INVESTIGATOR STUDY PLAN - REQUIRED

1. TITLE
Tele-Navigation of Lung Cancer Screening (Tele-Navi LCS)

2. EXTERNAL IRB REVIEW HISTORY*
NA

3. PRIOR APPROVALS:
NA

4. OBJECTIVES*
The main purpose of our study is to develop Tele-Navigation of Lung Cancer Screening (Tele-Navi LCS) – an intervention that is designed to improve patient awareness about the importance of LCS follow-up and to promote patient-provider communication about low-dose CT (LDCT) results, with the ultimate goal of increasing adherence to LCS. Our study has two specific aims:

> **Aim 1:** Develop Tele-Navi LCS, using a co-production approach with patients at UMMH, and refine Tele-Navi LCS based on feedback from LCS stakeholders at UMMH, Wake Forest, UCHealth, and UPenn.
>
> **Aim 2:** Pilot test Tele-Navi LCS and evaluate its feasibility, acceptability, and associated costs by implementing it in the clinical LCS workflow in primary care clinics at UMMH.

Because the data collected in Aim 1 may influence the activities of Aim 2, we will develop the majority of Aim 2 study materials at a later time. Aim 2 recruitment activities will not commence until these materials have been submitted to the IRB for review and approval.

5. BACKGROUND*
Adherence to follow-up after lung cancer screening (LCS) is essential to achieving mortality reduction and optimizing cost-effectiveness.[1-4] Large clinical trials, with adherence close to 100%, demonstrated that annual LCS with low-dose CT (LDCT) achieved approximately a 20% reduction in lung cancer death.[5,6] These benefits resulted from timely detection, evaluation, and treatment of early stage lung cancer. Therefore, adherence to recommended follow-up is critical to improve survival in LCS.

Yet, even prior to the COVID-19 pandemic, adherence to follow-up in LCS was suboptimal. Adherence rates in community-based programs were between 16-59% compared to more than 80% in comprehensive LCS programs with greater resources and infrastructure.[7-12] In interviews with patients who had been screened at UMass Memorial Health (UMMH) (conducted as part of my K12 project), I found that: (1) many patients were not aware that LCS required at least annual follow-up, and (2) patients desired more communication with their providers about the results of their LDCT, including a clear follow-up plan. Interventions to improve patient awareness about the importance of LCS follow-up and to promote patient-provider

communication about LDCT results are needed to improve adherence to LCS follow-up and achieve the full benefits of LCS.

The COVID-19 pandemic has been a major disruption to LCS, with routine LDCT postponed in order to minimize the risk of COVID-19 transmission.[13] Since the LCS population is at high risk for developing severe COVID-19 infection due to their smoking history and comorbid illnesses, these patients may be even more likely to avoid regular health care, including LCS follow-up from fear of COVID-19.[14,15] With expanded insurance coverage for telehealth during the present pandemic, many providers have started offering telehealth visits.[16,17] The LCS population is, however, older and may have less access to or familiarity with telehealth, and may not be able to utilize telehealth to maintain their preventive and medical care without support.[18,19] This digital divide may negatively affect their health outcomes. Our proposed intervention of providing patient navigation through telehealth will help to improve adherence to follow up among those undergoing LCS. In addition, by promoting and supporting the use of telehealth, this intervention may also help to reduce the "digital divide" in the LCS population.

Based on the well-established concepts of patient navigation that have been shown to promote cancer screening and its follow-up, and increased availability of telehealth, I propose to develop Tele-Navigation of Lung Cancer Screening (Tele-Navi LCS) using a patient portal and video-call with a navigator to improve adherence to LCS follow-up.[20-25] I will co-produce intervention components of Tele-Navi LCS with patients who have undergone LCS at UMMH over the last three years. I will obtain feedback from various stakeholders including LCS physician champions, navigators, primary care providers (PCPs) and IT leadership at UMMH, designing Tele-Navi LCS to be scalable. Tele-Navi LCS will provide: 1) telehealth coaching for patients undergoing LCS to access a patient portal and a video-call, 2) a video-call from a Tele-Navigator prior to the next follow-up LDCT to a) improve patient knowledge about the importance of LCS follow-up, b) identify barriers to follow-up, and c) encourage patients to ask their PCPs about the results of LDCT, 3) subsequent secured portal messages to provide continuous support to patients, and 4) communication guide to support providers in discussing LDCT results with their patients.

6. INCLUSION AND EXCLUSION CRITERIA*

Patient Participants

Inclusion Criteria:

- Is eligible for LDCT for LCS follow-up
- Has technology to complete study activities (e.g., video call visit)
- English speaker

Aim 1 Additional Inclusion Criteria:

- Has UMMH PCP
- Has undergone LCS at UMMH in the past three years

Aim 2 Additional Inclusion Criteria:

- Has undergone LCS at UMMH
- Is overdue for LDCT follow-up

Exclusion Criteria:

- Has previous diagnosis of lung cancer
- Has active cancer diagnosis
- Is a nursing home or group care resident
- Is pregnant

Stakeholder/Provider Participants

Inclusion Criteria Aim 1:

- Age ≥ 18
- Primary care provider/IT leader/lung cancer screening program leader/lung cancer screening navigator
- Works at UMass Memorial Health, Wake Forest Baptist Health, UCHealth, or UPenn

Inclusion Criteria Aim 2:

- Age ≥ 18
- Primary care provider
- Works at UMass Memorial Health

Vulnerable Populations

The following populations **will not be included** in this study:

- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Adults unable to consent
- Prisoners

Since this is a small-scale study (~65 total subjects in 4 groups, with 3 different interviews and one intervention) it is not possible to have the study materials translated into other languages. If this pilot study shows promise, larger follow-up studies may focus on translating the intervention into additional languages.

7. STUDY-WIDE NUMBER OF SUBJECTS*

NA

8. STUDY-WIDE RECRUITMENT METHODS*

NA

9. STUDY TIMELINES*

Aim 1: Patient participants will begin by completing a baseline survey which will take ~30 minutes or less. Stakeholder participants will complete a brief (~5-10 minutes) online demographics survey (study factsheet will be included in the REDCap survey). Both patient and stakeholder participation will involve completing a one-time interview session held by telephone or by webinar **(Please note: we will follow all COVID-19 related guidelines and precautions, favoring remote activity whenever possible).** Interviews are expected to last approximately

60-90 minutes for patients and about 30 minutes for stakeholders. Participation will be considered complete following the conclusion of the interview. Medical record review will occur to assess annual LCS follow-up; record review may occur over several follow-up years (up to 4 years).

Aim 2: Patient participation will involve completing a baseline survey which will take ~30 minutes or less. Following the baseline survey, the intervention will include a telehealth support call (or multiple calls) (~20 minutes) if the participant feels it would be helpful (to practice using a video call or accessing their patient portal), and at least one video call with a tele-navigator (educational outreach call) (~10 minutes). Finally, participants will be asked to complete a follow-up survey (~20 minutes). Participation is expected to take place over approximately 3-6 months. Medical record review will occur to assess annual LCS follow-up; record review may occur over several follow-up years (up to 4 years).

A sub-set of patient participants and providers of patient-participants will be recruited to engage in a one-time in-depth interview which is expected to last approximately 60 minutes.

Study Timeline*: Work Plan and Deliverables

Quarterly Milestones									
Aim	**Quarters**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
1	**Material Development**	**X**							
	Co-production		**X**	**X**					
	Stakeholder interview		**X**	**X**					
2	**Recruitment**				**X**	**X**	**X**		
	Data collection				**X**	**X**	**X**	**X**	
	Data analysis			**X**				**X**	**X**
	Manuscript							**X**	**X**
Grant Preparation								**X**	**X**

***Note:** We plan to conduct longer-term collection of clinical follow-up data and additional data analysis for ~2 additional years.

10. STUDY ENDPOINTS*

Primary outcomes are adherence to follow up LDCT and feasibility of Tele-Navi LCS. Adherence is defined as LDCT completion at 3, 6 and 12 months from the due date (as in previous studies; this definition may change depending on the status of COVID pandemic) and will be measured by EHR data.[7,8,10-12] For feasibility, we will assess how engaged patients are during telehealth coaching, video-calls by tele-navigator, telehealth visit and patient portal use. We will assess intervention fidelity by recording and comparing all telehealth coaching and video-calls by a tele-navigator against a pre-defined checklist of key elements.

Secondary outcomes are occurrence of patient-provider communication after LDCT; communication modality used; contents of the communication assessed by EHR review and a patient survey; patient understanding of the result of LDCT and follow-up plan assessed by patient surveys; and perception and acceptability of the intervention from patient surveys and

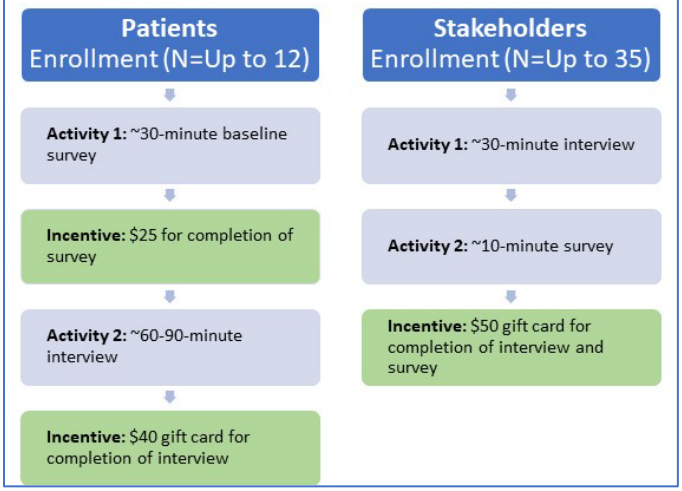
interviews and provider interviews. We will also measure cost by tracking time required for training for a Tele-Navigator, all the intervention components provided by the Tele-Navigator, and time and any other resources required to implement Tele-Navi LCS into clinical workflow.

11. PROCEDURES INVOLVED*

All recruitment and data collection materials will be submitted to the IRB for review and approval prior to use in the study. MyChart patient educational materials utilized by UMMH will also be utilized during the study (not research developed materials). All Electronic Health Record (EHR) and MyChart audit log data pulls will be requested following the UMass Chan Research Informatics Core processes (currently located here: https://www.umassmed.edu/research-informatics/data-services/how-to-obtain-data/). All interviews and study activities will be conducted at the convenience of the study participant and with safety precautions in mind; they will happen remotely (via phone, Zoom/Doximity, or similar). With explicit consent, interviews and study call activities will be audio-recorded and transcribed.

Aim 1 Patient Participants: We will recruit patients who underwent LCS within the past three years at UMMH. Potential subjects will be identified via the Electronic Health Record (EHR) (we may prioritize recruitment of eligible patients who have provided consent to re-contact from a prior study). Patients will be selected based on their age, gender, smoking status, adherence status, LDCT results (i.e., negative versus low-risk nodule), years in the LCS program, previous use of MyChart and telehealth, and access to necessary technology to use MyChart and telehealth. Following recruitment and screening, we will ask patient participants to complete a baseline survey. Next we will ask participants to complete a one-time semi-structured interview to co-produce patient educational materials and the program to help patients complete follow-up LCS by using telehealth. Prior to the interview, the research team will select the focus of the interview and the questions based on the participant's previous MyChart and telehealth use, and the research team's needs to complete the development of Tele-Navi LCS. During this co-production, we will first explain current gaps in LCS adherence and the goals of Tele-Navi LCS. We will seek feedback on each element of the intervention: education materials and portal messages, as well as the overall concept of Tele-Navi LCS. Patient educational materials will be updated based on the input of participants; participant suggestions may be incorporated into subsequent interviews to seek additional feedback.

Figure 1. Aim 1 Study Activities



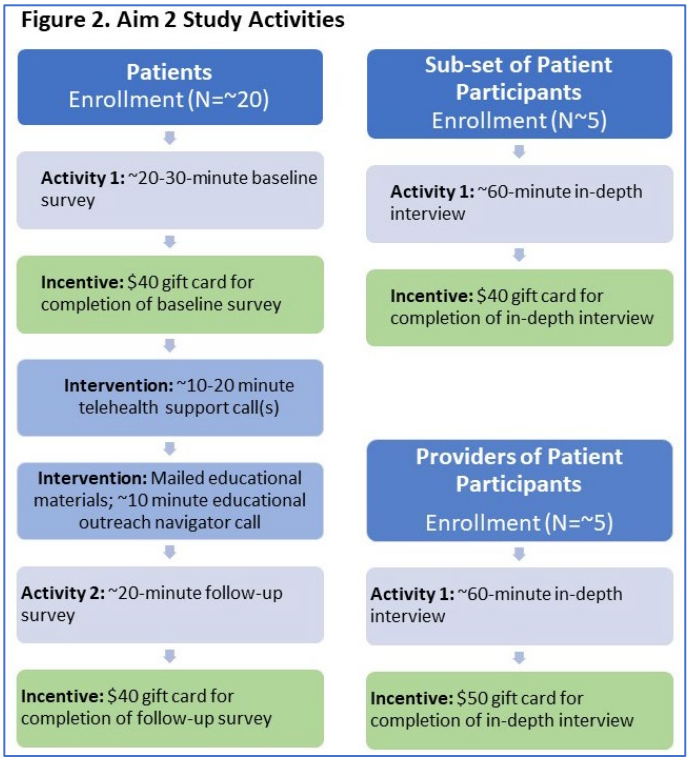
Medical record review will occur to assess annual LCS follow-up; record review may occur over several follow-up years (up to 4 years).

If a patient mentions having difficulty with MyChart or with a clinical provider/office within our clinical system we will provide the patient with appropriate contact information to obtain assistance when feasible.

Aim 1 Stakeholder Participants: Additionally, brief demographic surveys and interviews will be conducted with LCS Stakeholders (e.g. PCPs, LCS navigators, LCS program leaders, Population-Health leaders and IT leaders) from UMMH, Wake Forest, UCHealth, and UPenn. All interviews will be audio recorded and transcribed. We will synthesize feedback from patient and clinical stakeholders and refine the workflow and intervention components of Tele-Navi LCS accordingly.

Aim 2 Patient Participants: We will recruit patients who meet study inclusion criteria. Participants will also be selectively enrolled (purposeful sampling) based on a variety of demographic and other criteria (e.g., by age, gender, smoking status, results of previous LDCT, years in the LCS program, MyChart use, technology device, characteristics of the primary care and ordering providers). Following recruitment, research staff will administer a baseline survey to participants. Study staff will also assist participants with obtaining access to the patient portal and coach them on how to use the portal and video-call (Telehealth Support). Educational materials will be sent to participants via mail/email (based on participant preference) prior to the educational outreach session. Participants will receive a call (video call or telephone) from the Tele-Navigator to implement the rest of the intervention (Educational Outreach). Participants will be asked to complete a follow-up survey. We will also offer a truncated (5-item) version of the follow-up survey to participants who we have difficulty scheduling and completing the full version with; we will offer a reduced incentive ($10) to complete this version. Finally, we will conduct medical record reviews to collect clinical outcomes data.

Figure 2. Aim 2 Study Activities



Pilot Testing: We will recruit (~ 12) Aim 1 patient participants to pilot test the intervention processes and data collection (telehealth support and educational outreach calls – we will conduct both in one call for the pilot testing). With participant feedback, we will make iterative edits to the intervention materials as they are pilot tested. We will submit final iterations to the IRB for review and approval prior to initiating the intervention. Pilot testing participants will not

complete the Aim 2 surveys. We will offer a $40 incentive to pilot test the intervention (one intervention call, ~40-60 minutes).

Aim 2 Provider/Patient Participants: Following completion of the intervention implementation, we will invite a sub-set of patient participants to complete an interview with study staff in order to obtain in-depth feedback. Separately, we will invite providers of patient participants to complete an in-depth interview.

12. DATA AND SPECIMEN BANKING*

A limited data set will be securely stored for potential future use by the Principal Investigator. A limited dataset may be shared with study collaborators (with an executed Data Use Agreement) or with study funder/sponsors. A de-identified (by HIPAA standards) dataset may be made available to the public with PI approval; a data dictionary will be submitted to the IRB for review/approval prior to sharing the de-identified dataset.

13. Data Analysis and Management*

All patient-facing data collection materials will be submitted to the IRB for review and approval prior to use in the study. EHR and MyChart audit log data will be collected as described in the ISP, consent/fact sheet, HIPAA authorization/waiver materials reviewed and approved by the IRB.

Power analysis: The goal of this feasibility pilot is to determine the acceptability of the intervention and to estimate important process parameters (i.e. recruitment rates, completion rates of components) to inform a future study, including designing or refining outcome measures. As such, we have not conducted a sample size calculation.

Data analysis plan: To evaluate feasibility of Tele-Navi LCS, we will study process measures and effectiveness. Data sources include field notes, patient surveys, patient and provider interviews, Electronic Health Record (EHR) chart review, EHR administrative data and recording of telehealth coaching and a video-call. We will employ a mixed-methods process-outcomes pathway analysis.

> **Quantitative analysis:** For measures of outcomes and intervention fidelity, we will present summary statistics with means and standard deviations of study variables. Further, we will create useful visualizations, including treatment cascades – a common graph used in quality improvement to identify gaps in the flow of patients to treatment (or follow-up screening and post-LDCT patient-provider communication in this case).
>
> **Qualitative analysis:** We will analyze patient and provider interview transcripts to evaluate the acceptability of Tele-Navi LCS, understand their experiences, and elicit suggestions for improvement. Our analysis will be informed by constructs from the SCT, PRISM, and STM.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*
As the proposed study involves no more than minimal risk to participants, an intensive data and safety monitoring plan is not needed.

This study will be reviewed and approved by the Institutional Review Board of the UMass Chan Medical School (UMass Chan) prior to the initiation of any study activities. The study will continue to be monitored and reviewed by the IRB for the duration of the study.

See #16 for details related to the protection against risks to study subjects.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*
We do not anticipate withdrawing any participants without their prior consent. Any participant enrolled who later does not meet inclusion criteria (or meets an exclusion criterion) may be withdrawn. Participants will be notified by study staff and withdrawal documented in study records.

16. RISKS TO SUBJECTS*
Risks to All Study Subjects (Patients, Stakeholders, and Providers)
The proposed study poses minimal risks to the participants. The risks that do exist fall into three categories: (a) risks associated with participating in research interviews; (b) risks associated with potential loss of confidentiality; and (c) risks associated with the research content area. We address each in turn below.

Risks Associated with Participating in Research Interviews: Subjects will be recruited to participate in interviews and simulations. These activities can be time-consuming to complete and inconvenient to attend. Our procedures for protecting against such risks are described below.

Risks Associated with Potential Loss of Confidentiality: There is a slight risk that research records (data collection forms, interview notes and electronic data) might be obtained by persons not authorized to do so. There is a slight risk that research data files might be compromised, and obtained or viewed by unauthorized persons. Our procedures for protecting against such risks are described below.

Risks Associated with the Research Content Area: We recognize that the content of the interviews may be emotionally sensitive (related to lung cancer screening, healthcare practices and communication with providers). Our procedures for protecting against such risks are described below.

Protections Against Risk
Minimizing Risks: The training and monitoring of all study staff performance in accordance with an IRB-approved study plan will be the responsibility of the Principal Investigator. All efforts will be made to minimize risks and participant inconvenience.

Risks will be minimized by: 1) adequate training of all staff with proficiency testing; 2) ensuring participants are verbally informed of the details of the study activities in advance; 3) encouraging participant questions throughout the consent process; and 4) providing participants with resources to contact if they have any questions or require assistance.

Protection for Risks Associated with Participating in Research Interviews: Recruitment methods, standard informed consent procedures, and the entire study protocol will be reviewed and approved by the UMass Chan Institutional Review Board to ensure the protection of human subjects. Informed consent will be obtained prior to the interview.

Subjects will be recruited to participate in interviews and tele-health training sessions. Interviews and training sessions can be time-consuming to complete and inconvenient to attend. We will minimize the inconvenience by offering to conduct the interviews at a convenient time and mode (remote) of their choice.

All interviewees will be told that participation is voluntary, that they are free to not respond or to terminate involvement at any time, with no adverse consequences. Participation in the study will have absolutely no bearing on participants' medical care or employment. At the start of each interview, participants will be told that they can decline to answer any questions and that they can leave the interview at any time.

If a participant appears to be distressed at any point during any of these activities, study staff will suggest that the participant take a break. The session will recommence with the activity only when and if the participant reports the desire to do so. The interviews during the course of the study involve no specific risk or discomfort beyond those of a standard interview, and the simulation poses no risk beyond that of an outpatient encounter. Interviews will be conducted by a trained research interviewer sensitive to these issues.

Protection for Risks Associated with Potential Loss of Confidentiality: The organizations proposing this study have systems, oversight, experienced personnel, and an organizational culture that supports the appropriate use, access and storage of confidential information. All persons collecting or handling data will be trained in human subjects' procedures, confidentiality and privacy protection. All investigators and project staff are required to receive and complete IRB and HIPAA training. Data for all participants will be kept strictly confidential. See section #26 Confidentiality for additional details on our procedures for protecting against such risks.

Protection for Risks Associated with the Research Content Area: We recognize that the content of the intervention and interviews may be emotionally sensitive (related to lung cancer screening, healthcare practices and communication with providers).

Interviews will be conducted by a trained research interviewer sensitive to these issues. The interviews during the course of the study involve no specific risk or discomfort beyond those of a standard clinical interview. If a participant appears to be distressed at any point during any of these activities, the interviewer will suggest that the participant take a break. The interviewer will recommence with the activity only when and if the participant reports the desire to do so.

Content of Intervention Materials, Interview Guides, and Questionnaires. All of the materials for the study will be developed in collaboration with the interdisciplinary research team members. All materials will be submitted to the IRB for review and approval prior to use with study participants.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

It is possible that patients may directly benefit from taking part in this research. For example, they may gain skills and confidence to use telehealth modalities from their experience of telehealth coaching and the workflow of Tele-Navi LCS. In addition, patients may gain intrinsic knowledge about LCS and LCS follow-up.

18. VULNERABLE POPULATIONS*

The following populations will not be included in this study:

- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Adults unable to consent
- Prisoners

While we will be recruiting employees as part of the stakeholder interviews, no study team member will engage in recruitment/other study activities with a person whom they have supervisory responsibility of. All stakeholder potential participants will be informed that their decision to participate will not impact their employment in any way. We additionally will seek a waiver of documentation of consent for these participants (stakeholders/providers) as their consent document itself would be a confidentiality risk.

19. MULTI-SITE RESEARCH*

NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*

NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

There are no specific plans to share research results with patient subjects. If specifically requested, we will share any published study results with research subjects via e/mail (or as otherwise requested). Published results of the research will be made available to the greater community at large, including to study subjects. Stakeholder/provider subjects will be provided with study results in hopes to inform clinical practice.

22. SETTING

Patients will be recruited from primary care clinics at UMMH, as will stakeholders for Aim 2. Aim 1 stakeholders will be recruited from UMMH, Wake Forest, UCHealth, and UPenn. Research staff conducting recruitment, data entry, and analysis will complete study activities at the UMass Chan Medical School located in Worcester, MA.

23. RESOURCES AVAILABLE

All research personnel listed on this study will read the protocol and receive the appropriate supervision and possess the appropriate experience (both higher education and related work experience) needed to fulfill their roles and complete their responsibilities for this study. All investigators and project staff are required to receive and complete IRB and HIPAA training.

The **Principal Investigator** will oversee all personnel and all research activities conducted within this study. The Principal Investigator will have responsibility for the overall conduct of the project at this study site. She will have primary oversight of all study personnel. She will participate in the design and the execution of the respective study analyses and will be responsible for the reporting of study results. The Principal Investigator has extensive experience and expertise in pulmonary medicine and has qualified as PI under NIH guidelines. She will be responsible for recruiting and consenting study participants.

The **Co-Investigator(s)** will assist the Principal Investigator in research design and intervention development, as well as analytic aspects of the study. The Co-Investigators may include clinicians and researchers with varied expertise including: healthcare services research, qualitative and quantitative research design, health communication and health literacy, and biostatistics.

The **Programmer(s)/Analyst(s)** will perform a range of essential programming and data management activities. S/he will develop study data bases and perform analyses under the direction of the PI. Programmers in the Division of Health Systems Science at the UMass Chan Medical School all hold graduate-level degrees and have vast experience working with administrative claims data for research purposes.

The **Project Manager(s)** will assist the Principal Investigator and Co-Investigators in implementing all aspects of the project. Under the direction of Principal Investigator, the Project Manager will be responsible for day-to-day coordination and oversight of the project, including: developing timelines, allocating work, directing workflow, monitoring project progress, task completion, and spending and effort allocation, and managing correspondence and administrative tasks. S/he will monitor/manage ethics and regulatory approvals (IRB, HIPAA/DUA). The Project Manager will attend and plan for all project-related meetings as needed. S/he will work under the direction of the Principal Investigator to assist with all study activities, preparing IRB submissions and reports, and developing study materials such as data collection instruments and intervention-related tools. S/he will be responsible for maintaining communications with all parties participating in the project. S/he will track and provide feedback and serve as liaison between the research team. S/he will maintain project documentation and assist in developing and filing required project reports. Project Managers in the Division of Health Systems Science

at the UMass Chan Medical School all hold graduate-level degrees and have vast experience working on healthcare services research projects.

The **Research Assistant/Coordinator(s)** will work under the direction of the Principal Investigator and Project Manager to assist with all study activities. S/he will assist the PI and other project staff in managing the administrative activities of the project. S/he will prepare materials for team meetings and will facilitate communication between all project staff. S/he will be responsible for recruiting and consenting study participants. S/he will assist with database development, data collection and QA processes.

The **REDCap Administrator(s)** will assist with all REDCap administrative needs throughout the study. As the appointed REDCap administrator s/he will have access to all study data collected within REDCap.

24. LOCAL RECRUITMENT METHODS

All recruitment materials will be submitted to the IRB for review and approval prior to use in the study. While we will not accept referrals for the study, for communication purposes with clinical providers we will share/post a study flyer with various clinical groups within UMass Memorial Health (from which we will be recruiting patients). This flyer is intended to provide clinicians notification that the study is active and to provide contact information in case clinicians have questions about the study; it will not be patient-facing.

Patients: We will use a variety of methods to identify and recruit a diverse group of patient participants. Working with the informatics group at UMMH/UMass Chan we will search the UMMH patient database to identify eligible patients. Eligible patients will be sent an invitation to participate. The invitation will make clear that participation is voluntary, and will include contact information for expressing interest, or declining participation. We will follow-up about one week later by telephone with invitees who do not respond. We will make up to 10 phone call attempts (over a period of two to three weeks, varying the time of day and day of week phone attempts are made) and leave no more than 3 total voicemail messages. Research staff will confirm eligibility prior to enrolling subjects. We have successfully recruited and completed comparable interviews and research activities with patients in previous studies utilizing similar recruitment methods.

Stakeholders/Providers: We will recruit stakeholders/providers to complete a one-time interview.

Aim 1: Potential stakeholder participants (for example PCPs, LCS navigators, LCS program leaders, and IT leaders from UMMH, Wake Forest, UCHealth, and UPenn) will be identified by the Principal Investigator, leadership at LCS programs, leadership within the Implementation Science Center for Cancer Control at Wake Forest UCHealth, and UPenn (which have already provided letters of support), and stakeholder participants in Aim 1 using snowball sampling.
Aim 2: Potential UMMH provider participants (providers of patient participants in the intervention group) will be recruited as study participants.

The Principal Investigator (or study staff designee) will contact stakeholders/providers by email and potentially telephone. Introduction to non-UMMH stakeholders will be facilitated via email by the Principal Investigator's collegial relationship with leadership at LCS programs and the Implementation Science Center for Cancer Control at Wake Forest, UCHealth, and UPenn or the stakeholder participants in Aim 1. For UMMH personnel we will ask clinic leadership to forward the initial recruitment email (sent on the behalf of the PI). This email will also include a factsheet. If we are unable to identify sufficient numbers of participants via email request, the study's Principal Investigator will send a follow-up e-mail, and potentially reach out via telephone to encourage their participation. We will make up to three attempts to reach out to each stakeholder/provider.. We have successfully recruited providers for prior studies in this manner. Eligibility will be confirmed prior to scheduling sessions.

Stipends: As a thank you for their time participants will receive a gift card at the completion of study activities (see Figures 1 and 2 for further details and the table below).

Study Aim	Participant Type	Study Activity	Gift Card Amount
1	Patient	Baseline Survey	$25
1	Patient	Co-Production Interview	$40
1	Stakeholder	Survey & Co-Production Interview	$50
2	Pilot Test Intervention (Recruit Aim 1 Participants)	Telehealth Support and Educational Outreach Call	$40
2	Patient	Baseline Survey	$40
2	Patient	Follow-Up Survey	$40
2	Provider	In-Depth Interview	$50
2	Patient Subset	In-Depth Interview	$40

25. LOCAL NUMBER OF SUBJECTS

Aim 1: We will recruit up to 50 participants for Aim 1. We aim to recruit a diverse sample of stakeholders including: patients (~6-12), PCPs (n~8), LCS navigators (n~7), LCS program leaders (n~8), Population Health leaders (n~6) and IT leaders (n~5).

Aim 2: Up to ~12 Aim 1 participants will be recruited to pilot test the intervention (but not enrolled in the Aim 2 intervention study). ~20 patients will be recruited to participate in the intervention. A smaller subset of ~5 intervention patients and ~5 providers whose patient participated in the study will be interviewed for in-depth feedback. Approximately 25 participants will be enrolled for Aim 2.

26. CONFIDENTIALITY

We will use the data security procedures outlined by the UMass Chan Research Informatics Core to obtain, transfer, and secure data.

Training: All persons collecting or handling data will be trained in human subjects' procedures, confidentiality and privacy protection. All investigators and project staff are required to receive and complete IRB and HIPAA training.
Computerized Data: All computerized data will be kept on secured computers or network servers. These data will be accessible only to research staff with approved access, using confidential usernames and passwords.

Hard Copies/Paper Data: Any paper data will be kept in locked cabinets or a locked file room accessible only by research staff.

Audio Data: All audio-recordings will be kept in locked file cabinets, and never played for anyone who is not a member of the research team. Once transcribed and checked, the audio-recordings will be destroyed. Transcripts will be stripped of personal identifiers and labeled only with Study IDs.

Audio recordings will be transcribed utilizing a speech-to-text application Rev.ai (https://www.rev.ai/). All the files in Rev.ai are encrypted both at rest and transit (security information: https://cf-public.rev.com/security/Rev.com+Information+Security+Privacy+Overview.pdf).

Alternatively, we will use a professional transcriptionist or available study staff to complete transcription if needed.

If necessary, recordings will be transferred via upload to a secure folder on the network drive and removed from the portable device as soon as possible after the recording takes place. Recordings will then be uploaded to a secure file transfer site (e.g. https://www.sendthisfile.com, a HIPAA compliant website, which uses SAS70 type II/SSAE16 compliant data centers to ensure that private data is protected; features of this service include 128-bit Transport Layer Security (TLS) encryption and password protection, among other security precautions), to be transferred to a professional transcriptionist. The transcriptionist will use a password to access uploaded materials, work on a password-protected computer, and delete the audio file after the transcribed file is received by the client.

Data Collected via REDCap: Data will be captured via REDCap (Research Electronic Data Capture). The REDCap Consortium is comprised of thousands of active institutional partners from Clinical and Translational Science Awards (CTSA) and other institutions, and supports a secure web application (REDCap) designed exclusively to support data capture for research studies (http://www.project-redcap.org). University of Massachusetts Medical School is a REDCap Consortium site.

REDCap is used to build and manage online surveys and databases. The front end of REDCap is written in PHP, which is widely used, robust, open source scripting language. Web servers, database servers, and security of communication between servers occur locally at each Consortium site where data capture is stored. Thus, all project data is stored and hosted at the local institution, and no project data is ever transmitted at any time by REDCap from that institution to another institution or organization.

Some additional security features include: **(a)** Specification of "user access": by account, by project, or by User Access group; **(b)** System Log-in: assigned username and user-identified password required, automatic inactivity logout, password specificity requirements; and **(c)** System lock-out: following succession of unsuccessful login attempts, or if no login to the system within 30 days.

Data Processing/Management of Identifiers: Individual identifier information will be removed from study data files as soon as possible in the data processing steps. Study participants will be assigned a numerical code (Study ID) for identification in the files. Analyses will be performed using limited datasets and only de-identified data will be reported/shared publicly. All data will be used for research purposes only; published data will not contain any individual identifiers and will be reported in the aggregate.

27. Provisions to Protect the Privacy Interests of Subjects

Privacy: All study activities will occur with one participant at a time. Study activities will occur over the telephone/video calls/webinar. Confidentiality/privacy concerns will be addressed during recruitment, the consent process, and at additional times deemed necessary.

HIPAA Waiver Request: We are requesting a HIPAA Waiver of Authorization to access medical record (EHR) data; these data will be used for the purpose of recruitment and to conduct study procedures. See HIPAA Waiver request.

HIPAA Waiver of Documentation Request: Patient participants will be asked to provide HIPAA authorization to access and use medical record/healthcare data for study purposes. Each participant will be provided a copy of the consent/Fact Sheet/HIPAA Authorization form (enclosed with the recruitment letter) via USPS mail. Because all study procedures are being conducted remotely with no opportunity to obtain a "wet" signature, a waiver of HIPAA Authorization documentation is also being requested. See HIPAA Waiver request.

28. Compensation for Research-Related Injury

None; there are no resources available. We do not anticipate any research-related injuries as the research poses no more than minimal risk to subjects.

29. Economic Burden to Subjects

NA

30. Consent Process

Informed Consent

We will obtain informed consent from participants in accordance with HRP-802 INVESTIGATOR GUIDANCE: Informed Consent.

Participants may opt out of the research study at any time. If necessary, all participants will be given additional information throughout the course of the study to maintain informed consent.

All Interview Participants (Patients, Stakeholders, Providers)
All participants will provide verbal consent upon enrollment. Recruitment scripts will be submitted to the IRB for review and approval prior to use in the study. Consent for audio recording of interviews will be obtained prior to recording. Participants may choose to consent to the interview but not to audio recording of the interview. No audio recording will occur without explicit consent.

The process of informed consent will begin before the interview completed/intervention initiation or any data are collected for research purposes. The study procedures will be explained during the informed consent process. Participants will be given the opportunity to ask any questions or for clarifications before consenting to participation. It will be explained that the healthcare they receive at UMMH/or their employment with UMMH/Wake Forest Baptist Health/UCHealth/UPenn will not be affected by their decision to participate or to not participate in the study.

All Patient Participants
We will mail a written Fact Sheet to all patients invited to participate as study subjects. The study staff will review all elements of the Fact Sheet with study subjects by phone during the recruitment call (the recruitment script containing all elements of consent will be reviewed and approved by the IRB prior to use in the study). We will obtain verbal informed consent during the initial recruitment and screening phone call(s). Verbal consent will be documented by study staff (including who obtained informed consent and the date informed consent was obtained).

31. Process to Document Consent in Writing

Consent documents (Fact Sheets) will be submitted to the IRB for review and approval prior to use in the study. Because all study procedures are being conducted remotely with no opportunity to obtain a "wet" signature, a waiver consent documentation is being requested.

Waiver of Documentation of Consent
A waiver of documentation of consent is being requested for participants. We believe the research study activities meet the criteria for both *documentation not required outside of the research context* (for all study subjects), as well as, for stakeholder/provider participants, *the consent document would be the principal confidentiality risk*. We attest that the following criteria are met:

Consent Documentation Not Required Outside the Research Context

1. The research involves NO more than Minimal Risk to subjects (see below);
2. The research involves NO procedures for which written consent is normally required outside of the research context (see below);
3. The investigator has provided a written statement regarding the research that embodies the elements of consent;
4. The investigators will:

- offer to provide subjects with that written statement; and
- communicate the statement's information to subjects.

Consent Document is the Principal Confidentiality Risk (For Stakeholder/Provider Participants)

1. The only record linking the subject and the research would be the informed consent form;
2. The principal risk is potential harm resulting from a breach of confidentiality;
3. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
4. The investigator will provide a written statement regarding the research that embodies the elements of consent;
5. The investigator will:
   - offer to provide subjects with that written statement, and
   - communicate the statement's information to subjects;
6. The research is NOT FDA-regulated.

Minimal Risk Definition:
The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected.

Examples of Minimal Risk (similar to this current study):

- Study poses no more risk than expected in daily life (e.g., blood draw, physical exam, routine psychological testing).
- Survey/Questionnaire studies of a non-sensitive nature.

Completing surveys, interviews, and a training/coaching session to use technology readily available for clinical care meet the above criteria. **Additionally, these activities do not in general require consent outside of research.**

32. DRUGS OR DEVICES
NA.

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eIRB Section 7.0 Attachments Upload Checklist

Follow How to Manage Files in eIRB and upload the following items as applicable to your submission. This checklist is provided for your convenience and is not a requirement for review.

	Investigator Study Plan
	Sponsor protocol
	Research portion of the grant
	Human subjects portion of the grant
	Written approvals from ancillary reviews (Clinical Engineering, COI, IBC, PRC, RSC, Students as Subjects, etc.)
	Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.
	Data collection sheets, case report forms, etc.
	Surveys, measures, instruments, etc.
	Measures to assess capacity to consent
	DMC or DSMB charter
	Data safety monitoring plan
	Adverse event log
	Investigator brochure or package insert for drugs
	Instructions for use or approved FDA labeling for devices
	Sponsor justification or FDA documentation for non-significant risk device study
	IND or IDE documentation
	Patient information sheet for Humanitarian Use Device
	Approval order for Humanitarian Use Device
	Product labeling for Humanitarian Use Device
	HIPAA waiver
	HIPAA authorization
	Authorization to contact form
	Consent form(s)
	Assent forms(s)
	Fact sheet(s)
	Multi-site communication plan
	Study staff training plan
	SOPs or Manuals of Operations
	Screening log
	Compensation log
	Certificates of translation or translator attestations
	Data use agreements, memoranda of understanding,
	Documentation of data/specimen anonymity (i.e., provider will never break the code)