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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 |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **#** | **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