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| **Protocol Information** | |
| **IRB #:**  **Title:** | |
| **IRB of Record:** | **FWA Institution:** |
| **IRB Analyst:** | **Date of Analyst Review:** |
| **IRB Reviewer:** | |
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| **Summary of the Proposed Research:** |
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| **Directions:** When completing the sections below, if all suggested considerations are acceptable, check YES. Otherwise, indicate the items that are problematic. Describe the issue(s) in a comment box or in Requested Modifications at the end. |

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| **Submission is complete and provides evidence of substantive outside IRB review** | | |
| Yes | **The following items from the primary site have been submitted and are complete.** | |
|  | IRB Approval letter from the IRB of record | |
|  | Multi-center protocol | |
|  | IRB-approved consent documents(s) indicating both CHOP and IRB of record | |
|  | Signed and properly executed Cooperative Agreement with the proposed IRB of record | |
| Yes | **The research underwent substantive review and is approved under the correct criteria** | |
|  | Research does not meet criteria under 45 CFR 46.111(a) or 21 CFR 50.111(a) [Subpart A] | |
|  | Research fails to meet or determination incorrect for Subpart B, C or D | |
|  | Consent Form/Authorization does not contain all of the required elements of §46.116 /§50.25 or 45 CFR 164.512 | |
|  | Plan for obtaining or documenting assent does not meet the criteria of §46.408 and §50.55 | |
| Yes | **The following information in the eIRB application are complete and acceptable** | |
|  | All members of the CHOP investigative team have appropriate credentials and CITI training | |
|  | Financial COI statements for all CHOP investigators | |
|  | Description of CHOP recruitment plan (if applicable) | |
|  | Recruitment materials meet the requirements of CHOP SOP 703 (if applicable) | |
| **Approval, Modification or Disapproval** | | |
| **Accept Outside IRB as IRB of Record** – evidence of substantive review and all determinations appear appropriate  **Request Clarifications** – Information from Primary Site or IRB deficient in one or more areas (see above)  **Request Modifications** – CHOP eIRB application incomplete or requires revision  **Decline Cooperative Agreement**– The submission fails to meet one or more of the regulatory *Criteria for Approval* | | |
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| **IRB Reviewer Name/Signature:** | | **Date:** |

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| **Required Modifications** (if any) | **Addressed (Y/N)** |
| **eIRB Application** | Yes  No  N/A |

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| **Protocol:** | Yes  No  N/A |

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| **Consent Form:** | Yes  No  N/A |

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| **Other:** | Yes  No  N/A |

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| **Recommendations after Review of Modifications** | |
| Accept Outside IRB as IRB of Record – All stipulations addressed | Additional Modifications Required  Decline to enter Cooperative Agreement |
| **IRB Reviewer Signature:** | **Date:** |