**Screening and Enrollment Log**

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| **Study Title:** | **Investigator Name:** |

***\*Any participant who signs a consent form is considered enrolled regardless of whether they are screen failures.***

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening** | | | | | | **Enrollment\*** | | **Study Completion** | |  |
| **#** | **Screen Date** | **ID#** | **Gender** | **Race/ Ethnicitya** | **Screen Failure Reasonb** | **Consented by** | **Date Consent Form Signed** | **Date of Study Completion or Early Withdrawal** | **Reason for Withdrawalc** | **Comments** |
| 1 |  |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |  |  |

1. **Ethnic Origin:** 1. American Indian/Alaskan 2. Asian 3. Black/African 4. Hispanic/Latino 5. Native Hawaiian/Pacific 6. White/Caucasian 7. Other/Unknown
2. **Screen Failures:** 1. Did not meet inclusion/exclusion criteria 2. Participant withdrew consent during screening 3. Other (Specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. **Reason for Withdrawal:** 1. Participant Request 2. AE/SAE 3. Lost to Follow-up 4. Protocol non-compliance 5. Death 6. Other (Specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_