PROTOCOL TITLE:
Patient and Provider Engagement and Empowerment through Technology ($P^2E^2T^2$) to Improve Health in Diabetes

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Patient and Provider Engagement and Empowerment through Technology ($P^2E^2T^2$) to Improve Health in Diabetes

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- ☐ **Private Sponsor**
- ☐ **Cooperative Group**
- ☐ **Other: _____**

3) IRB Review History- New

4) Objectives

The overall goal of this proposal is to enhance the supports and resources available to patients with diabetes to assist them to achieve their health goals. We will evaluate an innovative program that uses nurse health coaching, motivational interviewing techniques, wireless sensors and mobile health (mHealth) technology based on input from patients, providers and technology experts as to how best to address the healthcare needs of persons living with diabetes and improve their health and wellness.

The $P^2E^2T^2$ program is funded by a grant from the Patient-Centered Outcomes Research Institute (PCORI). The focus of this proposal is to attend to the patient regarding what is needed from the health care team and from technology to optimally support patients to succeed in reaching self-identified goals to better manage their diabetes. In this program, patients will receive timely, tailored nurse coaching feedback to facilitate behavior change using mHealth technology, thus bridging bidirectional exchange of meaningful information among patient, nurse coach and provider. We will conduct a randomized controlled trial among patients receiving chronic disease management at the University of California, Davis Primary Care Network. The patients who are eligible for inclusion in the study will be randomized to one of two arms of the trial: 1) Care Coordination (usual care) administered by UC Davis Health Management and Education (new name); or 2) the Patient and Provider Engagement and Empowerment through Technology (P^2 E^2 T^2) Program to Improve Health in Diabetes.

Our hypothesis is that patients in the $P^2E^2T^2$ arm of the study will be more engaged in identifying and achieving health goals related to their diabetes and will achieve better health outcomes compared to patients receiving usual care.

We will achieve this project through the following Specific Aims:

Specific Aim 1: To evaluate the effectiveness of the $P^2E^2T^2$ program on diabetes management as measured by the following outcomes: 1) quality of life (QOL); 2) self-efficacy; 3) readiness to change; and 4) clinically relevant outcomes.

Specific Aim 2: Compare specific health and fitness outcomes of individuals participating in each study arm.

5) Background

Diabetes

Diabetes mellitus (DM) is a growing public health problem highly amenable to prevention and health promotion interventions. Over 26 million people are diagnosed with diabetes, and an estimated 79 million people have pre-diabetes (1). The incidence of DM in the United States is escalating at alarming rates and by 2050, 48.3 million people will be diagnosed with diabetes, an increase of 198% from 2005 (2, 3). Type-2 diabetes is the most common type of diabetes accounting for 80-95% of cases (2-4). DM is a major risk factor for vascular complications including heart disease and stroke, hypertension, blindness, lower limb amputations, lipid abnormalities and kidney disease (5-8).

Health Behavior and Disease

Physical inactivity, poor eating habits, obesity and smoking are common risk factors for multiple chronic diseases, including DM, and are associated with premature deaths in the United States (40% of premature deaths compared to other factors such as genetic predisposition (30%), social circumstances (15%), health care (10%), and environmental exposures (5%)) (9). Recent evidence suggests an association between sleep impairment and type-2 diabetes, where duration and quality of sleep were significant predictors of glycemic control, suggesting that interventions which address sleep quality may be of value in glycemic control and diabetes management (10-13). These connections between health behavior and disease outcomes indicate the importance of a patient-centered, proactive and evidence based approach to prioritizing and enacting behavioral choices (14).

Gaps in Traditional Management of Diabetes

Traditional interventions for diabetes include face-to-face counseling in clinics, individual visits with a diabetes educator, or group classes (15). These interventions emphasize education and typically do not address patient-generated goals and personal motivations. Another gap in usual treatment is the lack of community-based patient generated data that can inform patient-provider conversations about progress and about the impact of certain behavioral choices upon health outcomes. Such data could

increase awareness and reinforce patient engagement in health choices and provide feedback to providers about effectiveness of treatment approaches.
Some significant strides have been made in improving diabetes outcomes by delivering real-time diabetes management feedback to patients based on glucose readings that patients upload through mobile technology (16). Our proposal focuses on using commercially available, non-proprietary sensors that can capture a variety of measurements/types of data combined with nurse health coaching using Motivational Interviewing (MI) to support patients in setting and attaining health behavior goals. Benefits of our strategy are that the skills the patient discovers with the support of the nurse coach have the potential to translate to other types of behavior change going forward. The patient can learn what motivates them to improve their health, what empowers them to stay focus on health improvement, how to set reasonable goals and how to overcome barriers to change. These skills can be readily applied to behavior change aimed at improving diabetes or any other chronic disease or wellness goal. By creating a mHealth platform that is ubiquitous and works with non-proprietary sensing devices, patients can use the sensors to provide data essential to behavior change that may impact other disease processes. Creating a model for interaction that is flexible in the type of data that can be collected will allow for providers, health systems and insurers to invest in testing new models of care and scaling those that prove effective within a sustainable system.

Evidence for Motivational Interviewing as an approach
Interventions that involve active patient participation are likely to have longer and more positive clinical and psychosocial outcomes than didactic interventions in which there is limited patient input (15, 17) . MI is a counseling tool to improve self-efficacy and support behavioral changes that has been used successfully in treatment of addictions and chronic conditions including diabetes (18-23). MI focuses on enhancing goal-setting skills by encouraging focus on manageable steps to improve overall health, establishing reasonable goals, and managing barriers and obstacles to goal attainment. It helps build the patient's capacity to problem-solve and has a wider applicability to extend to other health and wellness goals. Because prevention of chronic disease involves multiple lifestyle and behavior choices across many domains (nutrition, physical activity, medication adherence, stress management, etc.), incremental improvements in a patient's capacity to set and attain reasonable goals could advance overall self-care. MI has been successfully used in treatment of weight loss and glycemic control (24-25).

In our previous study testing MI using telehealth (via telephone connection) with individuals living with diabetes in rural, underserved communities, we showed that short-term improvements in diabetes self-efficacy reported by other studies can be extended to lasting long-term effects (23). Through our experience coaching participants with diabetes to achieve their health goals, we learned that participants are motivated when they focus on goals that are important to them. As nurse coaches, we were able to help participants identify health goals (commonly selected by participants to focus on physical activity or healthy eating) they believed to be important and to

identify their motivation to consistently work toward achieving their goals. The gap we recognized in this previous study was that we were reliant on self-report of physical activity and other indicators and were unable to uncover trends in behavior that would allow participants to identify barriers to goal achievement or make adjustments. For example, we recognized that having timely community living data regarding physical activity would be useful to both patient and coach in evaluating progress to goals and addressing barriers, as well as providing an opportunity to reflect on trends which may help the patient recognize an opportunity for change or reinforce a positive health behavior. This technology, in essence, allows for a fuller understanding of a patient's experience outside the clinic walls and allows the health care team to provide timely and personal feedback to adjust and sustain health behaviors. If successful, the proof-of-concept and framework that is developed by the proposed project will not only benefit diabetic care, but will have far-reaching applications for other chronic disease management.

Role of technology in improving patient engagement and outcomes
When mobile health is connected with sensors that are either embedded in the environment or on the person, it "can produce continuous streams of data on an individual's biology, psychology (attitudes, cognitions and emotions), behavior, and daily environment (15). If this technology is harnessed to allow bi-directional, timely communication of data and tailored feedback, it has the potential to change an individual's health behavior and prevent or mitigate the factors that lead to disease. Given that 96% of the United States population is currently living in areas where mobile networks exist, the potential to reach underserved populations and reduce health care disparities is another great promise of mHealth technologies (16). Mobile technology allows care to move from traditional clinic and hospital-based care to where individuals are in their daily lives. With 91% of adults in the United States reporting they own a mobile phone (17) and 63% of adult cell phone owners reporting use of their phone to access the internet (18), it appears the barriers to mHealth technology access are being quickly overcome and will assume a larger role in future health care.

6) Inclusion and Exclusion Criteria

Participants will be recruited from UC Davis Primary Care Clinics, including the Hospital-based clinic and the Folsom Medical Group clinic. After enrollment in the study, participants will be randomized into one of two groups: Care Coordination (usual care) offered through UC Davis Health Management and Education; or the (P^2 E^2 T^2) Program to Improve Health in Diabetes (intervention), which includes nurse coaching paired with sensor technology to provide targeted feedback of patient generated real-world physical activity and sleep quality data to the nurse coach, participants and primary care providers to improve self-management of diabetes. Those randomized to receive the intervention will interact with their coach through mobile technologies by telephone, face-to-face videoconference, or by text/e-mail through EPIC MyChart, the electronic health record system used by UC Davis Health System, that is secure and HIPAA

protected. The secure mHealth dashboard platform (Synopsis) is developed within EPIC Hyperspace for communication and collection of data. The telephone and face-to-face videoconference interactions will be initiated by the nurse coach from a secure location. All other interactions with patient happen within the electronic health record environment which is secure.

Inclusion criteria will be:

1) At least 18 years of age
2) Diagnosis of Diabetes Mellitus (type 2)
3) Receiving care at one of the UC Davis Primary Care participating clinics (hospital-based Primary Care Clinic, the Folsom Primary Care Clinic)
4) Able to read, write, and speak English
5) Has access to a telephone and computing device
6) Has had experience with use of a mobile smartphone & applications
7) HgbA1C over 6.5%

Exclusion criteria will be:

1) Does not have Diabetes Mellitus
2) Primary language is not English
3) Pregnant women
4) Those that not have access to a telephone or computing device
5) Has a HgbA1C value under 6.5%

7) Number of Subjects

Sample Size and Power analysis: Based on our previous study of nurse coaching using MI to improve disease self-management (23), we found improvement in self-efficacy scores significantly higher in the intervention group compared to the control group. Based on these data, we expect to find self-efficacy scores to be 4.03 and 3.64, for the intervention and control group respectively, with a standard deviation of 0.70. Table 1 presents the sample size calculations for the number of eligible patients needed to detect significant differences in self-efficacy scores between the cohorts.

According to the anticipated enrollment calculations above, we expect to enroll at least 150 patients in each of the intervention and control cohorts. This sample size will be sufficient to detect differences between the two groups as demonstrated in Table 1. In the previous study, we had a low overall attrition rate of 16% using a similar intervention design with comparable demand on participants for time and response. Even under the conservative assumption that design effects and dropout rates may result in a reduced sample size of 100 per treatment group, our study will still have at

least 80% power to detect the specified clinically important effect size. We will not enroll more than 350 participants in total.

Table 1: Sample size required to detect differences

Difference in Self-Efficacy Scores	Significance Level (Alpha)	Power (1-Beta)	Intervention, N	Control, N
0.20	0.05	0.80	219	219
0.25	0.05	0.80	134	134
0.30	0.05	0.80	92	92
0.35	0.05	0.80	67	67
0.40	0.05	0.80	51	51

8) Recruitment Methods

We propose several approaches to accomplish our recruitment goals within the time frame of the funded study. These will be used in concert with one another to achieve the full sample.

Potential study participants will be identified by a query of the Electronic Health Record (EHR) at UC Davis Health System for specific elements essential for eligibility (over age 18; assignment to one of the participating primary care clinics & providers; diagnosis of Diabetes Mellitus-Type 2; and HgbA1C value of over 6.5 %). Affiliated clinic providers will be notified in advance that eligible patients from their census will be contacted for study participation.

Mailed letters: Potentially eligible patients (meeting the inclusion criteria) will receive a recruitment letter signed by the patient's provider as well as a brochure that describes the study and explains that they can call the study line if they are interested, or that a research assistant will call them in the next few weeks to find out if they might be interested in participating in the study. Patients who do NOT want to be contacted about the study will be asked to return an enclosed opt-out card to the study office within 4 days of receiving the brochure. The opt-out card (attached) will be generic in that it will not identify the potential participant by name, but rather will have a coded number assigned by the research team, and will not note any health information or UC Davis affiliation to ensure their privacy. In addition, it will provide a space for the individual to request that they not receive any additional solicitations for research participation by the institution. A research assistant will only call patients who have not returned the opt-out card within the stated time period (3-4 weeks after letters mailed). Patients who express an interest in the study will be contacted by study staff to discuss their participation and to set up an appointment to sign the consent and receive the technology training (either intervention or usual care). Consenting participants meeting eligibility will be randomized to either Care Coordination or the $P^2E^2T^2$ program.

Telephone Calls placed to potentially eligible participants: Research staff will screen patients for eligibility over the phone and set up an appointment to complete informed consent. Consenting participants meeting eligibility will be randomized to either Care Coordination or the $P^2E^2T^2$ program. Patients who provide an opt-out card for participating will not receive any telephone call inquiring about their interest in participating in the study.

Local recruitment: A study coordinator and/or nurse health coach from the study will work with clinic staff and providers to identify potential participants by reviewing physician appointment schedules. For these potentially eligible participants, recruitment and the consent process will be done in-person at the time of scheduled clinic appointments by CITI trained research staff or nurse coach with the provider's approval.

Practice alerts: With the approval of clinics and providers participating in the study, the informatics team may initiate pop-up practice alerts when a potentially eligible patient is in the clinic for an appointment. If the patient meets pre-set guidelines (over 18 years of age, diagnosis of Type 2 diabetes), an electronic alert in the EHR will appear that this patient may be eligible for a UC Davis Research study for the provider to review. The provider has an option of ignoring this alert or may briefly discuss that the patient may be eligible for a study and inquire if the patient would like further information. If the person requests further information, the provider clicks a button that will send information to the study coordinator, so that a member of the research team can call the participant or meet with them in person to discuss the study.

Advertisements: Participants will be recruited between January and August, 2016 through advertisements/flyers placed at participating clinics at local health systems. The flyers will provide information and describe the study as a Technology Enabled Support Program for Patients with Diabetes.

Health Management and Education: Trained study personnel may also promote recruitment for the trial by attending and describing the study to participants during diabetes education classes conducted at the UC Davis Center for Health Management & Education. The study will be presented as described and advertisements/flyers will be distributed. When study personnel are present, potential participants will be given the option to sign up to receive further information about the study. Participants may also be recruited directly through referral by local providers or Advisory Board Members**.**

Randomization will be conducted through computer generated randomization using REDCap data management system. This randomization will occur immediately following consent by computer generated randomization programming in Redcap. The participant will then be assigned a study ID number which will be used to track all of their activity within the study (questionnaires, fitness tests, coaching sessions). Only the study ID #, no personal identifiers, will be included on any of these study documents.

Copies of recruitment flyers; provider letters; and informed consent documents are attached to this document.

9) Compensation to the Subjects

All subjects, regardless of treatment arm, will be given a health monitoring device at the end of the study. Upon completion of study questionnaire and their regularly scheduled visit with their primary care physician all participants will receive $50 at baseline, 3 and 9 months. Those participants in the intervention ($P^2E^2T^{2)}$ arm will receive a health monitoring device at the beginning of the study; and those participants in the Care Coordination arm of the study will also receive a health monitoring device upon successful completion of all study questionnaires. If participants do not complete all aspects of the study, they will not receive the health monitoring sensor device. Each sensor device is worth approximately $75.

10) Study Timelines

Each individual will be enrolled in the study for 9 months. Each participant will complete a study questionnaire at baseline, 3 months and 9 months. Estimated duration of the study completion is 24 months from start of enrollment (January 1st, 2016 – December 31st, 2017).

11) Study Endpoints

Outcomes to be evaluated include: i) Quality of Life (QOL) measures; ii) Self-efficacy; iii) Readiness to Change; and iv) Clinically Relevant Indicators (HgbA1C, HDL, LDL, triglycerides). All measures will be collected in both groups at the study timelines. At baseline (time of recruitment), all participants will be asked to complete the surveys and the care coordinator will request the primary care provider orders for the laboratory tests measuring the clinical indicators. The lab tests are routinely used to monitor diabetes management and are typically covered by insurance. Should the patient not have a payment source for the laboratory assays, the project will cover the cost of the laboratory tests. At 3 months and 9 months, surveys links will be sent by email to each participant along with a reminder to complete the laboratory work ordered by their provider. If not completed, reminder emails or phone calls may be made by the study team. The primary endpoints of the study are: baseline data; data at the completion of five sessions of support calls during the 3 months of the intervention; and data at 6 months after the end of the intervention (9 months after baseline).

12) Procedures Involved

Usual Care: Care Coordination through Health Management and Education: This program is a well-established program within the UC Davis Health System, providing care coordination to individuals with chronic conditions. Patients can self-refer or are referred by their providers for this service. The role of the care coordinator is to assess needs of the patient and coordinate healthcare referrals and appointments for the patient, facilitate communication among members of the healthcare team, identify health goals in

collaboration with the patient and assist them in meeting those goals if requested by the patient. Contact is variable and conducted on a case by case basis.

$P^2E^2T^2$ Program

The $P^2E^2T^2$ intervention group will receive Nurse Health Coaching using MI, an approach designed to elicit and support behavioral changes and improve self-efficacy (18-21). Nurses delivering the intervention will have completed the Health Science Institutes Registered Health Coach (RHC) training program (www.healthsciences.org). The intervention protocol is as follows:

1. The first phone call or videoconference contact with the RN health coach (30-40 minutes): A personal and planning call for the participant and coach to discover the participant's priority health issues and desired goals. Conversation will explore barriers to addressing that issue, potential solutions to overcome barriers, and choices about types and frequency of activities.

2. Orientation to the technology (in person meeting): A member of the research team will meet with each participant to orient them to both the wireless health and fitness tracking sensor, other health applications and the mHealth dashboard in UC Davis' Electronic Health Record, EPIC. The selected sensors and applications will track numbers of steps traveled, approximate calorie expenditure based on movement, sleep quality, heart rate, and components of logged nutrition data. The data wirelessly uploads to the participant's personal, or study supplied, Apple device (iPhone, iPad, or iPod), allowing the participant to develop awareness of typical activity and to work toward goals to improve activity levels. The mHealth platform/dashboard will allow the health coach and participant a secure space to share the data generated by the participant through the sensor, to view activity trends, and to create and track progress toward specific, measurable, attainable, relevant and time bound goals. Data elements shared to the electronic health record include: steps traveled, activities performed in minutes, calorie expenditure, and logged nutrition data. Participants can access EPIC MyChart (web page/portal) through a smartphone, tablet, or personal computer. The research team will provide individual training on the use of the technology.

3. Five bi-weekly support calls (15-30 minutes each; over 3 month intervention period): Calls will be scheduled at times chosen by the participant. The purpose of these calls is to review progress and discuss approaches to solving problems in reaching goals. On each call, the coach and participant will review the patient-generated activity data from the sensors and compare in relation to goals. They will observe and discuss trends in the data that may provide opportunities for reinforcement and highlight opportunities for continued behavior change. Following each session, the nurse coach will enter details about the current goal set by the patient, a snapshot of progress made toward goals and other relevant information into the mHealth Dashboard so that the patient, the provider and the nurse can all track and review progress.

4. Action Plan (at the completion of the fifth session): The participant and coach will summarize the goal chosen, progress made, and plans for follow-up. Study staff will prepare a final form of the Action Plan and will send one copy to the participant and with their permission, one copy to their primary care provider with instructions to the primary care provider about recommended follow-up. Throughout the intervention, the performance of the certified health coaches will be monitored. The project manager and study research personnel will record and review the health coaching conversations for quality assurance.

For quality assurance purposes, participants will be asked if their coaching phone calls can be recorded for nurse training and education. The PI and research personnel will follow the UCD Media Authorization institutional policy for the use of recorded material for educational and training purposes that is outside the research. Digital recordings will be done with a handheld digital recorder, coded by assigned subject ID and coach ID and immediately uploaded to the research study's password protected, secure drive on the UCDHS system server. Upon upload to the secure drive, the recording will be deleted from the recording device. This folder is accessible only by Improving Health in Diabetes research staff. These recordings will be randomly selected for review and evaluation by the co-investigator on the study, Sheridan Miyamoto. Feedback and training will be given to the health coaches based on the review of these recorded calls. Recordings will be stored on the secure drive for five years and will then be destroyed.

Questionnaires

During initial orientation, at the conclusion of the intervention time period of 3months, and again at the 9 month follow-up date (6 months after completion of the intervention), subjects will be asked to complete the following questionnaires (estimated completion time 10-15 minutes each):

1. Initial intake questionnaire (attached) - completed at baseline, beginning of study
2. Follow-up questionnaire (attached) - completed at 3 months (completion of intervention) and 9 months follow-up date.

The questionnaires will be available for in-person completion at baseline and 3 month follow-up. The final 9 month survey will be sent securely using the REDCap data management system to the participant's email address. Participants may opt to complete the questionnaire on a written form if they prefer to do so.

13) Data and Specimen Banking

n/a

14) Data Management and Confidentiality

Data will be collected from participants at three time points: 1) baseline data at time of recruitment; 2) 3 months (coinciding with the program completion); and 3) 9 months (selected to assess sustained effects of the intervention). At baseline, in addition to

outcomes described in Table 2, all participants will complete a demographic survey which will include age, gender, race/ethnicity, education level, income level and insurance type and health history using the Charlson Comorbidity Index which includes common chronic conditions. All data for the study will be collected by the research coordinator and entered into the REDCap (Research Electronic Data Capture) system housed in the servers managed by UC Davis Clinical and Translational Science Center (CTSC) (26).
REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap stores data on a secure server and eliminates any confidential information from being stored on personal computers. Mental health diagnoses and treatment information will be directly entered into the REDCap database by the DHHS Quality Assurance Officer. No materials with confidential information will be removed from the DHHS site.

Nurse health coaching provided to the intervention group will have additional documentation related to the intervention and goal setting within an Epic module built for the project. Progress notes from the nurse health coach interactions will be available for other members of the care team to access when working within a participant's chart. This element is essential as one of our aims is to determine if the presence of patient-generated sensor data and personal health goals within the EHR results in differences in diabetes related outcomes.

Historical data, such as completed lab work values as identified above (Study Endpoints section), will be gathered by querying the EHR for all participants involved in the study. This will be accomplished by working with the Health Informatics for research group, led by Kent Anderson.

All data and data identifiers related to this study will be destroyed seven years after completion of the study. All data findings from the study will be presented as aggregate data with no individual subject identifiers.

Subjects will be using commercial off-the-shelf (COTS) sensors, smart phone applications, and web-based physical activity dashboard technologies. Participants must agree to use the sensors and applications required for data collection. If they are unwilling to use this sensor, they will not be able to participate. Immediately following consent and randomization into the "Care Coordination" and "$P^2E^2T^2$" arms, project staff will assist participants with technology set-up, configuration, use, and ensure that subjects understand the commercial terms of service agreements, before they begin the trial. In order to further protect individual privacy, subjects in the $P^2E^2T^2$ arm may choose to share with their coach only portions of the data streams from their devices/apps. That is, subjects have the option to filter the data streams shared with their coach by time of day, and specific metric (i.e. steps counted, calories burned, etc.).

Table 2. Variables, Outcome Measures and Data Collection

Variable	Measure	Data Collection		
		Baseline	3 months	9 Months
Age, Gender, Race/Ethnicity, Education Level, Income Level and Insurance Type	Demographic Data Form	X		
Specific Aim 1				
Focus Groups		X	X	X
Specific Aim 2				
Self-Efficacy	Diabetes Empowerment Scale – Short Form (DES-SF)	X	X	X
Readiness to Change	Readiness to Change Survey	X	X	X
Clinical Indicators (Abstracted)	Electronic health record	X	X	X
Quality of Life	Patient Health Questionnaire depression scale-9 (PHQ-9)	X	X	X
	Perceived Stress Scale (PSS)	X	X	X
	PROMIS Measures – Physical Function SF, Emotional Distress SF, Sleep Disturbance	X	X	X

15) Provisions to Monitor the Data to Ensure the Safety of Subjects

All subject questionnaires will be reviewed by the nurse researcher for the presence of mood symptoms that may require further assessment and possible intervention. If a participant relates information to any of the study personnel that leads the study personnel to believe the participant is a risk to themselves or others, immediate consultation with the principal investigator (HY) will be obtained. The lead nurse investigator for this study, Heather Young, is qualified to monitor and quickly address high-risk behaviors observed and reported by the nurse coaches. Should a safety issue become apparent in the course of interacting with the participant, appropriate referrals will be made, the event will be documented, and if necessary the IRB will be notified. Appropriate referrals may be to crisis hotlines, the participant's health care provider, or law enforcement as needed and deemed appropriate by the PI. There is a minimal risk that a subject's safety could be compromised by sharing historical data about activity. This risk is minimized with regard to this study, because only the intervening coach will have personal identifying information that links the participant with their coded activity data due to the personal and interactive nature of the coaching process. Activity data that is analyzed and health coaching worksheets filled out by the coach will be coded and no personal identifiers will be available to the rest of the research team at the point of analysis. Due to the commercial availability of these apps, investigators cannot prevent study subjects from sharing their data with other individuals should an individual choose to share their data.

16) Withdrawal of Subjects

Subjects may withdraw from the study at any time without harm or prejudice. If the participant would like their data to be removed from the study, any data or paperwork related to the participant will be immediately destroyed. If they consent to allowing data already collected to be kept, this data may remain in the study.

17) Risks to Subjects

There are little to no health risks associated with participation in this study and it is expected that participants receiving activity tracking and/or health coaching may receive some benefit. Increasing physical activity in incremental stages has known health benefits and low risk. The study does not involve diagnosis or treatment and targets health improvement rather than disease of a sensitive nature. There is possibility of loss of confidentiality, but appropriate steps will be taken to minimize those risks including coding of questionnaire and nurse coaching worksheets and maintenance of all data on secure, password protected servers. Additionally, subjects selected into one of the two treatment arms will be specifically counseled about potential losses of confidentiality relative to their use of commercial off-the-shelf (COTS) technology for health monitoring. What is learned may help improve diabetes care and diabetes management in general. For persons with sensitive skin, there is a slight risk that some of the assigned technology may cause skin sensitivity. If this occurs, the participants will be advised to stop using the technology immediately, and contact the study team. Alternative technology will be provided to mitigate the problem if the subject choses to continue participating in the study.

18) Potential Benefits to Subjects

Subjects receiving feedback about their health behaviors through technology or technology plus health coaching may benefit from increased awareness of their daily habits. Subjects receiving health coaching may benefit from receiving individual counseling and support for healthy behavior change that encourages the adoption of healthy behaviors including dietary changes and physical activity. Subjects receiving no intervention are not expected to benefit from this study. Subjects receiving the tech-plus-health-coaching interventions may or may not benefit from their participation.

19) Vulnerable Populations

No vulnerable populations will be included in this study

20) Multi-Site Research

n/a

21) Community-Based Participatory Research

n/a

22) Sharing of Results with Subjects

Once results have been analyzed, it is the intention of the research team to publish results and give public presentations about the aggregate outcomes of the study. All participants will be notified of publications stemming from the research as well as any public presentations on the UC Davis campus.

23) Setting

The orientation, questionnaire answering, and technology training will be conducted at a specified location at the participating clinics, where the patient obtains their routine care. There are numerous small and large conference rooms available to conduct all aspects of the intervention orientation and testing. Nurse health coaching sessions will be conducted over the phone, at times convenient to the participant.

24) Resources Available

Appropriate resources and funding are in place to conduct this study. Questionnaire administration and technology orientation will occur in-person at the clinic in which the participant receives their primary care services (see #23 above).

Personnel include:

PI and Co-Investigators: Responsible for overseeing the various aspects of the project: technology, recruitment, required training, nurse coaching, data analysis, data safety and management, IRB compliance, etc.

Health Coach: certified in Motivational Interviewing (MI) and trained to conduct initial intake and ~15 hours/week of health coaching and study administration. The Health Coach will have previous experience coordinating research trials and familiar with UCD IRB requirements.

Project Manager: The Project Manager has previous experience coordinating research trials and familiar with UCD IRB requirements. She will participate in recruiting subjects, screening, consenting, scheduling, and communicating along with the preparation and conduction of research procedures.

Junior Specialist: Will be supervised by one of the Co-investigators. The Jr. Specialist will be involved in scheduling orientations, procuring rooms for activities, recruitment, and data collection as well as providing technology on-boarding for participants and on-going technical support. He/She is familiar with UCD IRB requirements.

Patient Advisory Board Members: As part of the PCORI funding expectations, this project includes three Advisory groups: Patients, Providers and Technical/Computer Experts. The Patient Advisory Board provides input and guidance to the study team about study design, measures, recruitment strategies, and will assist in interpreting de-identified data. Several patient advisors have indicated interest in assisting with recruitment, and have offered to go to clinics to help recruit participants. Those interested will complete CITI training and will receive all appropriate training as members of the research team, and will be added to the research personnel list, before engaging in any direct contact with participants or data.

We anticipate, with increased advertising of this project, we can enroll 30 participants a month. This means total enrollment would take approximately 6 months.

Significant research staff time will be devoted to conducting this research. The Project Manager has 75% time devoted to the execution, completion, and analysis of this research. Two health coaches will be hired at 75% time over a 12 month period to accommodate the extent of health coaching required during a rolling enrollment over 6 months.

25) Prior Approvals

n/a

26) Provisions to Protect the Privacy Interests of Subjects

The study staff will offer detailed explanation of the study to subjects prior to consent. It will be emphasized that all of the data collected in the study will be de-identified. All results will be analyzed in aggregate. It will be stored in a secure server and used expressly in de-identified form exclusively for the purposes of the aims of this research project.

Following consent, participants will be randomized and receive a study identification number. This number will be entered into the secure REDCap database on a tablet. The participant will be offered the questionnaire on either the tablet with their unique study identification shown at top. Their name and other unique identifiers will not be asked during the survey. If the participant would prefer to fill out the survey on paper, the same procedure will be followed and research staff will transcribe the survey into REDCap. Clinical and lifestyle (physical activity, nutrition, sleep) data will be stored in their clinical record (EPIC Hyperspace) which is HIPAA protected. Clinical data in their record may be viewed by their treating physicians and clinical team as part of standard care at UC Davis Health System. Including this lifestyle data in the clinical record will promote a wellness conversation and foster collaboration between diabetes patients and primary care providers.

All data stored by UC Davis researchers will have all personal identifiers removed and labeled with participant's study identification number. All electronic data will be stored on a password protected server that is accessed only by study personnel. All paper data will be stored in locked cabinets in a room with access limited to research personnel.

27) Compensation for Research-Related Injury

This research involves only minimal risk to subjects.

In the event a patient suffers an injury as a result of participating in this research study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study

sponsor or may be billed to the patient's insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury.

28) Economic Burden to Subjects

There are no other monetary costs to participate in the study. All technology costs will be covered by the study except if a participant uses their personal smart-phone or computing technology to visualize data collected by the provided activity sensors. This cost is one that the participant was already incurring. If they do not have a personal computing device compatible with the sensor technology, one will be provided without cost for the duration of the study.

29) Consent Process

Patients who are interested to participate in the study or are referred by their primary care provider will receive an initial telephone call to conduct the pre-screening assessment (see attached document) to determine if they are eligible to participate in the study. If someone is determined to be eligible, an appointment will be scheduled to consent the patient. During the consent process, the study will be described to potential participants. A member of the research team will describe the study, what is required of the participant, study procedures and answer any questions the potential participants may have. If the subject would like to take time to consider participation, they will be offered an intake date in the near future.

Following consent using the Informed Consent Document (see attached), subjects are enrolled in the study and randomized into one of two study arms. Subjects will have the choice of receiving a hard copy of their signed consent form or receive the form by email. They will then be administered initial surveys.

A study telephone line is available to allow participants to reach the Project Manager with any concerns regarding ongoing consent or participation.

30) Process to Document Consent in Writing

The research team will follow the "SOP: Informed Consent Process for Research (HRP-090)" (attached) to consent participants.

31) Drugs or Devices

n/a

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