# Inclusion/Exclusion Criteria

**STUDY NAME:**

**Site Number:**_____

**Visit Date:** _____ / _____ / _____
dd        mmm        yyyy

**Pt_ID:**_____

**Visit Type (check one):** ☐ **Screening**          ☐ **Baseline**

## Inclusion Criteria

*Participant must:*

1. Inclusion 1 description — ☐Yes  ☐No
2. Inclusion 2 description — ☐Yes  ☐No
3. Inclusion 3 description — ☐Yes  ☐No
4. Inclusion 4 description — ☐Yes  ☐No
5. Inclusion 5 description — ☐Yes  ☐No
6. Inclusion 6 description — ☐Yes  ☐No

Note: All Inclusion Criteria must be answered YES, to be included in study.

## Exclusion Criteria

*Participant must not:*

1. Exclusion 1 description — ☐Yes  ☐No
2. Exclusion 2 description — ☐Yes  ☐No
3. Exclusion 3 description — ☐Yes  ☐No
4. Exclusion 4 description — ☐Yes  ☐No
5. Exclusion 5 description — ☐Yes  ☐No
6. Exclusion 6 description — ☐Yes  ☐No

Note: All Exclusion Criteria must be answered NO, to be included in study.

Did the participant meet the eligibility requirements for this study?     ☐ Yes     ☐ No

Investigator Signature:_____     _____ / _____ / _____
dd        mmm        yyyy