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| **SUBJECT ELIGIBILITY CRITERIA CHECKLIST** |

**Study Information**

|  |  |
| --- | --- |
| Protocol Title: |  |
| Protocol Number/Version: |  |
| Principal Investigator: |  |

**Subject Information:**

|  |  |
| --- | --- |
| Subject Name/ID: |  |
| Gender:  | [ ]  Male [ ]  Female |

Inclusion/Exclusion Criteria

|  |  |  |  |
| --- | --- | --- | --- |
| **Inclusion Criteria***(From IRB approved protocol)* | **Yes** | **No** | Supporting Documentation\* |
| 1.
 | [ ]  | [ ]  |       |
| 1.
 | [ ]  | [ ]  |       |
| 1.
 | [ ]  | [ ]  |       |
| 1.
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| 1.
 | [ ]  | [ ]  |       |
| **Exclusion Criteria***(From IRB approved protocol)* |  |
| 1.
 | [ ]  | [ ]  |       |
| 1.
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| 1.
 | [ ]  | [ ]  |       |

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

**Person completing form:**

|  |  |
| --- | --- |
| Signature: | Date: |
| Printed Name: |

**Confirmation of Eligibility (to be completed by a PI or Sub-Investigator)**

I have reviewed all relevant source documents and confirm this subject is:

 [ ] **Eligible** / [ ]  **Ineligible** for participation in the study.

|  |  |
| --- | --- |
| Signature: | Date: |
| Printed Name: |