D-HH IRB OVERSIGHT:

One of the following must be true in order to submit to the D-HH IRB. Please check all that apply:

☐ The Principal Investigator is employed by D-H
☒ The study will utilize any D-H data or specimens
☒ The study will enroll D-H patients or recruit from D-H sites
☒ The study will utilize any D-H resources, e.g. study procedures will occur at
☐ D-H locations and/or use of D-H equipment or shared resources

PROTOCOL TITLE:
The impact of sharing audio recorded clinic visits on self-management in older adults: a multi-site trial

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VERSION NUMBER/DATE:

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1.0 Study Summary

Study Title	The impact of sharing audio recorded clinic visits on self-management in older adults: a multi-site trial
Study Design	Multi-site, patient level, randomized controlled trial. The three sites are Dartmouth-Hitchcock Primary Care (D- H; Manchester, NH and Bedford, NH), Vanderbilt University Medical Center (VUMC; Nashville, TN), and University of Texas Medical Branch, (UTMB; Galveston, TX).
Primary Objective	To determine the feasibility of a multisite trial of audio-recording
Secondary Objective(s)	Gather preliminary data on impact on behavioral, health and health care utilization outcomes.
Research Intervention(s)/ Investigational Agent(s)	Audio-recording of clinic visit shared via HIPAA compliant website.
IND/IDE #	N/A
Study Population	Older adults (≥65 years) with diabetes mellitus (Type 1 or 2) and hypertension managed in an outpatient setting.
Sample Size	Aim 1: N=108 (30 patients and 6 clinicians per site) Aim 2: N=54 (6 trial patient-participants and 6 trial clinician-participants from each site total N=18 patients, N=18 clinicians and 6 caregivers of trial patient participants per site, total N=18-caregivers). In addition to this, we will plan to supplement our interviews with two additional Spanish language patient and caregiver participants at our UTMB site if participants wish to take part.
Study Duration for individual participants	3-4 months

Study Specific Abbreviations/ Definitions	

2.0 Objectives*

Aim 1. Conduct a multi-site, two-arm, parallel group, patient-randomized, blocked, controlled, pilot trial with 3-month follow up, to determine the feasibility and acceptability of sharing audio recordings of clinic visits (AUDIO) on self-management in older adults with diabetes and hypertension, compared to the after visit written summary (AVS) alone (Usual Care/UC). We will determine:

1.1 Feasibility of a larger trial by meeting recruitment targets at each site (n=30 patients and 6 clinicians per site; total N=108) and determining the optimal strategy to achieve a high retention rate and adherence to the study protocol.

1.2 Acceptability by assessing the proportion of patients and clinicians who agree to take part in the project and the proportion of patients who listen to the recording.

1.3 Potential effectiveness by collecting data on the impact of audio recordings on patient experience, understanding, self-management and clinician behavior. *We will explore our main hypothesis that compared to those receiving UC, patients randomized to also receive audio recordings (AUDIO) of clinic visits will report greater self-management (Patient Activation Measure – Short Form) at 3 months. We will also explore whether the effect of AUDIO on self- management compared to UC is greater for patients with low health literacy than those with high health literacy.*

Aim 2. Assess the acceptability of study protocol and the use of audio recording of visits as part of care by conducting semi-structured interviews with participating **clinicians, patients and caregivers** (i.e. person involved in the patient's care, including a family member, friend or formal caregiver).

We hypothesize that this multisite trial will be highly feasible and that recording and sharing of clinic visits will be highly acceptable.

3.0 Background*

3.1. Significance

Up to 80% of healthcare information is forgotten by patients *immediately* following a clinic visit.[1–4] Poor recall of medical information has been identified as a significant barrier to self-management, key to the Chronic Care Model.[5–7] This barrier is amplified in older adults with multimorbidity,[8–11] where reduced cognitive capacity,[12–14] low health literacy,[15,16] and complex treatment plans are common.[17–19] Older adults with multimorbidity account for 96% of Medicare expenditures, and in the absence of optimal self-management, they experience low quality of life and functional decline.[10,11,20–26] Yet,

when these patients are "activated," they recognize that they have an important role in self-managing their conditions and have the knowledge, skills, and confidence to do so resulting in better functional status and health outcomes.[27]

A written after-visit summary (AVS) is the current U.S. standard of addressing poor recall of visit information with the goal of improving patient's ability to self-manage.[28–30] The AVS includes information on diagnoses, medications, allergies, clinician visited, and visit summary recommendations.[29,31] While access to visit information is highly valued by patients,[30,32–34] several factors limit the usefulness of the AVS, such as the layout of information and the accuracy of the summary, resulting in confusion in patients and low AVS use.[30]

Audio recording of visits is a novel alternative that, in contrast to the standard AVS, provides a full detailed account of the clinic visit. Evidence suggests that sharing recordings can lead to greater patient recall and understanding of visit information[35–41] and is acceptable to clinicians and patients.[42–44] In our national survey (456 clinicians and 524 patients), 28% of clinicians reported having recorded a clinic visit for a patient's personal use at least once, while 18% of patients had recorded a visit for their own use at least once.[45] Clinics are becoming aware of the potential of sharing recordings of visits and some offer this to their patients.[44,46]

Despite their emerging use in clinical practice, we do not know the impact–positive or negative–of audio recordings on patients' self-management or other health-related outcomes: especially relevant to older patients with chronic disease where self-management is critical. To answer this question, we propose a multi-site pilot trial of older adults with diabetes and hypertension in preparation for a fully powered trial to evaluate the impact of augmenting the AVS with audio recordings of the clinic visit compared to the AVS alone (Usual Care; UC).

Consistent with *PA-18-376 Self-Management for Health in Chronic Conditions*, and aligned with *NIA Strategic Goal C*, our long-term goal is to improve patient health outcomes through better self-management. Our objective in the proposed project is to: (a) operationalize and determine the feasibility of a multi-site trial where clinic visits are audio recorded and shared with older adults with diabetes and hypertension; (b) gather preliminary data examining the impact of routinely adding audio recordings of clinic visits to UC on self-management ability; and (c) identify factors pertinent to the acceptability of our study protocol and the audio recording of visits. Hypotheses are based on our substantial preliminary work and supporting evidence from scoping and systematic reviews.[35–41]

3.2 Preliminary Data

Our research team has conducted substantial preliminary work in this area, highlighting the acceptability of recording, feasibility of our trial and scalability of recording in practice. We describe this work below.

3.2.1 The prevalence of clinic audio recording in the U.S. Our research group (MPIs Barr, Cavanaugh and Masel) conducted a cross-sectional survey of 456 U.S. based clinicians, using SERMO clinician panels, and 524 members of the U.S. public, using Qualtrics Panels with quotas based on U.S. census data for age, sex, education, language spoken at home, race and ethnicity.[45] As described above, a significant proportion of clinicians and the public have recorded or are willing to record clinic visits (see Section 3.6).

3.2.2 The routine sharing of audio recordings in America: a case study of clinics. Drs. Barr and Masel conducted a case study at three clinics that routinely share visit recordings: the Ryan Family Practice (Ludington, MI); the Barrow Neurosurgical Institute (BNI) (Phoenix, AZ); and the University of Texas Medical Branch (UTMB) Cancer Center (League City, TX). Seventy interviews were conducted with patients, caregivers, clinicians and administrators to understand implementation strategies, motivations, and recording use. Of the 34 patients and caregivers interviewed, 17 (50%) were ≥65 years, 28 (82%) reported listening to and 16 (47%) shared recordings. Major themes include the benefits of recording on patient understanding and recall, patient use of recordings to prepare for visits and greater engagement of caregivers. At BNI, clinicians who record now receive a 10% reduction in malpractice premiums and a $1 million increase in liability.[46]

3.2.3 "Taking the Message and the Medicine Home" program, UTMB, Galveston, TX. Dr. Masel led and coordinated the implementation of routine recording at UTMB beginning in 2010 with oncology outpatient clinics and breast health clinics. All patients in their first visit to the clinic are informed about recording and are offered a digital recorder. In 2017, a diagnosis code was added to the Epic EMR system to indicate when a patient records during the encounter. The system reports, in 2017, 1,100 unique patients' recordings.

3.2.4 Are patients allowed to audio record medical visits? The emergence of audio recording in clinic practice has raised questions about its legality. We published in *JAMA* an analysis of legal statutes related to recording.[46] Our analysis finds that patients recording clinic visits do not require clinician consent in 39 states and the District of Columbia (single party consent; including TN and TX), but they do require

consent in 11 states (all party consent; including NH). Health Insurance Portability and Accountability Act (HIPAA) regulations only applied to recordings that are owned by a health entity, not those that are owned by a patient.

3.2.5 Heart Sounds Pilot Trial. In collaboration with Dr. Bruce and Dartmouth CTSA support, Dr. Barr is currently leading a pilot trial to determine the acceptability and feasibility of sharing audio recordings of inpatient discharge instructions, compared toa written discharge summary (usual care), with cardiology inpatients (mean age: 67 years). This study mirrors the methods of the current proposal, including the approach to randomization, recruitment strategy, data collection procedures – however patients received a digital recorder. All eligible providers consented to take part in the project (N=6). We recruited 57 participants in 5 months (a recruitment rate of 56%) with an attrition rate of approximately 30%. The study protocol was administered with high fidelity.

3.2.6 Patient-Provider Communication in Patients with Diabetes and Depressive Symptoms. Dr. Cavanaugh led a project that included the audio recording of 95 primary care visits of adults with diabetes, evaluating the association between depressive symptoms and patient-centered communication.[47] Similar recruitment methods were used as in the current project. No primary care clinicians refused to participate. Procedures were developed to ensure integration into clinical practice workflow, including privacy protection of people in the clinic but not involved in the research study, and these will be applied in the current proposal.

3.2.7 Developing an audio personal health library (Audio PHL) for older adults with multimorbidity. We have developed an application that supports the recording of clinic visits, performs secure transfers of these recordings to a HIPAA-compliant server infrastructure at Dartmouth, and allows patient-participants to set up a password-protected account to listen, share and manage their recordings online (Barr, GBMF#4952, STUDY00030397, STUDY00030126; Barr, R01LM012815; STUDY00030531).[44] This system will be used in the current project.

3.2.8 Piloting of patient identification, recording strategies and data collection instruments. In preparation for this study, EMR reports were generated to estimate the number of patients meeting the study criteria on a weekly basis at each study site, demonstrating the feasibility of generating this report and confirming the pool of potential patients for our trial. All sites have experience in recording of clinic visits as described above. Across our study sites we conducted ten feedback sessions with clinical staff, leadership, and patients to guide study design and selection of recording device. We also piloted the proposed assessments with older adults (≥65 years).

Baseline assessment took approximately 20 minutes (n=12), provision of recording instructions took 10 minutes and follow up assessments by telephone (n=10) took 20 minutes.

4.0 Study Endpoints*

4.1 Primary endpoint

The primary endpoints of this pilot trial are:

1) Feasibility: We will determine the optimal strategy to achieve a high retention rate and adherence to the study protocol. We will also assess retention rates (proportion of included patients completing T2 follow up; we will target >70%), fidelity to the study protocol (Borrelli et al[48] criteria; we will target >90%) and the Feasibility of Intervention Measure[49] (FIM, 4 items, see Appendix 1. 3-month Follow Up Assessment (T2); we will target an average score of >3).

2) Acceptability: We will determine the acceptability of the AUDIO intervention and study protocol by assessing the proportion of patients and clinicians who agree to take part in the project and proportion of patients who listen to the recording. Our primary indicator of acceptability will be the recruitment of 108 participants (N=30 patients and 6 clinicians per site) over our planned data collection period of six months. We will determine the listening rates (we will target >70%): this will include the proportion of patients in the intervention arm that log in to the online system and listen to (and how often) the recording. We will also document the number of patients who share or report sharing the recording and caregivers who access the recording. Participants will complete the Acceptability of Intervention Measure[49] (AIM, 4 items, see Appendix 1. 3-month Follow Up Assessment (T2); target an average score of >3).

4.2 Exploratory endpoints

We will also gather data on exploratory endpoints. These are outlined in Table 1.

Table 1. Exploratory outcome measures and timing of data collection

Measure	**Description**	**Standard assessments***			**Corresponding Appendix**
		T0	**T1**	**T2**	
Exploratory outcomes					

Patient Satisfaction Questionnaire-18[50]M (S)[51]	18-item PROM of patient satisfaction with care, with seven domains.	**X**	**X**	**X**	Appendix 2
PAM-SF[52,53] (S)[54]	13-item PROM. Four domains: Patient: i) recognizes their role; ii) has knowledge and confidence; iii) takes steps to manage care; and iv) can manage care under stress	**X**	**X**	**X**	Appendix 2
Medical Outcomes Study General Adherence measure [55–57](S)[51]	Five-item PROM of patient adherence to treatment.	**X**		**X**	Appendix 2
Adherence to Refills and Medications (ARMS- 7)	Seven-item PROM of medication adherence.	**X**	**X**	**X**	Appendix 2
Global PROMIS[58] & EURO-QOL[59] (S)[60]	10-item PROM of mental and physical health. Scores can be converted to EURO-QOL scores.	**X**	**X**	**X**	Appendix 2
Patient Health Questionnaire (PHQ-8)	Eight-item PROM of depression	**X**		**X**	Appendix 2
Generalized Anxiety Disorder (GAD-7)	Seven-item PROM of anxiety	**X**		**X**	Appendix 2
Comprehensive Diabetes Stigma Scale (CDSS-15)	15-Item PROM of diabetes-related stigma	**X**		**X**	Appendix 2
Stigma Scale for Chronic Illness (SSCI-8)	Eight-item PROM of stigma related to chronic illness	**X**		**X**	Appendix 2
ER visits & hospitalization	ER visits and hospitalizations abstracted from the EHR during the study period.			**X**	

Health services utilization	Health services utilization including primary care contacts (e.g., phone calls and visits) and visits to specialists (e.g., endocrinology, nephrology and ophthalmology), abstracted from the EHR during the study period.			**X**	
Quality of diabetes care	Proportion of patients receiving guideline-concordant care in line with Standards of Medical Care in Diabetes (e.g., A1c, urine albumin, referral for retinal exam, and in those with HbA_{1c} > 8% we will collect data regarding intensification of medication therapy)	X		**X**	
Quality of hypertension care	Proportion of patients receiving guideline-concordant care in line with Standards of Medical Care in Hypertension			**X**	
T0 (Baseline Assessment; pre-visit); T1 (1 week); T2 (3 months); from enrollment; **PAM-SF** (Patient Activation Measure Short Form); Global Patient-Reported Outcome Measurement Information System (**PROMIS**); **QOL** (Quality of life); **ER** (Emergency Room). (**S**) Spanish language; **PROM** (Patient Reported Outcome Measure). **Note: the Interpersonal Process of care (**IPC) survey will be administered after T0 in clinic (or at T1 if not yet completed) AND within 7 days of interim scheduled clinic visits (Tx) during the data collection period.					

5.0 Study Intervention/Investigational Agent

5.1 ***Usual care (UC)****:* During the trial, patients will receive the AVS per the current standard at each site. The AVS is similar at all sites, as each clinic uses EPIC, and includes information such as clinician comments, diagnoses, orders and results. It is available both in paper and via the patient portal

5.2 ***Audio Intervention:*** We will audio record both in-person and telehealth visits of patients in the intervention group. For in-person visits, the RA will follow standardized instructions demonstrating how to start and stop the recording on the electronic tablet with patients and ask patients to demonstrate to confirm understanding. The RA will then enter the exam room and begin the recording with the patient's permission, after the medical assistant has completed rooming the patient and before the clinician enters. The patient and clinician can choose to stop or start the recording at any time and a sign on the door will indicate "Recording in Progress". The RA will wait outside the visit room. Once the visit is complete, the RA will enter the room, turn off the recording, and bring the patient to a private room where the RA will follow standardized instructions demonstrating how to access recordings.

Telehealth visits may be recorded in two ways. 1) the RA will meet the clinician in the private room where the visit will take place, and follow standardized instructions demonstrating how to start and stop the recording on the electronic tablet with the clinician and ask the clinician to demonstrate to confirm understanding. The RA will then begin the recording with the patient's permission. A sign on the door will indicate "Recording in Progress". The RA will wait outside the visit room. Once the visit is complete, the RA will enter the room and turn off the recording. 2) The RA will receive a link to the telehealth visit. They will join the visit at the time it is due to begin. The RA will inform the patient and clinician that the visit will be recorded and will notify them once the recording has begun. The recording will be captured directly in to HealthPAL and a digital back up will also be used.

In both instances the patient and clinician can choose to stop or start the recording at any time by indicating this to the RA or stopping the recording device directly *(e.g. where RA is outside of the room)*. The RA will schedule a time to meet with the patient via web conference, by phone or in person separate from the clinic visit, during which the RA will follow standardized instructions demonstrating how to access recordings. Pre- and post-visit surveys will be administered remotely, by email or telephone, for patients having telehealth visits.

The research team will maintain a copy of all recordings locally on a secure, HIPAA

compliant server, captured by a second recorder, which will also serve as a back-up; once transferred to the server, the recording will be deleted from the digital recorder. Patient **access to recordings** will be possible via a secure web-based platform: HealthPAL.

> HealthPAL. All patients with access to email will be able to access their recording online. The recording and sharing of the recorded data will be facilitated via HealthPAL, an online platform developed by PI Barr at Dartmouth (Appendix 4. HealthPAL system). The RA will register the patient in the HealthPAL system. Within the system they can record visits, which can then be accessed later online at home. The RA will demonstrate how to access and playback the recording on a computer or smartphone using each patient's unique login information. Access details (web address, login and use instructions) will be shared with patients both by email and on paper.
> HealthPAL is a web application that runs on Amazon's cloud infrastructure (AWS). The root account under which the application is hosted is owned by Dartmouth College, which has a Business Associates Agreement (available upon request) in place with Amazon for the use of Amazon's HIPAA-eligible cloud services with Protected Health Information. All cloud services used by HealthPAL are covered under this agreement (Appendix. 5 HealthPAL security document).

5.1.1 Listening regime: We will instruct patients to listen to their most recent recording both within 24 hours after their visit (as a means to reinforce and recall self-management information discussed), at one week (to reinforce learning) and within three days prior to their next visit (to identify information that needs clarification or goals of care they would like to raise with their clinician). A reminder to listen to the recording will be sent to patients by email and/or text message (Appendix 24. Patient HealthPAL Reminder Emails). Patients will have the option of providing the contact information (email) of a family member, or caregiver who typically assists, or is involved in their care, and the study team will send this person access to the recording via the website.

*5.1.2 Recording future visits***:** The RA will review the EMR of participants and document in REDCap scheduled patient visits (up to 6 months from recruitment). For patients in the AUDIO group, the RA will also attend each visit and assist with recording as described above, and administer the IPC survey post visit. While patients in the UC group have no further in clinic procedures following baseline assessment, we will plan to attend these visits when possible and offer participants the opportunity to complete the IPC survey post visit. We anticipate that patients will have one additional scheduled clinic visit over the 3-month period based on the average number of visits of these types of patients estimated from EMR data at each clinic site in 2017. We will neither record nor conduct follow-up assessments of unscheduled/urgent or acute visits so as to

minimize burden on both participants and study staff.

5.3 ***Device Handling***. An electronic tablet will be used to record clinic visits. By using the recording platform developed by PI Barr, the actual recording will be automatically transferred to the cloud and not stored locally on the electronic tablet, reducing the risk of data loss in the unlikely event the electronic tablet is lost. The electronic tablet will be maintained by the research staff, before and after clinic visits. It will be password enabled and will be clearly marked as property of the study team. When not being used to capture recordings in the clinic, the electronic tablet will be stored securely in the office of the research coordinator at each site.

6.0 Procedures Involved

Study Design: We will conduct a multi-site, two-arm, parallel group, patient-randomized, blocked, controlled, pilot trial with 3-month follow up, to determine the impact of sharing audio recordings of clinic visits (AUDIO) on self-management in older adults with diabetes and hypertension, compared to the AVS alone (Usual Care). We will recruit 108 adults (30 patients and approximately 6 clinicians per site), ≥65 years with diabetes and hypertension over a recruitment period of 3 months. We are primarily interested in determining the feasibility of the trial and acceptability of the AUDIO intervention. We will also explore the impact on the patients' ability to self-manage their care as well as exploratory outcomes, at baseline (T0 = pre-visit) and at regular intervals from enrollment (T1 = 1 week, T2 = 3 month). We will also adhere to the CONSORT Statement extension to randomized pilot and feasibility trials during the trial, publish a study protocol and register the study on ClinicalTrials.gov.[62] Our decision to use a patient level randomized trial design is justified for several reasons: 1) randomization reduces the impact of selection bias and confounding; 2) the risk of contamination is low as audio recordings will be reviewed outside of the clinic and the information will be unique to the each patient; 3) individual-level randomization is more efficient than cluster (e.g. clinic) randomization; 4) the use of blocking further improves the statistical precision of results by ensuring that the key characteristics are balanced across treatment groups, avoiding reliance on statistical models to adjust for any imbalances and 5) we will set up routine evaluations of key operational features of the study design e.g., recruitment rates, intervention use, fidelity - determining the need to make changes/refinements to study procedures throughout the trial.

6.1 ***Randomization process****:* Patients will be randomly allocated to AUDIO or UC alone using a block-randomization technique with the clinician acting as the blocking variable. Blocks of 2 patients per clinician will be generated to ensure an equal number of patients per clinician will be randomly assigned to the AUDIO and UC arm. The

project coordinator at Dartmouth College will prepare and send recruitment materials to each site prior to the beginning of data collection and will prepare the randomization sequence in REDCap. Upon completion of pre-visit baseline assessment (T0), the RA at the study site will reveal the participants group allocation using the randomization feature in REDCap. Patients will be offered an AVS per the usual practice at their clinic, either on paper or via patient portal, but only patients in the AUDIO arm will receive access to audio recordings from the RA to review online at home. The randomization process will be operationalized and supervised by study statistician (Co-I O'Malley).

Study procedures: All participating patients and clinicians will provide informed consent. Clinicians will proceed to complete a brief demographic survey. Patients will proceed to complete the pre-visit baseline assessment surveys. The baseline assessment will be administered in a private area of the waiting room in the clinic, private research office, or an available exam room. Patients will also have the option to complete baseline assessment online in REDCap or over the phone with research staff prior to the clinic visit if they opt for eConsent. We have piloted the administration of the patient surveys with older adults aged 65 or older and estimate that completion will take 20 minutes. After completing the pre-visit baseline assessment, patients will be randomly allocated to AUDIO or UC alone, and informed of which group they have been assigned to. If patients are unable to complete pre-visit surveys prior to meeting with the clinician due to time constraints, the surveys may be completed after the visit. Patients meeting the clinician in person will then be escorted by the RA to the vital sign area to meet a medical assistant and/or back to the waiting room.
Patients randomized to the AUDIO group will have their visit recorded using an electronic tablet; a second study recorder will also be used and act as a backup in case the primary recorder fails. For participants in the AUDIO arm, a sign will be placed on the clinic room door by the RA alerting others that a recording is taking place (see Appendix 6. Recording Sign). Upon completing their visit the RA will demonstrate to patients how to access their recording (see Appendix 7. HealthPal Instructions), and administer the post-visit baseline assessment survey items, specifically the PHQ-8 and GAD-7 surveys, and the Interpersonal Processes of Care Survey (IPC). These tasks may take place in clinic for patients having an in-person visit, or remotely by web conference, telephone, and/or email, for patients having a telehealth visit. Patients will identify times and days that are most convenient for follow up assessments, as well as contact information of a person who could be reached in the event they are unreachable. Patients will receive honorariums to promote retention; a thank you note will be mailed with $30 (gift card, egift card, or site-specific payment method such as Greenphire) following recruitment and $20 (gift card, egift card, or site- specific payment method such as Greenphire) upon completion of each follow-up assessment.

6.2 ***Monitoring, tracking, and retention***: RAs will receive standardized training on how

to collect data during a two-day 'kick-off' training session prior to patient recruitment. Study data will be directly inputted to electronic surveys using REDCap, providing an opportunity to prevent and monitor missing data. At recruitment, the RA will ask patients for an email and phone number to conduct follow-up assessments (by email and/or telephone calls), and to provide contact details for another person if they cannot be reached for follow-up. Follow-up contact attempts may be made by telephone, email, or post, but will be limited to no more than one attempt per day, for up to two weeks from planned T1 assessment, and three weeks from planned T2 assessment. Patients who cannot be reached by telephone will be approached in the clinic to determine their desire to remain in the study and complete follow-up assessments. or document reason for withdrawal if they do not wish to remain. All attempts to contact patients will be documented in REDCap. We will also conduct weekly workbench reports from the EMR to confirm scheduled visits of recruited patients during the follow-up period.

6.3 ***Description of what research material, data, and information will be collected:***
Data will consist of written and audio information. Where possible, we will use item phrasing compatible with items from the Common Data Elements (CDEs) database. Data will be collected by RAs at each study site using REDCap, transferred and stored centrally in a REDCap database at Dartmouth College. We will collect information on recruited patients from several sources:

The electronic medical record (EMR): We will collect information on patient demographics (age, sex) and contacts (address, telephone, email), primary language spoken, the number and type of patient conditions, current treatment (e.g., medication), laboratory tests (e.g., urine albumin, blood pressure, HbA_{1c}) number of clinic visits and contacts (e.g. phone calls, patient portal emails), and emergency room visits and hospitalizations. Baseline laboratory tests may be collected as much as 12 months prior to the T0 (baseline) timepoint, as certain tests (e.g., urine albumin and HbA_{1c}) are routinely done on a yearly basis.

Patient reported: We will collect the following information from patients: demographics (age, sex, race, ethnicity, language spoken at home, and educational attainment), cognitive function (Six Item Screener scale)[63], the Short Assessment of Health Literacy (SAHL-E)[64], brief health literacy screen (BHLS)[65,66], Patient Health Questionnaire(PHQ-8)[67], Generalized Anxiety Disorder (GAD-7)[68] the Patient Activation Measure – Short Form (PAM-SF)[69], an assessment of mental and physical functioning (PROMIS)[58], an assessment of Quality of life (EURO-QOL)[59], an assessment of satisfaction with care (PSQ-18)[50], clinic visit process (Interpersonal Process of Care)[61], comprehensive diabetes stigma scale (CSSS-15)[70], Stigma Scale for Chronic Illness (SSCI-8)[71], and treatment adherence (Medical Outcomes Study General Adherence measure[55–57]; ARMS-7[72]).

Assessments: A trained RA will collect data (**T0**= Baseline Assessment) by electronic tablet or by paper form if preferred by the patient prior to the visit. Patients who complete eConsent can also complete the baseline assessments via REDCap prior to the clinic visit. The PHQ-8 and GAD-7 will be administered after the clinic visit. Follow up is planned by email (Appendix 25 for the REDCap Survey Template) or telephone at **T1**= one week, **T2**= three months. For T1, the allowable window is up to two weeks from the scheduled timepoint. For T2, the allowable window is up to three weeks from the scheduled timepoint. Deviations from the follow up strategy (e.g., a patient who completes an assessment outside of the planned follow up window) will be reported to the IRB. No participant identifiers will be included on the labeling of study data. Study Unique ID code numbers instead of names will be used on participant materials, data and data-collection instruments to minimize risks regarding breach of confidentiality.

Patients will receive a printed schedule of follow-up assessments, tailored to times and days convenient to them.

Outside of the standard study follow up assessments, the patient will be met in clinic or contacted by email or telephone one week from any scheduled visit with a participating clinician to assess intervention use (AVS or AUDIO) and interpersonal processes of care (IPC) survey (immediately following the clinic visit, or within 1 week of the visit by email or telephone with the RA).

6.4 ***Outcomes:*** Our primary and exploratory outcome measures are outlined in Section 4.2 Table 1.

6.4.1 Covariates: Demographic information (age, sex, race, ethnicity, language used at home, educational attainment using categories from the 2016 American Community Survey) will be collected by the RA through patient report at enrollment. We will document if a caregiver (a support person, family member or friend) is present at the visit. We will collect demographic and practice information about participating clinicians including their age, sex, race, ethnicity and years in practice. The following covariates will be examined in our exploratory moderator analysis:

Health literacy: We will use two assessments, the 3-item validated Brief Health Literacy Scale (BHLS) and the 18-item validated Short Assessment of Health Literacy (SAHL-E). Both scales are validated in English and Spanish. Scores on the BHLS range between 3 and 15, with higher scores indicating higher subjective health literacy. Scores on the SAHL-E range from 0 – 18; ≤14 is considered low health literacy

Disease burden: The Charlson Comorbidity Index (CCI)[73] using EMR data. Each condition is assigned a score, based on risk of death, which is summed, with higher scores indicating higher disease burden.

Depression: The eight-item PHQ-8 validated in both English and Spanish. Scores range from 0 – 24; a score ≥10 indicates major depression, and a score of ≥20 indicates severe major depression.

Anxiety: The seven-item GAD-7 validated in both English and Spanish. Scores of 5, 10, and 15 represent cut points for mild, moderate, and severe anxiety, respectively.

Diabetes Stigma: The comprehensive diabetes stigma scale (CSSS-15) is a validated 15-item assessment of diabetes-related stigma. It is composed of four subscales: (1) enacted (0-6), (2) perceived (1-5) and (3) self-stigma(1-5), and (4) concealment (1-5). Subscale scores are means of responses, and an overall score is the sum of all items (11-96).

Stigma of Chronic Illness. The Stigma Scale for Chronic Illness (SSCI-8) is validated, eight-item assessment of stigma related to chronic disease. It is scored from 8 (low stigma) to 40 (high stigma), and can be converted on to a standardized T-distribution score with a mean of 50 and standard deviation of 10.

Audio & AVS Use: Intervention use by patients will be monitored within the HealthPAL application: we can determine when a **1.** patient logs into their account; **2.** listens to a recording; and **3.** shares the recording. AVS use will be assessed at standard outcomes assessments and one week from scheduled clinic visit during the data collection period: we will determine whether the patient reviewed the AVS and whether they shared it.

6.8 Debrief interviews (Aim 2): Upon completion of the data collection for Aim 1, we plan to enroll participants for Aim 2. We will evaluate the acceptability of our study protocol and AUDIO intervention, barriers and facilitators to implementation of audio recordings through semi-structured interviews with patients, caregivers of intervention arm participants (a person who assists with the patient's care e.g. family member, friend) and clinicians at the three study sites: Dartmouth-Hitchcock Primary Care (Manchester, NH and Bedford, NH), Vanderbilt University Medical Center (Nashville, TN), and University of Texas Medical Branch, Internal Medicine - Geriatrics Clinic (Galveston, TX). We will select a sample of trial patient-participants (N=6), caregivers of intervention arm participants (N=6) and clinicians (N=6) at each site, for a total of 54 participants (18 patients, 18 caregivers, and 18 clinicians). In addition to this, we will plan to supplement our interviews with two additional Spanish language patient and caregiver participants at our UTMB site if the participants wish to take part. Given estimates that thematic saturation typically occurs between 12-18 interviews, we expect that our sample size for each stakeholder group (patients, caregivers, clinicians) will be adequate to achieve saturation of key themes.

Study procedures: Interview procedures will be similar across the stakeholder groups.

When permission is granted, interviews (phone calls or in-person) will be conducted in a private area by a Research Assistant trained in qualitative methods and supervised by Dr. Carpenter-Song. Interviews are expected to be 20-30 minutes in duration. Interviews will be recorded using a digital recording device. These recordings will then be transcribed. When consent for recording is not granted, we will proceed with the interview and take detailed notes. If patients cannot be reached via telephone, an effort will be made to meet the patient at their next scheduled appointment to determine interest in continuing to that part in the project.

and Specimen Banking*

a storage and sharing plan

The Dartmouth Institute for Health Policy & Clinical Practice has a rich tradition of making final research data available to the public. The posting of all final data from the Dartmouth Atlas of Healthcare is perhaps the best example of this institutional commitment to reinforcing open scientific inquiry, encouraging diversity of analysis and opinion, promoting new research and critical review, and facilitating alternative analyses of datasets used in our published work. In keeping with our institutional policy for collaborating with the broad scientific community in the interest of advancing health and health care, we will publish results from this research work in peer-reviewed medical, economic and health policy journals. We will make analytic code and variable creation and restructuring de-identified information publicly available through the Dartmouth website (https://dataverse.dartmouth.edu).

In addition to the study-specific sharing plan outlined above, Dartmouth maintains the following universal data sharing policy for all investigators:

1. Data will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing) to all researchers in both the private and public sector free or for a nominal charge and with minimal restriction. In some cases the Trustees of Dartmouth College (the institution) may determine that the public and the research community are better served by a licensing program whether or not patents have been filed.

2. So that the entire research community can benefit from the data generated by the institution, pending third parties rights, the institution will transfer materials to outside researchers under Material Transfer Agreements (MTAs) generated and monitored by Dartmouth's Technology Transfer Office. Such MTAs will be made with no more restrictive terms than the Simple Letter Agreement (SLA) to non-profit institutions or the Uniform Biological Material Transfer Agreement (UMBTA) to for-profit ones.

   Generally, the MTA will also include a requirement that new data developed by

recipients of the tool becomes a part of publicly available data.

As a means of sharing knowledge, NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals, registered in PubMed Central database of the National Library of Medicine. Awardees therefore will strive to publish their findings in a timely manner and acknowledge that the research was supported by the NIH. Brief delays in publication may be appropriate to permit the filing of patent applications and to ensure that confidential information obtained from industrial collaborator is not inadvertently disclosed. However excessive publication delays, requirements for editorial control or withholding of data undermine the credibility of research results and would be unacceptable to the institution.

8.0 Sharing of Results with Subjects*

We plan to share a summary of results and next steps by email/post to all participants at the completion of data analysis.

9.0 Study Timelines*

Upon Notice of Grant Award (Year)	1				2			
Quarters	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Protocol & Consent Document Development								
DSMB and sIRB Approval								
Protocol Registration on ClinicalTrials.GOV								
Submission & Final Approval of Documents to IRBs								
Data & Safety Management Tasks								
Staff Training (two day kick-off meeting)								
Facility Site Preparation								
Site Activation Checklists Complete								
Recruitment and Enrollment								
Outcome Assessment								
Participant Interviews								
PI site meetings								
DSMB Annual Review								
Data quality checks and cleaning								
Data Analysis								
Dissemination Meeting								
Manuscripts and Reports								
R01 submission								

10.0 Inclusion and Exclusion Criteria*

10.1 Inclusion / Exclusion criteria (Aim 1 Trial)

Inclusion criteria (Aim 1): Inclusion criteria will be assessed by the RA by using the EMR to identify potential eligible patients followed by a telephone screening assessment (SA). We will include patients who are (1) ≥ 65 years (EMR abstraction); (2) with diabetes and hypertension and receiving medication for each (EMR abstraction); (3) have had one or more clinic visits in the previous seven months (EMR abstraction); and (4) plan on receiving ongoing care at the clinic for the subsequent 6months (SA). By selecting patients who have ≥ 1 visits in a seven-month period, we define a population who may require regular management and have a greater opportunity to benefit from visit recordings. We will only include patients of clinicians (MDs, NPs) who (1) are based at the study clinic; (2) who treat adult patients. Clinic leads have presented the project to clinical teams and confirmed willingness of clinicians to take part.

*Exclusion criteria (Aim 1)***:** We will exclude patients (1) without capacity to consent to the project (SA) (2) with dementia, schizophrenia and other psychotic disorders, substance-use disorders, uncorrectable hearing or visual impairment (EMR abstraction) or a six item screener (SIS) cognitive function score ≤ 4 as this indicates significant cognitive impairment (SA); (3) living in skilled nursing homes or hospice because they engage far less in self-management (SA); (4) patients who have audio- recorded a clinic visit for their personal use in the previous six months (SA); (5) patients who do not have their diabetes and hypertension medication managed by the study clinician; and (6) patients who (a) do not have access to a personal email, (b) do not have an email address shared with a family member or patient-identified caregiver, and/or (c) are not interested in creating an email account between the time they are first contacted by the study team to the time that the study team requires an email address to initiate the online recording software registration. The SIS of cognitive function is validated for use with older adults and highly correlated with Mini-Mental State Exam (MMSE). Study clinicians will be notified in-person, by telephone, or by site-specific secure communication method of any patients with a six item screener (SIS) cognitive function score ≤ 4, in order to alert them of a potentially clinically-significant finding which may require follow up. We will exclude clinicians who (1) are trainees, e.g., medical students or residents; or (2) commonly audio or video record clinic visits for patient's personal use.

10.2 Inclusion / Exclusion Criteria (Aim 2 Debrief Interviews)

10.2.1 Inclusion/Exclusion Criteria (Aim 2)

Patients: We will recruit a purposive sample of patient-participants from Aim 1 based on recording use (listened to none, one or all recordings; shared recording or not) and health literacy [SAHL-E score ≤14 (low health literacy) or >14 (high health literacy)].

Caregivers: Patients will identify family members / caregivers who are 1) ≥18 years ofage, 2) who can communicate in English or Spanish; and 3) have received access to the patient's audio recordings.

Clinic staff: We will include healthcare professionals and administrators who have been involved in the trial at each site including MDs, NPs, Nursing Staff, Medical Assistants, and Administrators.

11.0 Vulnerable Populations*

- *N/A.*

12.0 Local Number of Subjects

A total of 30 patients and 6 clinicians will be recruited at each site (N=108). Based on prior work, we anticipate that a total of 60 patients will be approached to reach a sample of n=30 eligible patient participant patients at each site.
Hertzog[74] estimated that a sample of 10 – 40 participants is adequate to detect feasibility issues and gather preliminary outcome data in a pilot project. With 30 patient participants and 6 clinicians per site (total sample, n=108) we will be able to estimate the operating diagnostics of a future study (e.g., retention rates) and approximate effect sizes with a satisfactory level of precision to 1) determine if a future study is feasible and 2) be able to accurately inform power and sample- size calculations for the future study. We are not powered to detect significant differences in outcomes.

13.0 Recruitment Methods

13.1 Recruitment procedures (Aim 1 Trial)

Identification of participants (Aim1): A standard procedure will be enacted at all study sites. We will identify a cohort of potentially eligible patients who have planned clinic visits with study clinicians. In line with privacy guidelines we will initially use the site-specific Data Warehouse which will identify potentially eligible patients of study clinicians who meet preliminary inclusion criteria, including age (≥65 years) and diagnosis of hypertension and diabetes. Additional study data will also be extracted including: patient contact information (name, telephone - cell and home, email address, home address), sex, primary language spoken, existing diagnoses (dementia, Alzheimer's, Schizophrenia or other psychotic disorder, substance use disorder, deaf, blind), Charlson Comorbidity Index (each condition contributing to Charlson: present/absent), number of visits to study clinician in prior 7 months, scheduled visit dates in upcoming 6 months with study clinician, and current medications. We will also

use the workbench feature of the Electronic Medical Record in order to generate lists of potential patients of study clinicians, and to check scheduled visits for recruited patients. A waiver of HIPAA Authorization has been applied for with the D-H Privacy Office. An RC in clinic, fluent in English (and in Spanish at our UTMB site where there is a significant portion of patients with Spanish as their preferred language), will review the scheduled appointment list for each upcoming month period from the EMR for patients who meet provisional eligibility criteria. This information will be transferred to a local REDCap Recruitment database for each site, which will only be accessible to IRB approved research staff at those sites. A list of potentially eligible patients will be sent to the study clinician for review, to ensure that they manage the patient's hypertension and diabetes medication. The study clinician will indicate any patients who do not meet the inclusion/exclusion criteria. Potentially eligible patients will receive a letter, signed by their clinician, informing them about the project, that they may be contacted by a member of a research team and offering them the opportunity to opt-out (by email or telephone). No less than two weeks after letters have been sent, an RA will contact patients by telephone to gauge their interest in the project. Patients will be given a number and email address to opt out of receiving a call. For those receiving a telephone call, the RC will briefly describe the project to the patient (Appendix. 9 Telephone Patient Recruitment Script): (1) their clinic visits during the study will be audio- recorded if they are randomly allocated to the AUDIO group for 3 months, or that they will continue to receive UC (an AVS); and (2) there will be a standard follow-up assessment for all study participants via telephone call or email at 1 week, and 3 months; additionally within one- week after any scheduled visit during the 3 month study period, the Interpersonal Processes of Care (IPC) Scale will be administered. Importantly it will be emphasized that willingness to get involved in the project will not affect their care and that no providers in the clinic are opposed to their patient participation. Interested patients will be asked screening questions to establish eligibility. We will gather minimal data on patients who fail screening (demographics, eligibility criteria failed). Patients who are eligible will be asked to arrive at clinic 30 minutes before their scheduled visit and will be reminded that the early arrival will not be indicated in appointment date/time reminders or MyChart/MyDH/MyHealthAtVanderbilt appointment times. Patients will also be sent a reminder letter/email/phone call prior to their scheduled visit (Appendix 10. Appointment Reminder Letter) and will also have the opportunity to complete eConsent and baseline assessment prior to the clinic visit (see Section 22).

Identification of clinicians (Aim1). Under the guidance of our clinic leads ([redacted]) clinicians (MDs, NPs) have demonstrated an interest in taking part inthe proposed project. Before the study commences, clinicians will receive an email fromPI Barr (Appendix 21. Clinician Aim 1 Recruitment Email) and be invited to learn about the purpose of the study in a large group setting (routine conferences attended by associate providers, fellows and

attendings and nursing staff meetings) or one-on-one including acknowledgment of support to conduct the study from clinic leadership and the intent to audio-record and share their clinic visits with patients. An opportunity to ask and answer questions about participation in the study will be provided.

We aim to recruit a minimum of 3 - 6 clinicians prior to the initiation of patient recruitment who will participate in both arms of the study. We will document the number of providers who are offered enrollment and the number who consent to participate in audio recordings. For clinicians who decline to participate in the study, we will anonymously document reasons for their refusal in a REDCap database. At the time of enrollment, we will ask providers to provide demographic information via survey including age, sex, race, ethnicity, years in practice and specialty (Appendix.11 Clinician Demographic Survey). Clinicians who enroll in the study will be offered the opportunity to participate in a brief semi-structured interview about their experience with recording when patient enrollment is complete (Appendix 12. Clinician Interview).

13.2 Recruitment procedures (Aim 2 Debrief Interviews)

All interviewees will be recruited after their involvement in Aim 1 activities to eliminate the possible impact of the interview on outcomes.

13.2.1 Patients: We will recruit a purposive sample of patient-participants who completed research activities in Aim 1 based on audio recording use and health literacy. At T2 follow up, the RA will assess the participant's interest in taking part in an interview about their experience with audio recordings. A list of patients who are interested will be compiled, from which we will identify patients to interview stratified by recording use and health literacy.

We will use the generated lists to identify potential patient interviewees. We will call by telephone or send a letter informing them that they have been selected for an interview. If a letter is sent, it will be followed by a telephone call to confirm interest and arrange a time and place to conduct the interview(Appendix 13. Patient Interview Guide). People interested in participating will meet with the research assistant at the clinic, office, or by telephone or videoconference to complete (Appendix 13b Patient Consent Form)

13.2.2 Caregivers: During telephone calls to patients from the AUDIO group, the RA will also explain that we would like to conduct interviews with caregivers who have received or listened to recordings from the patient. If the patient is willing to share the contact information of a caregiver (family member, friend) we will then contact them by a telephone call. We will inform the caregiver that the patient has given us permission to contact them about their experience using the recording. We will generate a list of interested caregivers stratified by recording use.

For caregivers, we will use the generated lists to identify potential interviewees. We will send a letter informing them that they have been selected for an interview, followed by a telephone call to confirm interest and arrange a time and place to conduct the interview (Appendix 14. Caregiver Interview Guide). People interested in participating will meet with the research assistant at the clinic, office, or by telephone or videoconference to complete (Appendix 14b. Caregiver Consent Form). A follow up call will be conducted with all caregivers who took part in an interview in order to obtain demographic information (Appendix 33. Caregiver Demographic Script).

13.2.3 *Clinical staff*: Clinical staff who took part in the project will be contacted by email by the site RA and invited to take part in an interview at a time convenient to them. Interested clinicians will meet with RA to complete informed consent.
In all instances, participants will be offered a $30 honorarium for taking part in an interview.

14.0 Withdrawal of Subjects*

Any participant can discontinue participation at any time. An investigator may also discontinue or withdraw a participant from the study for the following reasons: 1) disease progression which requires discontinuation of the study intervention, or 2) if the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation. The reason for participant discontinuation or withdrawal from the study in either case will be recorded on the Participant Withdrawal Case Report Form (Appendix 15. Participant Withdrawal Form).

15.0 Risks to Subjects*

The risks associated with participation in the project activities are deemed to be low and are outweighed by the potential benefits. Before data collection starts, all study personnel will be required to undertake appropriate CITI coursework, including, but not limited to, HIPAA training and Good Clinical Practice. The MPIs and research staff will meet weekly by teleconference, from the time of study award, to plan protocol implementation at each site. In month six, a two-day ‘kick off’ training event will be hosted at Dartmouth College, and all study team members will join in person and/or virtually. During this training event, we will review and train research coordinators and assistants in all aspects of the study protocol including identification of patients, screening administration, recruitment and consent, survey administration and follow-up calls/emails and plans for unexpected events. Additionally, patient recruitment will not begin until the clinical trials office at each site approves the study binder containing IRB approved protocol, surveys, protocol checklists, staff training and CITI certifications, and the trial is registered on ClinicalTrials.gov. The following sections provide a detailed overview of our specific efforts to minimize risks including risks to privacy and

confidentiality:

1. Information on eligible patients collected at each study site prior to consent will only be shared with Collaborative Institutional Training Initiative (CITI)-trained researchers from Dartmouth College, UTMB Health and VUMC, and will be stored securely on the HIPAA-compliant REDCap database. Names and contact details of patients who decline to take part in the study will be stored until recruitment is completed, to ensure the patient is not contacted to take part again. Following the completion of recruitment, we will immediately delete their information from the database.
2. We have consulted with research and privacy officers who have approved our proposed research, including the recording and sharing of clinic visits with patients. Patients will provide written consent for our research team to maintain a copy of all recorded clinic visits. The storage of all patient information collected for this project, including audio-recordings will be stored in HIPAA-compliant server (audio recordings), and REDCap database (all study data and audio recordings) housed in the Geisel School of Medicine, Dartmouth College. An additional copy of the study data and audio recordings may be housed securely at each participating site.
3. Steps taken to reduce the possibility of recruiting individuals with significant cognitive deficits: 1) a trained research assistant will review the medical record – individuals meeting any exclusion criteria will not receive a telephone call; 2) a trained Research Coordinator will administer a cognitive assessment using the validated Six Item Screener of Cognitive Function (SIS); and 3) the clinician may choose to exclude a patient due to significant cognitive deficits. Should a clinician choose to exclude a participating patient due to the development of significant cognitive deficit (or one of the other exclusion criteria) during the 3-month follow up, we will document this and the patient will be thanked and informed both in person and by mail, that participation in the project is complete.
4. Both in-person and telehealth clinic visits in each primary care setting happen in a private room. We will place a sign on the door of the consultation room indicating a recording is currently taking place and that those who enter may be recorded (see Appendix 6. Recording Sign). At any time, the clinician or patient may choose to pause the recording. In the case a medical translator is needed to support the visit, this will be identified ahead of the patient visit by the RA. The translator will be informed that the patient is participating in a research project where the clinic visit is being recorded and their consent (written or verbal) will be sought. This strategy has been used successfully at UTMB where visits at the cancer clinics are audio recorded and in our recently completed pilot

trial at Dartmouth Hitchcock Medical Center, Heart Sounds. In the unlikely situation that a translator is uncomfortable, a new translator for the patient will be sought prior to the visit.

5. It is extremely unlikely that an audio recording will be posted to social media or used as part of legal proceedings. Such events have not been documented during our previous studies. However, should either event occur we will follow these processes:
Social media post. While the study team is not monitoring participants' social media, in the event that the study team are informed that a patient has 'posted' an audio-recording created for the proposed study on a social media website the patient will be asked to remove the post by the study team. We will also inform our IRB, risk management at the clinic site and the participating clinician. Refusal to remove the recording from social media may result in the participant's administrative removal from the study.

Legal proceeding. Should the study team be informed that a recording has become part of the legal proceeding, we will also inform our IRB, risk management at the clinic site and the participating clinician. This would lead to administrative removal of the participant from the study

6. Patients who have consented to take part in the study will be assigned a unique study identification number. All data collected from participants will be identified only by these study identification numbers. This will minimize risks regarding breach of confidentiality with respect to the study data. The link between each study identification number and participant name will be kept in a password-protected file on a password protected computer.

7. Printed forms with identifiable patient data, e.g. signed consent forms and medical releases of information, will be stored in separate file folders in locked filing cabinets at the offices of the project coordinator of each clinicsite.

8. All digital data, including audio-recordings (clinic visits and debrief interviews),will be stored in secure, password-protected computer files on a password- protected computer, or in a HIPAA-compliant database.

9. No medical records or protected health information shall be re-disclosed, unless required by law.

10. De-identified data will be stored in the Dartmouth Dataverse, and available, upon request, to the broader research community and appropriate IRB approval; approval to use data in for this purpose will be included in the consent forms.

11. The entire research team will complete confidentiality training.

16.0 Potential Benefits to Subjects*

Participants who are randomly assigned to the AUDIO arm will have immediate post-visit access to audio-recordings of their clinical visits, evidence suggests such access may enhance understanding and recall of health care information. We hypothesize that patient will also be better able to manage their health due to recording access. While patients in the control group will not receive a recording, they will benefit from knowing that findings from this research may benefit future patients like themselves. The inclusion of older adult patients with a complex condition, who are often excluded from trials, is also a benefit, as patients may enjoy the opportunity to take part in research. As such, we believe the risks to research participants about potential loss of confidential information, which we will take rigorous precautions to avoid (see Protection Against Risks), are outweighed by the potential benefits of improved clinical outcomes through informing healthcare delivery practices aimed to support better self-management, and satisfaction with care, for both participants and the larger population of older adults with diabetes, hypertension, and complex multimorbid conditions more broadly.

17.0 Data Analysis, Management and Confidentiality

17.1 Data analysis plan (Aim 1 Trial)

Pilot studies can serve many purposes. Our pilot project is principally designed to determine the feasibility of implementing our proposed trial protocol and the acceptability of the AUDIO intervention. We will focus on the feasibility of study processes, resources, and study management, concurrent adaptations to the trial protocol as needed. We will review data weekly, and determine the need to make adjustments to the trial (in accordance with the current IRB policies regarding amendments to protocols). We will also gather preliminary data on the impact of the AUDIO intervention on: self- management ability at 3 months as measured by the Patient Activation Measure-Short Form (PAM-SF), interpersonal processes of care in the visit (Interpersonal Processes of Care Scale), patient satisfaction (PSQ-18), treatment adherence (Medical Outcomes Study, General Adherence survey; ARMS-7), physical and mental functioning (PROMIS 10), quality of life (EURO-QOL), quality of diabetes and hypertension care (EMR abstraction), number of clinic contacts e.g., phone calls, patient portal messages (EMR abstraction), ER visits (EMR abstraction) and hospitalizations (EMR abstraction). We will also explore whether the impact of audio recording is greater for individuals at highest risk of poor self-management including those with low health literacy (Short Assessment of Health Literacy), moderate to severe depression (PHQ-8) or anxiety (GAD-7), high perceived stigma and high disease burden (Charlson Co-Morbidity Index), or by patient sex, race or ethnicity. As such our analysis consists principally of descriptive statistics.

17.1.1 Feasibility (Aim 1.1)

We will determine the optimal strategy to achieve a high retention rate and adherence to the study protocol. We will also assess retention rates (proportion of included patients completing T2 follow up; we will target >70% retention), the Feasibility of Intervention Measure (4 items; we will target an average score of >3), and high fidelity to the study protocol (Borelli et al[48] criteria). Reasons for low-recruitment rates (e.g., eligibility criteria restrictions, participant refusal (and reason why, if available), and losses to follow-up) will be gathered as part of the fidelity checklist. If we fall short of targeted thresholds, we will determine the need for deviations from the existing study protocol. We will also gather data on management resources required to conduct the trial i.e., time required to recruit participants, and field notes on any idiosyncratic issues that arise at each site that will be documented and reported to site PIs.

17.1.2 Acceptability (Aim 1.2)

Assessing the proportion of patients and clinicians who agree to take part in the project and proportion of patients who listen to the recording (we will target >70%). Our primary indicator of acceptability will be the recruitment of 108 participants (n=30 patients and 6 clinicians per site) over our planned data collection period of six months. We will determine the listening rates (we will target >70%): this will include the proportion of patients in the intervention arm that log in to the online system and listen to (and how often) the recording. We will also document the number of patients who share or report sharing the recording and caregivers who access the recording. Finally, participants will complete the Acceptability of Intervention Measure (4 items; target an average score of >3). If we fall short of targeted thresholds, we will determine the need for deviations from the existing study protocol. We will contact participants who do not adhere to the listening regime, outside of the standard follow-up assessments to determine if changes are required to the intervention delivery.

17.1.3 Exploratory outcomes (Aim 1.3)

Compared to those receiving UC, patients randomized to also receive audio recordings (AUDIO) of clinic visits will report a greater self-management ability (PAM-SF) at 3 months. Despite their emerging use in primary care, we do not know the impact of audio recordings on patients' self-management. While we are not powered to test this primary hypothesis in the current project, our analytic strategy will enable us to gather crucial preliminary data on the potential effectiveness of AUDIO, preliminary data on mediators and moderators of the AUDIO intervention and refinements to the study protocol that may be required.[52,53] Our overarching analytic strategy fully exploits the benefits of randomization by making minimalist assumptions and thereby is the most protected from bias due to erroneous modeling assumptions in comparing the AUDIO and UC groups. We later describe more nuanced analyses to allow for problems such as non-compliance, that can enable more statistical power by analyzing the outcome data as a longitudinal series (including control for the baseline value of the outcome) as opposed

to distinct cross-sections, as well as the analyses for the exploratory outcomes.

Because patients' AUDIO status varies within clinician, our statistical analysis of the PAM-SF score at 3 months' accounts for any dependence of the outcomes due to clinician within site effects. Therefore, to maximally benefit from the randomization of patients in physicians and generalize our results to a broader population, we will use a mixed-effect regression model of the form:

$$Y_{ij} = \beta_0 + \beta_1 Dartmouth_j + \beta_2 Vanderbilt_j + \beta_3 Audio_{ij} + \theta_j + \varepsilon_{ij} \quad (1)$$

where denotes the outcome (e.g., PAM-SF score) for the ith patient treated by the jth clinician; and are indicator variables of whether clinician j is at D-H or VUMC, respectively, versus the UTMB; is the i'th patient's AUDIO status; is assumed to be a normally distributed random effect for clinician j; and is the idiosyncratic (or pure) error term. Although the data are clustered within study site, we will model study site as a random variable because with only three sites the estimated variance of any site effect would be unstable. The key parameter of interest is, the effect of AUDIO on the outcome—a positive value implies that being assigned to AUDIO increases PAM-SF compared to what it would have been under UC.

We will also explore the impact of AUDIO to UC on the interpersonal processes of care in the visit, patient satisfaction, adherence, physical and mental functioning, quality of life, quality of diabetes and hypertension care, number of clinic contacts, emergency room (ER) visits, and hospitalizations. Linear regression models analogous to the model in (1) will be used to estimate the effect of AUDIO versus UC alone on exploratory outcomes with continuous scales. These outcomes include clinic visit experience (Interpersonal Processes of Care), GLOBAL PROMIS (mental and physical functioning), patient satisfaction (PSQ-18), EURO-QOL measures and quality of diabetes and hypertension care. For the binary-valued outcome of general treatment adherence, and the non-negative count outcomes (phone calls, ER visits, hospitalizations), we will replace the linear model specification in (1) with the analogous logistic and Poisson (or negative-binomial) generalized linear mixed models, respectively.

17.1.4 Deviation from protocol: Patients assigned to AUDIO, and possibly also to UC, can deviate from the protocol under their assigned study group (e.g., AUDIO patients failing to receive a recording and UC patients who start recording and listening to their visits), the instrumental variable (IV) counterpart of the analysis of the model in (1) estimates the quantity, where is the proportion of compliers (patients who would listen to the audio recording if assigned to the AUDIO group but not otherwise). We will use the proportion of patients assigned to AUDIO who self-report that they did not receive a recording to estimate the quantity, the proportion of refusers, and the proportion of

patients assigned to UC who self-report that they recorded their visit and listened to the recording to estimate the quantity, the proportion of takers. Our estimator is based the relation with the just described proportions being substituted on the right-hand-side. This procedure corresponds to substituting the estimated value of for in (1) as the resulting model can be seen as the second-stage of the two-stage least squares procedure adapted to a mixed-effect outcome model.

17.1.5 Longitudinal use of recordings: Another extension of our basic analysis will be to analyze the data from the two follow-up time periods (T1–T2) simultaneously using a longitudinal model. An advantage of this analysis is that it allows the form of the trajectory of the outcome variable over the follow-up time (e.g., is it constant, does it have an initial rise at T1 and then decline, does it grow with time) to be compared to a null model having a constant effect. This analysis provides a more powerful test of the effect of AUDIO than a cross-sectional comparison. In both the cross-sectional analyses of the outcome at a single follow-up time and the longitudinal analyses, the inclusion of the baseline (T0) value of the outcome variable as a covariate and/or making the difference in the outcome between Tk (k = 1, 2) and T0 as the outcome are alternative analyses. Because our study is randomized, it is not necessary to include the outcome variable at T0 as a covariate from a bias standpoint, yet, doing so may improve the precision of our results. The chosen strategy will depend on the extent to which the baseline and follow-up outcomes cluster within patients. If clustering is high (e.g., intra-class correlation coefficient > 0.5) we will include the T0 value of the outcome variable as a covariate.

17.1.6 Overall Predictiveness, Direction of Causality and Meditator Role of PAM-SF: We first want to explore (i) whether self-management (PAM-SF), affects the exploratory (health) outcomes. We will then perform mediation analyses to decompose the overall effect of AUDIO into its indirect, or mediated, component that acts through PAM-SF and the direct component that affects the health outcomes independently of PAM-SF. With the availability of longitudinal data (1 week, and 3-months) we have the capability of regressing each health outcome on the lagged value of PAM-SF. The analyses in (i) will be performed by adding PAM-SF as a predictor variable and removing the intervention indicator variables from the statistical models used to analyze the health outcomes. Using the product of coefficients method,[75] the effect of the intervention on the mediator is estimated in regression analyses like those described for the analysis of PAM-SF while the effect of the mediator (PAM-SF) on a given health outcome is estimated in a second regression model that also conditions on the AUDIO intervention. The product of the two coefficients corresponding to these effects is the mediation (or indirect) effect of the intervention on the outcome via the mediator while the coefficient for the AUDIO effect is in the latter regression and represents the direct effect of AUDIO. Standard errors will be evaluated using the bootstrap[76] or the PRODCLIN program.[77] A new body

of research clarifies sequential ignorability and other assumptions required to obtain causal estimates of mediation effects in randomized studies.[78–81] In addition to basic exploratory analyses, we will incorporate these new methods of performing mediation analysis into our analyses.

17.1.7 *Missing data analysis*: We will use multiple imputation to cope with missing baseline, interim, and outcome data, protecting our results from bias against all forms of missing data that are classed as missing-at-random.[82] Unlike our primary outcome analyses, multiple imputation will be performed using observations from all time-points simultaneously to allow observed values of outcomes or predictors at one observation time to inform any missing values of study variables at other observation times. Multiple imputation creates multiple completed data sets by drawing random values of missing variables from their predictive distribution given the observed variables for each observation.[83] This approach will address both generalizability and causal validity bias. We will record and report all reasons for dropout and missing data for data-handling checks and to gauge the justifiability of the missing-at-random assumption. We will examine sensitivity of inferences to data missing-not-at-random specified based on information from the reasons for missing data we obtain.

17.1.8 *Moderator analyses:* To explore whether patient health literacy is a modifying factor of the effect of audio on the patient-reported ability to self-manage their care, we add health literacy (denoted HlthLit in the statistical model in (2) and abbreviated as HL) as a main and an interaction variable with AUDIO to the model in (1) to obtain the interaction-effect model:

$Y_{ij} = \beta_0 + \beta_1 Dartmouth_j + \beta_2 Vanderbilt_j + \beta_4 HlthLit_{ij} + (\beta_3 + \beta_5 HlthLit_{ij})Audi$

+ +

where quantifies the extent to which the patient's HL modifies the effect of AUDIO on PAM-SF. A in (2) implies that the effect of AUDIO is lower in patients with high HL and higher in patients with low HL. We will also explore whether the impact of audio recording is greater for individuals at highest risk of poor self-management including those with moderate to severe depression and high disease burden. The variables described for the exploratory analyses will be analyzed using the model in (2) to form an analogous series of secondary and extended analyses for depression, anxiety, stigma and disease burden. Furthermore, we will examine whether 1) the presence of a caregiver or 2) sharing information (recording or AVS) with a caregiver moderates the impact of audio on PAM-SF. We will repeat these analyses to explore interaction effects by sex, race and ethnicity **(Sex as a Biological variable),** reporting interaction size and statistical significance.

17.1.9 *Appropriateness of Study Design:* The use of patient level randomization greatly

simplifies the statistical analysis plan. Due to randomization, there is no need to include an elaborate array of predictors in the statistical model. Because patients are randomized the impact of clustering by clinician and site on standard errors will be minimal, however we will check to assure comparability of groups at baseline and control as needed. In fact, clinician and site act as blocks as we balance the proportion of patients assigned to AUDIO and UC within each of them to guard against the possibility that by chance any clinicians ended up with all patients being assigned to a given group and to maximally gain from the statistical efficiencies of a balanced design. That is, we essentially have a randomized block design. This allows analyses for site and clinician to be control variables whose inclusion sharpens the precision of our inferences, which are determined primarily off variation within clinician and site

17.1.10 *Appropriateness of Sample Size and Analysis*: Hertzog[74] estimated that a sample of 10 – 40 is adequate to detect feasibility issues and gather preliminary outcome data in a pilot project. With 30 patient participants and 6 clinicians per site (total sample, N=108) we will be able to estimate the operating diagnostics of a future study (e.g., retention rates) and approximate effect sizes with a satisfactory level of precision to 1) determine if a future study is feasible and 2) be able to accurately inform power and sample-size calculations for a future trial. We are not powered to detect significant differences in outcomes.

17.2 Qualitative Data analysis plan (Aim 2 debrief interviews)

Content analysis will be used to code and analyze qualitative data, informed by the CFIR constructs, and guided by a consensual approach.[84] Dr. Carpenter- Song will oversee key stages (e.g. development and application of code book, creation of memos and themes) to ensure rigor of the process and increase the validity of findings. All interviews will be transcribed using a HIPAA compliant medical transcription company and de-identified transcripts will be imported to NVIVO which has a CFIR constructs coding template. RCs at each site will independently review and code the same transcripts, one from each stakeholder group, using the CFIR constructs. Codes will be developed in a manner similar to the “template approach” using *a priori* domains from CFIR and additional categories that emerge from inductive review of transcripts and field notes.[85] Coded data will be aggregated and reviewed within and across codes. Coders will meet by web conference to compare codes, discuss disagreements, and settle on a final codebook with definitions and examples. To ensure consistent application of the codebook, coders will independently review every fourth transcript from another site and compare codes. Based on aggregated codes, summary memos will be created using the CFIR constructs and organized into a matrix of barriers/facilitators (major/minor) by site and CFIR construct. We will adhere to the Consolidated criteria for Reporting Qualitative research (COREQ) checklist.[86]

17.3 ***Data security***: Our research team is experienced in training, instrument construction, editing, and data management. We will use the same procedures for data acquisition and management used in prior studies, including: (1) a common core of initial and refresher training for the research team; (2) continuous team feedback to the site; and (3) final data editing and management at our institute, The Dartmouth Institute, Lebanon, NH.

17.3.1 *Training:* All members of the research team and clinic staff will be trained in the study protocol and will have completed appropriate CITI training. The MPIs and research staff will meet weekly by WEBEX, from the time of study award, to plan protocol implementation at each site. Additionally, in month 6, a two-day 'kick off' training event will be hosted at Dartmouth College, and all study team members will join in person and/or virtually. During this training event, we will review and train research coordinators and assistants in all aspects of the study protocol including identification of patients, screening administration, recruitment and consent, survey administration and follow-up calls and plans for unexpected events. All RAs and site leads/coordinators will receive training in the identification, recruitment, consent, intervention and assessment administration. Training will involve role-play and feedback, as well as piloting of the entire recruitment process supervised by site PIs at each clinic.

17.3.2 *Protocol Adherence:* *A* fidelity checklist will be used (see Appendix. 16 Fidelity Checklist) to ensure the standard delivery and receipt of the audio recording. RAs will complete the checklist during initial recruitment and interim follow-up visits, documenting deviations from protocol and reasons. Site PIs will administer the fidelity checklist on 10% of the sample (approximately 3 patients per site), checking for 1) protocol adherence and 2) high agreement between their fidelity assessment and the RAs. Deviations from the protocol will be reported to the PIs and a mitigation plan developed during the weekly PI meeting. Participants from all sites will be given the option to contact the Dartmouth-Hitchcock Health (D-HH) Human Research Protection Program (HRPP), if they are dissatisfied or concerned about any aspect of the project; this information will be shared in the consent form.

We will use a direct-entry of data collected to a HIPAA compliant web-based system for data collection, REDCap, at all study sites during the trial for both in-clinic and telephone outcome assessments. This system provides entry validation range tests for all fields, as well as default (missing) values. All study data will be identified only with study ID numbers. The database will be protected by daily backup. PI Barr will monitor weekly data quality checks of the REDCap database, where all study data will be held, carried out by the project coordinator (e.g. extent of missing data). Prior to analyses, data will be exported from the entry database into statistical analysis packages (e.g.,

Stata, SPSS, R) with complete labeling intact (variable names, variable labels, value labels, and missing value declarations). All clinic recordings will be labeled by participant number only. In all Aims participant identification numbers will be a sequential series (e.g., 1001, 1002, 1003) and the crosswalk to the participants' names will be kept separate from data and in a password-protected, encrypted file on a password-protected, HIPAA-compliant, secure server to which only the research team will have access, behind a restrictive firewall. To maximize data capture, patients can choose to complete baseline assessment using a paper form. These forms will be labeled with a patient unique identifier and entered immediately into REDCap by the RA.

17.4 ***Health Information Sharing and Security:*** An AVS will be offered to patients per the usual practice at their clinic, either printed or via the patient portal. Audio-recordings will be made available in via a HIPAA-compliant website developed for a related project, requiring a participant- specific username and password, which will be shared with patients on a paper card and by email. The web platform for recorded visits also provides a solution for patients to share their clinic visit information with their family and caregivers using a secure web application. This data-sharing mechanism will enable patients to share specific or all existing/incoming clinic visit recordings with another individual. The selected individual would receive an invite to the web platform through an email provided by the patient, and is required to register in our web application to have access to the visit recordings. Data- access privileges can be revoked by the patients, or study team, at any time. All patient data will be encrypted in a database residing within a Virtual Private Cloud which itself is within Dartmouth's domain on Amazon Web Services. Data will be managed in accordance with privacy and security policies that are consistent with the HealthCare Information Security and Privacy Practitioner Standards. All communication with the platform's servers will also be encrypted. See Appendix 5 for further information regarding the study's server infrastructure and security-related practices.

17.5 ***Data*** **quality**: Data quality is the responsibility of the research staff at the site under the supervision of the site PI. The RC, under the supervision of the site PI, is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Data, both clinical and patient reported assessments, will be directly entered into case report forms developed using REDCap. Separate Case Report Forms will be created for Screening data (including demographics); assessment (baseline(T0), T1, T2,); and intervention use. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents (EMR). Quality control (QC) procedures will be implemented beginning with the data entry system (REDCap) and data quality control checks that will be run on the database will be generated. Any missing data or data anomalies will be

communicated to the site(s) by the project coordinator for clarification/resolution, and reported to PIs and Trial Steering Committee.

Any Quality Control issues arising from this monitoring will be reported by Contact PI Barr to the other PIs and Trial Steering Committee during weekly team meetings. Action (further training, protocol change) will be considered, and if a protocol change is deemed necessary, it will be reported to the study Funder and IRB of Record. The investigational site will also provide direct access to all trial related sites, source data/documents, and reports for monitoring and auditing by the sponsor, and inspection by IRB and DSMB, if required.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

Strategies to monitor, track and retain participants will be based on the research team's experiences of successfully conducting multi-site trials with older adults in primary care and guidance outlined by Thoma et al.[87] Recruitment and Retention will be monitored by the research coordinator at Dartmouth, who will monitoring of enrollment, tracking of participants and retention of participants in REDCap across all sites. Reasons for loss (e.g., refusal, change in provider, death) to follow-up will be documented by the research assistant, reported to the Site PI immediately, and discussed at weekly PI Meeting, where mitigation plans will be considered.

While psychiatric or medical emergencies are very unlikely, they may be disclosed by participants during interactions with study staff. As such we have developed procedures for responding to psychiatric and medical emergencies and elevated levels of depression and anxiety, described in the Data Safety Monitoring Plan (see Appendix 17. DSMP). In any such case, the research assistant will follow up with the clinical team within 7 days to determine the patients continued involvement in the trial and document the outcome of the event.

18.1 ***Monitoring enrollment***: Enrollment will be closely monitored on a weekly basis by an on-site research assistant and reported to the PIs and coordinators. The research assistant will review the electronic medical record (EMR) and calculate 1) the number of eligible patients scheduled to visit the clinic; 2) the proportion of eligible patients scheduled in the previous week who were successfully contacted and agreed to learn more about the project in clinic and 3) the proportion of patients who met with the research assistant and consented to take part in the project. Should the proportion of patients contacted who agree to learn more about the project (2) or proportion who agree to meet with the research assistant in-clinic and consent to take part drop below 60% the Site PI (Barr, Cavanaugh, Masel) will visit the clinic to observe study recruitment (both telephone call to invite patients to learn more about the project and in-

clinic consent). *We will provide regular feedback* on recruitment numbers to clinicians and clinic staff involved in the project, as well as weekly reports at the Steering Committee meetings.

18.2 ***Tracking of participants***. The RA will review the EMR of participants and document in REDCap, scheduled patient visits (up to six months from recruitment). An RA will attend all scheduled visits of patients in the AUDIO group, to assist with recording visits as described above. Each Monday the RA will review the schedule of participating clinicians to confirm returning patients appointments. We will also use a tracking system within the EMR to alert the RA when a patient has scheduled a new appointment, which will be checked weekly by the RA.

18.3 ***Retention of participants***. We have identified several strategies to boost retention. **1)** The RA will review the EMR of participants and document in REDCap, scheduled patient visits (up to six months from recruitment); **2)** patients will receive a tailored schedule, based on their preferences, of days and times that are best for follow up telephone calls; 3**)** patients visiting the clinic within one-week of a planned follow-up assessment (T1, T2) will be met by the site research assistant and able to complete assessments in clinic if they wish; **4)** patients on the UC arm may be met in clinic by the RA if feasible during regularly scheduled interim visits; **5)** patients will provide the contact information of a family member or caregiver who could be contacted should they be unreachable **6)** patients will receive reminder letters a week prior to scheduled outcome assessments and **7)** Breuton et al.[92] identified monetary incentives as the most effective way of increasing participant retention. Patients will receive honorariums to promote retention; a thank you note (Appendix 20. Patient Participant Thank You Note) will be mailed with $30 (gift card or site-specific payment method such as Greenphire) following recruitment and $20 (gift card or site-specific payment method such as Greenphire) upon completion of each follow-up assessment.

18.4 ***Data and Safety Monitoring Board (DSMB)***. A Data and Safety Monitoring Board (DSMB) will be appointed to provide additional oversight of the trial and will meet prior to recruitment to review the study protocol, Data Safety Monitoring Plan (DSMP; see Appendix 17), DSMB Charter (see Appendix 18) and at the end of data collection. PIs will attend these meetings, with minutes documented and any recommendations documented. Minutes and recommendations will be shared with the trial steering committee. The DSMB will consist of four members identified through the NIA standard approval process. The DSMB will then meet by WEBEX to review study progress annually throughout the project (approximately every 6 - 9 months). The DSMB will review enrollment and attrition rates and advise the PIs on any potential risks as well as on any risk mitigation plans. The DSMB recommendations will be discussed with the PIs as well as the Steering Committee. All data will be reviewed for protocol adherence, including a data verification check that the appropriate outcome measures are given at

the appropriate time points. We do not expect any Serious Adverse Events (SAE) or Adverse Events (AE) in the trial that would require immediate reporting since there are no invasive procedures related to the interventions. If for any reason an SAE, AE or unanticipated problem were to occur, the DSMB would be immediately notified, as well as the sIRB at Dartmouth. The DSMB would convene by webinar within 72 hours and immediately review the Serious Adverse Events/Adverse Events and determine if in any way they were related to the research study. If an SAE or AE occur, a full review would be performed by the PIs, Steering Committee and the DSMB.

19.0 Provisions to Protect the Privacy Interests of Subjects

Before data collection starts, all study personnel will be required to undertake appropriate CITI coursework, including, but not limited to, HIPAA training and Good Clinical Practice. The MPIs and research staff will meet weekly by WEBEX, from the time of study award, to plan protocol implementation at each site. In month 6, a two-day 'kick off' training event will be hosted at Dartmouth College, and all study team members will join. During this training event, we will review and train research coordinators and assistants in all aspects of the study protocol including identification of patients, screening administration, recruitment and consent, survey administration and follow-up calls and plans for unexpected events. Additionally, patient recruitment will not begin until IRB approval is gained protocol, staff training occurs (including CITI certifications), and the trial is registered on ClinicalTrials.gov. We have extensive experience recruiting patients on to clinical trials and other projects. Participants will initially be contacted via a letter signed by their participating clinician to inform them about the project and given the option to opt out (Appendix 8. Recruitment Letter). Patients will then be contacted by phone by a member of the research team to further inform them about the research project and assess their interest in joining (Appendix 9. Telephone Patient Recruitment Script). This strategy was recommended by our patient partners as they reported it is easier to 'decline' participation in a study when speaking with a member of a research team vs. speaking with a clinician or member of the clinical team. Interested patients will arrive at the clinic early to allow time to complete consent processes and baseline assessment in an unhurried fashion. They will be informed of the data that is required (see 22.0 Consent Process) and will provide consent for the research team to access this data. They will be reassured that their data will be handled in confidence and maintained privately, and that neither their clinician or clinical team will have access to study data. Clear information will be provided on the study follow up schedule. Patients will be reminded that at any time, including after they leave the clinic, they can request to be removed from the project.

20.0 Compensation for Research-Related Injury

- *N/A*

21.0 Economic Burden to Subjects

- *N/A*

22.0 Consent Process

22.1 Consent Process (Aim 1 Trial)

22.1.1 Patients (Aim1)

***eConsent**:* A link to the consent form will be sent via REDCap immediately after the screening phone call with the RA to eligible interested patients willing to complete eConsent. The eConsent will consist of the same, age-appropriate materials as in-person consent (described below). Patients will be instructed to review the eConsent. Participants will have the ability to move forward or backward on the eConsent form as needed prior to completing consent. A short quiz to confirm patient understanding of the project will be completed electronically as part of the eConsent process - this is a common step in eConsent processes (Appendix 23. eConsent Comprehension Quizzes). Contact information will be available to participants should they have further questions or points needed to be clarified with the study team. Participants will also have the option to provide the name and email of a friend or family member who they involve in their care and would be willing to share their recording with. Those who complete eConsent will leave a digital signature; they will be emailed a copy of their signed eConsent form and will also be offered a mailed paper copy of the consent form. Participant and study staff signatures on the eConsent may have different dates, as participants may sign during non-business hours. Study staff will sign the eConsent electronically as soon as feasible after participant completion. Participants will also receive an email asking them to attend clinic 30 minutes early on the day of the research if they would prefer to complete pre-visit surveys in person rather than electronically. On the day of the visit, a member of the research team will meet with the participant, either in person or by telephone/web conference, and proceed with study procedures.

***In-person consent**:* For participant who prefer to complete consent in clinic, they will be met by the RA in the clinic waiting room. A member of the registration staff may also receive a list of patients who have agreed to learn more about the project, to facilitate a warm hand-off of patients to the RA. Patients will join the RA in a private room/area where they will confirm inclusion and exclusion criteria with the patient. This will be done using a short, standardized screening form. Once it is determined that the

participant meets all study criteria, the RA will review the consent form (Appendix13b. Patient Consent Form), stopping after each section to gauge understanding and to provide an opportunity to ask questions. During consent, patients will review the information discussed during the initial phone call (see above). All consenting patients will agree to best practice when using recordings. While sharing access to caregivers is allowed, we will request patients do not share the audio-recording on social media (this will be clearly stated on the informed consent form). In our experience of implementing recording in clinical practice and studying clinics that offer recordings, social media posting of recordings has not been documented. Patients will also be told that they can start, stop, and/or delete recordings at any time during the clinic visit. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The patient will also have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The patient will sign the informed consent document prior to any procedures being done specifically for the study. Patients will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the patients for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the patients undergoes any study-specific procedures. The rights and welfare of the patients will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study. The RA should scan the consent form to the participant's medical record and create a consent note in eDH using the study smartphrase (Appendix 22. Audio Trial Smartphrase for EMR). Should the patient be accompanied to the clinic visit by a caregiver (family member, friend or other person who assists the patient with their care) they will also accompany the patient and RA if the patient wishes.

22.1.2 Clinicians (Aim1). Clinicians who are interested in taking part will be invited to complete informed consent (Appendix 11b. Clinician Consent Form) and a brief demographic survey (see Appendix 11. Clinician Demographic Survey) with a member of the research team after the conference in a private room, by telephone or via email. Interested clinicians who are not present at the recruitment conference(s) and who respond to recruitment emails will be offered an appointment with a research assistant during business hours to review informed consent and enroll in the study, or can complete eConsent via email. Clinicians will have the ability to move forward or backward on the eConsent form as needed prior to completing consent. A short comprehension quiz will be administered electronically as part of the eConsent process; all questions must be answered correctly to determine understanding of key study procedures (Appendix 23. eConsent Comprehension Quizzes). Contact information will be available to clinicians should they have further questions or points needed to be

clarified with the study team. Clinicians will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the clinicians for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, or electronic signature, prior to the beginning of recruitment.

Family members & caregivers/companions (Aim1). As patients are the focus of the project we will initially identify, inform and consent patients. To be eligible, patients must meet inclusion / exclusion criteria and be able to provide consent independently. If a family member is present, we will provide them with study information upon patient consent, including whether the patient has been randomized to the AUDIO arm and explain that patients in the AUDIO arm will have their scheduled visits with this clinician audio recorded and shared for the patient's personal use during the study period (3 months). As such the caregiver or family member will be aware that recording is taking place at the visits. At each visit, the research assistant will remind accompanying caregivers or family members that the patient has consented for the visit to be audio recorded. It is important to note that patients will always be able to pause or stop a recording of the visit, and we plan to document such instances on our fidelity checklist. Family or other members may elect to not be in the visit room, and this will be documented. This approach was developed after careful discussion with clinic risk management, clinicians, patients and caregiver partners. It also reduces selection bias issues as the alternative approach of consenting accompanying family members or caregivers may impact the patient's decision to participate or not. This strategy has also been approved and successfully used in a prior project by the Dartmouth IRB (STUDY00031211).

22.1.3 Certified Translators (Aim1). In the case a medical translator is needed to support the visit, this will be identified ahead of the patient visit by the RA. The translator will be informed that the patient is participating in a research project where the clinic visit is being recorded and their consent (written or verbal) will be sought. This strategy has been used successfully at UTMB where visits at the cancer clinics are audio recorded. In the unlikely situation that a translator is uncomfortable, a new translator for the patient will be sought prior to the visit. Additionally, all study materials will be translated using a certified translation service, the Spanish Group LLC (Irvine, CA). The Spanish Group offer Certification by Translator document which is mandatory for USCIS acceptance and other government or academic institutions. All interactions with Spanish speaking participants will be conducted by our bilingual research staff at UTMB. Upon IRB approval of the English protocol, we will submit Spanish language versions of all study materials via a modification prior to commencing patient recruitment.

22.2 Consent Process (Aim 2 Debrief interviews)

Consent procedures will be similar across all groups and will be as follows:

Individuals interested in participating by telephone can proceed to complete consent and interview via telephone, complete eConsent via REDCap at home, schedule a time to complete consent and interview in the future, or make an appointment to meet the RA for the consent process at the clinic location. A waiver of written documentation of consent will be requested for participants who prefer to conduct interviews by telephone (Appendix 19. Waiver Alteration Request Form). Verbal consent will be documented and a copy of the informed consent form by mail, or email; we have successfully adopted this strategy in similar minimal risk studies previously. The informed consent form will be reviewed with all potential participants, informing them about the goals of the study, the nature of the information collected. Throughout this process, potential participants will be encouraged to ask any questions they may have about the study. Participants will be reassured that all information exchange will be held in confidence and not shared beyond the study team or noted HIPAA compliant transcription service. Additionally, participants will not be identified in any presentation or publications related to the work. Once they have had all their questions answered and have had the opportunity to fully review the informed consent form, if applicable, those who wish to take part in the study will be asked to provide written or verbal informed consent. All signed consent forms if available, will be stored securely in locked cabinets at each study site and collected monthly by the project coordinator. Audio-recorded consent will be uploaded to REDCap by research coordinators at each site, managed by the project coordinator.

23.0 Process to Document Consent in Writing

Aim1. Informed consent will be documented in writing or by eConsent in Aim 1. The process of documentation is described above (section 22). All Consent documentation will be stored securely in 1) locked cabinets at each study site 2) on REDCap. While we will attempt to gather written informed consent for Aim 2 debrief interviews, a waiver of written informed consent will be an option for those participants who would prefer to complete consent over the telephone.

24.0 Setting

We will identify and recruit participants from three sites: Dartmouth-Hitchcock Primary Care (D-H; Manchester, NH and Bedford,NH), Vanderbilt University Medical Center (VUMC; Nashville, TN), and University of Texas Medical Branch, (UTMB; Galveston, TX and League City,TX). The Dartmouth- Hitchcock Human Research Protection Program (HRRP) IRB will serve as the IRB of record. All sites have agreed to rely on

DH-HRPP as the IRB of record.

25.0 Resources Available

We are confident we can recruit the necessary number of patients at each site. D-H offers primary and specialty-care services, with 35 primary care clinicians, where in 2017, there were 1,144 unique patients ≥65 years with multimorbidity and at least 2 visits in the preceding 7 months, with only 7% cancellations. Like the geographic region it serves, the D-H clinic population is predominantly white, non-Hispanic (94%). The VUMC Adult Primary Care consists of two sites located on the VUMC campus; and two sites in the community. These four clinics are staffed by > 59 attending physicians. In 2017, they saw 1,500 unique patients ≥65 with multimorbidity. UTMB clinics are staffed by 11 attending clinicians, with 1,805 unique patients aged ≥65 with multimorbidity in 2017. We will have dedicated research assistants, with CITI training, who will lead in clinic recruitment. Each site has the necessary resources, infrastructure and experience of conducting trials. All research staff will meet for a 2-day training hosted by Dartmouth College, prior to recruitment and study PIs will meet together prior to the commencement of recruitment and at the end of data collection. Finally all clinic staff will be informed and educated about the project over the course of several presentations at standing clinical team meetings and one-on-one meetings with participating clinicians.

26.0 Multi-Site Research*

This is a multi-site study that will involve 3 sites and a total of 30 patients and 6 clinicians recruited per site for a study total of N=108 participants (90 patients and 18 clinicians). All procedures (identification, recruitment, consent, data collection) described above will be followed at each site. REDCap will be used to gather, share and store data securely, across all sites.

Weekly meetings will be planned between the MPIs (Barr, Dartmouth; Cavanaugh, VUMC; and Masel, UTMB).

26.1 ***Organization structure***. Drs. Barr, Masel and Cavanaugh will co-lead all aspects of the project: administrative, technical and scientific. We will complete and keep up-to-date the WORKSHEET: Communication and Responsibilities (HRP-830) and all PIs will be responsible for sharing the most current version of the protocol and consent documents with their study teams. Dr. Barr will serve as the Contact PI and will assume fiscal and administrative management and responsibility of the project. He will be responsible for communication with NIH and submission of annual reports. All PIs will be responsible for oversight of the project, including maintaining communication with

each other, key personnel, and project staff through scheduled weekly meetings. Each PI will be the primary responsible party for all activities at their respective site. During weekly meetings, the PIs will meet with site coordinators to discuss study progress e.g., recruitment and retention rates, protocol adherence and data quality. Should concerns arise such as recruitment rates falling below target thresholds, mitigation plans will be generated and the trial steering committee will be informed and a meeting will be convened to determine if changes in protocol are required. Significant changes in protocol will be communicated with the IRB and approved. PI Barr will be responsible for creation of annual reports, publication of trial protocol on ClinicalTrials.Gov and coordination of manuscript and conference proceedings to emerge from the project, with support from both PIs Cavanaugh and Masel. Publication authorship will be based on the relative scientific contributions of project personnel. The Trial Steering Committee and MPIs will work together to identify lead, senior and contributing authors.

The PIs will participate in activities with NIH under this agreement. The PIs will also actively participate in the preparation of reports, preparation of manuscripts for publication, and presentation of results at scientific meetings.

Decision-making Process on Scientific Direction. The partnership between the MPIs will leverage their strengths and their complementary expertise. The PIs view this collaboration as an essential cornerstone of successful operation of the research plan. Decision-making regarding study design and implementation will be done jointly through communication between PIs, and Trial Steering Committee (see below). Dr. Barr will be responsible for making final decisions following this process.

26.1.1 Communication: The PIs have held regular weekly telephone calls for 14 months in preparation for the original submission and resubmission of this proposal, as well as collaboration on related projects. PIs have also taken advantage of enterprise level software (e.g., Adobe Connect, and WebEx) for an interactive online collaborative environment. During the trial, the PIs will continue to meet weekly for at least one hour and will meet in person every 6 months, alternating between study sites. The PIs will meet weekly by teleconference with the Trial Steering Committee. The Steering Committee members provide expertise in all aspects of the proposed project. Steering Committee members also have a successful history of collaboration with the PIs and will provide strategic guidance for achieving the study aims. Steering Committee members will be available outside of the scheduled meetings to review study documents and provide guidance on unanticipated challenges, as needed. Communications will be conducted via email, teleconferences, and face-to-face meetings.

The Trial Steering Committee are all co-investigators on the project. The committee

consists of:
***Martha Bruce**, PhD* is a senior implementation scientist who conducts health services intervention effectiveness and implementation trials in community-based settings and care systems with older adults. Dr. Bruce provides implementation science expertise in conducting randomized trials in primary care in addition to offering guidance on trial management. Dr. Bruce is well positioned to complete this role given her extensive experience of successful multi-site trial design, management and completion in primary care.

***A. James O'Malley**, PhD,* will provide statistical expertise for all project and research aims. Dr. O'Malley will be the senior statistician responsible for overseeing and conducting the randomization procedures and statistical analyses for the project. Dr. O'Malley has developed novel statistical methods of accounting for confounding bias and heterogeneity in comparative effectiveness trials and likelihood methods for treatment noncompliance and subsequent nonresponse in randomized trials.

Sunil Kripalani, *MD MSc,* provides expertise in the impact of health literacy, trial execution and also implementation. His research has focused on studying the effect of health literacy on patient understanding, self-management, and outcomes, as well as using health communication interventions to improve processes and outcomes of care. He has examined gaps in traditional forms of written communication, such as hospital discharge summaries, and tested more innovative approaches to improve patient understanding and self-management, such as illustrated medication schedules. Dr. Kripalani is well positioned to offer guidance on this project and given his clinical experience and methodological expertise including survey research, randomized controlled trials, and implementation research. Furthermore, he and Dr. Cavanaugh have a long-standing collaborative research relationship and together co-Direct the Vanderbilt Center for Effective Health Communication.

***James S. Goodwin**, MD,* is a practicing clinician in the UTMB Internal Medicine Division of Geriatrics in Galveston, TX, a research site for this proposed study. Relevant to the proposed study, Dr. Goodwin is the director of the Center on Patient Centered Outcome Research in the Elderly. This center offers access to stakeholder and community groups, provides training on PCOR methods to investigators and offers the infrastructure to disseminate PCOR findings both regionally and nationally. Dr. Goodwin's content and trial design knowledge, and extensive experience serving as a project advisor, equip him to successfully complete his role.

26.2 *Conflict Resolution*: The MPIs have a respectful relationship that makes conflict very unlikely. However, should conflict occur, the PIs shall meet and attempt to resolve the dispute immediately, with consultation with senior co-investigators on the project

Trial Steering Committee (Bruce, Kripalani, O'Malley and Goodwin). In the unlikely event that this fails to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of one impartial senior executive from each of the PIs' institutions. It will be the responsibility of this committee to determine the method of resolution. Members of the arbitration committee will not be directly involved in the research grant or disagreement.

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Dartmouth-Hitchcock

Permission to Take Part in a Human Research

Title of research study: *The Impact of Sharing Audio Recorded Clinical Visits on Self- Management in Older Adults: A Multisite Trial*

Investigator: *Paul Barr, PhD*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because we are interested in understanding patient views on using audio recordings of doctor office visits and whether this can help people with their care. Your doctor or nurse is taking part in this research and has given us permission to contact you. Participants must be 65 years of age or older, have Type 1 or Type 2 diabetes mellitus and hypertension, be on medication for diabetes and hypertension, have had 2 or more doctor visits in the past six months, can provide consent and do not have any significant problems with their hearing or vision. We hope to include a total of 30 patients at Dartmouth-Hitchcock.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We want to understand if audio-recordings improve how we provide information to patients after their doctor's office visit compared to usual care, and whether this is acceptable and easy to do.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 3 months.

You will be asked to complete surveys at: (1) your next doctor's visit, (2) 1 week after your doctor's visit, and (3) 3 months after your doctor's visit. The surveys include questions about you, how you manage your health, and your care experience. A computer will decide which of two groups you will be part of for the study. If you are in the usual care group, you will receive information from your doctor's visit as normal. If you are in the audio-recording group, we will audio record any of your planned office visits with your doctor/nurse who is taking part in this research for 3 months.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

We do not believe there are any physical, legal, social, or economic risks from taking part in this study.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, the study may result in better memory and understanding of your doctor's visit. This may help you better manage your health conditions. Additionally, if we understand more about the use audio-recordings in doctor's visits, we may be able to develop better ways of communicating medical information for patients and caregivers.

What happens if I do not want to be in this research study?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (603) 646-7049.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (603) 650-1846 or irb@hitchcock.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be in this study?

We expect about 30 patients here will be in this research study out of 90 patients in the entire study nationally.

What happens if I say yes, I want to be in this research study?

We will ask you to come to your next doctor's office visit 30 minutes early to complete a brief intake interview, during which we will ask you questions about the following:

- Your demographic information, such as your age, race, education, and employment
- Your health-related information, such as your comfort level with medical information and ability to manage your health
- Your general physical, mental health, and well-being
- Contact information for a caregiver or family member in the case we cannot reach you for follow-up surveys

A computer will then decide which of two groups you will be part of for the study. You will have an equal chance of being in one of the groups.

- Group 1 (**Usual Care)**: You will receive information from your office visit as normal, including receiving access to your after visit summary; or
- Group 2 (**Audio Recordings)**: We will audio record any of your planned office visits with your doctor/nurse who is taking part in this research for 3 months. You will receive access to these audio-recordings at a secure website after each visit. We will give you simple instructions on how to access this. We will also send you reminders to listen to your recordings

and you may be contacted about using your recordings by the research team.

After recording your first visit, we will ask you to complete a survey at 1 week and 3 months. These surveys can be completed by email or by telephone with a member of the research team. Each survey should take approximately 15 minutes to complete and you will receive $20 each time. In this survey, we will ask about:

- Your ability to manage your health,
- Your mental and physical health,
- Your satisfaction and experiences with care,
- Your use of information given to you from your office visit.
- If you are in Audio Recording group, we will ask about your use ofthe recording.

We will also ask you to complete one survey on your care experiences within one week of any planned visit to the doctor's office during the 3-months of the study. This survey will take 5 minutes to complete You will receive $20 for completing the survey each time.

We will also take the following information from your medical record over the course of the study, up to about 6 months from the time you agree to participate:

- Your health conditions,
- Laboratory tests and imaging results (e.g., A1c testing, urine albumin testing, HbA_{1c}),
- The number of clinic visits, contacts (e.g. phone calls, patient portal emails,) and hospitalizations

At the time of completing the 3-month survey, people who were in the Audio-Recordings group will be invited to take part in an interview about their experience. A member of the research team will conduct this interview and it can happen by telephone or in person. We will ask for permission to record the interview. The interview should last no longer than 30 minutes and you will receive $30 for your time.

What are my responsibilities if I take part in this research study?

Your responsibilities as a person taking part in this study are:

(1) Be aware it is important for your safety that the research team knows about your medical history and current condition.

(2) Make reasonable efforts to follow the instructions of the research team.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. We will ask for permission to collect follow-up data.

Is there a possibility being in this study could be bad for me or harm me? (Detailed Risks)

We do not believe there are any physical, legal, social, or economic risks from taking part in this study.

As with any study, there is the possibility of a data breach occurring. If a data breach were to occur, there is the potential for psychological distress. While we do not anticipate this to occur in our study, we will take measures to ensure that any digital information is stored securely on encrypted servers and hard drives. Study data will be stored in a Dartmouth College-managed REDCap database. All printed forms will be kept in a locked filing cabinet.

We do not believe that participating in this study could harm you in any way.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

This study is federally funded by NIH and compensation for a research-related injury or illness is not provided by federal law.

If you are injured or become ill because of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- Federal funding agency

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 653-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, and the IRB will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Federal law provides additional protections of your medical records and related health information. By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Dartmouth-Hitchcock Health Institutional Review Board (D-HH IRB)
- A HIPAA compliant transcription service (responsible for transcribing the interviews for this study)

In order to conduct this study, researchers need to use your health care information. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you

give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware that if your PHI is disclosed to others, it may no longer be protected by federal privacy laws.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes, such as to contact you during the study, which are determined to be reasonable and in line with expectations by a review committee. Such data will include: your name, email address, physical address, telephone number, date of your clinic visit appointments with a study clinician, and your medical record number.

Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes, for example in a databank. A biobank/databank is a collection of samples and/or health information (data). Samples and de-identified health information from many people are stored so they can be used for research now and in the future. Researchers may apply to the biobank/databank to ask for data or samples for studies they wish to do. If a study is approved, the biobank/databank will give the researcher samples and/or information. While the biobank/databank will not give the researchers any information that could directly identify an individual, like name or address, there is a theoretical possibility that you could be identified through your genetic data. The researchers will then use the samples and/or health information to learn more about health and many different diseases.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

Your name, address, and social security number may be given to an office at DHMC that arranges for payments and reports payments to the IRS.

E-mail Privacy - Notification messages regarding information in HealthPAL may be sent the e-mail address you provide. Any person with access to this e-mail account will be able to see this notification. For example, this could include your spouse, employer, or anyone else that can access the account. Although no private medical information will be sent, the notification that new medical

information is available by accessing HealthPAL may be information that you or your proxy would not want others to know. Please take this into account when providing an e-mail address.

Your information may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

We plan to share a summary of the study results, by either email or mail, with all individuals who participated in the study once it is completed.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. You may be taken out of the study if:

- If you fail to follow instructions
- Your doctor/nurse requests you no longer participate
- You choose to withdraw from the study
- You no longer meet study inclusion criteria

In the unlikely event that you are withdrawn, we will contact you to let you know. If you leave the study early, Dartmouth College may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

What else do I need to know?

This research is being funded by the National Institute on Aging.

If you agree to take part in this research study, you will receive $30 for completion of the initial survey, plus $20 for completing surveys at one week and three months. You will receive an additional $20 for completing a survey within one-week of each planned doctor's office visits during the study period of three-months. On average, you will receive between $70 - $90 for your time. If you are invited to take part in an interview, you will receive an additional $30.

You will be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Dartmouth College exceed $600 per year, Dartmouth College will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us. Dartmouth-Hitchcock employees who participate in this research study will receive their stipends through payroll. Stipends will be included in the

employee's taxable wages and reported through their W-2 at the end of the year.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date