APPENDICES

Appendix A. Research Protocol

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I. Aims and Hypotheses

The first aim of the Nationally Representative Survey of Depression and Diabetes Treatment Preferences (Aim 1) is to develop and administer a widely applicable treatment preferences elicitation method for two conditions (depression and type II diabetes) that combines conjoint analysis with measurement of prior healthcare experiences and socio-cultural factors to more fully describe the influence of patient preferences and racial/ethnic health care disparities. Aim 2 of the study is to use survey results to inform semi-structured qualitative interviews to examine the validity of the patient preference results elicited in Aim 1 and inquire further into factors influencing respondents' reported preferences, past experiences with healthcare, and willingness to use such a tool to collaborate with their physicians on treatment decisions in the future. In Aim 3, we explore the incorporation of preferences and previous experiences into the development of treatment plans in a primary care team-based setting and examine the adaptability of the methodology to other chronic diseases.

II. Background and Rationale

We investigate patient preferences for depression and diabetes treatment because preferences are particularly salient to the success of treatment for chronic conditions such as depression and diabetes. Depression and diabetes were selected as exemplar chronic illnesses primarily because of their high disease burden and chronicity. Treatment plans for chronic illnesses are ideally developed via collaboration between patient and provider such that the risks and benefits of different treatments and outcomes are assessed and patients reflect on their preferences. Preferences, however, are based on limited information and are influenced by prior individual and collective experiences. Furthermore, racial/ethnic minorities may have negative, distrustful attitudes towards health care that manifest as a "preference" for different, perhaps less efficacious, treatments. Our proposed use of conjoint analysis is the first designed to identify preference differences among racial/ethnic minorities, and the extent that they have been influenced by prior positive, negative or discriminatory experiences in the healthcare system. Conjoint analysis (CA) elicits latent preferences for type of treatment ("attributes", in the language of CA) by asking the respondent to select between pairs of hypothetical scenarios that differ in potential treatment options. Respondents will be given a series of 10-12 such pair-wise options which vary on type, frequency, location of treatment, and cost.

Incorporating patient preferences into a treatment plan requires an understanding of patients' experiences and preferences, including past experiences of discrimination, and the influence of peers, family and community members regarding various treatment options. The nature and limited time of office visits can be a barrier to the elicitation of a nuanced picture of the factors influencing patient preferences. As a result, preferences are often incompletely or inaccurately assessed. Inaccurate elicitation of preferences may be particularly deleterious for individuals with chronic conditions like depression and diabetes, where a mismatch between treatment

and preferences contribute to lower rates of engagement and higher attrition. Understanding and addressing the factors that have contributed to a patient's preferences, especially outside of the constraints of an office visit, could allow for better adaptation of evidence-based recommendations to the individual experience of the patient.

An improved method of eliciting patient preferences was developed in Aim 1, using conjoint analysis to assess respondents' latent valuation of a number of treatment attributes. In Aim 2, we will qualitatively validate the accuracy of the quantitative survey results through semi-structured, in-person follow-up interviews with a subset of respondents. These interviews will also solicit explanatory narratives regarding patients' past experiences with healthcare and how these have informed preferences, as well as ask patients to reflect on their willingness to use such a tool to collaborate with their physicians on treatment decisions in the future. In Aim 3, we will conduct up to 25 in-person qualitative interviews with four groups of clinical stakeholders at CHA to explore ways for providers to reflect on the findings in Aims 1 and 2 and to incorporate the preferences into treatment plans.

A key part of the team-based treatment at CHA is the joint development of the treatment plan. The input of the patient is a key element of the development of the treatment plan. However, there is little guidance on how the patient can provide this input. Eliciting patient preferences and positive, negative or discriminatory past experiences can be more explicitly incorporated into the process of preparing for a visit, identifying patients with heightened needs, and could serve as a decision aid for patients to crystallize ways to discuss preferences with a provider. Inviting patients to reflect on these issues before a visit may allow them to feel more prepared to share negative experiences with a provider who asks, thereby giving provider and patients a chance to address concerns that may not otherwise be raised. Decision aids for patients such as this have been shown to help patient involvement in treatment decisions and promote active self-management of chronic conditions. Similarly, a positive/negative prior experiences "screener," could alert providers to patients with whom more time for discussion may be needed. Team-based care teams (that include our research team's CHA Volunteer Health Advisors) may be ideally organized to accommodate the addition of such questionnaires and the delicacies associated with probing questions about negative prior experiences. Given the high volume of process and quality improvements that clinics nationwide are tasked with implementing, and the possibly sensitive content that such questionnaires may raise, development of such instruments and guidelines necessarily must include patient and provider input to ensure value to the patients served and those who care for them. The qualitative interviews in Aim 3 will help us to combine patient stakeholder feedback from Aims 1-2 to better understand how to incorporate preferences and treatment experiences into the clinical appointment. Combined, they will offer valuable feedback to the clinical relevance of distilled qualitative and quantitative findings from Aims 1 and 2 regarding racial/ethnic differences in preferences for treatment, and the relationship between patient preferences and prior experiences with care.

*****Please refer to section V.(1-9) for Aim 2*****

III. Pilot at Cambridge Health Alliance

We will conduct pilot testing of the CA-based survey and questionnaire, including cognitive interviews, with 12 patients (4 Black, 4 Latino and 4 non-Latino white) in Spanish or English with patients at CHA Somerville Hospital Primary Care. Based on patient feedback, and in collaboration with our patient representative and stakeholder team, we will refine the survey instrument and scenarios depicted in the conjoint choice task in 45 minute sessions (20 minutes to complete the treatment preferences survey and 25 minutes for the semi-structured cognitive interview and the optimism scale).

***** The recruitment and administration of the Pilot at Cambridge Health Alliance was completed on June of 2017*****

1. Study Design

A. *Study Participant Population and Location*

We will pilot test the initial version of the survey with 12 participants at **CHA Somerville Hospital Primary Care**. A total of 12 participants, **4 Black or African American, 4 Latino or Brazilian, and 4 Non-Latino white participants** will be recruited: **half of the sample population will have a diagnosis of diabetes mellitus (DM) and half will have a diagnosis of depression**.

B. *Survey Components and Design*

Working with our team of representatives with lived experiences and stakeholder collaborators, we have designed a (1) **treatment preferences survey instrument** that includes previous experiences and conjoint analysis choice task and (2) a **semi-structured qualitative cognitive interview guide** (referred to as the "cognitive interview"). The cognitive interview is a follow-up interview guide that asks pilot test respondents to reflect upon the understandability and burden of the survey. As a part of the cognitive interview, the participant will also respond to an optimism scale, a 10-item validated questionnaire. During the interview process the participant will be asked to complete the survey electronically and then respond to the cognitive interview.

Because we have been working with community stakeholders and representatives with lived experiences, the development of the survey has been and will continue to be an iterative process. We will pilot test the initial version of the survey with 12 participants at CHA Somerville Hospital Primary Care (SHPC). The entire interview will last approximately 45 minutes (20 minutes to complete the treatment preference survey and 25 minutes for the semi-structured cognitive interview and the optimism scale). The initial drafts of both the survey and the cognitive interview are enclosed, and any subsequent modification to the survey instrument will be submitted to IRB for approval.

To develop and administer the electronic version of the treatment preference survey we are working with GfK (Knowledge Panel) a company that focuses on national polls and surveys, and

uses 100% probability-based panel that includes a valid nationally-representative sample of hard-to-reach populations. GfK will also translate the instrument into Spanish. Once the electronic version of the survey instrument is available both the English and Spanish versions will be submitted to IRB for approval. The forms and flyers (see attached) will be translated into Spanish (back translation can be provided upon IRB request).

C. *Pilot Recruitment Strategies*

We plan to implement three recruitment strategies to recruit the twelve study participants: (1) posting of flyers in the SPHC waiting room; (2) recruitment during check-in at the front desk; (3) recruitment during appointments with Mr. Garrett Lech, a clinical pharmacist at SHPC; (4) recruitment in the waiting room by research team members; and (5) identification of English-speaking African American/Black potential participant by word-of-mouth with the help of our community partner contacts at the Transformation Center. The SHPC Medical Director (Dr. Brian Green), the Nurse Manager (Fiona McCaughen) have approved this protocol at SHPC. For Spanish speaking participants, one of our Interviewers (also the Research Assistant), a native Spanish speaker, will be responsible for interviewing Spanish-speaking participants. The Spanish-speaking Interviewer will work under the guidance of Dr. Dharma Cortes, also a native Spanish-speaker, to ensure that the translated survey documents (survey instrument, informed consent forms, flyer, interview guide) are culturally and linguistically appropriate.

C1. Method I – Flyer

Flyers (see attachment) will be posted in the waiting room at the Somerville Hospital Primary Care department. The flyer will include the phone numbers of the Interviewers. When a potential participant reaches one of the Interviewers listed on the flyer by phone, the Interviewer will provide more information regarding the study project. If the potential participant indicates interest, then the Interviewer will administer the screener for eligibility (see attachment). If the potential participant qualifies to be in the study, the Interviewer will arrange a time to meet with the participant at the Somerville Hospital to conduct the informed consent process and the interview.

For Spanish-speaking participants, the Interviewer's phone number will be listed on the Spanish version of the flier. Any Spanish speaker contacting the listed number will reach the Interviewer who is a native Spanish speaker. The Spanish-speaking Interviewer will then administer the screener for eligibility, and then the Interviewer will schedule a time to meet with the potential participant to conduct the interview, during which the informed consent process will be administered as described above. The Spanish-speaking Interviewer will be the Interviewer for all Spanish-speaking participants.

For Method I, therefore, flyers will be posted in the SHPC waiting room but the eligibility screener may be conducted by phone if participants call the study interviewers. Again, the informed consent process will occur at the time of the interview in person, not over the phone.

For Methods II, III, and IV, recruitment will occur at the Somerville Hospital Primary Care, as described below. For those who are interested in participating in the study, the Interviewer will bring the potential participant to an exam room in the clinic. The interviewer will then fully describe the study and, if the potential participant continues to be interested in participating, conduct an informed consent process to fully explain the potential risks and benefits of study participation and then conduct the interview. For Method V, the Flyer will be given to our community partner contacts at the Transformation Center to disseminate to their community members. The interested participants may reach out to the listed contacts (Research Assistant and Project Manager), and the interview will be conducted at either 1035 Cambridge Street or the Transformation Center depending on the availability of the space and the participant.

C2. Method II – Front Desk

For Method II, three research team members will assist the front desk staff with the recruitment at SHPC. A study Recruiter will be stationed in the conference room across from the waiting room, while two Interviewers will be waiting in reserved examination rooms. The Recruiter will work as a coordinator and refer potential participants to the Interviewer in the exam rooms. The exact dates, when the research team will be at SHPC will be determined based on the clinical staff's availabilities and schedule. The Interviewers anticipate being on-site on a Monday, Wednesday, and Friday from 9am to 5pm for recruitment and interview.

When individuals check in for their routine, scheduled appointments at the front desk at SHPC, the receptionist will inform everyone checking in that there is a study being conducted at SHPC that involves trying to better understand treatment preferences in among those with depression and diabetes. The receptionist will indicate that if the potential participant has one of those conditions and is interested in participating, that they may speak about the study with the study recruiter who is stationed in the conference room across from the waiting room. Informational pamphlets will be available for those who may be interested in participating in the study at the front desk.

All front desk staff undergo training in how to present the information about the study in a non-coercive manner and will use a pre-written script to assist them in presenting information about the study to potential participants to ensure non-coercive, confidential and consistent language is used (see below). The study Project Director, the Project Manager and a study co-investigator who is a primary care physician at SHPC, will work with SHPC administrators to train the front desk receptionists.

If a potential participant goes to discuss the study with the Recruiter in the conference room across from the waiting room and indicates interest, the Recruiter will coordinate with the potential participant to speak with an Interviewer before or after the potential participant's doctor appointment, depending on the potential participant's availability. At the agreed upon time, the Recruiter will direct the potential participant to the Interviewer, who will be in an exam room at SHPC.

To avoid potential participants feeling discomfort in approaching the research staff in the clinic area, we give them the option of signing a "Consent to Contact" form, which is on the other side of the informational pamphlet (see attached). If they would like to be contacted by the research team at a later time to find out more about the study and/or schedule a time for the interview, the Interviewers will be able to reach out to the participants using the provided contact information from the Consent to Contact form. For potential participants who may want to schedule a later time for the interview, an Interviewer will call or email the potential participant.

For those who would be willing to participate in the study after their scheduled appointment, they may indicate their interest to their Medical Assistant (MA), when the potential participant is getting ready for their appointments with their doctors. The MA will ask if the potential participant is aware of the study. If the potential participant is interested in learning more, the MA will direct the potential participant to the conference room to speak with the Recruiter or any of the Interviewers stationed in the exam rooms.

Front Desk Script
"Thank you for checking in. One more thing, I'm saying this to everyone coming to the clinic today. We're doing a study to find out more about people's health care preferences. If you have been diagnosed with depression and/or diabetes and would like to participate in this study, please let the medical assistant know or fill out this form, so a research member can contact you later. The interview will be in English or Spanish."

If the potential participant has any further question about the study, the front desk staff can provide the following information. For any further details, the front desk staff will refer the potential participant to a research staff.

- Length of study: 45 minutes to an hour
- It will be a questionnaire and interview.
- There will be monetary incentive.
- The study is confidential.
- Language: Spanish or English
- Conditions: Depression and/or Diabetes

Medical Assistant Script
"Did you hear about the study that is happening today? If you're interested, I can direct you to the research team member."

C3. Method III – Clinical Pharmacist

Garrett Lech is a clinical pharmacist at SHPC who meets daily with SHPC patients with a diagnosis of diabetes to provide diabetes treatment education. He has agreed to inform

potential participants about the study after their meeting and direct interested potential participants to our on-site study interviewers for information about the study. The third recruitment method relies upon referrals by Garrett Lech, PharmD, a clinical pharmacist and diabetes educator at SPHC. When meeting with Mr. Lech, individuals will be informed of the opportunity to participate in this study on preferences for diabetes and/or depression management. A large proportion of SHPC patients with DM are referred to the clinical pharmacist to receive education about DM, self-management, and the effective and safe use of medications for diabetes control. Garrett Lech has 12 or so meetings per day with patients with type II DM. At the end of the potential participant's scheduled appointment with Garett, he will inform the potential participant that there is a study going on at SHPC that day and that it involves completing a brief survey and interview. Garrett Lech will ask the individual if they are interested in hearing about the study. If the potential participant indicates interrest, Garrett Lech will ask the study Interviewer waiting in the nearby exam room to meet with the potential participant. An Interviewer will meet with the potential participant in the reserved exam room. Garrett Lech will also use the pre-written script in discussing the study to ensure the use of non-coercive, confidential and consistent language.

C4. Method IV – Waiting Room Recruitment

One of the interviewers will pass out the Consent to Contact form to everyone in the waiting room. This will give the interviewers a chance to speak with all potential participants and give them the opportunity to ask any questions. If the potential participants were interested in participating in the study, they may fill out the Consent to Contact form in the waiting room or at a later time. The potential participant may express interest or agree to participate in the privacy of the exam rooms, away from the open space of the waiting room. The medical assistant will remind all potential participant of the chance to participate, when rooming the potential participants. Potential participants may give the form to the medical assistant during rooming or to the front desk staff at any point. If the potential participant expresses interest in finding out more about the study, the medical assistant would let a research team member know. The interviewer will meet with the participants at the end of the scheduled clinic visit to either conduct the interview or schedule a time in the future to conduct the interview.

C5. Method V – Identifying African American/ Black Participants by word-of-mouth from our community partners

The community partners from Transformation Center is a peer advocacy group for individuals living with mental and physical chronic illnesses. They routinely work with and are in contact with individuals living with mental or physical chronic illnesses, as peer advisors and support groups. The Transformation Center hosts workshops and events that promote awareness of mental health issues. Through word-of-mouth, our community partners at the Tranformation Center would be able to help us spread information about the opportunity to participate in this project. Our community partners will pass out hard copies and send the electronic version of the flyer to potential participants on their email list who meet the following criteria:

1. identifies as African American or black;
2. has been diagnosed with diabetes or depression;

3. is at least 18 years of age.

If the potential respondents are interested in finding out more about the project, they can directly reach out to the Research Assistant and Project Manager via email or phone. The Interviewers will contact these potential participants over the email or phone to ask them if they may be interested in participating in this project. If the participant expresses interest, the Interviewer will determine the eligibility of the potential participant in their correspondence (via email or phone). If the participant qualifies for the study and expresses interest, the Interviewer will schedule a time to conduct the interview in person at 1035 Cambridge Street or at the Transformation Center, whichever location would be more convenient for the participant. The Informed Consent process will take place at the scheduled interview in person.

For all Methods , if the potential participant is a Spanish-speaker, the potential participant will be referred to the Spanish-speaking Interviewer.

D. *Eligibility Screening*

For Method I (Flyer), the Interviewer will administer the screening tool over the phone, when the potential participant contacts a number listed on the flyers and before the Interviewer schedules the time to conduct the interview. For Method II, III, and IV, once the Interviewer and the potential participant are in the reserved exam room or the conference room, the Interviewer will administer an initial screening questionnaire to verify the participant's eligibility. For potential participants who fill out the Consent to Contact form, the screener will be conducted over the phone, with the oral consent of the potential participant, when the Interviewers reach out to the potential participants. If the Consent to Contact form indicates that the potential participant would prefer being contacted by email, the screener will be sent to the potential participant via email. If the potential participant is eligible (at least 18 years old, reports having been diagnosed with DM and/or depression, and identifies as the listed racial/ethnic group), then the Interviewer will move on to the informed consent process.

We request a waiver of documentation of informed consent process for the short eligibility screening described above. The Interviewer will ask for oral consent to administer the eligibility screener. After eligibility is determined, a written informed consent process (described below) will be implemented. The eligibility screener of those who complete the pilot will contain the assigned ID and filed and stored as a part of the individuals' documents. No names or other identifiers will appear on any of the documents. For more information about the study ID and confidentiality, please refer to the III.6 Confidentiality section.

E. *Informed Consent*

All informed consent discussions/processes will occur at Somerville Hospital Primary Care, once the participant and the Interviewer are in a reserved exam room or the the conference room (down the hall from the waiting room). If the participant is being recruited through Method I (Flyer), the Interviewer will go through the consenting process at the time of their meeting, after the participant has been deemed eligible over the phone at initial contact. For participants

recruited through Methods II/III/IV, the Interviewer will conduct the informed consent process after the participant has been deemed eligible from the initial screening (see Step D). If a potential participant is eligible and would like to participate but cannot do so at the time of the informed consent process, s/he will be scheduled to return at a later time or day to participate in the study. The Interviewer will give the potential participant contact information of the Interviewer and the Project Manager, who will coordinate with the participant to reschedule a time to finish the survey and interview.

During the informed consent process, the participant will have a chance to read through the consent form. The Interviewer will offer to read through the informed consent form (see attached) with the participant and answer any questions the participant may have. The Interviewer will explain the study project in greater detail and inform the potential participant that the incentive to participate is a $50 gift card. The Interviewer will remind the participant that the cognitive interview portion may be audio recorded using a digital voice recorder if the participant consents to be recorded. (For more information on the transportation and protection of the audio recording, please see section III.6 Confidentiality.) If the participant agrees to continue with the interview process, the Interviewer and the participant will each sign two copies: one for the study record and one for the participant. The Interviewer will let the participant know that the participant can stop the interview at any point. The Interviewer will then conduct the cognitive interview with the participant.

* Research Authroization Required, Informed Consent Form was previously used and submited durring intital IRB submission.
** This recrutiment has been completed.

F. *The Treatment Preferences Survey*

The participant will be asked to complete the **Treatment Preferences Survey** on a computer. There are two versions: one for individuals who have reported a diagnosis of type II diabetes, and the other for individuals that reported a diagnosis of depression. In the part of the survey that is tailored differently for the diabetes and depression participants, the survey elicits preferences for treatment. The rest of the survey is identical for both diabetes and depression participants and includes modules related to past experience with treatment, discrimination in treatment, social support, family cultural conflict, psychological distress, and depressive symptoms. Once the English versions have been approved, the approved versions will be **translated into Spanish** by GfK**.** Please see attached English versions.

G. *Semi-Structured Qualitative Cognitive Interview*

After the participant completes the Preferences Survey, the Interviewer will conduct a qualitative cognitive interview, soliciting the participants' experiences and thoughts on the survey they completed (interview guide is attached). Included in the cognitive interview, the participant will also respond to the optimism scale (attached). With the consent of the participant during the Informed Consent process, the interview will be recorded. If the

participant would like to participate in the study but do not wish to be audio-recorded, the Interviewer will take notes of the conversation without the audio recording. The notes will be typed into a Word document. (For more details regarding the consent for audio recording, please see section III.E. Informed Consent.) The audio recording will later be transcribed and incorporate feedback to improve the clarity and relevance of the Treatment Preference Survey. (For more information, see III.2. Analyses). Any modifications to the protocol, survey, and interview guide will be sent to the IRB for approval.

Once the survey and interview is completed, the participant will be provided with a monetary incentive of a $50 giftcard for participation. Feedback from these 12 participants will be used to improve future the survey design. Based on the survey data and interview information collected in this project, we will modify the survey for future research projects to administer this Treatment Preference Survey on a larger scale.

2. Analyses

The primary goal of the pilot is to test the feasibility of the Treatment Preference Survey. With only 12 individuals, we will conduct a basic descriptive statistical summary. Based on their responses in the qualitative cognitive interview, the survey will be modified for future administration on the national level.

The qualitative data collective from the Cognitive Interview will be transcribed by the Interviewers and Recruiter. After the audio recording has been uploaded to the secured shared drive, the Interviewers and the Recruiter will revisit the audio recording and transcribe the Cognitive Interview Word documents. (For more information on the transportation and protection of the audio recording, please see section III.6 Confidentiality.)

3. Risk/Benefit Assessment

We do not anticipate significant risks associated with the proposed study. Minimal risks include the possibility of discomfort when discussing experiences in seeking health care for depression or diabetes treatment. Participants may become upset in discussing their frustrations dealing with the health care system or provider or seeking adequate care for dealing with these problems. Participants being asked about their past experiences may experience mild emotional discomfort in responding to sensitive questions in the interview.

Another possible risk is that some participants may feel uncomfortable answering certain questions, or may feel a burden of answering questions. Respondents in the proposed study will be told during the research assessments that they have the option of terminating the interview at any time or not answering specific questions. The interviewers will be instructed to implement short breaks during the interview if the respondent becomes fatigued or comments about the length of the interview. If the participant at any point during the interview expressed desire to engage in self-harm or suicide, the Interviewer will administer the Paykal Suicidal Screener and proceed with the emergency protocol (see attached).

While breach of confidentiality is one of the inherent risks, every precaution will be taken to maintain all rights and privacy protections. A data release agreement will be signed by all investigators who work with the data in any way. Because the goal of the study is to report findings based on aggregate data, all information obtained will be held strictly confidential. These inherent risks are typically assessed to be low, as no individually identifiable information will be obtained beyond the Informed Consent Form. All survey, audio-recording, and notes taken for the purpose of research will be identified using only the assigned ID number. The key will be available only to the Project Director. No data with individually identifying information will leave CHA. No medical records will be obtained or disclosed. For more information on confidentiality measures, please see section III.6 Confidentiality.

4. **Development of a Data and Safety Monitoring Plan**

In this study, adverse events (AEs) are defined as any abnormal psychological occurrence in a study participant that is temporally associated with research participation. Serious adverse events (SAEs) are those that are life-threatening, result in hospitalization, jeopardize the participant's health, or result in a persistent or significant incapacity. We do not expect any adverse events or serious adverse events as a result of this study. Some participants might experience mild discomfort or discomfort as a result of survey questions about mental health or treatment. Unexpected study-related adverse events might involve participants reporting significant distress or discomfort or suicidal ideation.

Study-related AEs, whether serious or not, expected or not, will be recorded by the involved study staff and reported to the PI upon occurrence. This will also be the case for any unanticipated problems that are not adverse events (e.g., breach of study procedures or confidentiality; participant complaints about their rights).

The PI will make a determination of whether an AE is expected or not and whether it is study-related or not. If a study-related AE is not an unanticipated problem, it will be reported to the IRB at the next continuing review. For all SAEs, study-related unexpected AEs, and other unanticipated problems, the PI will report these using the appropriate forms to the IRB within 5 business days of the staff reporting the problem.

5. Personnel

Dr. Jonathan Delman, Ms. Deborah Delman will work with patient advocates from the Transformation Center (Ms. Valeria Chambers and Ms. Catherine Quinerly Rodriguez), Patient Improvement Team (TBD), and Volunteer Health Advisor (Heba Abolaban) to inform the design of the survey. Ms. Deborah Delman is the Director of Transformation Center, a patient advocacy organization representing patient navigators for patients with mental illness. Ms. Valeria Chambers serves as the Coordinator of Blacks United in Recovery, provides leadership in policy initiatives and is a training team member at the TC. An important dimension of her current work is convening community members and training teams to integrate culture-specific

approaches and language that expresses culturally resonant themes regarding mental health suffering and mental health recovery. Ms. Rodriguez Quinerly is the Community Voice Policy Director at the TC, overseeing policy and training projects to increase access to peer support including language access, disability access and trauma sensitive support. As a bilingual and bicultural Latina, she coordinated the development of Latinos En Accion that promotes Spanish language peer support, training initiatives, and is seeking to build a community-based interpretation unit. TBD is Patient Lead of the CHA Primary Care Practice Improvement Initiative. TBD works directly with patient partners that are integrated into Practice Improvement Teams across primary care settings at CHA that provide the majority of care for patients with depression and diabetes at CHA.

The interviews will be conducted by the Student Researcher, the Research Assistant, Maria Sanchez, Selma de Castro and Dr. Progovac , who will work under the supervision of Dr. Dharma Cortes and be trained by Dr. Delman. All analysis will be led by the Principal Investigator, Dr. Benjamin Cook, in collaboration with Drs. Susan Busch, Adam Carle, Danny McCormick, and Ana Progovac. Drs. Busch of Yale School of Public Health and Carle of University of Cincinnati will work as consultants to develop the survey and advise on the Treatment Preference Survey. Each investigator has had extensive research experiences in health policy, disparities research, and research methodology. Please refer to **Appendix 1** for Dr. Busch's exempt letter from Yale University School of Public Health. Dr. Carle will receive a letter of determination from the Cincinnati Children's Hospital Medical Center (CCHMC). Please refer to **Appendix 2** for the IRB letter of determination for Dr. Carle from CCHMC. The Principal Investigator will be responsible for research administration and documentation. The Project Director, Project Manager, and Research Assistant will facilitate IRB correspondence and data protection.

6. Confidentiality

A. Data Security

After the interview, the Interviewer will bring the signed Informed Consent Form, completed Treatment Preference Survey back to 1035 Cambridge Street. Only the consent form will contain individually identifiable information of the participant. The electronic version of the Treatment Preference Survey will be identified using the assigned ID number only. GfK will provide a link to the survey per respondent. The participant may leave and come back to the survey as many time as needed. Once the pilot is complete, the data will be hosted at GfK, and GfK will provide the PI with the data from the survey instrument and only authorized research staff approved by the site Institutional Review Boards will have access to the data. GfK will send the coded dataset (identified only by the assigned study ID number) to the PI via email in the form of a .sav file. The signed Informed Consent Form will be placed in the designated locked cabinet by the Interviewer. The Project Director will not handle the informed consent forms. The signed consent form and any individually identifiable information on paper will be kept in a locked file cabinet at 1035 Cambridge Street.

The audio recording of the Cognitive Interview will be uploaded to a folder on Health Equity Lab shared drive, maintained by the research team and CHA. Only authorized research team members (the Interviewers, Recruiter, and Dr. Dharma Cortes) will be granted access to the folders by the PI. Once uploaded to the shared drive, the file will be deleted from the digital recorder.

When using Method V to identify African American/ Black participants, the potential participant may reach out directly to the Research Assistant or Project Manager via email or phone. Therefore, the community partner contact would not be involved in determining eligibility or conducting interview. Potential participants' contact information would be available to the Research Assistant, Project Manager, and the Interviewer, but the contact information will be kept separately from any survey results and will not be linked to participant responses. Our community partner contact at the Transformation Center will not have access to the audio recording or transcript of the interview or the survey response.

B. Data Coding

Each participant will be assigned an ID number, after they have been screened to be eligible. Upon completion of the interview and return to the 1035 Cambridge Street office, the Interviewers will inform the Project Director of the participants' names and associated ID number. The Project Director will be responsible for setting a password protected Excel document to keep track of the ID numbers and associated participant name. The key with participants' names and ID number will be kept under password protection and only accessed by the Project Director. Any audio recording and notes will be assigned and identified by the same ID number when downloaded from the digital audio recorder to the shared drive.

C. Audio Recording and Notes from the Cognitive Interview

The audio recording taken during the cognitive interview will be uploaded from the digital recorder to a folder on Health Equity Lab shared drive, maintained by the research team and CHA, for transcription and analysis. Access to this folder will be granted by the PI and available only to authorized team members, including the Interviewers, Recruiter, and Dr. Dharma Cortes. The audio recording will be uploaded immediately after the interview from the SHPC. (Both the exam room and the conference room, where the interview will be conducted, have computers.) Any hand-written notes taken during the cognitive interview will be brought back to 1035 Cambridge Street, typed into a Word document and saved in the same folder. The hand-written notes will be shredded immediately after the electronic file has been created.

No reports will be made public using any names or identifying information. Computerized data will be identified by ID number only. The coded information will be stored on a secure central server. Only authorized research staff approved by the site Institutional Review Boards will have access to the data. All data will be destroyed according to CHA protocol, 7 years after study analysis has been completed. In the case of breach of confidentiality, the CHA IRB office, PCORI project officers, and the participants will be notified.

7. Dissemination

Working with our community stakeholders from the Transformation Center, Volunteer Health Advisors, and CHA Patient Partners, the research team will summarize the findings of this study in accessible language and present to our community collaborators and research participants. After de-identification and analyses in the aggregate, any significant findings pertinent to the SHPC will be shared with the SHPC provider team. Report of the findings will only be in the aggregate. Only results that are not individually identifiable will be shared with the providers.

The work of this project will lay the foundations for a larger, nationally-representative survey. The findings from this survey study will be presented to both individuals with lived-experiences and mental health providers. Their response to the findings will be the result of our next qualitative project.

IV. Administration and Study Design of an Online Survey via GfK Custom Research

1. Study Design

A. Overview of Survey Administered by GfK Custom Research

Our previously described efforts will be used to finalize and roll out an online pilot study to 25 English-speaking individuals and 25 Spanish-speaking individuals. Once the online pilot study is finalized, the survey will be administered to 1500 individuals, 500 White respondents, 500 Black, non-Hispanic respondents and 500 Hispanic respondents. GfK already has an established mechanism for administering surveys. Once our survey is finalized after testing at CHA (see above), it will be given to GfK Custon Research who will release the survey to their respondents according to established GfK protocols.

B. Recruitment Methodology

GfK Custom Research selects households using random-digit dialing (RDD) or address-based sampling. Once a person is recruited to the panel, they are contacted primarily by e-mail (instead of by phone or mail). This permits surveys to be fielded very quickly and economically. In addition, this approach reduces the burden placed on respondents, since e-mail notification is less obtrusive than telephone calls. Most respondents also find answering Web questionnaires to be more interesting and engaging than being questioned by a telephone interviewer. GfK Custom Research's panel recruitment methodology uses the same or similar quality standards established by selected RDD surveys and area probability surveys conducted for the Federal Government (such as the CDC-sponsored National Immunization Survey).

C. Administration of the Internet Survey by GfK Custom Research:

GfK Custom Research administers internet-based surveys, using an online research panel – KnowledgePanel® – that is representative of the U.S. population. Panel Members are randomly recruited by telephone and mail surveys, and households are provided with access to the Internet and hardware if needed. Unlike other Internet research panels sampling only individuals with Internet access volunteering for research, KP is based on a sampling frame

which includes both listed and unlisted numbers, those without a landline telephone and is not limited to current Internet users or computer owners, and does not accept self-selected volunteers.

When surveys are assigned to KP members, they receive notice in their password protected e-mail account that the survey is available for completion. Surveys are self-administered and accessible any time of day for a designated period. Participants can complete a survey only once. Members may leave the panel at any time. All KP panelists, when joining the panel, are given a copy of the Privacy and Term of Use Policy (also available electronically at all times to panelists via the Panel Member website). Once the participant receives the survey link, the information below will be shown in the email correspondence that provides the access to the instrument:

> Thank you for continuing to be part of the KnowledgePanel®. This survey asks about *your preferences in medical care*. This survey is being conducted by *a research study funded by the Patient Centered Outcomes Research Institute*. The study will help researchers *understand how patients receive health care treatment in the United States*.As with all KnowledgePanel® surveys, your response to this survey, or any individual question on the survey, is completely voluntary. You will not be individually identified and your responses will be used for analyses only. If you have questions about your rights as a participant in this survey, or are dissatisfied at any time with any aspect of the survey, you may contact the KnowledgePanel Panel Member Support at 800-782-6899.

(Please see attached GfK_Consent Language.pdf that verifies that GfK will display the above message at the time of administration of the survey instrument.

Additionally, at the time of administration, KP participants will fill out a standard consent form used in KP studies. This standard consent form will inform participants that there will be an option at the end of the study to opt-in to be contacted for an in-depth interview apart from the general survey administration. (See *Aim2_Summary.docx* attached for more information).

*Waiver of research authorization request.

D. Identification of patient treatment preferences

The online survey consists of a four-module questionnaire to elicit and measure patient treatment preferences and experiences. (1) The first part contains screening questions to identify survey respondents with depression or type II diabetes. All respondents will be prompted to answer the PHQ-9 and a question about their diagnosis of Type 2 Diabetes (See *SurveyInstrument_CHA_PatientPreferences2017.docx* for more information). After their PHQ-9 score and their Type 2 Diabetes status has been determined, GfK will assign participants to the survey instrument that best describes their condition.

We have worked with GfK to develop a protocol that will meet our pre-established sample sizes: 750 with mild to severe depression and 750 with type II diabetes; within each condition,

250 Blacks, 250 Latinos, and 250 non-Latino whites (Please see *SurveyInstrument_CHA_PatientPreferences2017* for more information):

The main questionnaire will be comprised of direct preference elicitation questions regarding preferences between treatment alternatives via conjoint analysis (See *LogIn_Online_Survey Instrument.docx* to see the images and examples of the conjoint analyses questions).(3) Consequently, respondents will be prompted to answer questions pertaining to their previous medical care experience and (4) questions that probes other influencing factors in the decision-making of participants such as their relationship with family/relatives.

*****The administration of the online survey was completed August 4, 2017*****

2. Analysis of Survey Data

Data analysis will be done at CHA by the PI, co-Investigators and consultants. Adam Carle, Ph.D will be working with the team as the Co-Investigator to assist with the data analysis.

Adam Carle, PhD, MA, Co-Investigator, is Associate Professor at the University of Cincinnati Children's Hospital Department of Pediatrics, with a PhD in Quantitative Methods and Clinical Emphases. His expertise in latent class analysis will be critical to analyzing results to understand the individual and contextual variables that influence patient preferences.

The goal of the analysis is to estimate overall differences in preferences between racial/ethnic groups, predict preferences for individuals with specific characteristics, and estimate the influence of past treatment experiences and other demographic factors on patient preferences and the extent which these factors and their influence vary between racial/ethnic groups.

8. 3. Risk/Benefit Assessment

We do not anticipate significant risks associated with the proposed study. Minimal risks include the possibility that some participants may feel uncomfortable answering certain questions, or may feel a burden of answering questions. Respondents in the proposed study will be told during the research assessments that they have the option of terminating the questionnaire at any time or not answering specific questions.

Because the goal of the study is to report findings based on aggregate data, all information obtained will be held strictly confidential. These inherent risks are typically assessed to be low, as no individually identifiable information will be obtained beyond the standard consent form that will be sent by GfK and those participants that wish to participate in the Aim 2 of our study. No medical records will be obtained or disclosed. For more information on confidentiality measures, please see page 8. in *KP_Fully Executed Contract_20160729.*

9. Respondent Privacy

GfK will not disclose the identity of respondents or any respondent-identifiable information to CHA, except if the respondent wishes to share their information for research purposes. If they do accept to share their information, then this will help researchers to follow up with further qualitative research to understand their answers and the validity of the survey instrument, please see page 8. In *KP_Fully Executed Contract_20160729* and *Aim2_Summary.docx. These analyses are proposed in Aim 2 of our study and we will be requesting an amendment to conduct this part of the study after we have more detail from Aim 1 findings.*

10. Potential Benefits of the Proposed Research to the Subjects and Others

The respondents who participate will help to improve our understanding of patient preferences. We expect that the risks to subjects are reasonable in relation to the anticipated benefits.The importance of this component of the project informs the overall goal of eliciting patient preferences to renew the focus of patient-centeredness on racial/ethnic disparities in care. The risks to subjects are reasonable in relation to the importance of the knowledge to be gained.

4. Development of a Data and Safety Monitoring Plan

In this study, adverse events (AEs) are defined as any abnormal psychological occurrence in a study participant that is temporally associated with research participation. Serious adverse events (SAEs) are those that are life-threatening, result in hospitalization, jeopardize the participant's health, or result in a persistent or significant incapacity. We do not expect any adverse events or serious adverse events as a result of this study. Some participants might experience mild discomfort or discomfort as a result of survey questions about mental health, diabetes or service use. Unexpected study-related adverse events might involve participants reporting significant distress, discomfort or suicidal ideation. GfK provides contact information in case of any AEs or SAEs that will be presented to the participants at the time that they receive the invitation to participate in the survey instrument (See IV.1. *B. Recruitment Methodology* for more information).

In case of any further complications, GfK will communicate with PI Dr. Benjamin Cook and he will make a determination of whether an AE is expected or not and whether it is study-related or not. If a study-related AE is not an unanticipated problem, it will be reported to the IRB at the next continuing review. For all SAEs, study-related unexpected AEs, and other unanticipated problems, Dr. Cook will report these using the appropriate forms to the IRB within 5 business days of the staff reporting the problem.

5. Personnel

Please see *III.5 Personnel* for more information.

All questionnaires will be administered and conducted by GfK. All analyses will be led by the Principal Investigator, Dr. Benjamin Cook, in collaboration with Drs. Susan Busch, Adam Carle, , Danny McCormick, and Ana Progovac. Drs. Busch of Yale School of Public Health and Carle of University of Cincinnati will work as consultants to develop the survey and advise on the Treatment Preference Survey. Each investigator has had extensive research experience in health policy, disparities research, and research methodology.The Principal Investigator will be responsible for research administration and documentation. The Project Director, and Research Assistant will facilitate IRB correspondence and data protection.
Dr. Busch's IRB approval was sent in with the previous submission sent on December 5th, 2016 Please refer to **Appendix 1** for Dr. Busch's exempt letter from Yale University School of Public Health. Please refer to **Appendix 2** for the IRB letter of determination for Dr. Carle from CCHMC.

6. Confidentiality

All de-identified data will be kept in password protected files. Only authorized research staff approved by the site Institutional Review Boards will have access to the data. Dr. Susan Busch of Yale School of Public Health (has already been approved by her institution's IRB) and the review and approval of Dr. Carle's collaboration is contingent upon the approval of this project from Cambridge Health Alliance. We have received a letter of exemption from the University of Cincinnati for Dr. Carle to work with de-identified data. Local investigators will access the data via a password protected network on the secure CHA server.

11. 1. Data Security at GfK. Electronic survey data records are stored in a secured database that does not contain personally identifying information. The staff members in the Panel Relations and Statistics departments, who have access to the personally identifying information, do not have access to the survey response data, with the exception of the aforementioned database and IT administrators who must have access to maintain the computer systems, do not have access to the personally identifying information. The secured database contains field-specific permissions that restrict access to the data by type of user, as described above, preventing unauthorized access.

12. 2. Data Coding. The survey response data are identified only by an ID number. The personally identifying information is stored in a separate database that is accessible only to persons with a need-to-know (described above). The survey data extraction system exports only anonymized survey data identified only by the Panel Member ID number. The data analysts with access to the survey data extraction system, cannot join survey data to personally identifying data, as they do not have access to personally identifying information. Panel Relations and Statistics staff members do not have access to the survey data extraction system, and therefore cannot join survey data to personally identifying data.

All personally identifying records are kept secured in a separate office in the Informational Technology section of the main GfK offices in Menlo Park, CA, and all data transfers from personal computers to the main servers pass through a firewall. GfK Custom Research never provides any respondent personal identifiers to any client or agency without the explicit and informed consent provided by the sampled Panel Members. Unless explicitly permitted as documented in a consent form to be contacted as part of Aim 2, no personally identifying information will be provided to any parties outside GfK Custom Research in combination with the survey response data. All de-identified survey data will be safely kept at the CMMHR. All data files will be stored in password protected electronic files, according to de-identified data protection rules described above.

As part of their work with the FDA, GfK Custom Research has implemented Good Clinical Practice guidelines to assure compliance with FDA requirements for systems documentation and privacy of stored survey data. Consequently, a system of standard operating procedures is in place for documenting all processes relating to maintaining confidentiality and privacy of the identities of Panel Members. GfK Research retains the survey response data in its secure database after the completion of a project. These data are retained for purposes of operational research, such as studies of response rates and for the security of our customers who might request at a later time additional analysis.

All inbound e-mail traffic for gfk.com is encrypted during the transmission (Transport Layer Security (TLS) protocol) - if the sender's mail system also offers this service. Outbound email traffic is protected by the corporate Exchange cluster and the smtp gateway mailout.gfk.com. GfK operates secure FTP sites for the transfer of data between ourselves and our clients.

3. Data Transfer. The data transfer will occur once the data collection has been completed and this will happen through a password-protected SPSS file that will be sent to the PI.

7. Dissemination

Working with our community stakeholders from the Transformation Center, Volunteer Health Advisors, and CHA Patient Partners, the research team will summarize the findings of this study in accessible language and present to our community collaborators and research participants. Report of the findings will only be in the aggregate. The findings from this survey study will be presented to both individuals with lived-experiences and mental health providers.

V. Administration and Study Design of Aim 2 Semi-Structured Qualitative Interviews Soliciting Patient Narratives and Reactions to the Survey

As part of Aim 1 during the pilot testing of the survey, we interviewed 12 individuals at CHA Somerville Hospital Primary Care (June 2017). In Aim 2, we will conduct up to 56 semi-structured follow-up interviews. 24-40 interviews will be follow-up phone interviews from the subset of online GfK survey respondents. 16 interviews will be conducted among patients recruited through our community partner, the Transformation Center. The Transformation Center will help us to identify 16 individuals (6 Black, 5 Latino and 5 non-Latino white). These individuals will be invited to conduct the online survey instrument and then an in-person follow-up. The follow-up interview questions will inquire into the reasons underlying survey responses to examine the validity of preferences generated in Aim 1 of the KP survey, and will solicit explanatory narratives regarding patients' past experiences with healthcare and how these have informed preferences, and ask patients to reflect on their willingness to use such a tool to collaborate with their physicians on treatment decisions in the future.

1. Study Participant Population and Location

The final version of the KnowledgePanel (KP) survey is being administered online (starting August 4, 2017 – anticipated end date is August 21, 2017) through GfK Custom Research to 1500 individuals, consisting of 500 White respondents, 500 Black respondents, and 500 Hispanic respondents. After completing the survey, respondents were asked whether they would be willing to participate in a brief phone survey to further discuss questions related to depression and type II diabetes treatment preferences.

For those interested in a follow-up interview, we will conduct up to **24-40** phone interviews with individuals from the GfK Knowledge Panel patient group (as few as 24 if we reach content saturation, and up to 40 if necessary), as well as up to **16** in-person interviews with patients recruited by word of mouth through Transformation Center, one of our community partners (please refer to Section III.C5). The phone and in-person interviews will last approximately 45 to 90 minutes to complete, (allowing 20 minutes for participants to complete the survey for the in-person interviews).

Half of the sample population will have a diagnosis of diabetes mellitus (DM) and half will have a diagnosis of depression. Interviews will be conducted using a semi-structured interview protocol developed in conjunction with our stakeholder/research team. Please see attached the Spanish and English version of the semi-structured interview guide.

The 16 in-person qualitative interviews will be completed with participants recruited through the Transformation Center, at private rooms either at the Transformation Center or 1035 Cambridge St. For these 16 individuals (6 Black, 5 Latino and 5 non-Latino white), approximately

half of the sample population will have a diagnosis of diabetes mellitus (DM) and half will have a diagnosis of depression.

2. Qualitative Interview Design

While the *cognitive* interview was used as part of survey pilot testing, the semi-structured follow-up *qualitative* interview guide for the 40-56 individuals will be developed in conjunction with our stakeholder/research team as part of Aim 2. This is a qualitative aim where patients will be asked to reflect on their survey responses in Aim 1. The interviewers will invite patients to reflect on their preferences for care from the CA, and the reasons for their selected options, as well as to reflect on any areas where preferences were not fully captured.We will pose the following types of questions: *"Your choices suggest a preference for X. What would best explain your preference for this type of treatment?"* In addition, we will ask: *"You have declared that you do not prefer Y. What were the reasons that you did not prefer this type of treatment?"* We will probe for underlying reasons, to be modified in initial stakeholder and patient focus groups. Additional questions will focus on a) how individual, family and socio-cultural factors (e.g. fear of addiction, family support for care, provider communication style) influence preferences; b) how preferences influence treatment choice; and c) how individuals adapt their preferences based on prior experiences of discrimination or poor quality treatment. Next, patients will be asked to consider whether they would be comfortable using this type of preferences elicitation method to aid in SDM with a provider, as well as to comment on to what extent they feel this method would improve their patient-provider interactions and satisfaction with their treatment plan.

All cognitive and qualitative interviews will be audio-recorded and transcribed, and conducted by our interview team: Dr. Progovac, Dr. Cortes, Esther Lee, and Maria Jose Sanchez. To ensure the validity and coherence of the emerging priorities represented by the data, we will conduct an initial analysis of the first five interviews, in order to confirm that we are collecting the relevant information and to establish whether we need to add additional questions in the interview guide. Because the nature of the interview is semi-structured, and most questions are based on the online survey responses that participants completed, the questions serve as a guide for Interviewers. Please see attached the Spanish and English version of the semi-structured interview guide.

3. Eligibility Screening

For the 24-40 phone interviews that follow-up with GfK online survey participants, GfK will conduct eligibility screenings incorporated into the online survey instrument prior to

participants completing the surveys. For more information about eligibility screening, please refer to section III.D

For the 16 in-person interviews recruited through the Transformation Center, the Interviewer will administer an initial screening questionnaire to verify the participant's eligibility. If the participant is eligible (at least 18 years old, reports having been diagnosed with DM and/or depression, and identifies as the listed racial/ethnic group), then the Interviewer will move on to the informed consent process. The Interviewer will ask for oral consent to administer the eligibility screener. We request a waiver of documentation of informed consent process for the short eligibility screening described above. After eligibility is determined, a written informed consent process (described below) will be implemented. The eligibility screener of those who complete the pilot will contain the assigned ID and filed and stored as a part of the individuals' documents. No names or other identifiers will appear on any of the documents. For more information about the study ID and confidentiality, please refer to the III.6 Confidentiality section.

A. *Informed Consent*

Participants who completed the 1500 online surveys via the KnowledgePanel will receive an email invitation by GfK to participate in the 45 to 90 minute semi-structured phone interview. Incorporated into the email invitation is the informed consent to participate in the semi-structured follow-up. GfK will follow-up with 24-40 individuals who have consented to the study to schedule a phone interview. During the phone interview, the Interviewer will verify that the participant understood the consent information and answer any questions the participant may have. GfK will provide articipants 50,000 points for their participation (worth $50). Please see attached the English and Spanish consent forms that will be administered via GfK in the email invitation.

For the 16 in-person interviews, all informed consent discussions/processes will occur at the Transformation Center or 1035 Cambridge Street, once the participant and the Interviewer are in a reserved, private exam room. Before the interview begins, the Interviewer will provide the participant with the following Health Research brochures created by the Harvard Catalyst as general information regarding research studies: Research Subject Bill of Rights, Research Data: How is my information protected and used, and Participating in a Survey. Please see attached the English and Spanish version of the brochures that will be given to participants prior to the survey and interview. The Interviewer will ask if the participant has any questions regarding the brochure. Then the Interviewer will conduct the informed consent process after the participant has been deemed eligible from the initial screening (see Section III Step D). If a potential participant is eligible and would like to participate but cannot do so at the time of the informed consent process, s/he will be scheduled to return at a later time or day to participate in the study. The Interviewer will give the potential participant contact information of the Interviewer and the Research Assistant, who will coordinate with the participant to reschedule a time to

finish the survey and interview. Please see attached below the English and Spanish consent forms for the 16 in-person interviews.

During the informed consent process for the 16 in-person interviews, the participant will have a chance to read through the consent form. The Interviewer will offer to read through the informed consent form (see attached) with the participant and answer any questions the participant may have. The Interviewer will explain the study project in greater detail and inform the potential participant that the incentive to participate is a $50 Target Visa gift card which is valid only in the U.S. at merchants that accept Visa debit cards. The Interviewer will remind the participant that the interview portion may be audio recorded using a digital voice recorder if the participant consents to be recorded. (For more information on the transportation and protection of the audio recording, please see section III.6 Confidentiality.) If the participant agrees to continue with the interview process, the Interviewer and the participant will each sign two copies: one for the study record and one for the participant. The Interviewer will let the participant know that the participant can stop the interview at any point. The Interviewer will then conduct the interview with the participant.

B. *The Treatment Preferences Survey*

For the 16 in-person interviews, the participant will be asked to complete the **Treatment Preferences Survey** on a computer. There are two versions: one for individuals who have reported a diagnosis of type II diabetes, and the other for individuals that reported a diagnosis of depression. In the part of the survey that is tailored differently for the diabetes and depression participants, the survey elicits preferences for treatment. The rest of the survey is identical for both diabetes and depression participants and includes modules related to past experience with treatment, discrimination in treatment, social support, family cultural conflict, psychological distress, and depressive symptoms. Please see attached the English and Spanish versions.

4. Analyses

For the 40-56 semi-structured qualitative interviews, we will conduct a content analysis of the areas of importance for understanding preferences for depression care. The analysis will be conducted based upon initial a priori identification of individual (i.e., cost, time, experience with discriminatory care), family (i.e., stigma, impact of illness on family), and socio-cultural factors (i.e., community perceptions of benefits of mental health care) associated with preferences for care. Similarities and differences among the respondents will be summarized in a matrix, separated according to these domains.

Drs. Progovac, Cortes, our research assistant, and our student researcher will code the interviews using two approaches simultaneously: 1) coding using revised a priori codes based on the conceptual model; and 2) open coding to identify new concepts found in the data. The researchers will consider coding themes stratified by racial/ethnic group. Trustworthiness of the data will be determined through regular investigator meetings, the application of analytic reflexivity in the interpretive process, and constant comparison of emerging themes. All codes generated will be iteratively compared and contrasted using the constant comparative method with the first and second coders meeting after coding sets of three interviews.

The consistency of coding a priori codes, new open codes, and coding challenges on themes will be discussed in these meetings and discrepancies will be resolved in discussion until consensus is reached. The coders will organize the data according to the axial coding scheme. We use NVivo software to organize interview extracts into thematic categories, and create a data dictionary. To refine themes, the team will further analyze all excerpts within a theme into sub-categories as well as define and name themes. Ultimately, the qualitative data analysis will provide contextual in- depth explanations to better understand the relationship between socio-cultural beliefs, prior positive, negative or discriminatory experiences in health care, and preferences for depression and type II diabetes treatment.

5. Risk/Benefit Assessment

**Protocols for the Risk/Benefit Assessment for this part of the project are identical to the protocol for Aim 1 as described above in Section III. Part D. Please refer to that section for details.

6. Development of a Data and Safety Monitoring Plan

** Protocols for the Development of a Data and Safety Monitoring Plan for this part of the project are identical to the protocol for Aim 1 as described above in Section III. Part 4. Please refer to that section for details.

7. Personnel

**For more details regarding personnel, please refer to section III.5

The interviews will be conducted by the Student Researcher, the Research Assistant, Maria Sanchez, and Dr. Progovac , who will work under the supervision of Dr. Dharma Cortes. All analysis will be led by the Principal Investigator, Dr. Benjamin Cook, in collaboration with Drs. Susan Busch, Adam Carle, Dharma Cortes, Danny McCormick, and Ana Progovac.

8. Confidentiality

a. Data Security

** Protocols for the Data Security part of the project are identical to the protocol for Aim 1 as described above in Section III. Part 6A. Please refer to that section for details.

b. Data Coding

** Protocols for the Data Coding part of the project are identical to the protocol for Aim 1 as described above in Section III. Part 6B. Please refer to that section for details.

c. Audio Recording and Phone Interview Notes

** Protocols for the Audio Recording and Phone Interview Notes part of the project are identical to the protocol for Aim 1 as described above in Section III. Part 6C. Please refer to that section for details.

9. Dissemination

Results from the interviews in this study will be analyzed for recurring themes and used to provide a practical contextual understanding of the association between treatment preferences and past experience, to supplement quantitative survey results from Aim 1. For short-term dissemination, integrated findings will be presented to patient stakeholders and clinicians in the form of a fact sheet explaining the methodology and proposed clinical potential of the preference elicitation tool. With input from clinicians on the feasibility of incorporating the tool into practice, integrated results will ultimately provide the basis for incorporating preference elicitation into joint treatment planning.

VI. Administration and Study Design of Aim 3 Semi-Structured Qualitative Interviews with Providers to Incorporate Findings into Clinical Encounters

1. Study Participant Population and Location

In Aim 1, we interviewed 12 individuals at CHA Somerville Hospital Primary Care. In Aim 2, we conducted 24 qualitative phone interviews with a subset of GfK survey respondents and 16 local in-person interviews with our community partners.

In Aim 3, we will conduct up to 25 qualitative interviews with four groups of clinical stakeholders involved in the implementation of primary care teams at CHA. Of the 25 participants, we will conduct seven interviews with Primary Care Providers, six interviews with Nurse Practitioners, six interviews with Care Coordinators, and six interviews with ACO coordinators. These stakeholders will be drawn from those delivering team-based primary depression and diabetes care at Somerville Primary Care Clinic and CHA administration. This urban safety net healthcare system is representative of underserved, urban, high-density minority communities in the U.S. Danny McCormick, Director of the Division of Social and Community Medicine and Director of Research in the Department of Medicine at the Cambridge Health Alliance and a Primary Care Physician at SHPC serves on the research team of this study. He will help us to identify the 25 individuals. These individuals will be invited by Dr. McCormick via email to participate in the in-person interview to reflect on the findings of Aims 1-2 to understand how we can further incorporate patient preferences into clinical encounters. Please see below a draft of the recruitment email. If participants are interested, they would reach out to the Research Assistant to schedule an interview time at SHPC. Interviews will be conducted in either at the provider's enclosed room/private room at Somerville Hospital Primary Care or at a private room at 1035 Cambridge Street.

Dear ___,

I hope this email finds you well. I am collaborating with Ben Cook, Director of the Health Equity Research Lab at CHA, and his research team on a research project to determine whether it is possible to improve treatments/outcomes for patients by using a novel way of eliciting patient treatment preferences. I'm writing to ask if you would consider participating in the study by doing an interview with a study team member to give your views about this issue.

This study is funded by a federal grant from PCORI. The primary aim of this study is to determine how the methods we use in primary care settings for understanding patient preferences for different treatment options can be improved, particularly for racial and ethnic minorities. We are focusing on two conditions, diabetes and depression. The idea here is that we might be able to better tailor patient treatment plans to their needs by better understanding what is important to them, and particularly, how past experiences, such as having been discriminated against in health care settings, might affect treatment preferences.

We are conducting 45-minute semi-structured interviews with providers at SHPC. It would be invaluable to get your insights in to how we currently elicit patient preferences and ***whether an alternative model could work better. As a token of our appreciation, you will receive a $75 Visa giftcard for your participation.***

If you are interested, please contact our colleague Esther Lee (estlee@challiance.org). She will follow up to schedule a time and place for the interview that is most convenient for you.

Please let us know if you have any questions.

Thank you,

Danny McCormick, MD

Ben Cook, PhD
Director, Health Equity Research Lab

Inclusion criteria: Identified staff delivering team-based primary depression and diabetes care at Somerville Primary Care Clinic and CHA administration

Exclusion criteria: CHA employees not delivering team-based primary depression and diabetes care at Somerville Primary Care Clinic and CHA administration.

Withdrawal/Termination criteria: For a variety of reasons, a subject enrolled in a research study may decide to withdraw from the research. If a subject decides to withdraw during or after the interview, their interview data will not be utilized and all recordings of their interview at that point will be deleted on the recorder after Interviewers have returned back to their office (1035 Cambridge Street). All withdrawal and termination cases will be documented by the PI. Participants will be informed that withdrawal will not involve a penalty or loss of benefits to which the subject is otherwise entitled. The $75 Visa giftcard is not contingent on the completion of their interview. As such, participants will still receive the Visa giftcard for their participation.

2. Qualitative Interview Guide

The 45-minute semi-structured interview guide for the 25 individuals was jointly developed by the community partners and research team and focus on three specific areas:

(1) *Clinical relevance of the elicited patient preferences and experiences in depression and diabetes treatment:* The interviewer will discuss the main findings from Aims 1-2 and then

inquire stakeholders about the role (if any) of elicited preferences in the treatment of depression and diabetes. In this focus area, we ask clinicians if and how they would raise questions about patients' prior experiences of care, and how these conversations would fit into the primary care encounter. We will prove to see where and how preferences elicitation can be implemented at CHA. Questions will focus on how these preferences would affect shared-decision making between providers and the patients and aid in treatment plan development.

(2) *Feasibility of incorporating a refined preferences elicitation understanding to improve joint treatment plan development between patient and provider in a clinical setting:* We will focus on the feasibility of incorporating a refined preferences elicitation understanding to improving join treatment plan development between patient and provider in the contents of depression and type II diabetes care. This portion of the interview will focus on clarifying facilitators and barriers to implementation such as resources needed to implement refined preferences elicitation in the clinic, organizational constraints and perceived acceptability among colleagues.

(3) *Adaptability of the preference elicitation methodology to other chronic diseases (asthma, cardiovascular disease, and obesity).* Finally, we will discuss how this methodology could be adapted to develop preferences elicitation guidelines across a range of chronic diseases that could be useful in helping physicians and patients corroborate treatment plans with patient concerns and goals. We will explain the methodology and examples of results to physicians, and then supply them with a list of chronic diseases and ask them to comment on whether they believe this methodology could be adapted to these diseases, as well as give them the opportunity to offer other disease for which they believe this method could be adapted.

4. Informed Consent

For the 25 individuals, all informed consent processes will occur at Somerville Hospital Primary Care or 1035 Cambridge Street, once the participant and the Interviewer are in a reserved, private room. Before the interview begins, the Interviewer will re-inform the participant of the study and will then ask the participant if he/she has any questions. The Interviewer will then ask if the participant is interested in participating in the study. If the participant is interested, the Interviewer will conduct the informed consent process.

During the informed consent process, the participant will have a chance to read through the consent form. The Interviewer will offer to read through the informed consent form (see attached) with the participant and answer the questions participants may have. The Interviewer will explain the study project in greater detail and inform the potential participant that the incentive to participate is a $75 Target Visa gift card which is valid only in the U.S. at merchants that accept Visa debit cards. The Interviewer will remind the participant that the interview portion may be audio-recorded using a digital voice recorder if the participant consents to be recorded. If the participant agrees to continue with the interview process, the Interviewer and the participant will each sign two copies: one for the study record and one for the participant. The Interviewer will let the participant know that the participant can stop the interview at any point. The Interviewer will then conduct the interview with the participant. Because the interviewees are identified by Danny McCormick, no eligibility screening will be conducted.

* Research Authroization Required, Informed Consent Form was previously used and submited durring intital IRB submission.
** This recrutiment has been completed.

5. Analyses

For the 25 semi-structured qualitative interviews, we will conduct a content analysis of the areas of importance for understanding how providers elicit patient preferences of their patients. The analysis will be conducted to identify themes that arise from the interviews.

Drs. Progovac, Cortes, Rodgers, our research assistant, and our student researcher will code the interviews using two approaches simultaneously: 1) coding using revised a priori codes based on the conceptual model; and 2) open coding to identify new concepts found in the data. Trustworthiness of the data will be determined through regular investigator meetings, the application of analytic reflexivity in the interpretive process, and constant comparison of emerging themes. All codes generated will be iteratively compared and contrasted using the constant comparative method with the first and second coders meeting after coding sets of three interviews.

The consistency of coding a priori codes, new open codes, and coding challenges on themes will

be discussed in these meetings and discrepancies will be resolved in discussion until consensus is reached. We use Dedoose software to organize interview extracts into thematic categories, and create a data dictionary. To refine themes, the team will further analyze all excerpts within a theme into sub-categories as well as define and name themes. Ultimately, the qualitative data analysis will provide contextual in-depth explanations to better explore the methods providers use in primary care settings to understand patient preferences for different options, particularly for racial and ethnic minorities and how it can be better improved.

To ensure the validity and coherence of the emerging priorities represented by the data, we will conduct an initial analysis of the first five interviews, in order to confirm that we are collecting the relevant information and to establish whether we need to add additional questions in the interview guide. Because the nature of the interview is semi-structured, and most questions are based on the online survey responses that participants completed, the questions serve as a guide for Interviewers. Please see attached the English version of the semi-structured interview guide. Any modifications to the protocol and interview guide will be sent to the IRB for approval.

6. Risk/benefit Assessment:

1. **Physical risk:** N/A
2. **Psychological risk:** Although the risk to participants is minimal, some participants might experience mild discomfort or discomfort as a result of discussing their experience developing treatment plans with their patients and their patient's past health care experiences. Participants will be informed at the beginning of the interview that they may stop or skip any questions at any point in the survey and they will still receive the giftcard.
3. **Social risk:** N/A Although we anticipate that social risks, if any, are minimal, one may include a feeling of embarrassment as a result of not participating.
4. **Economic risk:** If interviews are scheduled during the workday, possible economic risks include the unpaid time that could have been spent with a patient but instead is being spent to be interviewed. However, participants will be informed that this study is voluntary and they are able to stop the interview at any point. Furthermore, participants will be compensated with a giftcard for their participation.
5. **Potential benefit of participating in the study:** This study provides benefits to both the participant and general community. From this study, participants will receive a financial compensation through the $75 giftcard. Furthermore, participants will also be able to learn the

findings from our survey administration and interview data from Aim 1-2 which presents on patient preferences of treatments among patients with diabetes and/or depression and their experience with discrimination in the healthcare setting (Please refer to Domain 3 of interview guide). There are great potential benefits of this research for the general population. Little is known about the ways in which patient preferences affect perceived quality of care for patients. The analyses proposed in this study could be of great significance in improving patient-provider interaction and engagement for treatment plans.

Subject Timeline: We anticipate to complete qualitative interviews by November 2018. Data analysis will begin shortly after interviews are completed and will run until January 2019.

Transportation: Participants will not be reimbursed for transportation due to the fact that we will conduct interviews at their office.

Subject fees: N/A

Study results: No study results will be given to subjects. Study results will be presented with dissemination purposes in academic conferences as well as with completion of manuscripts.

7. Development of a Data and Safety Monitoring Plan

** Protocols for the Development of a Data and Safety Monitoring Plan for this part of the project are identical to the protocol for Aim 1 as described above in Section III. Part 4. Please refer to that section for details.

8. Personnel

**For more details regarding personnel, please refer to section III.5

The interviews and informed consent process will be conducted by Research Assistants, Ora Nakashand Drs. Cortes and Progovac. Drs. Cortes and Progovac and the Research Assistants will be providing ongoing information to the study sponsor at the IRB. All analysis will be led by the Principal Investigator, Dr. Benjamin Cook, in collaboration with Drs. Susan Busch, Adam Carle, Dharma Cortes, Danny McCormick, Caryn Rodgers, and Ana Progovac.

9. Confidentiality

a. Data Security

The audio recording taken during the interviews will be uploaded from the digital recorder to a folder on Health Equity Lab shared drive, maintained by the research team and CHA, for transcription and analysis. Access to this folder will be granted by the PI and available only to authorized team members, including the Interviewers, Recruiter, and Dr. Dharma Cortes. The audio recording will be uploaded immediately after the interview.

No reports will be made public using any names or identifying information. Computerized data will be identified by ID number only. The coded information will be stored on a secure central server. Only authorized research staff approved by the site Institutional Review Boards will have access to the data. All data will be destroyed according to CHA protocol, 7 years after study analysis has been completed. In the case of breach of confidentiality, the CHA IRB office, PCORI project officers, and the participants will be notified.

b. Data Coding

** Protocols for the Data Coding part of the project are identical to the protocol for Aim 1 as described above in Section III. Part 6B. Please refer to that section for details.

c. Audio Recording and Phone Interview Notes

** Protocols for the Audio Recording and Phone Interview Notes part of the project are identical to the protocol for Aim 1 as described above in Section III. Part 6C. Please refer to that section for details.

Team Members:

ALL CHA Research Team Members	Individual's Role	Human Subject Training
Benjamin Le Cook	Principal Investigator	CITI, 3/24/2017
Ana Progovac	Co-Investigator	CITI, 1/11/2018
Danny McCormick	Co-Investigator	CITI, 10/28/2019
Caryn Rodgers	Co-Investigator	CITI, 04/04/2019
Leslie Adams	Co-Investigator	CITI, 9/30/2019
Ora Nakash	Consultant	CITI, 8/14/2018
Dharma Cortes	Co-Investigator, Interviewer	CITI, 1/02/2018
Nathaniel Tran	Research Assistant	CITI, 06/17/2019
Michael Flores	Postdoctoral Fellow	CITI, 11/15/17
Nicholas Carson	Co-Investigator	CITI, 10/29/2019
Margo Moyer	Research Assistant	CITI, 06/27/2019