FORM: IRB Proposal - Standard Submission	
NUMBER	VERSION DATE
HRP-UT901	10/10/25

INSTRUCTIONS

- **This form is intended for studies that are considered greater than minimal risk (full board), for minimal risk research qualifying for expedited review (fits in one or more expedited review categories), OR for any study where you are unsure of the appropriate IRB review level**.
    - See sections 5.3 and 5.4 of the UT IRB Policies and Guidance page for guidance on what research qualifies for expedited (single reviewer) and exempt review.
    - **If your study qualifies for exempt review**, you are encouraged to instead use the HRP-UT902 Template IRB Proposal Exempt Submission Form, which is streamlined for exempt research. You can download proposal templates from the Templates tab in UTRMS-IRB Library.
    - **If you are ONLY using secondary data that will not be initially collected solely for this research project AND you will not interact with participants,** you are encouraged to instead use the HRP-UT903 Template IRB Proposal Secondary Use form which is streamlined for secondary use only projects where there is no interaction with participants. You can download proposal templates from the Templates tab in UTRMS-IRB Library.
- For studies following a sponsor protocol, please use this guidance to assist in your completion of this form.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, click on the check box (or double click and type an "X" if using Google Docs). Please note, Word online does not support Word checkboxes. Please download the file and use your desktop version of Microsoft Word.
- To fill in a text box, make sure your cursor is within the grey text box before typing or pasting text.
- **Do not convert this Word document to PDF.** The ability for UTRMS-IRB to implement "tracked changes" is required to facilitate efficient review.

INDEX

GENERAL STUDY INFORMATION

Study Title

Include the study title below.

Using pharmacy extenders to optimize non-statin agents for secondary atherosclerotic cardiovascular disease (ASCVD) prevention in a federally qualified health center (FQHC)

1 Review Type (Choose one)

Please choose which level of review best fits your research. This is an investigator's assessment of review and does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination of review conflict, the IRB's determination will be considered the official determination.

***Note**: Expedited review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by OHRP. If you would like help determining which type of review best fits your research study, please contact the IRB staff in the Office of Research Support & Compliance:*
https://research.utexas.edu/ors/human-subjects/get-help/

a ☐ **Full Board Review – Greater than Minimal Risk Research**

b ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypotheses

Please describe the research aims and hypotheses in the box below. To input text, click in the box below and start typing.
Note: Procedures will be explained in a separate section below.

We predict that the utilization of a pharmacist/student pharmacist targeted outreach to initiate the optimization of low-density-lipoprotein cholesterol (LDL-C)-lowering medications for secondary ASCVD prevention in a FQHC will significantly reduce LDL-C levels and improve the % of patients meeting LDL-C targets.

Primary Aim 1: To determine if pharmacy extenders' targeted outreach to patients with clinical ASCVD can result in a higher percentage of patients who are meeting LDL-C targets after 6 months of intervention

Primary Aim 2: To assess the real world % LDL-C lowering of add-on ezetimibe and/or proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor's therapy for patients with clinical ASCVD who are not meeting LDL-C targets with maximally tolerated statin

3 Study Background

Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

Cardiovascular diseases (CVD) are the most common cause of death in the United States and globally (Hammersley et al. 2016). A near 18 million global deaths per year can be attributed to cardiovascular disease, such as coronary heart disease (CHD) and stroke (McClellan et al. 2019). A major indicator of increased risk of cardiovascular diseases, particularly atherosclerotic cardiovascular disease (ASCVD), is dyslipidemia. Dyslipidemia is characterized by suboptimal low-density lipoprotein cholesterol (LDL-C). Studies have shown that there is a direct correlation between elevated LDL-C and risk of cardiovascular diseases. Patients with a history of clinical ASCVD have a high risk of recurrent CV events, and management of dyslipidemia is critical in reducing this risk. Two major US cholesterol management publications have been released within the last 4 years including the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol and the 2022 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of ASCVD. Both of these publications recommend maximally tolerated statins with second line, add-on therapy including non-statin agents such as ezetimibe and/or PCSK9 inhibitors to achieve an LDL-C goal of at least a 50% reduction or <70 mg/dL for patients with ASCVD and encourages an even lower LDL-C target of at least a 50% reduction or <55 mg/dL for patients in the very high-risk category.

Despite the known mortality and morbidity benefits of optimally treating dyslipidemia in patients with ASCVD, data reveals that dyslipidemia remains undertreated. This phenomenon is known as therapeutic inertia, where therapy is not started or modified to meet patient-specific goals (Lazaro et al. 2010). This appears to be the case with primary and secondary prevention of ASCVD. Of patients in the U.S. with ASCVD, nearly 80% have not reached their LDL-C goals, despite being on statin therapy (Lazaro et al. 2010). According to a 2001 article on clinical inertia, Phillips et al. determined that therapeutic inertia may be a result of prescriber's overestimating patient adherence or the prescriber's lack of training in properly using the guidelines to make their clinical decisions. Other causes for therapeutic inertia may be due to the nature of the patient's individual health—with multiple conditions, such as diabetes mellitus, thyroid dysfunction, kidney diseases, or cancer, to name a few, or prescribers are not prioritizing the patient's dyslipidemia management (Phillips et al. 2001).

Within the last 20 years, there has seen a rise in the non-statin medications available to treat patients that are not at goal. One particular medication of interest is ezetimibe (Zetia), a non-statin that works by reducing the absorption of cholesterol. A large driver for ezetimibe being incorporated early on in treatment algorithms for secondary ASCVD prevention come from the IMPROVE-IT trial. This study concluded that ezetimibe, when added to statin therapy, resulted in further lowering of LDL-C values and improved cardiovascular outcomes by approximately 24% (Cannon et al. 2015). Other medications, such evolocumab (Repatha) and alirocumab (Praluent) from the PCSCK9 inhibitor class, have also shown significant reductions in LDL-C levels and positive outcomes in ASCVD related events. In the
FOURIER trial, patients who had clinically evident ASCVD, an LDL-C of >70 mg/dL, and were on statin therapy received evolocumab to evaluate cardiovascular outcomes when adding evolocumab to moderate- or high-intensity statin therapy (Sabatine et al. 2017). Investigators found that evolocumab significantly reduced cardiovascular events and had a 59% lowering of LDL-C from baseline compared to the placebo. Additionally, in the ODYSSEY trial, patients who had acute coronary syndrome (ACS), an

LDL-C >70 mg/dL, and on a high-intensity statin or maximally tolerated dose received alirocumab to evaluate a potential lower risk of recurrent ischemic cardiovascular events (Schwartz et al. 2018). This study found that alirocumab had an average of 62.7% lower LDL-C at 4 months of therapy compared to the placebo group and lowered the risk of major adverse cardiovascular events. Thus, with these clinically significant trials, ezetimibe, evolocumab, and alirocumab are recommended as an adjunct to statin therapy.

Initial findings from Part 1 of this project showed that ezetimibe was underprescribed in patients with elevated LDL-C and history of ASCVD at CommUnityCare (CuC). The percentage of patients with clinical ASCVD who are meeting LDL targets at CuC (35.9%) is above the national average (16-28%). While CuC is
higher than the national average, there is still an opportunity to optimize cholesterol management. Therefore, the purpose of this study is to initiate a clinical pharmacy initiative to increase the number of patients on appropriate therapy to achieve LDL-C goals for secondary ASCVD prevention.

Acknowledgements: Paola Pina and Sabrina Guerra for their contributions to the background writing and initial findings from part 1 of this study.

Resources:

1. Grundy, S. M., Stone, N. J., Bailey, A. L., et.al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology, 73(24), 3168–3209. https://doi.org/10.1016/j.jacc.2018.11.002
2. McClellan, M., Brown, N., Califf, R. M., & Warner, J. J. (2019). Call to Action: Urgent Challenges in Cardiovascular Disease: A Presidential Advisory From the American Heart Association. Circulation, 139(9), e44–e54. https://doi.org/10.1161/CIR.0000000000000652
3.Writing Committee, Lloyd-Jones, D. M., Morris, P. B., Ballantyne, C. M., Birtcher, K. K., Covington, A. M., DePalma, S. M., Minissian, M. B., Orringer, C. E., Smith, S. C., Jr, Waring, A. A., & Wilkins, J. T. (2022). 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. Journal of the American College of Cardiology, 80(14), 1366–1418. https://doi.org/10.1016/j.jacc.2022.07.006
4. Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, de Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R, Heidenreich PA, Hlatky MA, Jones DW, Lloyd-Jones D, Lopez-Pajares N, Ndumele CE, Orringer CE, Peralta CA, Saseen JJ, Smith SC Jr, Sperling L, Virani SS, Yeboah J. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019 Jun 18;139(25):e1082-e1143. doi: 10.1161/CIR.0000000000000625. Epub 2018 Nov 10. Erratum in: Circulation. 2019 Jun 18;139(25):e1182-e1186. PMID: 30586774; PMCID: PMC7403606.
5.Cannon CP, Blazing MA, Giugliano RP, McCagg A, White JA, Theroux P, Darius H, Lewis BS, Ophuis TO, Jukema JW, De Ferrari GM, Ruzyllo W, De Lucca P, Im K, Bohula EA, Reist C, Wiviott SD, Tershakovec AM, Musliner TA, Braunwald E, Califf RM; IMPROVE-IT Investigators. Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. N Engl J Med. 2015 Jun 18;372(25):2387-97. doi: 10.1056/NEJMoa1410489. Epub 2015 Jun 3. PMID: 26039521.
6. Sabatine, M. S., Giugliano, R. P., Keech, A. C., et.al. Evolocumab and Clinical Outcomes in

Patients with Cardiovascular Disease. The New England Journal of Medicine, 376(18), 1713-1722. https://doi.org/10.1056/NEJMoa1615664
7. Schwartz, G. G., Steg, P. G., Szarek, M, et.al. Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome. The New England Journal of Medicine, 379(22), 2097-2107. https://doi.org/10.1056/NEJMoa1801174

4 Design and Methodology

Provide a brief description of the study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

This will be a prospective intervention study utilizing a mirror image control outcome (reduction in LDL-C) after exposure (pharmacist/student pharmacist outreach).

5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

Descriptive statistics will be used to analyze demographics and percentage-based outcomes. Paired t-tests will be utilized compare pre-post data. Statistical significance will be based on an alpha of <0.05.

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Check each research procedure included in your study.
A full description of all study procedures should be provided in the Procedures (Details) section below.
Procedures with highlighted checkboxes and denoted with "*" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.

☐ Bio-specimens*	☐ Biometrics	☐ Registry or Repository*
☐ Focus Group	☐ Genetic Analysis	☐ Genomic Data Sharing
☐ International Research*	☒ Interview/Survey	☐ MRI

☒	Protected Health Information*	☐	Observation	☐	Radioactive Material/PET/Nuc. Med
☒	Record review	☐	Sensors (Externally Placed)	☐	Sensors (Inserted)
☐	Audio (only) Recording	☐	Video Recording	☐	X-Ray/CT/DEXA

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.
A full description of all study interventions should be provided in the Procedures (Details) section below.
**** Interventions with highlighted checkboxes and denoted with "*" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.***

☒	Behavioral	☐	Device*	☐	Drug/Biologic*

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

9 Additional Oversight

Check the box(es) below if you are implementing research procedures that require oversight from additional UT committees.

☐	Energy introduced to the subject (electrical, magnetic, light)	☐	Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos	☐	Radiation exposure without direct clinical benefit

☐ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus UT IBC approval is needed.

a ☐ **UT IBC has (or will have) oversight.**

Provide UT IBC Number:

b ☐ **Biological samples collected will not be stored at UT Austin and another agency has responsibility for biospecimen safety.**

10 Alternatives to Participation in This Study

Provide a description of alternatives to participation in this study, as applicable.

Patients will still have a follow-up phone call from their clinical pharmacy team. They will continue receiving usual care and follow-ups from the clinical pharmacy team.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

*Describe all study procedures, **including a step-by-step narrative of what participants will be asked to do or allow, and/or how data will be collected and used, such that someone else could replicate the study based on this description**. Be sure to describe all of the following in detail, as applicable:*

- ☐ *Description of all research procedures being performed and when they are performed, in sequential order.*
- ☐ *Describe/list all research measures/tests that will be used [**NOTE: upload copies of all measures, surveys, scripts, data collection forms, etc., in "Other Attachments" in UTRMS-IRB**].*
- ☐ *Secondary data or specimens that will be obtained, how they are collected, how are they used.*
- ☐ *Where research activities will take place and duration (include expected time commitment of participants).*
- ☐ *Study elements checked in #6 above must all be described here.*

Note: if this is a multi-site or collaborative study include the following:

- ☐ *This is a "Multi-site Study that involves more than one site performing ALL aspects of the research procedures as outlined above." OR "This is a collaborative study that involves UT Austin researchers working with external researchers who are engaged in performing the following study activities (list activities)."*
- ☐ *For assistance with multi-site/collaborative research, download HRP-UT932 Request to Rely Assessment Form from the UTRMS-IRB Library and email irbreliance@austin.utexas.edu.*

In this prospective study, approximately 1,000 patients with a documented history of clinical ASCVD will be identified from Part 1 of the Zetia Project and a new report, generated after IRB approval, to capture newly diagnosed patients with ASCVD who may benefit from therapy optimization. This population health initiative will occur regardless of the proposed research in this protocol.

CommUnityCare Standard Procedure - Standard of Care

As part of routine population health care at CuC, clinical pharmacists assess and evaluate for the optimization of LDL-C lowering medications according to the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol and the 2022 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of ASCVD. Clinical pharmacists will review lipid panels drawn within the past 12 months. If there are no recent lab history available, patients will be scheduled for standard of care fasting lipid panel. Labs will be collected by CuC phlebotomists, nurses, or other trained healthcare professionals outside of the research team. Clinical pharmacists will review, assess, and analyze lipid panel lab results. If LDL levels are at goal, the patient will continue their standard lipid-lowering therapy and continue routine follow-up with the clinical pharmacy team. This standard of care follow-up may occur either in-person or through telehealth visits conducted by the clinical pharmacists. The purpose of this routine call of clinical management and patient education as part of standard of care is to ensure medication adherence, safety, and efficacy per established guidelines. For patients not at goal, clinical pharmacists will provide guideline-directed therapy adjustments at a scheduled clinic visit. This may involve adjusting the intensity of the statin therapy or adding a non-statin agent, such as ezetimibe or a PCSK9 inhibitor, if the patient is not already on the maximally tolerated statin therapy.
Intensification of statin dose will occur if: (1) LDL is not at goal for respective risk category (LDL ≥ 70 mg/dL for very high-risk ASCVD patients and LDL ≥55 mg/dL for high-risk patients) and (2) Patient is not on maximally tolerated statin therapy. Patients who are on maximally tolerated statins and who are not at respective LDL goals will be considered for the initiation of ezetimibe and/or PCSK9 inhibitors. A follow-up lipid panel will be ordered for 4-12 weeks after therapy adjustments and a follow-up clinical pharmacy appointment will also be scheduled within the same timeframe.
Regardless of participation status in the study, all patients will continue to receive the routine care and follow-up from CuC clinical pharmacists described above.

Alterations to Standard Procedure - Intervention

The research intervention consists of outreach conducted by a Texas-licensed pharmacist intern under the supervision of CuC-employed pharmacists. Eligible patients will be contacted by a student pharmacist after the clinical pharmacists' appointment (described above in the standard of care) using CuC's RingCentral telehealth system. During this outreach, student pharmacists will review current lipid-lowering therapies, medication adherence, education about lipid-lowering therapies, and review of labs. Student pharmacists will not make independent prescribing or care decisions. All prescribing authority and therapeutic adjustments remain under the direction of CuC-employed pharmacists in accordance with the standard operating procedures. Patients will be informed about the research project during the outreach call or during a separate call dedicated to recruitment prior to the outreach call. Informed consent will be sent and obtained via either the EHR messaging system (MyChart) or text message through the Ring Central application.
Only data from patients who provide informed consent will be included in the research dataset and subsequent chart review. For patients who decline participation after being contacted through the telehealth outreach, any information collected during the call will remain part of their standard clinical documentation in the EHR and will not be included in the research dataset. These patients will

continue to receive standard clinical pharmacy care, and no data will be abstracted or analyzed for research purposes. Enrolled patients will then be followed through prospective chart review to evaluate outcomes at 3-6 months after consent and student pharmacist outreach.

SUBJECT POPULATION

12 Protected Subject Populations

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐ Active Military Personnel	☐ Children/Minors	☐ Decisionally Impaired Adults
☐ Emancipated Minors	☐ Fetuses	☒ Individuals with Limited English Proficiency
☐ Neonates (Uncertain Viability)	☐ Neonates (Non-Viable)	☐ Prisoners
☐ Pregnant Women	☐ UT Staff/Employees	☐ UT Students

13 Research Participant Information

Describe the general characteristics of the subject populations or groups including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g., teachers and students), clearly outline characteristics for each group.***

a

Adult patients at CommUnityCare in the previous 12 months at time of enrollment, who have a documented history of clinical ASCVD, and are not achieving LDL targets (either <55 or <70 mg/dL based on risk factors)

b Minimum Age

Include the minimum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state the minimum age for each group.***

18 years old

c Maximum Age

*Include the maximum age range for target population. If you have multiple research populations **(e.g., teachers and students), clearly state maximum age for each group.***

No maximum age

d Inclusion Criteria

Describe the specific criteria that will be used to decide who will be INCLUDED in the research from interested or potential subjects. Define technical terms in lay language, as applicable.

Adult patients (>18 years) who have seen a CommUnityCare provider in the previous 12 months at time of enrollment, who have a documented history of clinical ASCVD, and are not achieving LDL targets (either <55 or <70 mg/dL based on risk factors)

e Exclusion Criteria

Describe the specific criteria that will be used to decide who will be EXCLUDED from the research. Define technical terms in lay language, as applicable.

Patients will be excluded if they do not have a clearly documented history clinical ASCVD, are already achieving LDL targets (either <55 or <70 mg/dL based on risk factors), having cholesterol managed by outside provider (e.g. outside cardiologist/lipid specialist), current pregnancy, have not seen a CUC provider in the previous 12 months, or otherwise do not qualify for clinical pharmacy intervention

f Justification for Target Population(s)

If the inclusion/exclusion criteria target or exclude a particular segment of the population(s) relevant to the research topic, provide a rationale for why this target population is appropriate to address the research questions. *Specific groups should not be targeted for research based solely on convenience/availability. [For example, if **only** UT students are targeted for research affecting a broader population, explain why this is equitable and appropriate for this study.]*

Inclusion criteria are appropriate for this study as this population would have benefit from a pharmacist/student pharmacist intervention of add-on non-statin therapy for secondary ASCVD prevention according to clinical guidelines. Exclusion criteria are appropriate for this study as patients either do not require intervention (i.e. they are already at goal an therapy does not need to be changed or initiation of therapy is not appropriate due to lack of documented history of ASCVD), do not receive cholesterol management at CommUnityCare, and/or may have a drug safety concern due to pregnancy status.

i If the study will involve snowball sampling and/or recruitment of the researchers' students or personal contacts/friends/family, explain how the

study procedures will be designed to mitigate potential for coercion or undue influence to participate or continue participation.

14 Total Sample Size

Enter the total target sample size below.

Approximately 1000

15 Sample size rationale

Describe your sample size rational below.

This sample size was based on a prior research study on the prescribing patterns of ezetimibe at CommUnityCare (Part 1 of the Zetia Project); however, a new report will be run to have a more up-to-date list of patients who meet the inclusion criteria.

RECRUITMENT AND SCREENING

16 Recruitment Procedures and Materials

*Select each type of recruitment method that will be used **AND upload copies of all materials to UTRMS-IRB in the "Recruitment Materials" section.***	*Describe **when/where/how** this method will be used, as applicable; be sure to address special points indicated in the instructions for each method.*	*Provide **the schedule and frequency of recruitment attempts** using this method, when applicable.*
a ☐ **E-mail/Letter** *Explain how emails/mailing addresses for potential subjects will be obtained by the study team.* *Describe the initial invitation and any follow-up reminders, and address if there will be a way for recipients to opt-out of future emails. Templates should include subject line(s).*		

b ☐ **Flyer(s)**		
c ☐ **Social Media/Web Posts** *Address which sites and accounts will be used to post ads. Templates should include all text/images that will be included in posts.*		
d ☐ **Text/Direct Messaging** *Describe sites/accounts that will be used. Explain how participants' contact information is obtained, when applicable. Templates should include the initial invitation and any follow-up reminders.*		
e ☐ **Study-specific Website** *This refers to websites created specifically for this research study. Templates should include screenshots/mock-ups of all aspects of the website that will be created; include all text/images.*		
f ☒ **In-Person or Phone Scripts/Presentations** *Explain how phone numbers for potential subjects will be obtained by the study team, when applicable. If researchers will be cold-calling subjects, provide a rationale for why this method is needed to accomplish the research.*	After identifying patients who meet the inclusion criteria via medical record review, recruitment will occur through phone outreach by a pharmacist student intern using CommUnityCare's phone system (Ring Central) with interpreter access at the University of Texas at Austin. Phone numbers will be obtained from the patient's EHR via Epic.	Approximately 1000 patients will be called within 6 months (~17 patients/week). Each outreach will be attempted up to 3 times.
g ☐ **Research Recruitment pool** *Specify which pool will be used (e.g. SONA, Prolific, Amazon MTurk, etc.) and describe how offered studies are advertised to users. Provide templates of all*		

	researcher-provided advertising language that will be posted and confirm it meets the pool's standards for formatting, content, word limits, etc.		
h	☐ **Newspaper ads/TV spots/Radio ads** *When applicable, include scripts and descriptions for planned ads; final versions can be provided in a modification after IRB approval.*		
i	☒ **Medical Record Review** *If your study includes identifying potential participants using PHI (e.g., a partial HIPAA waiver for recruitment is needed), note this here and complete HRP-UT907 - Template IRB Supplemental Form PHI. Download HRP-UT907 from UTRMS-IRB Library Templates.*	A CommUnityCare clinical pharmacist will run an initial report through CommUnityCare's EHR system (EPIC) at the beginning to identify patients with documented history of clinical ASCVD.	An initial report at the beginning of the study after IRB approval will be run to identify potential participants. This report will be run only once.
j	☐ **Other recruitment material/method**		

17 Screening for Eligibility Prior to Consent

*Check the box below if this study involves a screening process **prior** to the informed consent process.*

☒ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**
1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

18 Screening Procedures

Describe the procedures to screen individuals to determine whether inclusion/exclusion criteria are met. ***Please upload all screening questionnaires/tools in the "Other Attachments" in UTRMS.***

From the initial report of individuals, a review of the patients' EHR will be conducted to determine if the patient will need a clinical pharmacy visit for obtaining baseline labs, if there is not a lipid panel within the previous 12 months. If the patient is at LDL goal (<55 mg/dl for very high risk ASCVD and <70 mg/dl for high risk ASCVD), they will continue therapy, receive standard care, and be excluded

from the study. If not at goal (>55 mg/dl for very high risk ASCVD and >70 mg/dl for high risk ASCVD), they will meet the inclusion criteria for the study. Other characteristics screened for will be age (≥18 years), visit with a CommUnityCare provider in the last 12 months, not pregnant, documented clinical ASCVD (as defined as history of coronary artery disease (CAD), ischemic heart disease (IHD), myocardial infarction (MI), stroke/transient ischemic attack (TIA), coronary revascularization event, stable/unstable angina, peripheral artery disease (PAD)/peripheral vascular disease (PVD)), and lipids being managed by a non-CommUnityCare cardiologist/provider.

OBTAINING INFORMED CONSENT

19 Consent Overview

Check the box(es) for consenting procedures that will be used.

☒	**Obtaining Written Informed Consent/Parental Permission**	☐	**Requesting a Waiver of Documentation (signature) of Informed Consent**
☐	**Requesting a Waiver of Informed Consent**	☐	**Requesting an Alteration of the Required Elements of Informed Consent**
☐	**Obtaining Child Assent**	☐	**Obtain Consent Using a Short Form with a Witness**

20 Consent and Assent Processes

Provide a detailed description of consent/assent procedures in the box below. Include: who will obtain consent, where will consent be obtained, how is consent obtained, how consent/assent is documented, and ***when the consent process will occur in such a manner that participants will have sufficient time for adequate consideration.***

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp consent forms for approval.

Informed consent and the research processes will be explained through the phone outreach by the pharmacist student intern. If patient is amenable, they will be sent a link via text, email, and/or MyChart message to DocuSign to sign the consent form (either in English or Spanish). Signed consent forms will be stored through UT DocuSign online platform accessible only to study personnel through an online, password protected account.

21 Research Involving Children - Age of Majority Re-Consent Process

The age of majority *is the age at which a person is legally considered an adult and can provide informed consent for their own participation on research. In most states, including Texas, the age of majority is 18, but this can vary depending on the where the research is conducted.*

If the research involves children as subjects, either A or B must be checked:

A ☐ **All study activities with minors will be complete AND all data collected from minors will be anonymized before any participants will reach age of majority.**

B ☐ **The study enrolls minors who may reach age of majority while study activities and/or research use of their identifiable data is ongoing.**

If true, specify the method of obtaining adult informed consent from these participants upon reaching age of majority. ***At least one of the following must be checked:***

i ☐ **Participants will be re-consented using an adult consent form/script**

Describe the re-consent procedures below. Be sure to upload an adult consent document that will be used for this group. If signature will not be collected (e.g. if re-consent is conducted via phone or other remote method), please complete the waiver of documentation (signature) section later in this form.
NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section.

ii ☐ **A waiver of adult re-consent is requested in the Waiver or Alteration of Informed Consent section later in this form.**

22 Electronic Consent

Check the box below if this study involves obtaining consent with an electronic signature. Be sure the section above is consistent.
NOTE: This box should NOT be checked participants are responding "yes" or clicking "I Agree" on a consent form. ***This section should only be completed if an electronic signature is being obtained.***

☒ **This study involves documenting informed consent/parental permission using an electronic signature.**

If true, specify method for obtaining e-consent below (e.g., DocuSign):

DocuSign

23 Translation for Individuals with Limited English Proficiency

Check the box below to indicate that consent documents/scripts and other relevant study materials (e.g. advertisements, study measures, etc.) will be translated to a language other than English.

☒ **The study population will likely include participants whose limited English speaking status requires translation of the consent documents and other relevant study materials.**

Translation Process

If above is checked, complete the below information describing the translation process. Either A or B must be checked.

A ☒ **The consent documents and other relevant study materials will be translated by a certified translator.**

B ☐ **A non-certified translator will translate the consent documents and other relevant study materials.**

If selected, complete the next two items below. Section describing qualifications must be completed and backtranslation (ii) must be true.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

ii ☐ **Another individual will confirm that the translation is accurate and appropriate**

24 Waiver of Documentation (signature) of Informed Consent

Only complete this section if you are requesting to waive the requirement to collect a written signature of informed consent from participants (a full informed consent form/script is still required). To approve a waiver of documentation of consent, one of the following options must be appropriate and justified by the researcher.

*Please choose **one** waiver option and provide additional information as prompted.* ***Waiver option 2 is most common.***

A Waiver Option 1

Check the box below for each item (all required – #1-4) and provide protocol-specific information as to how the criteria below are met.

NOTE: This is the only applicable waiver of documentation option for greater than minimal risk research. If your study is greater than minimal risk and does not meet Option 1 criteria, you will need to obtain written consent.

1 ☐ **The only record linking the subject and the research would be the consent document.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

2 ☐ **The principal risk would be potential harm resulting from a breach of confidentiality.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

4 ☐ **Describe the mechanism for documenting that informed consent was obtained**

Briefly explain how the researcher will document that consent was obtained from participants.

B Waiver Option 2

Check the box below for each item (all required – 1-3) and provide protocol-specific information as to how the criteria below are met.

1 ☐ **The study is minimal risk.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

2 ☐ **Written consent would not be required outside the research context.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **Describe the mechanism for documenting that informed consent was obtained**

Briefly explain how the researcher will document that consent was obtained from participants. To input text, click in the light grey area below.

i

C Waiver Option 3

Check the box below for each item (all required – 1-4) and provide protocol-specific information as to how the criteria below are met.

1 ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

i **Describe the cultural group or community.**

2 ☐ **The research presents no more than minimal risk of harm to subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

4 **Describe mechanism for documenting that informed consent was obtained**
To input text, click in the light grey area below

25 Waiver or Alteration of Informed Consent

Only complete this section if a waiver or alteration of consent is requested. *To approve a waiver or alteration of consent, all of the following criteria must be appropriate and justified by the researcher.* ***All boxes must be checked.***

SKIP THIS SECTION IF NOT REQUESTING A WAIVER/ALTERATION OF CONSENT

A ☐ **The research involves no more than minimal risk to the subjects.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

B ☐ **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below.

C ☐ **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining consent is required and not just impracticable to obtain consent).**

i **Provide protocol specific information as to how this criterion is met.**

Acceptable justifications should be based on the study's scientific design rather than issues of time or inconvenience.
To input text, click in the light grey area below.

D ☐ **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below.

26 Deception/Incomplete Disclosure and Debriefing

Only complete the sections below if requesting an alteration of informed consent for research that involves deception/incomplete disclosure.
Deception (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.
Incomplete disclosure means that the principal investigator withholds some information about the real purpose of the study or the nature of the research procedures.
See IRB Policies and Procedures Section 15 for a description of deception.
If this study does not involve deception/incomplete disclosure, skip this section.

A ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive the subject to the nature of the study).**

B ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

C **Describe the nature of deception/incomplete disclosure and why it is necessary to conduct the research.**
To input text, click in the light grey area below.

D **Describe debriefing procedures.**

To input text, click in the light grey area below. ***NOTE: Upload the debriefing form to UTRMS-IRB in the "Consent Forms" section.***

BENEFITS

27 Benefits to Society

Describe the scientific and societal benefit(s) below.

The majority of patients with clinical ASCVD fail to achieve their LDL targets to prevent secondary ASCVD events. Cholesterol management is one of the mainstays of secondary ASCVD prevention. This project's pharmacist/pharmacy student's initiative to optimize cholesterol pharmaceutical therapy through guideline directed medical therapy of maximizing current lipid-lowering therapy or add-on, non-statin therapy has the potential to significantly reduce ASCVD risk and prevent secondary ASCVD events in CuC patients. Additional benefits include improving patients' quality of life, reducing healthcare costs for patients, improving medication adherence and management, and improving health outcomes in underserved populations. Adequate interventions, monitoring, and follow-up by the clinical pharmacy team for cholesterol management has the potential to improve health-related outcomes. Upon significant findings of utilizing pharmacy extenders to optimize non-statin agents to achieve LDL goals and prevent secondary ASCVD events at CommUnityCare, patients at other federally qualified health centers may benefit from this study's initiatives.

28 Potential Direct Benefits to Participants

Click on the applicable check box. A or B must be checked.

A ☐ **There is no anticipated direct benefit to participants.**

B ☒ **There are anticipated benefits to participants.**

i **If applicable, describe the potential direct benefits to participants.**

Although the percentage of patients with clinical ASCVD who are meeting LDL targets at CuC is above the national average, the opportunity to focus on cholesterol management remains. This project's pharmacist/pharmacy student's initiative to optimize cholesterol pharmaceutical therapy through guideline directed medical therapy of maximizing current lipid-lowering therapy or add-on, non-statin therapy has the potential to significantly reduce ASCVD risk and prevent secondary ASCVD events in CuC patients. Additional benefits include improving patients' quality of life, reducing healthcare costs for patients, improving medication adherence and management, and improving health outcomes in underserved populations.

Describe potential direct benefits to participants below.

RISKS

29 **Describe the risks associated with each activity in this research**

To input text, click in the light grey area below. Note: Risks should also be outlined in the consent form(s).

For this project, the risk is minimal for CuC patients and is no higher than standard care given medications changes will be implemented in alignment with current guidelines and clinical pharmacist therapy protocols/collaborative practice agreement. Minimal risk of loss of privacy may occur with very low chance of data being leaked and would provide minimal impact to the patient.

30 **Describe how each risk is mitigated/minimized.**

To input text, click in the light grey area below. Note: Risks mitigation should be outlined in the consent form(s), as applicable.

Any potential risk regarding standard of care will be mitigated via clinical pharmacist monitoring and follow-up. Any potential risk of loss of privacy will be mitigated by storing patient data in UT Box, which is password-protected and HIPAA compliant. Access to data will be limited only to individuals who need access for purposes related directly to this research study.

31 **Data Safety Monitoring**

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.
One of the following must be checked (A, B, or C).

A ☒ **In the investigator's opinion, this study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

PLEASE NOTE: The IRB may determine minimal risk studies do require data safety monitoring under certain circumstances (e.g., if there is a known risk with an expected frequency).

B ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan to monitor for safety (Data Safety Monitoring Plan (DSMP)).**

Complete Data Safety Monitoring Details

C ☐ **This study has a Data Safety Monitoring Board (DSMB).**

*Complete Data Safety Monitoring Details section below **or** upload this study's Data Safety Monitoring Board's charter that contains the information below.*

32 Data Safety Monitoring (Details)

Complete this section if the study has a Data Safety Monitoring Plan. ***SKIP this section there is not a DSMP/DSMB.***

If the study has a DSMB, ensure all items below are addressed in the charter (and charted uploaded to UTRMS-IRB) or provide additional information below, as needed.

A How is safety information collected?

To input text, click in the light grey area below.

B When will safety data collection start (for each participant or for the whole study, as applicable)?

To input text, click in the light *grey area below.*

C How frequently will safety data be collected?

To input text, click in the light grey area below.

D Who will review the data for safety?

To input text, click in the light grey area below.

E How frequently will data be monitored for safety concerns?

To input text, click in the light grey area below.

F What data will be reviewed?

To input text, click in the light grey area below.

G **State the frequency or periodicity of the review of cumulative data.**

To input text, click in the light grey area below.

H **State any conditions that would trigger an immediate suspension of the research.**

To input text, click in the light grey area below.

33 Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to next section. Include this information in your consent form.*

A **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

To input text, click in the light grey area below.

Drug side effects and laboratory monitoring, inability to comply with protocol

B **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

Patients can voluntarily withdraw from the study at any time, which will not affect their ongoing care at CommUnityCare. Patients withdrawn from the study will not have further data collected, and past data will be filed and stored in a password protected, encrypted cloud software (UT Box) that restricts access to only relevant personnel. Patient safety will be monitored according to standard of care by clinical pharmacists by patient reports of side effects and laboratory monitoring. Upon findings of adverse responses due to therapy, patients will be immediately discontinued ezetimibe and/or PCSK9i and reassessed for an alternative LDL-lowering medication.

34 **Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

To input text, click in the light grey area below.

REQUIRED DISCLOSURES

35 **Required Consent Disclosures**

Identify each element below that may require additional information to be disclosed in the consent form. Click on the check box (or double click and type an "X" if using Google Docs).

A ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**

Add appropriate disclosure in consent form(s).

B ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

Add appropriate disclosure in consent form(s). See Title IX and Research Guidance for information and download the Title IX Reporting Form on the Special Topics page.

C ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

Add appropriate language to consent form(s).

i **Articulate methods for addressing and reporting incidental findings, if applicable.**

Ensure appropriate information is in consent form(s), as applicable.

N/A

PRIVACY AND CONFIDENTIALITY

36 **Participant Privacy**

Privacy refers to an individual's right to control how others view, record, or obtain information about them. *Privacy protections apply to people, while confidentiality protections (addressed in the section below), apply to data.*

In this section, ***describe how the study team will protect participants' privacy throughout all phases of the research, including during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.***

For example, consider the locations where you will approach and question participants, the locations where data will be viewed/analyzed, how data collection procedures will limit the amount of sensitive or invasive data collected to only what is necessary to answer the research questions, how participants will be described in publications/presentations, etc.

The initial report will only be viewed by the study team and be stored in the study's secure UT Box folder. During the recruitment process via phone outreach by the pharmacy student, protection of patient privacy will be ensured in that only the pharmacy student and/or clinical pharmacist will hear the content of the call. Study participants will consent to PHI collection and usage in the study by agreeing and signing the informed consent form as outlined above. All data will be filed and stored in a password protected, encrypted cloud software (UT Box) that restricts access to only relevant personnel. At time of intervention, patients will be randomly assigned ID numbers to keep track of therapy adherence and pertinent lab values.

37 Data Confidentiality and Security Plan

Confidentiality refers to the way private information about a participant or defined community is maintained and shared. *It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.*

In this section, describe whether any participant identifiers (e.g. names, contact info, etc.) will be collected during the conduct of the research and if identifiers will be linked to research data for <u>any</u> period of time. Include the following, as applicable:

- *If identifiers will be used for contact or compensation purposes only, and will <u>never</u> be linked to specific responses, describe the methods used to accomplish this.*
- *If identifiers will be coded/pseudonymized to protect confidentiality, describe whether or not a code key will be created linking study IDs/pseudonyms to identifiers, who will have access to the key, and how it will be stored separately from the research data.*

PHI anticipated to collect:

- ☐ Demographics: Age, gender, race and/or ethnicity, language
- ☐ Past medical history
- ☐ Past social history: smoking status and alcohol consumption
- ☐ Medications: current medications, current lipid-lowering and triglyceride-lowering medications (including statin, ezetimibe, PCSK9i, bempedoic acid, inclisiran, fibrate, icosapent ethyl, omega-3 fatty acids, niacin, bile acid sequestrants)
- ☐ Labs: Results of current/most recent lipid panels
- ☐ Social determinants of health
- ☐ Kept appointments with PCP and/or clinical pharmacist
- ☐ Notes from appointments with clinical pharmacist

☐ % days covered (if information available from EPIC Willow) for cholesterol lowering medications during the study period

At time of intervention, patients will be randomly assigned ID numbers to keep track of therapy adherence and pertinent lab values. All data will be filed and stored in a password protected, encrypted cloud software (UT Box) that restricts access to only relevant personnel.

A Electronic Materials - Storage and Access

In this section, select all methods that will be used to protect the confidentiality of research data.
At least one of the following must be checked, select all that apply.

☒ **Electronic data and records will be stored in UT Box, which is password-protected and HIPAA compliant. Access to data will be limited only to individuals who need access for purposes related directly to this research study. (Strongly recommended)**

☐ **Electronic data and records will be stored on another password-protected cloud service that is approved by UT Austin's Information Security Office (ISO). Access to data will be limited only to individuals who need access for purposes related directly to this research study.**

Guidance on UT Austin ISO approved platforms and security requirements is available here: https://security.utexas.edu/iso-policies/cloud-services/decision-matrix

☐ **Electronic data and records will be stored on a third-party cloud service/platform that is not currently approved for research data storage by UT Austin's Information Security Office (ISO).**

☐ **The PI attests that the service/platform will be submitted for security assessment by UT Austin ISO and if the ISO determines the platform is not acceptable to store research data, a modification will be submitted to the IRB to update the protocol.**

☐ **Other method(s) of storing and limiting access to electronic data and records, describe in the text box below:**

Examples might include use of a platform approved by a collaborating institution, use of non-cloud-based electronic storage methods (e.g. hard drive), etc.

B Physical Materials – Storage and Access

One of the following must be checked.

☐ **Physical data/records/specimens (e.g. Signed research consent forms, paper surveys/notes, physical recordings, samples etc.) will be stored in a secure location with access limited only to authorized study personnel at all times.**

☒ **N/A – no physical materials**

38 Research Records Retention Attestation

Confirm that research records will be maintained in compliance with all relevant records retention policies.

UT Austin's research record retention policy requires that data and copies of relevant study documents (e.g. consent forms, protocol, recruitment materials, etc.) be maintained for at least 3 years. Note that researchers are NOT required to maintain identifiers linked to data for 3 years. To protect confidentiality, identifiers can be unlinked from study data and destroyed as soon as feasible (described in the next section). UT Austin's records retention policies are available here: https://records.utexas.edu/utrrs

Some research may be subject to other retention policies that require longer retention periods and retention of other specific data or materials (e.g. collaborating institutions, funding agencies or sponsors, FDA, HIPAA, etc.). For example, studies that involve use of protected health information (PHI) covered by HIPAA must retain all relevant records for at least 6 years.

Check the box below to acknowledge the above information and confirm the study team will comply with UT Austin's policy as well as any other records retention policies that apply to this research.

This box must be checked.

☒ **Confirm**

39 Destruction of Identifiable Information

One of the following must be checked.

A ☒ **Identifiable information will be destroyed.**

If checked, describe at what point in the research process identifiable information about participants will be destroyed (e.g. after data collection is complete, after the study is completed, etc.).
If identifiable information is never obtained during the conduct of the study, check this box and note "NA" below.

PHI will be destroyed at least 6 years after the study is completed. Identifiers will be unlinked from the study data and deleted from the UT Box folder after data collection completion. Participants will be randomly assigned ID numbers to keep track of therapy adherence and pertinent lab values. Consent forms will be kept in the password protected UT Box folder for three years following completion of the study, then the entire folder will be deleted.

B ☐ **Identifiable information will not be destroyed.**

If checked, explain the rationale for retaining identifiers indefinitely and specify if identifiers will remain linked to research data (either directly or indirectly via a code key).

ii

40 Data Sharing and Future Use

Check the box below that best describes your plans for use and sharing of data beyond the scope of the current research. You are strongly encouraged to consider the broadest possible future plans you might have. ***One of the following must be checked.***

A ☒ **There are no plans to use or share data/specimens for other research purposes not related to this study.**

B ☐ **Data/specimens may be shared with other researchers or banked for future research purposes not related to the current research.**

i **Describe data sharing plan/future use and state whether researchers plan on sharing/banking identifiable, coded, or anonymized data.**

To input text, click in the light grey area below. Ensure that data sharing and future use is addressed in the consent form(s).

NOTE: *If private, identifiable research data will be banked indefinitely for future, unspecified research by this study team or other researchers, then the study involves a registry. Registry information should be included in the consent form(s) when applicable, and you must complete HRP-UT910 - Template IRB Supplemental Form Registry-Repository. Download HRP-UT910 from UTRMS-IRB Library Templates*

41 Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.
If a Certificate of Confidentiality is not applicable for this study, skip this section.

A ☐ **NIH has issued a Certificate of Confidentiality for this study.**

Ensure CoC language is included in the consent form(s).

B ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

Ensure appropriate CoC language is included in consent form(s). Apply for a CoC for non-NIH funded research here: NIH Certificate of Confidentiality System. Once CoC is granted by NIH, you must update the consent form language and ensure a copy of the CoC approval (only for non-NIH funded research) is uploaded to UTRMS-IRB.

COMPENSATION AND COSTS

42 Compensation

Click on the check box (or double click and type an "X" if using Google Docs). A or B must be checked.

A ☐ **Subjects receive compensation.**

i ☐ **Confirm: Amount of compensation and its form is reasonable for this population for the activities requested of them.**

ii Total Amount of Compensation

Include the total amount of compensation below.

iii Type of Compensation

☐ **Cash** ☐ **Check** ☐ **Gift Card**

☐ **Course Credit** ☐ **ClinCard** ☐ **Tango Card**

☐ **Other**

Describe other form of compensation below.

iv Proration Schedule

Describe the proration schedule for multi-visit/session studies. Skip if not applicable.

B ☒ **Subjects will not receive compensation.**

43 Costs

A or B must be checked.

A ☐ **Participants will have no costs associated with this study**

B ☒ **Participants will have the following costs associated with this study.**

☒ **Standard of care procedures contributing to study data**

☐ **Research procedures not associated with standard of care**

☐ **Administration of drugs / devices**

☐ **Study drugs or devices**

☐ **Transportation and parking**

i **Describe all costs below.**

To input text, click in the light grey area below.

Cost of standard of care clinic visits and medications depends on insurance/health plan coverage

CONFLICTS OF INTEREST

*This section is **required** for all studies. Please confirm that all research personnel who meet the definition of "covered individuals" are designated as such in the* Local Study Team Members *section of the SmartForm application in UTRMS-IRB.*

44 **Financial Conflicts of Interest**

Financial interest includes utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project. Additional guidance on financial conflicts of interest is available on the COI website

A or B must be checked.

A ☐ **The PI and/or other covered individual(s) has/have a financial interest related to this study**

i **If A is checked above, please provide the name(s) of the covered individuals involved, and briefly describe the interest:**

To input text, click in the light grey area below.

B ☒ **To the best of your knowledge, no one on the study team has financial interest related to this study**

45 Non-financial Conflicts of Interest

Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity,
- equity or business ownership in a company that has yet to make a profit and is related to this project,
- conflict of time/effort,
- personal and professional relationships/affiliations,
- intellectual passions or personal beliefs
- other factors that could create bias in the study

A or B must be checked.

A ☒ **The PI and/or other covered individual(s) has/have a non-financial interest related to this study**

i **If A is checked above, please provide the name(s) of the covered individuals involved, and briefly describe the interest:**

To input text, click in the light grey area below.

Investigators of this study are employed or hold clinical practice at the study site:
Morgan Stewart - CommUnityCare
Kathryn Litten - CommUnityCare

B ☐ **To the best of your knowledge, no one on the study team has non-financial interest related to this study**