PROTOCOL TITLE:

Official Title:

A Patient-Centered Framework to Test the Comparative Effectiveness of Culturally and Contextually Appropriate Program Options for Latinos with Diabetes from Low-Income Households

Short Title Also Used on Consents and Participant Documents:

Comparing Program Options for Latinos with Diabetes

PRINCIPAL INVESTIGATOR:

Name

Janet Page-Reeves

Department

Family & Community Medicine

Telephone Number

505-306-3041

Email Address

JPage-Reeves@salud.unm.edu

VERSION NUMBER:

V.5

DATE:

8-3-17

Table of Contents

1.0 Objectives*

1.1 Describe the purpose, specific aims, or objectives.

The purpose of the data collected through this project is to investigate the comparative effectiveness of two evidence-based models for creating program cultural competency in diabetes self-management programming. We will compare two diabetes self-management programs that serve a large low-income Latino population and that employ different evidence-based models of culturally competent health promotion. *A priori*, we believe patient populations for each program will be similar, yet we will compare sample characteristics and assess treatment differences after adjusting for possible population differences within our statistical models to mitigate self-selection bias and possible confounding. We will use a quasi-experimental design with an embedded, mixed-method approach.

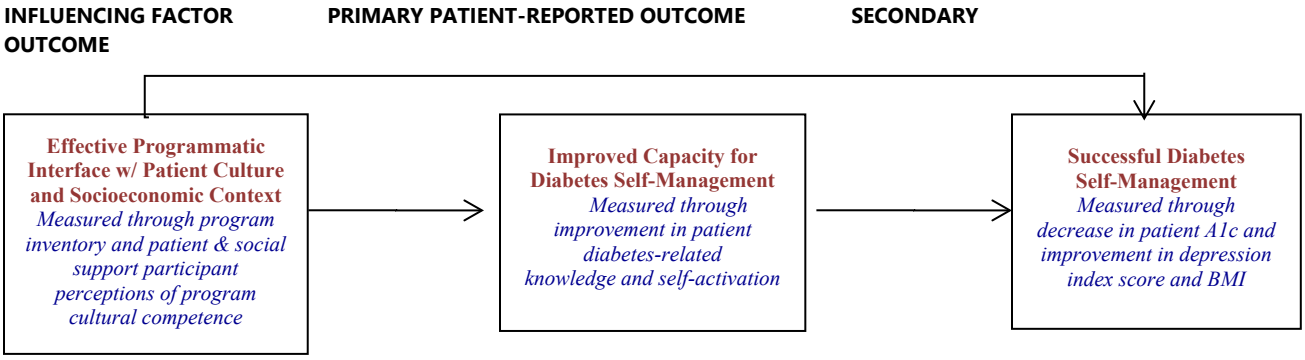
Specific Aims:

*Aim #1: Characterize the ways that two culturally competent diabetes self-management programs **interface** with patient culture and socioeconomic context*

*Aim #2: Measure and compare improvement in patient **capacity** for diabetes self-management*

*Aim #3: Measure and compare patient **success** at self-management*

1.2 State the hypotheses to be tested.



The hypothesis of our study is that diabetes self-management programs are most successful if their design is culturally and contextually "*situated*."[36–38] Trickett proposes that cultural competence entails integrating components of an intervention "into the local expression of culture as reflected in the multiple levels of the ecological context."[38] Rather than merely "tailoring" an existing intervention to target a specific context or population (for example, by offering recipes for healthy meals using Latino cuisine or providing educational materials in Spanish), he emphasizes the need for interventions to be "situated" to fit synergistically within broader community dynamics (culture and socio-

economic context). Following Trickett, and reflecting input from our patient partners, we believe that getting people to adopt lifestyle and behavior changes outlined in guidelines for diabetes self-management requires positively leveraging the cultural values and accommodating the socio-economic circumstances of a patient population in a way that creates synergy with specific social dynamics that define patients' everyday lives.[22–29,32,33]

2.0 Background*

2.1 Describe the relevant prior experience and gaps in current knowledge.

The Specter of Uncontrolled Diabetes. Diabetes is among the Institute of Medicine's top 25 national priorities for Comparative Effectiveness Research (CER).[1] Twenty-nine million people or 9.3% of the U.S. population have type 2 diabetes.[2] If trends continue, one third of U.S. adults will develop diabetes by 2050.[2] While statistics this large can seem remote and impersonal, the patient members of our project team can put a human face on the numbers. Each of them has life-altering personal experience with diabetes. Not only do they have diabetes or pre-diabetes themselves, they also have family members or *multiple* family members with diabetes. Grimly, because uncontrolled diabetes is widespread among Latinos from low-income households, our patient team members have witnessed the terrible consequences of the disease: death, amputations, blindness, debilitating depression, and shattered lives. They report that diabetes is so common in the Latino community that people just *assume that they will get it*, and if they are diagnosed with diabetes, given what they have seen happen to their family and friends, *they believe that diabetes is a death sentence about which there is nothing that they can do*. So most of the time, *they do nothing*. As researchers, we were starkly confronted by this reality when two individuals affiliated with our preliminary patient-engaged research project died one month apart from complications of uncontrolled diabetes. These deaths were deeply disturbing and underscored the gravity of our work to understand the most effective way to help people develop the skills for diabetes self-care. Our patient team members fear diabetes not only for themselves and their adult family members, but also for the future that awaits their children growing up with the specter of diabetes but without the knowledge, capacity, or skills to take control of their own health destiny. Our proposed project seeks to disrupt this fatalistic dynamic of despair. As such, our partners, who are Latino patients from low-income households, their family members, and healthcare providers who serve this population of patients recognize effective diabetes self-management as a matter of life-and-death.

Diabetes Health Disparities. Although diabetes is a national health crisis, risk is not the same for everybody. Individuals from minority and ethnic

populations and those with low-income status are at significantly higher risk.[3] This disparity brings the life-and-death reality of diabetes discussed in the preceding section even more negatively into relief. For example, Latinos are more likely (12.8%) than non-Hispanic whites (7.6%) to be diagnosed with diabetes,[2] and Latino youth have the fastest growing rate of diabetes.[4] According to an analysis of data from the U.S. National Longitudinal Mortality Study, Latinos are also 28% more likely to *die* from diabetes, with Mexican Americans (representing 33.5 million people or 64.6% of U.S. Latinos and the overwhelming majority of the patients associated with the proposed research)[5] *50% more at risk*.[6] Not surprisingly, a recent national poll by Harvard, NPR, and the Robert Wood Johnson Foundation found that diabetes is the top health concern for Latino families.[7] Similarly, poverty has an impact on diabetes risk. Research shows that individuals from low-income communities experience higher rates of diabetes.[8–11] Analysis of National Health Interview Survey data found that *the "*greatest disparities [for diabetes risk] were experienced by the groups who had the lowest level of education, were living below the Federal Poverty Level (FPL), or both."[3] This is a troubling concern for Latinos given the high level of Latino poverty (23.2%).[12] In New Mexico, where Latinos make up 47% of the population,[13] ethnicity and poverty both play a significant role in diabetes health and health disparities. For Latinos, rates for diabetes diagnoses (11.9%) and the diabetes death rate (45.9 per 100,000) are both more than twice those for non-Hispanic whites (5.3% and 22.5).[14,15] Similarly, New Mexico is the second-poorest state in the nation after Mississippi, with poverty among Latinos (24% for 18-64 year-olds and 37% for 17-and-under) significantly higher than among non-Hispanic whites (12% and 13%).[16] Individuals in New Mexico from low-income households are nearly three times more likely to be diagnosed with diabetes (14%) than individuals from households making more than $50,000 (5.2%),[17] meaning that given the Latino poverty rate, diabetes risk for individuals from low-income Latino households is disproportionately high.

Gaps in Evidence Related to Health Promotion Models for Diabetes Self-Management. Biomedical approaches to diabetes care are well-established, but pharmacologic therapies are often extremely costly, may have problematic health side effects, do not always result in the intended improvement in patients' diabetes health, and regimens are not always easy to follow given social and environmental barriers faced by low-income patients. Instead, health guidelines emphasize the important role of patient self-care over narrow reliance on medical treatments for reducing the health impact of diabetes and improving diabetes health outcomes. The *Guide to Community Preventive Services* instructs individuals to engage in lifestyle changes based on combined diet and physical activity improvements as the best way to prevent and manage type 2 diabetes.[18] The *Michigan Quality Improvement Consortium Guidelines for Management of Diabetes Mellitus* recommend that

individuals be given "comprehensive diabetes self-management education."[19] *Recommended Lifestyle and Self-management Guidelines from the American Diabetes Association* discuss the importance of individualized education, monitoring, and counseling.[20] We know how individuals can self-manage their diabetes or prevent pre-diabetes from becoming full diabetes – patient self-care through daily physical activity, a healthy diet, minimizing stress, and for those with full diabetes, regular glucose self-monitoring.[21] But these are not things that can happen in the clinic or via prescription; they are things that the patient must do to care for him- or herself every day. The various guidelines tell us what needs to happen, but diabetes health outcomes are not improving.[2] The guidelines do not provide a roadmap for getting individuals to embrace necessary self-care practices. However, *systematic reviews* have repeatedly demonstrated that culturally competent health promotion approaches that account for culture and the social context of poverty can be key to improving health outcomes.[22–31] In particular, culturally competent self-management interventions have been shown to significantly improve both glycemic control and behaviors related to diet and physical activity, and also to increase diabetes-related knowledge. As a result, "*cultural competence*" has become a buzz phrase in diabetes health promotion. A variety of different models have been developed to create "*culturally competent*" diabetes self-management programming. [22–31] Yet, there is no agreement on what cultural competence actually means or entails, and because of a continued emphasis on individual behavior in approaches to diabetes health promotion, the design of self-management programs does not always create cultural competence in a way that makes sense in relation to patients' lives or improves their health.

2.2 Describe any relevant preliminary data.

How We Selected Appropriate Interventions and Comparators.
We are collaborating on this project with two diabetes programs in Albuquerque. We selected these programs as comparators because they represent distinct evidence-based models for culturally competent diabetes self-management programming. We chose two sites implementing these models that actively serve a large number of Latino diabetes patients from low-income households in Albuquerque, New Mexico. Following Trickett,[37,38] we believe that the program model that interfaces most synergistically with patient's culture and everyday life circumstances will have the best diabetes health outcomes.

Comparator #1.
The Diabetes Self-Management Support Empowerment Model (DSMS).[41]
The Center for Diabetes Education at the University of New Mexico Hospital (CDE-UNMH) bases its program on the Diabetes Self-Management Support Empowerment Model (DSMS).[41] The CDE-UNMH follows National Standards for Diabetes Self-Management Education,[20] is certified by American Diabetes Association,[42] and is accredited by the American Association of Diabetes Educators (AADE).[43] The DSMS

Framework: The DSMS is a patient-centered, theoretically based educational framework. The DSMS combines a series of clinically informed group didactic sessions that use a patient self-determination approach to empower patients to take control of their own diabetes health with follow-up supports to sustain self-management gains achieved during the sessions. The AADE requires that educators acquire proficiency in culturally competent supportive care across the lifespan as one of five domains for certification so that educators can be informed about and aware of specific challenges that might accrue in the patient's diabetes self-management experience. This program represents the gold standard for diabetes self-management education focusing on changing eating and physical activity behaviors, self-monitoring, risk reduction, and stress management.

Implementation of the DSMS at CDE-UNMH: The CDE-UNMH program uses the DSMS group education approach. Patients attend a six-week group instructional session with nine hours of class plus a one-on-one follow-up with a certified diabetes educator to provide individualized support by creating a customized education plan. The group sessions have discussion supported by didactic conversation "maps" where the facilitator guides but does not control the conversation based on session thematic goals. Patients then complete self-assessment forms. This format is the foundation of the DSMS Model for creating patient empowerment and program cultural competence.

Comparator #2.

The Chronic Care Model (CCM).[31,44] The One Hope Centro de Vida Health Center Diabetes Program (One Hope) is based on the Chronic Care Model (CCM).[31,44] The Chronic Care Model Framework: The CCM is "a systematic approach to restructuring medical care to create partnerships between health systems and communities"[44] by addressing not only the medical but also the cultural and linguistic needs of patients through the inclusion of cultural competence in the delivery system design.[31] The CCM involves six synergistic domains: 1.) Improved access to care, 2.) Patient self-management support, 3.) Patient decision support, 4.) Care coordination, 5.) Integrated health information systems, and 6.) Access to community resources. The use of the CCM framework has been shown to yield significant results in the treatment of diabetes and is being used widely in chronic disease management.[45] To create a holistic care regime, the CCM focuses on addressing social determinants of health by meeting the medical, cultural, and linguistic needs of patients through integration of cultural norms and social relationships from the patient population into program design.[31]

Implementation of the CCM at One Hope: The One Hope program is designed to address the specific needs of Latino patients from low-income households[32,33] by creating comprehensive, integrated, wrap-around services focused on culturally competent care.[31,44] One Hope emphasizes Spanish as the language for service provision[33] and access to care

regardless of ability to pay. The One Hope facility provides a physical environment that reflects the lifestyle and economic capacity of patients to make them feel comfortable and that they "belong" (in contrast to more clinical, corporate, or academic medical settings). One Hope is a community-run clinic with a director and staff who are members of the community and who are culturally and economically similar to the patients they serve, reducing the hierarchical power relationship that generally exists between patients and providers. This approach is evident in the way that doctors at One Hope share decision-making by engaging the patient and their family members in creating a plan for diabetes self-management.[46,47] In addition, patients, caregivers and family members participate in a variety of program activities including cooking and nutrition workshops, zumba classes, and citas compartidas sessions ("shared appointments").[30,47–49] These shared appointment sessions allow patients, social supports and family members to share their stories and experiences in a peer support setting with facilitation by medically trained providers. But providers also "co-learn" from the patients.[27,35,36] Through shared decision-making and shared appointments, providers learn about the realities of patients' lives and their daily struggles at a level that goes beyond the interaction that normally occurs in a clinic. This helps the provider to be culturally competent by understanding diabetes from the perspective of the patient. Sharing experiences with peers and providers and including family members in activities offers a different level of social support for the patient by creating an enhanced feeling of intimacy and inclusion within the program. Innovative salidas (exit interviews), conducted routinely with all patients by a bilingual health navigator ensures that the patient understands and feels capable of implementing a doctor's instructions, and integrates health system information by allowing the health navigator to communicate details of patient status back to the provider.[32]

Using the CCM model, One Hope has had many patients improve their health, including individuals who have been able to reduce or stop taking their diabetes medication. One Hope staff note that people participating in the diabetes program have changed their food- and physical activity-related behaviors and attitudes. Lowered blood sugar levels and improved diabetes self-maintenance have been reported anecdotally. One Hope conducted a preliminary analysis of patient medical records and found that CCM diabetes patients demonstrated statistically significant decreases in A1c values at months #5, 8, 11, 14, 18 and 22 after they joined One Hope's program.[102]

Our comparator choice will reduce the potential for biases and allow for direct comparisons. The two comparator sites are distinct in their diabetes management program models, thus allowing (after controlling for other factors) for direct comparison of the effects of the program on the primary and secondary outcomes. This choice of comparators will

reduce the potential for bias for the following reasons: *1.)* The two comparators serve relatively similar populations in terms of socio-demographic attributes. *2.)* Diabetes self-management program models in use at the two comparator sites have program attributes that are sufficiently distinct to allow contrast and comparison. And, *3.)* Each of the comparator sites is implementing a program in a "real life" setting, thus providing the opportunity for a pragmatic assessment of the comparative effectiveness of the program models under externally valid and generalizable conditions.

2.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Different models are being used to make diabetes self-management programs culturally competent. However, this variation creates uncertainty for a patient with diabetes who does not understand that programs can differ significantly, how they differ, or which programs offer them the best option. For Latino patients from low-income households, it is not clear which type of culturally competent self-management programming most effectively integrates their culture and accommodates their socio-economic circumstances in a way to best improve their diabetes health. The proposed research will help to fill this gap by using patient-identified issues of importance as measures for directly comparing different evidence-based models for culturally competent diabetes self-management health promotion being implemented by programs that are currently available to Latino patients from low-income households in Albuquerque, New Mexico. PCORI supported us to develop this application through two "pipeline" awards (Tier I 2014 & Tier II 2015) to engage our patient stakeholders in conceptualizing CER to investigate "*Culturally Appropriate Options for Diabetes Prevention and Care for Low-Income Latinos*." Outside of our Tier I and Tier II projects, the cultural and contextual framework for research that we present here has not previously received PCORI funding. This framework aligns with PCORI's interest in inclusiveness for under-served minorities. Our patient-engaged preliminary research and the work of our PCORI Tier projects suggests that the proposed project will offer significant benefit to patients trying to find support for developing the knowledge and capacity to self-manage their diabetes.[32,33] Our Patient Advisors recognize the imperative of everyday diabetes self-care stragegies. But the reality is that too many lack the skills to leave behind fatalistic attitudes regarding diabetes as their destiny and they have no way to develop the knowledge and capacity to successfully adopt the changes outlined in the guidelines, improve their Hemoglobin A1c (glycosylated hemoglobin), or successfully control their diabetes. Improving models and approaches for diabetes self-care health promotion is critical to the health of our Advisors, their adult family members, and their children. The results of this research have

implications for other Latino populations, for other minority patients, and for models for self-management for other chronic conditions.

How the Research is Focused on Questions that Affect Outcomes of Interest to Diabetes Patients and their Caregivers.

> *"I have diabetes, but I am not just a patient. I am a person. I have cultural values and concrete realities that shape my everyday life. Both need to be considered for me to be able to feel that my care is making me well and to make it more likely that I can control my A1c. With this in mind, which of two self-management programs is the most culturally and contextually appropriate option for me to take the best care of myself in relation to my diabetes*?"[Translation from Spanish]

We co-developed this research question with a 10-member Patient Advisory Board of patients, social supports and researchers through our PCORI Tier I and II awards. Diabetes has been identified by our patient partners as a health issue of extreme urgency. Specifically, they are concerned about the failure of diabetes self-management programming to account for important dimensions of Latino culture or the social context created by poverty. At our PCORI Tier I Patient Advisory Board meetings, patients and social supports discussed these issues with us extensively and with emotion. What they had to say supported what we heard in previous conversations with patients and community members, and in our preliminary research.[32,33] Patients, social supports and community members report: *a.)* A lack of cultural competence on the part of providers, *b.)* A lack of programming in Spanish, *c.)* Failure of program design to understand or accommodate the dynamics of Latino culture related to core values that prioritize both the importance of social relationships and the need to avoid personal conflict,[34,35] *d.)* Poor program accommodation of the fact that patients lack resources,[36] and *e.)* A lack of attention to the extent to which poverty results in low diabetes health literacy, low capacity to deal with chronic disease, and high stress.[36] All of these factors influence patients' ability to comply with recommendations regarding drugs, diet, and physical activity to self-manage their diabetes. We will use the above question and patient-reported outcome measures to guide a mixed-method comparative study of the effectiveness of two models of diabetes self-management programming currently being used by programs that serve a large population of Latino patients from low-income households in Albuquerque, New Mexico. Each program employs a distinct evidence-based approach to create program cultural competence.

3.0 Inclusion and Exclusion Criteria*

3.1 Describe how you individuals will be screened for eligibility.

Staff & Providers (n=36):

Our Program Liaison at each site will identify up to 6 key program staff and/or providers per site each year for assessment interviews that will contribute to our understanding of the program sites. Our Research Manager will contact them using an IRB-approved script to invite them to participate and schedule appointments with those interested. At the appointment, the Research Manager will ask them to sign the consent and complete the contact portion of the Data Sheet only, and then will conduct the interview.

Patient (n=240) & Social support (n=240) participants:

All patient participants will be individuals who have been identified by a provider as having pre-diabetes (A1c 5.7-6.4) or diabetes (A1c 6.5 or above) and are newly entering one of the two programs involved in this study (CDE-UNMH or One Hope). We will not enroll individuals who have already been participating at the sites as this would not allow us to gather data in line with our data collection protocol (baseline, 3, 6, and 12 months).

At CDE-UNMH, when patients register for the program, CDE-UNMH staff will tell them about the study using an IRB-approved script and a flyer with pull-off tabs will be posted in the CDE office. An invitation with further detail about the research and contact information for our PDCSs--the *Patient Data Collection Specialists* (PDCSs)--will be sent in a mailing that all new patients receive from CDE-UNMH with their class schedule confirmation and logistics. A staff person at CDE-UNMH or a member of the research team will phone new participants to tell them about the study. For those who indicate that they are interested, the staff person will ask the patient's permission to release their name and contact information to our PDCSs. If the patient agrees, a member of the research team will contact the patient. Interested patients can also contact the PDCS using the information on the mailing. For all interested patient participants, the PDCS will screen them per our recruitment criteria.

At One Hope, participants will be identified in three ways: 1) New patients who call the clinic and indicate that they need to see a provider specifically about diabetes will be told about the study using an approved script, 2) Every patient seen at the clinic has an exit interview (*salida*) conducted by a Community Health Worker. For patients who have been told by their provider to have their A1c checked or that they have a diagnosis of diabetes or prediabetes, they will be told about the study using an approved script, and 3) Flyers about the study will be posted in the One Hope waiting room. For those who indicate interest in participating, a PDCS will contact them, inform them about the research per IRB requirements, and screen them for eligibility. For those who are eligible, the PDCS will schedule an appointment to consent them and gather baseline data.

At both sites, interested patients who qualify will provide contact information for a person that they identify from their social network (family or friend) whom they consider as their primary "social support." A member of the research team will contact the social support, provide them with information about the study, and invite them to participate. The PDCS will schedule an appointment with supports who are interested.

At the appointment, the PDCS will ask all participants to sign the consent, collect the information in the Participant Data Sheet, and collect responses to the baseline survey questions. The PDCS will also obtain a blood sample, measure BMI, and gather a hair sample for the patient only.

Subset of Patient and Social support Participants for Interviews (72) and Focus Groups (72): At each of the sites, the PDCS will identify a convenience sample of interviewees and focus group participants from those already recruited to be in the study and invite them to participate. Our Research Manager will contact those interested to schedule.

3.2 Describe the criteria that define who will be included or excluded in your final study sample.

Staff & Providers will be individuals who work at one of the two sites.

Patients will be screened by a member of the research team. Patients will be adults (men and women) who have been identified by a provider as having pre-diabetes (A1c 5.7-6.4) or diabetes (A1c 6.5 or above) and: 1.) Enter one of the two diabetes programs during the study; 2.) Self-identify as "Latino;" 3.) Can identify a social support or key member of their social network who will agree to participate with them; 4.) Are not pregnant (participants who become pregnant during the study will be excluded); and 5.) Have household income 250% of the FPL or below. Participants who become pregnant during the study will be excluded. Additionally, we have discovered that there is a difference between the A1c test that CTSC runs and the test run at Quest or TriCore. The test CTSC uses is reliably .2 lower and this is cited in the literature. Therefore, it is appropriate for us to enroll individuals who have a test at another lab that shows them to be pre-diabetic (A1c 5.7-6.4) even if our baseline lab comes back lower (5.5-6.2). However, any individual whose blood gathered by our data collectors at baseline returns with an A1c below 5.5 will be disenrolled.

Social supports will be adult individuals who are identified by the patient participants and who agree to participate.

Advisory Board Members will be seven members of our Project Patient Advisory Board.

3.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

1. *Adults unable to consent*
2. *Individuals who are not yet adults (infants, children, teenagers)*
3. *Pregnant women*
4. *Prisoners*

We will not recruit:

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

At enrollment, we will screen to specifically exclude participants who are pregnant. There is no risk to a pregnant woman or a fetus entailed in participation in this study because the study only involves data collection from individuals who have been instructed to participate in a diabetes self-management program by their provider. However, we will exclude pregnant individuals because we recognize that pregnancy could impact outcomes in a way that will influence our scientific analysis of diabetes self-management. At each data collection point, we will ask female participants if they are pregnant. If we discover that a participant has become pregnant during the course of the study, they will be given an end–of-study visit to end their participation and their data will be excluded. Co-I Burge will give them a referral to the UNM specialty prenatal clinic for high-risk pregnancies. It will be made clear to them that ending their participation in our study does not affect their ability to continue participating in the diabetes program that they attend.

This study involves regular screening for A1c levels. For A1c (>10), we will notify the participant's PCP. If we see a lab value that could indicate an emergency (Glucose > 400 mg/dl, < 60 mg/dl), we will contact the participant to make sure they are aware of their A1c status and that they are receiving appropriate care. If the participant would like more information about what to do, Co-Investigator Dr. Mark Burge will advise them. For women with an elevated A1c, when we contact them to tell them about their elevated test results we will inquire whether or not they are or think they might have become pregnant since entering the study.

If so, Co-Investigator Burge will provide them with a referral to UNM's High Risk Obstetrics Clinic.

4.0 Study-Wide Number of Subjects*

4.1 If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

N/A

5.0 Study-Wide Recruitment Methods*

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.

N/A

6.0 Multi-Site Research*

6.1 If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:

N/A

6.2 Describe the method for communicating to engaged participating sites:

N/A

6.3 If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.

N/A

7.0 Study Timelines*

7.1 Describe:

1. The duration of an individual subject's participation in the study.

Each year up to 12 staff or provider participants (6 per site) will be enrolled to do one 2-hour interview.

Each patient and social support participant will be enrolled for 12 months. We will gather data at baseline, 3 months, 6 months and 12 months. Data collection appointments will last approximately 1 hour. A subset of patient and social support participants will be invited to do an interview or a focus group. Interviews and focus groups will last approximately 1-2 hours.

Seven Patient Advisory Board members will be asked to participate in a series of interviews between June 1, 2017 and August 4, 2017. Interviews will last 1-3 hours.

2. The duration anticipated to enroll all study subjects.

Enrollment will begin in month 3 of the study.
Enrollment will end in month 22.
Data collection will end in month 34.

3. The estimated date for the investigators to complete this study (complete primary analyses)

This study is a 3-year project. It is slated to end in month 36. The study was funded to begin November 1, 2016 and the official end date is October 31, 2019. We anticipate continuing to analyze data for six months to one year following the official end of the project.

8.0 Study Endpoints*

8.1 Describe the primary and secondary study endpoints.

Participation is voluntary and participants may continue participation or stop at any point with no safety concerns. This study involves data collection only. We are not asking anyone to participate in health-related activities as an intervention. They are participating in a diabetes self-management program recommended to them by their doctor and we are inviting them to help us understand their experience with that. There are no drug or device interventions for this research project. Women who become pregnant during the study will be given an end-of-study meeting and their participation will end. Additionally, we have discovered that there is a difference between the A1c test that CTSC runs and the test run at Quest or TriCore. The test CTSC uses is reliably .2 lower and this is cited in the literature. Therefore, it is appropriate for us to enroll individuals who have a test at another lab that shows them to be pre-diabetic (A1c 5.7-6.4) even if our baseline lab comes back lower (5.5-6.2). However, any individual whose blood gathered by our data

collectors at baseline returns with an A1c below 5.5 will be disenrolled.

8.2 Describe any primary or secondary safety endpoints.

See above 8.1.

9.0 Procedures Involved*

9.1 Describe and explain the study design.

This project adheres to PCORI methodological standards. Patient-reported outcomes measured with validated and reliable instruments will be the basis for us to compare the effectiveness of two distinct evidence-based models for culturally competent diabetes health promotion through research with two diabetes self-management programs that each currently serve a large Latino patient population from low-income households in Albuquerque, New Mexico. Data will be gathered at baseline, and 3, 6, and 12 months by paid PDCSs (PDCSs) from the target patient population who will be members of the research team. *A priori*, we believe patient populations for each program will be similar, yet we will compare sample characteristics and assess treatment differences after adjusting for possible population differences including the use of propensity scores in our statistical models to mitigate self-selection bias, possible confounding, and heterogeneity of treatment effects. Trickett's conceptualization of "cultural situated-ness" discussed above provides the theoretical framework for this study.[37,38] We follow National Institutes of Health (NIH) standards for mixed method research set by Creswell and colleagues[39] in our "embedded mixed method" research approach, integrating data from quantitative and qualitative components of the study in an iterative fashion.[39] Our quasi-experimental research design with pre-/post-testing will accommodate the fact that we are working with existing programs at two sites and that we will recruit patients who enter those programs during the study.[40] Our sample size (N=240) and power estimates are based on realistic evaluation of effect size. We provide a detailed project timeline with specific deliverables that include scientific and engagement milestones. We have assembled a research team with the expertise and experience in patient-engaged research necessary to conduct the proposed study and we have an institutional infrastructure that supports our academic and community partnerships.

9.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

Data Collection.

We have created a high-quality and feasible data collection plan. The purpose of the data collected will be to investigate the comparative effectiveness of two evidence-based models for culturally competent

diabetes self-management programming. We are obtaining approval for this study from the UNM Human Research Protections Office and we will obtain written informed consent from all participants.

Pre-Screening: Potential patient participants at the CDE-UNMH program will be called by a CDE-UNMH staff member or a member of the research team and asked if they might be interested in participating in the study. If they say yes, they will be asked for their contact information to be contacted for an eligibility screening appointment. The information will be collected on a Pre-Screening form and given to the Patient Engagement Coordinator, who will enter it into the Pre-Screening project in REDCap.

Eligibility Screening: potential participants who agree to being screened for eligibility will be contacted by a member of the research team and asked the eligibility screening questions, including requesting information about a potential social support partner. The patient participant will be offered the opportunity to contact their potential social support partner to inform him or her that a research team member will be in contact to conduct an eligibility screening. When the patient partner gives permission to contact the potential social support partner, a member of the research team will contact the potential social support partner and conduct the eligibility screening. If both the patient participant and his or her social support partner are deemed eligible, baseline data collection appointments will be scheduled with both participants. The information collected during the eligibility screening will be hand-written on an Eligibility Screening form and given to the Patient Engagement Coordinator, who will enter it into REDCap in the Eligibility Screening project. The Patient Engagement Coordinator will then create a record for the participant in the PCORI Diabetes Project in REDCap and assign a participant ID (PID) to the participant. The Patient Engagement Coordinator will keep a master list of the participants' names and PIDs both electronically and in hard copy. The electronic copy will be saved on her password-protected laptop, which is stored in a locked cabinet at One Hope when not in use. The hard copy will also be stored in a locked cabinet at One Hope.

Data Collection: at the baseline data collection appointment, the PDCS will collect and enter contact and demographic information into separate data collection instruments in the PCORI Diabetes Project in REDCap. At the baseline and all three follow-up appointments, the PDCSs will also administer the survey instrument to the participants, responses to which will be entered into a third data collection instrument in the same project. The PCDSs will also collect BMI measurements (weight and height) and draw blood for A1c testing at the baseline and all follow-up appointments and will collect a hair sample at the baseline and six-month follow-up appointment. The BMI measurements will be entered into a fourth data collection instrument in the PCORI Diabetes Project by the PDCS during

each appointment. The A1c results will be entered into a fifth data collection instrument and the hair cortisol results entered into a sixth in the same project by the Data Manager when the results are provided to her by the respective labs.

The contact and demographic information data collection instruments are the only data collection instruments in the PCORI Diabetes Project that contain personally identifying information. The data collection instruments that contain the participant's survey responses and biological measures do not contain any personally identifying information. Each participant's data is linked across the six data collection instruments in the PCORI Diabetes Project by his or her unique Study ID, which is automatically generated by REDCap when the Patient Engagement Coordinator generates the initial record (when assigning the PID).

In sum, there will be three separate projects in REDCap: the Pre-Screening project, the Eligibility Screening project, and the PCORI Diabetes Project, which contains the participant contact information, demographic information, survey responses, BMI measurements, A1c results, and hair cortisol results in six separate data collection instruments. The PID that is generated before the baseline data collection appointment will be retroactively added to the relevant record in both the Pre-Screening and Eligibility Screening projects by the Research Manager or the Data Manager to allow for tracking of recruitment, enrollment, and attrition. This will be the only link across the three projects.

Participants' personally identifying information will be gathered and entered into REDCap at all three stages – pre-screening, eligibility screening, and baseline data collection. We will protect and limit access to this information in the following ways:

1) after the Patient Engagement Coordinator enters the information from the hard copy pre-screening and eligibility screening forms into REDCap, the hard copies will be turned over to the Research Manager, who will file them in a locked filing cabinet in a locked office at the UNM HSC OCH;

2) Access to the data in both the Pre-Screening project and the Eligibility Screening project will be limited to the Patient Engagement Coordinator, the Data Manager, the Research Manager, the PIs, the Senior Statistician, and the Biostatistician for purposes of entering data (Patient Engagement Coordinator) and exporting data for quality control, and data analysis (PIs, Data Manager, Research Manager, Senior Statistician, and Biostatistician. Any data resulting from the quality control or analysis processes that will be shared with others on the research team will be de-identified before sharing.);

3) Access to the instruments within the PCORI Diabetes Project can be limited. Access to all the data (including identifying information) in all the

data collection instruments will be limited to the Data Manager, the Research Manager, the PIs, the Senior Statistician, and the Biostatistician for purposes of quality control and data analysis (any data resulting from these processes that will be shared with others on the research team will be de-identified before sharing). The Patient Engagement Coordinator, the PI and the Co-I will have access to de-identified data in this project. Appointments will be scheduled and tracked in this project using the Calendar tool in REDCap. In order to be able to provide the data collectors with the information necessary to meet with participants, the appointments in the Calendar tool will include the participant's name, phone number, and address (if meeting the participant in his/her home).

REDCap is a safe place to store personally identifying information because it is a password-protected site that is stored behind the UNM HSC firewall. In order for research team members to access it from on-campus, they must be logged into the HSC secure wifi; off-campus (i.e., outside the firewall), they must use the Cisco virtual private network ("VPN"), access to which is only allowed after being approved by the university's Information Technologies Department. Access to the REDCap database is further secured by the fact that the iPads used by the data collectors and the laptops or desktops used by other members of the research team (with user rights) are password-protected. In addition, project administrators have the ability to limit access to data collection instruments or projects for other members of the research team.

The length of participation in the project for each individual participant is 12 months. All study activities will be conducted in English or Spanish, depending on the language preference of the participant. For each component of the study (e.g., survey/A1c/BMI data collection/hair data collection, interviews, focus groups, etc.), the participant will receive a $50 incentive. We will use a variety of data sources including program inventories, surveys, interviews, focus groups, and patient physical measures. Domains of inquiry for both quantitative and qualitative methods include: *a.)* Program accommodation of patients' language preference, cultural values, and socio-economic limitations, *b.)* Program-related interpersonal interaction and communication, *c.)* Program design to encourage social support among participants, *d.)* Social "fit" with and social support from program peers, *e.)* Social support from program staff, *f.)* Diabetes health knowledge, *g.)* Diabetes self-activation, *h.)* Stress management, *i.)* A1c control, and *j.)* Lifestyle changes to support diabetes health. Program assessment data will allow us to characterize the nature of each program and its approach to cultural competence. Survey responses and clinical test results from a large sample at each site will yield empirical (quantitative) data on patient-reported outcomes. Interviews and focus groups with a subset of participants will provide rich, in-depth, empirical (qualitative) data regarding the domains of inquiry from the perspective of patients, social supports, and program

staff/providers. It is not possible to gather this latter type of data through a survey or in quantity. Both quantitative and qualitative data are necessary for us to achieve the understanding entailed in comparing the effectiveness of the two models for creating program cultural competence in relation to the domains of inquiry.

Programmatic assessment. We will inventory each program regarding program design, size, structure, operation, and theoretical/philosophical orientation; professional qualifications/training of program providers; activities or resources available through the programs; strategies in place for Spanish language use or acceptance, inclusion of social supports and family, accommodation of challenges created by patients' limited socioeconomic circumstances, and the inclusion of stress management techniques; and data on referrals to the program, sign-ups, participation, no-shows, and attrition. We will conduct up to 36 interviews with key staff and/or providers (6/year x 2 sites x 3 years) to obtain their perspectives on implementation of the programs during the period of the study. Interview questions will be semi-structured to allow participants to contribute to the direction of the interview in relation to issues and ideas that they consider to be most relevant and important. Interviews will be audio-recorded and transcribed. We will assess patient and social support perceptions of the program interface using a cultural competence survey[88,89] that asks about physician bias, inter-cultural understanding, respectful interactions, language barriers, experiences of discrimination, and issues of trust. Administration of the survey is described in the paragraph immediately below this one. The cultural competence portion of the survey will not be administered at baseline as the participant will not yet have experience with which to rate the program. To gather qualitative information, we will include questions on programmatic interface in interviews and focus groups with patients and social supports that are described two paragraphs below.

Surveys. We will hire four individuals from the population of study to work as PDCSs. The PDCS at each site will administer a survey orally to all patient and social support participants at baseline (when they enter the study), with follow-up at 3, 6, and 12 months. The survey will consist of questions from or modified from four validated and reliable tools: *1.)* The *Consumer Assessment of Healthcare Providers and Systems Cultural Competence Set* (CAHPS-CC)[88,89] [as part of the programmatic assessment discussed in the preceding paragraph—will be administered at 3, 6 and 12 months only]; 2*.)* The *Diabetes Knowledge Questionnaire* (DKQ)[51–53,112]; *3.)* The *Patient Activation Measure* (PAM-13)[55–62,113]; and *4.)* The *Patient Health Questionnaire 9* (PHQ-9).[70–73]

Interviews with patient and social support participants. We will conduct 72 interviews with patients and social supports (12/year x 2 sites x 3 years). Following Guest, Bunce and Johnson,[112] and Janet's own experience with interview data, we believe that data sets of 12 interviews per site per year will capture a sufficient range of responses to achieve

thematic saturation. Our sampling frame for each set of 12 interviews will include six patients and six social supports. Interviews will be conducted with the social supports who correspond to the six patient interviewees. Interviews will follow the same format described in the programmatic assessment above. Spanish transcripts will be translated into English for analysis.

Focus groups. We will conduct 12 focus groups (2/year x 2 sites x 3 years). Focus group participants will be distinct from those recruited to participate in the interviews described in the preceding paragraph. Focus groups will include six distinct participants each (three patients and their corresponding social supports per focus group x 12 focus groups = 72 participants). The focus group questions and protocol will be an adaptation of that described above for the interviews.

Physical Measures. These measures will be obtained from patients at baseline with follow-up at 3, 6, and 12 months:

A1c: The PDCSs will be trained in phlebotomy. The PDCS will draw blood samples at the same time they administer the survey. The UNM Clinical and Translational Science Center (CTSC) Clinical Research Laboratory will provide the collection kits for specimen collection. Blood will be drawn, labeled and stored using standard phlebotomy protocols, and the *Patient Engagement Coordinator* will deliver specimens to the CTSC lab where they will be tested on whole blood following the lab's "*Hemoglobin A1c*" procedure using the DCA Vantage 2000 analyzer[91]. After testing, specimens will be disposed of according to CTSC lab protocol. For A1c (>10), we will notify the participant's PCP. If we see a lab value that could indicate an emergency (Glucose > 400 mg/dl, < 60 mg/dl), we will contact the participant to make sure they are aware of their A1c status and that they are receiving appropriate care. For women with an elevated A1c, when we contact them to tell them about their elevated test results we will inquire again whether or not they are or think they might be pregnant. If so, Co-Investigator Dr. Mark Burge will provide them with a referral to UNM's High Risk Obstetrics Clinic. Additionally, we have discovered that there is a difference between the A1c test that CTSC runs and the test run at Quest or TriCore. The test CTSC uses is reliably .2 lower and this is cited in the literature. Therefore, it is appropriate for us to enroll individuals who have a test at another lab that shows them to be pre-diabetic (A1c 5.7-6.4) even if our baseline lab comes back lower (5.5-6.2). However, any individual whose blood gathered by our data collectors at baseline returns with an A1c below 5.5 will be disenrolled.

Body Mass Index (BMI): The PDCS will document patient participant height and weight and calculate his or her BMI. Height and weight measurements will be taken using a standardized protocol. Height measurements will be collected using SHORR boards against

flat walls on level, firm (not carpeted) flooring. Weight measurements will be collected using calibrated, research-grade SECO scales. Two measurements will be taken for height and two for weight for each participant at each data collection point. An average of the two measures of height and an average of the two measures of weight will be used in the BMI calculation.

Hair cortisol: We will measure patient stress levels by testing hair samples to identify circulating levels of cortisol as a biological marker for chronic stress. Hair will be gathered from patients only and not from social supports, and will only be gathered at two timepoints: baseline and 6 months. Hair cortisol is an emerging valid biomarker for chronic stress.[92] Alternations in cortisol have been uniformly identified in various forms of chronic stress.[93–97] Cortisol inhibits glucose uptake, and as an anabolic hormone, it activates glucose production. Cortisol levels are altered in people with chronic stress (sometimes low, but most often higher than normal). Chronic levels of cortisol can be measured in hair, similar to chronic levels go glucose measure in A1c. Recently, measurements of cortisol levels in hair have proven useful to determine the long-term effects of stress.[83,92,99,100] Typical hair growth rate is 1 cm per month. Thus, by testing 1 cm of 100-150 strands of hair from the crown of the head (a thickness less than that of a pencil), an average cortisol level over the corresponding month can be obtained. This measure will provide important novel data because we believe that a culturally competent diabetes self-management program would help people deal with not only the stress of having diabetes and feeling like it is a death sentence by learning everyday self-management strategies, but also because having a feeling of connectedness through a health promotion program can provide emotional support and relief and thereby decrease the stress and decrease insulin resistance (which is the pathophysiological basis of diabetes type 2 in most a cases).

Co-I Bearer will lead analysis of hair samples. In preliminary studies Bearer's group has found that more than 90% of subjects agree to hair samples. The PDCS will use scissors to collect a pencil-width of hair from the crown of the head. One centimeter of hair closest to the scalp will be used to measure hair to determine the average cortisol level over the previous month. The hair will be stored in a plastic bag in a cool locked drawer in the office of the PI. In Bearer's lab at UNM, hair will be pulverized in a Retsch Mixer Mill Type MM 400 100-240V 50/60HZ an, extracted in methanol overnight, dried and resuspended in buffer. Cortisol concentration is measured by an immunoassay or by high-pressure liquid chromatography. Control samples containing specific amounts of cortisol are provided by the vendor with each assay kit, and we also use an internal control. We will use an automated colorimetric 96-well plate reader to measure the results. Cortisol levels are compared with average levels from normal subjects. The Bearer group has determined the normal average levels

and the 95% confidence interval. Control measurements are done with random hair samplings from non-diabetic individuals combined and used as a standard for all measurements. Measurements are compared to the average and determined to be within normal limits or not. This is a standard method for reporting all clinical pathology laboratory measurements diagnostically.

Interviews with Project Patient Advisory Board members. Our Summer Research Intern will conduct a series of interviews with the seven members of our Patient Advisory Board during June and July 2017, and we will hold a quarterly meeting of the Advisory Board in July. The interviews will be designed to obtain information about their personal experience with diabetes, their experience on our Patient Advisory Board and working on a research project, and how they would like to deepen their involvement over the next three years in this new phase of the research. At the end of July we have a Patient Advisory Board meeting scheduled. Patient Advisors normally attend these meetings. At the July meeting, our Research Intern will present her findings and a poster she is required to create based on her research back to the group.

9.3 Describe:

1. Procedures performed to lessen the probability or magnitude of risks.

We do not foresee any major risks, hazards or side effects to the subjects related to participation in the research. Risk of a breach of privacy is low because of procedural safeguards in place and because RedCAP is a secure data capture system and because access to identifying information will be limited. Some individuals feel anxious when they answer questions about themselves or their experiences and perspectives. To minimize the risk of this, before gaining informed consent of individuals, investigators will clearly explain the research, the risks to participants, and the procedures for safeguarding their privacy. Participants will be informed that they can refuse to answer any questions and stop the survey, interview, data collection, or participation in a focus group at any time. The investigators will have training and will understand the importance of these issues and their responsibility for maintaining high ethical standards and they will have current human subjects research training certification. In relation to A1c, participating in our study will not impact A1c levels, but because we will be gathering information about patient A1c, we have developed a response protocol if we detect elevated A1c levels: For A1c (>10), we will notify the participant's PCP. For A1c (>10), we will notify the participant's PCP. If we see a lab value that could indicate an emergency (Glucose > 400 mg/dl, < 60 mg/dl), we will contact the participant to make sure they are aware of their A1c status and that

they are receiving appropriate care. For women with an elevated A1c, when we contact them to tell them about their elevated test results we will inquire again whether or not they are or think they might be pregnant. If so, Co-Investigator Dr. Mark Burge will provide them with a referral to UNM's High Risk Obstetrics Clinic and they will be excluded from the study.

2. *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
N/A

3. *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*

Attached please find:

1. One Hope Waiting Room Flyer
2. One Hope Patient Recruitment Script (Revised)
3. CDE-UNMH Patient Recruitment/Consent Script (Revised)
4. CDE-UNMH Patient Recruitment Letter
5. Social Support Recruitment Script (Revised)
6. Staff & Provider Interview Recruitment Script
7. Patient Advisory Board member interview Recruitment Script (English and Spanish)
8. Consent Form (Revised)
9. Advisory Board Consent Form (English and Spanish)
10. Participant Data Sheet (Revised)
11. Survey Instrument (Revised)
    a. The Consumer Assessment of Healthcare Providers & Systems Cultural Competence Set (CAHPS)
    b. The Diabetes Knowledge Questionnaire (DKQ)
    c. The 13-Question Patient Activation Measure (PAM-13)
    d. The Patient Health Questionnaire #9 (PHQ-9)
    e. Stress and Hair Questionnaire
    f. Additional questions for survey (English and Spanish)
12. Key Provider/Staff Interview Questions
13. Patient Interview Questions
14. Social Support Interview Questions
15. Focus Group Questions
16. Advisory Board Interview Questions (English and Spanish)

9.4 What data will be collected including long-term follow-up.

Consent forms, Contact sheets, Participant Data Sheets, responses to the Survey Instrument, Interview Data, Focus Group data, patient A1c, patient BMI, patient hair samples for cortisol testing, program inventory data from both sites.

9.5 For HUD uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

N/A

10.0 Data and Specimen Banking*

10.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

Hair samples are being collected as part of the data collection for this project. We are seeking funding to allow us to analyze the hair samples. Hair samples can be stored for up to two years before being analyzed. We will store hair samples in plastic bags in a cool, locked drawer in the office of the PI. The PDCS will gather the sample, wrap it in tin foil to keep the sample in a coherent bunch, place the foil-wrapped sample in a plastic bag, label it with the PID and give the bag to the Patient Engagement Coordinator. The Patient Engagement Coordinator will transfer the sample to the UNM Research Manager. When we obtain funding for the analysis, we will send the de-identified numerically labeled samples to the UNM lab of Co-I Bearer for analysis. The names correlating with the ID will be kept in a locked drawer in the PI's office.

In general, we are committed to making our data available to other researchers to contribute to knowledge about cultural competence and diabetes self-management program models. Following the end of the study, the quantitative data will be de-identified within nine months and made available to PCORI and to researchers by request. Interview and focus group transcripts will not be shared because this data will have been gathered from a small sample that represents a small community and will contain a large amount of personal information that would identify the participant.

The UNM CTSC Bioinformatics Data Warehouse will assist us in assuring all the quantitative data is properly de-identified at the end of the project. Blood samples will be destroyed following analysis. Hair samples will be

stored until they can be analyzed. After analysis, any left over hair will be stored until we are certain that we had enough of a sample for testing. The data gathered for the A1c analysis, BMI, and hair cortisol will include the participants' study ID but no personally identifying information that could be linked to the participant.

The de-identified data will then be placed in the UNM data repository, LoboVault and embargoed for at least five years. LoboVault is a designated long-term digital archive resource maintained by the University of New Mexico Libraries. In addition to the use of Dublin Core for descriptive metadata, the archive provides daily file integrity and format verification and will additionally create and maintain technical and administrative metadata using the widely adopted Metadata Encoding and Transmission Standard (METS) and Preservation Metadata Implementation Strategies (PREMIS) metadata standards. These additional metadata include digital file signatures and checksums for bitwise integrity validation and chain of custody documentation. Primary responsibility for curating and preparing the data for archiving rests on the Data Librarians at the University of New Mexico Libraries. As a publishing and sharing platform, LoboVault is an instance of the widely adopted DSpace repository application (http://www.dspace.org/). Data will be embargoed for a specified period of time, during which descriptive information and metadata are discoverable but the data and content files themselves can only be accessed via an email request to the authors. Should a researcher be interested in accessing the data, he or she would then request access by emailing the PI and/or members of the research team chosen by the PI. When a request to access the project data is received, we will implement the following data sharing protocol, which conforms to the data sharing standards established by the NIH. We will provide the opportunity for data sharing through the following avenues: *1.)* We will share all research data as requested in accordance with federal regulations and the Freedom of Information Act (FOIA). *2.)* We will share research tools and data with other researchers for analysis and/or replicating the research. The Research Team will review requests from researchers and, after approval from our patient partners, we will work with the requesting researchers to create a data-sharing agreement per NIH protocol, policies and procedures. *3.)* We will make the data and associated documentation available to users only under a **Data-Sharing Agreement** that: *a.)* defines a commitment to using the data only for research purposes and not to identify any individual participant; *b.)* defines a commitment to securing the data using appropriate computer technology; *c.)* demonstrates a high-quality research proposal (significance, innovativeness, approach, and community benefit); *d.)* proposes a comprehensive dissemination plan (to community and scientific audiences); *e.)* covers administrative costs to prepare data and related documentation requested; *f.)* demonstrates appropriate approvals of research protocols by the institutional Human Research Review Committee; *g.)* demonstrates certification in research ethics, including the

HIPAA Research Training Course and the Collaborative Institutional Training Initiative (CITI) Human Subjects Protection Training; and *h.)* demonstrates a commitment to destroying or returning the data after analyses are completed. The requesting researchers will be required to acknowledge our project, research team, our patient partners, and PCORI as a funder in any presentations, abstracts, or publications developed from use of the shared data.

10.2 List the data to be stored or associated with each specimen.

Hair samples will be labeled with the PID assigned to the participant. Hair samples labeled with the PID will be stored in a locked drawer in the office of the PI until they can be analyzed. They will not be associated with data. Results that are obtained from analysis of the hair samples will be stored on a secure database in REDCap. Results of the hair analysis will be stored together in REDCap with data obtained from: Results of patient A1c analysis, patient height and weight, psychosocial data from survey results, and participant data sheet information. Information about participation in interviews and focus groups will also be stored in REDCAP but the transcripts will be stored separately. The Patient Engagement Coordinator will keep a master list of the participants' names and PIDs both electronically and in hard copy. The electronic copy will be saved on her password-protected laptop, which is stored in a locked cabinet at One Hope when not in use. The hard copy will also be stored in a locked cabinet at One Hope.

10.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Co-I Bearer will be in charge of all analysis of hair samples. Analysis will be conducted by her lab staff in her lab at UNM. Part of the hair samples will be destroyed in the process of testing with solvents. We will retain left-over hair samples with PID markers for three years following the end of the study to ensure that we have enough hair to complete the analysis. We will not release the hair samples or share them with anyone other than Dr. Bearer and her lab staff. We will not use the hair for purposes other than cortisol testing as indicated in this protocol. Results of the cortisol testing will be entered into our project database.

Blood samples will be delivered to the CTSC lab for analysis. Following analysis, remaining blood will be destroyed using good lab procedures. Result of the A1c testing will be stored on REDCap.

In general, we are committed to making our data available to other researchers to contribute to knowledge about cultural competence and diabetes self-management program models. Following the end of the

study, the quantitative data will be de-identified within nine months and made available to PCORI and to researchers by request. Interview and focus group transcripts will not be shared because this data will have been gathered from a small sample that represents a small community and will contain a large amount of personal information that would identify the participant.

The UNM CTSC Bioinformatics Data Warehouse will assist us in assuring all the quantitative data is properly de-identified at the end of the project. The data gathered for the A1c analysis, BMI, and hair cortisol will include the participants' PID but no personally identifying information that could be linked to the participant.

The de-identified data will then be placed in the UNM data repository, LoboVault and embargoed for at least five years. LoboVault is a designated long-term digital archive resource maintained by the University of New Mexico Libraries. In addition to the use of Dublin Core for descriptive metadata, the archive provides daily file integrity and format verification and will additionally create and maintain technical and administrative metadata using the widely adopted Metadata Encoding and Transmission Standard (METS) and Preservation Metadata Implementation Strategies (PREMIS) metadata standards. These additional metadata include digital file signatures and checksums for bitwise integrity validation and chain of custody documentation. Primary responsibility for curating and preparing the data for archiving rests on the Data Librarians at the University of New Mexico Libraries. As a publishing and sharing platform, LoboVault is an instance of the widely adopted DSpace repository application (http://www.dspace.org/). Data will be embargoed for a specified period of time, during which descriptive information and metadata are discoverable but the data and content files themselves can only be accessed via an email request to the authors. Should a researcher be interested in accessing the data, he or she would then request access by emailing the PI and/or members of the research team chosen by the PI. When a request to access the project data is received, we will implement the following data sharing protocol, which conforms to the data sharing standards established by the NIH. We will provide the opportunity for data sharing through the following avenues: *1.)* We will share all research data as requested in accordance with federal regulations and the Freedom of Information Act (FOIA). *2.)* We will share research tools and data with other researchers for analysis and/or replicating the research. The Research Team will review requests from researchers and, after approval from our patient partners, we will work with the requesting researchers to create a data-sharing agreement per NIH protocol, policies and procedures. *3.)* We will make the data and associated documentation available to users only under a **Data-Sharing Agreement** that: *a.)* defines a commitment to using the data only for research purposes and not to identify any individual participant; *b.)* defines a commitment to securing the data using appropriate computer

technology; *c.)* demonstrates a high-quality research proposal (significance, innovativeness, approach, and community benefit); *d.)* proposes a comprehensive dissemination plan (to community and scientific audiences); *e.)* covers administrative costs to prepare data and related documentation requested; *f.)* demonstrates appropriate approvals of research protocols by the institutional Human Research Review Committee; *g.)* demonstrates certification in research ethics, including the HIPAA Research Training Course and the Collaborative Institutional Training Initiative (CITI) Human Subjects Protection Training; and *h.)* demonstrates a commitment to destroying or returning the data after analyses are completed. The requesting researchers will be required to acknowledge our project, research team, our patient partners, and PCORI as a funder in any presentations, abstracts, or publications developed from use of the shared data.

11.0 Data Management* and Confidentiality

11.1 Describe the data analysis plan, including any statistical procedures.

Descriptive statistics will be calculated to *summarize patient characteristics*. Means and standard deviations or medians and quartiles will be calculated for continuous variables and will be compared across site by ANOVA or Kruskal-Wallis test, depending on the distribution of the data. Frequencies and percentages will be calculated for categorical variables and will be compared with the chi-square test or Fisher's exact test, as appropriate. Significant differences will be noted and to adjust for possible confounding, those variables will be considered for inclusion as covariates in the analyses for the primary and secondary outcomes in addition to other clinically meaningful variables and their interactions. We expect patient characteristics to be similar across the two treatment sites; however, to control for potential differences in the populations, we will adjust for potential confounding covariates by using propensity scores to stratify subjects into groups based on the probability that they attended a particular treatment site given particular demographic characteristics including sex, age, primary language, level of education, nativity, and type of insurance. Patients will be grouped by quintile of propensity score for a total of five strata and each will be analyzed for the primary and secondary outcomes independently. Analyses will be performed in standard statistical software such as SAS 9.4, R 3.1, and/or Stata 14. Propensity score matching allows for causal inference in our non-experimental settings by selecting similar subsets of comparison units between treatment groups across a high-dimensional set of pretreatment characteristics.

We will complement our quantitative analyses by conducting a rigorous, disciplined, empirical analysis of data from key staff/provider interviews (Aim #1), patient/social support interviews and focus groups (Aims #1 & 2), and Patient Advisory Board interview transcripts.

We will create a database with all interview and focus group transcripts. We will conduct a theory-driven qualitative content analysis. We will read through transcripts to identify conceptual categories and patterns related to specified domains of inquiry, create a qualitative codebook, and develop conceptual summaries for each transcript. Following review and summary, we will code transcripts for systematic themes and sub-themes within the domains. We will explore interconnections between theme categories and develop a holistic interpretation of the data.

Statistical Analysis Aim 3. We will conduct analyses to assess successful patient management of their diabetes (Aim #3), our secondary outcomes, by measuring their A1c from blood samples drawn, BMI calculations, cortisol from hair samples, and PHQ-9 scores obtained at baseline, 3, 6, and 12 months. Clinical analysis of blood samples will use A1c tested on whole blood as described previously. Change in A1c over the four time points in each of the diabetes self-management program models will be evaluated by fitting a linear mixed model to A1c with the primary independent variable treatment site while adjusting for demographic covariates, social support and knowledge, the measures hair cortisol indicating stress levels, and participant and social support scores on the CAHPS-CC. An interaction between time and site will be included to explore how A1c scores change over time. For the secondary endpoint analysis, REML-adjusted least-squares mean estimates of change in A1c from baseline to 6 months post-intervention will be reported along with their 98.3% confidence intervals (the significance level includes a Bonferroni adjustment for three secondary outcomes). A model incorporating the 12 month time point will also be evaluated. BMI and depression scores will be analyzed similarly.

11.2 Provide a power analysis.

Hypothesized Effect Size for Intervention on Main Patient-Centered Outcome. We hypothesize that the CCM model, because following Trickett it is more effectively *situated* with patient culture and socio-economic context,[37,38] will be superior to the DSMS in its ability to increase diabetes knowledge and patient activation, lower A1c, and improve depression scale scores and BMI among participants. Using the CCM model, One Hope has had many patients improve their health, including individuals who have been able to reduce or stop taking their diabetes medication. One Hope staff note that people participating in the diabetes program have changed their food- and physical activity-related behaviors and attitudes. Lowered blood sugar levels and improved diabetes self-maintenance have been reported anecdotally. One Hope conducted a preliminary analysis of patient medical records and found that CCM diabetes patients demonstrated statistically significant decreases in A1c values at months #5, 8, 11, 14, 18 and 22 after they joined One Hope's program.[102]

The quantitative <u>Primary Outcome</u> for this study is improved patient capacity for diabetes self-management:

1.) Diabetes knowledge will be measured using the *DKQ summed score*. Hypothesis: The CCM model will result in a larger increase in DKQ summed scores from baseline to 6 months with a Cohen's f effect size (ES) = 0.09 as compared to the DSMS. Previously published studies evaluating culturally competent diabetes management programs report meaningful changes in DKQ summed scores with effect sizes of 0.03 to 0.16 in studies ranging in sample sizes per arm from 10 to 189.[51,53,54,103]

2.) Patient activation will be measured using the *PAM-13 raw score*. Hypothesis: The CCM model will result in a larger increase in PAM-13 raw scores from baseline to 6 months with Cohen's f ES = 0.07 as compared to the DSMS. Previously published studies evaluating culturally competent diabetes management programs report changes in PAM-13 raw scores with meaningful effect sizes of 0.01 to 0.16 in studies ranging in sample size per arm from 26 to 133 (per Shah, Co-I Burge, and colleagues[104]).[66,105–107]

The quantitative <u>Secondary Outcome</u> for this study is successful diabetes self-management as measured by improvement in A1c, BMI, and PHQ-9.

Self-management will be measured through change in A1c, BMI, and depression index (PHQ-9).

1.) Hypothesis: The CCM model will result in a larger decrease in percent *A1c* from baseline to 6 months with Cohen's f ES = 0.06 as compared to the DSMS. Previously published studies and institutional experience evaluating culturally competent diabetes management programs report changes in percent A1c with effect sizes of 0.01 to 0.06 in studies ranging in sample size per arm from 26 to 133.[66,105–107]
2.) Hypothesis: The CCM model will result in a larger decrease in BMI from baseline to 6 months than DSMS with a clinically meaningful difference of 1.5 kg/m2 between the groups (Cohen's f ES = 0.06).[67,68]
3.) Hypothesis: Compared to DSMS, CCM will result in a larger decrease (by 3 points) in PHQ-9 scores from baseline to 6 months (Cohen's f ES = 0.06).[107–109]

Note: It is coincidental that the effect sizes (and power) are the same for each of the three secondary outcomes

Power Calculations. We will recruit N=240 patient-social support pairs (n=120 per site) with anticipated 20% attrition to obtain complete data on at least n=96 per site. Comparing response changes on the DKQ, PAM-13, and DHQ-9 from baseline to 6 months between the CCM to the DSMS, the two-sided Type I error rate was adjusted for the number of comparisons made (four comparisons for the co-primary outcomes) using a Bonferroni correction (α=0.0125). The power analyses for detecting site differences among change scores were based on multiple linear regression models including demographic characteristics, participants' perceived cultural competence of providers (CAHPS-CC), and social supports' change scores on the DHQ, PAM-13, and DHQ-9 as covariates. We report Cohen's f effect sizes based on the regression method.[110,111]

The <u>power</u> for the <u>primary endpoints</u> with n=96 per site and α=0.025 are as follows:

1.) Change in DKQ summed score: $\Delta_{CCM\text{-}DSCS}$ = 2.2 (SD = 3.8), power = 96%, Cohen's f effect size (ES) = 0.09

2.) Change in PAM-13 raw score: $\Delta_{CCM\text{-}DSCS}$ = 12.7 (SD = 24.8), power = 85%, Cohen's f ES = 0.07

The <u>power</u> for the <u>secondary endpoints</u> with n=96 per site and α=0.017 for comparing the CCM to the DSMS:

1.) Change in A1c: $\Delta_{CCM\text{-}DSCS}$ = -0.5 (SD = 1.0), power = 84%, Cohen's f ES=0.06.

2.) Change in BMI: $\Delta_{CCM\text{-}DSCS}$ = -1.5 (SD = 3), power = 84%, Cohen's f ES=0.06.

3.) Change in depression scores (PHQ-9): $\Delta_{CCM\text{-}DSCS}$ = -3 (SD = 6), power = 84% Cohen's f ES = 0.06.

Note: It is coincidental that the power (and effect sizes) are the same for each of the three secondary outcomes

11.3 Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

<u>Training Requirement for Members of the Research Team</u>: All members of the Research Team will receive training in research on human subjects. Each will take the online Human Subjects Research Training Modules from the Collaborative Institutional Training Initiative (CITI) which fulfill the requirement for NIH human subjects training. They will also take a HIPAA compliance training. PDCSs will be trained in phlebotomy. The CTSC Clinical Research Laboratory's ASCP-certified Medical Laboratory Scientist will also provide additional Good Laboratory Training and Competency to assist with site-specific collection and quarterly technical competency testing through direct observations of the PDCS phlebotomists at each site. A certified phlebotomist at One Hope, will be available to provide technical assistance to the PDCSs in an ongoing way. All Data Collectors will also receive a 2-day Mental First Aid training (Training was conducted in Spanish in April 2017 by a certified trainer).

<u>Certificate of Confidentiality</u>: We have obtained a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). CoC's are issued by NIH to protect the privacy of research subjects by protecting investigators and institutions from being compelled

to release information that could be used to identify subjects with a research project. The process for obtaining a CoC is that we must first obtain approval from the UNM HSC HRPO and then we submit the approved consent form to NIH for their approval. We obtained our approved CoC on December 1, 2016 (see attachment).

Data Handling and Storage: Guidelines for the protection of participant privacy and confidentiality will be followed in all cases. All members of the research team will maintain current Human Subjects training. They will understand the importance of privacy issues and their responsibility to maintain the highest research ethical standards in all respects. Surveys, blood-draws, BMI data gathering, hair sampling, interviews and focus groups will be conducted at a location to provide privacy. Prior to beginning each focus group, the facilitator will instruct participants regarding group privacy measures. All participants will be asked to sign a receipt for a merchandise card incentive which will be used for project accounting purposes only and will not be linked with or associated with research data. Consent Forms will be stored in a locked cabinet in the office of the PI. Consent Forms will be kept for 3 years following the end of the project, at which time they will be destroyed. Participant information will be considered confidential and will not be shared. De-identified project data will be shared only per our Data Sharing Protocol. De-identified project data will be kept for at least 5 years.

Data Management: Consent Forms will be stored in a locked cabinet in the office of the PI. De-identified data from REDCap will be exported and stored on a secure, managed network share maintained by our university's Health Sciences Library and Informatics Center's IT services. Blood will be destroyed following analysis. A1c results will be entered into REDCap. Hair samples will be stored in plastic bags in a locked drawer in the office of the PI. Some hair will be destroyed in the process of analyzing the sample. We will continue to store remaining hair for 3 years after the end of the study to ensure that we have had a sufficient sample for analysis. Results of hair cortisol testing will be entered into REDCap. Data from interviews and focus groups will be captured on an audio-recording device and transcribed. If in Spanish, transcripts will be translated into English for analysis. Following transcription/translation, audio-recordings will be destroyed. Transcripts of interviews and focus groups will be identified by the project ID. Electronic transcript files will be stored on secure UNM computers, accessible only to the researchers via their password-protected machines. Hard copy data will be stored in binders in the locked offices of the PI.

11.4 Describe any procedures that will be used for quality control of collected data.

The Patient Engagement Coordinator will provide daily oversight of the PDCSs that enrollment and data collection are occurring on schedule and per our protocol

The Co-PI will provide oversight and guidance at regular meetings with the Patient Engagement Coordinator regarding this process.

The Research Manager will check-in with the Patient Engagement Coordinator and the staff at CDE-UNMH once a week to ensure that enrollment is occurring per our protocol.

The Data Manager and Research Manager will conduct quality checks on the data being entered into all three of the projects in REDCap and will work with the Patient Engagement Coordinator to address any issues that are identified.

The Office for Community Health Accountant will meet with the One Hope Finance Manager to reconcile information about incentives to ensure budget compliance.

The CTSC Lab will provide baseline and quarterly QC training for good laboratory/phlebotomy procedure.

The Phlebotomy supervisor will be available to provide technical assistance to PDCSs.

11.5 Describe how data and specimens will be handled study-wide:

1. What information will be included in that data or associated with the specimens?

i. <u>Programmatic assessment.</u> We will inventory each program regarding program design, size, structure, operation, and theoretical/philosophical orientation; professional qualifications/training of program providers; activities or resources available through the programs; strategies in place for Spanish language use or acceptance, inclusion of social supports and family, accommodation of challenges created by patients' limited socioeconomic circumstances, and the inclusion of stress management techniques; and data on referrals to the program, sign-ups, participation, no-shows, and attrition. We will conduct up to 36 interviews with key staff and/or providers to obtain their perspectives on implementation of the programs during the period of the study. Interview questions will be semi-structured to allow participants to contribute to the direction of the interview in relation to issues and ideas that they consider to be most relevant and important. Interviews will be audio-recorded and transcribed. We will assess patient and social support perceptions of the

program interface using a cultural competence survey that asks about physician bias, inter-cultural understanding, respectful interactions, language barriers, experiences of discrimination, and issues of trust. To gather qualitative information, we will include questions on programmatic interface in interviews and focus groups with patients and social supports.

ii. Surveys. The PDCS at each site will administer a survey to all patient and social support participants at baseline (when they enter the study), with follow-up at 3, 6, and 12 months. The survey will consist of questions from or modified from four validated and reliable tools: *1.)* The *Consumer Assessment of Healthcare Providers and Systems Cultural Competence Set* (CAHPS-CC) [as part of the programmatic assessment discussed in the preceding paragraph]; 2*.)* The *Diabetes Knowledge Questionnaire* (DKQ); *3.)* The *Patient Activation Measure* (PAM-13); and *4.)* The *Patient Health Questionnaire 9* (PHQ-9). Because the CAHPS-CC is an assessment of program cultural competence and requires participant experience with the program, it will not be administered as part of the baseline survey.

iii. Interviews. We will conduct 72 interviews with patients and social supports. Our sampling frame for each set of 12 interviews will include six patients and six social supports. Interviews will be conducted with the social supports who correspond to the six patient interviewees. Interviews will follow the same format described in the programmatic assessment above. Spanish transcripts will be translated into English for analysis.

iv. Focus groups. We will conduct 12 focus groups. Focus group participants will be distinct from those recruited to participate in the interviews described in the preceding paragraph. Focus groups will include six distinct participants each. The focus group questions and protocol will be an adaptation of that described above for the interviews.

v. Physical Measures. These measures will be obtained from patients at baseline with follow-up at 3, 6, and 12 months:

1.) **A1c**: For patients from CDE-UNMH, we will obtain baseline A1c results from the CDE program files. For One Hope patients, the PDCS who will be trained in phlebotomy will draw blood samples at the same time they administer the baseline survey. For patients from both sites, the PDS will draw blood samples at the 3-month, 6-month and 12-month data collection sessions. Blood will be drawn, labeled and stored using standard phlebotomy protocols, and the *Patient Engagement Coordinator* will deliver specimens to the CTSC lab where they will be tested for A1c.

2.) **Body Mass Index (BMI)**: The PDCS will document patient height and weight and calculate his or her BMI. Height and weight

measurements for all participants will be taken using a standardized protocol. Height measurements will be collected using SHORR boards against flat walls on level, firm (not carpeted) flooring. Weight measurements will be collected using calibrated, research-grade SECO scales. Two measurements will be taken for height and two for weight for each participant at each data collection point. An average of the two measures of height and an average of the two measures of weight will be used in the BMI calculation.

3.) **Hair cortisol**: We will measure patient stress levels using testing of hair samples to identify circulating levels of cortisol as a biological marker for chronic stress. We will only gather hair samples from patient participants and not from social supports, and hair will only be gathered at two time points: baseline and six months. Cortisol is an an insulin antagonist and may contribute to insulin resistance in diabetes type 2. The PDCS will use scissors to collect a pencil lead-width of hair from the crown of the head of patient participants. One centimeter of hair closest to the scalp will be used to measure hair to determine the average cortisol level over the previous month. The hair will be stored in a plastic bag in a cool, locked drawer in the office of the PI. We are seeking to obtain funding from the CTSC to analyze hair samples from this project. Co-I Bearer will lead analysis of hair samples. In preliminary studies Bearer's group has found that more than 90% of subjects agree to hair samples. Hair will be pulverized in a Retsch Mixer Mill Type MM 400 100-240V 50/60HZ an, extracted in methanol overnight, dried and resuspended in buffer. Cortisol concentration is measured by an immunoassay or by high-pressure liquid chromatography. Control samples containing specific amounts of cortisol are provided by the vendor with each assay kit, and we also use an internal control. We will use an automated colorimetric 96-well plate reader to measure the results. Cortisol levels are compared with average levels from normal subjects. The Bearer group has determined the normal range of human cortisol hair levels . Control measurements are done with random hair samplings from non-diabetic individuals combined and used as a standard for all measurements. Measurements are compared to the average and determined to be within or outside normal limits. Comparision to normal limits is the standard method for reporting clinical pathology laboratory measurements diagnostically.

vi. Interviews with Project Patient Advisory Board members. Our Summer Research Intern will conduct a series of interviews with the seven members of our Patient Advisory Board during June and July 2017, and we will hold a quarterly meeting of the Advisory Board in July. The interviews will be designed to obtain information about their personal experience with diabetes, their experience on our Patient Advisory Board and working on a research project, and how they would like to deepen their involvement over the next three

years in this new phase of the research. At the end of July we have a Patient Advisory Board meeting scheduled. Patient Advisors normally attend these meetings. At the July meeting, our Research Intern will present her findings and a poster she is required to create based on her research back to the group.

2. *Where and how data or specimens will be stored?*

Consent forms will be kept for 3 years following the end of the project, at which time they will be destroyed. Contact information for all study participants will be maintained in REDCap during the project to allow us to follow-up with participants for interviews, if they have a high A1c, and for the end-of-project event. Contact information for all participants in the project (name, phone number(s), and the name and contact information of the person identified as someone who would be able to help contact them) will be downloaded and stored in a locked cabinet in the office of the PI for at least five years to allow the research team to invite them to participate if we conduct a follow-up study.

Participant information will be considered confidential and will not be shared. Research data will be de-identified and kept for at least 5 years. Data from REDCap will be exported and stored on a secure, managed network share maintained by our university's Health Sciences Library and Informatics Center's IT services. Blood will be destroyed following analysis. A1c results will be entered into REDCap. Hair samples will be stored in plastic bags in a locked drawer in the office of the PI. Some hair will be destroyed in the process of analyzing the sample. Remaining hair will be stored for 3 years to ensure that we have a sufficient sample for analysis. Results of hair cortisol testing will be entered into REDCap. Data from interviews and focus groups will be captured on an audio-recording device and transcribed. If in Spanish, transcripts will be translated into English for analysis. Following transcription/translation, audio-recordings will be destroyed. Transcripts of interviews and focus groups will be identified by the project ID. Electronic transcript files will be stored on secure UNM computers, accessible only to the researchers via their password-protected machines. Hard copy data will be stored in binders in the locked offices of the PI.

3. *How long the data or specimens will be stored?*

Research data in REDCap and transcripts will be de-identified and kept for at least 5 years. Following transcription/translation, audio-recordings will be

destroyed. Following A1c analysis, blood samples will be destroyed. Remaining hair samples will be stored for 3 years following the end of the project. Participant identifying information will be kept on REDCap with limited access. Consents will be kept for 3 years following the end of the project, at which time they will be destroyed.

4. *Who will have access to the data or specimens?*

Only members of the research team will have access to the data.

5. *Who is responsible for receipt or transmission of the data or specimens?*

The PDCSs will gather contact and demographic information, survey responses, BMI data, hair and blood samples. The contact and demographic information, survey response, and BMI measurements will be entered into REDCAp by the PDCSs at the time of collection.

Hair samples will be gathered in plastic bags and labeled with the PID. The PDCS will give the bags to the Patient Engagement Coordinator. The Patient Engagement Coordinator will give the bags to the Research Manager. The Research Manager will store them in a locked drawer in the office of the PI. When funding is obtained, the Research Manager will give them to Dr. Bearer for analysis in her lab. Some of the hair samples will be destroyed in the process of analysis. Remaining hair will be stored for 3 years following the end of the project. The hair cortisol results will be entered by the Data Manager into the PCORI Diabetes Project on REDCap once received from the lab.

The PDCSs will draw the blood and label it with the PID. The PDCS will transport the blood in a padded biohazard blood storage bag and deliver them to the Patient Engagement Coordinator. The Patient Engagement Coordinator will have a set schedule for delivering the blood 3x a week to the CTSC lab. Following analysis, the blood samples will be destroyed using good lab protocol.

The lab will transmit electronic A1c results to the PI and the Data Manager and will send the PI the results as hard copy documents. The A1c results will be entered by the Data Manager into the A1c data collection instrument in the

PCORI Diabetes Project on REDCap once received from the lab.

The Research Manager or the PI will upload audio recordings from interviews and focus groups onto his/her computer as MP3 files and will send those to the transcriptionist/translator consultant via a secure UNM FTP process. The consultant will return the transcripts as an email attachment to the Research Manager.

The Research Intern will be responsible for obtaining interview data.

6. How data and specimens will be transported?

The PDCSs will gather data from the participants for the contact information, the participant data sheet and the survey orally and enter the answers directly into password-protected tablet. If the tablet is able to be connected to wireless internet at the location, then the data will be entered directly into the secure UNM REDCap data storage system using a database created specifically for this project. BMI data will also be entered into the tablet. If there is no wireless internet connection at the data collection point, the PDCS will upload the data when there is. If entering the data onto the tablet is not possible for some reason, the PDCS will use paper copies of the instruments and later the responses will be double data entered by the Project Coordinator and the Co-PI into REDCap, where the Data Manager will conduct a double data entry analysis to ensure quality.

Blood will be gathered for A1c testing and labeled with the PID. Blood samples will be transported in a padded biohazard transport bag. They will be stored at room temperature at One Hope Clinic in a locked office. Three times a week, the Patient Engagement Coordinator will deliver the blood samples to the UNM CTSC lab for testing. Following testing, the lab will destroy the blood samples using standard laboratory protocol. Results of the blood testing will be sent to both the PI and the Data Manager in hard copy (the results sheet will not include any identifying information, only the PID). The PI will ensure that the Data Manager has entered the results into the database, and then the hard copies of results will be stored in a locked filing cabinet in the Data Manager's locked office for three years (for quality check purposes) when it will be destroyed.

The PDCS will use scissors to collect a pencil lead-width of hair from the crown of the head. One centimeter of hair closest to the scalp will be used to measure hair to determine the average cortisol level

over the previous month. The hair will be placed in a plastic bag and labeled with the PID. Hair samples will be stored in a plastic bag in a cool, locked drawer in the office of the PI. When we obtain funds for analysis, hair will be pulverized in a Retsch Mixer Mill Type MM 400 100-240V 50/60HZ, extracted in methanol overnight, dried and resuspended in buffer. Cortisol concentration is measured by an immunoassay or by high-pressure liquid chromatography. Control samples containing specific amounts of cortisol are provided by the vendor with each assay kit, and we also use an internal control. We will use an automated colorimetric 96-well plate reader to measure the results. Cortisol levels are compared with average levels from normal subjects.

Interview and focus group data will be gathered using a small, hand-held electronic audio recorder. Audio-recordings will be uploaded as MP3 files onto the computer of the Research Manager. The Research Manager will upload the MP3 audiofiles into a secure electronic file for transmission to the transcriptionist/translator contractor. The transcriptionist/ translator contractor will download the audio recording. Following transcription/translation, the contractor will destroy the copy of the audiofile and send the transcript to the Research Manager as an email attachment. Once the Research Manager receives the transcript, the original audiofile on the Research Manager's computer will be destroyed.

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

This section is required when research involves more than Minimal Risk to subjects.

N/A

13.0 Withdrawal of Subjects*

13.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

We do not anticipate that individuals will be withdrawn without their consent.

13.2 Describe any procedures for orderly termination.

Participation for women who become pregnant during the study will be ended. They will be given an end-of-study visit where we will inform them that we are unable to continue their participation in the study and we will thank them for their participation. They will be told that their participation in the diabetes program they attend will not be affected by the fact that they have ended participation in the study.

13.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

Participation for women who become pregnant during the study will be ended. They will be given an end-of-study visit where we will inform them that we are unable to continue their participation in the study and we will thank them for their participation. They will be told that their participation in the diabetes program they attend will not be affected by the fact that they have ended participation in the study.

Our Data Manager will create a separate project on REDCap to track individuals who have withdrawn themselves, been withdrawn due to pregnancy, or who have discontinued as a result of attrition.

Statistical methods using validated methods to handle missing data (MD-2, MD-3). As described above, all attempts to minimize missing data will be made. Despite these attempts, we realistically expect there to be some degree of missingness. Of particular interest is whether participants are missing any outcome data. We will determine whether it is missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR). MCAR is defined as missingness that is independent of the observed and unobserved data (example: A1c measurement not obtained due to random machine failure); MAR is defined as missingness dependent only on an observed variable within the data (example: participant accidentally skips one question on the PAM-13); and MNAR is a systematic pattern to or a reason for the missingness (example: many participants exclude answering a question on the DKQ for a specific reason, either accidentally or intentionally). For MNAR, we will perform sensitivity analyses such as conducting the primary and secondary analyses on the intention-to-treat and per-protocol populations and compare the results. Under the assumption that most missing data is MAR or MCAR, we may use multiple imputation[126–129] to create imputed data sets containing estimates from a random sample of missing values for each observation based on other non-missing covariates for each subject. Each imputed data set is then analyzed as described in the statistical analysis plans for the outcome measures, and the results from each analyzed data set are combined for statistical inference. Multiple

imputation will be performed using PROC MI and PROC MIANALYZE in SAS 9.4 or in Stata 13.1 or higher.

14.0 Risks to Subjects*

14.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

The risks involved in participating in this study are minimal and we do not think that the participant will experience any negative consequences or effects. However, there are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality that can happen in any research study where the participant answers questions about themself, their experiences, and their opinions, or where they provide blood samples, BMI information, or hair samples. We have obtained a Certificate of Confidentiality from NIH to further protect participant privacy.

14.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

N/A

14.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

N/A

14.4 If applicable, describe risks to others who are not subjects.

N/A

15.0 Potential Benefits to Subjects*

15.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

Participants may find the experience of being interviewed and thinking about their own personal experience during the Interview to be interesting. Patient participants will receive information about their blood sugar levels when we provide them with results of the A1c test.

15.2 Indicate if there is no direct benefit. Do not include benefits to society or others.

Participants may find the experience of participating and thinking about their own personal experience to be interesting. Patient participants will receive information about their blood sugar levels when we provide them with results of the A1c test. All participants will be invited to an end-of-study presentation of study results.

16.0 Vulnerable Populations*

16.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

N/A

17.0 Community-Based Participatory Research*

17.1 Describe involvement of the community in the design and conduct of the research.

1. <u>PLANNING THE STUDY</u>

a. Patient partners participated in identification of diabetes as a focus for research. The idea for this study came from our patient partners. In 2009, a One Hope staff member who knew Janet, already a trusted partner to their work, asked her to help figure out how to address problems related to diabetes. In 2011, Janet and her colleague, Shiraz (a Co-Investigator for the project), obtained funding to conduct pilot research to assess the dimensions of the problem and to obtain community input regarding diabetes health and ideas for prevention.

b. Patient partners participated in pilot research. Patient partners participated in the conceptualization, implementation, and translation of preliminary research for the project. Janet and Shiraz worked with One Hope to implement a pilot study. Lidia was the Project Coordinator for the pilot and a member of the pilot Research Team. The pilot research involved GIS data mapping of secondary data, a survey and blood analysis for A1c with 100 people, interviews with key community stakeholders, and a series of focus groups with patients and social supports. Lidia administered the survey, facilitated the focus groups, and participated in the analysis of the data. We had a Patient Advisory Board consisting of patients and caregivers who participated in designing focus group/interview questions and interpreting findings. Findings from the pilot provided a roadmap for the diabetes self-management initiative that One Hope has since developed and implemented. We presented data

about the research to the Patient Advisory Board, to the broader community,[136] and at professional conferences.[137] Lidia was a presenter at both community and professional venues. We published two articles in peer-reviewed journals, and Lidia is a co-author on both.[32,33] One of our articles is among the top 10 most-downloaded articles for that journal.[32]

c. Patient partners participated in our PCORI Tier I & II Awards, and in planning for the proposed study. The experiences described above provided the foundation for us to receive PCORI Tier I (2014) and Tier II (2015) awards. One Hope was the applicant for both, with Lidia as the PI and Janet as the Co-PI. Janet and Lidia collaborated to develop the study, obtaining input and commitment from stakeholders from different diabetes programs and from university researchers. Patients and social supports were involved through a Patient Advisory Board and Lidia was the lead in the planning process. The Patient Advisory Board generated the research question, and identified the outcomes and measures.

2. CONDUCTING THE STUDY

a. Patient partners will participate as integral parts of the Research Team. Patients, caregivers, and other patient partners will participate as **paid** members of the Research Team, including six people with diabetes. Mary Johnston, the CDE-UNMH diabetes education program Manager, although she has chosen not to be a member of the Research Team *per se*, will be a Program Liaison for the project. Patients and caregivers involved in our PCORI Tier I and II awards will participate as members of the Patient Advisory Board for this research. In addition to Lidia (the Co-PI and a patient) and Janet (the PI), the Advisory Board includes seven patients and caregivers, plus Maria (our Patient Engagement Coordinator).

b. Patient partners will participate in data collection and analysis. We will hire four individuals from our patient population to work as paid PDCSs to gather data from participants. They will be trained in Human Subject and HIPAA research ethics and protocols, and will learn how to recruit and consent participants, to conduct surveys, to gather clinical data and samples, and to handle blood specimens according to project protocol. Patients who are members of the Research Team and members of the Patient Advisory Board will all have structured opportunities to participate in analyzing and interpreting the data.

3. DISSEMINATING THE STUDY RESULTS

a. We value patient partner participation in dissemination of results of the research. Lidia participated in dissemination of the results of the pilot study. We made a conscious effort for her to be involved in and often take the lead on both community and academic presentations, and she was a co-author on publications.[32,33]

b. We place a high value on ensuring that our research is not only relevant from a patient partner perspective, but that the results of

research get shared with patient partners and other community members. We will present our work at academic and professional conferences, but we will also look for community venues at which we can present it. A number of local organizations support our work and provide us with venues for dissemination. We presented results of the pilot at their meetings and we plan to present there with future research findings. We also were explicit in producing a version of findings from the research in lay language that was disseminated to community members who would not have been interested in or had the capacity to utilize a jargon-filled academic manuscript.

4. PRINCIPLES FOR ENGAGEMENT

a. How We Created Reciprocal Relationships.

i. We created a Project Patient Advisory Board involving patient partners. The 10-member Patient Advisory Board will meet quarterly to provide guidance and oversight for the research. Lidia will facilitate the meetings.

ii. We provide a respectful and culturally appropriate environment for Patient Advisory Board meetings through our choice of default language. Our Board includes individuals who are not comfortable speaking in English or who do not understand English. Patient Advisory Board meetings are conducted in Spanish as the default language. The PI is fluent in Spanish and the Co-PI has Spanish as her first language. If we bring in content experts or researchers who do not speak Spanish, we provide them with an English translation, but we still hold the meetings in Spanish to acknowledge patients as the core of the process. For the proposed research we have members of the Research Team who do not speak Spanish but we will continue to prioritize Spanish as the primary language for the project, requiring the researchers to make the extra effort to experience meetings in translation rather than always expecting patient partners to be the ones who have to operate in a language that is not their own.

iii. In our PCORI Tier 1 award, we budgeted to be able to create an electronic internal communication infrastructure that would involve smart phone, social media, and email messaging. However, in consultation with our Patient Advisory Board, we made a decision not to pursue this approach. Members of our Board were unanimous in their belief that an electronic communications infrastructure is not only unnecessary but it would be culturally and contextually inappropriate and counter-productive. The majority of our Advisory Board members do not have a smart phone, a computer, or their own internet service, and few even have an email account, so they do not necessarily know how to use or have easy or continuous access to electronic messaging systems. Instead, it was decided as a group that an old-fashioned approach is preferable and more likely to be effective. Maria, our project Patient Engagement Coordinator, contacts Advisory Board members by phone (and email if the person has an email account) to tell them about logistics.

b. How We Incorporate Co-learning.

i. <u>During the planning process created by our Tier I and Tier II awards, we endeavored to provide trainings and to help our Patient Advisory Board develop their capacity to participate in and contribute to the research.</u> When we applied for PCORI Tier I and II awards, we were concerned about our patient partner stakeholders understanding the concept of research and the methodological approaches we are required to use to make a study scientifically valid. During our Tier I award in 2014, we brought content experts, including Co-I Burge, to attend our Advisory Board meetings to provide training and instruction to our Board members. Building the capacity of Advisory Board members to understand and participate in research has been a foundational activity for both of our Tier projects.

ii. <u>We believe that researchers and health providers have much they can learn from patient stakeholders</u>. This is a fundamental precept of the innovative model of diabetes self-management that has been developed at One Hope and that forms the foundation for our PCORI Tier projects. We are committed to making sure that researchers participating in our study are cognizant of the perspective and everyday reality of patient partner members. Lidia uses her skill at facilitation to lead meetings in a way that accomplishes this. Listening is a core skill that we nurture in our meetings.

18.0 Sharing of Results with Subjects*

18.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

We will actively disseminate knowledge gained from this patient-engaged and community-based research to all partners in language that will be understandable and respectful. We place a high value on ensuring that our research is not only relevant from a patient partner perspective, but that the results of research get shared with patient partners and other community members. To this end, we not only present our work at academic and professional conferences, but we look for community venues where we can present. Local groups partner with us, and they support our research efforts. We presented results of our pilot research at local meetings and we plan to do so with future research findings. Community-based dissemination activities will include, but not be limited to, presentations at the International District Healthy Communities Coalition, the Healthy Here Coalition, the Bernalillo County Community Health Council, and community centers, as well as at information dissemination sessions at community-sponsored events, and press releases to local media. We will hold an end-of-study event to present findings to a lay audience and we will invite all participants to attend.

Interviews with Project Patient Advisory Board members. Our Summer Research Intern will conduct a series of interviews with the seven members of our Patient Advisory Board during June and July 2017, and we will hold a quarterly meeting of the Advisory Board in July. The interviews will be designed to obtain information about their personal experience with diabetes, their experience on our Patient Advisory Board and working on a research project, and how they would like to deepen their involvement over the next three years in this new phase of the research. At the end of July we have a Patient Advisory Board meeting scheduled. Patient Advisors normally attend these meetings. At the July meeting, our Research Intern will present her findings and a poster she is required to create based on her research back to the group.

19.0 Setting

19.1 Describe the sites or locations where your research team will conduct the research.

1. Identify where your research team will identify and recruit potential subjects

The purpose of the data collected through this project is to investigate the comparative effectiveness of two evidence-based models for creating program cultural competency in diabetes self-management programming. We will compare two diabetes self-management programs that serve a large low-income Latino population and that employ different evidence-based models of culturally competent health promotion. We will gather data from participants at One Hope Centro de Vida Health Center in Albuquerque's International District and the Center for Diabetes Education at the University of New Mexico Hospital located on University Avenue near the Pitt.

2. Identify where *research procedures will be performed.*

Most One Hope data collection will occur on the premises of One Hope, although if participants would like to have an appointment off-site at a location of their convenience, that will be possible.

Data collection from participants at CDE UNMH will occur at the facilities of CDE UNMH or at a location of convenience to the participant.

Interviews will be conducted at a location of convenience to the participant.

Focus Groups will be held at the facilities of One Hope.

Blood analysis will be conducted at the CTSC lab.

Analysis of hair samples will be conducted in the UNM lab of Co-I Bearer in Department of Pathology, on the UNM-HSC campus, Fitz Hall rm 329.

3. *Describe the composition and involvement of any community advisory board.*

We created a Project Patient Advisory Board involving patient partners. The 11-member Patient Advisory Board will meet quarterly to provide guidance and oversight for the research. The Advisory Board consists of 4 Latino diabetes patients and 3 caregivers for people with diabetes, plus the PIs, the Patient Engagement Coordinator, and Dr. Will Kaufman. We formed this board with support from 2 PCORI Tier Awards and members of the board met once a month over a two year period to plan this research. The patient and caregiver members identified the research question and the measures for this study.

4. *For research conducted outside of the organization and its affiliates describe:*

N/A

20.0 Resources Available

20.1 Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.

RESEARCH TEAM AND ENVIRONMENT

Research Team Member	Title & Institutional Affiliation	Expertise	Role on Project
Janet Page-Reeves, Ph.D.	Research Assistant Professor UNM Office for Community Health (OCH) Department of Family & Community Medicine	Cultural Anthropology, Community/Patient-Engaged Research	**PI** + Senior Qualitative Researcher
Lidia Regino, BS	**Diabetes Patient** + Director, One Hope *Centro de Vida* Health Center	Diabetes, Latino Health, Cultural Competency	**Patient & Co-PI** + Patient-Engagement Expert

Virginia Sandoval, Blanca Pedigo, Denisse Guerrero, and Loida Varela	**Patient Data Collection Specialists (PDCSs)**	Diabetes	**Researchers from the patient population (4)**
Mark Burge, MD	Professor, Medicine, Endocrinology & Metabolism + Deputy Director, CTSC	Endocrinology, Diabetes	**Mentor to PI & Diabetes Research Expert**
Elaine Bearer MD, Ph.D.	The Harvey Family Professor Department of Pathology	Social Determinants of Health	**Project Laboratory Scientist** + Senior Researcher
Erik Erhardt, Ph.D.	Assistant Professor Department of Mathematics & Statistics	Statistics	**Senior Statistician**
Cristina Murray-Krezan, MS	Research Assistant Professor Epidemiology, Biostatistics & Preventive Medicine	Biostatistics	**Biostatistician**
Shiraz Mishra MBBS, Ph.D.	Professor, Department of Pediatrics + Director of Community-Engaged Research, CTSC	Methodology	**Project Research Methodologist** + Senior Researcher
Maria Tellez	Community Coordinator, One Hope	Patient-Engagement	**Patient Engagement Coordinator** + Data Collection Supervisor
Molly Bleecker, MA	Research Scientist III, OCH	Data Management, Qual/Quant Research	**Project Data Manager** + Qualitative Researcher
Hannah Cole-McGrew	Masters Level Research Manager	Research Project Management	**Research Project Manager at UNM**
Hannah Cole-McGrew	Qualitative Researcher	BS/BA or above	**Qualitative Researcher**
Samantha Katz	Research Intern	Undergraduate Research Assistant through the UPN	**Research Intern**

Research Team Expertise. **Janet (the PI) and Lidia (the Co-PI)** have a close partnership and have assembled a seasoned multi-disciplinary team at UNM that includes collaboration with the two sites. The investigators have extensive experience working on issues of health disparity and demonstrated ability to conduct research in Spanish-speaking contexts, including with the population of study. The diverse composition of the Research Team will create a powerful, complementary blend of patient-engagement, knowledge, and experience; academic and medical knowledge; and research acumen. This synergistic skill set will make this unique project successful.

Describe other resources available to conduct the research: For example, as appropriate:

1. *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*

21.0

Our recruitment plan is feasible based on our previous experience. Below we provide a detailed presentation of our recruitment rate and plans for follow-up. We attempted to create a realistic recruitment plan that would fit seamlessly with the work required for all parts of the study. Below is the recruitment detail:

Year	Month	total	Baseline # participants recruited and appointments each month	3 months # of appointments each month	6 months # of appointments each month	12 month # of appointments each month	Total # of appointments each month	Total Appoint-ments for each data collector each month
2017	Jan							
	Feb		32				32	8
	Mar	64	32				32	8
	Apr	96	32				32	16
	May	128	32 25% achieved	32			64	16
	Jun	160	32	32			64	16
	Jul	192	32	32			96	24
	Aug	224	32	32	32		64	24
	Sept	256	32 50% achieved 25% required	32	32		96	24
	Oct	288	32	32	32		96	24
	Nov	320	32	32	32		96	24
	Dec	352	32	32	32		96	24
2018	Jan	384	32 75% achieved 50% required	32	32	32	128	32
	Feb	416	32	32	32	32	128	32
	Mar	448	32	32	32	32	128	32
	Apr	480	32 100% achieved	32	32	32	128	32
	May			32	32	32	96	24
	Jun		75% required	32	32	32	96	24
	Jul			32	32	32	96	24
	Aug				32	32	64	16
	Sept		100% required		32	32	64	16

	Oct				32	32	64	16
	Nov					32	32	8
	Dec					32	32	8
2019	Jan					32	32	8
	Feb					32	32	8
	Mar					32	32	8
	Apr					32	32	8
	May							
	Jun							
	Jul		All data collection will be complete					
	Aug							
	Sept							
	Oct							

1. *Describe the time that you will devote to conducting and completing the research.*

   This project is funded for 3 years.

2. *Describe your facilities.*

   One Hope is a clinic just north of Central in the International District in NE Albuquerque. CDE UNMH is a program of UNM Hospital located at the UNMH facility on University Avenue near the Pitt.

3. *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*

   We do not anticipate that any participants will require medical or psychological resources as a result of their participation in this research since we are not asking them to "do" anything--our research is about a program that has been prescribed to them by their doctor and we are merely gathering survey, BMI, blood, hair, interview and focus group data regarding their participation in that program. However, as we are gathering A1c data, if results of the A1c analysis indicate a situation of concern, we will use that information to contact the patient and their provider. In a case where a patient needs a referral, team member Dr. Mark Burge will provide one. If the patient is pregnant, Dr. Burge will provide a referral to the UNM high risk maternity clinic.

4. *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

Training Requirement for Members of the Research Team:
All members of the Research Team will receive training in research on human subjects. Each will take the online Human Subjects Research Training Modules from the Collaborative Institutional Training Initiative (CITI) which fulfill the requirement for NIH human subjects training. They will also take a HIPAA compliance training. PDCSs will be trained in phlebotomy. The CTSC Clinical Research Laboratory's ASCP-certified Medical Laboratory Scientist will provide additional Good Laboratory Training and Competency to assist with site-specific collection and quarterly technical competency testing through direct observations of the PDCS phlebotomists at each site. A certified phlebotomist at One Hope, will be available to provide technical assistance to the PDCSs in an ongoing way. PDCSs will meet regularly with the Patient Engagement Coordinator to make sure they are following protocol and to trouble-shoot any challenges.

22.0 Prior Approvals

22.1 Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)

N/A

23.0 Recruitment Methods

23.1 Describe when, where, and how potential subjects will be recruited.

Staff & Providers (36): Our Program Liaison at each site will identify up to 12 key program staff and/or providers each year for assessment interviews that will contribute to our understanding of the program sites. Our Research Manager will contact them using an IRB-approved script to invite them to participate and schedule appointments with those interested. At the appointment, she will ask them to sign the consent and complete the Data Sheet, and then she will conduct the interview.

Patient (240) & Social support (240) participants:

At CDE-UNMH, when patients register for the program, CDE-UNMH staff will tell them about the study using an IRB-approved script and a flyer with pull-off tabs will be posted in the CDE office. An invitation with further detail about the research and contact information for our PDCSs--the *Patient Data Collection Specialists* (PDCSs)--will be sent in a mailing that all new patients receive from CDE-UNMH with their class schedule confirmation and logistics. A staff person at CDE-UNMH or a member of the research team will phone new participants to tell them about the study. For those who indicate that they are interested, the staff person or research team member will ask the patient's permission to release their name and contact information to our research team. If the patient agrees, a research team member will contact the patient. Interested patients can also contact the research team using the information on the mailing. For all interested patient participants, the research team member will screen them per our recruitment criteria.

At One Hope, participants will be identified in three ways: 1) New patients who call the clinic and indicate that they need to see a provider specifically about diabetes will be told about the study using an approved script, 2) Every patient seen at the clinic has an exit interview (*salida*) conducted by a Community Health Worker. For patients who have been told by their provider to have their A1c checked or that they have a diagnosis of diabetes or prediabete, they will be told about the study using an approved script, and 3) Flyers about the study will be posted in the One Hope waiting room. For those who indicate interest in participating, a PDCS will contact them, inform them about the research per IRB requirements, and screen them for eligibility. For those who are eligible, the PDCS will schedule an appointment to consent them and gather baseline data.

At both sites, interested patients who qualify will provide contact information for a person that they identify from their social network (family or friend) whom they consider as their primary "social support." A member of the research team will contact the social support, provide them with information about the study, and invite them to participate. The PDCS will schedule an appointment with supports who are interested.

At the appointment, the PDCS will ask all participants to sign the consent, collect the information in the Participant Data Sheet, and collect responses to the baseline survey questions. The PDCS will obtain a blood sample and measure BMI for the patient only.

Subset of Patient and Social support Participants for Interviews (72) and Focus Groups (72): At each of the sites, per our sampling frame described above, the PDCS will identify interviewees and focus group participants from those already recruited to be in the study and invite them to

participate. Our Research Manager will contact those interested to schedule.

23.2 Describe the source of subjects.

We will recruit patients from two sites: The Center for Diabetes Education at UNMH and One Hope Clinic. Patients will identify a corresponding social support participant to be invited. We will also identify site staff and provides to participate in interviews.

23.3 Describe the methods that will be used to identify potential subjects.

At CDE-UNMH, when patients register for the program, CDE-UNMH staff will tell them about the study using an IRB-approved script and a flyer with pull-off tabs will be posted in the CDE office. An invitation with further detail about the research and contact information for our PDCSs--the *Patient Data Collection Specialists* (PDCSs)--will be sent in a mailing that all new patients receive from CDE-UNMH with their class schedule confirmation and logistics. A staff person at CDE-UNMH or a member of the research team will phone new participants to tell them about the study. For those who indicate that they are interested, the staff person or research team member will ask the patient's permission to release their name and contact information to our research team. If the patient agrees, a member of the research team will contact the patient. Interested patients can also contact the research team using the information on the mailing. For all interested patient participants, the research team will screen them per our recruitment criteria.

At One Hope, participants will be identified in three ways: 1) New patients who call the clinic and indicate that they need to see a provider specifically about diabetes will be told about the study using an approved script, 2) Every patient seen at the clinic has an exit interview (*salida*) conducted by a Community Health Worker. For patients who have been told by their provider to have their A1c checked or that they have a diagnosis of diabetes or prediabetes, they will be told about the study using an approved script, and 3) Flyers about the study will be posted in the One Hope waiting room. For those who indicate interest in participating, a PDCS will contact them, inform them about the research per IRB requirements, and screen them for eligibility. For those who are eligible, the PDCS will schedule an appointment to consent them and gather baseline data.

At both sites, interested patients who qualify will provide contact information for a person that they identify from their social network (family or friend) whom they consider as their primary "social support." A member of the research team will contact the social support, provide

them with information about the study, and invite them to participate. The PDCS will schedule an appointment with supports who are interested.

At the appointment, the PDCS will ask all participants to sign the consent, collect the information in the Participant Data Sheet, and collect responses to the baseline survey questions. The PDCS will also obtain a blood sample, measure BMI and gather a hair sample for the patient only.

Subset of Patient and Social support Participants for Interviews (72) and Focus Groups (72): At each of the sites, per our sampling frame described above, the PDCS will identify interviewees and focus group participants from those already recruited to be in the study and invite them to participate. Our Research Manager will contact those interested to schedule.

The seven patient members of our Patient Advisory Board will be invited to participate in the Advisory Board Member interviews.

23.4 Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

At CDE-UNMH, when patients register for the program, CDE-UNMH staff will tell them about the study using an IRB-approved script and a flyer with pull-off tabs will be posted in the CDE office. An invitation with further detail about the research and contact information for our PDCSs--the *Patient Data Collection Specialists* (PDCSs)--will be sent in a mailing that all new patients receive from CDE-UNMH with their class schedule confirmation and logistics. A staff person at CDE-UNMH or a member of the research team will phone new participants to tell them about the study. For those who indicate that they are interested, the staff person or research team member will ask the patient's permission to release their name and contact information to our research team. If the patient agrees, a member of the research team will contact the patient. Interested patients can also contact the research team using the information on the mailing. For all interested patient participants, the research team will screen them per our recruitment criteria.

At One Hope, participants will be identified in three ways: 1) New patients who call the clinic and indicate that they need to see a provider specifically about diabetes will be told about the study using an approved script, 2) Every patient seen at the clinic has an exit interview (*salida*)

conducted by a Community Health Worker. For patients who have been told by their provider to have their A1c checked or that they have a diagnosis of diabetes or prediabetes, they will be told about the study using an approved script, and 3) Flyers about the study will be posted in the One Hope waiting room. For those who indicate interest in participating, a PDCS will contact them, inform them about the research per IRB requirements, and screen them for eligibility. For those who are eligible, the PDCS will schedule an appointment to consent them and gather baseline data.

At both sites, interested patients who qualify will provide contact information for a person that they identify from their social network (family or friend) whom they consider as their primary "social support." A member of the research team will contact the social support, provide them with information about the study, and invite them to participate. A member of the research team will schedule an appointment with supports who are interested.

At the appointment, the PDCS will ask all participants to sign the consent, collect the information in the Participant Data Sheet, and collect responses to the baseline survey questions. The PDCS will also obtain hair and blood samples, and measure BMI for the patient only.

Subset of Patient and Social support Participants for Interviews (72) and Focus Groups (72): At each of the sites, per our sampling frame described above, the PDCS will identify interviewees and focus group participants from those already recruited to be in the study and invite them to participate. Our Research Manager will contact those interested to schedule.

For staff and provider interviews, the Research Manager will obtain names from our site liaison and will invite them using an approved script.

For Patient Advisory Board interviews, we already have names and contact information for the seven patient members of our Patient Advisory Board. We will invite them to participate using an approved script.

23.5 Describe the amount and timing of any payments to subjects.

Research Appointments

For patients and social supports, Research Appointments to gather survey, blood BMI, and hair data will last approximately 1 hour.

Patient and Social Support Interviews

Interviews will last approximately 1-2 hours.

Focus Groups

Focus Groups will last 1-2 hours.

Advisory Board Interviews
Interviews will last 1-3 hours.

Compensation
For each component of the research, the participant will receive a merchandise card:

- For patients and social supports, for each of the 4 Research Appointments, they will receive a Walmart card worth $50
- For patients and social supports invited to do an interview or focus group, they will receive a Walmart card worth $50
- For staff and provider interviewees, if they are not UNM employees, they will receive an Amazon card worth $50

Following the data collection appointment, interview or focus group, when we give a participant a card, we will ask them to sign a receipt and provide some information for our financial record files using the UNM research participant receipt form. Apart from a signature to verify they received the card, they do not have to provide any information that they do not care to share.

While we hope that they will complete each activity they agree to, and it is best for our study results to have complete information from each activity, they will receive the merchandise card if they participate in a research activity even if they have to leave early or if they decide to stop in the middle.

24.0 Local Number of Subjects

24.1 Indicate the total number of subjects to be accrued locally.

Local Comparator Sites: We will compare 2 diabetes self-management program models used by many Latino patients from low-income households in Albuquerque, New Mexico: 1) The Diabetes Self-Management Support Empowerment Model at the University of New Mexico Hospital and 2) The Chronic Care Model at One Hope Centro de Vida Health Center.

Subjects: We will recruit a total of 240 patient-social support pairs from the two program sites: patients (N=240: 120 at each site) and a corresponding social support of each enrolled patient (N=240 – 120 at each site). We will also recruit up to 6 staff and providers from each site each year to participate in interviews.

In addition, we will recruit the seven members of our Patient Advisory Board.

24.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

Our experience with successful recruitment leads us to believe that we will be successful enrolling according to the plan we have laid out. Based on our experience working with this population in Albuquerque, our retention rates average 80-85%, which are consistent with other studies involving a similar population. To assure a conservative estimate, we estimated an attrition rate of 20% in our target recruitment.

Our previous study experience has demonstrated that we have the capacity to retain participants. We would like to emphasize our expertise and skill working with this patient population. The PI and the Co-PI have a strong record of working closely with individuals in the community and we have a cultural, linguistic and intellectual understanding of things that are important to patients and how to engage them. This makes a huge difference in the way that we, as researchers, interact with patient participants. Moreover, our PDCSs at both sites will be members of the patient population—Latino diabetes patients from low-income households. We believe that this will make a significant difference in the way that participants respond to and interact with our research project. These factors will assist us in retaining participants.

25.0 Provisions to Protect the Privacy Interests of Subjects

25.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

Privacy and Confidentiality: Guidelines for the protection of participant privacy and confidentiality will be followed in all cases. All members of the research team will maintain current Human Subjects training. They will understand the importance of privacy issues and their responsibility to maintain the highest research ethical standards in all respects. Surveys, blood-draws and other clinical data gathering, interviews and focus groups will be conducted at a location to provide privacy. Prior to beginning each focus group, the facilitator will instruct participants regarding privacy measures. All participants will be asked to sign a receipt for a merchandise card incentive which will be used for project accounting purposes only and will not be linked with or associated with research data. Potential participants' contact and eligibility screening information will be kept in separate projects on REDCap. Enrolled participants' contact information, demographic information, survey responses, and biological measures will be entered and stored in separate data collection instruments within a third project in REDCap. The PID assigned to eligible

participants will be retroactively assigned to these participants' records in the Pre-Screening and Eligibility Screening projects, making this the only link across the three projects. The Study ID generated by REDCap will be the only link across the data collection instruments within the PCORI Diabetes Project. User rights to the three projects will be limited such that personally identifying information is only accessible to a few members of the research team. All biological samples will be uniquely labeled with the Participant ID.

We need to be able to maintain a link between the participant and the data to be able to notify participants if their A1c level is dangerously high or to be able to notify the participant's PCP if their A1c is above 10, to schedule follow-up appointments at 3, 6, and 12 months, and to be able to invite the participant to the end-of-study presentation of project results.

Consent Forms will be stored in a locked cabinet in the office of the PI and with access only by the investigators. The contact information, demographic information, and research data for all study participants will be stored electronically on our secure REDCap database. Contact information will be kept for five years after the end of the project to be able to invite the participant to participate in future follow-on studies. Consent Forms will be kept for 3 years following the end of the project, at which time they will be destroyed. Participant information will be considered confidential and will not be shared. De-identified project data will be shared only per our Data Sharing Protocol. Transcripts from interviews and focus groups will not be shared. De-identified project data will be kept for at least 5 years.

25.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

PDCSs will be members of the patient community/population and will be fluent Spanish speakers. Data collection will not be hurried. PDCSs will spend time building rapport with participants.

25.3 Indicate how the research team is permitted to access any sources of information about the subject

Pre-Screening: Potential patient participants at the CDE-UNMH program will be called by a CDE-UNMH staff member of the research team and asked if they might be interested in participating in the study. If they say yes, they will be asked for their contact information to be contacted for an eligibility screening appointment. The information collected will be hand-

written on a Pre-Screening form and later given to the Patient Engagement Coordinator, who will enter it into the Pre-Screening project in REDCap.

Eligibility Screening: potential participants who agree to being screened for eligibility will be contacted by a member of the research team and asked the eligibility screening questions, including requesting information about a potential social support partner. The patient participant will be offered the opportunity to contact their potential social support partner to inform him or her that a research team member will be in contact to conduct an eligibility screening. When the patient partner gives permission to contact the potential social support partner, a member of the research team will contact the potential social support partner and conduct the eligibility screening. If both the patient participant and his or her social support partner are deemed eligible, a baseline data collection appointment will be scheduled. The information collected during the eligibility screening will be hand-written on an Eligibility Screening form and given to the Patient Engagement Coordinator, who will enter it into REDCap in the Eligibility Screening project. The Patient Engagement Coordinator will then create a record for the participant in the PCORI Diabetes Project in REDCap by assigning a PID to the participant. The Patient Engagement Coordinator will keep a master list of the participants' names and PIDs both electronically and in hard copy. The electronic copy will be saved on her password-protected laptop, which is stored in a locked cabinet at One Hope when not in use. The hard copy will also be stored in a locked cabinet at One Hope.

Data Collection: at the baseline data collection appointment, the PDCS will collect and enter contact and demographic information into separate data collection instruments in the PCORI Diabetes Project in REDCap. At the baseline and all three follow-up appointments, the PDCSs will also administer the survey instrument to the participants, responses to which will be entered into a third data collection instrument in the same project. The PCDSs will also collect BMI measurements (weight and height) and draw blood for A1c testing at the baseline and all follow-up appointments and will collect a hair sample at the baseline and six-month follow-up appointment. The BMI measurements will be entered into a fourth data collection instrument in the PCORI Diabetes Project by the PDCS during each appointment. The A1c results will be entered into a fifth data collection instrument and the hair cortisol results entered into a sixth in the same project by the Data Manager when the results are provided to her.

The contact and demographic information data collection instruments are the only data collection instruments in the PCORI Diabetes Project that contain personally identifying information. The data collection instruments that contain the participant's survey responses and biological

measures do not contain any personally identifying information. Each participant's data is linked across the six data collection instruments in the PCORI Diabetes Project by his or her unique Study ID, which is automatically generated by REDCap when the Patient Engagement Coordinator generates the record.

In sum, there will be three separate projects in REDCap: the Pre-Screening project, the Eligibility Screening project, and the PCORI Diabetes Project, which contains the participant contact information, demographic information, survey responses, BMI measurements, A1c results, and hair cortisol results in six separate data collection instruments. The PID that is generated before the baseline data collection appointment will be retroactively added to the relevant record in both the Pre-Screening and Eligibility Screening projects by the Research Manager or the Data Manager to allow for tracking of recruitment, enrollment, and attrition. This will be the only link across the three projects.

Participants' personally identifying information will be gathered and entered into REDCap at all three stages – pre-screening, eligibility screening, and baseline data collection. We will protect and limit access to this information in the following ways:

1) After the Patient Engagement Coordinator enters the information from the hard copy pre-screening and eligibility screening forms into REDCap, the hard copies will be turned over to the Research Manager, who will file them in a locked filing cabinet in a locked office at the UNM HSC OCH;

2) Access to the data in both the Pre-Screening project and the Eligibility Screening project will be limited to the Patient Engagement Coordinator, the Data Manager, the Research Manager, the PIs, the Senior Statistician, and the Biostatistician for purposes of entering data (Patient Engagement Coordinator) and exporting data for quality control, and data analysis (PIs, Data Manager, Research Manager, Senior Statistician, and Biostatistician. Any data resulting from the quality control or analysis processes that will be shared with others on the research team without their own access to these data will be de-identified before sharing.);

3) Access to the instruments within the PCORI Diabetes Project can be limited. Access to all the data (including identifying information) in all the data collection instruments will be limited to the Data Manager, the Research Manager, the PIs, the Senior Statistician, and the Biostatistician for purposes of quality control and data analysis (any data resulting from these processes that will be shared with others on the research team will be de-identified before sharing). The Patient Engagement Coordinator, the PI and the Co-I will have access to de-identified data in this project. Appointments will be scheduled and tracked in this project using the Calendar tool in REDCap. In order to be able to provide the data collectors with the information necessary to meet with participants, the

appointments in the Calendar tool will include the participant's name, phone number, and address (if meeting the participant in his/her home).

REDCap is a safe place to store personally identifying information because it is a password-protected site that is stored behind the UNM HSC firewall. In order for research team members to access it from on-campus, they must be logged into the HSC secure wifi; off-campus (i.e., outside the firewall), they must use the Cisco virtual private network ("VPN"), access to which is only allowed after being approved by the university's Information Technologies department. Access to the REDCap database is further secured by the fact that the iPads used by the data collectors and the laptops or desktops used by other members of the research team (with user rights) are password-protected. In addition, project administrators have the ability to limit access to data collection instruments or projects for other members of the research team.

A1c results will be sent electronically from the CTSC lab to the PI and the Data Manager, and the PI will also receive hard copy results. The Data Manager will enter those data into the secure UNM REDCap database and then destroy the hardcopy documents.

Hair samples will be stored in plastic bags in the office of the PI. When funding for analysis is obtained, the Research Manager will give them to Dr. Bearer for analysis in her UNM lab. Remaining hair will be stored for up to two years after the project to ensure we had a sufficient sample for analysis.

Interviews and focus groups will be audio recorded. The Research Manager will upload audio recordings from the recording device into his/her password protected UNM computer as MP3 files. Once this has been done, the Research Manager will delete the files from the recording device.

The MP3 files will be stored on the secure password-protected UNM computer of the Research Manager. The Research Manager will send those audio recordings to the transcriptionist/translator using a secure UNM FTP electronic file process. The transcriptionist/ translator will send back the transcription/translation as an electronic doc file. Once the Research Manager receives the electronic doc file of the audio recording, he/she will destroy the original MP3 file.

The electronic doc files of the interview and focus group transcripts will be stored on the password protected UNM computers of the Qualitative Research team. Hard copies of transcripts used for coding will be stored in a locked cabinet in the PIs office.

26.0 Compensation for Research-Related Injury

26.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

This research does not involve more than Minimal Risk to subjects.

26.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury.

This research does not involve more than Minimal Risk to subjects. We do not anticipant any situation where participants could be injured as a result of their participation in this research.

27.0 Economic Burden to Subjects

27.1 Describe any costs that subjects may be responsible for because of participation in the research.

Patients may experience impacts on their time, they may incur travel expenses or require that others who provide travel to them wait while they have their appointment with us, they may have to miss work, and they may have child care expenses or have to expend social capital to call on others to watch their children.

28.0 Consent Process

28.1 Indicate whether you will you be obtaining consent, and if so describe:

1. *Where will the consent process take place*

   Consent will be obtained at One Hope Clinic, UNMH Diabetes Education Program or at a location of convenience to the participant.

2. *Any waiting period available between informing the prospective subject and obtaining the consent.*

   We do not plan to schedule a specific waiting period, as we do not forsee any major risks, hazards or side effects to the participants related to participation in the research. Participants have the ability to withdraw from the study at any time.

3. *Any process to ensure ongoing consent.*

At each data collection appointment, interview or focus group, before beginning the data collection, the research team member conducting the data collection event will remind the participant about the consent they signed and the fact that they have the capacity to withdraw at any time.

4. *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:*
   - *The role of the individuals listed in the application as being involved in the consent process.*

     To recruit participants from CDE-UNMH, the CDE staff member or research team member who calls the patient to tell them about the study and inquire if they might be interested will use an approved recruitment script. If the patient indicates interest, the staff or research team member will ask for oral permission from the patient to release the patient's name and contact information to the research team so that the PDCS can contact the interested patient and conduct the screening to determine eligibility. Oral permission will not be used for consent to participate, only for consent to share the patient's name and contact information for recruitment.

     For actual participation in the study, we will obtain written consent from all participants.

     If both the patient participant and his or her social support partner are deemed eligible, a baseline data collection appointment will be scheduled, at which time the participant will be consented into the study. At the baseline data collection appointment the research team member will provide information about the study and about the nature and length of the participant's involvement, and let them know that their participation and the data they provide will be considered confidential. The research team member will go over the Consent Form individually with each participant, making sure that they understand the research and their participation in it. The research team member doing the consenting of patient and social support participants will be required to be bilingual to accommodate English and Spanish-speaking participants. The research team member will ensure that participants understand that their participation is voluntary and that they can choose not to participate or to withdraw their participation at any point in the study. Both

the participant and the research team member will sign the consent form. The participant will be given a copy of the consent to keep for their files. In addition, participants will be asked to provide contact information and demographic information. The contact information will be kept in a separate data collection instrument on REDCap from the demographic data and research data from the participant. The contact information will be used to schedule 3-, 6-, and 12-month follow-up appointments, to contact patients in case of elevated A1c results, to invite the participant to an end-of-project presentation of data to participants, and to invite the participant to participate in future follow-up research. We do not anticipate any reason for participants to be withdrawn from the research without their consent.

- *The time that will be devoted to the consent discussion.*

  We anticipate that the consent discussion will take 15 to 20 minutes.

- *Steps that will be taken to minimize the possibility of coercion or undue influence.*

  The research team member will go over the Consent Form individually with each participant, making sure that they understand the research and their participation in it. The research team member doing the consenting of patient and social support participants will be required to be bilingual to accommodate English and Spanish-speaking participants. The research team member will ensure that participants understand that their participation is voluntary and that they can choose not to participate or to withdraw their participation at any point in the study.

- *Steps that will be taken to ensure the subjects' understanding.*

  Consent documents will be available in English or Spanish depending on the preference of the participant. The research team member will go over the Consent Form individually with each participant, making sure that they understand the research and their participation in it. The research team member doing the consenting of patient and social support

participants will be required to be bilingual to accommodate English and Spanish-speaking participants. The research team member will ensure that participants understand that their participation is voluntary and that they can choose not to participate or to withdraw their participation at any point in the study.

Non-English Speaking Subjects

5. *Indicate what language(s) other than English are understood by prospective subjects or representatives.*

   This is a study with participants from the Latino community in Albuquerque. We anticipate that some participants will speak Spanish. Some Spanish-speaking participants will be fluently bilingual in English and Spanish, others will not speak or understand English well.

6. *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

   All of our study participant materials will be available in English or Spanish. The participant will be able to choose the language they prefer. In addition, all of our PDCSs will be fluent in Spanish.

7. *Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)*

   To recruit participants from CDE-UNMH, the CDE staff member who calls the patient to tell them about the study and inquire if they might be interested will use an approved recruitment script. If the patient indicates interest, the staff member will ask for oral permission from the patient to release the patient's name and contact information to the research team so that the PDCS can contact the interested patient and conduct the screening to determine eligibility.

   Oral permission will not be used for consent to participate, only for consent to share the patient's name and contact information for recruitment.

For actual participation in the study, we will obtain written consent from all participants.

8. Subjects who are not yet adults (infants, children, teenagers)

N/A

9. Cognitively Impaired Adults

N/A

10. Adults Unable to Consent

N/A

11. For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

N/A

29.0 Process to Document Consent in Writing

29.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

To recruit participants from CDE-UNMH, the CDE staff member who calls the patient to tell them about the study and inquire if they might be interested will use an approved recruitment script. If the patient indicates interest, the staff member will ask for oral permission from the patient to release the patient's name and contact information to the research team so that the PDCS can contact the interested patient and conduct the screening to determine eligibility.

Oral permission will not be used for consent to participate in the study, only for permission to share the patient's name and contact information for recruitment.

For actual participation in the study, we will obtain written consent from all participants.

29.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

We plan to obtain written consent.

29.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.)

See attached CDE-UNMH Recruitment Consent Script for permission for CDE to release patient name and contact information to the research team.

See attached consent form for participation in the study.

30.0 Drugs or Devices

30.1 If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

N/A

30.2 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

N/A

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