STUDY PROTOCOL

Refinement and Pilot Testing of the "My Health Priorities" Program for Rural and Underserved Older Adults with Multiple Chronic Conditions in the Deep South (MyHP-South)

Principle Investigator: Deborah Ejem, Ph.D.

Sponsor: The University of Alabama at Birmingham

Protocol Number: IRB-300016725

NCT Number: Not Available

Approval Date: September 17, 2026

UAB INTEGRATED RESEARCH ADMINISTRATION PORTAL

IRB ePortfolio

1. GENERAL QUESTIONS

Protocol Number IRB-300016725

Principal Investigator Name Ejem, Deborah Blessing

Title of proposed project:

UAB SIRB - Refinement and Pilot Testing of the "My Health Priorities" Program for Rural and Underserved Older Adults with Multiple Chronic Conditions in the Deep South (MyHP-South)

* Select the type of application you are submitting to the IRB for review. Initial Application

NOTE: The ePortfolio should NOT be used for submitting Reliance Agreements, Expanded Access (including emergency use), or Humanitarian Use Device applications.

For Reliance Agreements, submit a copy of the Institution Review Form.

•For Expanded Access and HUD submissions, contact the OIRB Assistant Director for Regulatory Compliance for assistance with your submission.

The OIRB has developed a**IRB Submission Handbook: Best Practices, Resources, and Support. Review the document here for assistance in developing your application.**

Initial IRB Protocol Application

* **PURPOSE:** In non-technical, lay language, provide the purpose of the project. The contents of this section are copied to other areas of IRAP. As such, provide **only** the purpose of the project here.

Older adults with multiple chronic conditions often face complex medical decision-making, and their care may not fully reflect their personal values and priorities. This study expands evaluation of the My Health Priorities (MyHP) program to rural and underserved older adults in the Deep South. The purpose of this study is to evaluate the feasibility and acceptability of the MyHP program. The program is designed to help participants clarify their health-related values and improve communication with family caregivers and healthcare providers to support medical decision-making. Participants and, when applicable, their family caregivers will complete questionnaires and participate in a qualitative interview following completion of the program to assess their experiences and perceptions.

BACKGROUND: In 2-3 paragraphs, summarize the past experimental/clinical findings leading to the design of this project. Include any past or current research that informed the study design and any previous results that are relevant to understanding the project. Lastly, list the study outcomes that will be measured to evaluate the purpose of the project . It is not necessary to include methodology in this section. NOTE: Technical terms must be defined in simple language. Abbreviations must be spelled out. Provide references for any specific citations.

Preliminary Studies

C1. Diversity Supplement to ENABLE CHF-PC: Dyadic Relationships & Spirituality in African Americans with Heart Failure (2015–2019; NINR 3 R01 NR013665-01A; PI: Ejem; Mentor: Bakitas)

This qualitative study explored the role of religion and spirituality in patient-clinician communication among African American adults with advanced heart failure and their family caregivers. Interviews with 15 patient-caregiver dyads found that religion and spirituality were rarely discussed during clinical encounters, although family caregivers more often emphasized the importance of incorporating these topics into healthcare discussions.

Patients' perspectives on the inclusion of religion and spirituality in clinical encounters reflected two primary themes: (1) religion and spirituality should not be routinely introduced in clinical encounters, and (2) these discussions should occur when initiated by the patient. Family caregivers identified three themes: (1) these discussions were not a clinical priority, (2) clinicians should acknowledge patients' religious and spiritual beliefs, and (3) clinicians should be open to discussing these beliefs when appropriate.

Current Study Relevance: Findings highlighted gaps in communication about patients' values and preferences, including spiritual and personal beliefs. These insights informed development of the My Health Priorities (MyHP) program to support communication and align care with what matters most to patients.

C2. Addressing Communication Challenges Confronting Older African Americans with Multiple Chronic Conditions and Family Caregivers (2021–2023; National Palliative Care Research Center, Kornfeld Scholar Award; PI: Ejem; Mentors: Bakitas, Durant, Tinetti)

This two-phase, single-arm formative evaluation examined the cultural acceptability and feasibility of the My Health Priorities (MyHP) program among older African American adults with multiple chronic conditions and their family caregivers in a primary care setting. Participants found the program acceptable and useful for identifying and communicating their health priorities and values.

Participants also identified opportunities to improve the program, including increasing emphasis on common health conditions, enhancing the representativeness and personalization of program materials, optimizing use on mobile devices, and simplifying the program layout.

Current Study Relevance: Findings directly informed refinement of the MyHP program for broader implementation among rural and underserved older adults with multiple chronic conditions. The current study builds on these findings by refining program content to improve its relevance, usability, and cultural responsiveness.

METHODS: Describe the procedures for all aspects of your protocol. Tell us what you are doing.

METHODS

Study Overview

This study will refine and pilot test My Health Priorities for the Deep South (MyHP-South), a patient- and family caregiver-centered program designed to help older adults with multiple chronic conditions identify and communicate their health priorities. The study consists of three aims.

Aim 1 will use feedback from a Community Advisory Group (CAG) of older adults with multiple chronic conditions, family caregivers, and clinicians to refine the MyHP-South materials and implementation procedures. Aim 2 will conduct a single-arm pilot with 20 older adults with multiple chronic conditions and 20 family caregivers. Aim 3 will assess clinicians' experiences using patients' completed MyHP-South priorities templates during clinical visits.

Prior or current use of MyHP is not required for participation in any study aim. The version of MyHP-South used in this study is a paper-based prototype, not an online program or downloadable application. Participants will not be required to create an account, provide login credentials, or independently access MyHP online. Ownership of a computer or smartphone is not required and will not be used as an eligibility criterion.

AIM 1: COMMUNITY ADVISORY GROUP

Aim 1 will engage a CAG consisting of approximately 3–5 older adults with multiple chronic conditions, 3–5 family caregivers, and 3–5 clinicians. CAG members will serve as community advisors and will not be enrolled as research participants. Their feedback will be used solely to refine the content and delivery of MyHP-South before the pilot study begins.

IDENTIFICATION AND INVITATION

Potential older adult and family caregiver Community Advisory Group advisors will be identified primarily from individuals who participated in the Principal Investigator's National Palliative Care Research Center Kornfeld Scholars Award study, which was conducted at UAB under protocol IRB-300007623. Only individuals who previously indicated that they were willing to be contacted about future research opportunities will be contacted. The MyHP-South research team will invite these individuals directly to consider serving as Community Advisory Group advisors. They will not be asked to recruit, refer, or contact other potential advisors.

Clinician advisors will be invited from the UAB Whitaker Primary Care Clinic through the Principal Investigator's established collaborative relationship with clinic leadership and providers. Clinician advisors may include physicians, nurse practitioners, social workers, and care coordinators.

Potential older adult and family caregiver advisors may receive the Aim 1 Patient and Family Caregiver CAG Recruitment Flyer by mail or email and may also be contacted directly by telephone. Individuals previously enrolled in the Principal Investigator's Kornfeld Scholars Award study (UAB IRB-300007623) will be contacted only if they previously agreed to be contacted about future research opportunities. Potential clinician advisors may receive the Aim 1 Clinician CAG Recruitment Flyer by email or may be contacted directly by telephone through the Principal Investigator's established collaboration with the UAB Whitaker Primary Care Clinic.

The Patient and Family Caregiver CAG Contact and Inquiry Script and the Clinician CAG Contact and Inquiry Script will be used for both outgoing calls initiated by study staff and incoming calls from individuals responding to a recruitment flyer. Study staff will explain the purpose of the advisory group, confirm the applicable advisor category, describe the meeting schedule and compensation, answer questions, and determine whether the individual is interested in serving as an advisor. Contact information and meeting-format preferences will be collected only from individuals who express interest. Individuals who decline will not be contacted again about the advisory group. CAG advisors will not be enrolled as research participants or complete informed consent.

COMMUNITY ADVISORY GROUP MEETINGS

CAG members will participate in three advisory meetings, each lasting approximately 90 minutes, for a total time commitment of up to 270 minutes, or 4.5 hours. Meetings may be conducted in person or through Zoom, depending on member preference and scheduling feasibility. Older adults, family caregivers, and clinicians may initially meet separately to encourage open discussion within each stakeholder group.

Meetings will be guided by the Community Advisory Group Discussion Guide. Advisors will provide feedback on the clarity, cultural relevance, usability, content, and proposed delivery of MyHP-South. Discussions may also address healthcare values, communication priorities, and barriers and facilitators to using MyHP-South in primary care.

CAG members will not complete research surveys or questionnaires. Meetings will not be audio- or video-recorded or transcribed. Research staff will take nonidentifiable summary notes documenting general recommendations for intervention refinement. Comments will not be attributed to individual advisors, and the notes will not be analyzed or reported as research findings.

AIM 2: SINGLE-ARM PILOT WITH PATIENT AND FAMILY CAREGIVER DYADS

AIM 2 PARTICIPANTS

Aim 2 will enroll 20 adults aged 65 years or older with multiple chronic conditions and 20 family caregivers. Each patient will participate with a family caregiver as a dyad. The patient and family caregiver will be enrolled as separate research participants, provide verbal informed consent separately, and complete the study measures applicable to their respective participant group.

The total duration of participation in Aim 2 will be approximately 12 weeks.

IDENTIFICATION OF POTENTIAL PATIENT PARTICIPANTS

Potential patient participants will be identified through i2b2. Study personnel authorized to access i2b2 will use the approved inclusion and exclusion criteria to identify individuals who may qualify for the study. Medical record information will be reviewed to determine whether an individual appears to meet the study criteria, including whether the record contains a diagnosis of dementia that may affect the individual's ability to provide informed consent.

Potentially eligible individuals will first receive a mailed Opt-Out Letter that describes the study and provides instructions for declining further contact. Individuals will be given 10 business days, approximately 14 calendar days, to opt out. Individuals who opt out will not receive any additional recruitment contacts.

AIM 2 PATIENT RECRUITMENT CONTACTS

If an individual does not opt out within 10 business days, trained study personnel will initiate recruitment contact. A maximum of five contact attempts will be made using the following sequence:

1. First telephone call attempt.
2. Second telephone call attempt.
3. One text message.
4. Third telephone call attempt.
5. Second text message.

Contact attempts will occur on different days. Telephone calls will be made at different times of day when feasible. If the individual does not respond after the fifth total contact attempt, no further contact will be made, and the individual will be classified as a passive refusal.

Telephone recruitment will be conducted only by IRB-approved study personnel who have completed the UAB-required "IRB Training – Telephone Recruitment for Human Subject Research Participants." Study personnel will use the UAB IRB-issued telephone recruitment script verbatim when making initial telephone contact with individuals with whom the study team has no pre-existing relationship.

The Opt-Out Letter, UAB telephone recruitment script, Participant Contact Script, and Text Message Recruitment Script are provided in Section 31, Attachments.

AIM 2 PATIENT RECRUITMENT AND ENROLLMENT

When an individual expresses interest in participating, trained research staff will explain the study and confirm relevant information during the recruitment and consent discussions. Research staff will confirm that the individual is community-dwelling and does not reside in a nursing home or assisted living facility. No separate telephone eligibility screening or Patient Eligibility Screening Form will be used.

Research staff will review the verbal consent information with the patient, answer all questions, and assess whether the individual can understand the study and provide informed consent. This assessment will include determining whether the individual can describe the study's purpose, procedures, voluntary nature, and potential risks and benefits. Verbal informed consent will be obtained before beginning any research procedures. The date of verbal consent and the name of the staff member obtaining consent will be documented in the study record.

IDENTIFICATION AND RECRUITMENT OF FAMILY CAREGIVERS

After providing consent, the patient will be asked to identify an unpaid family member or other person who provides assistance or support and may be willing to participate as the patient's family caregiver partner. The patient will be asked for permission for research staff to contact the identified individual.

After the patient provides permission to contact the identified family caregiver, research staff will make up to five telephone contact attempts using the Family Caregiver Recruitment Contact Script. Attempts will occur on different days and, when feasible, at different times of day. Text messages and email will not be used to recruit family caregivers. Contact attempts will stop if the caregiver declines participation, requests no further contact, or enrolls in the study. Each attempt and its outcome will be documented on the study recruitment log.

Research staff will contact the potential family caregiver using the Partner Recruitment Contact Script and explain the study. During the recruitment and consent discussions, research staff will confirm that the individual is at least 18 years old, provides unpaid assistance or support to the patient, can communicate with research staff, and is available to participate in the dyadic MyHP-South session and required assessments. No separate telephone eligibility screening or Family Caregiver Eligibility Screening Form will be used.

The same Patient and Family Caregiver Verbal Consent Script will be used for both participant groups. Research staff will conduct the consent discussion separately with the patient and family caregiver, review the information applicable to that individual's role, answer all questions, and assess the individual's ability to understand the study and provide informed consent. Each member of the dyad must provide verbal consent before beginning any research procedures. The date of consent and the name of the staff member obtaining consent will be documented separately for each participant in the study record.

The patient and family caregiver will participate as a dyad. Therefore, both individuals must provide informed consent before the dyad begins the Aim 2 study procedures.

AIM 2 BASELINE TELEPHONE ASSESSMENTS

Immediately after providing verbal consent, each patient and family caregiver participant will be offered the option to complete the baseline telephone assessment during the same call. If the participant prefers to complete it later, research staff will schedule the baseline assessment during the consent call for a mutually convenient date and time, generally within seven days of consent. At the scheduled time, research staff will call the participant using the telephone number provided during enrollment and verbally administer the applicable baseline questionnaires. Because the appointment will be arranged directly during the consent call, no separate scheduling or invitation script will be used. The patient and family caregiver may complete their baseline assessments at different times.

Before the MyHP-South session, trained research staff will schedule separate baseline telephone assessments with the patient and family caregiver. All baseline questionnaires will be administered verbally by trained research staff over the telephone. Research staff will read each questionnaire item and applicable response options aloud and record the participant's responses directly in the secure study database. Patient and family caregiver assessments will be conducted separately.

Measures Completed by Both Patients and Family Caregivers

Both patients and family caregivers will complete a Demographic Questionnaire assessing age, gender, marital status, religion, education, employment, occupation, and living arrangement.

Both patients and family caregivers will also complete the Shared Care Instrument (SCI), a 19-item questionnaire assessing perceptions of communication exchange between the patient and family caregiver regarding the illness experience. The instrument includes communication, decision-making, and reciprocity subscales.

Patient Baseline Measures

In addition to the Demographic Questionnaire and SCI, patient participants will complete:

1. **Older Patient Assessment of Chronic Illness Care (O-PACIC):** A 10-item questionnaire assessing the patient's perception of the quality and patient-centeredness of chronic illness care delivery.
2. **Treatment Burden Questionnaire (TBQ):** A 13-item questionnaire assessing the patient's perceived burden associated with managing chronic illness and treatment and the effect of that burden on quality of life.
3. **CollaboRATE:** A 3-item patient-reported measure assessing the extent to which the patient experienced shared decision-making during clinical care.

Family Caregiver Baseline Measure

In addition to the Demographic Questionnaire and SCI, family caregivers will complete:

1. **Bakas Caregiver Outcomes Scale (BCOS):** A 10-item questionnaire assessing changes in the family caregiver's social functioning, subjective well-being, and physical or somatic health associated with providing care.

AIM 2 MYHP-SOUTH SESSION

After both members of the dyad complete their baseline assessments, research staff will contact the patient and family caregiver by telephone to schedule the MyHP-South session for a mutually convenient date and time. The session will generally occur within 14 days after the second member of the dyad completes the baseline assessment. The session will be scheduled as a separate study activity and will not normally occur on the same day as the baseline assessments.

During the scheduling call, research staff will confirm whether the dyad prefers to participate in person or by Zoom. After the session is scheduled, research staff will send a text-message reminder to both participants, provided they have agreed to receive study-related text messages. The reminder will not include personal health information. The MyHP-South Session Scheduling and Reminder Script will be used for the telephone call and text message and is provided in Section 31, Attachments.

The MyHP-South session will use a paper-based prototype of the program and will last approximately 60 minutes. During the session, the patient will be guided through a structured process to identify and articulate personal health priorities. The family caregiver will participate in the dyadic process and provide assistance and support as appropriate. In-person sessions will be conducted at the UAB Plaza Building, 2112 11th Avenue South, Birmingham, AL 35205.

Participants attending an in-person session will receive paper copies of the MyHP-South materials during the visit. Participants attending by Zoom will receive the materials in advance by mail or email. Participants who do not have access to a computer or smartphone may select an in-person session and receive paper materials. Therefore, lack of access to a computer or smartphone will not exclude an individual from participation.

Participants will not be required to create a MyHP account or independently access an online platform or downloadable application. Prior experience using MyHP is not required.

Research staff will document the amount of time required to complete the MyHP-South session using a Staff Timing Sheet. The MyHP-South session will not be audio- or video-recorded.

AIM 2 IMMEDIATE POST-SESSION ASSESSMENTS

Immediately following the MyHP-South session, trained research staff will administer separate post-session telephone assessments to the patient and family caregiver. Research staff will read each questionnaire item and applicable response options aloud and record the participant's responses directly in the secure study database.

Both patients and family caregivers will complete:

1. **System Usability Scale (SUS):** A 10-item questionnaire assessing participants' perceptions of the usability, clarity, and ease of use of the MyHP-South materials and process.

AIM 2 ACCEPTABILITY INTERVIEW

Immediately after completing the MyHP-South session and immediate post-session questionnaires, the patient and family caregiver will participate together in one semi-structured acceptability interview conducted by trained research staff. The interview will occur during the same scheduled study visit as the MyHP-South session and will not be scheduled as a separate study activity. Therefore, research staff will not contact participants separately by telephone, text message, or email to invite or schedule them for the acceptability interview.

The interview will be conducted through Zoom or by telephone and will assess participants' perceptions of the usefulness of the MyHP-South materials; cultural and contextual relevance; clarity and ease of use; comfort with the dyadic process; perceived burden associated with completing and using the program; perceived value of the program for clinical visits; barriers to completing or using the program; and recommendations for improving MyHP-South.

With the participants' permission, an interview conducted through Zoom will be audio- and video-recorded. An interview conducted by telephone will be audio-recorded using an approved recording method. Only the written transcript generated from the recording will be retained and analyzed as research data. Audio and video files will not be analyzed.

After the transcript has been generated, reviewed for completeness and accuracy, and transferred to the secure study storage location, the corresponding audio and video files will be permanently deleted from Zoom, the recording device, and any temporary storage location.

If either participant declines recording, the dyad may still complete the interview. In that case, research staff will document the interview using structured written notes. Recruitment contacts, consent discussions, baseline and post-session questionnaires, the MyHP-South session, and 12-week follow-up assessments will not be audio- or video-recorded.

The MyHP-South Session Telephone Scheduling Script and Text-Message Reminder Script apply to the complete scheduled study visit and are provided in Section 31, Attachments. No separate acceptability interview invitation or scheduling script will be used.

AIM 2 PREPARATION FOR THE CLINICAL VISIT

Following the MyHP-South session, the patient will receive a completed copy of the MyHP-South priorities template for use during the patient's upcoming primary care visit. The template will be sent to the patient by mail or email according to the patient's preference. Research staff will confirm the patient's preferred delivery method and the applicable mailing or email address before sending the template. The family caregiver may also receive a copy if authorized by the patient.

To allow sufficient time for patient recruitment, family caregiver enrollment, baseline assessments, and completion of the MyHP-South session, the i2b2 recruitment query will identify potentially eligible patients with a UAB primary care appointment scheduled approximately 3 to 6 months in the future. Patients without a scheduled primary care appointment will not be included on the i2b2 recruitment list.

The i2b2 recruitment list will include the date of each potentially eligible patient's scheduled primary care appointment and the name of the primary care clinician associated with that appointment. Research staff will enter the appointment date and clinician's name provided by i2b2 into REDCap and review the recruitment list on a rolling basis, prioritizing recruitment contacts according to the scheduled appointment dates. The research team will use the clinician information provided by i2b2 rather than asking patients to identify the applicable clinician from memory.

With the patient's authorization, research staff will document the clinician's name and obtain the clinician's clinic contact information from the UAB directory or other institutional contact information for use in Aim 3.

Approximately one day before the appointment date provided by i2b2, a REDCap reminder will prompt research staff to send the patient an approved text message. The message will remind the patient to bring the completed MyHP-South priorities template to the appointment or otherwise have it available to share with the clinician. The Aim 2 Patient Reminder Text is provided in Section 31, Attachments.

AIM 2 TWELVE-WEEK FOLLOW-UP ASSESSMENTS

At 12 weeks, trained research staff will contact patients and family caregivers by telephone and text message to schedule and remind them about their follow-up telephone assessments.

All 12-week questionnaires will be administered verbally by trained research staff over the telephone. Research staff will read each questionnaire item and applicable response options aloud and record the participant's responses directly in the secure study database. Patient and family caregiver assessments will be conducted separately.

Patient participants will complete:

1. Older Patient Assessment of Chronic Illness Care.
2. Treatment Burden Questionnaire.
3. CollaboRATE.
4. Shared Care Instrument.

Family caregiver participants will complete:

1. Bakas Caregiver Outcomes Scale.
2. Shared Care Instrument.

The Demographic Questionnaire will be administered only at baseline. The System Usability Scale will be administered only immediately following the MyHP-South session. These measures will not be repeated at 12 weeks.

AIM 2 FEASIBILITY DATA

Recruitment feasibility will be evaluated using recruitment and enrollment logs. These logs will be used to document the numbers of potential patient participants contacted, patients and family caregivers who enroll, individuals who decline participation, passive refusals, and reasons for refusal when provided.

Retention feasibility will be evaluated using study tracking forms documenting completion of the baseline assessments, MyHP-South session, immediate post-session assessments, acceptability interview, and 12-week assessments.

Research staff will document the length of each MyHP-South session using the Staff Timing Sheet. These feasibility data will be obtained from study records and will not require participants to complete additional questionnaires.

The Demographic Questionnaire, O-PACIC, TBQ, CollaboRATE, SCI, BCOS, SUS, semi-structured acceptability interview guide, Staff Timing Sheet, recruitment materials, consent materials, and applicable participant reminder scripts are provided in Section 31, Attachments.

AIM 3: CLINICIAN POST-VISIT ASSESSMENT

Aim 3 will include approximately four primary care clinicians who provide care to enrolled Aim 2 patient participants. During Aim 2 participation, patients will be asked to identify the primary care clinician with whom they anticipate discussing their completed MyHP-South priorities template. With the patient's authorization, research staff will obtain the clinician's name and clinic contact information.

Before the applicable clinical visit, research staff will send the patient a text message reminding the patient to bring and share the completed MyHP-South priorities template with the clinician.

Following the visit, research staff will invite the clinician by email to complete a one-time electronic post-visit survey through REDCap. The survey will begin with brief study information. Clinicians who choose to participate will indicate their agreement electronically before proceeding to the survey. Participation is voluntary.

The survey will take 5 minutes and will assess:

1. The clarity and usefulness of the patient's stated priorities.
2. The fit of the MyHP-South priorities template within the clinical workflow.

3. Whether the template influenced communication or discussion during the visit.

4. Whether the template influenced care planning or treatment decisions.

5. Whether the template helped the clinician understand the patient's family or caregiver context.

6. Barriers and facilitators to using the template during clinical care.

7. The clinician's willingness to use a similar tool during future visits.

Survey responses will be submitted directly to the secure REDCap study database. The patient study ID and applicable visit date will be linked to the survey by research staff and will not be entered by the clinician. No paper survey will be required. The survey will not be audio- or video-recorded.

Aim 3 feasibility will be evaluated using the proportion of invited clinicians who complete the survey. Feasibility will be defined as a survey completion rate of at least 75%.

The clinician recruitment email, post-visit clinician survey, and Aim 3 Patient Reminder Text are provided in Section 31, Attachments.

Completion of Study Involvement

Aim 1 CAG advisors will complete their advisory involvement after the final CAG meeting. Aim 2 patients and family caregivers will complete study participation after their respective 12-week telephone assessments. Aim 3 clinicians will complete study participation after submitting the post-visit clinician survey.

REQUIRED - SELECT ONE OR BOTH: Will this be a retrospective study and/or a prospective study?

☐ Yes ☑ No * Retrospective

☑ Yes ☐ No * Prospective

☑ Yes ☐ No * Will the study involve the prospective collection or analysis of data, documents, or records?

☐ Yes ☑ No * Will the study involve the prospective collection or analysis of biospecimens?

What is the expected end date of the study (including data analysis)? 31-Oct-2028

* Provide the total number of subjects to be included at all sites, both retrospectively (including records) and prospectively. 120

* Provide the total number of subjects to be included at UAB, both retrospectively (including records) and prospectively. 120

Select the status of the Principal Investigator.

☑ Faculty/Staff

☐ Student/Trainee

☐ Yes ☑ No Are any of the investigators listed on the IRB Personnel Form students using this research for their capstone project, thesis, or dissertation?

☐ Yes ☑ No Is the project to be conducted internationally?

Procedure List

Select all study procedures and indicate whether the procedures are research only or routine.

Procedure	Select whether the procedure is research or routine.
Record review (which may include PHI)	Protocol Driven
Telephone Interview	Protocol Driven
Recordings - A/V, image	Protocol Driven
Data, not publically available	Protocol Driven
Surveys, questionnaires, or interviews (one-on-one)	Protocol Driven
Telephone Interview	Protocol Driven

☐ Yes ☑ No Does the protocol involve any procedures not described in the above table?

Research Area

Select the type of research.

☐ Biomedical (non-oncology)

☑ Behavioral (non-oncology)

☐ Oncology

5. RESEARCH DETERMINATION

Research Determination Form

☑ Yes ☐ No * Is the activity a systematic investigation?

☑ Yes ☐ No * Is the activity designed to develop or contribute to generalizable knowledge?

☑ Yes ☐ No * Does the project involve obtaining information about living individuals?

☑ Yes ☐ No * Does the project involve an intervention or an interaction with participants?

☐ Yes ☑ No * Does the project involve an FDA regulated test article?

☐ Yes ☑ No * Is the project defined as a clinical investigation?

Briefly describe the proposed project, including what materials are being obtained and their sources. **If you provided this information on Page 1 (General Questions), enter "See above."**

See above

Risk Level - Not FDA Regulated

* **REQUIRED: Select whether the project involves minimal risk or greater than minimal risk to participants.**
Minimal Risk

☐ Exempt Categories

☑ Expedited Categories

Expedited Categories

Select the categor(ies) that apply to the project. If none of these categories apply, select none of the above apply to this project.

1 ☐ 2 ☐ 3 ☐
4 ☐ 5 ☐ 6 ☑
7 ☑

Expedited Category 1: Clinical studies of drugs and medical devices when either of these conditions are met.

Expedited Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture under these conditions.

Expedited Category 3: Prospective collection of biological specimens by noninvasive means (examples here).

Expedited Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves (more information here).

Expedited Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Expedited Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

☐ None of the above apply to this project.

Sources of Private Information

Indicate the information that may be obtained, accessed, used, disclosed, or shared from an individual (living or deceased). Select all that apply.

☐ An individual's genetic tests

☐ Genetic tests of family members of a particular individual (including an embryo or fetus)

☐ Genetic manifestation of a disease or disorder in family members of a particular individual

☐ Any request for, or receipt of, genetic services, or participation in a clinical study which includes genetic service, by the individual or any family member of the individual

☐ Education records of an individual

☐ Alcohol or substance abuse information, including diagnosis, treatment, or referral of treatment for alcohol abuse, substance abuse, or chemical dependency

☑ Yes ☐ No Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)?

☐ Identifiable, but not private, information

☐ Other identifying information

☐ Yes ☑ No * Is the project subject to the 2023 NIH Data Management and Sharing (DMS) policy?

☑ Yes ☐ No * Will information be received from outside of UAB?

From where will the information be received?

Transcribed interview data will be received from Landmark Associates, the study's outside transcription vendor. Audio recordings will be securely provided to Landmark Associates without participant names or other direct identifiers, and completed transcripts will be securely returned to the UAB study team.

☑ Yes ☐ No * Will you share the information with an institution other than UAB?

Provide the names of the institution(s).

University of Colorado Anschutz Medical Campus, serving as the ASCENT Research Coordinating Center (de-identified study data only).

☑ Yes ☐ No * Will you need to obtain information from a department other than your own?

Provide the names of the department(s).

The study team will obtain information from the UAB Whitaker Primary Care Clinic, a UAB Medicine clinical site, to identify potentially eligible participants. Following approval of a partial HIPAA waiver, study personnel will access or receive the minimum necessary information from the clinic's electronic medical record to identify and recruit eligible participants in accordance with IRB-approved procedures.

Provide any additional information for the IRB to consider. Upload any relevant files in the Attachments section.

The study team will obtain information from the UAB Whitaker Primary Care Clinic, a UAB Medicine clinical site, to identify potentially eligible participants. Following approval of a partial HIPAA waiver, study personnel will access or receive the minimum necessary information from the clinic's electronic medical record to identify and recruit eligible participants in accordance with IRB-approved procedures.

6. NON-AFFILIATED PERSONNEL

Non-UAB/CoA Personnel

☐ Yes ☑ No * Are there any NON UAB, Children's of Alabama (CoA), Lakeshore Foundation, or Birmingham Veteran's Affairs Medical Center (BVAMC) key personnel on this study? NOTE: UAB, CoA, Lakeshore Foundation, and BVAMC investigators must be listed on the IRB Personnel Form. Additionally, this page does not apply to adding sites for Single IRB or multi-site research.

7. SPONSORS AND ENTITIES

Funding, University Contracts, Subcontracts, MTAs, or DUAs

☑ Yes ☐ No * Is this project funded in any way?

☐ Yes ☑ No * Is the funding internal?

☐ Yes ☑ No * Is this project industry sponsored?

Select the study sponsor and/or the entity(ies) providing support for the study.

Study Sponsor/Entity(ies)
National Institute on Aging/NIH/DHHS

Provide the OSP Assigned Number(s) or myUABResearch number(s). NOTE: The OSP assigned number is 9 digit number and myUABResearch number begins with either FP or AWD.
NOT PROVIDING THE RECORD NUMBER(S) WILL RESULT IN DELAYS OF YOUR REVIEW.

FP00000022

Is the project funded by either of the 20 common rule agencies? No

☐ Yes ☑ No Does the project involve any University Contracts, MTAs, DUAs, or subcontracts/subawards? NOTE: Subawards are identified by the OSP Assigned Number with a three digit suffix (e.g., 000500000-001).

☐ Yes ☑ No Will the project receive non-monetary support (i.e., drugs, devices, services, etc.) from another entity?

9. PROSPECTIVE

☐ Yes ☑ No * Drugs/Dietary Supplements

☐ Yes ☑ No * Biologics

☐ Yes ☑ No * Radiopharmaceuticals

☐ Yes ☑ No * Medical Devices

☐ Yes ☑ No * In-vivo imaging, image guided interventions (e.g., CT, PET/CT, MRI, PET/MRI, x-ray, DEXA, fluoroscopy, nuclear imaging, ultrasound) or radiation therapy

☑ Yes ☐ No Is this a multi-site study?

☑ Yes ☐ No Is UAB the lead site?

Submit IRB approvals from all sites.

Description	Attachment	

☑ Yes ☐ No Does the study involve access, review, or disclosure of Protected Health Information (PHI) ?

☐ Yes ☑ No Does the study involve randomization?

☐ Yes ☑ No Does the study require clinical services at any of these sites?

☐ Yes ☑ No Will this study involve direct interaction with participants who have an infectious disease?

Target Accrual Information

200 Approximately how many subjects will need to undergo screening procedures to determine whether they qualify to be enrolled? Enter 0 if not applicable. NOTE: This number is an approximation based on previously completed projects.

59 How many subjects do you intend to enroll at UAB? Enter 0 if not applicable.

0 How many subjects will be enroll at other sites? Enter 0 if not applicable.

Describe how the screening and enrollment numbers above are determined (e.g., provide a power analysis, explain the pilot data, or reference prior studies.

The target accrual is based on the objectives of this early-stage feasibility and acceptability pilot study rather than statistical power for hypothesis testing. Approximately 200 individuals are expected to undergo screening to enroll 59 research participants across all study aims, including 15 Community Advisory Group (CAG) members, 20 older adult participants, 20 family caregivers, and 4 primary care clinicians. The screening estimate is intentionally conservative to account for individuals who may not meet eligibility criteria, decline participation, or withdraw before enrollment. The proposed sample size is appropriate for evaluating feasibility, acceptability, recruitment, retention, and study procedures and will inform the design of a future larger-scale trial.

What are the target age range(s) of the potential subjects with which you will interact?

1. <18 ☐
2. 18-89 ☑
3. >=90 ☐

Indicate which of the following populations you will be **targeting** (enrolling, interacting, or intervening with) for your study. Select all that apply.

☐ Cognitively impaired adults

☐ Economically or educationally disadvantaged

☑ UAB employees

☐ Fellows

☐ Individuals with Limited English Proficiency (LEP) or non-English speakers. Recruitment of study with LEP or non-English speakers is generally required, if the study holds the prospect of a direct therapeutic benefit to the participant.

☑ Individuals of specific racial, religious, or ethnic groups

☐ Individuals living outside the 50 US states

☐ Pediatric and neonates

☑ Patients (This includes existing patients)

☐ Persons who are institutionalized

☐ Pregnant women or fetuses

☐ Prisoners

☐ Medical Residents

☐ Study Staff or investigators named on this application

☐ Students

☐ Others

☐ None of the above, not targeting specific populations

How will the study team identify potential subjects? Select all that apply.

☐ Non-UAB physicians ☑ Non targeted/unknown (e.g., chart review) ☐ Other

If chart reviews will be used to identify potential subjects that are not your own patients, request a partial waiver of HIPAA Authorization for the purpose of identifying individuals for recruitment.

*Describe participant inclusion/exclusion criteria, including sex, race/ethnicity, age, and health status.

Inclusion Criteria (Patients):

1. Identify as African American or White/Caucasian;
2. Age ≥ 65 years;
3. Have at least two of the following chronic conditions: cancer, heart disease, kidney disease, liver disease, or lung disease;
4. English-speaking and able to complete baseline study measures;
5. Cognitively able to participate in decision-making discussions;
6. Have a family caregiver, defined as a relative, friend, or partner who has a close relationship with the participant, assists with health-related decision-making, may or may not live in the same residence, and is not paid for their assistance; and
7. Have reliable telephone access.

Exclusion Criteria (Patients):

Patients will be excluded if they have a documented diagnosis of dementia, are unable to understand the study and provide informed consent, or reside in a nursing home or assisted living facility.

A documented diagnosis of dementia will be assessed through medical record review during prescreening and confirmed with the potential participant during the telephone eligibility screening. The individual's ability to provide informed consent will be evaluated during the consent discussion by assessing whether the individual can describe the study's purpose, procedures, voluntary nature, and potential risks and benefits.

Residence in a nursing home or assisted living facility will be operationalized as an exclusion criterion in the i2b2 cohort request. The research team will instruct i2b2 personnel to exclude individuals identified in available electronic health record data as residing in either type of facility. Accordingly, these individuals will not be included on the list of potential candidates provided to the research team and will not be contacted for recruitment. The exclusion criterion will be documented in the i2b2 cohort request and will not be assessed through a participant survey or recruitment script.

Inclusion Criteria (Family Caregivers):

1. Identify as African American or White/Caucasian;
2. Age ≥ 18 years;
3. Self-identified or identified by the patient as a family caregiver (defined as a relative, friend, or partner who has a close relationship with the participant, assists with health-related decision-making, may or may not live in the same residence, and is not paid for their assistance);
4. Providing care for a patient with multiple chronic conditions (as defined above);
5. English-speaking and able to complete baseline study measures; and
6. Have reliable telephone access.

Exclusion Criteria (Family Caregivers):

Family caregivers will be excluded if they are unable to understand the study and provide informed consent, communicate with research staff, or participate in the dyadic MyHP-South session and required assessments. These criteria will be

assessed during the telephone eligibility screening and consent discussion.

Community Advisory Group (CAG) Members

Community Advisory Group members will include **older adults with multiple chronic conditions, family caregivers, and primary care clinicians** who are able to participate in advisory meetings and provide feedback on the My Health Priorities (MyHP) Program. Older adult members must be **65 years of age or older**, and family caregivers must be **18 years of age or older**.

Clinician Post-Visit Survey Participants

Eligible clinician participants must be **primary care clinicians** caring for an enrolled study participant who have reviewed the participant's MyHP template during a clinical visit and are willing to complete a one-time post-visit survey.

Describe the estimated time commitment of each subject. Examples: 1) One hour once a week for 52 consecutive weeks; 2) Twenty minutes to complete a one-time survey; 3) One interview lasting 60 minutes. Enter "N/A" if participants are not directly involved.

Community Advisory Group Members (Aim 1)

Community Advisory Group members will participate in three meetings, each lasting approximately 90 minutes. The total estimated time commitment is up to 270 minutes, or 4.5 hours.

Aim 2 Patient Participants

Patient participation will last approximately 12 weeks. The estimated time commitment for each study activity is:

1. Recruitment, eligibility screening, and verbal consent: approximately 30 to 45 minutes.
2. Baseline assessment: approximately 45 to 60 minutes.
3. MyHP-South session with the family caregiver: approximately 60 minutes.
4. Immediate post-session questionnaires: approximately 15 to 20 minutes.
5. Joint acceptability interview with the family caregiver: approximately 45 to 60 minutes.
6. Twelve-week follow-up assessment: approximately 35 to 45 minutes.

The total estimated time commitment for patient participants is approximately 3 hours and 50 minutes to 4 hours and 50 minutes over 12 weeks.

Aim 2 Family Caregiver Participants

Family caregiver participation will last approximately 12 weeks. The estimated time commitment for each study activity is:

1. Recruitment, eligibility screening, and verbal consent: approximately 30 to 45 minutes.
2. Baseline assessment: approximately 30 to 45 minutes.
3. MyHP-South session with the patient: approximately 60 minutes.
4. Immediate post-session questionnaires: approximately 15 to 20 minutes.
5. Joint acceptability interview with the patient: approximately 45 to 60 minutes.
6. Twelve-week follow-up assessment: approximately 20 to 30 minutes.

The total estimated time commitment for family caregiver participants is approximately 3 hours and 20 minutes to 4 hours and 20 minutes over 12 weeks.

Aim 3 Clinician Participants

Clinician participants will complete a brief post-visit survey requiring approximately 5 to 10 minutes.

☑ Yes ☐ No * Will a Certificate of Confidentiality be obtained from the NIH?

NOTE: Specific language must be added to the informed consent document and approved by the NIH. In addition, the consent documents must not be filed in the medical record.

What recruitment materials/methods will be used to recruit subjects. Select all that apply.

☑ Flyer

Where will the flyer be distributed?

A patient recruitment flyer will be distributed to potentially eligible patients receiving care through the UAB Whitaker Primary Care Clinic. The flyer will be included with the opt-out letter mailed to individuals identified through electronic medical record (EMR) review under a partial HIPAA waiver. A separate Community Advisory Group (CAG) recruitment flyer will be distributed through community partners and other appropriate recruitment channels to identify eligible older adults, family caregivers, and primary care clinicians for participation in the CAG. Both recruitment flyers are included with this IRB submission for review and approval.

☐ Internet posting/website

☐ ResearchMatch

☐ Subject pool/repository

☐ Printed brochure

☐ Letter to healthcare providers

☑ Letter to potential subjects

☐ Printed ad

☐ Radio/TV ad

☑ Email solicitations

☑ Direct subject contact

Describe the methods used to recruit the subject (i.e., how, when). If participants without an existing relationship with study personnel will be recruited via telephone, provide a copy of the required "Phone Script Template for Recruitment of Patients from an Electronic Health Record" and complete the IRB Training - Telephone Recruitment for Human Subject Research Participants course. Please visit the Office of the IRB website for additional information and Guidance for Using Phones Scripts for the Recruitment of Human Subjects.

After medical record prescreening, potentially eligible patients will be mailed an opt-out letter. If no opt-out is received within 10 business days, trained study personnel will contact the patient by telephone using the UAB IRB-issued recruitment script. Interested patients will be screened for eligibility.

With the patient's permission, study personnel will contact the identified family caregiver by telephone using the applicable IRB-approved recruitment script. Interested caregivers will then be screened for eligibility.

Telephone recruitment will be conducted only by IRB-approved study personnel who have completed the required UAB telephone recruitment training

☑ Electronic Medical Record query using i2b2, Electronic Data Warehouse, or IMPACT

Describe.

Patient listing will be generated using i2b2 and then medical charts will be reviewed using IMPACT

☐ Other

*Describe all activities to identify and recruit prospective participants.

Identification, Recruitment, and Enrollment

Community Advisory Group (Aim 1): CAG members will serve as community advisors and will not be enrolled as research participants. Older adult and family caregiver advisors will be identified primarily from individuals who participated in the Principal Investigator's National Palliative Care Research Center Kornfeld Scholars Award study and agreed to be contacted about future opportunities. Clinician advisors will be invited from the UAB Whitaker Primary Care Clinic through the Principal Investigator's established collaboration with clinic leadership and providers. Potential advisors will be contacted using the CAG Invitation Script and provided with information about the advisory group's purpose, activities, voluntary nature, and time commitment.

Patient and Family Caregiver Pilot (Aim 2): Potentially eligible older adults will be identified through electronic medical record review at the UAB Whitaker Primary Care Clinic under a partial HIPAA waiver. Potentially eligible patients will receive an opt-out letter and study flyer. If they do not opt out, trained study personnel will contact them by telephone using the UAB IRB-issued recruitment script to confirm eligibility and assess interest. With the patient's permission, the identified family caregiver will be contacted by telephone using the applicable recruitment script and screened for eligibility. Eligible patients and caregivers who agree to participate will complete separate informed consent processes and be enrolled as a dyad.

Clinician Post-Visit Survey (Aim 3): Primary care clinicians caring for enrolled patients will be invited by email to complete a voluntary, one-time post-visit survey after reviewing the patient's MyHP-South priorities during a clinical encounter.

(For assistance with the development of a Recruitment Plan, please contact the Clinical Research Support Program (CRSP).)

Select the types of data collection tools that will be used in this study. Select all that apply.

☑ Survey/questionnaire(s) (UAB recommends using Qualtrics or RedCap for electronic surveys)

☑ Audio or video recordings

Describe what data will be captured via audio/video recordings.

CAG meetings under Aim 1 will not be audio- or video-recorded or transcribed. Research staff will take nonidentifiable summary notes solely for intervention refinement.

Under Aim 2, separate acceptability interviews with patient and family caregiver participants may be conducted by Zoom or telephone. Zoom interviews will be audio- and video-recorded, and telephone interviews will be audio-recorded. Recordings will be used to prepare written transcripts. Only the transcripts will be retained and analyzed. Audio and video files will be deleted after the transcripts have been reviewed for accuracy and transferred to secure study storage.

The MyHP-South sessions, eligibility screenings, consent discussions, questionnaires, and 12-week follow-up assessments will not be recorded.

☑ Yes ☐ No Will the recordings be transcribed?

Describe who/what entity will perform the transcription.

Landmark Associates will serve as the study's transcription vendor and will transcribe audio-recorded study interviews.

☑ Interview guides/scripts

☐ Subject diaries

☐ Mobile or web application

☐ Electronic Medical Record query using i2b2, Electronic Data Warehouse, or IMPACT

☐ Other

Clinical Trials

* Select whether this protocol meet the definition of a clinical trial. ○ Clinical Trial ◉ Non-clinical trial

Institutional Biosafety Committee (IBC)

☐ Yes ☑ No * Does this project involve gene transfer, recombinant DNA, or CAR T cells?

11. LOCATIONS

In

☑ UAB Hospital/UAB Clinics

☑ The Kirklin Clinic of UAB Hospital

☐ UAB Callahan Eye Hospital

☐ UAB Hospital - Highlands

☐ The Kirklin Clinic at Acton Road

☐ UAB Clinical Research Unit

☐ Children's of Alabama (CoA)

☐ Jefferson County Department of Health (JCDH)

☐ Jefferson County Department of Health (JCDH)

☐ Child Health Research Unit (CHRU)

☐ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol)

☐ Yes ☑ No * Is this a field study?

18. PATIENTS

Pa mi

☐ Yes ☑ No * Will the investigators (any investigator listed as key personnel) be recruiting their own patients?

19. EMPLOYEES AND STUDENTS

Th ac be

Provide the rationale for inclusion of students and/or employees.

UAB employees may be included because UAB primary care clinicians may participate as Community Advisory Group (CAG) members (Aim 1) and/or complete the Aim 3 clinician post-visit survey. Their participation is based on their professional role and experience caring for older adults with multiple chronic conditions, not because of their employment at UAB.

What safeguards are in place to ensure students/employees are not coerced into participation.

Participation by UAB employees is entirely voluntary. Recruitment will not occur through supervisory relationships, and participation or non-participation will not affect employment, performance evaluations, job responsibilities, or professional standing. Potential participants will be informed that they may decline or withdraw from the study at any time without penalty.

☐ Yes ☑ No * Will students and staff that work under or are students of key personnel on the project be included in the study?

22. SPECIFIC BACKGROUNDS

Racial, Religious, or Ethnic Backgrounds

Indicate the specific racial, religious, or ethnic groups being targeted for enrollment (e.g., Native Americans, Mormons, Roman Catholics, Maasal tribe members, etc.).

African American and White

Provide the rationale for targeting special racial, religious, or ethnic groups.

Older adults with multiple chronic conditions often experience challenges communicating their healthcare priorities and preferences to clinicians, particularly in rural and underserved communities where access to healthcare resources may be limited. This study includes both African American and White/Caucasian older adults because they represent the intended population for the My Health Priorities (MyHP) Program. Including both groups will allow evaluation of the program's feasibility and acceptability across the target population while informing future implementation.

Describe the additional protections that will be implemented to protect this population from unintentional harm (coercion, undue influence, threat to employment or reputation, and the like).

Participation is voluntary, and individuals may decline or withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled. Participants will be informed that their decision to participate or not participate will not affect their healthcare, relationships with their healthcare providers, or access to services. Participant confidentiality will be protected by assigning unique study identification numbers, limiting access to identifiable information to authorized study personnel, and reporting study findings only in aggregate.

The modest reimbursement (up to $75) is not expected to be coercive, and participants will be informed that their clinical care and relationship with their healthcare providers will not be affected by their decision to participate or decline participation.

All appropriate measures will be taken to protect participant confidentiality. These measures include assigning unique study identification numbers to all data, storing paper records in locked file cabinets within a secured office, maintaining electronic data on password-protected, secure institutional servers, limiting access to authorized study personnel, and reporting study findings only in aggregate form.

☐ Yes ☑ No Have you received community approval from the targeted population?

No * If you are targeting individuals of Native American ancestry, do you have approval from the appropriate tribal or the Indian Health Service (IHS) IRB?

25. COST AND PAYMENT

Cost, Reimbursement, or Compensation

☐ Yes ☑ No * Will subjects (or their insurance providers) experience costs associated with any of the procedures, drugs, biologics, devices, tests, or any aspect of their participation in the study?

☑ Yes ☐ No * Will subjects receive any reimbursement or compensation for their participation (compensation should not be an amount that could be considered coercive or create undue influence)?

Select whether participants will receive payment and/or reimbursement.

☑ Payment

Provide the payment details, including amount, frequency of payment (e.g., $20 at visits one, two, and three), and the method of payment (e.g., cash, check, direct deposit, etc.).

Community Advisory Group (Aim 1) patient, family caregiver, and clinician members will receive $25 for each of three Community Advisory Group meetings (up to $75 total). Aim 2 patients and family caregivers will receive $25 upon completion of each compensated study activity (baseline assessment, 8-week follow-up assessment, and qualitative interview), for a maximum of $75 per participant. Compensation will be provided through a ClinCard prepaid debit card. The ClinCard will be mailed within approximately one week after completion of the first qualifying study activity, and subsequent payments will be added to the same ClinCard as additional compensated study activities are completed. Clinicians participating only in the Aim 3 post-visit survey will not receive compensation.

NOTE: If subjects are being paid for their participation (not reimbursed for study-related expenses) in an amount of $600 or more in a single calendar year, their information will be reported to the IRS in accordance with federal requirements. This must be clearly stated in the informed consent form.

☐ Reimbursement

26. RISKS

Risks and Risk Minimization

Determine any anticipated risks or potential discomforts experienced by subjects for this study. Select all that apply.

☐ Physical risks (e.g., pain, bruising, and infection associated with venipuncture, adverse reactions to drugs, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test, radiation risk (e.g., x-ray, CT scan, radiation therapy, radioisotopes, fluoroscopy))

☑ Psychological risks (e.g., depression and confusion as a result of administration of drugs, feelings of guilt precipitated by a sensitive survey)

Provide details of the risks, including expected frequency and severity.

Participants may experience mild emotional discomfort when discussing their health, chronic conditions, healthcare experiences, or personal priorities. These risks are expected to be temporary and no greater than those encountered during routine conversations about health or medical care. Serious psychological distress is not anticipated.

Describe any steps taken to mitigate the expected risks.

Participants may decline to answer any question, take breaks, or stop participation at any time without penalty. Study staff are trained to recognize signs of participant distress and respond appropriately. If a participant expresses thoughts of self-harm or presents an immediate safety concern, the study team will follow established safety procedures, notify the Principal Investigator, and facilitate appropriate clinical or emergency referral as needed

☑ Social risks (e.g., invasion of privacy, breach of confidentiality, loss of community standing)

Provide details of the risks, including expected frequency and severity.

The primary social risk is the potential loss of privacy or confidentiality. This risk is considered minimal and unlikely.

Describe any steps taken to mitigate the expected risks.

Participant information will be coded using unique study identification numbers. Paper records will be stored in locked cabinets within secured offices, and electronic data will be maintained on password-protected UAB servers with access limited to authorized study personnel. Study findings will be reported only in aggregate to protect participant confidentiality.

☐ Economic risks (e.g., loss of employment, loss of potential monetary gain)

☐ Other risks

Indicate how safety is being monitored in this study.

☐ Data Safety Monitoring Board (DSMB)

☐ Independent medical monitor

☑ Data will be monitored by PI.

Describe how safety will be monitored locally and, if this is a multi-center study, how data and safety will be monitored across sites. Additionally, describe how often data will be monitored. If the only risk is breach of confidentiality, descrbe the method of monitoring for breaches.

The Principal Investigator will oversee participant safety and study conduct throughout the study. Study staff will receive protocol-specific training and promptly report any adverse events, protocol deviations, or confidentiality concerns to the Principal Investigator. Participant safety, study procedures, and data quality will be reviewed regularly during study team meetings, and any reportable events will be managed in accordance with UAB IRB policies.

☐ Data will not be monitored.

27. BENEFITS

What are the potential benefit(s) of the study (e.g., benefits to society, increased knowledge of the particular disease, increased scientific knowledge, etc.)?

Participants may benefit from improved communication with family caregivers and healthcare providers regarding their health priorities and treatment preferences, although direct benefit cannot be guaranteed. The knowledge gained may contribute to improving the My Health Priorities (MyHP) Program and future person-centered care for rural and underserved older adults with multiple chronic conditions.

28. PRIVACY AND CONFIDENTIALITY

Select the identifiers.

☑ Names

☐ All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

☑ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

☑ Phone Numbers

☐ Fax Numbers

☑ Email Addresses

If you are a member of a HIPAA covered entity, electronic correspondence with research participants may require a HIPAA-compliant platform, such as encrypted email. Contact your Information Security team for additional information: UAB IT at DSO-RiskMgt@uab.edu or UABHS HSIS at infosec@uabmc.edu.

☐ Social Security Numbers

☑ Medical Record Numbers

☐ Health plan beneficiary numbers

☐ Account numbers

☐ Certificate/license numbers

☐ Vehicle identifiers and serial numbers, including license plate numbers

☐ Device identifiers and serial numbers

☐ Web universal resource locators (URLs)

☐ Internet protocol (IP) addresses

☐ Biometric identifiers, including finger and voice prints

☐ Full face photographic images and any comparable images

☐ Any other unique identifying number, characteristic, or code

☑ Medical history

☑ Surgical history

☐ Laboratory results

☐ Other

Provide the length of time the identifiers will be stored or retained.

Identifiers will be stored for a total of 5 years.

Describe how data will be collected, recorded, and shared, including the specific safeguards to protect the confidentiality of data. Select all that apply.

☑ Working with an entity outside of UAB to collect, record, share, or otherwise utilize the data.

Working will an outside entity may require the use of a Business Associates Addendum (BAA). The following questions will help the IRB determine whether or not a BAA is required for this work:

☐ Yes ☑ No * Does the outside entity/individual exposed to PHI need it to perform the work?

☑ Data will be stored in REDCap.

☐ Data will be stored in ShareFile

☑ Data will be kept on a UAB encrypted device (i.e., computer, tablet, etc.).

☐ Yes ☑ No * Will anyone other than the study team have access to the device?

☑ Data will be stored on a UAB encrypted server.

☐ Data will be stored in the UAB Cheaha Supercomputer

☐ Data will be recorded on paper.

☑ Data will be coded.

☑ Yes ☐ No * Will a key to the code be maintained?

Who will have access to the key?

The master linking file will be maintained on a secure, password-protected UAB server. Access will be limited to the Principal Investigator and authorized UAB study personnel who require access to identifiable participant information for study purposes.

☑ Data will be kept in a locked office/filing cabinet.

What is the location of the office/filing cabinet?

Magnolia Building Room 233

☐ Data will be stored on a password protected computer/drive not maintained by UAB.

☐ Data will be stored in a location not described above.

☐ Data will NOT be coded.

Describe the plan to destroy the subject identifiers at the earliest opportunity consistent with the conduct of research, unless retention is required for reasons of health, research, or law (including the methods that will be used to discard data at the end of the study life cycle). NOTE: Research records must be retained and subsequently discarded in accordance with applicable regulatory guidelines.

Identifiable information will be stored separately from study data and replaced with unique study ID numbers. The master linking file will be maintained on a secure, password-protected UAB server with access limited to authorized study personnel. Once data collection is complete and identifiers are no longer needed for research purposes, the master linking file will be destroyed, and all remaining study data will be de-identified. Electronic files containing identifiers will be permanently deleted, and paper records will be securely shredded. Research records will be retained and destroyed in accordance with applicable institutional and regulatory requirements.

HIPAA Authorization

Indicate whether you will obtain HIPAA Authorization, a HIPAA waiver, whether the data meet the specifications for a Limited Data Set, or whether the study does not involve access, review, or disclosure of Protected Health Information (PHI). Select all that apply.

- [x] Request for partial HIPAA waiver for recruitment/screening purposes.

Indicate which identifiers will be included *under the request for partial HIPAA waiver* for recruitment/screening purposes.

- [x] All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- [ ] All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- [x] Phone numbers
- [ ] Fax numbers
- [x] Email addresses

If you are a member of a HIPAA covered entity, electronic correspondence with research participants may require a HIPAA-compliant platform, such as encrypted email. Contact your Information Security team for additional information: UAB IT at DSO-RiskMgt@uab.edu or UABHS HSIS at infosec@uabmc.edu.

- [ ] Social Security numbers
- [x] Medical record numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) addresses
- [ ] Biometric identifiers, including finger and voice prints
- [x] Full face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code
- [x] Medical history with no other identifiers or PHI
- [x] Surgical history with no other identifiers or PHI
- [ ] Laboratory results with no other identifiers or PHI
- [ ] Other
- [ ] HIPAA Authorization will be obtained for some or all of the subjects.
- [ ] Request for HIPAA waiver for some or all of the subjects (e.g., for retrospective review of PHI, and/or to review PHI for recruitment purposes and obtain HIPAA authorization during enrollment)
- [ ] The data meet the specifications for a limited data set. NOTE: A limited data set will only apply if you receive data from an outside source as a limited data set or if you are sending data to an outside source as a limited data set (in which case, documentation of authorization or a Waiver of Authorization will be required). A Data Use Agreement (DUA) is required for this option.

HIPAA Covered Entities

Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.

- [x] UAB Hospital or UAB Hospital - Highlands
- [x] The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
- [ ] UAB Callahan Eye Hospital
- [ ] Children's of Alabama
- [ ] Jefferson County Department of Health
- [ ] School of Dentistry
- [ ] School of Health Professions
- [ ] School of Medicine
- [ ] School of Nursing
- [ ] School of Optometry

☐ University of Alabama Health Services Foundation

☐ Valley Foundation

☐ Medical West - UAB Health System Affiliate

☐ Birmingham Veteran's Affairs Medical Center

☐ Yes ☑ No Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)?

29. CONSENT

Informed Consent

Indicate all that apply to the informed consent process.

☐ Informed consent with written documentation will be obtained from all or some of the subjects.

☑ Request a Waiver of Documentation of Informed Consent (e.g., subject may not sign an informed consent document, but will be given an information sheet)

Which of the following conditions apply to the study? NOTE: If neither of the conditions are met, the study does not qualify for a waiver of documentation of consent.

☐ The only record linking the subject and the study would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject be asked whether the subject wants documentation linking the subject with the study, and the subject's wishes will govern.

☑ The study presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the study context.

Justify why the study meets this condition.

This study presents no more than minimal risk to participants and involves procedures, including questionnaires, interviews, Community Advisory Group meetings, and clinician surveys, for which written consent is not normally required outside the research setting. Therefore, a waiver of documentation of informed consent is appropriate.

All * Will this waiver of documentation of informed consent be for all or some of the subjects?

Describe how subjects' verbal informed consent will be obtained. NOTE: The IRB may require an information sheet be given to subjects.

Verbal informed consent will be obtained by a trained member of the research team before any study procedures begin. Participants will receive the information sheet by mail or email before or at the time of the consent discussion. The study team will review the information sheet, explain the study procedures, risks, benefits, confidentiality protections, and participant rights, answer any questions, and obtain verbal consent before enrollment.

Describe how the study team will ensure the subjects understand the information presented.

A trained member of the research team will review the information sheet with each participant, answer questions, and confirm the participant understands the study before proceeding. Participants will be informed that participation is voluntary, that they may decline to answer any question or withdraw at any time without penalty, and that their decision will not affect their healthcare or relationship with their healthcare providers.

☑ Yes ☐ No * Will the subjects be provided with a written statement regarding the study (e.g., information sheet)?

Submit copies of each information sheet.

Information Sheet Name	Description of Document	Clean Copy	Tracked Copy
MyHP-South Patient Information Sheet	Aim 2 Information Sheet for Patients		
MyHP-South Caregiver Information Sheet	Aim 2 Information Sheet for Caregivers		

☐ Request a Waiver or Alteration of some or all elements of informed consent or a FULL waiver of informed consent.

31. ATTACHMENTS

Attachments

Document Name	Document Type	Description of Document (50 words or less)	Clean Copy	Tracked Copy
Survey/Questionnaire	Data Collection	Aim 2_Caregiver Measure: Bakas Caregiver Outcomes (BCOS)		
Survey/Questionnaire	Data Collection	Aim 2_Patient Measure: CollaboRATE Scale Questions		
Survey/Questionnaire	Data Collection	Aim 2_ Patient Measure: Older Patient Assessment of Chronic Illness Care Scale		
Survey/Questionnaire	Data Collection	Aim 2_ Patient and Caregiver Measure: Shared Care Instrument		
Survey/Questionnaire	Data Collection	Aim 2_ Patient Measure: Treatment Burden Questionnaire		
Flyer	Participant Communications	Aim 1_Patient and Caregiver CAG Recruitment Flyer		

Flyer	Participant Communications	Aim 1_Clinician CAG Flyer		
Interview Guide	Data Collection	Aim 2_Patient and Caregiver Acceptability Interview Guide (Older Adult and Family Caregiver Dyadic Interview)		
Other Relevant Documents	Other	Aim 1_CAG Facilitator Guide		
Survey/Questionnaire	Other	Aim 3_Clinician Post-visit Survey		
Recruitment Letter	Participant Communications	Aim 2_Participant Opt-out Letter		
Other Recruitment Documents	Participant Communications	Aim 2_Participant Recruitment Text Message Script		
Other Recruitment Documents	Participant Communications	Aim 2_Data Collection Reminder Text Message Script		
Telephone Script	Participant Communications	Aim 2_Caregiver Telephone Recruitment Script		
Telephone Script	Consent/Assent Document (CF, AF, Info Sheet, Phone Script, etc.)	Aim 2_Patient and Family Caregiver Verbal Consent Script		
Protocol Oversight Review Form	IRB Submission Form	PORF for MyHP South		
Flyer	Other	Aim 2_ Participant Recruitment Flyer version 1		
Other Relevant Documents	Other	LOS for SIRB		
Telephone Script	Participant Communications	Aim 2_Patient Telephone Recruitment Script		
Survey/Questionnaire	Data Collection	Aim 2__Patient and Caregiver Measure: System Usability Scale		
Survey/Questionnaire	Data Collection	Aim 2_Patient and Caregiver Demographic Survey		
Other Relevant Documents	Participant Communications	Aim 2_Patient Clinical Visit Reminder Text		
Other Recruitment Documents	Participant Communications	Aim 3_Clincian Recruitment Email		
Other Data Collection Tools	Data Collection	Aim 3_ Clinician Post-visit Survey		
Other Data Collection Tools	Data Collection	Aim 2_ Staff MyHP South Timing Sheet		
Telephone Script	Participant Communications	Aim 1_Clincian CAG Inquiry Script		
Telephone Script	Participant Communications	Aim 1_ Patient Caregiver CAG Inquiry Script		
Telephone Script	Participant Communications	Aim 2_ MyHP South Session Telephone Scheduling		
Other Relevant Documents	Participant Communications	Aim 2_ MyHP South Session Text Message Reminder Script		
Telephone Script	Participant Communications	Aim 2_12-Week F/U Telephone Reminder Script		
Other Relevant Documents	Other	Aim 2_Paper-based MyHP-South Participant Materials		

Updated By: Deborah Blessing Ejem @ 14-Sep-2026 04:35:33 PM