INVESTIGATOR STUDY PLAN – REQUIRED

Cover Page

Study Title: Evaluation of the Paramedic Evaluation for Acute COPD Exacerbation (PEACE) Intervention.

Study Document: Study Protocol

ClinicalTrials.GOV ID: STUDY00002240

NCT Number: NCT07072039

Document Last Updated: August 18th, 2026

eIRB study ID number: STUDY00002240
Current Version date for this document: 08/18/2026

1. TITLE
Evaluation of the Paramedic Evaluation for Acute COPD Exacerbation (PEACE) intervention.

2. EXTERNAL IRB REVIEW HISTORY*
NA

3. PRIOR APPROVALS:
NA

Conflict of Interest (COI):
NA

Clinical Engineering Department:
NA

Biohazardous Agents:
NA
Radiation*:*
NA

Students as Subjects*:*
NA

Research Informatics Core:
The Research Informatics Core will be providing support for this project including assistance with participant recruitment. Details of their involvement will be described in Section 11: Procedures Involved and Section 24: Local Recruitment Methods.

UMCCTS Protocol Review Committee (PRC)
NA

4. OBJECTIVES*

Evidence-based strategies to ensure that patients with COPD have reliable, timely, equitable access to treatment are lacking. This deficit is particularly evident in communities impacted by determinants of health that adversely impact preventive health behavior and care access.[1]

On-demand Mobile Integrated Health (MIH) teams, comprised of community paramedics supported by centralized physicians, have been developed to care for patients outside of conventional hospital settings.[2-5] These teams empower physicians to provide enhanced remote care by collecting essential clinical information about patients in their living environment, performing diagnostic testing, and administering therapy in the home.[3, 6] MIH programs decrease emergency medical

services utilization and improve patient satisfaction in select populations, but the impact of MIH programs on the outcomes of patients with COPD exacerbation has not been evaluated.[7]

In this project, the study team will implement and refine an MIH intervention for patients living with COPD. The Paramedic Evaluation for Acute COPD Exacerbation (PEACE) intervention will dispatch community paramedics to execute a home-based evaluation and treatment strategy in collaboration with a supervising physician and the patient's ambulatory medical team during and after acute COPD exacerbation to promote wellness and recovery. This intervention is intended to improve clinical outcomes and reduce acute care costs by eliminating barriers to care, generating actionable clinical data that can facilitate appropriate diagnosis, accelerating treatment, and simplifying care coordination. Our central hypothesis, based on preliminary data and input from key informants, is that an intervention that facilitates community-based management of COPD exacerbation will be acceptable and highly adoptable by patients and clinicians.
The Practical Robust Implementation and Sustainability Model (PRISM) implementation framework [8, 9] will be used to describe factors impacting project implementation, with the embedded Expanded RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) model guiding outcomes measurements.[10]

Beta Testing Phase:

Leveraging our prototypical intervention design, we will test and refine the prototype PEACE intervention in real clinical practice with a cohort of patients who are at high risk of COPD exacerbation. We will use a mixed-methods approach to evaluate the usability and acceptability of each operational and clinical component of PEACE. Measures will include a systematic assessment of protocol adherence, survey instruments, and qualitative interviews to explore contextual factors impacting intervention performance.[11, 12] We will confirm our findings and adapt the protocols informed by a working group comprised of clinicians and community partners. Up to 25 patient participants will be enrolled in the intervention, plus up to 11 clinician participants will be enrolled to participate in usability/acceptability ratings and qualitative evaluations/focus groups.

Randomized Control Trial Phase:

Subsequently, we will evaluate the preliminary effectiveness of PEACE by performing a pilot randomized controlled trial comparing PEACE services to usual care with up to 50 patients. The objective of this pilot trial is to determine whether PEACE improves outcomes amongst patients living with COPD.

5. BACKGROUND*

Chronic obstructive pulmonary disease (COPD) claims 150,000 lives every year in the United States, diminishes patient quality of life, costs billions of dollars in healthcare expenditures, and widens health disparities.[13-16] Acute COPD exacerbations cause 873,000 emergency department visits and 700,000 hospitalizations annually,[13, 17] with disproportionate morbidity and mortality in patients impacted by social and racial inequities.[1, 18-20] **Frequent assessment and early treatment are effective in mitigating COPD exacerbations** and preventing severe complications including hospitalization, worsening disability, and mortality.[21-24] **However, evidence-based strategies to**

ensure that patients with COPD have reliable, timely, equitable access to treatment when experiencing acute symptoms are lacking. This project seeks to address this question and provide evidence describing the use of MIH models to care for patients living with COPD.

6. INCLUSION AND EXCLUSION CRITERIA*

Beta Testing Phase:

Inclusion Criteria/Exclusion Criteria for Patient Subjects:

- Inclusion Criteria: 1) Diagnosis of COPD, 2) At least one COPD exacerbation resulting in ED utilization in the six months prior to enrollment, 3) Over 18 years of age, 4) Speaks English, 5) Resides in the geographical catchment area allowed by the UMass Memorial Medical Center MIH Program's license
- Exclusion Criteria: 1) No prior diagnosis of COPD, 2) Under 18 years of age, 3) Does not speak English, 4) Pregnancy, 5) Cannot provide informed consent

Inclusion Criteria/Exclusion Criteria for clinician subjects:

- Inclusion Criteria: 1) Pulmonologist, primary care physician, emergency physician, or paramedic affiliated with the UMMH system, 2) Has provided care to an enrolled patient subject, 3) Speaks English, and 4) Over 18 years of age.
- Exclusion Criteria: 1) Has not provided care to an enrolled patient subject 2) Does not speak English, 3) Under 18 years of age, and 4) Cannot provide informed consent.

Randomized Trial Phase:

Inclusion Criteria/Exclusion Criteria for Patient Subjects:

- Inclusion Criteria: 1) Diagnosis of COPD, 2) At least one COPD exacerbation resulting in ED utilization in the six months before enrollment, 3) At least or older than 40 years of age, 4) Speaks English, 5) Resides in the geographical catchment area allowed by the UMass Memorial Medical Center MIH Program's license
- Exclusion Criteria: 1) Participated in Beta Testing Phase 2) No prior diagnosis of COPD, 3) Under 40 years of age, 4) Does not speak English 5) Pregnancy, 6) Cannot provide informed consent

Inclusion Criteria/Exclusion Criteria for clinician subjects:

- Inclusion Criteria: 1) Pulmonologist, primary care physician, emergency physician, or paramedic affiliated with the UMMH system, 2) Has provided care to an enrolled patient subject, 3) Speaks English, and 4) Over 18 years of age.
- Exclusion Criteria: 1) Has not provided care to an enrolled patient subject 2) Does not speak English, 3) Under 18 years of age, and 4) Cannot provide informed consent.

Justifications for Criteria:

-Our intervention targets community-dwelling patients who have a diagnosis of COPD, so patients who do not meet this criteria are necessarily excluded.

a. Children are excluded as they rarely have a diagnosis of COPD and will not meet any inclusion criteria as clinician subjects

b. prisoners represent a special population that is routinely excluded from similar research studies. They represent an inaccessible population. Additionally, they will be excluded as they are not residing in a community setting. They will not meet any inclusion criteria as clinician subjects

c. COPD is rare in young women of childbearing age, thus pregnant women are extremely unlikely to be eligible as patient subjects for this study. Pregnant women will be ineligible for inclusion as patient subjects. They will be eligible as clinician subjects as the components of the study in which they participate are minimal risk and will have no bearing on their pregnancy.

d. In this preparatory, feasibility study, enrollment will be limited to English-speaking participants. The study requires iterative development and refinement of study instruments, interview guides, and study protocols. At this stage, inclusion of non-English speakers would necessitate translation, back-translation, and validation of study materials to ensure linguistic and cultural appropriateness. Such processes are resource-intensive and premature prior to establishing feasibility and content validity in English. Restricting the study population to English-speaking participants will facilitate efficient instrument development and protocol refinement, while minimizing threats to internal validity introduced by early translation. Subsequent phases of this research will include intentional efforts to adapt and validate study materials for non-English speakers to ensure inclusivity and generalizability.

-To ensure scientific rigor, patients who participated in the beta testing phase will be excluded from the RCT to avoid contamination

7. STUDY-WIDE NUMBER OF SUBJECTS*

NA

8. STUDY-WIDE RECRUITMENT METHODS*

NA

9. STUDY TIMELINES*

Beta Testing Phase:

Overall timeline: Recruitment will begin upon the disbursement of study funding and will be completed within 18 months of that date. Primary analyses will be completed no later than two years from the disbursement of funds.

Involvement of Subjects in PEACE Beta Testing:

1.0 Recruitment (Day 0)

1.1 Informed consent

1.2 Patient-facing education

1.3 Data Intake Patients
- 1.3.1 Demographic and Background Survey
- 1.3.2 Baseline COPD Assessment Test
- 1.3.3 Baseline Data collection

2.0 Intervention Period I (~Day 1-182)
- 2.1 The subject will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians as well as the Wellinks team if applicable
- 2.2 Subjects will be asked to fill out a survey within 7 days of each PEACE encounter
- 2.3 PEACE visits and Healthcare utilization will be tracked by the research team

3.0 Working Group 1 (~Day 182)
- 3.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview on Zoom

4.0 Intervention Period II (~Day 182-365)
- 4.1 The patient will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians, as well as the Wellinks team if applicable.
- 4.2 Subjects will be asked to fill out a survey within 7 days of each PEACE encounter
- 4.3 PEACE visits and Healthcare utilization will be tracked

5.0 Working Group 2 (~365)
- 5.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview.
- 5.2 Follow-up COPD Assessment Test (patient subjects only)

6.0 Follow-up Data Collection (~Day 365-Day 730)
- 6.1 Records review only, no subject interaction

Randomized Control Trial Phase (starting days at 0 for new participants)

1.0 Randomization Phase Recruitment (~Day 1)
- 1.1 Patient identification
  - 1.1.1 PEACE Data Dictionary
- 1.2 Confirmation of pre-randomization
- 1.3 Informed consent
- 1.4 Patient-facing education
- 1.5 Data Intake Forms
  - 1.5.1 Demographic and Background Survey
  - 1.5.2 Baseline COPD Assessment Test
  - 1.5.3 Baseline Data Collection

2.0 Intervention Period III (~Day 1-365)
- 2.1 The subject will participate in their assigned intervention arm (usual care, usual care plus MIH)
  - 2.1.1 Subjects in PEACE arm will receive PEACE intervention as above

2.1.2 Subjects in the usual care arm will receive usual clinical care
2.2 Subjects in the intervention arm will be asked to fill out a survey within 7 days of each PEACE encounter in addition to scheduled surveys
2.3 PEACE visits and Healthcare utilization will be tracked by the research team
2.4 Patient-Facing surveys for all participants as described below in Section 11

3.0 Working Group 3 (~Day 365)
3.1 Qualitative working group. Participating subjects will be asked to attend a single (~1-2 hour) structured interview.

4.0 Follow-up Data Collection and Secondary Data analysis (~Day 365-Day 730)
4.1 Records review only, no subject interaction
4.1.1 Documents: PEACE Data Dictionary

10. STUDY ENDPOINTS*

Our primary outcome The primary feasibility measure in both study phases will be the recruitment rate. The primary process outcome will be the number of PEACE referrals during the study period. Additional qualitative outcomes are described below in Table 1, organized by PRISM domain. Primary and secondary outcome measures, their timing, and how they will be measured are summarized in Tables 1 and 2 below.

There are no primary or secondary safety measures being recorded for this study.

Table 1: Outcomes by PRISM Domain			
PRISM Domain	**Outcome**	**Data Source**	**Analysis**
Patient Characteristics	• Sample Demographic characteristics • Excluded/Declined Demographics	Study Records Interviews	Descriptive Qualitative
Organizational Characteristics	• Participating clinic size/structure	Interviews	Descriptive Qualitative
Intervention *Clinician and Patient Perspective*	• Affective Attitude • Intervention Coherence • Self-Efficacy • Ethicality • Burden and anticipated cost • Opportunity cost • Fidelity to PEACE protocol • Perceived Effectiveness • Usability	Interviews Study Surveys *Intervention Usability Scale* *Acceptability E-Scale*	Qualitative Descriptive
External Environment	• Institutional, local, and state resources that could be leveraged for intervention delivery	Interviews Literature Review	Descriptive
Implementation and Sustainability Infrastructure	• Staff Fidelity to Intervention (see Figure 3) • Cost of intervention	Clinical Records Interviews Study Records	Descriptive Qualitative

Table 2: Feasibility and Clinical Measures				
Outcome	**Measure**	**Frequency**		
		0	6	12
Sample Description	*Demographic Characteristics of Study Sample*: Participant age, gender identity, race and ethnicity, education level, smoking status, insurance type, employment status, living arrangements, driving status, and comorbidities	**X**		
	Sample COPD Severity: Gold Score, ED visits and hospitalizations in year before enrollment	**X**		
Feasibility Outcomes	***Recruitment and enrollment:* Number of participants approached, met eligibility, and randomized; reason for refusal of nonparticipants (primary feasibility outcome)**	**X**		
	Baseline Measures: Completeness of data collection	**X**		
	Retention: Loss to follow-up, perceived reason for discontinuation, completeness of post-intervention data collection		**X**	**X**
	***PEACE Referrals during study period:* Number of encounters requested (Primary process outcome)**		**X**	**X**
Clinical Outcomes	*PEACE Visits and Disposition:* Number of PEACE visits completed and rate of home treatment versus ED referral		**X**	**X**
	Ambulatory Visits: Number of ambulatory visits for COPD (routine/acute)		**X**	**X**
	EMS Utilization: Number of prehospital encounters related to COPD		**X**	**X**

	Hospitalizations: Number and length of hospitalizations for COPD		**X**	**X**
	Other institutional stays: Number and length of stay in skilled nursing facilities or acute rehabilitation settings		**X**	**X**
	COPD Assessment Test (CAT): health-related quality of life and COPD symptom severity assessment	**X**	**X**	**X**
	Unanticipated ED visits: ED visits within 72 hours after PEACE visit		**X**	**X**
	Mortality: Death will be ascertained through chart review		**X**	**X**
	Exacerbation Relapse: An event where COPD symptoms worsen and require a second pharmacological intervention[25]		**X**	**X**
	COPD related medication changes: Number of adjustments made to study participants' treatment regimen (initiation, discontinuation, dosage adjustment, or substitution of medications aimed at managing COPD)		**X**	**X**

11.PROCEDURES INVOLVED*

Beta Testing Phase

Subject Screening (day -1)

→ The UMass Chan research informatics core will identify eligible patients by creating an automated report that flags patients who meet the inclusion criteria (filtering by diagnosis and city of residence)

→ The RIC will securely (via encrypted secure excel document) provide the study team with reports containing the contact information for potentially eligible patients

» STUDY00002240_PEACE_HIPAA Waiver of Authorization

Enrollment & Intake Visit of Patient Subjects:

- ***Recruitment:*** *See Section 24.*
  - → ***Documents:***
    - STUDY00002240_PEACE_HIPAA Waiver of Authorization
    - STUDY00002240_PEACE Study Flyer
    - STUDY00002240_PEACE_SCREENER
    - STUDY00002240_PEACE_DeclinedIneligibleLog
      STUDY00002240_SOLICITATIONMESSAGEPATIENTSUBJECT

- ***Consent:*** *See Sections 30 & 31.* Study Staff will obtain at least three ways (email address, primary phone number and mailing address) to contact participants to schedule interviews and fill out surveys.
  - → ***Documents:***
    - STUDY00002240_PEACE_Consent
    - STUDY00002069_PEACE_PATIENTMASTERCODE

- ***Intake:*** After obtaining consent, the study staff will access EMRs to obtain baseline data. Patients will also be asked to complete a baseline COPD Assessment Test.
  - → ***Documents:***
    - STUDY00002240_PEACE_DemographicsData
    - STUDY00002240_PEACE_COPD_Assessment Test

Enrollment of clinician subjects:

- ***Recruitment:*** *See Section 24*.
  - → ***Documents:***
    - STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS
    - STUDY0002240_PEACE_QualitativeIntake
    - STUDY00002240_PEACE_DeclinedIneligibleLogClinician

- ***Consent:*** *See Sections 30 & 31*
  - → ***Documents***
    - STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS

- **Master Code *Contact Information:*** Study Staff will obtain at least two ways (primary phone number and mailing address) to contact participants to schedule interviews and prompt participants to complete surveys.
  - → ***Documents:***
    - STUDY00002069_PEACE_CLINICIANMASTERCODE

- **Intervention Period I (~Day 1-182)**
  - → The patient will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians as well as the Wellinks team.
    - 1..1 *The Paramedic Evaluation for Acute COPD Exacerbation (PEACE)* intervention is a mobile integrated health home visit specifically designed to manage acute COPD exacerbation in the community. PEACE was developed using high-quality literature, stakeholder feedback, and observations from the UMMHC pilot MIH studies.
    - 1..2 Ambulatory teams are empowered to refer patients for PEACE visits when patients need more focused, in-person care but a brick-and-mortar setting is inaccessible or inappropriate. PEACE visits are available 7 days a week/24 hours a day. All clinical teams participating in this study are familiar with the MIH program as they have engaged with it for other purposes
    - 1..3 Once a visit is requested via an electronic health record (EHR) order or call to the MIH hotline, a community paramedic presents to the patient's home within 2 hours, evaluates the patient using mobile diagnostic testing, and initiates pharmacological therapy if necessary. A standardized clinical approach and documentation strategy is used, including a focused history and physical exam, venous blood gas, trending pulse-oximetry, medication reconciliation, smoking cessation resources, mobile x-ray etc.
    - 1..4 The community paramedic is supervised in real-time by a physician to establish a care plan and disposition- either treatment at home with

ambulatory follow-up or, if the patient is too acutely ill to be treated in place, transfer to the ED. While often used during periods of acute exacerbation, PEACE can also be used to support post-acute care and augment telepulmonary rehabilitation services.

→ PEACE visits and Healthcare utilization will be tracked throughout the beta testing period.
→ Every time a patient undergoes a PEACE visit, the study team will ask the patient, their primary care physician, pulmonologist, and the treating paramedic (if enrolled in the study) to complete a post-visit evaluation survey.

1..1 Documents:
1..1.1 Study00002240 PEACE Visit Data
1..1.2 STUDY002240 PEACE Post Visit Form
1..1.3 STUDY00002240_PostVisitFormClinician

- **Working Group 1 (~Day 182)**

1.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview in a focus group-type setting
1.2 The focus of these focus groups will be on 1) Selecting and engaging patients most likely to benefit from the PEACE intervention 2) Determining the best timing of the PEACE intervention in each patient's healthcare trajectory, 3) optimizing the clinical and diagnostic capabilities of the mobile intervention 4) establishing relationships between the mobile clinical team and other members of patients' personal and medical care team, and 5) measurements of the effectiveness of the program.
1.2.1 Patient subjects will be informed that if they choose to participate in the focus groups, they may be asked to discuss their health and health information regarding their diagnosis of COPD with other patients and clinicians in the mixed-subject focus groups.
1.3 Structured interviews will be scheduled at a mutually convenient time for subjects and study staff.
1.4 Each subject will participate on one day for approximately 1-2 hours.
1.5 Interviews may be held in person or via secure zoom video chat
1.6 Interviews will be held in groups of 3-4 with a mix of subject types in each group
1.7 After a brief reiteration of the study purpose, the interviewer will confirm consent to record the interview for transcription and analysis purposes before proceeding. Interview responses will be recorded by hand on the interview guide or typed into a document on the interviewer's encrypted computer, and also digitally recorded to capture verbatim content and professionally transcribed by a member of the study team for later qualitative analysis.
1.8 At the end of the interview, all participants will be asked to fill out a brief (10 minute) structured Redcap Survey.
1.9 All interviews will be digitally recorded using the Zoom recording application with Microsoft Teams as a backup. This program will be run on a computer present in the room for in-person interviews or on the computer of the study team member

conducting any Zoom interviews. Only audio recording will take place. No video recording will take place at any time.

1.9.1 Immediately following each interview, the recording will be transcribed, and the original recording subsequently deleted once transcription is complete.

1.9.2 Documents

1.9.2.1 STUDY00002240_PEACE_SampleInterviewGuide

1.9.2.2 Transcribed Interviews

1.9.2.3 STUDY00002240_PEACE_QUALITATIVEINTERVIEWPOSTSURVEY

2.0 Intervention Period II (~Day 182-365)

2.1 The patient will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians as well as the Wellinks team as described above

2.2 PEACE visits and Healthcare utilization will be tracked

2.3 Every time a patient undergoes a PEACE visit, the study team will ask the patient, their primary care physician, pulmonologist, and the treating paramedic (if enrolled in the study) to complete a post-visit evaluation survey.

2.3.1 Documents:

2.3.1.1 Study00002240 PEACE visit form

2.3.1.2 Study00002240_PEACE_POSTVISITINSTRUMENT

2.3.1.3 STUDY00002240_PostVisitFormClinician

3.0 Working Group 2 (~365)

3.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview in a focus group setting as described above
At the end of the interview, all participants will be asked to fill out a brief (10 minute) structured Redcap Survey.

3.2 Patient subjects will be asked to also complete a follow up COPD Assessment Test

3.2.1 Documents:

3.2.1.1 STUDY00002240_PEACE_SampleInterviewGuide

3.2.1.2 Transcribed Interviews

3.2.1.3 STUDY00002240_PEACE_QUALITATIVEINTERVIEWPOSTSURVEY

3.2.1.4 STUDY00002240_PEACE_COPD_Assessment Test 2

4.0 Follow-up Data Collection (~Day 365-Day 548)

4.1 Records review only, no subject interaction. The study team will query the EHR to collect follow-up data points about enrolled subjects

→ *Documents:*

- *Study00002240_PEACE_Utilizationsummary*

<u>Randomization Phase</u>

Identification of Eligible Patients **(Day -1)**

Eligible patients will be identified from a registry list of patients within the UMass Memorial Health System with COPD and restricted to those who are English-speaking and residing within the geographic catchment area served by the PEACE program.

Patients will be stratified by high, medium, and low risk for inpatient hospitalization based on their previous healthcare utilization patterns and COPD-related hospitalizations.

→ ***Documents:***
- PEACE_datadictionary.xlsx

Randomization:

Prior to patient contact, eligible individuals within their risk state (high, medium, or low risk as above) will be pre-randomized in a 1:1 allocation to one of two study arms: 1) Usual Care (control) and 2) The PEACE arm (intervention).

Randomization will occur at the patient level using a computer-generated allocation sequence executed by a data analyst. Patients will be approached as described in section 24.

"Pre-randomization" designs (also called Zelen designs) randomize eligible patients to study arms before seeking consent for the experimental intervention. In this approach, patients allocated to the intervention arm are then approached for consent only to receive the new intervention, and patients randomized to usual care receive the current standard without any change of their clinical management.[26, 27] The primary methodological rationale is to reduce bias introduced when patients are consented before randomization and subsequently feel disappointed or dissatisfied if assigned to usual care, which can adversely affect adherence and reported outcomes.

Pre-randomization can also improve accrual and practicability in pragmatic trials where uptake of a new intervention is expected to be incomplete and where the policy question is the real-world effect of offering an intervention rather than its efficacy under ideal/controlled conditions, as is the case for this study.[26] By enrolling only participants who are willing to receive their assigned intervention, this approach reduces inefficiencies related to unused intervention capacity and recruitment burden.[26] Pre-randomization also enables assessment of intervention acceptability by capturing differential uptake across study arms, which is particularly valuable for informing future implementation and scale-up.[26] Potential selection bias introduced by this approach will be acknowledged and addressed analytically and is considered appropriate given the present study's pragmatic and implementation-focused objectives.

Subjects will be informed of their study assignment before providing informed consent and will only consent to the activities in their study arm. Subjects will be informed that pre-randomization occurred, how it occurred, and that other participants in the same study may receive a different intervention.

Patients who decline participation will continue to receive usual clinical care. Basic demographic and registry-level characteristics will be used to assess differences between enrolled and non-enrolled patients to evaluate reach and potential participation bias.

Enrollment & Intake Visit of Patient Subjects: (Day 1)

- ***Recruitment:*** *See Section 24*.
  - → ***Documents:***
    - STUDY00002240_PEACE_HIPAA Waiver of Authorization
    - STUDY00002240_PEACE Study Flyer
    - STUDY00002240_PEACE_PilotRCT_Questionnaires (Screener)
    - STUDY00002240_PEACE_DeclinedIneligibleLog
      STUDY00002240_MDH_InviteStudyInformation

- ***Consent:*** *See Sections 30 & 31*. Study Staff will obtain at least three ways (email address, primary phone number and mailing address) to contact participants to schedule an onboarding call with the research team.
- Through either phone call or email, participants will be introduced to the study and asked to download the MyDataHelps application hosted by CareEvolution (the parent company). All surveys will be completed using the MyDataHelps app unless otherwise stated.
  - → ***Documents:***
    - STUDY00002240_PEACEINFORMEDCONSENTText_8.24.2026_RANDOMIZATION INTERVENTION
    - STUDY00002240_PEACEINFORMEDCONSENTText_8.24.2026_RANDOMIZATION CONTROL

- ***Intake:*** After obtaining consent, the study staff will access EMRs to obtain baseline data. Patients will also be asked to complete a baseline COPD Assessment Test.
  - → ***Documents:***
    - STUDY00002240_PEACE_PilotRCT_Questionnaires

- **Randomization Phase Intervention Period (~Day 1-365)**
  - → Subjects will be assigned to one of the two study arms
    - Usual care (Control): Patients will not receive any study intervention; they will receive usual care. If they are referred to telepulmonary rehabilitation or MIH by their care teams, it will not impact their standing in the study.
      - ➢ Patients will be asked to complete self-reported functional status assessments (Document: STUDY00002240_PEACE_PilotRCT_Questionnaires) at baseline 6, and 12 months
      - ➢ The study team will track health utilizations for 1 year after completion of study activities (~2 years after study enrollment)

- Usual care +PEACE (Intervention): Patients will receive usual care plus referral to PEACE as described above. If they are referred to telepulmonary rehabilitation or MIH by their care teams, it will not impact their standing in the study.
  - Patients will be asked to complete self-reported functional status assessments (Document: STUDY00002240_PEACE_PilotRCT_Questionnaires)) at baseline, 6, and 12 months
  - See "Beta Testing" description above for a detailed description of the PEACE intervention
  - The study team will track health utilizations for 1 year after completion of study activities (~2 years after study enrollment)

5.0 Follow-up Data Collection (~Day 365-Day 720)

5.1 Records review only, no subject interaction. The study team will query the EHR to collect follow-up data points about enrolled subjects

→ *Documents:*

- *Study00002240_PEACE_Utilizationsummary*

Enrollment of clinician subjects: Clinician Subjects will be recruited to participate in a post-implementation working group that will occur after completion of the randomization period.

- ***Recruitment:*** *See Section 24*.
  - → ***Documents:***
    - STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS
    - STUDY0002240_PEACE_QualitativeIntake
    - STUDY00002240_PEACE_DeclinedIneligibleLogClinician

- ***Consent:*** *See Sections 30 & 31*
  - → ***Documents***
    - STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS

- **Master Code *Contact Information:*** Study Staff will obtain at least two ways (primary phone number and mailing address) to contact participants to schedule interviews and prompt participants to complete surveys.
  - → ***Documents:***
    - STUDY00002069_PEACE_CLINICIANMASTERCODE

6.0 Post-Study Working Group (~Day 365)

6.1 Qualitative working group. Subjects enrolled in the randomization phase working group will be asked to attend a single (~1-2 hour) structured interview in a focus group-type setting

6.2 The focus of these focus groups will be on 1) Selecting and engaging patients most likely to benefit from the PEACE intervention 2) Determining the best timing of the

PEACE intervention in each patient's healthcare trajectory, 3) optimizing the clinical and diagnostic capabilities of the mobile intervention 4) establishing relationships between the mobile clinical team and other members of patients' personal and medical care team, and 5) measurements of the effectiveness of the program.

6.2.1 Patient subjects will be informed that if they choose to participate in the focus groups, they may be asked to discuss their health and health information regarding their diagnosis of COPD with other patients and clinicians in the mixed-subject focus groups.

6.3 Structured interviews will be scheduled at a mutually convenient time for subjects and study staff.

6.4 Each subject will participate on one day for approximately 1-2 hours.

6.5 Interviews may be held in person or via secure Zoom video chat

6.6 Interviews will be held in groups of 3-4 with a mix of subject types in each group

6.7 After a brief reiteration of the study purpose, the interviewer will confirm consent to record the interview for transcription and analysis purposes before proceeding. Interview responses will be recorded by hand on the interview guide or typed into a document on the interviewer's encrypted computer, and also digitally recorded to capture verbatim content and professionally transcribed by a member of the study team for later qualitative analysis.

6.8 At the end of the interview, all participants will be asked to fill out a brief (10 minute) post-interview survey titled "STUDY00002240_PEACE_QUALITATIVEINTERVIEWPOSTSURVEY."

6.9 All interviews will be digitally recorded using the Zoom recording application with Microsoft Teams as a backup. This program will be run on a computer present in the room for in-person interviews or on the computer of the study team member conducting any Zoom interviews. Only audio recording will take place. No video recording will take place at any time.

6.9.1 Immediately following each interview, the recording will be transcribed, and the original recording subsequently deleted once transcription is complete.

6.9.2 Documents

6.9.2.1 STUDY00002240_PEACE_SampleInterviewGuide

6.9.2.2 Transcribed Interviews

6.9.2.3 STUDY00002240_PEACE_QUALITATIVEINTERVIEWPOSTSURVEY

Secondary Data Analysis

At the end of the study period, patients who met eligibility criteria but were not enrolled in the study will be included in a secondary data analysis of health records to enable comparison with both the intervention and control groups by developing a synthetic control group. Patients who are approached for participation in the study but decline will not be included in the secondary analysis. We will keep a record of those who decline in the *Declined/Ineligible Log. Only MRN will be kept on this log. See Destruction of Identifiers for additional details.*

This analysis will rely exclusively on retrospective medical record review using automated data extraction reports from the patient registry. No additional patient contact or intervention will occur for individuals included solely in this component, and we will request a waiver of informed consent for this part of the project. The study team will not directly access any patient's medical record in the secondary data analysis, and only a deidentified report will be downloaded in the report used for analysis.

To enhance comparability, propensity score methods will be used to weight the non-enrolled cohort so that baseline characteristics approximate those of the intervention group, thereby creating a synthetic control population. Weighted analyses will compare healthcare utilization outcomes (as described in the Outcomes section) between enrolled participants and the synthetic control group. This approach will allow for evaluation of utilization patterns while minimizing selection bias and preserving the observational nature of the secondary analysis.

Periodic data quality checks may be performed to assess completeness and accuracy, including review of a subset of records by a second team member. No data will be downloaded to personal devices, stored locally, or transmitted outside institutional systems. We request to waive informed consent as this is a retrospective secondary analysis and entails no more than minimal risk.

12. DATA AND SPECIMEN BANKING*
NA

13. Data Analysis and Management*

Sample Size:

Analysis Strategy:

Quantitative Analysis: Analyses will be performed using the latest version of STATA, R, or SAS. All tests of inference will use the standard alpha level of 0.05. Feasibility measures and participant demographics will be reported descriptively. Outcomes will be ascertained and compared between the intervention and control arms. We will compare participants in the control standard of care and PEACE intervention arms using parametric (t-test) or nonparametric (Mann-Whitney U test, Chi-square analysis) tests depending on the observed outcome distribution. Intent-to-treat analysis will be performed. Count models (Poisson, negative binomial, or zero-inflated negative binomial) will be used to compare healthcare utilization patterns between control and intervention groups over the 12-month trial.

Qualitative Analysis: Analysis of qualitative data will be conducted using ATLAS.ti qualitative software. Three independent coders will inductively develop a preliminary set of codes organized by PRISM domain.[8] The codebook will be elaborated upon based on emergent themes and adjusted as the interviews proceed. The entire qualitative team will subsequently review each transcript and develop a revised codebook after reviewing ~ 20% of the interviews together. We will apply the codebook to all interviews, using constant comparison methods to generate

higher-level themes and synthesize our results into a formative evaluation report of the key findings.

Data Management Plan:

Beta Testing Phase
All study data will be recorded on a REDCap database established on a secure encrypted server on Amazon Web Services. All access to the database will be through permissions established by the IT REDCap administrator. Investigators will have to log into the REDCap database to enter or view data. Logic data checks will be built into the data entry process to help clean the data at entry. Quality control edits will be run to identify inconsistencies and questionable values in the data. The audit trail will be activated for the duration of the study.

Data for analysis will be downloaded directly from REDCap and converted to SAS, STATA, datasets or R data frames for analysis. The downloaded datasets will be deidentified and are HIPPA as well as 21 CFR Part 11 compliant.

Randomization Phase
All data will be kept in secure databases that are password protected and to which only authorized personnel have access. The databases that will be used during the study are: CareEvolution and REDCap. REDCap may be used as back-up to CareEvolution database and to support clinical coordination using PII if necessary. The REDCap system will be maintained within UMass Chan firewalls by the UMass Chan Data Core. CareEvolution will have access to the information put into the app including the answers to the surveys. Data uploaded in CareEvolution will be securely stored on servers in the United States or by third-party service providers that CareEvolution works with to store and secure information in the United States.

Survey and app use data will be collected using a CareEvolution application and web platform called MyDataHelps. The consent process via MyDataHelps is 21 CFR Part 11 compliant. Data required for analysis is exported and transmitted to a secure FTP site for uploading into the analytic database at UMass Chan. Survey responses will be stored under a participant ID and will be transmitted to the secure CareEvolution server. Information collected by the CareEvolution app will be securely stored on CareEvolution servers in the United States, or on servers owned by third party service providers that CareEvolution contracts with to securely store information in the United States. The following link contains CareEvolution's security guidelines: https://rkstudio-customer-assets.s3.amazonaws.com/CareEvolution/MyDataHelpsPrivacy.html

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

All unanticipated adverse events will be reported, and the study PI will closely monitor all aspects of the study.

The PI will be responsible for monitoring adverse events during the study. If an adverse event occurs, their role will be to identify the concern, to develop an appropriate response to alleviate or minimize any adverse event, and to ensure that the adverse event is reported in a timely manner to the appropriate authority. We anticipate that these adverse will be rare. We will assess whether an undesirable experience (adverse event) occurred and will record details of all adverse events on an adverse event case report form. We do not anticipate that any serious adverse events (death, life threatening illness, new serious or permanent disability) will occur. However, should such an event occur, we will report the event within five business days to the University of Massachusetts Chan Medical School (UMCMS) Institutional Review Board per HRP-103-Investigator Manual guidelines.

The adverse event case report form will include a description of all undesirable experiences, required interventions, and an assessment of the participant after the event if possible. An estimate of the extent of injury and prevention strategies will be reported. The principal investigators will classify the relationship of the study protocol to the event as follows:

• Unrelated: The event is clearly related to factors not related to the study protocol.
• Possibly Related: The event follows a reasonable temporal sequence associated with participating in the study and/or is consistent with events related to the study protocol but is possibly related to factors such as the participant's clinical state.
• Related: The event follows a reasonable temporal sequence associated with participating in the study and/or is consistent with events related to the study protocol and cannot be reasonably explained by factors such as the participant's clinical state.

The severity of an adverse event in both groups is defined as a qualitative assessment of the degree or intensity of an adverse event as determined by the principal investigator as follows:

• Mild: No impact (in any way) on the participant.
• Moderate: Impacts on the participant but is not life-threatening or incapacitating.
• Severe: Fatal, life threatening, permanently disabling; severely incapacitating; requires/prolongs inpatient hospitalization.

All adverse events will simultaneously be reported to institutional officials. The report will summarize the facts of the case, including the date and a description of the participant; whether the event is related to the study's protocols; the steps that have been taken to address the issue; whether the event provides emerging knowledge about the risks of the study that should be conveyed to participants; and whether the consent form should be revised.

As this is a minimal-risk study, we do not plan on having a data safety monitoring board review. The UMMH MIH program is a fully licensed program that meets clinical standards of care; it is supervised by the Massachusetts Department of Public Health and its medical director submits clinical data to them quarterly for quality and safety review. The program also has an internal quality improvement/assurance protocol for all completed visits. The program is accustomed to providing peri-acute care, particularly to patients with COPD.

The frequency of data review for this study is summarized in the following table:

Data Type:	Frequency of Review:
Participant recruitment (adherence to protocol on inclusion & exclusion criteria)	The PI will directly observe recruitment for the first five cases, then will observe random cases bi-monthly once the study is established.
Data collection methods	The PI will directly observe data collection on the first five cases, then will observe random cases bi-monthly once the study is established.
Integrity of data storage procedures	The PI will directly monitor data storage the first five cases, and then will review all data monthly once the study is established.

The PI will report all new information required by the IRB within 5 business days including: Information that indicates a new or increased risk, or a new safety issue, a protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm or any of the other required reporting parameters.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

Subjects may be removed from the research study without their consent if:

- They move out of the MIH service area previously define
- They move into a long-term care facility, such as a nursing home
- It becomes unsafe for the MIH team to perform home visits at the participant's house
- Other scenarios not listed above, but deemed by the PI of this study as unsafe for either the participant or the MIH team to continue the study

16. RISKS TO SUBJECTS*

The main risks to participants are:

- Delays in definitive emergency care
- Loss of confidentiality or privacy given that their contact information and PHI will be collected
- Psychological distress from participating in the survey or qualitative interview

1) **Delays in definitive emergency care**
    a. The mobile integrated health service provided as part of this study is licensed under the purview of the state Department of Public Health and is considered a standard of care. It is an already active program and is utilized by patients daily under the supervision of Dr. O'Connor, who is the medical director of the program, to provide peri-acute care. To mitigate any risk of patients' delaying emergency care by inappropriately requesting an MIH visit, patients and clinicians will be extensively educated about the purpose of the MIH program and its capabilities and limitations. They will be counseled in symptoms and

conditions necessitating immediate use of the 911 system instead of the MIH hotline. A copy of the licensure letter provided by the Massachusetts Department of Public Health is included with this application.

b. The MIH team is also extremely well positioned to transition care into the traditional 911 care pathway should a participating patient be determined to be experiencing a medical emergency. The dispatch and ambulance services that support the MIH program are the same services that perform emergency transportation in the geographical catchment area where the study will be performed; therefore, their communications are integrated, and the nature of the care being performed can be transferred at any time.
c. The MIH care pathway has several safeguards to transition care into an emergency response if needed. If a community paramedic is dispatched to the patient's home and the paramedic or the consulting physician feels that the patient is experiencing an emergency, he/she may contact the program's dispatch and activate the 911 pathway. If this happens, a transporting vehicle will be immediately dispatched to the patient's home. The community paramedics are all experienced professionals with years of work functioning in an urban 911 system and will render care until the transporting vehicle arrives.
d. All community paramedics will be equipped with a full cadre of advanced life support level medications and supplies. The MIH program will only function in the geographical zone where the community paramedics belong to the same organization as the 911 responding service and no other organization's involvement is anticipated.
e. If the patient has any questions or clinical concerns during any research or clinical visit, there will always be both a physician on call for the research study as well as a clinical physician on call for the mobile integrated health program who can be contacted for additional real-time support.

Protections against the specific risks identified above include the following:

- **Loss of Privacy/Confidentiality**
  - All data will be managed securely as noted above. We view this risk to be minimal. All data and personal information about subjects from both the PEACE intervention cohort, secondary analysis, and the qualitative arm will be managed securely and accessible only by authorized members of the study team. All identifiers will be disposed of as soon as appropriate (see section 26).

- **Psychological Distress**
  - The informed consent process will discuss the potential risk that participating in discussions related to health and emergency care might cause distressing rumination about overall health and aging. We will inform all subjects verbally and in writing that they may decline to answer any question asked and may stop participating in the interviews at any time. We view this risk as minimal.

17. POTENTIAL <u>DIRECT</u> BENEFITS TO SUBJECTS*

Patients who participate in an interventional arm of the study may experience improved outcomes related to their COPD from the enhanced healthcare access provided by the PEACE program. Otherwise, there is no direct benefit to subjects.

18. VULNERABLE POPULATIONS*

Employees of site

Employees who are the clinicians of patients who are enrolled in the PEACE intervention arm of the trial will be approached for their completion of study surveys regarding the PEACE visit. Clinicians will be made aware that the survey is optional and that their responses are confidential and will not be used in any work-based assessments or performance reviews.

Employees who are clinicians in the ambulatory care setting will be invited to participate in the working group sessions. All participants who are invited will be made aware that these working group sessions are optional and their responses are confidential and will not be used in any work-based assessments or performance reviews.

Children
Children will not be included in this study.

Prisoners
Prisoners will not be included in the study.

Adults Unable to Consent
Adults unable to consent will not be included in this study

Pregnant Women

Pregnant women will be excluded from enrolling as patient participants.

Pregnant women may be included as clinician participants. This part of the study is minimal risk and presents no intervention that will impact or pose additional risk to their pregnancy. No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate.

Secondary Analysis: NA

19. MULTI-SITE RESEARCH*
NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*
NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

PEACE Participants: Individual results from surveys and interviews will be shared with subjects upon their request. Completed deliverables such as manuscripts, whitepapers, and posters may be shared with subjects at their request.

Secondary Data Analysis: NA, results will not be shared with subjects

22. SETTING

- ***Enrollment & Informed Consent:*** Patients will be located in the community, in the hospital, or in the UMMH ambulatory clinic; the study team will be located in the hospital or ambulatory clinics at UMMH, or in private offices at the University Campus in the departments of medicine and emergency medicine

- ***Data Abstraction:*** Private offices at the University Campus in the departments of family medicine and emergency medicine

- ***Interviews:*** Subjects will be located in the community or in private offices at the university campus; the study team will be located in private offices at the University Campus in the departments of medicine and emergency medicine

- ***Follow-up data collection and secondary data analysis:*** Private offices at the University Campus in the departments of medicine and emergency medicine

- **Data analyses and manuscript writing** will occur in private offices at the University Campus in the departments of medicine and emergency medicine

23. RESOURCES AVAILABLE

Study Staff: All Study Staff members are up to date on CITI certification and are aware that this training must be renewed every three years. They will conduct this research in accordance with the current, IRB-approved protocol.

- ***Study Investigators:***
  - → ***Principal Investigator (PI):*** The PI is a board-certified Emergency Medicine physician with experience in human subjects research.
    - ***Responsibilities:*** The PI will be responsible for overseeing the entire study including, but not limited to (1) dissemination of the research protocol to all Study Staff; (2) recruitment; (3) enrollment; (4) data collection; (5) data analysis; and (6) dissemination of results. The PI will ensure all Study Staff are adequately trained and monitor their progress to ensure they are following the protocol.
  - → ***Co-Investigators (Co-Is):*** The Co-Is are physicians from the departments of Emergency Medicine and Medicine

- ***Responsibilities:*** The Co-Is will assist the PI with all aspects of the study including, but not limited to: (1) recruitment; (2) enrollment; (3) administering questionnaires; (4) interpretation of results; and (5) preparation of the resulting manuscripts.

- ***Additional Study Staff Roles:***
  - → ***Research Assistants (RA):*** The RA will have basic training in research methods and human subjects' research, as well as a bachelor's degree in a human science field or equivalent.
    - ***Responsibilities:*** They will be trained by the PI and co-investigators to complete most aspects of the study including, but not limited to: (1) explaining the study to eligible individuals; (2) obtaining informed consent; (3) how to conduct a chart review; (4) data handling; and (5) administering questionnaires.
  - → ***Data Analyst:*** The Data Analyst will assist in the design and performance of analyses relevant to the project.
    - ***Responsibilities:*** They will have formal training in biostatistics and epidemiological methods as well as a bachelor's degree in computational sciences or field equivalent**.** Examples of responsibilities held by the data analyst include but are not limited to: (1) Creation of data collection tools; (2) ingestion of de-identified electronic medical record information; and (3) interim and formal analyses.

24. LOCAL RECRUITMENT METHODS

Feasibility*:* We have completed similar studies in the target population and were able to recruit 100 participants in one year.[28] Therefore we feel that the small number of patients anticipated for inclusion in this pilot study will be minimal.

Procedures: We have created a one-page basic *solicitation and study Flyer* to provide to prospective subjects that outlines the study details in an easy-to-read format.

- Study staff will identify potentially eligible individuals through EHRs with assistance from the Research Informatics Core, partners in the health system, and referrals to the study team from patient's clinicians. As described above, the RIC will securely provide the team with a list of patients who are potentially eligible for the study based on their age, city of residence, diagnosis of COPD, and participation in the Wellinks program. The UMMMC ACO will aid in the recruitment of patients, allowing the study team access to the patient list maintained by their organization. Clinicians of the pulmonary and adult medicine disciplines will be encouraged to refer patients for study team review as well.
- As described in Section 11, all eligible patients will be pre-randomized to a study arm assignment before being approached for recruitment.

  - → If the individual seems eligible based on the above information, the study staff will query other portions of the EMR (medical history, healthcare utilization patterns etc.) to verify EMR-based eligibility.

→ If the individual is still eligible, the study team will send the patient a MyChart message or email from MyDataHelps soliciting participation in the study. The message will include PI contact information for questions and prompt interested patients to fill out an online screener indicating interest.

→ If patients are currently inpatients when they are identified, the study team will direct-approach the patient while they are in the hospital and ask for permission to share information about the study. Before approaching any patient, the study team will obtain verbal permission from the treating provider.

→ If identified patients are scheduled to have upcoming ambulatory visits, the study team will direct-approach the patient when they present for their scheduled clinic visit and ask permission to share information about the study. Before approaching any patient, the study team will obtain verbal permission from the treating provider.

→ Additionally, the study team will place study flyers in high-visibility places, including clinic rooms, waiting rooms, and the hospital cafeteria. The flyers will have a link and QR code leading to the RedCap or MyDataHelps Eligibility screener.

→ Interested subjects will be prompted to complete the eligibility screener independently or with the help of a study team member. Once subjects have completed the screener, the study team will contact them via phone or in person to discuss the study, answer any further questions, and proceed with study activities.

→ We will inform patients during this initial phone conversation that consent forms and surveys will be sent via email which is not a secure form of communication and receive permission to email them links or QR codes to access the REDCap or MyDataHelps consent form/survey. If patients do not want to receive links/QR codes to study instruments via email, we will offer patients the option of receiving them via snail mail or completing them verbally over the phone with a Research Assistant.

→ Patients will be given the option of reviewing and signing the consent form independently, in person with an RA, or doing it while on a teleconference with a member of the study team so that the consent can be reviewed in real-time.

→ A $(50) gift card will be given to each participant after they complete baseline intake forms, and then again after completing scheduled study instruments during the study. Patients will be eligible to receive up to $150 throughout their participation in the study if they complete all study instruments. To be eligible to receive the research stipend, the subject's name, address, phone number, and type of phone (mobile, landline) will be collected by the study team and provided to the UMass Chan business office to procure the payment. Once this information is provided to the business office, this identifying information will be destroyed by the PI.

→

- Documents
  - STUDY00002240_PEACE_HIPAA Waiver of Authorization
  - STUDY00002240_SCREENER_12.4.2024_V1for the Beta testing phase or STUDY00002240_PEACE_PilotRCT_Questionnaires (Screener) for the Randomization Phase

- STUDY00002240_PEACE_DeclinedIneligibleLog
- STUDY00002240_SOLICITATIONMESSAGEPATIENTSUBJECT

Destruction of Identifiers:

- ***Declined or Ineligible:*** Any participants who decline will be noted in the MyDataHelps screener by the RA or on the *Declined/Ineligible Log*. Patient MRNs will be included in this log / screener to ensure that their data is not included in any secondary analyses. This information will be kept securely on UMass Chan drives and/or the CareEvolution platform and will be deleted 6 years after study completion. There will not be any paper copies of these records.
- ***Agree to Participate:*** Following the enrollment and intake visit, identifiers from the *Screening Log* will be transferred to the *Master Code,* and de-identified demographic information will be transferred to the appropriate Redcap or MyDataHelps Database.

Professional Subjects:

- The study team will identify and subsequently email each subject (e.g. clinician, administrator) using a standardized email script to describe the study.
- Potential subjects will be identified and contacted individually. The invitation will include a description of the project and a summary of the topics to be covered in the interview.
- Only publicly available contact information (i.e., email address) will be used to contact clinicians
- After initiating the recruitment email or phone call, the team will make a single follow-up attempt for non-responders.
- Interested participants will be invited to self-schedule interview in an online scheduling portal
- Once the interview has been scheduled, the study team will proceed with informed consent as per section 30.
- A $(50) gift card will be given to each participant after they complete each of their interviews and surveys. To be eligible to receive the research stipend - the subject's name, address, phone number, and type of phone (mobile, landline) will be collected by the study team and provided to the UMass Chan business office to procure the payment. Once this information is provided to the business office – this identifying information will be destroyed by the PI.
- Documents*:*
  - STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS_12.4.2024_V1
  - STUDY00002240_PEACE_DeclinedIneligibleLogClinician_12.6.2024_v1

For Secondary Data Analysis Only Cohort: Given the minimal risk entailed by the study, we have requested a HIPAA waiver, which is included in this application, and no consent will be obtained. Patients' clinical information will be accessed via the reporting process described above in Section 11. We do not anticipate that any subjects who meet initial screening criteria will need to be withdrawn due to ineligibility. If it comes to pass that a subject initially meets criteria during the initial report generation but subsequently must be withdrawn, all information collected about that patient will be deleted. No compensation will be offered to any subjects involved only in secondary data analysis.

25. LOCAL NUMBER OF SUBJECTS

Beta testing phase: We expect up to 25 patient participants will be enrolled in the intervention, plus up to 11 clinician participants will be enrolled to participate in usability/acceptability ratings and the qualitative evaluation.

Randomization phase: We expect 50 patient subjects will be enrolled in the intervention, plus up to 11 clinician participants will be enrolled to participate in usability/acceptability ratings and the qualitative evaluation.

Secondary Analysis: We expected up to 10,000 subjects may be included in the secondary data analysis.

26. CONFIDENTIALITY

Because the National Institute of Health (NIH) is funding this research, this study will automatically have a Certificate of Confidentiality. The Certificate protects the study team from being forced to release information that may identify participants as part of a court, legislative, administrative, or other proceeding.

Procedures to Secure the Data:

- Intervention Participants will be assigned a unique Study ID# and most data related to a given participant will use this ID *(see table below)*.
- We may quote participant comments in presentations and publications; however, any direct quotations will be carefully reviewed to ensure that they do not include any potentially identifiable content.
- UMMS computers are password-protected and encrypted.
- Data will be stored in REDCap and/or MyDataHelps

Document	***Coding***	***Access***	***Storage***	***Destruction***

Declined Ineligible Logs - *De-identified demographic information will be recorded on this document*	- *Identifiable information; Will contain declined participants' MRN	- Authorized Study Staff & Support Personnel	- Securely stored on a password-protected UMMS computer	Forms will be retained for 6 years following completion of this research
PEACE Study Flyer	- Will not contain any of the 18 HIPAA identifiers	- Authorized Study Staff & Support Personnel	- Securely stored on a password-protected UMMS computer	-Flyer will be archived once study results are published
Email Script/Solicitations-Patients	- *Identifiable information; Will contain potential participants' name and email address	- Authorized Study Staff	- Securely stored on a password-protected UMMS computer	- Contact information will be deleted for each participant once data collection is complete.
Email Script/Solicitations-Clinicians	- *Identifiable information; Will contain potential participants' name and email address	- Authorized Study Staff	- Securely stored on a password-protected UMMS computer	- Contact information will be deleted for each participant once data collection is complete.
Master Codes for Patient Subjects - *Identifiers will be transferred to the Master Code; All other information will be entered into RedCap or MyDataHelps under a random ID*	- *Identifiable information; The only place that identifying information will be linked with Study ID#	- Authorized Study Staff	- Securely stored on a password-protected UMMS computer	- Name, date of birth, and contact information will be deleted for each participant once data collection is complete.
Master Code for-Clinician Participants - *Contact information will be collected from participants using Redcap (Contact Info) or MyDataHelps and then transferred to the Master Code*	- *Identifiable information	- Authorized Study Staff	- N/A	- Contact information will be transferred to the *Master Code* following completion of the enrollment and intake visit and the Redcap form will be destroyed
Consent - *Written documentation*	- *Identifiable information	- Authorized Study Staff	- Securely stored in the PI's locked office	- Forms will be retained for 6 years following

				completion of this research
Transcribed Interviews	No Identifiers	Authorized Study Staff	- Securely stored on a password-protected UMMS computer	1) Transcriptions will be archived once results have been published
ALL Data Collection Sheets *Collected using the Redcap or MyDataHelps form*	Study ID# only	Authorized Study Staff	Directly entered by the RA or subject into Recap	REDCap and/or MyDataHelps databases will be archived once results have been published
Interview Guide	No Identifiers	Authorized Study Staff	Written in advance by study staff	1) Interview guide will be archived once results have been published
HIPAA Waiver of Authorization	No Identifiers	Authorized Study Staff	Written in advance by study staff	1) HIPAA Waiver of authorization will be archived once results have been published
PEACE Data Dictionary		Authorized Study Staff	- Securely stored on a password-protected UMMS computer	Identifiers will be deleted once enrollment is complete
Deidentified Report for secondary Data analysis	No	Authorized Study Staff	- Securely stored on a password-protected UMMS Drive	Will be archived once results have been published

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

Procedures to Protect Subjects:

- To make subjects feel at ease, Study Staff will clearly explain the function of the PEACE program and the additional steps entailed by the research study. Patients will be notified explicitly that they may participate in the home visits as part of the clinical protocol without participating in the research study.
- Participants will be informed that they can skip any question in the questionnaires or interviews that they feel uncomfortable answering.
- Study Staff will remind participants that their participation is voluntary and withdrawal of participation at any time will not involve any penalty or loss of benefits to which they are otherwise entitled.
- Participants will be given contact information for Study Staff should they have any questions or concerns at any time or if they wish to withdraw from the study.

- Participants will be offered copies of all signed forms *(Consent* and *HIPAA Authorization)* and given contact information for Study Staff should they have any questions or concerns at any time, or if they wish to withdraw from the study.
- Study Staff members directly involved with recruiting and consenting participants will not be involved in their clinical care.
- The collection of sensitive information will be limited to the information that is necessary to conduct this research.

Protected Health Information:

- A HIPAA Waiver of Authorization has been obtained to allow Study Staff to identify eligible participants for recruitment (see Section 24).
- Following consent, a signed HIPAA Authorization will be obtained to access and record additional information from the participant's EMR. This information will be limited to information directly related to the study.

-Secondary Data Analysis

This study qualifies as no more than minimal risk to subjects. Therefore, we request a waiver of HIPAA authorization because the research involves retrospective review of existing clinical data collected during routine care. The study could not practicably be conducted without access to protected health information, as identifiers are necessary to accurately identify patients that need inclusion criteria. No direct patient contact will occur, and no interventions will be performed. Data will be stored on secure, institutionally approved locations as described in section 26. These safeguards ensure that risks to privacy and confidentiality are minimal and reasonable in relation to the anticipated scientific value of the study.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

No funds have been set aside for research-related injury.

29. ECONOMIC BURDEN TO SUBJECTS

There are no anticipated costs for which participants will be responsible because of participation in this research.

The Mobile Integrated Health (MIH) program is currently grant-funded because most insurance providers do not reimburse for it. Thus, while it is a clinical standard of care and licensed under state OEMS protocols, patients will not be billed for UMMH MIH services during research home visits.

30. CONSENT PROCESS

Study Staff Education: Only Study Staff with prior approval who have reviewed **HRP-090 Informed Consent** will be obtaining consent.

Patient Subjects Consent Process

- We will be obtaining informed consent.

- All consent will be collected electronically via the Redcap or MyDataHelps application. Patients will be able to review, sign, and date consent electronically
- Subjects will be invited to independently read and sign the consent form, sign it with teleconferencing support from a member of the study team to review the consent document, or sign it in person with a member of the study team.
- All of the potential risks, reasoning, and goals of this research will be explained to each individual prior to obtaining consent. They will be informed that enrollment is voluntary and declining to participate will not affect their treatment. Ample time will be given to answer any questions, and they will be informed that they may opt out of this voluntary study at any point.
- -An electronic or printed copy of the consent will be provided to patients after the electronic signature, depending on the subject's preference.
    - The electronic consent document/process allows subjects to proceed forward or backward or pause for review later if they choose.
    - Several measures are present to ensure that subjects have access to all of the consent-related materials, including hyperlinks or other external documents.
    - These measures include active guidance from the study team while reviewing the consent form to point out salient sections and key language, and access to paper copies of all relevant documents that patients may need to make their decision about participation. Patients will be allowed to read a paper copy of the consent before signing electronically if they prefer.

***Clinician Subjects**:*

This study entails minimal risk for clinician subjects. Specifically, it will not cause harm or discomfort that is greater than those ordinarily encountered in daily life or routine medical practice. This intervention does not impact clinician's ability to provide care, nor will participation in this study reflect in any performance evaluations or review processes.

Potential clinician subjects will be emailed the CONSENTEMAILCLINICIANSUBJECTS document (included with this application) at the time of solicitation, which explains the study and its potential (minimal) risks.

This email contains all of the potential risks, reasoning, and goals of this research. Clinician participants will be informed that enrollment is voluntary and that declining to participate will not affect their employment. Ample time will be given to answer any questions, and they will be informed that they may opt out of this voluntary study at any point.

Secondary Data Analysis: This part of the project entails no more than minimal risk to subjects, as this is a secondary data analysis and we are requesting a waiver of consent. The waiver or alteration will NOT adversely affect the rights and welfare of the subjects because the research does not affect their usual care, as the patients are being treated according to established clinical protocols.

Appropriate confidentiality measures are in place for the information collected. The research could not be practically carried out without viewing and recording Identifiable Private Information because we require identifiers to accurately identify patients who are eligible for inclusion in this cohort. In the event that it becomes appropriate to provide subjects with additional pertinent information after participation, we will seek the guidance of the IRB. This research could not be reasonably carried out without a waiver of consent because the involved patients are unreachable since their contact information will not be accessed. Additionally, contacting all eligible subjects not enrolled in the primary study would be logistically infeasible and could introduce selection bias that would compromise the validity of the analysis.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

Study Staff Education: Only appropriately trained Study Staff with prior approval who have been trained on best practices in Documentation of Informed Consent and are familiar with HRP-091 SOP: Written Documentation of Consent will be obtaining consent during this study. The PI will train all co-investigators and research assistants on obtaining informed consent prior to initiating study activities. Additionally, there will be a detailed study manual for the project which will obtain HRP-091 for quick reference when needed for this study.

Documentation of Consent: Informed consent will be documented in writing for patient subjects. Written consent will not be obtained for provider subjects as the study activities for this cohort entail no more than minimal risk and do not entail any activities that would normally require written consent outside of the research setting. We request a waiver of written consent for clinician subjects.

Secondary Data Analysis: *NA*

32. DRUGS OR DEVICES
NA

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