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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.