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| **Protocol Information** |
| **PI:**       | Department/Division/Center:       |
| **Study Title:**      |
| Review Committee:       | # Members Present:  | Date of Review:       |
| Scientific Review Committee Chair/Designee:       | [ ]  **Initial Review**  | [ ]  **Re- Submission** |  |
| **In performing the scientific review, the Scientific Review Committee will consider:*** the quality, originality, and importance of the scientific hypothesis;
* the scientific and statistical validity of the study design;
* the resources required to complete the study; and
* the relationship of the study to other studies within and outside the CHOP to avoid inappropriate duplication.
* the feasibility of the study
 |
| **Review Criteria** |
| **Background and Rationale** |
| [ ]  Yes [ ]  No | 1. Has an appropriate literature search been performed such that the rationale for the study has been adequately presented?
 |
| [ ]  Yes [ ]  No | 1. Are there adequate preliminary data in the literature (or from the investigator) to justify the research?
 |
| [ ]  Yes [ ]  No | 1. Are the study objectives and hypotheses appropriate and clearly stated?
 |
| [ ]  Yes [ ]  No | 1. Are there other studies being conducted to address the proposed primary aims? (describe below)
 |
| **If “No” to any of the above (or “Yes” to #4), changes required to address the issue**:       |
| **Study Design** |
| [ ]  Yes [ ]  No | 1. Is the study design appropriate to achieve the objectives?
 |
| [ ]  Yes [ ]  No  | 1. Is the study design (e.g. longitudinal or cross-sectional, cohort or case control, a randomized controlled trial, etc.) clearly presented?
 |
| [ ]  Yes [ ]  No | 1. Are the inclusion and exclusion criteria complete and appropriate for all subject groups?
 |
| [ ]  Yes [ ]  No | 1. Are the study endpoints (outcomes) identified and appropriate?
 |
| [ ]  Yes [ ]  No | 1. Are all of the study measures listed and all measurement tools included?
 |
| [ ]  Yes [ ]  No | 1. Is an appropriate sample size justification provided, including power calculations (when appropriate)?
 |
| [ ]  Yes [ ]  No  | 1. Is the analytic plan adequate, addressing the study hypotheses and all proposed statistical tests and approaches to data analysis?
 |
| **If “No” to any of the above, changes required to address the issue**:       |

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| **Study Procedures** |
| [ ]  Yes [ ]  No | 1. Are study procedures clearly identified?
 |
| **If “No” to any of the above, changes required to address the issue**:       |
| **Investigator and Resources** |
| [ ]  Yes [ ]  No | 1. Are the individuals who are conducting the trial properly qualified and trained to perform the procedures as required in the protocol?
 |
| [ ]  Yes [ ]  No | 1. Does the investigator have access to an adequate number of subjects in the target population to complete the study in the proposed time period?
 |
| [ ]  Yes [ ]  No | 1. Are there existing studies that are targeting the same population? Describe below
 |
| **If “No” to any of the above or “Yes” to question #3, changes required to address the issue**:       |
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| **Scientific Committee Assessment** |
| **Overall Assessment (check one of the following)** |
| [ ]  This protocol is acceptable in its present format. |
| [ ]  This protocol is acceptable, pending clarifications and modifications as listed below. The Investigators should submit this form and the response to the scientific review in a cover letter with the IRB submission |
| [ ]  This protocol is NOT acceptable as currently written for the reasons stated below.The investigators should submit a written response and revised protocol to this Scientific Review Committee |
| **Committee Comments:**       |

[ ]  The Scientific Review Committee would like a copy of the IRB stipulations after the initial review.