asked to pay any costs related to this research.

You will be paid up to $116.00 for completing one phone survey and two visits to the Environmental Health Clinic:

$25.00 after participating in the baseline Environmental Health Clinic visit
$25.00 after participating in the phone call/survey at month 6
$50.00 after the Exit Interview/Visit to the Environmental Health Clinic at the end of the 1 yr intervention (month 12)

You will receive cash or a check from Baylor College of Medicine during or 3-4 weeks after each visit or phone call, as appropriate. Your travel costs/parking that may result from making the visits to the Environmental Health Clinic will also be reimbursed up to $8.00 per visit.

In addition, each participant will have the option to receive tools to improve asthma control and home safety, with a value of up to $350 per home.

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.

The investigator, WINIFRED J HAMILTON, 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: Principal Investigator, Winifred J. Hamilton, at (713) 798-1052; the dedicated Environmental Health Service asthma study line, 713-798-1082, which is continuously monitored by study staff; or study project manager, Laura Achenbaum, at (713) 798-6860.

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.

In the event of injury resulting from this research, Baylor College of Medicine and/or the Harris Health System 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.

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-34115
Approval Date: 12-20-16
Expiration Date: 03-10-17