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| **#** | **Inclusion Criteria**  | **Criterion Met?****All Must be “Yes”** | **Supporting Documentation\*** | **Comments** |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |

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|  **#** | **Exclusion Criteria** | **Criterion Met?****All Must be “No”** | **Supporting Documentation\*** | **Comments** |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |
|  | Copy from FDA/IRB Approved Protocol | Yes [ ]   | No [ ]  |  |  |

*\*All subject files must include supporting documentation to confirm eligibility. The method of confirmation can include, but is not limited to, laboratory test results, radiology test results, subject self-report, and medical records.*

**STATEMENT OF ELIGIBILITY** (based on review of above listed inclusion/exclusion study criteria)

Subject is: [ ]  Eligible [ ]  Not Eligible

Form completed by:

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Printed Name Signature Date

Eligibility confirmed by:

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 Physician Investigator’s Printed Name Physician Investigator’s Signature Date