May 21, 2018

WINIFRED J HAMILTON
BAYLOR COLLEGE OF MEDICINE
MEDICINE: GENERAL MEDICINE

Baylor College of Medicine
Office of Research
One Baylor Plaza, 600D
Houston, Texas 77030
Phone: (713) 798-6970
Fax: (713) 798-6990
Email: irb@bcm.tmc.edu

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

APPROVAL VALID FROM 1/8/2018 TO 1/7/2019

Dear Dr. HAMILTON

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was reviewed and approved by Expedited procedures on 1/8/2018 by Board 5.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

FLOR MUNOZ-RIVAS, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-34115
Status: Approved
Initial Submit Date: 5/17/2014
Approval Period: 1/8/2018 - 1/7/2019

Section Aa: Title & PI

A1. Main Title

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

A2. Principal Investigator

Name:	WINIFRED J HAMILTON	Phone:	713-798-1052
Id:	780887	Fax:	713-798-2770
Department:	MEDICINE: GENERAL MEDICINE	Email:	hamilton@bcm.edu
Center:		Mail Stn:	BCM296

A3. Administrative Contact

Name:	AAKANKSHA NAIK	Phone:	713-873-3970
Id:	175349	Fax:	
		Email:	aakanksn@bcm.edu
		Mail Stn:	BCM285

A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

Name:	REBECCA JENSEN BRUHL	Phone:	832-472-2941
Id:	146047	Fax:	713-798-2770
Department:	MEDICINE: GENERAL MEDICINE	Email:	rj4@bcm.edu
Center:		Mail Stn:	BCM296

Name:	CHARLES G. MINARD	Phone:	713-798-2353
Id:	174095	Fax:	
Department:	MEDICINE: HEMATOLOGY & ONCOLOGY	Email:	minard@bcm.edu
Center:		Mail Stn:	BCM122

Name:	DANIELLE GUFFEY	Phone:	713-798-2442
Id:	180893	Fax:	713-798-2816
Department:	MEDICINE: HEMATOLOGY & ONCOLOGY	Email:	guffey@bcm.edu
Center:		Mail Stn:	BCM450

Name:	JESSE R. CRAIN III	Phone:	713-798-1044
Id:	192962	Fax:	713-798-2770
Department:	MEDICINE: GENERAL MEDICINE	Email:	jrcrain@bcm.tmc.edu
Center:		Mail Stn:	BCM296

Name:	CHRISTOPHER JANSSEN	Phone:	713-798-1364
Id:	193725	Fax:	713-798-2777
Department:	MEDICINE: GENERAL MEDICINE	Email:	cjanssen@bcm.tmc.edu
Center:		Mail Stn:	BCM296

Name:	ABIODUN OLUYOMI	Phone:	713-798-1052
Id:	197439	Fax:	713-798-2770
Department:	MEDICINE: GENERAL MEDICINE	Email:	oluyomi@bcm.tmc.edu
Center:		Mail Stn:	BCM296

Name:	RITUPREET VIRK	Phone:	713-798-1079
Id:	200696	Fax:	713-798-2770
Department:	MEDICINE: GENERAL MEDICINE	Email:	rituprev@bcm.tmc.edu
Center:		Mail Stn:	BCM296

Name:	ADRIANA RANGEL	Phone:	713-798-1364
Id:	201865	Fax:	713-873-2545
Department:	MEDICINE: GENERAL MEDICINE	Email:	ar27@bcm.tmc.edu
Center:		Mail Stn:	BCM296

Name:	NICOLA ALEXANDER HANANIA	Phone:	713-798-2347
Id:	671351	Fax:	713-798-2679
Department:	MEDICINE: PULMONARY	Email:	hanania@bcm.edu
Center:		Mail Stn:	BCM621

Name:	LORNA MCNEILL	Phone:	713-563-1103
Id:	Non-Baylor	Fax:	713-792-1152
Institution:	University of Texas M.D. Anderson Cancer Center	Email:	lmcneill@mdanderson.org
Address:	1400 Pressler St, Unit 1440, Houston, TX 77030		

Name:	LOREN RAUN	Phone:	832-393-5155
Id:	Non-Baylor	Fax:	713-794-2988
Institution:	Houston Department of Health and Human Resources	Email:	loren.raun@houstontx.gov
Address:	8000 N Stadium Dr, 2nd floor, Houston, TX 77054		

Name:	DAVID PERSSE	Phone:	832-394-6800
Id:	Non-Baylor	Fax:	
Institution:	City of Houston Emergency Medical Services	Email:	david.persse@houstontx.gov
Address:	600 Jefferson, 8th Floor		

Name:	WILLIAM PERKISON	Phone:	713-500-9468
Id:	Non-Baylor	Fax:	713-500-9442
Institution:	University of Texas School of Public Health	Email:	William.B.Perkison@uth.tmc.edu
Address:	1200 Herman Pressler Dr., Suite W1040		

A5. Funding Source:

Organization: PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
HCHD: Harris County Hospital District

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Substantial evidence has accrued documenting disparities in the severity, morbidity and mortality associated with asthma among minority populations when compared with non-Latino whites. The underlying factors and their interrelationships are still poorly understood. What is increasingly clear is that asthma is a complex, multifactorial disease with risk factors that vary in their relative importance in different populations and even among individuals within population subgroups. Asthma outcomes in turn are directly and indirectly mediated by a variety of factors that operate at individual, environmental, social, and system levels. Some of these include biologic and genetic risk factors, health beliefs, patient adherence and self-management skills, economic status, cultural and language barriers, health literacy, provider knowledge and communication skills, racism, stress, and exposure to environmental triggers. In the U.S., higher asthma prevalence rates are consistently found among African American, American Indian and Puerto Rican populations.

Harris County, in which most of the City of Houston is located, is exceptionally racially and ethnically diverse, with approximately 19.5% African American, 41.5% Hispanic/Latino, 32.2% Caucasian and 6.8% residents with other (mainly Asian) profiles in 2012. Harris County is the third most populous county in the U.S., with an estimated population of 4,253,700 residents. The region's Hispanic/Latino population is predominately from Mexico, with only a small percentage from Puerto Rico; the area's Native American population is also small. There is, however, a large African-American population in the region and significant evidence to suggest that this population is disproportionately affected by asthma. Our proposal targets this population.

Accurate asthma prevalence data for the Houston region are not available, although several local but limited studies in Houston suggest an overall prevalence around 8.2%, with higher percentages among the African-American community. In Texas Health Service Region 6, the 12-country region in which Houston is located, 2010 Texas Behavioral Risk Factor Surveillance System data indicate an asthma prevalence of 6.6% for both African Americans and Caucasians. These same African Americans, however, were more than twice as likely to be hospitalized or die from asthma as Caucasians or Hispanic residents. Although the hospitalization rate for asthma has decreased over the past 10 years, the rate for African Americans remains higher than for Caucasians: 16.4 vs. 7.5 per 10,000.

In 2006, the 10 hospitals within the City of Houston and Harris County with the largest number of admissions for asthma admitted 1,258 African Americans with residential addresses in the same geographical area. Two of these hospitals (Ben Taub and Lyndon B. Johnson) are part of the Harris Health System. Harris Health is a

key partner for this proposal as it serves a large percentage of African-American adults in the area who have severe asthma. During Harris Health's most recent fiscal year (March 1, 2012 through February 28, 2013), the system had 1,742,429 visits at its more than 40 community-based, school and other clinical locations, and 34,538 hospital admissions at its three hospitals.

Of the 5,339 asthma-related visits to the Harris Health System, 2,131 (39.9%) were by African Americans. This is disproportionately high relative to their percentage (19.5%) of the county's population. Similarly, in FY 2013 African Americans accounted for 47.5% of visits to the emergency department and 45.4% of hospital admissions to Ben Taub General Hospital or asthma—significantly disproportionate to their proportion of the area population.

This effort is noteworthy because it has the capacity—through extensive use of a single EMR system by Baylor College of Medicine, Harris Health and others in the region, and because of our close collaboration with Harris Health System on which many of our target population rely for their asthma care—to reach a large number of the African-American adults in the region with inadequate asthma control, a group with especially high rates of emergency department utilization, hospitalization, and mortality risk. Our effort is also aided by a strong Community-Based Participatory Research (CBPR) component, which includes a Patient/Stakeholder Advisory Board that is helping us to refine the protocol in numerous ways to be most effective for the targeted group.

Our protocol focuses on home-based exposure reduction and self-management. Reducing exposure to environmental hazards—such as dust mites, mold, volatile organic compounds, combustion gases, particulates and cigarette smoke—can reduce the morbidity associated with a number of cardiorespiratory conditions, especially asthma, remarkably. A comprehensive home-based strategy that includes both an environmental component focused on reducing exposure to multiple triggers and irritants and a patient-centered self-management educational component can result in signicantly improved asthma.

A number of studies have linked relatively low-cost interventions with measurable reductions in symptoms and urgent healthcare use and improvements in quality of life; these benefits exceed their program costs by roughly a factor of 10.

Our study tests the effectiveness of a patient-centered, home-based year-long environmental intervention to improve asthma control and quality of life in African American adults who live in the Houston region and have poorly controlled asthma. Our protocol is somewhat unusual in the degree to which it is holistic and patient-centered. The intervention, although focused on asthma, will likely benefit other disease states such as obesity and cardiovascular disease, which are important drivers of the growing chronic disease epidemic among the nation's aging population, which the Institute of Medicine has recently called a crisis that is being inadequately addressed and in need of new models of comprehensive health.

Our partnerships with Prairie View A&M and the disparities research group at MD Anderson Cancer Center will help us to work with participants and their communities to define the barriers, needs and methods best suited for this effort, and to define outcomes that are meaningful to our target population. Our Environmental Health Specialty Clinic paradigm addresses not only environmental factors in the home that may be causing or exacerbating an individual's asthma but also, as appropriate, depression, job stress, obesity, nutrition, neighborhood pollution, parenting issues and other "environmental factors" that may be contributing to the disease. Our partnership with the City of Houston will allow easy referrals for a number of indoor and outdoor pollution issues, as well as access to mental health and other help. The city also has enforcement powers, especially with regard to rental housing.

Based on studies elsewhere and on the collective expertise of the collaborators, we anticipate that the convenience and support of our home-based program will lead to measurable and lasting improvements in asthma control, quality of life, and utilization of health services for this population.

Section D: Purpose and Objectives

Our hypothesis is that the addition of a holistic, home-based environmental intervention to a standard in-clinic asthma protocol will result in statistically significant improvements in key measures of health and quality of life among Houston-area African-American adults with poorly controlled asthma.

This is a pragmatic randomized controlled clinical trial that compares the effectiveness of a customized, holistic, patient-centered, home-based environmental intervention for improving asthma control (the

"intervention") with enhanced clinic-based care (enhanced "usual care"). Both arms would receive identical in-clinic care, including a tailored asthma self-management education program delivered using motivational interviewing techniques. The intent of this study is to assess-real-life effectiveness of our interventional arm in patients with complex asthma.

The specific aims of this effort include:

1. Address the needs of the target population by actively engaging a patient and stakeholder advisory panel; 2. Improve provider adherence to asthma standard-of-care guidelines by adding a tested environmental health history and referral module to the Harris Health and Baylor College of Medicine EpicCare electronic medical records (EMR) system and training area clinicians who treat asthma patients in its use; 3. Institute a holistic, patient-centered, home-based intervention for improving asthma control; 4. Analyze key outcome measures; and 5. Disseminate findings.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
Black Or African American

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

z.r) Randomized, Efficacy Study -- Surgical Techniques/Interventions

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This is a pragmatic randomized controlled clinical trial that compares the effectiveness of a customized, home-based environmental intervention for improving asthma control (the "intervention") with enhanced clinic-based care (enhanced “usual care”). Each enrollee will be randomly assigned by a researcher not involved with patient care using a permutated block design with varying block size into one of two groups: (1) enhanced usual care, or (2) enhanced usual care plus home-based intervention. Based on known differences between younger and older adults, we will stratify the randomization by age (less than 55 and 55 or older years of age). Both arms would receive identical in-clinic care, including a tailored asthma self-management education program delivered using motivational interviewing techniques.

Inclusion Criteria:

The study population will be composed of African-American adults who are (1) 18 years of age or older; (2) have a diagnosis of poorly controlled asthma; (3) have a fixed address within Harris County, Texas with no intention of moving within the following 12 months; (4) have a working telephone number; and (5) are verbally fluent in English.

For purposes of this study, an individual with “poorly controlled asthma” (1) has been diagnosed by a physician as having asthma in the past and currently has asthma; and (2) fulfills one or more of the following criteria of poorly controlled asthma: * Has had one or more emergency department (ED), urgent care visits or hospitalizations for asthma in the preceding year; * Meets the definition of “very poorly controlled” asthma as defined by the National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma; this definition includes daily asthma symptoms, nighttime awakenings two or more times per week, extremely limited normal activity, and/or daily use of a short-acting beta agonist for symptom control; and/or * Has an Asthma Control Test score of 19 or lower.

Exclusion Criteria:

Patients with severe co-morbid conditions—such as a poorly controlled psychiatric illness or a condition requiring intense medical treatment that could reasonably be expected to (1) confound the effects of this study's intervention, (2) make it unlikely that a participant could follow the treatment plan, or (3) pose a safety issue for the home-visit team—will generally be excluded. Patients involved in a concurrent pulmonary study that could reasonably be expected to confound the effects of this study’s intervention will also be excluded. In addition, we will exclude patients who live in a group living facility, such as a nursing home.

F2. Procedure

Subjects will be recruited via the recruitment procedures noted in sections J1a and J2.

Following eligibility screening (see attachments, HIITBAC_1_PARTICIP-INFO-LTR_20160112 or HIITBAC_1_PARTICIP-INFO-LTR-EMS_20160420 and HIITBAC_1_SCREENING-QUESTIONNAIRE_20160809), which may be done either on the phone or in person at a community venue or clinic, patients who meet the inclusionary criteria and are interested in enrolling in the study will be scheduled for a visit at the Environmental Health Clinic (multiple possible sites but primarily Harris Health's Smith Clinic). Dr. Hanania (co-PI and pulmonary specialist) or his designee is available for a consultation as needed.

Team members with Harris Health Epic access for this study schedule the client’s baseline clinic visit in Epic. This includes reviewing the demographic and insurance status, coding the potential enrollee for research, providing information for billing, and ordering study-related laboratory tests as appropriate.

The 12-month effort includes the following:

ENVIRONMENTAL HEALTH CLINIC (EH Clinic): BASELINE VISIT At the EH Clinic, the study will be explained in detail and written informed consent and HIPAA authorization (if not on file with HH) obtained. Once enrolled, the patient will be assigned a randomly generated study ID number and will be randomized into either the control or intervention arms; the randomization is hidden until the conclusion of the EH Clinic baseline visit. This baseline visit will typically take place at the Harris Health Smith Clinic. It may also be conducted at Ben Taub, Casa de Amigos, a community site (e.g., City of Houston Multi-Service Center or

Northside Health Center), or in a participant's home (only if they have already given written informed consent as per section J2).

Study staff will administer a baseline questionnaire (see attachment, HIITBAC_4_BASELINE-QUESTIONNAIRE_20151210) to assess asthma control (Asthma Control Test), quality of life (mini Asthma Quality of Life Questionnaire), general health and emotional status, healthcare utilization (e.g., hospitalizations, ED, and urgent care visits) for asthma, medication adherence, asthma care access, and social support. Staff will assist the enrollee in completing an environmental exposure history as appropriate. The exposure history (see attachment, HIITBAC_4_EXPOS-HISTORY_20151009) includes questions about the indoor home environment (e.g., pets, dust and cleaning techniques, the presence of pests, home structural characteristics, moisture, smoking), the school/work environment, food and water, air pollution and outdoor environment, and toxic chemical exposure.

The EH provider then reviews with the enrollee the patient’s medical history from their Epic EMR and from the study questionnaires and conducts an exam (see attachment: HIITBAC_3_CLINIC-CONSULT_20160504). In addition to exposure triggers, this review includes medications, insurance coverage, access to care and other issues as pertinent to asthma management. The provider also performs a pulmonary function test, orders labs (e.g., total IgE and zone 6 allergen panel), and reviews (or creates if one is not in the patient's EMR) an Asthma Action Plan.

All enrollees receive tailored self-management and trigger avoidance education delivered using motivational interviewing techniques. This education program stresses self-management to avoid triggers, anticipate problems, and use medication appropriately.

An optional blood sample is obtained for banking if the subject consents. The blood sample is obtained at the same time as another blood draw (e.g., allergy testing), or can be done separately.

At the end of the visit, participants are given an After Visit Summary (AVS; HIITBAC_3_BASELINE-AVS_20150114), summarizing the initial findings and plan of action. The AVS also reveals randomization status. For those in the intervention group, the home assessment is scheduled during the baseline visit if possible and the participant is asked to sign a form agreeing to the scope of the environmental assessment (HIITBAC_2_FIELD-CONSENT_20150213).

HOME ASSESSMENT Investigators from BCM EHS and/or the City of Houston Bureau of Community and Children's Environmental Health (BCCEH) conduct a Healthy Homes-based exposure assessment within one month of the clinic visit and obtain baseline measurements, such as humidity, carbon monoxide, and particulate counts, as appropriate (see attachment, HIITBAC_5_FIELD ASSESSMENT_20151007). Project staff will follow up from the clinic visit at this time, and will discuss the patient’s concerns, beliefs, and goals for the intervention. Following the home-based exposure assessment (HV1), the project team will produce the assessment report and tailored multifocal action plan (HIITBAC_5_MAAP-RPT-TEMPLATE_20160219).

HOME VISITS During the subsequent four home visits (at approximately months 2, 5, 9, and 12 after the baseline clinic visit), a two-person team consisting generally of a community health worker (CHW) and either an environmental hygienist, a second CHW or a nurse practitioner will communicate the results of the assessment and phase in implementation of the clinically driven home-based action plan, with on-going patient-centered communication, monitoring and reinforcement. In limited circumstances and with prior approval of the PI, some follow-up visits may be conducted by only one person (community health worker or nurse). The action plan includes specific exposure reduction protocols (e.g., allergen covers, increased ventilation, and moisture control), help with medical compliance and adherence to the Asthma Action Plan, and assistance with related issues, such as mental health issues or housing code violations, affecting asthma control. During each home visit, project personnel may obtain pulmonary function, medication adherence and healthcare utilization updates, and Asthma Control Test scores, which may be used to refine the action plan. At the fifth (and final) home visit, the home-based exposure assessment will be repeated.

PHONE CALLS AND STUDY-RELATED LETTERS Participants in both the control and intervention arms will receive a phone call at month 6 to assess asthma control (ACT) and healthcare utilization (see attachment, HIITBAC_6_PHONE-6MO-FU_20160512). Participants may also receive a letter to ask them to call in to complete their mid-year survey if that is more convenient for them or if we are having difficulty reaching them by phone (HIITBAC_6_LETTER-6MO-FU). Participants in the control arm are also called at months 3 and 9 to check in and to verify their current phone, address and other contact information (HIITBAC_6_PHONE-3-9MO-FU_20151009). As per standard of care, lab results (e.g., Total IgE and the Zone 6 allergen panel) will be mailed to the patients in both arms shortly after the results are posted in Epic. This correspondence

includes a letter explaining the results and invites participants to call our provider to discuss. Participants are also notified by phone and/or at a home visit, as appropriate. Participants also receive scheduling calls and mail/email/phone/text appointment and/or study reminders as appropriate and to aid in retention.

ENVIRONMENTAL HEALTH CLINIC: POST-INTERVENTION HEALTH ASSESSMENT The follow-up clinical assessment will occur approximately 12 months after the baseline clinic visit and obtain data similar to that collected during the baseline visit (see attachment, HIITBAC_4_EXIT-QUESTIONNAIRE_20151211), plus some questionnaires on participant behavior change during the study and participant satisfaction (HIITBAC_4_SATISFACTION_Q_20151211). Additional questions about the impact of Hurricane Harvey on the participant's health and well being were added in September 2017 (HIITBAC_4_EXIT-QUESTIONNAIRE_Harvey_Addendum). Self-administered questionnaires may be mailed to the participant just prior to their exit visit, if desired, in order to shorten the length of the exit visit. At this visit, the usual care group will be given the option of scheduling a home environmental assessment, and subsequent home-based intervention (up to two additional visits). As with the baseline visit, the post-intervention clinic visit will typically take place at the Harris Health Smith Clinic. It may also be conducted at Ben Taub, a community site (e.g., Casa de Amigos Health Center, a City of Houston Multi-Service Center), or the participant's home.

If a study participant will become ineligible for the study (e.g., they move out of the study area) after they have participated for 10 months but before they are due for the post-intervention health assessment, they may be scheduled for a "premature exit visit." This visit will be identical to the standard "post-intervention health assessment," but could be conducted up to 6 weeks earlier than the regular exit at approximately 12-months post-enrollment. Similarly, to accommodate scheduling difficulties and/or special circumstances (such as an early move within the study area, which “restarts” the intervention clock), some patients may exit slightly later than 12 months after enrollment.

All data collected over the course of the study is documented in the protected ICTR study database. This includes insurance status pulled from the medical record.

Once participants have completed the intervention, study staff will request a data pull from Harris Health detailing the participants’ healthcare utilization over the course of the study (e.g., emergency department visits, hospitalizations, and office visits for asthma). This data will be used in health care utilization analysis as described in Section G2. Data Analysis.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 5000 Worldwide: 5000

Please indicate why you chose the sample size proposed:

Power and sample size calculations were performed using the PS program of Dupont and Plummer. Our study aims to recruit 300 patients in total. With a 65% follow-up rate, we will have 97 patients per arm at the end of study.

For the asthma quality-of-life measure, assuming a standard deviation of 0.6 for AQLQ score, the sample size of 97 per arm will give greater than 99% power to detect a minimal clinically important difference (MCID) of 0.5 in the AQLQ score at the significance level of 0.05 (2-sided).

For the asthma control measure, assuming a standard deviation of 4 and a MCID of 3 for the ACT scores, a sample size of 97 patients per arm will give greater than 99% power to detect a MCID at the significance level of 0.05 (2-sided).

For healthcare utilization outcomes (e.g., ED visits), assuming a standard deviation of 3 for the number of ED visits for asthma per person per year and nearly 90% power, a sample size of 97 per arm will allow us to detect a difference of 1.4 in annual number of ED visits between the two groups at the significance level of 0.05 (2-sided).

For this protocol, we are requesting approval of a sample size of 5,000. This includes approximately 4,000 possible screen/fails. This will also allow us to enroll slightly more than 300 without submitting an amendment to the IRB. The primary reason for enrolling more than 300 would be an unexpectedly high drop-out rate.

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

All analyses will be performed according to treatment assignment, and all available data will be included in the evaluations, regardless of whether or not the subjects discontinue the assigned treatment (modified intention-to-treat analysis). Bivariate associations will be examined using Student t-tests and chi-square tests, as appropriate. Linear and logistic regression models with generalized estimating equation variance estimates will be used to evaluate differences among treatment groups for continuous or dichotomous outcomes, respectively. Unadjusted analysis will be performed as the primary results. If baseline covariate imbalance is detected, the analysis will adjust for imbalanced covariates. Subgroup analyses will be performed in pre-specified groups defined by age, sex, race, and asthma severity. P values of less than 0.05 (2-sided) will be considered statistically significant. P values will not be adjusted for multiple comparisons. Analyses will be carried out using the current versions of SAS, Stata, or R.

The study will use simple paired methods (e.g., Wilcoxon signed-rank test) to compare changes in primary outcome measure (health care utilization) from the pre- to post-intervention period. Longitudinal analysis (e.g., generalized estimating equation or mixed-effects linear regression model) techniques will be used to examine changes in health care utilization over time with an indicator for time periods, controlling for potential confounders, such as gender, income, education, asthma severity, exposure to cigarette smoke and race/ethnicity. Subgroup analyses will be performed in pre-specified groups. P-values less than 0.05 (2-sided) will be considered statistically significant. Analyses will be carried out using the current versions of SAS, Stata or R. Geospatial models of selected risk and distribution parameters will also be developed and assessed for spatial patterns.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

INTERVIEWS/QUESTIONNAIRES The questionnaires contain a few questions that some participants may feel are too personal or sensitive in nature. Participants can refuse to answer any question that makes them feel uncomfortable. Efforts will be made to ensure that participants understand that such refusal is their right and that the investigators understand and appreciate their candor.

VIOLATION OF PERSONAL SPACE Our intervention involves entering and assessing a person's home and personal habits. Although our team members are trained to be nonjudgmental and are chosen in part because of their interest in community-based medicine, some participants may be embarrassed by or apologetic with regard their living situation or may not trust our personnel (e.g., may be afraid of things being stolen) or the study aims (e.g., bad experiences with BCM in the past). We are working with our Patient/Stakeholder Advisory Board and other centers across the U.S. in addressing these issues. Effective approaches include the use of Community Health Workers, clear and consistent identification of personnel, training in Motivational Interviewing techniques, extensive training and role playing, humor, sensitivity, oversight of the interactions between the participants and home-visit personnel including unannounced participation by the PI, and easy access to the PI to discuss any concerns.

SPIROMETRY This pulmonary function test may cause some people to feel dizzy or lightheaded or cause them to cough. Very rarely it may cause fainting. Study personnel performing spirometry are certified in its use and will monitor the patient's response. Most asthma patients are familiar with this test.

LANDLORDS For patients living in substandard rental property, working with the participant and his or her landlord (directly or through the City of Houston) may be an effective approach to addressing selected asthma triggers. In many instances, our intervention enhances the owner's property value and is welcomed. However, in some instances approaching a landlord may create a difficult situation for the rentor or even make them at risk for losing needed housing. Project personnel are sensitive to this issue and are aware that some landlords may not respond well if they are asked to make changes to their property or if they receive a citation due to a condition in the housing unit. The project staff, including staff from the City of Houston, will assist participants if the landlord attempts to take action against them. In similar studies in Seattle, there have been no cases of landlords taking action against participants.

PEST CONTROL The protocol utilizes and teaches Integrated Pest Management (IPM), which uses nontoxic means of pest control (e.g., plugging holes, eliminating food and water, and regular cleaning regimens) whenever possible, generally reducing the current use of chemical pesticides--which are often asthma triggers--by the study participant. In some instances in which a participant has a recalcitrant problem with pests (especially cockroaches, to which many asthmatics are allergic), the project personnel may suggest the use of a low toxicity bait station that contains a gel that contains a pesticide. Bait stations would be placed in areas where pests had been found but inaccessible to children or pets. The gel contains a pesticide that can harm people if eaten in large amounts or if it gets on the skin or in the eyes. Participants would be thoroughly advised of the risks and can choose not to use the bait stations. This decision would in no way affect participation in the study.

BLOOD COLLECTION AND CONFIDENTIALITY Procurement of the blood sample will be done using sterile techniques and published methodology and poses minimal discomfort to the subject. Numerous procedures are in place to protect the confidentiality of the participants, as are described elsewhere.

Blood samples will be part of a biorepository, which may pose a privacy risk. The current risk of tracing genetic information back to the participant is very small, but may grow as new methods are developed in DNA sequencing. Researchers who access the genetic information will have a professional obligation to protect participant privacy and maintain confidentiality. Investigators will need to obtain their own IRB approval prior to coming and asking for these samples.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Adults participating in the study are likely to experience a number of benefits, including improved asthma control; reduced exposure to asthma triggers and environmental substances implicated in inflammation; improved asthma self-management skills; and receipt of a set of supplies tailored to the participant and his or her situation that will make their home healthier, such as dust mite-proof pillow encasements, integrated pest management tools, a HEPA vacuum cleaner or air cleaner, and cleaning supplies. As appropriate, participants (and/or family members) may receive additional help relevant to their situation, such as help stopping smoking or receiving help for depression. Both groups will receive these benefits (the “enhanced clinic group" [control] would have the option to receive the in-home intervention at the end of the study).

Describe potential benefit(s) to society of the planned work.

Despite the abundance of studies on the effectiveness of asthma self-management programs for improving asthma-related health outcomes, there are few rigorous studies of asthma self-management interventions in high-risk minority populations, or even many studies of asthma interventions with a majority of non-white participants. There are even fewer studies examining home-based exposure reduction in adult minority populations. In addition, there is suggestive evidence that conducting much of the assessment, clinical follow-up and trigger reduction activities in the home has mental health and empowerment effects that broadly reinforce asthma control. Studies, such as this one, are needed to evaluate real-world effectiveness of intervention programs, establishing benefits in a population that is representative of actual practice.

This study is designed to represent a broad group of African-American asthmatics; we will not exclude individuals based upon smoking status or other common co-morbid conditions (with the exception of very serious conditions that require intense medical treatment). As a result, this work should be broadly applicable.

Indeed, our intent is to refine the protocol into a package that can be replicated in other communities. We hope that the pilot—if successful and after integrating lessons learned—would lead to introducing the program in other community clinics, for asthmatics and others.

The model can also be easily applied to other chronic diseases, such as COPD or cardiovascular disease, in which, for example, inflammation caused or exacerbated by environmental exposures (including factors such as stress and nutrition) is a key factor.

If this project shows that home visits improve asthma control, it 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.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Yes, the anticipated benefits to the participants, their neighborhoods and minority at-risk individuals are substantial. There are two primary areas of risk: (1) patient confidentiality, and (2) violation of personal space since our intervention involves entering and assessing a person's home and personal habits. We have in place numerous protections to safeguard our databases and patient confidentiality, and are working with our Community Advisory Board and other centers across the country with home-based programs on the procedures (e.g., the use of Community Health Workers and extensive training, including motivational interviewing and role playing) needed to build effective respect and trust for the home-based intervention. The experience of and information collected from the proposed study could help to improve asthma programs across the region, as well as elsewhere, and to improve public health and especially to reduce the disability and cost of chronic disease.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

Chart and/or database (Harris Health or HFD EMS) review to determine subject eligibility.

Medical record review to assess healthcare utilization (e.g., ED visits for asthma) and insurance status over the course of the study period.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

The screening is done with the least amount of intrusion into the participant's health as possible. The chart and/or database review covers only key eligibility criteria (e.g., asthma diagnosis, recent asthma symptoms and healthcare utilization for asthma, address within Harris County, and any other medical conditions that may interfere with their ability to participate). The principal risk would be potential harm from a breach of confidentiality. Significant harm is unlikely given that asthma is a common chronic disease.

Review of insurance status is already a component of standard of care in the research clinic (insurance status is required by Harris Health when making the appointment in our clinic; our providers may also review insurance status if/when they prescribe a medication or treatment to ensure it is covered).

We already ask participants about their healthcare utilization over the course of the study, but the review of Harris Health records will provide a more systematic method for gathering information on utilization for use in our final analyses.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

PHI will not be reused or disclosed to or shared with any other person or entity, except as required by law. Screening information will not be kept unless the subject is enrolled with written consent into the full study.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

Because this study targets African Americans with poorly controlled asthma and our primary recruitment sources are the Harris Health System and the Houston EMS, we need to do database/chart reviews in order to identify the subset of Harris County patients who may qualify, contact these patients' healthcare providers for their approval to contact the patient (if a PCP can be identified), and to contact the patient by letter and/or phone about their interest in participating in the study.

Study enrollment is already complete; the consent included access to EMR information necessary for their care. It would not be practical to re-consent participants who have already completed the study or who are mid-intervention. Insurance status and healthcare utilization data are essential pieces of data needed for standard of care and for assessment of the effectiveness of the intervention.

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

The databases used by staff to track database and chart reviews is kept on a secure server (by ICTR) and password protected. Only authorized study staff who have received appropriate human subjects training have access to the charts and the databases.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

The screening information is destroyed if the patient does not meet eligibility criteria.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Unless the patient provides written consent to participate in the study (with written assurances regarding use of PHI), all screening information is destroyed.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

No

Billing or financial records:

Yes

Photographs, videotapes, and/or audiotapes of you:

No

Other:

No

If Yes, explain how subjects will be provided additional pertinent information after participation.

Asthma-related education will be provided during the study. Participants will receive copies of test results and action plans; information will also be shared with the PCP if possible. Participants are asked as part of the exit visit whether they'd like to receive aggregate study results; if yes, aggregate study results will be mailed to participants when available. As appropriate, significant findings will be shared with the community, government officials and others.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

This research requires a waiver for written documentation of consent for the review of HHS and EMS databases and HHS Epic medical records, as well as the phone screening. The risk associated with screening for eligibility is considered minimal. The phone screening is done with the least amount of intrusion into the participant's health as possible. The principal risk would be potential harm from a breach of confidentiality. Significant harm is unlikely give that asthma is a common chronic disease. Employability, insurability, and educational opportunities would not be affected. PHI will not be reused or disclosed to or shared with any other person or entity, except as required by law.

The screening is conducted by phone or in-person at a recruitment event. Prior to calling a patient, the study team sends a letter to the home address describing the study (HIITBAC_1_PARTICIP-INFO-LTR_20160112 or HIITBAC_1_PARTICIP-INFO-LTR-EMS_20160420). The screener follows a scripted questionnaire (HIITBAC_1_SCREENING-QUESTIONNAIRE_20160809). The screener asks about race/ethnicity, recent asthma symptoms and healthcare utilization for asthma, other health conditions that may interfere with their ability to participate in the study, and whether they are homeless or plan to move in the coming year). Both documents and screening encounters stress that participation is voluntary.

If the patient is deemed eligible, then they are scheduled for a baseline visit to the study clinic. At that point, they would receive information about the full study and be asked to give written consent to participate.

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Potential participants will be identified and recruited using a tiered strategy.

1. We will query the HH EpicCare-supplied database (see J3) to identify African-American adults with asthma who had one or more visits to a HH facility for asthma in the study area in the previous 18 months. We will recruit patients who appear to meet our key inclusionary criteria by contacting their asthma-care providers through EpicCare (see HIITBAC_1_PROV-INFO-LTR_20160830); patients with no regular asthma-care providers within the HH system may be contacted directly. Using geospatial analysis and/or the assistance of our Patient/Stakeholder Advisory Board (PSAB) we may target locations with the highest number of potential study participants and post or otherwise make available study flyers and postcards (HIITBAC_FLYER_HH-STAMPED_20160325; HHIITBAC_POSTCARD_HH-APPROVED_20151123). Once we are given permission by a provider to contact a patient, we receive no response from the identified provider after 3 business days, or we have determined that the patient has no regular asthma-care provider, we will send the patient a letter and/or e-mail (HIITBAC_1_PARTICIP-INFO-LTR_20160112). After a potential participant contacts us and/or they have received a letter, we will conduct a scripted telephone interview to briefly describe the study, ascertain the person’s interest, and as appropriate their eligibility (HIITBAC_1_SCREENING-

QUESTIONNAIRE_20160809).

We will also post flyers and postcards at other venues suggested by our PSAB, such as key African-American churches, FQHCs, apartment complexes, etc. Upon approval of the appropriate leadership, study staff may screen and consent patients on site at a Harris Health community clinic, Ben Taub General Hospital, or other community site. All other study-related procedures would be conducted during the baseline clinic visit, as described in F.2.

2. Geospatial modeling may be used to target and market within ZIP codes with high concentrations of adult Africans Americans who were hospitalized for asthma in 2012. We will distribute flyers/postcards and meet with key physician providers and clinics within the ZIP codes within Harris County and that have high concentrations of African-Americans. Providers not utilizing EpicCare will be given electronic and/or paper materials with information about the study and how to refer their patients.

3. We also, with Department of Health & Human Services / Houston Fire Department approval, utilize data from the Emergency Medical Services database, which identifies persons who live within the study area and utilize the city ambulance system for asthma exacerbations. We send the identified persons a letter (HIITBAC_1_PARTICIP-INFO-LTR-EMS_20160420), then follow up with a scripted telephone interview to briefly describe the study, ascertain the person's eligibility, and identify their asthma provider if they have one.

Once individuals are deemed eligible for the study, staff will explain the study in detail and obtain written informed consent. The principles of informed consent in the current edition of the Declaration of Helsinki will be implemented before any protocol-specific procedures are carried out. Informed consent will be obtained in accordance with US 21 CRF 50.25. Information will be given in both oral and written form. Subjects will be given ample time to inquire about details of the study. Consent will be documented by the written dated signature of the subject. The signature confirms that the consent is based on information that has been understood. The participant will receive a copy of the form.

In most cases, the study consent will be obtained at the EH Clinic baseline visit. It may also be done following screening at a community clinic or event. No study-related procedures will be conducted until informed consent is obtained.

Are foreign language consent forms required for this protocol?
No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?
Yes

J4. Children

Will children be enrolled in the research?
No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
No

At what institution will the physical research data be kept?
Baylor College of Medicine

How will such physical research data be secured?
Physical PHI data are stored in dedicated locked file cabinets and closely monitored or locked at all times. Charts are filed by study ID number and identifying information redacted as appropriate.

At what institution will the electronic research data be kept?
Baylor College of Medicine Dan L. Duncan Institute for Clinical and Translational Research (ICTR)

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
Yes, (describe below):
Study data are entered into a secure electronic database developed specifically for the project by the Baylor College of Medicine Dan L. Duncan Institute for Clinical and Translational Research (ICTR). Patient clinical appointments are recorded in Harris Health's EpicCare system; home-visit appointments are recorded on a secure calendar system developed in collaboration with BCM's IT group.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable

research data?
No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
Transmission of PHI to sponsors and collaborators is via secure/encrypted e-mail, SSL encrypted web portals and eCRF applications. The study-specific ICTR database utilizes different levels of permissions based on need.

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.
We will collect blood samples, which may be stored for a long time or indefinitely, in the Dan L. Duncan Cancer Center Population Sciences Biorepository. Totally de-identified parts of participants' genetic information, and in some instances, clinical information, may be released to one or more scientific information sources. This may pose a privacy risk, as new techniques are developed that may allow scientists to trace information back to participants. Every reasonable effort will be made at all times to maintain the confidentiality of study records and of research information.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.
No. All study-related costs associated with the EH Clinic visits and home visits will be covered by the research study.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:
116

Distribution Plan:
Financial incentives include:

$8 per clinic visit for travel costs ($16 total) $25 after participating in the baseline visit to the EH Clinic $25 after participating in the phone call/survey at month 6 $50 after exit visit at the EH Clinic at month 12

Travel costs as well as incentives related to the clinic visits will be paid at the time of the clinic visit. The $25 after participating in the phone call/survey at month 6 will be made by cash or check from Baylor College of Medicine.

In addition, each participant in the interventional arm will receive a tailored set of tools to improve asthma control and home safety, with a value of up to $350 per home. These tools may include, for example, dust mite-proof pillow encasements, a HEPA vacuum or air filter, integrated pest management services, and cleaning products. Control subjects who complete the study will be eligible to receive the intervention and related tools at the end of the study.

Section M: Genetics

How would you classify your genetic study?
DNA diagnostic study

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research.

Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Although investigators will have a record that the blood was obtained from the subject, the subject's identity will be kept strictly confidential using a coding and neutral intermediary system. In the worst case scenario in which asthma-specific sample information and linkage documents were obtained, significant harm is unlikely. Asthma is a common and treatable chronic disease that is not infectious or otherwise transferrable. Therefore employability, insurability, and educational opportunities should not be affected.

Although not currently possible, there is a small chance that as technology advances there may be new ways of tracing the DNA information from the samples themselves back to the subject or their close biological relatives, increasing the risk over time that their privacy would be breached. There are state and federal laws that protect against genetic discrimination by employers or insurance companies, but potential risks remain.

Researchers who access participant genetic and clinical information have a professional obligation to protect data confidentiality. Although we believe that the risks to the subject and their family are very low, we are unable to tell the subject exactly what all of the risks are.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

No, we do not anticipate any type of genetic counseling for this cohort.

Section N: Sample Collection

SAMPLE: Blood

What is the purpose of the sample collection?

Currently, the most useful analyses for better understanding the disproportionate burden of asthma and resistance to conventional treatment in this population appear to be DNA analysis and metabolomics.

For blood draws, specify the amount drawn, in teaspoons, at each visit and across the course of the subjects entire participation time.

Approximately 2 teaspoons of blood will be collected once at the beginning of the study.

Is there the possibility that cell lines will be developed with this sample?No

Sample will be obtained from:

Other: Research subject

Will the sample be stripped of identifiers?

No

If sample will be released outside the hospital:

Will sample be released to anyone not listed as an investigator on the protocol? Will the information be identifiable, coded or de-identified?

No. The information will be coded, as previously described.

Will sample material be sold or transferred to any third parties? Will the information be de-identified?

Any samples or information subsequently released to third parties would be de-identified.

If sample will be banked for future use:

Where will the sample be banked and for how long?

Samples will be banked indefinitely in the BCM DLDCC Population Sciences Biorepository.

Does the banking institution have an approved policy for the distribution of samples?

Yes.

If the entire sample will NOT be used during the course of this research study:

Will the remaining tissue be discarded? If not what will be done with the remaining sample after study completion and how long will the sample be kept?

All of the processed sample will be stored.

Will samples be made available to the research subject (or his/her medical doctor) for other testing?

No

If a subject withdraws from the study:

Will subject have the option to get the remaining portion of their sample back?

No

Will samples be destroyed? If not, will they be kept anonymously? What will happen to the sample if the subject revokes authorization?

If the subject revokes authorization, the sample would be destroyed.

Will data obtained from their sample be deleted? What will happen to the sample if the subject revokes authorization?

Yes. All data from the sample would be deleted and the sample would be destroyed.

Will study data or test results be recorded in the subject's medical records?

No

Will results of specific tests and/or results of the overall study be revealed to the research subject and or his/her doctor?

No.

Please identify all third parties, including the subject's physician, to receive the test results.

No one.

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug that is not approved by the FDA?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Newspaper

Exact language of Advertisement:

[same language and format as flyer/postcard]

[BCM logo with Environmental Health Service "lock-up"] Asthma Study

Home-Based Asthma Study

We provide: • FREE help in reducing your asthma triggers -- at home and elsewhere! • FREE tools to make your home healthier. • COMPENSATION for your time and parking.

You are eligible if: • You are an African-American adult, age 18 or older. • You live in Harris County. • You have asthma that is not well controlled.

713.798.1082 environmentalhealth@bcm.edu

This research study is funded by the Patient-Centered Outcomes Research Institute (PCORI).

Mode of Advertising: Bulletin Board

Exact language of Advertisement:

The attached flyers include the following text:

[BCM logo with Environmental Health Service "lock-up"] Asthma Study

Free services for African-American adults with asthma 713.798.1082 environmentalhealth@bcm.edu This is a research study funded by the Patient-Centered Outcomes Research Institute

We will: • Help you learn more about your asthma. • Teach you about asthma triggers & how to control them. • Provide tools to make your home healthier. • Compensate you for your time and parking.

This is a one-year research study. It involves two visits to the BCM Environmental Health Clinic and may include up to five in-home education visits.

You are eligible if: • You are an African-American adult, age 18 or older. • You live in Harris County. • You do not plan to move in the next year. • You have asthma that is not well controlled OR you have been hospitalized or visited the emergency room in the past year because of asthma.

[The flyer includes a pull-off tabs, each of which says "BCM ENVIRONMENTAL HEALTH ASTHMA STUDY environmentalhealth@bcm.edu 713-798-1082".]

Note that this research project has a strong Community-Based Participatory Research (CBPR) component. Our Patient/Stakeholder Advisory Board consists of patients, community activists, asthma specialists, representative of the faith-based community, representatives of the African-American community and others. This Board will review our advertisements and recuritment protocol for appropriateness and effectiveness for the targeted community; all advertisements will be professionally created by the BCM Graphic Communications group. Any significant changes in content will be re-submitted to the IRB as amendments.

Mode of Advertising: Internet

Exact language of Advertisement:

Home-Based Asthma Study

We provide: • FREE help in reducing your asthma triggers -- at home and elsewhere! • FREE tools to make your home healthier. • COMPENSATION for your time and parking.

You are eligible if: • You are an African-American adult, age 18 or older. • You live in Harris County. • You have asthma that is not well controlled.

This research study is funded by the Patient-Centered Outcomes Research Institute (PCORI).

If you meet the above criteria and live within 60 miles of this clinic (Smith Clinic, 2525-A Holly Hall St, Houston, TX 77030) please enter your information below and click "I Am Interested In This Study" to be contacted by the study coordinator.

If you would like to be contacted by the clinical trial representative, please enter your contact information, then click "I Am Interested in This Study."

Mode of Advertising: Internet

Exact language of Advertisement:

(Same as newsletter; to be posted on our BCM website, www.bcm.edu/environmentalhealth. Additional information will be added later as finalized, including speakers, a registration portal, and a list of prizes).

Join area patients, healthcare professions, policy makers and the media on World Asthma Day for the first-ever Houston-area Town Hall on Asthma!

Tuesday, May 1, 2018 6:30 to 8:30 pm United Way of Greater Houston 50 Waugh Drive, Houston, Texas 77007

• Speak out on the burden of asthma in our community. • Test your asthma trigger IQ. • Hear about a recent study of Houston-area African-American asthmatics. • Explore ways to reduce flooding-related asthma. • Help form a list of actions to make Houston more lung healthy. • Win cool prizes.

The event is FREE but you must RSVP. Space is limited. Visit www.bcm.edu/environmentalhealth/2018townhall to register and for more information.

Hosted by Baylor College of Medicine and the Harris Health System, with support of the Jacob & Terese Hershey Foundation and the Patient-Centered Outcomes Research Institute (PCORI).

Mode of Advertising: Other: Flyer

Exact language of Advertisement:

The attached flyer (see Attachments, H-34115_HHStamped Flyer_20151123) and postcard (see Attachments, H-34115_Postcard_20151123) includes the following text:

[BCM logo with Environmental Health Service "lock-up"] Asthma Study

Home-Based Asthma Study

We provide: • FREE help in reducing your asthma triggers -- at home and elsewhere! • FREE tools to make your home healthier. • COMPENSATION for your time and parking.

You are eligible if: • You are an African-American adult, age 18 or older. • You live in Harris County. • You have asthma that is not well controlled.

713.798.1082 environmentalhealth@bcm.edu

This research study is funded by the Patient-Centered Outcomes Research Institute (PCORI).

Mode of Advertising: Other: Newsletter

Exact language of Advertisement:

Join area patients, healthcare professions, policy makers and the media on World Asthma Day for the first-ever Houston-area Town Hall on Asthma!

Tuesday, May 1, 2018 6:30 to 8:30 pm United Way of Greater Houston 50 Waugh Drive, Houston, Texas 77007

• Speak out on the burden of asthma in our community. • Test your asthma trigger IQ. • Hear about a recent study of Houston-area African-American asthmatics. • Explore ways to reduce flooding-related asthma. • Help

form a list of actions to make Houston more lung healthy. • Win cool prizes.

The event is FREE but you must RSVP. Space is limited. Visit www.bcm.edu/environmentalhealth/2018townhall to register and for more information.

Hosted by Baylor College of Medicine and the Harris Health System, with support of the Jacob & Terese Hershey Foundation and the Patient-Centered Outcomes Research Institute (PCORI).

Mode of Advertising: BCM Clinical Trials Website

Exact language of Advertisement:

The Houston Home-Based Integrated Intervention Targeting Better Asthma Control (HIIT-BAC) in African Americans (H-34115)

Baylor College of Medicine's Environmental Health Service (BCM EHS) is currently recruiting volunteers for an asthma study examining the effectiveness of home-based environmental interventions for improving asthma control and quality of life in African-American adults.

You are eligible if: - You are an African-American adult, age 18 or older. - You live in Harris County. - You do not plan to move in the next year. - You have asthma that is poorly controlled OR you have been hospitalized or visited an urgent care center or emergency room in the past year because of asthma.

We will: - Help you learn more about your asthma. - Teach you about asthma triggers & how to control them. - Provide tools to make your home healthier. - Compensate you for your time and parking.