Request for Exemption language

Please answer the following questions so the IRB can determine if the study meets the criteria for this category: Describe the nature of the benign behavioral intervention(s) used in this study and how the prospective agreement is obtained or reference where in the protocol the description can be found:

In this multisite trial study, we aim to provide medication-specific educational brochures directly to Veterans who may be deprescribing candidates for three cohorts taking potentially inappropriate medications (PPI's, diabetes medications, and gabapentin), in advance of scheduled primary care visits. Mail-based surveys will be sent after the scheduled primary care visit to assess patient engagement with the brochure and its impact on patient-provider communication. Focus groups and interviews with clinicians and staff at the end of the study will assess perceptions of the intervention and impact on clinical workflow. This can be found in the protocol on pages 11-13 (section 6), and pages 15-16 (section 8).

Rationale/Justification for inclusion of patients with cognitive impairment

Note about Patients with Cognitive Impairment – Due to the eligibility criteria for the Diabetes cohort, it is possible that patients with cognitive impairment will be recruited. Veterans with cognitive impairment represent a population at potentially increased risk for worsened outcomes associated with overtreatment of diabetes, especially for hypoglycemia (low blood sugar). Thus, it is important to understand the effect of promoting deprescribing on this vulnerable population. Veterans with mild cognitive impairment may still comprehend the brochure well enough to ask their primary care provider about the need for diabetes medication. Veterans with more severe cognitive impairment may not interact with the brochure, but a caregiver may on their behalf. Veterans with cognitive impairment significant enough to not interact with the brochure are likely at greater risk of harm from potentially inappropriate medication use and subsequent risk for hypoglycemia than they are from hyperglycemia should they decide to stop taking their medication prior to discussing with their PCP. It is unlikely that patients with significant cognitive impairment would return the survey, and for those with mild impairment, their perspectives are still considered important to include.

Justification of Risk to Subjects

1) Risk of the intervention – It is important to note that the decision to deprescribe or not remains in the purview of the patient-provider dyad; we are not randomizing patients to have medications withdrawn. The primary intervention is distribution of information directly to patients. As such, this study involves a low level of risk to all human subjects.

It is possible that Veterans could feel discomfort receiving information about their medications, expressing their beliefs and perspectives, or have concerns that their subsequent health care services will be affected. Bringing the issue of potential medication overuse to Veterans' attention may also lead them to worry that they are taking too many medicines or that the targeted medications (PPIs, diabetes medications, or gabapentin) may have caused them harm.

The intervention could lead to the actual discontinuation of unnecessary medications as intended; nonetheless, there is a slight possibility that the intervention could unintentionally lead to discontinuation of medications that are necessary or that the discontinuation of medications perceived as unnecessary could actually result in adverse drug withdrawal events. It is also possible that patients will stop a medication after receiving the brochure but without consulting their primary care provider.

The risks of deprescribing medications include, but are not limited to, adverse drug withdrawal reactions and return of a medical condition. Adverse drug withdrawal reactions are rare, especially in comparison to adverse drug events. It is more common for patients to experience a return of symptoms for which the medication was initially prescribed. Serious adverse events resulting from inappropriately discontinuing a medication include upper gastrointestinal bleeding for the PPI cohort, diabetic ketoacidosis or hyperosmolar hyperglycemic state for the DM cohort, and seizure for the gabapentin cohort.

2) Procedures to Minimize Risk – Veterans receiving the intervention (brochure) and survey – Exclusion criteria have been carefully incorporated to help minimize Veteran risk prior to enrollment. Further, as noted, we are not randomizing patients to have medications withdrawn. The primary intervention is distribution of information directly to patients. It is important to note that the decision to deprescribe or not remains in the purview of the patient-provider dyad. We will provide a brief cover letter when sending the EMPOWER brochure to patients, and the EMPOWER brochure states multiple times to not decrease or discontinue a medication without first consulting with a clinician. We are also mailing the brochures two weeks prior to a primary care visit, so if patients decide they want to stop a medication, they will already have an appointment scheduled. Taken together with the fact that patients and providers already have the ability to make deprescribing decisions, the risk of this study is not greater than current standard practice.