RESEARCH PROTOCOL

Protocol Title:	A comprehensive disease management program to improve quality of life in disparity Hispanic and African-American patients admitted with exacerbation of chronic pulmonary diseases
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Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template.*
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1) PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

2) BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

COPD, the leading cause of hospitalization for older adults in the United States, accounted for 15.4 million office visits in 2003, nearly equal to total visits for heart disease, stroke, and heart failure combined. The World Health Organization estimates that by 2020, COPD will become the third leading cause of death worldwide. Disparity populations unquestionably bear a greater burden of suffering, with death rates rising faster than in whites. The Hispanic population is one of the largest and fastest-growing minorities in the United States, encompassing 17.4% of the population and expected to double by 2050. Hispanics are disproportionately affected by social and economic inequalities that impact access to care including language, acculturation and immigration status. Both African American and Hispanic patients bear a high burden of illness and death due to COPD and Asthma. 28 per 1,000 Latinos have COPD, Six percent of African Americans and 4% of Hispanics carry a diagnosis of COPD, with many cases likely undiagnosed. Both Hispanic and African American patients are twice as likely to visit the emergency room for COPD-associated conditions as compared to non-Hispanic whites. Higher rates of smoking, reduced health access (especially to PR), and lower socioeconomic status (SES) all contribute to this high disease burden, in both African American and Hispanic disparity patients. Lower SES and ethnic minority COPD patients are also at increased risk for readmission. COPD patients admitted for COPD exacerbation have a 23% and 50% risk of 30-day and 12 month readmission, and both African American and Hispanic race/ethnicity is associated with an almost two-fold increase in hospitalization risk. Patients and their caregivers suffer discontinuity of care and decreased quality of life with each of these transitions into and out of the hospital. In fact, this has been adopted as a marker of quality care marker and is tied to penalties and incentives imposed by large payers including the Centers for Medicare and Medicaid (CMS).

Fortunately, early Pulmonary Rehabilitation (PR) after admission has been shown to improve QOL, and decrease readmission. Unfortunately, referral and uptake rates are poor, particularly for Hispanic and African American patients, with only a small proportion of the intended target population receiving PR. In fact, during interviews with local

pulmonologists who serve a predominantly disparity Hispanic population, several noted that they no longer make referrals to PR, because they are "ineffective" primarily due to access barriers.

Telehealth-administered PR has been proven to be equivalent to standard PR (SPR) in terms of improvement in QOL and at least equivalent to SPR in COPD patients. This study will not only measure whether Telehealth delivered PR works in Hispanic and African-American patients, but also how it compares to SPR and what adaptations need to be made for these patients who stand to benefit the most from PR.

3) INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

Pulmonary rehabilitation has been recognized as a core component of the management of individuals with chronic respiratory disease by the American Thoracic Society. Despite proven benefits, many patients with COPD do not receive PR. Telehealth-administered PR has been proven to be equivalent to standard PR (SPR) in terms of improvement in QOL and improved exercise capacity, and superior in terms of adherence to PR. Although there is data on standard pulmonary rehabilitation (SPR) improving outcomes in Hispanic and African-American patients, disparity patients are not included in studies exploring the efficacy of Telehealth delivered PR despite the evidence that underserved Hispanic and African-American patients have positive perceptions of Telehealth interventions in general.

Our study aims to improve health outcomes for Hispanic and African-American patients living with moderate to severe COPD, because it directly addresses several known barriers to PR adherence for our target populations - based on research on barriers to healthcare access for disparity patients, and data provided by our patient partners and pulmonologists treating disparity patients. The data provided by PR demonstrates improved quality of life and decreased hospital readmission. As noted above, barriers to access that disproportionally affect disparity patients include lack of referral to PR due to perceived ineffectiveness, lack of insurance coverage/high copayments, and difficulty accessing PR due to transportation costs, distance and lack of caregiver support. This study aims to overcome many of these major barriers by providing PR outside a SPR setting via Telehealth (CPDMP) settings. Participants will have the option of choosing to receive CPDMP either within the patient's home or in a community center.

4) OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

Specific Aims: We will compare the effectiveness of a referral to standard PR (**SPR**) versus Telehealth delivered PR (CPDMP) in patients discharged for COPD exacerbation. Our Telehealth delivered PR will be within a Comprehensive Pulmonary Disease Management Program (**CPDMP**) which includes follow up by a social worker and close partnership with patients' pulmonologists. The social worker's role is to help identify the most significant barriers or challenges that patients face during the course of the research study. They will be in contact with each participating hospital site's own social workers, who will meet with the patients and deduce their needs. This study's social worker will be in communication with the hospital social workers on a weekly basis in order to get the patients the support they need.

Aim 1: To ensure the acceptability and usability of the CPDMP by conducting a process evaluation among Hispanic and African-American COPD patients. We will use a mixed methods approach to look at indicators of acceptability and usability of CPDMP in two stages: 1) focus groups with key stakeholders (patients, caregivers, clinicians, patient advocates, etc.); and 2) testing the CPDMP with a "run-in period," enrolling patients to identify further barriers prior to normal randomization.

Hypothesis 1.1: Focus group participants will identify barriers to acceptance and usability of CPDMP implementation and will inform the iterative refinement of the program.

Hypothesis 1.2: "Run-in period" users of the CPDMP program will have positive perceptions regarding its usability and usefulness and will identify necessary additional refinements.

Aim 2: To conduct a randomized controlled trial (RCT) among Hispanic and African-American patients discharged from the hospital for COPD exacerbation, comparing outpatient pulmonologist follow-up with CPDMP referral *versus* outpatient pulmonologist follow-up and SPR referral. The primary outcome will be decrease in readmission. Secondary outcomes will include PR adherence, improvement in QOL, self-efficacy, and other patient reported health outcomes.

Hypothesis 2.1 CPDMP participants will have decreased 6-month readmission compared to SPR.

Hypothesis 2.2 CPDMP participants will have increased uptake and adherence to PR, compared to SPR.

Hypothesis 2.3 CPDMP participants will have increased QOL, functional capacity, knowledge about COPD, sense of social support, self-efficacy about disease management, and decreased symptom burden, compared to patients in the SPR arm. This will largely be due to increased adherence to CPDMP compared to SPR.

5) RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

We will recruit patients hospitalized for COPD exacerbation at seven hospitals within Northwell Health (LIJ, NSUH, Forest Hills, Southside, Glen Cove, Huntington and LIJ Valley Stream) and at Wyckoff Heights Medical Center. The source of referrals will be inpatient admissions to the targeted hospitals. Patients will also be recruited from their homes or outpatient doctor's offices immediately after discharge (up to 2-3 weeks post-hospital discharge). We aim to recruit 138 patients in each of the two arms of this RCT (total of 276 patients), as well as 4 patients into each of the two arms in the run-in period (total of 8 patients) prior to the beginning of formal randomization.

Feasibility was assessed by querying databases at all eight hospitals for COPD, and stratifying by race. Based on the responses from a needs assessment, all of the Hispanic and African American patients with severe COPD who were asked whether they would participate in the CPDMP expressed interest. In addition, a recent randomized controlled trial of a behavioral intervention with physical activity and dietary intervention targeting low-income, predominantly Latino patients in a primary health care clinic found that 78% of eligible patients agreed to enrollment and 81% were still enrolled at 6-months of follow up. The intervention included community and clinician stakeholder engagement which is at the heart of our study.

An inaugural meeting will be held with the research core team (steering committee) to review the study protocol and outline trial related duties and functions before the study begins. This will be an opportunity for the research team to ask the PI questions and understand project milestones and recruitment strategies. When the study is initiated, the PI will hold monthly meetings with the steering committee to ensure that the protocol is adequately being followed and that project milestones are being met.

We will assemble a Community Advisory Board (CAB) for the study, including key stakeholders to provide guidance/feedback regarding the study, including barriers encountered. Meetings will be held with the CAB 6 times for the duration of the study. They will assist with study design, analysis of results, and overall community support to ensure success for this study.

6) RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

Identification of patients who are hospitalized for COPD exacerbation will occur at each of the eight hospitals (seven within Northwell Health and 1 at Wyckoff hospital as described above) by daily review of admission records. These records will be obtained via an algorithm querying EHRs within these hospitals for COPD admissions. These algorithms have already been developed and tested by the hospitals in their efforts to decrease COPD readmissions in response to recent penalties imposed by CMS for COPD readmissions. Patients will also be recruited from their homes or outpatient doctor's offices immediately after discharge (up to 2-3 weeks post-hospital discharge). A brochure has been designed to provide patients with more information about the study.
All of the hospitals from which we will recruit patients serve patients who are of lower socioeconomic, backgrounds, many with limited English proficiency. Our EHR query found that Hispanic patients comprise about 10% of all COPD admissions at these hospitals. Each day, research coordinators will review the EHR admission data in these hospitals and will approach all COPD patients that meet our inclusion criteria.

Run-in Period Recruitment: Eligible patients will be approached for consent (run-in consent 1) to have longitudinal data collected, including surveys at specified time points over the 2-4 weeks of their participation in order to determine health outcomes related to pulmonary rehabilitation. Next, the research coordinator will obtain the randomization number for the patient to determine if they were allocated to the CPDMP arm or SPR arm. If the patient is randomized into the CPDMP arm, the coordinator will approach to obtain a second consent (run-in consent 2) to receive Telehealth delivered PR. A recruitment video, in Spanish or English, will be shown to each patient approached for consent 2, in order to standardize the consent process across the seven participating sites. Informed consent for CPDMP will include a detailed description, in English and Spanish, of the risks and benefits of the study with user-friendly images of the equipment. If the patients decline to participate in CPDMP they will continue to receive standard of care including referral to SPR, and still have surveys administered and data collected over 2-4 weeks (as agreed to in run-in consent 1). These patients will not be included in the final analysis of the study; they will inform the design of the study and help to improve upon the trial prior to study enrollment. After completing the 2-4 weeks of pulmonary rehabilitation, all patients (8 total) will be invited to participate in a focus group with the members of the research team to inform them of their opinions on the strengths/weaknesses of the study design and inform improvements that should be made prior to study enrollment.

Formal Study Recruitment: Eligible patients will be approached for consent (consent 1) to have longitudinal data collected, including surveys at specified time points over the 12 months after hospital discharge, in order to determine health outcomes. Next, the research coordinator will obtain the randomization number for the patient to determine if they were allocated to the CPDMP arm or SPR arm. If the patient is randomized into the CPDMP arm, the coordinator will approach to obtain a second consent (consent 2) to receive Telehealth delivered PR. A recruitment video, in Spanish or English, will be shown to each patient approached for consent 2, in order to standardize the consent process across the eight participating sites. A patient testimonial video will also be shown to participants. Informed consent for CPDMP will include a detailed description, in English and Spanish, of the risks and benefits of the study with user-friendly images of the

equipment. If the patients decline to participate in CPDMP they will continue to receive standard of care including referral to SPR, and still have surveys administered and data collected over time (as agreed to in consent 1). Based on intention to treat (ITT), they nevertheless will be analyzed as part of the CPDMP group.

7) ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

Inclusion Criteria:

1) Adult patients with a diagnosis of COPD (defined by one pulmonary function test and/or physician diagnosis) and who have not done pulmonary rehabilitation within the past 1 year
   and
2) Hispanic or African-American (as defined by the patient him/herself).

Exclusion criteria:

1) individuals who completed PR in the past year
   or
2) those unable to exercise as determined by pulmonologist/cardiologist
3) those unable to follow directions [eg. Diagnosis of advanced dementia in the patient's electronic medical record]
   or
4) Patients that weigh over 300 pounds.

8) NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

4 patients will be recruited into each of the two arms for the run-in period, for 8 patients total prior to enrollment. 138 patients will be recruited into each of the two arms in the formal study, for 276 patients total.

9) STUDY TIMELINES

- *Describe the duration of an individual's participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

The first two months of the study will focus upon the engagement of and feedback from stakeholders to adapt the CPDMP. Further barriers will be identified before the randomized trial begins, using qualitative ("run-in" patient focus group) and quantitative methods (e.g., percentage adherence) as well as identification of any other technical or logistical barriers encountered.

All patients will be referred to either SPR or CPDMP, which requires medical clearance. The research team will facilitate this medical clearance for patients recruited into this research study through the Pulmonary and Cardiology (if the patient has a heart condition) Divisions of Northwell Health and through Wyckoff Heights Medical Center. Pulmonary rehabilitation intake is also necessary prior to beginning PR. This intake will be performed by the research study's respiratory therapist and will include standard pulmonary function tests.

Run-in Period Timeline: Eligible patients will be identified daily by members of the research team. These patients will be approached to obtain consent to collect longitudinal data for 2-4 weeks. After obtaining run-in consent 1 for eligible patients, the coordinator will obtain run-in consent 2 when applicable. This study will follow the enrolled participants for 2-4 weeks after hospital discharge, with outcome measurements taken in person after PR has been completed.

Formal Study Timeline: Eligible patients will be identified daily by members of the research team. These patients will be approached to obtain consent to collect longitudinal data for 12 months. After obtaining consent 1 for eligible patients, the coordinator will obtain consent 2 when applicable. This study will follow the enrolled participants for 12 months after hospital discharge, with outcome measurements taken in person or via phone/teleconference after PR has been completed (approximately 2 months), and over the phone at 6 month and 12 month intervals.

10) ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

The primary endpoint will be the composite of readmission or death within 6 months of discharge. The primary comparison is the difference in the proportion of rehospitalizations for participants enrolled in the CPMDP versus SPR at 6 months after hospital discharge.

Secondary outcomes will include Change in quality of life; Change in functional capacity; Change in symptom management; Change in patient self-efficacy; Change in patient sense of social support; Change in time to readmission, and; Adherence to rehabilitation referral

11) RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

- Patients admitted to any one of the hospitals included in this study will be assessed for inclusion criteria (1. Moderate to severe COPD based on PFT, 2. Hispanic or African-American). If inclusion criteria are met, the patient will be approached by a member of the study team to obtain consent (consent 1 or run-in consent 1) to collect longitudinal data via surveys.
- Next, the research coordinator will determine the patient's randomization assignment. Subjects will be randomized in a 1:1 fashion to either telehealth delivered pulmonary rehabilitation or standard of care delivered pulmonary rehabilitation. The Biostatistics Unit will develop a randomization procedure using a permuted block design and the randomization process will occur in the Biostatistics Randomization Management System (BRMS). BRMS is a secure, HIPAA-compliant, web-based application that allows investigators to randomize subjects into randomized clinical trials (RCTs) using their personal computer. The BRMS allows for multi-center, stratified, and single/double blinded RCTs, using permuted blocks. Randomization notifications are automatically sent to the PI and other authorized personnel. Using BRMS is a good way to maintain compliance in RCTs. Details of the procedure, including required record keeping, will be further developed upon approval of this protocol.
- If selected for interventional arm, a recruitment video, in Spanish or English, will be shown to each patient approached for a second consent (consent 1 or run-in consent 2) (modified Zelen's randomized consent form (mZCRF), in order to standardize the consent process across the seven participating sites. If selected for control arm, the video is not shown and no additional consent is obtained. Pulmonary and possibly cardiac clearance will be needed in order to confirm study eligibility. A pulmonary and cardiology clearance template (designed by the research team) will be provided to physicians to expedite the clearance process.
- Outcome measurements in survey form will be assessed to establish baseline measurements of quality of life and other measures will be obtained by study personnel at the initiation of PR, prior to beginning the pulmonary rehabilitation regimen. The outcome measurement tools are as follows:
    - 6-Minute Walk Test – measures functional capacity; measures how far the patient is able to walk over 6 minutes, dyspnea, heart-rate,

SpO_2; takes 6 minutes to complete. This test is only used in the standard pulmonary rehabilitation arm.
    - 2-Minute Step Test – indicates the level of aerobic endurance of the participant. It is associated with the ability to perform lifestyle tasks such as walking and climbing stairs. This is an alternative test if there is not sufficient space to conduct the 6 minute walk test. Therefore, this test is only used in the tele-rehab arm and conducted in the patient's home. Modified Borg Dyspnea Scale – measures Dyspnea symptoms with exercise; single question in 0-10 scale format; takes approximately 2 minutes to complete
    - Modified Medical Research Council Scale, dyspnea (MMRC) – measures dyspnea symptoms with ALDs; single question with 0-4 scale format; takes approximately 1 minute to complete
    - Bristol COPD Knowledge Questionnaire – measures patient's knowledge of COPD; several topics containing multiple choice statements (yes/no/I don't know); takes approximately 20 minutes to complete
    - PROMIS Short Forms – measures symptoms (anxiety, fatigue, depression) and social support; 8 items rated 1-5; takes approximately 20 minutes to complete
    - COPD Self-Efficacy Scale (CSES) – measures self-efficacy (to avoid or manage breathing difficulty); 34 items rated 1-5; takes approximately 15 minutes to complete
    - CAT (COPD Assessment Test) – measures the impact of COPD on a person's life and this changes over time; 8 items rated on a scale of 0-5; takes approximately 4 minutes to complete
- Additionally, the MMRC and CAT assessments as well as a demographics sheet will be done at the time that consent is obtained.
- In the formal study, for 8 weeks (2-4 weeks for run-in participants), twice a week for 60 minutes, patients in both arms will complete their respective pulmonary rehabilitation treatments (SPR or CPDMP). The exercises utilized in both arms of this study are identical in design, as it is the current standard of care for patients with COPD.
    - Those randomized into the interventional arm will receive an exercise bike, dumbbells, and Thera-Bands delivered to their home. This is the same equipment that would be used within a standard PR clinic. Patients randomized into the standard of care arm will complete these same exercises as those in the telehealth PR arm. They will use bikes, weights, and Thera-Bands as well. Both arms will also have education and socialization with other COPD patients included with their PR treatments. Patients in the Standard PR arm will also have the option to utilize additional exercise equipment which is typically offered in a pulmonary rehab program. This is done in an effort to mimic standard of care that is offered through traditional pulmonary rehab programs.
    - The respiratory therapist will conduct the PR sessions in a private office within the pulmonary clinic located at 410 Lakeville Road. She/he will connect to the electronic tablet mounted onto the patients' telehealth exercise bikes through a secure HIPAA compliant server provided by

eCare Solutions and vetted by Northwell Health's research information security team. The respiratory therapist will be able to view all 3 PR patients on his/her screen, while each of the patients will be able to see the respiratory therapist as well as the other two PR patients simultaneously. During the telerehab session, the respiratory therapist will be able to view each patient, monitor their vital signs, and call for emergency help if necessary. All participants will be able to communicate with each other throughout the duration of the session as well.

- Outcome measurements (same questionnaires and tests from Week 1 baseline measurements) as well as a Satisfaction with Program questionnaire will be administered in-person or via phone after completion of pulmonary rehabilitation.
- A Mini-Mental State Exam (MMSE) will be completed for all telehealth patients at baseline intake and/or 8 week follow up. This will allow us to detect cognitive impairment and how it is associated with the patients' ability to participate in the telehealth sessions. The exams takes approximately 5 – 10 minutes to complete.
- At 8 week follow up, once sessions are complete, patients will be asked if they will be looking for more pulmonary rehabilitation or other exercise programs. Their answers will be recorded, as well as their reasons why and their experience.
- At the 6 and 12 month follow-ups, patients will be assessed using the MMRC, CAT and Promis tests. Patients will also be asked if they participated in any pulmonary rehabilitation programs since the end of the study sessions and if they participated in any exercise programs since the end of the study sessions. Their answers will be recorded, as well as their reasons why and their experience.
- Monthly EHR queries and follow-up phone calls will be implemented throughout the duration of the study to confirm or deny re-hospitalizations to hospitalization within or outside of Northwell Health System.
- The research study's social worker will be in contact with each participating hospital site's own social workers, who will meet with the patients and deduce their needs. This study's social worker will be in communication with the hospital social workers on a weekly basis in order to get the patients the support they need. All patients that complete PR in both arms will be contacted each month to confirm any re-hospitalizations that may have occurred.
- For run-in participants, they will complete only 2-4 weeks of pulmonary rehabilitation before their participation is complete. Since the timeline for the run-in period is a total of 8 weeks, the 8 patients recruited will complete as much PR as possible within those 8 weeks (for a maximum of 4 weeks, or 8 PR sessions) before enrollment for the formal study begins. At this point, the run-in participants will be invited to a focus group that will identify barriers and possible improvements that can be made to the design of the study prior to formal enrollment. After the focus group, the run-in patients' participation in the study will be complete and they will not be followed any longer.

- Usability testing: Usability testing (pilot testing) of the PR sessions will be conducted to understand how patients feel about the sessions and how we can fine tune sessions to meet their needs. We will invite 2-8 patients to evaluate usability in their homes and at the community centers. The goal of usability testing of the PR sessions is to provide a valuable aid to patients' clinical management by identifying any barriers or facilitators. Following the PR session, patients will be asked to complete two surveys: 1) usability questions for thorough review of their experience and opinions regarding the PR session and 2) a system usability scale. Participants who chose to be a part of the usability testing will be asked to complete the Northwell Health Authorization to be Audio/Visually Recorded, per institutional policy.
- Semistructured interviews will be conducted to gather richer and more contextualized information about patient experiences with telehealth PR. This can give us a better understanding of our quantitative results. For example, if we find a significant quantitative result, the qualitative interviews can provide us with context as to why this occurred from the patient's own perception and perspective.

12) STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

For Aim 1: To ensure the acceptability and usability of the CTPR by conducting a process evaluation among racial and ethnic minority COPD patients from low-income communities: We will use a mixed methods approach to look at indicators of usability and acceptability in two stages. First, we will analyze focus group sessions of key stakeholders (patients, caregivers, respiratory therapists and other clinicians) using qualitative analytic methods. All focus group discussions will be audio recorded and professionally transcribed. Structural coding will be used to mark responses to topical questions in the interview guide. The data will be categorized using grounded theory that will be used to develop a codebook and independently coded using NVivo qualitative data analysis software (QSR International, Inc.). The main themes that emerge will specify any necessary adaptation that the CAB (community advisory board) believes should occur to increase the usability and acceptability of CPDMP. Second, we will measure whether CTPR sessions are able to be completed by patient participants in the "run-in period," using both qualitative ("run-in" patient focus group) and quantitative methods (e.g., percentage adherence, study completion, patient rating of satisfaction with CPDMP) as well as identification of any technical or logistical barriers encountered

For Aim 2: To conduct a randomized controlled trial (RCT) among Hispanic and African American patients discharged from the hospital for COPD exacerbation, comparing

outpatient pulmonologist follow-up with CPDMP referral *versus* outpatient pulmonologist follow-up and standard (outpatient) PR referral.

Primary Analysis for Aim 2. The primary endpoint will be the composite of readmission or death within 6 months of discharge. The primary comparison is the difference in the proportion of re-hospitalizations for participants enrolled in the CPMDP versus SPR at 6 months after hospital discharge. We will use the modified Zelen RCF method.

We will stratify the patients not only by Race/Ethnicity but also by place of enrollment (Inpatient/Outpatient enrollment). Patients will be randomized within the following four strata: 1) Hispanic Inpatient 2) African American Inpatient 3) Hispanic Outpatient and 4) African American Outpatient. We will perform a subgroup analysis by place of enrollment. We have calculated that we will have at least 60% power to detect a difference of 20% in our primary outcome between the two arms at a significance level of 0.05, by place of enrollment using the following assumptions: more patients will be recruited from the outpatient setting compared to the inpatient setting in a 60:40 split; there will be equal distribution of Race/Ethnicity as compared to those enrolled from the inpatient setting; the effect size of telehealth vs SPR will be the same in the outpatient vs inpatient groups – however, the overall risk of rehospitalization will be approximately 20% lower in the outpatient cohort than in the inpatient cohort.

We will explore associations between place of enrollment and our outcomes in univariable analyses and further in multivariable analyses after controlling for the other covariates. We will also explore interaction effects between place of enrollment and other variables on the outcomes in multivariable analysis.

Secondary Analyses for Aim 2. Our secondary outcomes measure whether CPDMP relative to SPR: 1) Increases functional capacity using the 6-minute walk test (6MWT), an objective measure of functional capacity; 2) Increases symptom management, using: i) the Modified Borg Scale, a subjective measure of patient dyspnea after the 6MWT (i.e., with exercise); ii) the MMRC, a subjective rating of dyspnea with activities of daily living (ADLs); iii) the PROMIS Short Form surveys, which are also subjective and measure depression, anxiety, and fatigue. 3) Increases patient self-efficacy to avoid and manage breathing difficulty, measured using the COPD Self Efficacy Scale; 4) Increases patient sense of social support using the PROMIS Short Forms for Companionship, Informational Support, Emotional Support, Instrumental Support, and Social Isolation; 5) Increases patient knowledge about COPD using the Bristol COPD Knowledge Questionnaire; and 6) Increases time to readmission. For continuous data, we will use a mixed model repeated measures analysis of variance ("MMRMA"; SAS PROC MIXED; SAS Institute, Cary, NC) to compare the change in pre-post intervention measures with the pre-post control/comparator arm (standard rehab) measure. Of particular interest is the group x time interaction, which will indicate whether the amount of change over time depends on the treatment group. Data transformations will be considered for all MMRMA analyses. Subgroup analyses are outlined separately below. MMRMA will be applied to test for differences between groups for all outcomes. For all analyses, data transformations will be considered to meet the usual required assumptions for MMRMA. Kaplan-Meier survival curve and log-rank test will be used to test whether there is difference in time to readmission between the two arms. Cox proportional hazard model will be applied to see whether there is difference in time to readmission between the two

arms after controlling for the other covariates. If we use change in QOL as our outcome on which to base the sample size calculation, we would need a sample of 60 per arm to detect a significant difference in QoL with 90% power – which falls within our proposed sample size. This is based on the largest study of early, post-hospitalization delivered PR. In the control arm, the total SGRQ score decreased by 3.4 (Signifying improved QoL), and by 16.1 (sd=15) in controls, for a mean change difference of 12.7. Though there likely is a correlation between individual pre/post QOL scores, the literature provides no information about this correlation; we therefore conservatively estimate our sample size by assuming no correlation. In this case, the effect size is 0.6 (ie., standardized difference calculated as 12.7/21.2=0.6). This QOL improvement is clinically meaningful, evidenced by empirical data patient interviews (SGRQ mean change score of 4 units= slightly efficacious treatment, 8 units= moderate change and 12 units for very efficacious treatment.

Qualitative Analyses: We will conduct qualitative analyses to gain a deeper understanding of: (1) the barriers to initiating Pulmonary Rehabilitation despite a referral, for both Telehealth and Standard PR; and (2) the barriers to participating in more than one Pulmonary Rehabilitation session once started. Based on anticipated numbers required for qualitative saturation of themes identified we propose to recruit 10 patients for 1:1 interviewing from each of the following categories: patients referred to Telehealth PR who did not begin any sessions; patients referred to Standard PR who *did not* begin any sessions; patients referred to Telehealth PR who *did begin, but did not adhere* to more than 50% of sessions; patients referred to Standard PR who *did begin, but did not adhere* to more than 50% of sessions. We will included qualitative results from the CAB meetings and results of usability testing in these analyses. Semi-structured interview responses for usability testing of the telehealth platform will also be incorporated. The 1:1 interviews will systematically record and analyze real-world experiences (barriers, facilitators and perceptions) once a referral has been made to pulmonary rehabilitation. We will explore the link between individual and socio-environmental level factors impacting both willingness to participate in telehealth at baseline, and adherence over the 8 week time-course. Interviews will be recorded and transcribed for thematic analysis. Deductive analysis will be based on *a priori* themes rooted in Leventhal's Common Sense Model which shows that understanding of illness and cognitive and affective response to the illness impacts a patient's medical treatment and adherence decisions over time. Inductive analysis will involve the identification of new themes not linked to prior hypotheses or conceptual models that can shed new light on factors driving patient-level participation in telehealth. The questionnaires and results of analysis will be reviewed with CAB members. In addition to the one-one semi-structured interviews we will also convene 2 focus groups with participants who *did* completed > 50% of sessions to obtain feedback about barriers they encountered and suggestions for improving the process for others. Participants will be given the option of phone-interview or in-person interview including the option of an in-home interview. All interviews and focus groups will be audio-recorded, translated (for Spanish speaking – anticipated to be for at least 20 interviews, and will be conducted by a trained interviewer with Spanish fluency) and transcribed professionally for analysis. NVIVO software will be used for analyses after codebook development and testing by two qualitative researchers. Results will be presented to our two patient partners (Ms. Gray and Mr. DeLeon) as well as our CAB to enrich our interpretation of results from qualitative analysis.

Tertiary analyses for Aim 2: Finally, we will measure whether, relative to the SPR, patients in the CPDMP arm have more uptake (defined as participating in at least one session) and adherence to PR (defined as percentage complete of the 16 sessions). These two outcomes will be measured using analysis of the CPDMP log and weekly follow up with SPR sites. The data will be analyzed using Poisson regression (PROC GENMOD), adjusted for length of follow up, since subjects will be followed for differing lengths of time after rehabilitation completion, due to different dates of enrollment. Utilization outcomes will be analyzed using Poisson regression to compare rates between the two groups. The uptake outcome is a simple binary variable and will be compared between groups using the Chi Square test. The adherence percentage will be treated as a

continuous variable and will be compared using the two-sample t test (possibly with a transformation to achieve normality and equal variance). Despite the discreteness of many of the scales cited above, the relatively large sample size (138 per group) allows for the use of MMRMA, a parametric procedure based on the Gaussian distribution. EHR queries will automatically alert the team if patients are readmitted, and participants will be contacted monthly to confirm these reports. These algorithms have been validated within the health system as part of the decreasing COPD readmission initiatives. **Sample size calculations** assume that the odds ratio (OR) for readmission 6 months after hospital discharge between the CPDMP arm and the SPR arm is 0.40. We justified this assumption based on the hypotheses that (1) most patients in the standard PR arm would not adhere to the PR program and this would therefore resemble the usual care in the meta-analysis studies; and (2) the efficacy of CPDMP would resemble that of standard PR because it has been shown to be at least as effective as standard PR. With the assumption of OR as 0.40, the estimated sample size with varying levels of proportion of readmission for the SPR arm (from 30% to 50%) are shown in the table. The biggest sample size is estimated to be 138 per arm or 276 in total for our study to have 80% power to detect difference in readmission between the two groups. This happens when the proportion of readmission for the SPR am is assumed to be 0.40 (which is at least half the rate of admission in Hispanic patients with usual care based on our EHR analysis, plus 5% of death rate during the 6 months after discharge which can be expected for moderate to severe COPD patients) and 0.211 for CPDMP, using two-sided chi-square test, α 0.05. Assuming a 20% loss to follow-up (conservatively based on the CHF Telehealth study described in c.b.1), we aim to enroll 138 patients per arm (276 total). According to common practice, baseline demographic and clinical variables for the two arms will not be formally compared for statistical significance. Only descriptive summary statistics will be presented. Logistic regression will be applied to see whether there is difference in the proportion of readmission between the two groups after controlling for the other covariates including clinical site.

13) SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

N/A

14) DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*

- *Who will have access to the data?*
- *Who is responsible for receipt or transmission of data and specimens?*

- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

All clinical data storage will adhere to institutional/IRB sanctioned safety protocols including encrypted and password protected laptops, the use of firewalls for internet access, storage of data within locked cabinets/secured storage drives. All researchers will receive training in data safety. Patient identifiers will only be stored where absolutely necessary to the study.

Sources of data include: 1) Patient-reported data (questionnaires) at baseline, 8 weeks, 6 months and 12 months; 2) audio recording of Patient and Community Advisory Board focus groups in Year 1, allowing for transcription and analysis, 3) healthcare utilization data extracted from the Electronic Health Record. The information we will access from the Electronic Health Record includes: 1) name, 2) medical record number, 3) gender, 4) age, 5) whether or not they are institutionalized 6) comorbidities 7) severity of COPD as obtained from Pulmonary Function Tests 8) number of ED visits in the year prior 9) number of hospitalizations in the year prior and 10) reason for hospitalization. All identifiable information collected will be kept confidential in accordance with related regulations.
Only the study personnel listed on the IRB application will have access to data with personally identifying information.

15) DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

Part I – this part should be completed for all studies that require a DSMP.
Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- *Where applicable, describe rules which will guide interruption or alteration of the study design.*

- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

We do not expect any adverse events directly attributable to the intervention. Although the risk proposed by this intervention does not meet the requirements for establishing a Data Safety Monitoring Board, we will still establish a monitor (biostatistician) independent of the study who will review aggregate data on a monthly basis to review possible safety issues.

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

N/A

16) WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

All participants will be able to withdraw their consent at any point and will be informed of this right during the informed consent process. For subjects who cannot be contacted, the procedures are as follows in both arms of the study: 1) We will inform them during their PR intake that they are expected to tell us in advance if they won't be able to make sessions. They will be required to sign this Acknowledgement of Attendance at Pulmonary Rehabilitation Sessions (attached). 2) We will attempt to reach them multiple times during the weeks that they are enrolled in pulmonary rehabilitation on different dates at different times. 3) If we are not able to reach them after 2 consecutive sessions, they will be withdrawn from the study (i.e. in the standard arm the sessions are cancelled and in the telehealth arm the bike will be picked up from the patient's home). 4) We will still ask the patients if they can complete the questionnaires at each time point specified during consent 1. We will also still check their electronic health record to see if they are readmitted to the hospital (which is our primary outcome).

17) RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result.*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

We do not anticipate any significant physical, psychological, or social risk to the study patients. All subjects will receive usual care, and those who receive the intervention or comparator (CPDMP or SPR) do not incur any greater risk than would otherwise normally be the case within usual care.

Michael Stickland is a researcher and expert consultant on this study. He has over 8 years of experience with designing and implementing telehealth delivered pulmonary rehabilitation program for patients with COPD. In all of the years of conducting this work, he has not experienced any serious adverse events in the ~150 patients enrolled each year to receive rehabilitation via telehealth. As such, we do not anticipate having any within this study,

The potential risks to patients, in either arm of this study, would be due to the physical nature of the activity. Pulmonary rehab patients might also be at risk for falling off the bike. This is unlikely since patients have to obtain pulmonary/cardiology clearance to complete pulmonary rehab – this clearance includes the assessment of muscle or bone injuries due to inadequate ability to perform the exercises. There are also several safety precautions in place, which include real-time monitoring of patients and capturing biometric data, in addition to a 911 call feature.

Even if the addition of the intervention were to increase risk, the informed consent process would disclose such risk. Furthermore, even after randomization, subjects are free to reject the treatments. Second, there is no deception in this design because all subjects are told the truth about what they are consenting to.

18) RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

We do not anticipate any significant physical, psychological, or social risk to the study patients. Patients need to be screened by their pulmonologist and a cardiologist before participation in PR (as is convention in usual care). A registered respiratory therapist will be overseeing all exercise sessions in real-time, (which is standard of care in PR) whether in person or Telehealth-administered. The vendors will also design a 911 call button in the unlikely event of medical illness requiring emergency response (this is also the SPRotocol in SPR clinics). All risks and benefits of participation will be explained to participants and included in the written consent forms. Participants will be at minimal risk and will be informed of their right to withdraw from the study at any time. All identifiable information will be maintained with strict confidentiality measures by the investigators.

19) POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

Potential benefits of the participants include decreased hospitalization and are transitions, improved quality of life and functional status, as well as self-efficacy from participating in pulmonary rehabilitation. Participants may also benefit from the knowledge that they are representing the Latino and African American community in research and therefore making sure that research results are applicable to their own communities.

20) PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

The investigators will use IRB-approved and HIPAA-compliant measures to maintain confidentiality, privacy and data security. Data privacy and security procedures will include: a) training staff on data sensitivity and protocols for safeguarding confidentiality; b) storing and processing sensitive hardcopy in a secured, centralized location; c) securing sensitive hardcopy in locked files when not in use; d) removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for patient tracking and then using encrypted codes for subsequent identification of participants; e) destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed; f) using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

21) COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

In this randomized control study, patients randomized into the CPDMP arm will receive Telehealth delivered pulmonary rehabilitation which will be paid for by the research study. Patients who are randomized into the control arm will be referred for standard pulmonary rehabilitation (SPR), which will be billed to the patient's insurance, since this intervention falls within the standard of care for patients with acute exacerbation of COPD.

Patients who cannot afford insurance or copays may be disposed to decline SPR, leading to an unintended bias within the study. In such cases, the research study will then cover the costs to those individuals who are underinsured or uninsured.

22) PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

Run-in Payment: Participants in the run-in period will be paid $25 after completion of the first set of surveys at their pulmonologist appointment (~1 week after discharge from hospital), and $50 after completion of the surveys after pulmonary rehabilitation (~2-4 weeks after discharge from hospital). If the participant chooses to participate in the focus group at the conclusion of the run-in period, they will be compensated an additional $100.

Formal Study Payment: Participants will receive $25 for completion of the baseline visit; $50 for completion of the 8 week visit; and $50 each for completion of the 6 month and 12 month phone assessment.

Formal Study Payment: Participants will receive $75 for participating in the interviews and or $75 for participating in 1 of the 2 focus groups.

We offer continued financial incentives at each time point to maximize retention. Patients will be compensated in the form of a ClinCard, a reloadable debit card available to patients engaged in clinical research.

23) CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*

- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

Written, informed consent will be obtained prior to the participants taking part in any aspect of the study. Patients will be informed of the study's risk and benefits, and that their choice to participate or not will have no effect on their medical care. The Research Coordinator will obtain informed consent after thoroughly explaining all aspects of participation, including the use of audio recording where relevant (we will have the participants sign the audio/visual consent form for this aspect of the research), assessing understanding, and answering any questions from potential participants. Participants will receive written consent forms detailing the study, what participation entails, potential risks and benefits, the voluntary nature of their participation, and contact information for the Principal Investigators and Northwell Health/Feinstein IRB. Patients' contact information will be collected in secure electronic documents only accessible to the PI and research team. For the focus groups, which will be audio recorded, participants will give informed consent to participate and separately give consent to be audiotaped. Of note, there will be two separate consent forms used via the mZRCF. Run-in consent 1 is consenting to have data collected for 2-4 weeks post hospital discharge via surveys. Consent 1 is consenting to have data collected for one year post hospital discharge including via surveys and monthly phone calls to determine how patients do over time. Run-in consent 2and consent 2 is obtained after randomization into CPDMP arm. This overcomes barriers to participants wanting to participate in a RCT because they desire to be in the 'hi-tech' arm of the study. The study would not be feasible to perform without the Zelen consent process because if we disclose the true purpose of the study and describe the randomized controlled trial, we anticipate that patients will not want to participate if they are not placed into the telehealth arm – which has advanced technology and is more convenient for the patient. Debriefing is not warranted for this study, because we believe that the patients will be confused about the different types of PR if we disclose the true nature of the study.

If a patient is not cleared for PR by a Pulmonologist or a Cardiologist, they can no longer enroll into the program. At that time, the Research Coordinator will explain to the patient why it's not safe for them to participate in PR. At this point, patients who are not cleared by their doctors will be disenrolled from this study.

The process of informed consent may take more than 30 days prior to the initiation of the research because further eligibility has to be assessed after a patient consents to join the study. A PFT has to be conducted to confirm COPD. Also, pulmonary and possibly cardiology clearances need to be obtained for the patient. This process does not always happen within 30 days if the patient's complete eligibility is not confirmed

in the inpatient setting. In the outpatient setting, PFTs and clearances take a longer time to receive based on the availability of the doctor and/or PFT lab.

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

N/A

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

N/A

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

Informed consent for CPDMP will include a detailed description, in English and Spanish, of the risks and benefits of the study with user-friendly images of the equipment. For audio-recorded data (focus groups) we will ensure dual audio-recording and the use of licensed transcription and translation services.

24) WAIVER OR ALTERATION OF THE CONSENT PROCESS ☐ N/A

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

This study involves no more than minimal risk to the subject because participating in pulmonary rehabilitation is standard of care and poses a minimal risk. For patients that are participating at home, there are several safety precautions in place, which include real-time monitoring of patients by a respiratory therapist as well as a 911 call feature. Also, patients will be followed over the course of 12 months (2-4 weeks for those in the run-in period) to determine their outcomes post hospital discharge. This is minimal risk because it involves the collection of longitudinal data via surveys.

The waiver will not adversely affect the rights and welfare of subjects because we are not withholding the standard of care; we are actually facilitating the receipt of it with our study design.

It is impracticable to conduct this research if elements (disclosing the purpose of the study and the randomization procedure) of informed consent are required because we believe if we tell people which arm they are in, the people who are randomized to the non-telehealth arm will not want to participate because the telehealth arm has advanced technology and is more convenient for the patient. This creates a

major barrier for the successful completion of the intervention and therefore, the study would not be feasible to complete without the Zelen consent process.

We will not debrief with patients after completion of the study because we believe that they will be confused about the different types of PR and it is not necessary.

We would like to request a waiver for consent alteration for consent forms/recruitment documents can be sent through the mail. This is useful for re-consenting purposes, as patients are initially approached while they are hospitalized and it is not feasible for all re-consenting to be done in-person after discharge. Also, e-consenting will be done via REDCap.

Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

N/A

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

N/A

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25) WAIVER OF HIPAA AUTHORIZATION ☒ N/A

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*

- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*
- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

26) VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☐ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☐ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☒ *Minorities*
- ☐ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

All research procedures will be conducted in a culturally sensitive way. In fact, the CPDMP patient facing team is comprised of ethnic minorities (Hispanic and African-American) to provide a comforting and trusting introduction into the program. In addition, all of the Hispanic staff are bi-lingual and fluent in both Spanish and English.

27) MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

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 risks to subjects or others, or protocol modifications) among sites to protect subjects.

The PI at Northwell Health will monitor all of the data by holding monthly meetings with the other sites to ensure standard data collection methods as well as to inform the other sites about protocol modifications or updates on new information. For the Northwell sites, all study related files will be saved and shared between sites on a PHI drive on Northwell Health's servers. For Wyckoff Heights Medical Center, all study related files will be shared between sites on Syncplicity data storage (a secure cloud sharing system provided by Northwell Health).

28) REFERENCES/BIBIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.

1. National Institutes of Health/National Heart, Lung and Blood Institute. National Heart Lung Blood Institute Factbook FY-20062006.

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Figure 1. Study flowchart