# Inclusion/Exclusion Worksheet

|  |  |
| --- | --- |
| Protocol Number: | Qualified Investigator/Principal Investigator: |
| Site Number/Name: | Product: |

|  |  |
| --- | --- |
| Participant ID: | Visit Date: |
| Visit type (e.g. screening, baseline): |

## Inclusion Criteria

 *Participant must:*

|  |  |  |
| --- | --- | --- |
| 1. Inclusion 1 description
 | [ ] Yes | [ ] No |
| 1. Inclusion 2 description
 | [ ] Yes | [ ] No |
| 1. Inclusion 3 description
 | [ ] Yes | [ ] No |
| 1. Inclusion 4 description
 | [ ] Yes | [ ] No |
| 1. Inclusion 5 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 |
| 1. Exclusion 2 description
 | [ ] Yes | [ ] No |
| 1. Exclusion 3 description
 | [ ] Yes | [ ] No |
| 1. Exclusion 4 description
 | [ ] Yes | [ ] No |
| 1. Exclusion 5 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

Was the participant enrolled? [ ]  Yes [ ]  No

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Investigator Signature |  | Date (dd/mmm/yyyy) |