Tailored Approaches to Reduce Distress and Improve Self-Management for Veterans with Diabetes (TARDIS) – Survey & Qualitative Interview

NCT04587336

Protocol version approved on 10/29/2020

PROTOCOL TITLE: Tailored Approaches to Reduce Distress and Improve Self-Management for Veterans with Diabetes (TARDIS) – Survey & Qualitative Interview

PRINCIPAL INVESTIGATOR: Allison Lewinski, PhD, MPH (PhD non-clinician)

VERSION NUMBER AND DATE: Version 3 – 09/28/2020

SPONSOR/FUNDING SOURCE: Health Services Research & Development, Nursing Research Initiative

Purpose

Veterans with type 2 diabetes (T2D) may become overwhelmed with the self-management behaviors needed to maintain optimal health. Veterans may experience diabetes distress (DD), a concept distinct from depression, due the amount and frequency of these behaviors. Diabetes distress negatively influences the Veteran's engagement in self-management and subsequent glycosylated hemoglobin (HbA1c) levels. Previous interventions aimed at improving T2D self-management and reducing DD do not tailor T2D self-management information to a Veteran's DD, which may be one reason interventions are ineffective at reducing DD.

The etiology of DD in Veterans may be different than non-Veterans due to the cumulative nature of Veteran-related comorbid psychosocial factors (e.g., post-traumatic stress disorder (PTSD), depression). Conceptually, DD, depression, and PTSD are unique and independent factors; however, in each individual, these factors may overlap and negatively impact a Veteran's engagement in self-management. Thus, this proposal examines the impact of correlating factors (e.g., sociodemographic, psychosocial, and environmental) on DD using surveys and semi-structured interviews.

The proposed Nursing Research Initiative (NRI) includes several projects designed to develop a novel intervention to help Veterans with type 2 diabetes (T2D) engage in self-management. The purpose of this research study is to understand diabetes distress and associated factors in veterans with type 2 diabetes. The current IRB protocol covers surveys and semi-structured interviews. This study will be performed entirely by our team at the Durham Center of Innovation to Accelerate Discovery and Practice Transformation (ADAPT). These data collected will inform the development of an intervention that will provide tailored self-management information in conjunction with supportive services based upon a Veteran's DD.

Background and Significance

An estimated 20-25% of Veterans are diagnosed with diabetes,[1] an incidence three times higher than the national rate. Treatment and management of poorly self-managed diabetes is costly as medical care costs are 2.3 times higher for individuals with diabetes than for those who do not have the disease.[2] Regular preventative care is essential to prevent comorbidities and maintain optimal health.

Individuals with T2D provide 99% of their own care; self-management of T2D is person-specific and ever-present.[3] Consistent and sustained self-management decreases comorbidity development, and positively influences quality of life and psychosocial outcomes.[4] Inconsistent self-management increases the risk of poor health outcomes including microvascular and/or macrovascular problems and psychosocial complications.[5] Yet rates of self-management remain sub-optimal.

T2D self-management is omnipresent, inescapable, and burdensome. A Veteran may become overwhelmed and/or frustrated because of the amount and frequency of T2D self-management behaviors, and these negative feelings may lead to inattention to critical self-management behaviors such as eating healthy or blood glucose checks.[6,7]

Veterans often experience challenges to self-management despite knowing the importance of these behaviors.[3] Self-management challenges include limited access to a healthcare provider, unreliable transportation, limited knowledge of healthy food options, beliefs about T2D medications, or a lack of support.[6-9] Additionally, diabetes distress (DD)[10] and other psychosocial factors (i.e., depression, post-traumatic stress disorder)[11,12] negatively influence an individual's engagement in self-management and health outcomes. Due to the inherent complexity of T2D self-management, we propose that tailoring on DD is one way to focus the provision of tailored self-management information and connections to supportive services.

Diabetes distress encompasses the cognitive, physical, and affective experience of living with T2D. Diabetes distress occurs when an individual is overwhelmed with T2D, related self-management behaviors, and knowledge that T2D is progressive and uncurable.[10] Diabetes distress is subjective and person-specific; and while DD may fluctuate over time, DD may be continually present.[10,13-15] Undiagnosed and untreated DD, may be one cause of a Veteran's poor self-management, thus resulting in poor health outcomes.

Diabetes distress is commonly assessed via the *Diabetes Distress Scale*[14] or the *Problem Areas in Diabetes Scale.*[16] Research indicates both measures demonstrate the construct of DD is distinct from general anxiety, stress, and depression.[13,17-19] Both the *Diabetes Distress Scale* and *Problem Areas in Diabetes* scales assess DD in several domains, and each DD domain addresses a separate aspect of the burden of T2D.[14,20,21] The *Diabetes Distress Scale* measures DD in four domains (i.e., regimen, emotional, interpersonal, healthcare provider),[14] and the *Problem Areas in Diabetes Scale* assesses DD using similar domains (i.e., emotional, diabetes management, treatment, and social support burden).[10,22] The *Diabetes Distress Scale* and *Problem Areas in Diabetes Scale* have demonstrated content validity in measuring an individual's perception of the resources available, or not available, for self-management.[13,19]

Diabetes distress is associated with more T2D complications, increased stress, being prescribed insulin by a healthcare provider, poor diet and exercise, inadequate support environments, and is more prevalent among women.[10,19,23-26] Diabetes distress levels correlate with self-management behaviors such as monitoring one's diet, engaging with providers, and monitoring one's blood glucose.[9,15,27-29] High to moderate levels of DD are related to poorer glucose regulation[15], higher HbA1c[20], lower medication adherence[30], and poorer quality of life.[31] Additionally, individuals with DD report diabetes-related physical burden, health care system distress, and distress with comorbid conditions.[9] In this proposal, we will first examine the association between DD, the Veteran's engagement in self-management, and the Veteran's HbA1c.

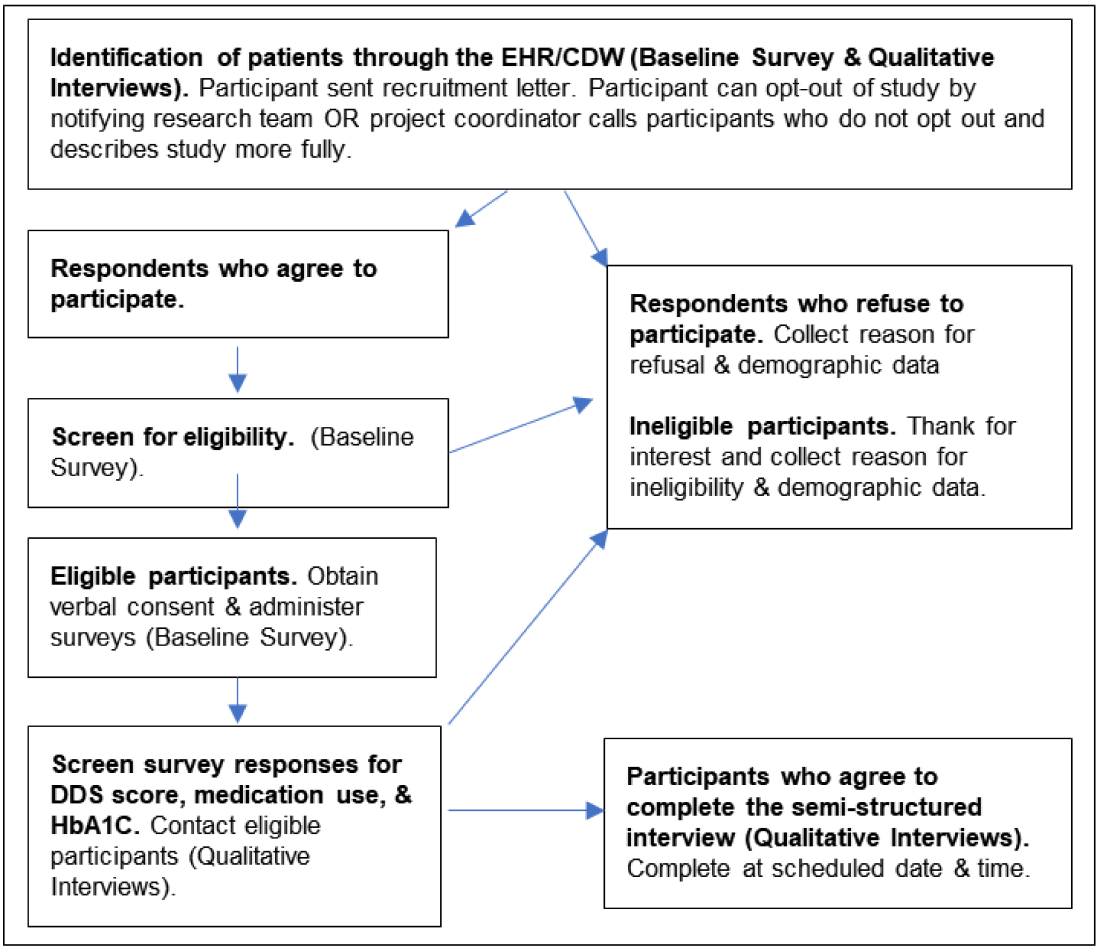
***Guiding Framework*.**

The self-directed learning (SDL) theory provides a useful lens for examining factors that influence DD. The self-directed learning theory posits that adults diagnose their learning needs, formulate goals, identify necessary resources, select applicable strategies, and evaluate their learning needs with or without the help of others.[32] Three components are key to applying SDL: (1) *person*—characteristics such as life

experience, education, motivation; (2) *process*—learning style, technology skills; and (3) *context*—social, environmental, and physical context.[32]

Design

We will use an explanatory, sequential mixed-methods design[33] to describe DD in a sample of Veterans who receive care at Durham. We will quantitatively and qualitatively examine DD. We will consent up to 250 veterans to participate in the study. Study flow is described in the **Figure**.



Conduct Baseline Survey: **Examine the association of psychosocial factors (depression, PTSD), environmental factors (finances, support), self-management behaviors, and HbA1c with DD.**

Surveys will enable examination of the factors associated with the *Diabetes Distress Scale* score in order further confirm the use of the *Diabetes Distress Scale* for the tailoring of the intervention approach. We will use the 17-item *Diabetes Distress Scale* due to its stronger associations than the *Problem Areas in Diabetes Scale* with self-management challenges, physician-related distress, and clinical outcomes.[17] *Diabetes Distress Scale* scores are reported as both a total score and as scores for each of the four domains.[14,34] The *Diabetes Distress Scale* is reliable and valid in assessing DD in

diverse populations, the factor structure is stable across sites and populations, the measure is parsimonious, and items are clear and readable.[8,34,37,38,40] The surveys will provide insight into potential facilitators and barriers to DD and T2D self-management such as symptom severity, minimal social support, and/or high chronic illness needs.

Measures. We will use surveys to understand DD, and facilitators and barriers to T2D self-management, in a sample of Veterans who receive care at Durham.

Variables and data collection methods for the baseline survey.		
Variable	**Measure**	**Source**
HbA1c	Most recent value in the past 180 days	EHR/CDW
Diabetes Distress	Diabetes Distress Scale. 17-items that use a 6-point Likert scale that measures diabetes distress in 4 domains: emotional, interpersonal, healthcare provider, regimen.[14,18,34] Scores indicate low, moderate, or high diabetes distress.[14] Internal reliabilities of 0.92 - 0.93 demonstrated.[14,18]	PRO
Correlating Factors		
Sociodemographic		
Demographics	Age, sex, gender, race/ethnicity, etc.	EHR/CDW
Comorbidities	Current medical diagnoses during the past 180 days	EHR/CDW
Medications	Currently prescribed medications during the past 180 days	EHR/CDW
Symptom severity	Diabetes Symptom Checklist-R. 37-items to assess physical and mental symptoms related to living with diabetes in the past month.[35]	PRO
Chronic Illness Needs	Chronic Illness Resource Survey. 20-items that use a 5-point Likert scale to assess current level of social support for T2D self-management from multiple sources: family and friends, neighborhood, community, and health policies.[36]	PRO
Psychosocial		
Depression	The Patient Health Questionnaire-2 (PHQ-2). A two-item measure that uses a Likert scale to assess for depression.[37] Established reliability and specificity for assessing depression in adults with diabetes.[37]	PRO
PTSD	Primary Care PTSD Screen for DSM-5. 5-items that identify respondents with probable PTSD in primary care settings. Scores “yes” to 3 or more questions is considered *positive* for PTSD. Established reliability and specificity.[38]	PRO
Environmental		
Social Needs	Health Related Social Needs Survey. 10-items to assess unmet, health-related social needs in 5 domains: housing instability, food insecurity, transportation needs, utility needs, and interpersonal safety.[39]	PRO
Motivation		

Self-Efficacy	Diabetes Empowerment Scale-Short Form (DES-SF). 8-items to assess diabetes related self-efficacy. Demonstrated validity and reliability.[40,41]	PRO
Self-Management Behaviors	Summary of Diabetes Self-Care Activities. We will use the core 11-items that measure completion of T2D self-care behaviors in the past seven days. Validity and reliability have been demonstrated.[42]	PRO
Note: EHR/CDW=electronic health record/corporate data warehouse, data will be obtained by the RA upon study enrollment prior to the survey completion; PRO=patient reported outcome, data will be obtained via survey/interview.		

Cognitive Interviews: Examine the understanding and interpretation of diabetes distress and the Diabetes Distress Scale in Veterans with T2D.

Cognitive interviews examine how individuals construct and select answers as they complete a survey.[43,44] Cognitive interviews are an essential method to assess and improve how measures operate.[43,44] During a cognitive interview, individuals are read each survey question and asked to 'think aloud' and/or are probed regarding what they believe the question is asking and describe what information they are using to formulate a response.[45] The resulting interview data indicates the individuals' comprehension, retrieval process, judgments, and the breadth of information underlying the pre-specified response categories.[43-45] These data from the cognitive interviews in this pilot study will help us to develop an understanding of how the *Diabetes Distress Scale* operates in Veterans with T2D. Obtaining Veteran's perceptions of DD in the context of the DDS is essential in verifying what constitutes DD, identifying barriers to addressing DD, and creating potential solutions to DD. The data obtained will guide our decisions about retaining, deleting, modifying, or adding to the *Diabetes Distress Scale*. We will conduct cognitive interviews with ~12-15 Veterans with T2D who receive care at VA.

Qualitative Interviews: Describe self-management challenges and preferred learning strategies to inform intervention components and delivery approach for Veterans with T2D.

We purposefully chose the sequential explanatory design to identify to what extent, and in what ways, Veteran perceptions of DD describe the survey results and the overall study purpose.[33] Qualitative data will enable us to develop tailored components that: (1) promote the Veteran's active learning; and (2) address commonly occurring learning needs in a sample of Veterans. Due to the potentially normalized experience of DD, and our desire to develop tailored resources, other data collection methods are not be conducive to eliciting in-depth descriptions of DD.

Semi-structured interviews will last 45-60 minutes and will be recorded as permitted by the Veteran. If the Veteran does not consent to being recorded, the qualitative analyst will take detailed notes throughout the interview. We will use a semi-structured interview guide to elicit Veterans' experiences self-managing their T2D. Interviews will provide insight into how the Veteran interprets T2D self-management, strategies the Veteran uses in self-management, learning needs and preferences, including interactions with healthcare providers as part of self-management, and the associated

challenges with self-management, in their sociodemographic, psychosocial, and environmental context. To obtain rich data we will use probes and follow-up questions to elicit descriptions of diabetes self-management.[46] The qualitative analyst will not be informed of the Veteran's data prior to the interview to ensure objectivity.

Sources of Materials

This study uses materials from several different sources. The following human subjects related data elements will be collected for this study, with the source(s) of information noted:

Data element	Source(s)
Cognitive Interviews	
Perceptions of the *Diabetes Distress Scale*	Audio recordings and field notes from cognitive interviews
Survey	
Type 2 diabetes diagnosis	DVAHCS medical records/CDW
HbA1c, medications, comorbidities	DVAHCS medical records/CDW
Demographics, computer literacy, diabetes distress, post-traumatic stress disorder, depression, self-management behaviors, social needs, chronic illness needs	Self-reported survey responses
Qualitative Interviews	
Perceptions of DD, self-management strategies and barriers, and intervention delivery strategy	Audio recordings and field notes from semi-structured interviews

Only individuals officially assigned to the study team will have access to individually identifiable information about human subjects. This will include the principal investigator, mentors and consultants, statistician, computer programmer, research assistant, project coordinator, qualitative analyst, and interventionists. All of these individuals will have completed VA required human subjects training and will be included on a staff listing with the DVAHCS IRB. Some data described above (e.g., HbA1c, health conditions noted in medical records) will be accessed from information already collected as part of usual care. All additional data collected from subjects will be specifically for the proposed research project and not a part of clinical care.

Risk/Benefit Assessment

We do not anticipate any significant medical risks to be associated with participation in this study. There are no financial or legal risks associated with this study. The types of research risk we anticipate are listed below.

1. Risk of loss of confidentiality, specifically, loss of data or breach of confidentiality.
2. Survey Burden, specifically, temporary unease related to answering survey questions and/or interview questions, particularly related to any questions or discussion around diabetes distress, post-traumatic stress disorder, depression, social relationships, health related social needs, chronic illness needs, or environmental concerns.

We will use the following strategies to minimize risks.

1. In order to minimize any risks regarding privacy of individuals and confidentiality of data, we will take specific measures to protect both paper and electronic data. To ensure confidentiality, all records will be coded by the participant's study identification number, not by name. Except when required by law, participants will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Durham VA Healthcare System. We will only collect the data necessary for the study. Survey Data will be collected and will be entered directly into the RedCAP survey application for the project. Electronic study data will be kept in folders and databases that are stored on a secure VA server behind the VA firewall, on secure password-protected computers, and access will be restricted to project personnel who are IRB-certified and whose job functions require access to these data. Data will be maintained on this server throughout the study duration and for at least 6 years after study completion, per records control schedule. When data are collected on hard copy such as questionnaires and interview notes, a study ID number used. Hard copies of data will be stored separately from the identifiable data in a locked file cabinet in a secure research office at the DVAHCS. Finally, all project staff will complete educational units required by the Durham VAHCS IRB. Server hardware, operating system and database service performance will be constantly monitored by OIT technicians. If loss or theft of study data occurs, study personnel will follow local guidelines by immediately notifying the VA police, the PI, the ISO, and the Privacy Officer.
2. Potential risks will be minimized by closely monitoring emotions during surveys and interviews. Participants will be informed that participation in any and all aspects for the project are completely voluntary that they are free to refuse to answer any items on the questionnaires or questions from the interview that they do not wish to answer. They are also informed that they are free to decline participation in any procedure and can withdraw from the study at any time. Regarding qualitative data, Veteran participants will be informed that all published results will be anonymized, including any mention of city/medical center/clinic to protect the identity of participants.

Selection of Subjects

Potentially eligible patients will initially be identified via VA CDW/electronic health records data extract. (ICD-10 codes: E11.9, E11.8, and other inclusionary criteria detailed below, as well as the absence of any exclusionary diagnoses).

Inclusion and Exclusion Criteria

Veterans must meet **all** inclusion criteria

- Diagnosis of type 2 diabetes (ICD-10 codes: E11.9, E11.8)
- Documentation of HbA1c drawn within the past 180 days
- Able to speak and read English
- Be able to provide informed consent to participate in the study.

Veterans who meet **any** one of the exclusion criteria will be excluded.

- New diagnosis of T2D within the last 60 days
- Hospitalization for mental illness within the past 30 days
- Receiving active chemotherapy and/or radiation treatment
- Diagnosis for Metastatic Cancer
- Recent hospitalization within the past 60 days that would influence their diabetes medication regimen (e.g., myocardial infarction, cerebrovascular accident, coronary artery bypass grafting, etc.)
- Currently receiving Kidney Dialysis
- Limited hearing or speech difficulties that influence the Veteran's ability to complete the survey
- Dementia, delirium, or other cognition issues that influence the Veteran's ability to provide consent and complete the survey.

We will use the quantitative surveys to describe the prevalence of DD and the sociodemographic, psychosocial, and environmental factors of DD and DD domains. We will survey up to Veterans (*n*=250), and balance enrollment by HbA1c (<9 or ≥9) and medication (no insulin, insulin), to describe DD. Using the same population of enrolled participants we will conduct the cognitive interviews (n=~12-15) to guide our decisions about retaining, deleting, modifying, or adding to the DDS as well as qualitative interviews with Veterans with T2D (*n*=~36) to obtain perceptions of DD, self-management strategies and barriers, and intervention delivery strategy. We will balance enrollment by HbA1c, medication, and *Diabetes Distress Scale* score (low, moderate, high).

Subject Recruitment

For the purposes of screening, recruiting, and determining eligibility information will be obtained through written communication with the prospective participant and/or identifiable private information will be obtained by accessing medical records. Potential

participants will be identified utilizing the VA's Information and Computing Infrastructure (VINCI) Corporate Data Warehouse (CDW) and/or local electronic health record (EHR). With approval of a HIPAA waiver, we will initially conduct a data pull with real Social Security Numbers (SSNs) from VINCI. In order to identify potential participants, we will complete computer-based screening using the VA Corporate Database Warehouse and our established inclusion/exclusion criteria. Based on protocol we will select the appropriate number of participants to be included in each letter batch and create the letters for each batch of potential participants. Multiple batches of letters will be sent until we reach our recruitment goal. An IRB approved letter along with study information documents will be sent to the potential participant informing them of the study and providing a phone contact for study staff.

Each week eligible participants will be mailed introductory letters that provide basic information about the study and let patients know that a study team member will call them to ask whether they are interested in participating. The letter will also provide patients with a telephone number they may call to leave a message saying they are not interested in participating and do not want to receive a call from the study team. Between 5-7 days after the letter is sent, the research assistant (RA) will call Veterans who do not opt out to assess interest in participation. Veterans who do not opt out will be screened for eligibility. Participants contacted will next complete a brief telephone-based screening questionnaire to assess eligibility criteria that are not captured in DVAHCS electronic medical records. We will only ask a limited number of questions that are needed to determine study eligibility. The RA will conduct a verbal consent process with eligible Veterans. Participants will then be asked if they would like to complete the surveys at that time or another date and time. The informed consent process will include the option to collect and use the Veteran's health record data in analysis for current study and future studies and re-contact the participant for the qualitative interviews. The surveys will be completed by a study research assistant. After the Veteran completes the quantitative surveys, we will screen the Veteran for eligibility based upon the Veteran's HbA1c, medication use, and Diabetes Distress Scale score. Eligible Veterans will be invited to complete the semi-structured interviews.

Consent Process

We will request a waiver of written consent, waiver of consent documentation and waiver of HIPAA authorization from the IRB to conduct recruitment activities described above. Every effort will be made to talk via telephone with participants in privacy of their own home when completing the consent and questionnaires for data collection. Participants will be able to indicate to study staff if they are in a private environment or if they would like to be called at another time. This will ensure privacy and protect against embarrassment of sensitive survey questions and interview details.

Prior to beginning recruitment, the PI will meet with key personnel to review the protocol, the informed consent process, and the collection of questionnaires. Research study staff will demonstrate the essential steps in how to implement the protocol to ensure proper technique is communicated to participants. PI will ensure all study staff are up-to-date with required VA security and privacy training. PI will also ensure

research study data are no longer accessible to study personnel when they are no longer part of the research team.

Study Procedures

All participants will participate in the survey, there is no randomization or groups. After the consent process, Veterans will complete a battery of survey questions administered by the RA. These surveys will be collected in the study RedCAP survey. In anticipation of recruitment challenges, we will use methods: (1) flexible staffing of the PC and RA, to recruit and enroll Veterans who have varying work and life commitments; (2) clear language in the initial recruitment letter, to indicate the time commitment for the survey; (3) using a call schedule developed by the Durham COIN PCs, we will make three calls on three different days, at three different times, and leave two messages. We will offer Veterans the option of completing the surveys via telephone. However, if the Veteran prefers to complete the surveys in person, we will meet with these Veterans in conjunction with their scheduled medical appointment at Durham VA.

Variables/data collected in RedCAP survey		
Variable	**Measure**	**Source**
HbA1c	Most recent value in the past 180 days	EHR/CDW
Diabetes Distress	Diabetes Distress Scale.	PRO
Demographics	Age, sex, gender, race/ethnicity, etc.	EHR/CDW
Comorbidities	Current medical diagnoses during the past 180 days	EHR/CDW
Medications	Currently prescribed medications during the past 180 days	EHR/CDW
Symptom severity	Diabetes Symptom Checklist-R.	PRO
Chronic Illness Needs	Chronic Illness Resource Survey.	PRO
Depression	The Patient Health Questionnaire-2 (PHQ-2).	PRO
PTSD	Primary Care PTSD Screen for DSM-5.	PRO
Social Needs	Health Related Social Needs Survey.	PRO
Self-Efficacy	Diabetes Empowerment Scale-Short Form (DES-SF).	PRO
Self-Management Behaviors	Summary of Diabetes Self-Care Activities.	PRO
Stigma, shame	PROMIS Stigma Short Form	PRO

Pain and physical activity	PROMIS Pain Interference – (Short Form 6a)	PRO
Note: EHR/CDW=electronic health record, data will be obtained by the RA upon study enrollment prior to the survey completion; PRO=patient reported outcome, data will be obtained via survey/interview.		

The RedCAP survey will provide RA information pertaining to the Veteran's eligibility for the qualitative interview, based upon the Veteran's HbA1c, medication use, and Diabetes Distress Scale score. Those identified will be invited to complete the semi-structured interview. If patients decline to participate in the cognitive or qualitative interview no further contact will be made. For those who, accept the invitation, the RA will, based on patient and interviewer availability, schedule the interview to take place within the next 2 weeks. Prior to beginning the either the cognitive or qualitative interview, a verbal consent script will be reviewed with the participant and verbal willingness to continue participation will be captured at the beginning of the audio recording. Recording and transcription of the qualitative interviews will be conducted utilizing VA approved software installed and configured by VA OI&T personnel. Audio recordings will be captured using WebEx as the software to record the audio portion of the patient interviews. WebEx recordings will be saved directly to the restricted study folder on the R drive. We will use the approved version of Audacity software (http://trm.oit.va.gov/ToolPage.aspx?tid =5566#) to edit the audio file in the study folder on the HSRD VA project server.

Adverse Events

There are no hazards associated with the study protocol; however, there are several hazards that could potentially occur to the adult population with type 2 diabetes and include sickness or infection, hospital admissions, falls, etc. Dr. Lewinski is a licensed registered nurse and will be involved in every aspect of the study. Any concern about patient health status will be communicated to Dr. Lewinski by study staff. If Dr. Lewinski is on leave or unavailable, Dr. Bosworth and/or Dr. Crowley (a licensed VA-credentialed endocrinologist) will serve as the contact for research staff. The PI will work closely with the research coordinator throughout the study to identify individual hazards, if any occur. The PI will be notified of any hazard that occurs and will determine if the participant should be removed from the study. If it is agreed that the subject be removed, the PI and research coordinator will explain to the participant why it is in her best interest to withdraw from the study. The participants will be assured that nothing related to her during the study will affect any medical care in the future.

Given that we propose contacting a small group of patients for a telephone interview, we will not utilize a Data Safety Monitoring Board. All adverse events will be reported per Durham VAMC requirements. All Serious, Unanticipated and Related adverse events will be reported to IRB within 5 business days of hearing of the event. All other adverse events will be reported at continuing review.

Costs and/or Payments to Subjects

There will be no cost to participants for care they receive as a participant in the VA research project. To compensate participants for their time, they will receive a direct deposit /check by mail from the VA for $30 four to six weeks after survey completion. If they are selected to complete the cognitive interviews, they will receive a direct deposit /check by mail from the VA for $30 four to six weeks after completion. If they are selected to complete a qualitative interview, they will receive an additional $30. The total amount participants can receive through the study is $90. If participants withdraw from the study early, they will be paid for the survey/interviews they have completed. We will use the current established process for providing compensation to patients at this facility.

Data and Safety Monitoring

Because risks to subjects will not exceed usual care, and all subject contact takes place within the context of telephonic survey collection and discrete qualitative interviews, no Data Safety Monitoring Board will be utilized. The PI assumes responsibility for monitoring all data and safety information collected during the conduct of the program evaluation described in this research proposal.

One aspect of our data and safety monitoring plan will involve reporting to the principal investigator and DVAHCS IRB. Study team members who become aware of any adverse event related to the study (who can include the research assistant, project coordinator, and qualitative analyst) will notify the principal investigator, Dr. Lewinski, immediately. Safety monitoring for adverse events (AEs) will be conducted in real time by Dr. Lewinski and/or the project coordinator. The following information about AEs will be collected: 1) the onset and resolution of the AE, 2) an assessment of the severity or intensity (use existing grading scales whenever possible), 3) an assessment of the relationship of the event to the study (definitely, probably, possibly or not related), and 4) action taken (e.g., none, referral to physician). The PI, in consultation with Dr. Bosworth (primary mentor) will determine the severity of the event, will assign attribution to the event, and will monitor the event until its resolution. Any adverse events will be reported to the IRB in accordance with the local Human Research Protection Program's Standards of Practice. Reports of non-serious AEs are required as part of these progress reports.

Study team members will have contact information for Dr. Lewinski for evening / weekend hours. (Most study activities will occur during regular business hours, but some participants may request to be contacted for a screening interview during evening or weekend hours.) If Dr. Lewinski is not available for contact when a study team member becomes aware of a study-related AE, Dr. Bosworth (Dr. Lewinski's primary mentor) or Dr. Crowley (Dr. Lewinski's co-mentor), will be contacted. Once Dr. Lewinski (or Dr. Bosworth or Dr. Crowley) is contacted about the AE, she/he will decide about the reporting requirements in accordance with the DVAHCS IRB guidelines.

Dr. Lewinski will meet at least weekly with study personnel to discuss participants' reactions to the survey/interviews and any AEs or unanticipated problems. Dr. Lewinski will also meet weekly with Dr. Bosworth (primary mentor) and biweekly with Dr. Crowley (co-mentor). Monthly meetings between the investigators and the project coordinator

will allow for ongoing progress reports, including the number of participants currently involved in the study, attrition rates, and scheduled data collection from participants, as well as notification and review of any AEs. All individuals involved in the study will develop and implement methods of verifying entered data and of quality control.

Future Data Use

We may want to run secondary data analyses related to the original aims of the grant (e.g., mediator/moderator analyses, analyses of baseline data, etc.). It is also possible that data collection under this proposal might be used to inform future surveys, interviews, and/or intervention development among patients with diabetes. Data would only be used from patients who agreed that their data could be stored and used for future analysis. A de-identified data set from the variables obtained for the project will be created. A separate protocol, defining the possible new project(s) would be submitted to the Durham VA IRB. These future studies would request either a waiver/alteration to the ICF/HIPAA requirements or a consent form and updated HIPAA Authorization, as appropriate.

Withdrawal of Participants

VA Patients who no longer want to participate in the survey or qualitative interviews, may inform the staff. The staff will document that change in status, so they are not prompted to contact the patient in the future.

Data Analysis and Statistical Considerations

Survey—Detailed study design and sampling plan. We will recruit Veterans (*n* = 200) with T2D and who receive care at the Durham VA. We will conduct targeted recruitment to ensure equal numbers of well- and poorly-controlled Veterans. We will classify the Veterans into *well-controlled* (defined by HbA1c value < 9 during the past 180 days) and *poorly-controlled* (HbA1c value ≥ 9 during the past 180 days); our sampling strategy is guided by VA/DoD clinical practice guidelines.[47] Using EHR/CDW data, we will classify Veterans into *no insulin* (defined by taking only oral T2D medications and/or non-insulin injectable medications during the past 180 days) and *insulin* (defined by taking any insulin during the past 180 days; these Veterans may/may not also take oral T2D medication(s)). We are balancing enrollment because Veterans with different medication regimens may experience different challenges that influence DD.[34,48] We will oversample women and younger Veterans to ensure we obtain diverse perspectives about DD. We will address sampling challenges as these challenges arise in order to ensure we obtain a diverse sample while aiming for the numbers shown in the Table.

Table. Sampling plan for surveys.

HbA1c	Medication		
	No Insulin	Insulin	Total

< 9	50	50	100
≥ 9	50	50	100
Total	100	100	200

Sample Size Considerations. Although our sample size of 200 Veterans with completed surveys is driven by practical considerations of feasibility, we will have a sufficient sample size to test our specified hypotheses regarding differences in DD. With our sampling plan, we assume an equal distribution of 100 patients within each HbA1c level and with/without insulin use. Given a sample size of 200 Veterans, we will be able to estimate 95% confidence intervals for a mean difference in the *Diabetes Distress Scale* with precision equivalent to an effect size of 0.28. Additionally, with a type-I error of 5%, we will have 80% power to detect mean differences in DD of effect size magnitude 0.4 between groups. Note that our conclusions from these analyses will be based on defining a clinically meaningful difference, such as a decrease in DD, and relationships via estimates and confidence intervals, rather than by p-values.

Analysis Plan. Standard descriptive statistics (e.g., mean, standard deviation, median, IQR, proportions, etc.) will be generated to characterize the *Diabetes Distress Scale* as well as the associated factors (e.g., psychosocial, sociodemographic) in the sample. In particular, we will examine the distribution of variables for sparsely populated categories or for deviations from normality. Descriptive statistics will be generated separately by HbA1c level and by insulin use. Rather than p-values, standardized differences will characterize differences between these sample subgroups.[49] The primary goal of the surveys is to examine differences in *Diabetes Distress Scale* score by HbA1c level (HbA1c < 9 and HbA1c ≥ 9) and by medication regimen (no insulin, insulin). We hypothesize that mean DD will be higher in: (1) Veterans with HbA1c ≥ 9 vs < 9; and (2) Veterans who use insulin vs those who do not. These hypotheses will be evaluated via separate multiple regression models with continuous *Diabetes Distress Scale* score as the outcome variable, and with the primary predictor being either an indicator for HbA1c ≥ 9 or an indicator for insulin use. A limited number of additional predictors will be included in the adjusted model, chosen *a priori* by the guiding framework and by evidence of imbalance as indicated by the standardized differences. As exploratory analyses, we will also examine the interaction of HbA1c level and insulin use upon *Diabetes Distress Scale* score. Descriptive statistics will be generated by these four subgroups, and statistical inference will be conducted via a two-way ANOVA model including the main effects and interaction. All analyses will be performed using SAS software (SAS Institute Inc., Cary, NC). These analyses will enable us to determine which population of Veterans we should target for a diabetes self-management intervention. For instance, if we identify that DD is highest in Veterans with HbA1c ≥ 9, who do not use insulin, who are younger, and are male, we will target those Veterans for a self-management intervention. Knowledge of the factors associated with DD will provide insight into potential modifiable and unmodifiable barriers to T2D self-management.

Cognitive interviews—detailed study design and sampling plan. Audio recordings will be transcribed by the DVAHCS staff. When transcribed, names and other identifying information will be redacted. Transcripts will be saved in the secured VA project drive (v06.med.va.gov\DUR\HSRD\TARDIS_Aim1-2). We will use a convenience sampling plan to recruit ~12-15 Veterans with T2D who receive care at the

Durham VA and who are eligible to complete the surveys described above. The preferred method of data collection will be via telephone. Interviewing Veterans via the telephone may decrease barriers to participation (e.g., access, time, transportation).

Cognitive interviews will enable us to establish Veterans' comprehension, retrieval process, judgments, and the breadth of information underlying the pre-specified response categories in the DDS (i.e., not a problem, slight problem, moderate problem, somewhat serious problem, serious problem, very serious problem).[43,45,50] Cognitive interviews will be conducted by a qualitative analyst, will last 45-60 minutes, and will be recorded as permitted by the Veteran. If the Veteran does not consent to being recorded, the qualitative analyst will take detailed notes throughout the interview. We will use a cognitive interview guide to elicit Veterans' understanding and interpretation of the DDS. Items in the DDS are not ordered by dimension as items for each of the four dimensions are randomly dispersed throughout the survey. The qualitative analyst will read each item aloud to the Veteran and ask them to state their understanding of the meaning of the item and any response to the item. As the focus will be on the interpretation of the items rather than how the Veteran would respond to the items, we will not ask the Veteran to complete the DDS during the interview.

We will use verbal probes as a way to elicit Veteran's understanding and interpretation of DD and the DDS.[43,45,50] The use of *concurrent* (e.g., to assess real-time thoughts and feelings about DD and the DDS) and *retrospective* (e.g., to assess thoughts of the DDS at interview completion) probes will enable us to obtain specific and global feedback on DD and the DDS.[45] During the interview, we will encourage the Veteran to paraphrase the item, state their opinions of the wording, and any judgements about the item using probes such as: "What do you mean by that?", "I noticed you hesitated. Tell me more about that.", "How did you arrive at that answer?", and "What do you like best/least about this item/survey?"[43,45,50]

Analysis Plan. We will begin analysis after the first three interviews and preliminary analysis will guide future data collection.[51] The analysis process will be guided by the analysis steps for cognitive interviews detailed in Knafl et al.[44] Each interview will be transcribed and identifying information will be removed. Limited demographic information (e.g., gender, medication) will be noted within the transcript to facilitate consideration of the Veteran's responses. We will use thematic analysis with the software NVivo for this study.[52]

A coding team consisting of Dr. Lewinski and the qualitative analyst will code these data. They will meet weekly during interviewing, coding, and analysis to identify emerging areas, refine the interview guide, and address emergent questions. The coding team will independently read all transcripts to become familiar with these data; the coding unit for each *a priori* code will be a response to an item. The coding team will independently create examples from the transcripts for the *a priori* codes, and any emergent codes, for 20% of the transcripts, and then meet to discuss codes and coding units. We will compare examples and discuss findings until agreement is reached on coding definitions and application of the definitions to these data. The coding team will repeat the described process until we have total agreement on the first level coding; following discussions, the coding team will re-code transcripts using any new codes.

The coding team will identify and create higher level codes based upon created and agreed upon codes after the completion of first level coding and discussion of preliminary findings with the co-mentors. Second level coding will mirror the first level coding approach in that the coding team will independently code 20% of the transcripts and meet to discuss emerging patterns. To ensure reliability and validity of the coding process and the creation of these descriptive summaries, the coding team will meet weekly to compare coding and resolve disagreements. All findings will be discussed and reviewed with other study team members to ensure reliability and validity.

Emerging codes. A Veteran may indicate that the DDS does not capture an aspect salient to DD or living with T2D. Should this occur, the QA will: (1) use probes to obtain further data about this aspect from the Veteran during the interview; (2) discuss these emerging topics with Drs. Lewinski and King; and (3) amend the interview guide to query subsequent Veterans about the emerging topic(s).

A priori codes. We will use the coding scheme described in Knafl et al.[44] to capture challenges to describing DD in the context of the DDS. These codes include: (1) *limited applicability*, responses which indicate the item is not appropriate for Veterans with T2D; (2) *unclear reference*, responses that indicate lack of clarity for the item; (3) *unclear perspective*, responses that indicate lack of clarity about perspective to answer the question; and (4) *wording/tone*, responses that indicate the wording of the question is confusing or negative. Additionally, we will use codes to denote: the need for more questions, ease of recall of information needed tor response, and ease of fitting personal experiences to the measure/response options.

Analysis Step 1: Data Overview. First, we will analyze responses for each survey item in aggregate. For each survey item, we will identify responses that are similar, different, or if the item was deemed not relevant. When we identify differences or if the item was deemed not relevant, we will examine the responses to determine if these differences are related to certain characteristics of the Veteran (e.g., gender, medication).

Analysis Step 2: Summarizing Responses. After noting general differences, we will write a descriptive summary of each unique response to each survey item. These summaries will enhance our ability to compare and contrast responses to each survey item. We will look for items in which there are multiple interpretations or misunderstandings, as these indicate a threat to the reliability of the DDS. After we write a descriptive summary for all responses for each item, we will use the matrix function in NVivo to identify higher level summaries. For each survey item, we will examine summaries within identified themes.

Sampling plan for qualitative interviews.

HbA1c	DDS Score[18]						
	Low		Mod.		High		Total
	No Ins.	Ins.	No Ins.	Ins.	No Ins.	Ins.	
< 9	3	3	3	3	3	3	18
≥ 9	3	3	3	3	3	3	18
Total	12		12		12		36
Note: No Ins. = No insulin; Ins. = Insulin.							

Analysis Step 3: Identifying Problems & Modifying the DDS. We will examine the summaries created in Step 2 to identify where, if any, problem exists for each survey item. We will generate an overall interpretation of DD in the context of the DDS, describe the identified problems with specific survey items, and then decide the appropriate action (e.g., retain, delete, modify, add) for the survey item and/or DDS.

Semi-structured Interviews—Detailed study design and sampling plan. Audio recordings will be transcribed by the DVAHCS staff. When transcribed, names and other identifying information will be redacted. Transcripts will be saved in the secured VA project drive (:.v06.med.va.gov\Dur\HSRD\TARDIS_Aim1-2). We will use a combination of maximal variation and extreme case sampling strategies,[53] to interview ~36 Veterans, or until saturation is reached. The combination of these sampling strategies will ensure that we obtain a diverse range of responses. We will balance enrollment on HbA1c level (< 9 or ≥ 9) and medication (no insulin, insulin); we will also balance enrollment on the Veteran's *Diabetes Distress Scale* score[14] (low, moderate, high). We will use the *Diabetes Distress Scale* score due to its established and confirmed four domains of DD.[14] We are balancing enrollment on Diabetes Distress Scale score to ensure we obtain descriptions of each level of DD (low, moderate, high). Our actions will help us qualitatively describe what, and to what extent, differences exist between DD levels. A maximal variation sampling plan is ideal in order to obtain diverse perspectives (e.g., HbA1c, medication, *Diabetes Distress Scale* score) on T2D self-management.[33,53] Including well- and poorly controlled Veterans with low distress will provide insight into these Veteran's self-management strategies and behaviors. When we begin to see saturation, we will begin to oversample Veterans based upon certain characteristics (e.g., race/ethnicity, gender, age). Extreme case sampling will enable us to purposively obtain diverse perspectives in the presentation of DD; we will work during data collection to determine when to use extreme case sampling. When appropriate, we will use NVivo, a qualitative data analysis software program that facilitates management of data analysis across transcripts.

The preferred method of data collection will be via telephone. Interviewing Veterans via the telephone may decrease barriers to participation (e.g., access, time). Semi-structured interviews will be completed by a Qualitative Analyst. We will develop an operating manual for the interviews, review interviewing techniques that encourage openness, and review active listening techniques.[46,54] Prior to the first interview, we will practice interviewing to ensure the qualitative analyst is familiar with the interview guide and purpose of the interviews. We will observe the qualitative analyst for the first 3 interviews to ensure she is using the interview guide correctly, and then we will listen to recordings of every fourth interview to ensure that the qualitative analyst is following the interview guide.

Analysis Plan. We will begin analysis after the first three interviews and preliminary analysis will guide future data collection.[51] The analysis process will be iterative, as initial analysis will inform interview guide questions.[51] A coding team consisting of Dr. Lewinski and Ms. Shaprio will code these data. They will meet weekly during interviewing, coding, and analysis to identify emerging areas, refine the interview guide, and address emergent questions. All transcripts will be de-identified and will not contain information about the HbA1c level, medication, or DD score to ensure objectivity during coding and analysis. Throughout coding and analysis, Dr. Lewinski will work closely with Drs. Tanabe and Barcinas, and findings will be discussed with other mentors to ensure reliability and validity of the interpretation. The coding team will use content analysis[55] with the software ATLAS.ti. The analysis plan will occur in two steps. First, the transcribed text from the interviews will be coded and analyzed for aggregate themes specific to DD and T2D self-management. Then, using matrices, we will identify similarities and differences between levels of DD and participant characteristics

Analysis Plan: Step 1. First, we will upload the transcripts into ATLAS.ti and then begin coding. First level coding will be guided by *a priori* codes based upon how Veterans describe DD and the variables in the guiding framework (**Figure 1**). Emergent codes about DD, T2D self-management, and learning will be identified in relation to observations of self-management unique to Veterans. Codes will be examined in the context of DD and self-management of T2D to focus the analysis.[33] The coding team will independently read all transcripts to become familiar with these data, and then identify appropriate coding units for each *a priori* code prior to beginning coding. The coding team will independently create examples from the transcripts for the *a priori* codes, and any emergent codes, for 20% of the transcripts, and then meet to discuss codes and coding units. We will compare examples and discuss findings until agreement is reached on coding definitions and application of the definitions to these data. The coding team will repeat the described process until we have total agreement on the first level coding; following discussions, the coding team will re-code transcripts using any new codes. The coding team will identify and create higher level codes based upon created and agreed upon codes after the completion of first level coding and discussion of preliminary findings with the co-mentors. Second level coding will mirror the first level coding approach in that the coding team will independently code 20% of the transcripts and meet to discuss emerging patterns. We anticipate that a multidimensional structure will be present in these data, thus no limit will be placed upon codes to which a coding unit can be assigned.

Analysis Plan: Step 2. We will begin Step 2 once we identify the overall themes for the entire data corpus. We will use the co-occurrence feature in ATLAS.ti and explore the findings in matrices to identify patterns of similarities and differences. To enable the analysis in Step 2, we will first label each transcript in ATLAS.ti with the Veteran's HbA1c level, medication, and Diabetes Distress Scale score. Dr. Lewinski has previously used the co-occurrence feature to identify points of similarities and differences.[56]

Validity and reliability. Validity and reliability of findings and the iterative generation of codes will be ensured by working closely with Ms. Shaprio and the research team.[33] The

coding team will: provide rich descriptions of all codes and themes; discuss coding until consensus is reached for each code and theme; triangulate data from quantitative and qualitative sources; and present any discrepant information.[33] The codebook will describe the codes and emerging themes and serve as an audit trail. Regular meetings with the study team will ensure validity and reliability, higher level code development, and discussion of emerging findings.

Primary Outcomes.

- Surveys. The primary goal of the baseline survey is to examine differences in *Diabetes Distress Scale* score by HbA1c level (HbA1c < 9 and HbA1c ≥ 9) and by medication regimen (no insulin, insulin).
- Cognitive interviews. Individual interviews will enable us to identify how Veterans describe DD and interpret items in the DDS.
- Semi-structured interviews. Interviews will provide insight into how the Veteran interprets T2D self-management, strategies the Veteran uses in self-management, learning needs and preferences, including interactions with healthcare providers as part of self-management, and the associated challenges with self-management, in their sociodemographic, psychosocial, and environmental context.

Privacy, Confidentiality, and Information Security

1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

The Personal Health Information that will be obtained, used, and/or shared for this study includes

Identifier(s)	Source(s) of Health Information
☒ Names	☒ Medical history & physical exam information Describe: Blood Pressure, HbA1c, lipid labs, RX for lipids, HTN, DM
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: street address, City, Zip, County	☒ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: birth date, dx dates, admission date, discharge date, visit or treatment dates, RX dates, lab dates, survey dates	☐ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe:
☒ Telephone numbers	☒ Progress notes
☐ Fax numbers	☒ Diagnostic / Laboratory test results

Identifier(s)	Source(s) of Health Information
☐ Electronic mail addresses	☐ Operative reports
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☐ Medical record numbers	☒ Discharge summaries
☐ Health plan beneficiary numbers	☒ Survey / Questionnaire responses
☐ Account numbers	☐ Billing records
☐ Certificate and/or license numbers	☐ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☐ Sickle cell anemia information
☐ Device identifiers and serial numbers	☐ Alcoholism or alcohol use information
☐ Web Universal Resource Locators (URLs)	☐ Drug abuse information
☐ Internet Protocol (IP) address numbers	☐ Mental health (not psychotherapy) notes
☒ Biometric identifiers, including finger & voice prints	☐ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☒ Any other unique identifying number, characteristic, or code, describe: Anonymous/Randomly assigned study ID# **Note: This is not the unique code assigned to otherwise de-identified health information for re-identification purposes.*	☐ Other, describe:

2. Data and/or Specimen Acquisition:
Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes: We will collect information from patients using telephonic survey collection methods.

☒ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.):

We will use the current VA CDW/VINCI resources to identify the necessary participants with the requested inclusion/exclusion criteria. Using the real SSNs from that subset, we will retrieve current mailing addresses, telephone number, as well as the specific medical record data (using approved VA data bases) via the VHA Corporate Data Warehouse (CDW) dataset via the VINCI or another secure platform.

☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: .

Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.

3. Level of Data:

The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

☒ Identifiable—Data contains direct identifiers.
☒ Coded—Data linked to a specific by a code rather than a direct identifier for re-identification purposes. Only someone possessing the key to the code can link the data to a particular participant.
☒ De-Identified (all 18 HIPAA identifiers removed
- ☐ Verified Statistically

OR

- ☒ Verified by Absence or Removal of 18 HIPAA identifiers

☐ Limited Data Set
☐ Other: Describe:

4. Location of Data and/or Specimens, and Data Retention Plan:

A. Data and/or Specimen Location: All survey data will be collected and stored on VA secure server for the Study RedCap survey located on VINCI.

Data will be stored electronically in \\ v06.med. va.gov \Dur\HSRD\TARDIS_Aim1-2. Data that will be stored electronically include electronic versions of recruitment letters, scanned copies of completed surveys hard copy surveys, database with study cohort criteria.

Paper records of data include study team meeting minutes, hard copy of telephone screening documents, and surveys, etc., will be stored at Legacy tower, suite 600, cubical 632H and office 605.

☒ Data will be also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan

☒ Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-

0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 “Research Investigator Files” for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager.

☐ Other data retention plan, describe:

5. Data Access and Data Recipients:

Only members of our DVAHCS research team will have access to identifiers and coded data. All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one’s password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

6. Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

I. ☒ Data and/or specimens will not be transported or transmitted outside of Durham VAMC environment.

II. ☐ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center.

III. ☐ Data and/or specimens will be transmitted to other VA sites using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).

☐ Data are coded or contain identifiers and thus will be sent <

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).

☐ Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.

☐ Other, describe:

IV. ☐ Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.

☐ Data are coded or contain identifiers and thus will be sent via using VA—approved carrier with tracking.

☐ Data are coded or identified and will be sent via the Safe Access File Exchange (SAFE) at https://safe.amrdec.army.mil/safe/. SAFE is a secure method of exchanging files <2GB to and from individuals with a valid .gov, .mil, .com, or .edu email address. <insert information including collaborator name.>

☐ Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF).

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:

☐ Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or

spreadsheet) that includes the participant's name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

C. ☐ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

D. ☐ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:

NOTICE!!!

Access to these records is limited to: AUTHORIZED PERSONS ONLY. Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

V. ☐ We will communicate with veterans enrolled as participants in this research study through MyHealtheVet.

7. Risk Mitigation Strategies:

Participant's identifying information (name and last 4 of social security number) will be linked to a study code to be used for all data sets. There will be one key of the last 4SS#/Name and study code, on the secure computer server. The VA server will only be accessible to study personnel with rights to the folder. These data will be entered into the database on the secure VA server. Any paper form will be kept in a secure, locked file cabinet in a locked research office in the ADAPT HSRD at Legacy Tower, suite 600, office 602 or cubical 632H. They will be identified only by a study code. All data will be retained in accordance to the Records Control Schedule, the Records Management Officer will be contacted for the current policy, prior to any destruction.

☒ Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.

☐ Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.

☒ Data or specimens are coded and the code is not related to, or derived from, information about the individual and that code is not otherwise capable of being translated as to the identify the individual. Only someone possessing the key to code can link the data to a particular participant.
☐ Other, specify:

8. Suspected Loss of VA Information:
Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

9. Reporting of Results:
☒ Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.

☐ Other results reporting plan, describe:

10. Future Use of Data:
☒ Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.

☒ Future Use of data is optional (i.e., not required by the research subject).

☐ Future Use of data is required for participation in the study.

☐ No future use of data is currently planned.

11. Use of Mail Merge Technology
☐ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly “matched”. If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

12. Use of Non-Standard Software
☐ I do NOT intend to use any new specialized software (i.e. Software that’s not already approved OR installed) in this study.

☐ I intend to use specialized software that has not already been installed and it has been approved for use by the VA Technical Reference Model (TRM) Group.

(Note: All new software must be approved by TRM before it can be installed on VA systems.)

☒ I intend to use previously installed software on my VA computer.

13. Use of Cloud Computing Services
☒ Cloud computing services will NOT be used in this study.

☐ Cloud computing services WILL be used in this study as described below and have been approved nationally by the VA Chief Information Officer (CIO). (Note: ONLY cloud computing services that have been approved nationally may be used.)

References
Provide references, if applicable.

1. Veterans Health Administration. VA Research on Diabetes. In: Atlanta, GA. : U.S. Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development; 2016: https://www.research.va.gov/pubs/docs/va_factsheets/Diabetes.pdf. Accessed 1/3/2018.
2. American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. *Diabetes Care.* 2018.
3. Funnell M, Anderson RM. Working toward the next generation of diabetes self-management education. *Am J Prev Med.* 2002;22(4 Suppl):3-5.
4. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care.* 2002;25(7):1159-1171.
5. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. *N Engl J Med.* 1993;329(14):977-986.
6. Ahola AJ, Groop PH. Barriers to self-management of diabetes. *Diabet Med.* 2013;30(4):413-420.
7. Laranjo L, Neves AL, Costa A, Ribeiro RT, Couto L, Sa AB. Facilitators, barriers and expectations in the self-management of type 2 diabetes--a qualitative study from Portugal. *The European journal of general practice.* 2015;21(2):103-110.
8. Gariepy G, Smith KJ, Schmitz N. Diabetes distress and neighborhood characteristics in people with type 2 diabetes. *J Psychosom Res.* 2013;75(2):147-152.
9. Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. *J Diabetes Complications.* 2016;30(6):1060-1068.
10. Fisher L, Hessler D, Glasgow RE, et al. REDEEM: a pragmatic trial to reduce diabetes distress. *Diabetes Care.* 2013;36(9):2551-2558.

11. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The prevalence of comorbid depression in adults with diabetes: a meta-analysis. *Diabetes Care.* 2001;24(6):1069-1078.
12. Aronson B, Palombi L, Walls M. Rates and consequences of posttraumatic distress among American Indian adults with type 2 diabetes. *J Behav Med.* 2016;39(4):694-703.
13. Aikens JE, Zivin K, Trivedi R, Piette JD. Diabetes self-management support using mHealth and enhanced informal caregiving. *J Diabetes Complications.* 2014;28(2):171-176.
14. Fisher L, Hessler DM, Polonsky WH, Mullan J. When is diabetes distress clinically meaningful?: establishing cut points for the Diabetes Distress Scale. *Diabetes Care.* 2012;35(2):259-264.
15. Adriaanse MC, Pouwer F, Dekker JM, et al. Diabetes-related symptom distress in association with glucose metabolism and comorbidity: the Hoorn Study. *Diabetes Care.* 2008;31(12):2268-2270.
16. Welch GW, Jacobson AM, Polonsky WH. The Problem Areas in Diabetes Scale. An evaluation of its clinical utility. *Diabetes Care.* 1997;20(5):760-766.
17. Schmitt A, Reimer A, Kulzer B, Haak T, Ehrmann D, Hermanns N. How to assess diabetes distress: comparison of the Problem Areas in Diabetes Scale (PAID) and the Diabetes Distress Scale (DDS). *Diabet Med.* 2016;33(6):835-843.
18. Fisher L, Glasgow RE, Strycker LA. The relationship between diabetes distress and clinical depression with glycemic control among patients with type 2 diabetes. *Diabetes Care.* 2010;33(5):1034-1036.
19. Baek RN, Tanenbaum ML, Gonzalez JS. Diabetes burden and diabetes distress: the buffering effect of social support. *Ann Behav Med.* 2014;48(2):145-155.
20. Berry E, Lockhart S, Davies M, Lindsay JR, Dempster M. Diabetes distress: understanding the hidden struggles of living with diabetes & exploring intervention strategies. *Postgrad Med J.* 2015;91(1075):278-283.
21. Dennick K, Sturt J, Speight J. What is diabetes distress and how can we measure it? A narrative review and conceptual model. *J Diabetes Complications.* 2017;31(5):898-911.
22. Chesla CA, Chun KM, Kwan CM, et al. Testing the efficacy of culturally adapted coping skills training for Chinese American immigrants with type 2 diabetes using community-based participatory research. *Res Nurs Health.* 2013;36(4):359-372.
23. Carolan M, Holman J, Ferrari M. Experiences of diabetes self-management: A focus group study among australians with type 2 diabetes. *J Clin Nurs.* 2015;24(7-8):1011-1023.
24. Fisher L, Mullan JT, Skaff MM, Glasgow RE, Arean P, Hessler D. Predicting diabetes distress in patients with Type 2 diabetes: a longitudinal study. *Diabet Med.* 2009;26(6):622-627.
25. Faber-Wildeboer AT, van Os-Medendorp H, Kooy A, Sol BGM. Prevalence and risk factors of depression and diabetes-related emotional distress in patients with type 2 diabetes: A cross-sectional study. *Journal of Nursing Education & Practice.* 2013;3(6):61-69.

26. Lipscombe C, Smith KJ, Gariepy G, Schmitz N. Gender differences in the association between lifestyle behaviors and diabetes distress in a community sample of adults with type 2 diabetes. *Journal of diabetes.* 2016;8(2):269-278.
27. Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with Type 2 diabetes: a systematic review and meta-analysis. *Diabet Med.* 2017.
28. Sturt J, Dennick K, Hessler D, Hunter BM, Oliver J, Fisher L. Effective interventions for reducing diabetes distress: systematic review and meta-analysis. *International Diabetes Nursing.* 2015;12(2):40-55.
29. Dennick K, Sturt J, Hessler D, et al. High rates of elevated diabetes distress in research populations: A systematic review and meta-analysis. *International Diabetes Nursing.* 2015;12(3):93-107.
30. Chew B-H, Vos RC, Pouwer F, Rutten GEHM. The associations between diabetes distress and self-efficacy, medication adherence, self-care activities and disease control depend on the way diabetes distress is measured: Comparing the DDS-17, DDS-2 and the PAID-5. *Diabetes Res Clin Pract.* 2018;142:74-84.
31. Carper MM, Traeger L, Gonzalez JS, Wexler DJ, Psaros C, Safren SA. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. *J Behav Med.* 2014;37(3):501-510.
32. Knowles MS. The modern practice of adult education (revised and updated). *New York: Cambridge.* 1980.
33. Creswell J, Plano Clark V. *Designing & Conducting Mixed Methods Research.* 2 ed. Thousand Oaks, CA: Sage; 2011.
34. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. *Diabetes Care.* 2005;28(3):626-631.
35. Naegeli AN, Stump TE, Hayes RP. A psychometric evaluation of the Diabetes Symptom Checklist-Revised (DSC-R) cognitive distress, fatigue, hyperglycemia, and hypoglycemia subscales in patients with type 1 and type 2 diabetes. *Diabetes Metab Syndr Obes.* 2010;3:27-30.
36. Glasgow RE, Toobert DJ, Barrera M, Jr., Strycker LA. The Chronic Illness Resources Survey: cross-validation and sensitivity to intervention. *Health Educ Res.* 2005;20(4):402-409.
37. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care.* 2003;41(11):1284-1292.
38. Prins A, Bovin MJ, Smolenski DJ, et al. The Primary Care PTSD Screen for DSM-5 (PC-PTSD-5): Development & Eval. Within a Veteran Primary Care Sample. *J Gen Intern Med.* 2016;31(10):1206-1211.
39. Billioux A, Verlander K, Anthony S, Alley D. Standardized Screening for Health-Related Social Needs in Clinical Settings. 2017.
40. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The diabetes empowerment scale-short form (DES-SF). *Diabetes Care.* 2003;26(5):1641-1642.
41. Kerfoot BP, Gagnon DR, McMahon GT, Orlander JD, Kurgansky KE, Conlin PR. A Team-Based Online Game Improves Blood Glucose Control in Veterans With

Type 2 Diabetes: A Randomized Controlled Trial. *Diabetes Care.* 2017;40(9):1218-1225.
42. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care.* 2000;23(7):943-950.
43. Willis GB, Artino AR, Jr. What Do Our Respondents Think We're Asking? Using Cognitive Interviewing to Improve Medical Education Surveys. *J Grad Med Educ.* 2013;5(3):353-356.
44. Knafl K, Deatrick J, Gallo A, et al. The analysis and interpretation of cognitive interviews for instrument development. *Res Nurs Health.* 2007;30(2):224-234.
45. Drennan J. Cognitive interviewing: verbal data in the design and pretesting of questionnaires. *J Adv Nurs.* 2003;42(1):57-63.
46. Drabble L, Trocki KF, Salcedo B, Walker PC, Korcha RA. Conducting qualitative interviews by telephone: Lessons learned from a study of alcohol use among sexual minority and heterosexual women. *Qualitative social work : QSW : research and practice.* 2016;15(1):118-133.
47. Department of Veterans Affairs, Department of Defense. VA/DoD Clinical Practice Guidelines for The Management of Type 2 Diabetes Mellitus in Primary Care: Pocket Card. In. Vol 5.02017.
48. West C, McDowell J. The distress experienced by people with type 2 diabetes. *Br J Community Nurs.* 2002;7(12):606-613.
49. Austin PC. An Introduction to Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies. *Multivariate behavioral research.* 2011;46(3):399-424.
50. Willis GB. *Cognitive interviewing: A tool for improving questionnaire design.* Sage Publications; 2004.
51. Sandelowski M. Qualitative analysis: what it is and how to begin. *Res Nurs Health.* 1995;18(4):371-375.
52. Guest G, MacQueen KM, Namey EE. *Applied thematic analysis.* Los Angeles : Sage Publications, c2012.; 2012.
53. Onwuegbuzie AJ, Collins KM. A typology of mixed methods sampling designs in social science research. *The qualitative report.* 2007;12(2):281-316.
54. Musselwhite K, Cuff L, McGregor L, King KM. The telephone interview is an effective method of data collection in clinical nursing research: A discussion paper. *Int J Nurs Stud.* 2007;44(6):1064-1070.
55. Krippendorff K. *Content Analysis An Intro. to its Methodology.* Thousand Oaks, Calif.: Sage; 2004.
56. Lewinski AA, Anderson RA, Vorderstrasse AA, Fisher EB, Pan W, Johnson CM. Type 2 Diabetes Education and Support in a Virtual Environment: A Secondary Analysis of Synchronously Exchanged Social Interaction and Support. *J Med Internet Res.* 2018;20(2):e61.

Appendix A: Expedited Review of Research

The categories of research that may be reviewed by the IRB through the expedited review procedure include research activities that present no more than minimal risk to human subjects **AND** involve procedures listed in one or more of the specific categories listed below.

The expedited review procedure is not to be used when identification of the subjects or their responses would reasonably place them at risk of criminal or civil liability; be damaging to the subjects' financial standing, employability, insurability, or reputation; or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The IRB must apply the standard requirements for informed consent (or its waiver, alteration, or exception) to all studies that undergo expedited review.

EXPEDITE CATEGORIES
1-Drugs and Devices: One of the following must be met: (1) The research is on drugs for which an IND application is not required. (2) The research is on medical devices for which an investigational device exemption (IDE) application is not required; or the medical device is cleared or approved for marketing, and the medical device is being used in accordance with its cleared or approved labeling.
2-Blood Samples: Collected by finger / heel / ear stick or venipuncture: (1) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 milliliters (ml) in an 8-week period, and collection may not occur more frequently than two times per week; or (2) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kilogram (kg) in an 8-week period, and collection may not occur more frequently than two times per week.
3-Noninvasive Collection of Biological Specimens: Collected prospectively for research purposes by noninvasive means: (1) Hair and nail clippings in a non-disfiguring manner. (2) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction. (3) Permanent teeth if routine patient care indicates a need for extraction. (4) Excreta and external secretions (including sweat). (5) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue. (6) Placenta removed at delivery. (7) Amniotic fluid obtained at the time of rupture of the membrane prior to, or during, labor. (8) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques. (9) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings. (10) Sputum collected after saline mist nebulization.

EXPEDITE CATEGORIES
4-Noninvasive Collection of Data: Data must be collected through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. (1) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy. (2) Weighing the subject. (3) Testing sensory acuity. (4) Magnetic resonance imaging (MRI). (5) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography. (6) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual.
5-Collected Material: Research involves: (1) Materials (data, documents, records, or specimens) that have been collected for any purpose, including previous research; or (2) Materials (data, documents, records, or specimens) that will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
6-Collection of Data From Voice, Video, or Photographs: Research involves collection of data from voice, video, or photographs.
7-Group Characteristics, Surveys, Interviews, and Quality Assurance: Research must be on individual or group characteristics or behavior (including, but not limited to: research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or will employ survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. ***NOTE****: Some research in this category may be exempt from the VA regulations for the protection of human subjects (38 CFR 16.101(b)(2) and (b)(3)). This listing refers only to research that is not exempt.*