**[Inclusion and Exclusion Criteria to be listed here]**

Is the participant/subject eligible for study enrollment based on the above criteria? \*

[ ] Yes

[ ] No

**If no, specify:** Inclusion Criterion Number(s):

and/or Exclusion Criterion Number(s):

*\**Element is classified as Core

## General Instructions

The study inclusion and exclusion criteria specify the characteristics of potential study participants/subjects that must be met prior to enrollment. Criteria may specify the appropriate age range, symptoms, disease area, etc. Additionally, circumstances that may hamper adherence to the protocol may also be listed in the inclusion and exclusion criteria (e.g., patient has another life-threatening disease or does not understand English.)

All Inclusion Criteria must be answered YES and all Exclusion Criteria must be answered NO or N/A in order for the participant/subject to be considered eligible for study participation.

Data system edit checks may need to be implemented on a study by study basis for situations where participants/subjects do not meet the eligibility criteria, but are still enrolled in the study.

Important note: One of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). The remaining data elements are supplemental and should be collected only if the research team considers them appropriate for their study.

## Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

* **Is the participants/subject eligible for study enrollment based on the above criteria?** - The participants/subject is eligible for study enrollment if all the inclusion criteria are answered YES and all the exclusion criteria are answered NO or N/A.
* **Inclusion Criterion Number(s)** - Enter the number(s) for the inclusion criterion/criteria the participant/subject did not meet. Multiple numbers should be separated by a comma.
* **Exclusion Criterion Number(s)** - Enter the number(s) for the exclusion criterion/criteria the participant/subject did not meet. Multiple numbers should be separated by a comma.