**Subject Eligibility Criteria Checklist**

All subjects enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the application and approved by the IRB.

**I. Study Information**

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| **Protocol Title:** |  |
| **IRB #:** |  |
| **Principal Investigator:** |  |
| **Sponsor:** |  |

**II. Subject Information:**

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| --- | --- |
| **Subject Initials/ID:** |  |
| Gender:  Male  Female | |

III. Inclusion/Exclusion Criteria

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

IV. Statement of Eligibility

This subject is **[** **eligible** /  **ineligible**]for participation in the study.

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

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