Title of Protocol:

PI and Study Team Members:

Reviewer(s):

Type of Support (check all that apply):

- CCTR/CTSA
- INTERNAL VCU
- NIH/FEDERAL
- INDUSTRY
- OTHER

- □ Pilot/CCTR Endowment
- □ K Award
- □ T Award
- □ Other CCTR Funding
- □ Departmental/ School Funds
- □ Presidential Research Quest (PeRQ)
- □ Other internal pilots
- □ NIH/Singel Center
- □ NIH/Multicenter (VCU is the main Site)
- □ NIH/Multicenter (VCU is NOT the main Site)
- □ DOD
- □ FDA
- □ Other Federal Support

- □ NIH/Single Center
- □ NIH/Multicenter (VCU is the main Site)
- □ NIH/Multicenter (VCU is NOT the main Site)
- □ DOD
- □ FDA
- □ Other Federal Support

- □ Industry
- □ Hybrid Industry (PI Initiated/ Industry assisting)
- □ Other industry Support

- □ Not Funded
- □ Funding Pending
- □ Foundation
- □ Private
- □ Other Support

The study (check all that apply):

- □ Funder completed a scientific, peer review of the protocol
- □ Funder DID NOT complete a scientific, peer review of the protocol
- □ Massey competed a scientific peer review of the protocol
- □ Will be required to register with clinicaltrials.gov

- □ This is a student or trainee project in which activities will be carried out by that individual under PI supervision

- □ Has a community partner

To which IRB is this being submitted?

- □ VCU IRB
- □ Western IRB
- □ NCI Central
- □ Other IRB

- □ Exempt
- □ Expedited
- □ Clinical Investigation (Indicate phase)
- □ Exception From Informed Consent for Planned Emergency Research
- □ Emergency Use of Investigational Drug, Biologic or Device
- □ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
- □ Center or Institute Administrative Grant Review

This box will be filled out by the SRC Executive Director or designee before assigned to reviewers

1. **OBJECTIVES**: Clearly stated specific aims and hypothesis.

   - □ Present/Acceptable
   - □ Present/Not Acceptable
   - □ Absent
   - □ Not Applicable

   Comments:

   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________
2. **SCIENTIFIC MERIT/BACKGROUND AND RATIONALE:** Justification for conducting the study; results of similar or pilot data; current literature cited.

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

3. **DESIGN:** Clearly describes: how stated objectives will be achieved, identification of how the methods to acquire research data align with standard of care data collection, strategies identified to overcome anticipated barriers. Addresses randomization, minimization of bias, patient follow-up, and blinding (if applicable).

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

4. **POPULATION STUDIED:** Scientific justification provided for including or not including vulnerable and limited or non-English speaking participants.

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

5. **ELIGIBILITY CRITERIA:** Specific Inclusion/Exclusion requirements and stratification factors (if applicable).

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

6. **OUTCOME CHARACTERISTICS AND ENDPOINT DEFINITIONS:** Clearly defined primary and secondary endpoint/outcomes.

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:
7. **STATISTICAL ANALYSIS AND SAMPLE SIZE:** (The SRC statistician will also be contributing to this topic) Appropriate and adequate study design statistical analysis plan. Prospective analysis plan, including sample size justification to achieve study objectives and plans to minimize missing data.

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

________________________________________________________________________________________

8. **DATA AND SAFETY MONITORING PLAN:** Appropriate DSMP and oversight (EX: DSMB, external auditing) in place as appropriate for the study related risks. Study related risks have been minimized.

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

________________________________________________________________________________________

9. **DATA MANAGEMENT:** Practices and procedures in order to manage data analysis, quality, cleaning and storage.

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

________________________________________________________________________________________

10. **PRINCIPAL INVESTIGATOR AND STUDY SITE QUALIFICATIONS AND RESOURCES:** Has the necessary skills, experience and reasonable study recruitment plan to ensure that the study may be successfully completed, including the identification of personnel to provide statistical computations and statistical expertise. PI time and resources will be determined/evaluated by the division or department chair.

- Present/Acceptable
- Present/Not Acceptable
- Absent
- Not Applicable

Comments:

________________________________________________________________________________________

**Overall Assessment:** The protocol was assigned to the (date and time) SCR meeting and the following consensus was reached

- Forward to the IRB for consideration (fully accepted/no changes)
- Forward to the IRB for consideration (accepted with minor changes)
- Return to PI with comments (PI required response)
- Return to PI with recommendations (PI response/face-to-face meeting with core member, CCTR Research Innovator, or reviewer is required)
Summary: The communication to the IRB and the PI should include the following:

___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________

How long did it take for the primary reviewer to complete the review?

How long did it take for the secondary reviewer to complete the review?

How long did it take for the SRC to complete the review and arrive at a consensus?

This box will be filled out by the SRC Executive Director or designee AFTER the SRC meeting.