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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:**        |