Comprehensive Home-based Self-management Support for COPD Patients
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Mount Sinai	Protocol Name:	Comprehensive Home-based Self-management Support for COPD Patients
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HRP-503 Application (Protocol Supplement)

- *This application can only be used in conjunction with a protocol. If this project does not have a protocol from the sponsor or is already included in a grant application then a comprehensive protocol should be developed. A comprehensive template and online wizard is located at: NIH Wizard.*
- *Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable, or may have been fully covered in the protocol. Provide information if and when applicable. If the answer is found in the protocol please provide a page reference. If the question is not applicable to the study, mark the section "N/A". Do not delete any sections.*
- *Be sure to complete any supplement questions from one or another ancillary office that you receive during the RUTH application process. Please make certain that the protocol, this 503 application and responses to ancillary offices do not contradict each other and the information is incorporated in all documents where appropriate. Be sure to save the Ancillary office responses you provided within RedCap and upload them to Ruth.*
- *Throughout this application are references to checklists. These tools are used by the IRB to make specific regulatory findings. To allow us to do that it is the applicant's responsibility to ensure that your protocol has sufficiently addressed these additional regulatory criteria for approval, and that the applicant identifies those protocol specific findings required by the checklist. how will they do that, here or a separate form?*
- *Keep an electronic copy of this version of the document. You will need to modify this copy when making changes.*

1. Setting of the Human Research:

Mount Sinai is the lead site for this project. Northwestern is the second research site of this study (phase 1 only). City Health Works is the third research site. Research study activities will be conducted within the Center for Advanced Medicine at Mount Sinai.

For phase 1 of the study, we will recruit 20 participants from the Mount Sinai Health System in Manhattan, Queens, and Brooklyn in NYC, and 1-4 practices of the Northwestern University in Chicago, IL. These practices provide care to a population of >80,000 adults ages ≥55 years with considerable sociodemographic diversity (~40% Latino and ~30% Black, ~50% with household incomes <$1,350/month). For phase 2 of the study, we will recruit participants from the only Mount Sinai Health System in Manhattan, Queens, and Brooklyn in NYC. We will randomize 58 COPD patients (29 per arm) to the intervention or an attention control and follow them for 9

months to assess health and SMB outcomes. This project is currently in phase 2.

The research team will meet by conference call weekly to discuss logistical issues, refinement of protocol, and other issues pertaining to the study. The project manager at the lead coordinating site will email any modifications to the IRB protocol to Northwestern PI and research coordinator within one day of receiving approval. The project manager will also email a copy of the amendment approval letter. The Northwestern PI will abide by their institution's policies through an sIRB.

2. Resources Available to Conduct the Human Research: (the aim here is to assess if the research is likely to be successful and thus justify the efforts and risks taken by the subjects):

- *Explain the feasibility of meeting the recruitment goals of this project, and demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period. (For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? If this has been reviewed by a committee for recruitment feasibility [e.g. PR&MC], please indicate so.)*

This feasibility of meeting the recruitment goals for this project is high, given the low recruitment goal (58 participants) and the high prevalence of COPD in the United States. Approximately 16 million Americans have COPD, affecting 16% of U.S. adults, and recent trends show a more rapidly rising burden among women and African-Americans. Based on an existing COPD patient cohort we maintain, it will be feasible to recruit the proposed number of participants. For an ongoing COPD cohort study, we have identified 1147 potentially eligible participants.

The Mount Sinai Data Warehouse receives clinical, operational, and financial data derived from day-to-day patient care activities and captured in our transactional systems. The Data Warehouse will identify potential study participants and retrieve electronic data of study subjects.

At the Northwestern University site, Dr. Michael S. Wolf, MA MPH PhD (MPI) directs the Health Literacy and Learning Program (HeLP) which facilitates ongoing interdisciplinary faculty collaboration aimed at the development of innovative strategies to respond to the highly prevalent problem of limited health literacy. Dr. Wolf created a network of multidisciplinary faculty that could partner together to generate applied, innovative research that would help transform the delivery of healthcare for vulnerable patients (older adults a specific target). Since the inception HeLP, has received >$40 million in

NIH, AHRQ, private foundation and industry funding. This resource is used in for the refinement of study materials.

City Health Works has a well-established Community Health Worker program that extends the reach of overburdened clinics by serving as eyes and ears for clinicians and empowering clinicians with critical insights to better serve their patients. CHW delivers health coaching and care coordination by engaging patients referred from clinic or community settings or those referred during hospitalization. Service planning and delivery is supported by a Health Coach Supervisor and a team of community health workers who act as Health Coaches. Its neighborhood-based, clinically-supervised community workforce is cross trained to address multiple health and social issues through medical partnerships and patient referrals, community based engagement, health coaching and care coordination.

Key Personnel involved in the study from Mount Sinai:

Name	Department	Role
Alex Federman, MD, MPH	Medicine - General Internal Medicine	Principal Investigator
Juan Wisnivesky, MD, DrPH	Medicine - General Internal Medicine	Principal Investigator
Stacey-Ann Bailey, MD	Pulmonary	Co-Investigator
Natalia Egorova, PhD	Population Health Science and Policy	Co-Investigator

Key Personnel involved in the study from Other Sites:

Name	Site	Role
Michael S. Wolf, PhD, MPH	Northwestern University	Principal Investigator
Rachel O'Conor, PhD, MPH	Northwestern University	Co-Investigator
David Strefling, MPH	City Health Works	Site Principal Investigator

Non-Key Personnel involved in the study will be managed by the PI. Requisite certifications and records for these individuals will be included in the Regulatory Binder and Financial Conflicts of Interest will be reported on Sinai Central.

The Principal Investigator will ensure the adequate training and monitoring of trial-related duties and activities. Investigators and staff will be informed of updates to the trial design and activities via biweekly meetings. Research Staff in the Division of General Internal Medicine are required to undergo general training in adhering to study protocols, obtaining informed consent, administering questionnaires, safeguarding data, and other related quality metrics. Staff assigned to this project will also undergo a scheduled training session for study-specific activities. All staff will be monitored by a Project Manager experienced in management of research studies. The Principal Investigator will oversee the Project Manager.

3. Study Design:

a) Recruitment Methods (see PPHS policy):

We will recruit 58 participants the Mount Sinai Health System in Manhattan, Queens, and Brooklyn in NYC (phase 2 only).

Potentially eligible patients will be identified through queries of the Epic clinical record system, including review of spirometry testing. Additionally, physicians at participating Mount Sinai clinics will be informed of the study and encouraged to refer potential participants.

The treating physician of potentially eligible patients will be sent a consent to indicate if they allow their participant to be enrolled in the study. The Research Assistant (RA) will send physician approved patients a recruitment letter, which will include information about the study. The recruitment letter will have an opt-out number to call. Potential participants will be given a record number they can mention in the study telephone line voicemail if they wish to opt-out. A member of the research staff will check the voicemail daily and remove from the recruitment list those patients who have opted out. In this way, we will ensure that patients who do not wish to participate are not re-recruited by the research staff.

Seven (7) days after the recruitment letter has been sent, an RA will contact the patient by telephone. The RA will follow a recruitment script to introduce the study to the patient and obtain verbal consent to administer the study eligibility screener.

If the participant provides verbal consent to screening over the telephone or in person, the RA will administer the brief eligibility screener. Participants who screen eligible will be offered participation and will be scheduled for the baseline interview with the RA.

b) Inclusion and Exclusion Criteria:

Inclusion Criteria

1) Age >40 years;
2) community dwelling;
3) FEV1<70% predicted or >1 COPD-related hospitalization or ED visit in past 12 months
4) prescribed a daily chronic use medication for COPD;
5) English or Spanish speaking;
6) Smoking history > 10 pack-years

Exclusion Criteria

1) Diagnosis in the clinical record of dementia, because the study focuses on patients with capacity to independently perform SMB.

Participants are screened for eligibility through chart review. To conduct these chart reviews, a waiver of informed consent was requested. This information is needed to recruit patients from the Data warehouse housed at Mount Sinai Hospital. We would be unable to recruit these patients without access to this information. No further information about the patient will be collected unless we get research consent from the patient. We propose to use this information as there is no other way to ensure a representative patient sample.

c) Number of Subjects:

Phase 1 will consist of a total of 20 participants from both the Mount Sinai and Northwestern sites.

A total of 58 patients will be enrolled in the phase 2 study over a 1-year period and followed for 9 months. Participants are enrolled in the research only at the Mount Sinai site.

d) Study Timelines:

The study will take place from May 1, 2019 to April 30, 2022. The image below describes the timeline of events for this proposed study.

Table 4. Feasibility Trial Timeline (also see Table 1)

	Months				
	1-12	13-18	19-24	25-30	31-36
Recruitment		X			
Interviews/data collection		X	X		
Data cleaning		X	X	X	
Data analysis			X	X	X
Data dissemination				X	X

Study Duration:
The anticipated duration of participation will be 9 months. Participants will be participate in the intervention or control group for 6 months. Participants will complete a consent form at the time of enrollment and complete the baseline interview. The participant will complete 6 month and 9 month follow-up interviews.

We have allotted 24 months to recruit and enroll all participants.

We anticipate 12 additional months to finish preliminary analysis. The estimated date to complete analysis is the end of April 2022.

e) Procedures Involved in the Human Research:

Description of the Study Design

A. Phase I will focus on intervention development (months 1-12).

We will focus on adapting the SAMBA protocols for COPD self-management support. Much of the existing structure and content of the SAMBA asthma materials and protocols will be retained in the SaMBA-COPD model since there is a great deal of overlap in the SMB of the two conditions and for chronic illness self-management support in general.

A.1) Preparation of Materials and Methods for SaMBA-COPD: The process will have 1) stakeholders identify new content; 2) concurrently create the COPD 1-2-3 education booklet, adapt the screener, and revise the patient engagement protocol; 3) develop the HBEP protocol; 4) conduct cognitive interviews with patients to assess materials and HBEP protocol for comprehension and salience; 5) revise materials and the HBEP protocol; 6) pretest the intervention (n=5; 4 weeks of follow-up); 6) finalize materials and protocols.

A.2) Identifying and Integrating Coping Strategies: We will recruit patients for qualitative interviews to learn how they cope with COPD and SMB and document the narratives they use to explain their strategies. Interviews are also conducted with COPD patients to assess comprehensiveness, clarity, utility, and acceptability of program materials and procedures, to identify weaknesses and important omissions, and devise solutions. In-person interviews will proceed until we reach thematic saturation, which can typically be reached with 12-15 patients. We plan to conduct 20 interviews as coping strategies may vary widely among patients and we want to ensure representation by individuals of both sexes, and the races and ethnicities predominant in the surrounding communities (African- American, white non-Hispanic, and Latino). Next, we will conduct an in-depth exploration of their coping behaviors in response to these beliefs. Patients will be asked to describe their SMB, especially successful and unsuccessful strategies, and how they link to the beliefs they described. Interviews will last approximately 45 minutes. The interviewer and note taker will debrief immediately after each session and document impressions, critical points and notable quotes.

Each interview will be audiotaped and transcribed. We will use an iterative process of thematic content analysis. Specifically, we will independently read five interviews to begin identifying the various issues and concerns that were discussed in relation to their COPD management. We will then share and discuss the topics identified and collaboratively construct a list of preliminary codes after reconciling interpretive differences. Each coder will

independently test the provisional codes in 5 new interviews. The team will meet again to update the coding scheme. Next, coders will apply the final coding scheme on the full set of interviews using ATLAS.ti, a qualitative data analysis software program. Coping strategies will be additionally coded as adaptive or maladaptive. Dr. Wolf and Ms. O'Conor will train the coders and supervise them throughout the process for fidelity. Finally, stakeholders will meet to review the coping strategies and determine, by consensus discussion, which of them have the most promise as targets for the intervention. The list of adaptive coping strategies will be used by the CHWs as possible alternative strategies for patients to employ.

A.3) Home-Based Exercise Program (HBEP): HBEP will be potentially available to all patients who are able to ambulate with or without an assistive device (cane or walker), regardless of supplemental oxygen use.
If the patient expresses interest in HBEP, the CHW will schedule the appointment and accompany the patient and caregiver (if available) to a clinical site at Mount Sinai Hospital and the patient will undergo an evaluation for the exercise program by a clinician. This aspect of the intervention is described further in Step 6.

A.4) The Screener is the tool CHWs will use to comprehensively and efficiently identify barriers to COPD self- management and disease control. Most items on the current SAMBA screener are applicable to chronic illness self-management and include costs of medications and medical care, mental health disorders like anxiety and depression, alcohol and other substance use disorders, tobacco use, physical and cognitive impairment, social support, and environmental factors (e.g., stable housing, exposure to second hand tobacco smoke). Inhaler technique, controller medication adherence, and action plans are also relevant to COPD patients. Unique COPD items will include behaviors pertaining to oxygen use and exercise, acceptance of influenza and pneumococcal pneumonia vaccines, and beliefs about COPD illness and medications. The screener is implemented after the RA enrolls a participant in the study. The screener is only used for participants in the intervention group.

B. Phase II will focus on intervention implementation and evaluation (months 13-36).
We will randomize 58 COPD patients (29 per arm) to the SaMBA-COPD intervention or an attention control and follow them for 9 months to assess health and self-management behavior (SMB) outcomes.

B.1) CHW Training. Training will cover the basics of COPD pathophysiology and treatments and COPD SMB. It will also review the procedures of the SaMBA-COPD model and core skills, including motivational interviewing,communication with healthcare providers, and other topics. After training, CHWs will engage in observed role play until they have mastered the basic

elements of the protocol. They will then work with actual patients during pre-testing. CHWs will be observed in the field and must be certified before they can provide support to patients independently as was required for SAMBA. Supervisors will do monthly field observations to ensure that quality is maintained.

B.2) CHW Personnel. City Health Works, a non-profit community health worker organization not affiliated with the Mount Sinai Healthcare System will provide the CHWs who will deliver the service. All services are provided in the home or, if patients prefer, in community settings like schools or churches. CHWs typically have high school or bachelor's degrees. Some have CHW certificate training. Their foundational skills include motivational interviewing, linkage to community-based resources for specific needs, and basic chronic illness SMS like medication handling and reminding. Community Health Workers will be supervised by health coach supervisor (David Strefling, Site PI).

CHWs are identified and selected by the Chief Health Officer of City Health Works. They are not recruited into the study. City Health Works a study site, who will implement the intervention. It is up to the discretion of the director of City Health Works on who will work on this research study. They are not considered study subjects because we are not collecting data for research purposes on the CHWs. They are a part of the study team. They will conduct the intervention with enrolled participants (i.e. study subjects). Their performance in this research has no bearing on their employment standing at City Health Works. The Chief Health Officer at City Health Works will determine which CHWs will work on this study and their job function. Their performance is being evaluated for internal quality assurance for this study. The CHWs are not doing any work outside of their normal workflow. While the exercise program and emergency pack/action pack medication research components are new concepts for the CHWs, these components are overseen by clinicians, not the CHWs.

Research Recruitment and Study Arm Assignment: We will identify potentially eligible patients and will obtain permission from the physician to recruit their patient. We will send a letter to the patient describing the study. One week later, the RA will phone the patient to answer questions and check eligibility of the participant. Eligible patients will be scheduled for an in-person or phone baseline interview, consented and enrolled in the study. We will assess the participant's inhaler technique, electronic medication adherence, and physical activity through a wearable activity monitor. The data from the electronic medication adherence device is for research purposes only. There are no studies demonstrating that providing such data to patients or their doctors improves their medication adherence, thus providing these data to them is unwarranted. The participant will then be randomized to the intervention or control arm.

B.3) SaMBA-COPD Intervention.

Step 1: Outreach and Engagement. The project manager will notify the CHW supervisor when an eligible and consented patient is randomized to receive care the intervention and will provide the patient's name and contact information (see Description of Procedures Being Performed for recruitment and randomization). The CHW will call the patient within 7 days of consent to schedule a home visit. The CHW will encourage caregivers to join all meetings.

Step 2: Intake. The CHW will perform an intake interview that includes collection of basic information about the patient and their health and healthcare, including medications, intended to enable them to understand their health problems and provide them with chronic illness self-management support.

Step 3: Symptom assessment, medication adherence, and inhaler technique. The CHW will assess the patients' symptoms, adherence to medications, and check inhaler technique following a standardized protocol, and correct errors in inhaler use if identified.

Step 4: SMB barrier screening with the Screener. The CHWs will assess barriers to good SMB that lie within 4 domains: 1) social context, 2) physical health and functioning, 3) cognitive factors, and 4) psychological factors. To assess elements in each domain, we will use questions drawn from validated surveys used in our research and in the SAMBA screening tool. Screening questions are a part of the study intervention, of which they consented to in the research consent. Examples of barriers follow:

(1) Social context. Factors include adequacy of social support, financial and access concerns (costs, insurance, pharmacy convenience), language and literacy skills, coping with illness, alcohol and drug use, and use of culturally- rooted therapies like herbals and spiritual remedies.

(2) Physical health and functioning. These include physical functioning and medication concerns (e.g., side effects, multiple medications).

(3) Cognition. The CHW will screen for cognitive impairment with the validated Quick mild cognitive impairment screen (QMCI) because cognitive impairment may challenge their ability to perform SMB.

(4) Psychology. Factors include depression and anxiety, and maladaptive beliefs about COPD and COPD medications.

Step 5: Addressing identified barriers. Each identified barrier links to a menu of actions for the patient and CHW to employ to resolve or work around it. Other actions may be identified by patient or CHW and pursued if desired. Wherever appropriate, the CHW will engage the

patient's physicians and or a social worker to enact some of the action steps. Examples of barriers follow:

(1) Social context barriers. Examples of actions include enrolling the patient in the New York State pharmaceutical assistance program to reduce drug costs or ask physicians to consider generic or formulary approved alternatives. If retrieving or renewing prescriptions is a problem, the CHW may pick up the medication or arrange delivery. The CHW can contact the physician to request a renewal if needed, and refer the patient to a social worker for assistance with home aid services, entitlements, insurance matters, and assistance when second hand smoke is a problem.

(2) Physical health and functioning barriers. Examples include asking the physician to consider reducing medicines if the patient finds the regimen too burdensome, requesting occupational or physical therapy to address physical limitations, or engaging the social worker to arrange transportation.

(3) Cognition barriers. We will specifically target memory but also use strategies to compensate based on type of impairment, including medication organization, slower-paced and explicit verbal instructions, use of tangible external aids, repetition and teach-back, use of plain language, and guided imagery to reduce cognitive load. Such strategies have been shown to improve SMB in low-literacy populations. The CHW may have more frequent encounters (in-person, phone) with memory impaired patients. Daily cell phone text reminders are another option that patients can select when memory problems impact regular medication use.

(4) Psychological barriers. The CHW will notify the PCP if a participant voluntarily divulges any feelings of depression or anxiety. The PCP may evaluate and treat or refer to a mental health specialist.

COPD action plan and medication rescue pack. We will obtain consent from each patient's primary care provider to have a pharmacist counsel patients about rescue medications (oral steroids and antibiotics, "rescue pack") to be used in the event of an exacerbation of COPD. This consent will be obtained at the time of obtaining consent from the physician to recruit the patient for study participation. If the physician provides consent to recruit the patient but refuses consent to counsel the patient about the rescue pack, the patient will receive all intervention components with the exception of rescue pack counseling by a pharmacist.

For patients for whom we have consent from the PCP to provide counseling about the rescue pack, the CHW will suggest to the patient that they meet with the pharmacist. The meeting will be voluntary. For patients who agree, a referral will be made to the pharmacist and a visit scheduled, to take place in a clinical setting. The pharmacist will counsel the patient on the use of the rescue pack. If the patient agrees to receive a rescue pack, the pharmacist will place an order in the Epic electronic health record for the rescue pack medications, then pend and route the order to the patient's PCP. The PCP can choose to sign the order, cancel or delete it. The

pharmacist will check to determine whether the prescription order was signed by the PCP. If it was not, the pharmacist will assume that the physician does not wish to provide the patient a rescue pack prescription. If the prescription order was signed by the physician, the pharmacist will contact the patient 7-10 days later to determine whether the patient picked up the medication and to ensure that the patient understands when and how to use the medications appropriately, and will notify the CHW that the patient received the medications. The CHW will discuss the use of the rescue pack medications with the patient at subsequent encounters to ensure that they continue to understand how to use them appropriately. Should the patient use the medications, the CHW, pharmacist, and or patient will notify the PCP, who will be encouraged to follow up with the patient.

Step 6: Home-Based Exercise Program (HBEP)
HBEP will be available to all patients who are able to ambulate with or without an assistive device (cane or walker), regardless of supplemental oxygen use. If the patient expresses interest in HBEP, the CHW will schedule the appointment at a clinical practice at the Mount Sinai Hospital. Patients in the intervention arm of the study will undergo an evaluation at Mount Sinai Hospital for home exercise by a clinician. Dr. Federman and Dr. Wisnivesky will serve as clinicians. Dr. Federman is a board-certified internist who practices general internal medicine. Dr. Wisnivesky is a pulmonologist. Both have done extensive research with the COPD population. If in-person evaluation is not possible, the patient will undergo an evaluation by video call. The video encounter will only occur if the patient has previously demonstrated during the study that they are capable of communicating clearly and visibly by video call. The patient will undergo a standard evaluation by a clinician employed by Mount Sinai Hospital. The evaluation will have two components, assessment of aerobic capacity using the 6-minute walk test (6MWT), and an assessment of muscular strength using elastic resistance bands. Target exercise intensity will be set at 60-80% of the maximum work rate achieved during the 6MWT, a conservative goal intended to achieve benefit while minimizing risk of fatigue and shortness of breath. Based on the patients' performance during the evaluation, the clinician will select an appropriate band for home use for strength training exercises. During the evaluation, the clinician will monitor the patient's oxygen saturation, heart rate, and respiratory rate. If a video evaluation will be conducted, the study team will mail the patient the following materials before the evaluation is performed: color-coded and latex-free resistance bands of varying resistance levels, a digital pulse-oximeter pre-set up with batteries, a digital automated blood pressure monitor, and a digital wristband activity monitor. These items are easy to use and instructions will be provide for their use, including written instructions, and guidance by video call, and by telephone as need. They will be allowed to keep these materials when their participation in the study ends, no matter the duration of their participation.

The video evaluation will be performed by a clinician and only if the patient is accompanied by an adult who is physically capable of supporting the patient and participating in the evaluation procedures. The clinician will follow the same procedures described above for the in-person evaluation. This includes 1) the 6-minute walk test, and 2) demonstration of ability to perform various maneuvers using the resistance bands. The accompanying adult will measure the patient's blood oxygen saturation and pulse using the pulse-oximeter and blood pressure prior to the start of physical activity and at the immediate conclusion of the activity, and provide that information to the clinician performing the evaluation. The clinician will use this information to plan a home-exercise regimen for the patient.

Tablets and Internet access will be provided, as needed, to patients in both the intervention and control arms. If patients have a smart phone, tablet, or computer (hereafter termed "electronic device"), a study tablet will not be provided to them.

If the patient does not have Internet access, the study will provide them with an Internet-wifi connection at no cost to them; the cost-free Internet will be available to them for the duration of the study. At the conclusion of the study, the patients will be allowed to keep the tablet device and the study team will provide them with information about low cost Internet plans in their area.

Tablets will be pre-loaded with videos demonstrating proper inhaler technique for COPD inhaled medicines, breathing techniques, and exercises. They will also be set up with video conference capability. Patients will be provided with a telephone number to call if they have difficulty using the device. If they already own or have access to an electronic device, the study team will send them the videos by email or text message.

During the home visit or telehealth visits that follows, the CHW will provide a timer, a fitness tracker bracelet to measure steps, an elastic resistance band, and an exercise diary. They may also provide the patient with a ergo cycle to enable them to conduct the aerobic exercises sitting down if walking is too burdensome or the patient is considered to be at high fall risk. The CHW and patient will consider the space available for exercise, such as a hallway, common space in the building (e.g., lobby, gathering room, etc.), outdoors during favorable weather, and local facilities like senior centers or churches. Once the area for exercise is selected, the CHW will demonstrate or explain the walking and resistance training routines and observe the patient perform them on his/her own. The two will set a schedule for exercising and post the schedule and instructions prominently in the home.

If the patient is unable to ambulate, or their gait appears unstable, they will be provided with a hand pedal ergometer, which they will use in place of walking for exercise. They will be allowed to keep the ergometer at completion of the study.

Resistance training will consist of a simple routine of upper and lower extremity extension and abduction movements with the elastic band. Each movement will be performed for 8-12 repetitions. The walking routine will last 20-40 minutes and the patient's pace will be guided by an audible click from the timer that is set by the CHW. The patient will be asked to perform the complete exercise routine 5 days a week. The CHW will directly supervise the patient in person or over the phone multiple times over the 6-month intervention period. She will call periodically to support the patient when she is unable to visit.

The clinician will provide supervision of the CHW. This will include reviewing all cases in person or by phone every 7-14 days. Patients will be asked to reduce the intensity of exercise or rest for 5-10 minutes if they develop an uncomfortable level of shortness of breath or fatigue, and to stop exercising if they have symptoms that cause distress or discomfort and do not resolve after rest. Low literacy education methods will be used to ensure their understanding and retention of these instructions. The CHW will maintain communication with the clinician by HIPAA compliant secure email and telephone to report patient performance, trouble shoot problems, and to receive continuing education.

Step 7: Follow-up and Maintenance. The CHW will recommend that meetings occur 1, 4, 8, and 12 weeks after intake and telephone follow-ups weekly through week 8 and monthly thereafter until month 6 when the intervention ends. Calls may be made more often to cognitively impaired patients to enhance information retention. Importantly, the patient and CHW will have the flexibility to tailor the number and frequency of encounters as they see fit. During follow up the CHW will assess patients' progress with SMB, their goals, and their symptoms.

Step 8: Graduation. SaMBA-COPD patients will receive a certificate upon program completion.
Description of Procedures Being Performed

a. Patients and Settings. We will recruit patients from the outpatient general medicine and pulmonary practices of Mount Sinai Hospital. Inclusion Criteria: 1) age >40 years; 2) community dwelling; 3) chart-document severe or very severe COPD (FEV1<70% predicted); 4) prescribed any daily medication for COPD; 5) English or Spanish speaking; 6) Smoking history # 10 pack-years; 7) COPD-related ED/hospitalization # 1 visit within the past 12 months. Exclusion Criteria: Diagnosis in the clinical record of dementia, because the study focuses on patients with capacity to independently perform SMB.

b. Community Health Workers: CHWs are a part of the study team and will be assessed for internal quality assurance purposes only. Currently there is not a clear intent to contribute to generalizable knowledge with this data. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application will be submitted to the IRB. Their performance is being evaluated for internal quality assurance for this study.

c. Recruitment and Interviewing. We will identify potentially eligible patients through queries of the Epic clinical record. RAs will obtain permission from the physician to recruit their patient then send a letter to the patient describing the study. One week later, the RA will phone the patient to answer questions and check eligibility of the participant. Eligible patients will be scheduled for an in-person baseline interview and enrolled in the study. Baseline interviews will occur at a location/time of the patient's choosing. RAs will reschedule missed interview appointments up to three times, after which patients will be considered dropouts. RAs blinded to treatment allocation will interview patients at 6 and 9 months.

d. Video Conferencing. Some visits with the community health worker may take place over Zoom conferencing or VSee video call, the Icahn School of Medicine approved HIPAA compliant version. Both Zoom and VSee ensure HIPAA compliance by preventing the sharing and collection of PHI and by encrypting audio and video data (for more information: https://zoom.us/docs/ doc/Zoom-hipaa.pdf; https://vsee.com/hipaa).
Enrolled participants will be contacted via phone or email, based on their preferred method of contact, and provided with a link and password to access a Zoom session. A trained member of the research staff will meet with the participant over Zoom at the scheduled time to complete the visit. As an alternative method, participants will be sent a text or email with a link to open up a VSee video call.
If participant responses during the visit raise any concerns about patient safety, the research staff member will follow a modified version of the study protocol for risk assessment. The modification will be as follows:

- Rather than bringing the Principal Investigator or other licensed clinician into the room to meet with the participant in person, the clinician will be contacted via phone and, with the participant's permission, will be given access to join the video conference and conduct an additional assessment via this platform.
- If the clinician determines that that participant is at elevated risk for suicide, the patient is notified by the clinician that 911 will be called and that this will result in an ambulance being sent to their residence to make sure that the subject is okay. The study coordinator remains on the telephone with the patient until the ambulance arrives. The 911 operator is notified if the patient ends the video conferencing call abruptly or hangs up.

e. Randomization. Randomization will occur immediately after the baseline interview is complete. To obtain the assignment, the RA will access an online program in REDCap that implements the algorithm.

f. Control Arm. The attention control is designed to isolate the impact of screening for self-management barriers, targeted self-management support, and HBEP. The attention control will consist of 3 visits by a CHW to the home to review the COPD education booklet (COPD 1-2-3). During the first visit, this CHW will review the COPD 1-2-3 booklet in its entirety with the patient. During visits 2 and 3, the CHW will make a visit to "check in" with the patient, ask how they are doing with their respiratory symptoms, and review any sections of the COPD 1-2-3 booklet the patient chooses. The CHW will recommend visits every 2 months but the patient and CHW may choose to modify the interval as needed. If the patient appears to be experiencing worsening respiratory symptoms during any visit, the CHW will notify the patient's physician.

g. Quantitative Data Collection. Baseline, 6- and 9-month interviews will be in-person or over the phone in English or Spanish. Bilingual RAs will conduct them at home or in clinical spaces, by patient preference, using laptop computers and REDCap software, as we do with all of our research.

Primary Outcomes: COPD symptoms, inhaler technique, and exercise activity. COPD symptoms will be measured with the 8-item COPD Assessment Test (CAT) (score range 0-40), the 14-item Chronic Respiratory disease Questionnaire (CRQ), and the Medical Research Council Scale. Inhaler technique: We will assess proficiency in use of MDI and DPI placebo devices (Spirit Medical Devices, Murrysville, PA) and medication tracking devices (Propeller Health, Madison Wisconsin) using validated checklists and adapt these checklists for technique assessment with users of Elipta and Respimat inhalers. The Propeller Health devices can aid patients in medication adherence and understanding of their triggers for COPD and asthma. Exercise in the past 7 days will be measured with the 13-item Physical Activity Adult Questionnaire (PAAQ) and a wearable activity monitor, the Actigraph, which will be worn for 1 week intervals at baseline, 6 and 9 months. Secondary Outcomes. Self-reported medication adherence will be measured with the self-reported Medication Adherence Reporting Scale (MARS)., and with an electronic monitoring device that is attached to the inhaler. Exercise tolerance will be measured at baseline, 6- and 9-months using the 6- minute walk test (6MWT). We will ask about use of an action plan for COPD exacerbation.

h. Fidelity. Fidelity will be assessed through abstraction of CHWs' documentation in Community Health Works' documentation, direct observation of the CHWs, and qualitative exit interviews with patients and CHWs. The project manager will conduct unannounced

observations of each CHW monthly during the trial. She will also audio/video tape these encounters to review with the CHW for skills development.

i. Qualitative Data Collection and Analysis. We will conduct semi-structured exit interviews with patients and CHWs to assess feasibility and perceptions of SaMBA-COPD to guide refinement. Interviews will follow the month 9 interview or at study dropout (30-45 minutes; compensation, $20). Topics will include satisfaction, burden (physical, emotional, social), convenience, perceived positive or negative effects, and appropriateness. At trial completion, we will conduct qualitative interviews with CHWs and their supervisor and PR staff and physicians to assess the same topics. All interviews will be audio/video-recorded. These interviews will be used for internal evaluation and quality improvement.

j Quantitative Data Analysis.
Primary analyses. We will analyze outcomes on the intention-to-treat principle. The primary outcomes are CAT score, ICS technique, and PAAQ scores at 9 months.

Description of Data that Will Be Collected Including Long-Term Follow-Up
Disease beliefs: will be measured with the brief Illness Perceptions Questionnaire (IPQ; available in English and Spanish) that includes items for each of the 5 cognitive domains of the SRM.(15) Medications Beliefs: We will use the Beliefs about Medicines Questionnaire, an English and Spanish validated 10-item scale that measures beliefs about controller medication in 2 subdomains: necessity and concerns (reliability: 0.80). (16) Items will be added to assess expectations of benefits and emotional representations about medications (worried about side effects or addiction, upset about medication regimen, etc.).

Adherence: COPD controller medication adherence, electronically measured: Objective measurement using the Smartinhaler electronic device for metered dose inhalers (MDIs) and the Smartdisk for dry powder inhalers (DPIs) for 4 weeks after each research interview. RAs will attach the monitoring device to the inhaler, and patients will return them in a pre-stamped envelope. Adherence will be defined as use of medications on #70% of days prescribed, a commonly applied convention.

Cognitive: Quick mild cognitive impairment screen (QMCI).

Lifestyle: physical activity, electronically measured: objective measurement using Actigraph. Physical activity adult questionnaire (PAAQ). Smoking/alcohol/drug activity. Activities of daily living questionnaire (ADL), general health (single item). Comorbidities (Charlson Index).

Depression/anxiety: Patient health questionnaire 9 (PHQ-9), General anxiety disorder 7 (GAD-7)

Health services: health service utilization (ED/hospitalizations). We will obtain data on these outcomes by self-report and from the NYS SPARCS data system.

f) Specimen Banking for Future Uses Not Part of This Project:

N/A

g) Data Storage, Transmission and Confidentiality:

Data Storage: Each subject will be assigned a unique alphanumeric identifier. The alphanumeric identifiers will be unrelated to the identity of the study subjects. All clinical data/information will be entered into a secure, online research database called REDCap only using that unique identifier. Data downloaded from REDCap and stored on MSSM computers will be encrypted and password protected, and only members of the study team will have access to the study data. All research specimens obtained will be stripped of personal identifiers (such as name, date of birth, medical record number) and will be processed/stored utilizing only the unique alphanumeric identifiers in the participating laboratories. Data abstraction forms will be completed only online. Only the research team will have access to this data. A confidential list linking subjects and their alphanumeric identifier will be recorded on a separate password protected database. This database will be located on a secure password protected desktop computer on the Division's encrypted research drive. Only the PI and the research coordinator will have access to the linking database. Databases with linked information are maintained on computers supported by the Mount Sinai server network. The research team will download deidentified data from RedCAP as needed for analysis and store all such data in password-protected files on the PI's secure study drive. MSSM policies regarding data transfer and security will be followed.

Data Access: Only authorized personnel listed on each institution's IRB will have access to the data.

Data Transfer from Recording Devices to Local Network Drive: Research interview data files from the audio/video recording devices must be transferred to each site's secure network drive within 48 hours of the interviews.

Data Transfer to Data Coordination Center (Northwestern; phase 1 only): Data will be collected separately by the NU and Mt. Sinai teams. All data will be transferred to Mt. Sinai and combined. Only de-identified study data will be transferred back to Mt. Sinai. A back-up copy of all transferred data will be maintained at Mt. Sinai. The project manager and data analyst

from our team will combine the data and maintain the master data file containing all data from each location, create a data dictionary, and be responsible for data cleaning and providing updated data to study investigators when requested.

Claims data will be requested from New York State Statewide Planning and Research Cooperative System (SPARCS) and will be managed in accordance with an executed data use agreement.

h) Data and Safety Monitoring Plan:

- **For projects with a Data Safety Monitoring Board/Data Safety Committee (DMSB/DMC):**

The board members will meet prior to implementation of the pilot RCT of the intervention to review the study protocol and measures to ensure that adequate protections and the plan to monitor for adverse events are adequate. They will then meet every 6 months after implementation of the pilot to review data, including the following elements: recruitment rate, study withdrawal, reasons for withdrawal, and adverse events, for a total of 3 meetings.
The DSMB will specifically review: 1) hospitalization and mortality rates; 2) study disenrollment unrelated to death; 3) any patient, caregiver, and healthcare provider concerns.

i) For other projects with greater than minimal risk a monitoring plan must be provided:

1. List the name(s) of the individual(s) at MSSM who will be responsible for data and safety monitoring of this study. For each individual, indicate their role, name, title, and department information. The Principal Investigator may be the only monitor of a study.

2. If the qualifications of an individual to serve as a monitor are not contained in the PPHS application, they must be added to the DSMP either as a narrative description or as a CV.

MSSM Principal Monitor (MPI):
Last Name: Federman
First Name: Alex
Academic Title: MD,MPH
Department: Division of General Internal Medicine
Mailing Address: One Gustave L. Levy Place, Box 1087, New York, NY 10029
Phone: (212) 824-7565
E-mail: alex.federman@mountsinai.org

MSSM Additional Monitor (MPI):
Last Name: Wisnivesky

First Name: Juan
Academic Title: MD, DrPH
Department: Division of General Internal Medicine
Mailing Address: One Gustave L. Levy Place, Box 1087, New York, NY 10029
Phone: (212) 824-7567
E-mail: juan.wisnivesky@mountsinai.org

MSSM Additional Monitor (Co-I):
Last Name: Wolf
First Name: Michael
Academic Title: MA, MPH, PhD
Department: Division of General Internal Medicine & Geriatrics
Mailing Address: [redacted], Chicago, IL 60611
Phone: (312-503-5592)
E-mail: mswolf@northwestern.edu

3. Justify your choice of principal monitor in terms of the assessed risk to the research subject's health and wellbeing. In high risk studies when the principal monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and the rationale for selection.

The Principal Investigator is the individual who understands the benefits and risks associated with the research. The clinical experience and expertise in the field of COPD and self-management behavior interventions of the principal monitor is an adequate choice to assess the risk of research subjects' health and well-being.

4. List the specific items that will be monitored for safety (e.g., adverse events, subject compliance with the protocol, drop outs, etc.).

The DSMB will monitor patient safety, consider new scientific or therapeutic developments that could impact safety or trial ethics, and make recommendations to continue, terminate, or modify the trial based on interim analyses. The DSMB will specifically review: 1) hospitalization and mortality rates; 2) study disenrollment unrelated to death; 3) any patient, caregiver, and healthcare provider concerns. Adverse events that may result in subject withdrawal include disruption of previously established regular care such that the patient's health is jeopardized or excessive burden created by the time required to participate in the study.

5. Indicate the frequency at which ACCUMULATED safety and data information (items listed in number 3 above and interim analysis of efficacy outcomes) will be reviewed by the monitor(s) or

the Data Monitoring Committee (DMC). Although this information must be reviewed at least annually, the higher the study risks, the more frequently reviews must be scheduled.

Every 6 months for a total of 3 meetings

6. Where applicable, describe rules which will guide interruption or alteration of the study design.

The DSMB may recommend stopping the trial if there is clear evidence of harm or overwhelming benefit. Adverse events will include disruption of previously established regular care such that the patient's health is jeopardized or excessive burden created by the time required to participate in the study. The study team will monitor and report on self-reported accidents, primary care visits, participants using oxygen therapy, and unanticipated problems to the DSMB. The DSMB can recommend changes in study protocol or termination of the study if it concludes the study design causes disruptions in patient-provider continuity which jeopardized the health of the study subject or if the study imposes excessive burden on patients. Finally, the DSMB, at the request of the sponsor, will review accrual and evaluate study progress towards meeting recruitment targets.

7. Where applicable, indicate dose selection procedures that will be used to minimize toxicity.

N/A

8. List any specialized grading system that will be used to evaluate adverse events (e.g., National Cancer Institute Common Toxicity Criteria).

N/A

9. Describe procedures that will be used to assure data accuracy and completeness.

Additional review of data accuracy by study analyst and statistician. Aggregated data is shown to the DSMB in both closed and open meetings.

10. Should a temporary or permanent suspension of your study occur, in addition to the PPHS, indicate to whom (NIH, FDA, sponsor, IRB) will you report the occurrence.

Should a temporary or permanent suspension of the study occur, in addition to the PPHS, we will report this to NIH.

j) Withdrawal of Subjects:

Procedures for Subjects to Request Withdrawal

Participants that wish to withdrawn from the study can do so by contacting the Principal Investigator or research staff. Participants may also withdrawn their permission for the use and disclosure of any of their protected information for research, but they must do so in writing to the Principal Investigator. Even if the participant withdrawn their permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study.

Procedures for Investigator to Withdraw Subjects

The Principal Investigator may stop the participant's involvement in the research study at any time without their consent. If so, Principal Investigator will communicate the participant of his decision through writing.

4. Provisions for Research Related Harm/Injury:

Principal investigators will review all data collection forms on an annual basis for completeness and accuracy of the data as well as protocol compliance. A statement reflecting the results of the review will be sent to the IRB and the sponsor in the annual report.
Adverse event grading
Attribution scale: An adverse event is defined as both an expected side effect that is of a serious nature, or an unexpected side effect/event regardless of severity. All events will be graded as to their attribution (unrelated to protocol, or possibly, probably, or definitely related to protocol). Any event that is reported to either a principal investigator or their designated research associates by the subject or medical staff caring for the subject and which meets the criteria will be documented as such.
Expected risks: As detailed in the consent form, the expected risk include: Potential risk for loss of private information.
These risks are considered to be minimal and are addressed in the protocol and consent form.
Plan for reporting both anticipated and unanticipated adverse events: All expected and unexpected serious adverse events will be reported according to protocols defined by the NIH. We will expedite reporting of serious adverse events to the IRB, where applicable, when such events are unexpected (within 7 calendar days when life-threatening or fatal; within 15 calendar days for all other unexpected serious adverse events). Copies of reports will be sent to the NIH Project Officer responsible for the study.
The research staff, including project managers and research coordinators, will be trained to identify and report all adverse events, regardless of severity, as well as problems of data security, to the PIs. Weekly study conference calls will involve the MPIs, project managers, and research coordinators. One of the main purposes of the calls will be to ensure patient and study

safety and ensure compliance with monitoring and reporting. Toward these objectives, every meeting will include: (1) a report of the number and nature of all adverse events occurring during the previous week (monitoring study safety); (2) a discussion of the adverse events and development of a plan or change in study protocol to prevent similar or related adverse events, where possible (minimizing research- associated risk); (3) initiation of the process of reporting adverse events and unanticipated problems to the IRB if they have not yet been reported already (adverse event reporting); (4) identification of breaches of confidentiality of participant data or problems of data security, and discussion and development of plans to prevent problems of data security (ensuring data security). The protocol will be modified as needed to ensure patient safety and data security.

5. Recordings:

- *Will any video or audio recordings be made for research purposes? If so please describe:*

Audio recordings will conducted for qualitative interviews of participants for phase 1. Within phase 2, participants may also be contacted to participate in an optional exit interview. This audio/video recorded interview will gather information on the participant's experience in the randomized controlled trial and obtain qualitative data on the RCT's facilitators and barriers to program implementation.

- *How will the data be recorded, transmitted and stored, keeping in mind that this is likely PHI and should be encrypted, etc.?*

Recorded files will be encrypted and password protected. They will be stored in a folder on the shared network drive for the Division of which only those on the study have access. Each file will be identified by a code. All identifying information will be removed.

- *How long will the data be held?*

The data will be held for 12 months after the participant completed the recording.

- *Is this an optional part of the project, and if not, what is the scientific need to compel people to be recorded in order to participate in the research?*

The phase 1 qualitative research is not optional. If a participant volunteer chooses to participate and consent to the research, they would be audio/video recorded. The recording is necessary to interpret the qualitative analysis in order refine the phase 2 pilot, proposed in the original grant submission.

The exit interview is optional.

- *How can subjects ask to have the recordings and transcripts destroyed?*

The participant can request to have their recording and/or transcript destroyed at anytime throughout the study and we will not use them in the research. They can call, mail or email our research team to request to have their recording data destroyed.

6. Provisions to Protect the Privacy Interests of Subjects:

Confidentiality

A. Protection of subject privacy. Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To preserve patient confidentiality, study subjects will be assigned code numbers. Using these codes, none of the collection forms will contain the names or medical record number of the participants or other personal identifiers. There will be a master list at each institution matching the names of the participants to the code numbers. The list will be safely stored in a separate REDCap project. Paper-based consent and HIPAA documents will be stored in locked cabinets within locked offices, separate from the master lists. All electronic data will be stored on mainframe servers, and terminals and Tablet PCs will be password protected and maintained in locked offices.

B. Database protection. Participant information will only be accessible to the PI, project manager, data analysts and research coordinators associated with the research. Data collected on Mt. Sinai computer servers and recording devices will be uploaded on a daily basis to mainframe servers supported by the local institutions. These data will lack personal identifiers other than a study identification code. Following the upload, the data on the recording devices and will be deleted. Encrypted data from the Northwestern site will be stored electronically in the Mount Sinai REDCap servers, which will serve as the data coordinating center, on a weekly basis. The transferred data will be free of personal data that qualifies as PHI. All data received at the data coordinating center (Mount Sinai) will be entered into a computerized database and stored in encrypted files on a mainframe server that is backed up nightly by the Mount Sinai Hospital IT Department.

C. Confidentiality during adverse event reporting. Adverse event reports and annual summaries will not include subject-identifiable material. Each will include the coded identification number only.

To ensure that subjects feel at ease throughout the interviews and intervention sessions, the research personnel will remind the subjects that if at any point he/she becomes frustrated or does not wish to answer a particular question, he/she does not have to do so. In addition, the research personnel will give opportunities for breaks throughout the interviews and sessions.

7. Economic Impact on Subjects:

A

8. Payments/Reimbursements to Subjects:

If participants agree to take part in this research study, they will be paid for time and effort to participate in the research interviews. They will not be paid for intervention or control activities, and thus will not be paid for visits with the community health worker, pharmacist, or clinician, or visits with the research coordinator to review the COPD educational booklet.

For research interviews, a participant may receive up to $255 for participating in this study. A participant will be paid $65 after the completion of the each interview. If all 3 interviews are completed, participants will be paid a total of $195. Up to an additional $20 will be given to subjects after every interview once they return the electronic monitoring device for the medication ($10) and an accelerometer ($10). Participants will be paid in cash or money order at the completion of each interview. Payments will be for the research interviews only.

9. Consent Process:

Setting:
Consent will take place in a private room in the Center for Advanced Medicine at Mount Sinai Hospital or over the phone

Process:
Only members of the research team who have been fully trained in the protocol will obtain the treating provider's permission to recruit potential patients.

Subjects will be informed about the nature of the study by a CITI certified RC and asked to provide informed consent, including HIPAA authorization. They will be informed that their care at Mount Sinai or Northwestern Medicine will not be affected in any way if they decline to participate in the study. Additionally they will be notified that only those contents of their medical record that are necessary to evaluate the effectiveness of the intervention will be released to the research team at Mount Sinai (all phases) or Northwestern University (phase 1 only). The patients will complete a written informed or verbal consent document and will be given a copy of the consent document. They will be informed that they may withdraw from the study at any time and given contact information for the PI and study coordinator.

Once the investigator/RA is convinced that the subject verbally demonstrates understanding and agrees to the process, the consent is signed by the subject and/or the research delegate.

Individuals authorized to obtain written consent are the principal investigator, co-investigators, and RAs specifically designated by the principal investigator to work on this project.

Before including a patient in the study, the investigator or research assistant will verify that the given consent documents are written in the language that the subjects can understand them. Also the investigator or research assistant will verify that the subjects understand the objectives of the study, the type of information that will be collected, when and how it will be collected, and that participation in this study is voluntary. This will be done by asking the patient to describe to us what they understand the study entails and also to state the potential risks and benefits of the study.

***Non-English Speaking Subjects** (See PPHS policy)*

Spanish.

Subjects who speak Spanish will be enrolled in the study by a Spanish-speaking RA. The consenting process for Spanish speaking participants is identical to the process for English speaking participants. All research materials (consent form, recruitment letter, recruitment script and survey) will be translated to Spanish. Only English and Spanish participants are permitted to participate because there are not enough personnel resources to accommodate adding more languages.

Waiver or Alteration of the Consent Process

The waiver of informed consent that is being requested is for a research report query from the data warehouse. This will allow the research staff to identify potentially eligible adults being seen in the Mount Sinai Health System.

How the Research Involves No More Than Minimal Risks to Participants

The database will be password protected and study subjects will be assigned a study ID number to protect the subject's identifiers. Study subjects will be identified by their ID numbers moving forward. Potential subjects who are not interested in participating will not be enrolled in the study.

How the Waiver / Alteration Will Not Adversely Affect the Rights and Welfare of Participants

We are requesting the minimal information to identify potential participants that will be stored in a password protected database. This information will not be released and information about potential participants and their unique IDs will not be linked in any other place.

Why It Is Not Practical To Conduct this Research Without a Waiver or Alteration of Informed Consent

This information is needed to recruit patients from the data warehouse housed at Mount Sinai Hospital (MSH). We would be unable to recruit these patients without access to this information. No further information about the patient will be collected unless we get research consent from the patient. We propose to use this information as there is no other way to ensure a representative patient sample.

Plans for Providing Participants with Additional Pertinent Information After Participation Where Appropriate

Results will not be communicated with study participants as part of the study is not to influence decision making. However, if the physician has a concern about the health or well-being of a participant (especially in reference to the clinical trial) then the physician will ask the participant's permission to discuss with the participant's physician or another provider.

10. Process to Document Consent in Writing:

Informed consent is obtained by the following process:

- Subject reviews the study consent form.
- The PI or RAs speak with the subject to review the consent, confirm subject's understanding, and answer any questions.
- Once the investigator/RA is convinced that the subject verbally demonstrates understanding and agrees to the process, the consent is signed by the subject and/or the research delegate. Individuals authorized to obtain written consent are the principal investigator, co-investigators, and RAs specifically designated by the principal investigator to work on this project.

For any subject being consented via phone we will follow the following procedure:

- Send the approved phone consent authorization to the prospective research subject for review.
- Arrange for a conversation between the participant and an authorized member of the research team to allow for full discussion of the combined consent/authorization. If verbal consent is obtained, collect identifiable data as applicable.
- If there is an adult witness on the phone at the time of the initial verbal consent, the documents will not be returned.

- If there is no adult witness to the phone consent/authorization, the written document will be requested to be returned via regular mail, fax, or email. If after two weeks, the signed document is not returned the data will be stripped of all identifiers and links such that the de-identified data are permanently anonymized.

11. Vulnerable Populations:

a) Unless already detailed in the protocol, please indicate which of the following populations are either included or excluded in this project: Indicate specifically whether you will include (target) or exclude each of the following populations:

Include	*Exclude*	*Vulnerable Population Type*
	X	*Adults unable to consent*
	X	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	X	*Wards of the State (e.g. foster children)*
	X	*Pregnant women*
	X	*Prisoners*

Based on the demographics of the communities served by Mount Sinai and the characteristics of our prior COPD studies, we expect that women will comprise approximately 60% of enrolled subjects, Hispanics approximately 40% to 45%, and Black, non-Hispanic 30% to 35%. The proportion of women and minorities in this population is in accordance with the epidemiology of COPD in these communities.

12. Multi-Site Human Research:

Dr. Federman will be responsible for overseeing data collection activities and quality of data collected. For the research study (Aims 1-2), we selected validated tools and electronic measures that are known to be highly valid and reliable. Data will be collected using paper handouts and then entering the data onto our Redcap with built in logic patterns to minimize data entry errors. Dr. Federman will train research coordinators in survey administration techniques. We will also conduct random checks of 10% of all collected data to assess for data entry errors, ranges of

input values, missing data, and overall data quality. Study team members will meet monthly to review progress in recruitment goals, review preliminary results, and identify and resolve emerging problems.

a) If coordinating center functions are taking place at Sinai, whether or not it is also a clinical site, please answer the following with appropriate justification and documentation, if needed:

(i) Are the management, data analysis, and Data Safety and Monitoring (DSM) systems adequate, given the nature of the research involved?

YES

(ii) Is the sample protocols and informed consent documents developed and distributed to each collaborating institution?;

YES

(iii) Does each collaborating institution hold an applicable OHRP-approved Assurance?;

YES

(iv)Will each protocol be reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects?;

YES

(v) Have all substantive modifications by the collaborating institution to the sample consent, especially related to risks or alternative procedures, been appropriately justified?;

YES

(vi) Will informed consent be obtained from each subject in compliance with HHS regulations?

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g., results, new information, unanticipated problems involving risk to subjects or others, or protocol modifications) among sites to protect subjects.

YES

13. Community-Based Participatory Research

All involvement of community advisory board for research will be conducted inside MSSM.

14. Sharing of individual and study Results with Subjects:

Results will not be communicated with study participants as part of the study is not to influence decision making.

15. External IRB Review History

N/A

16. Control of Drugs, Biologics, or Devices:

N/A