**ClinicalTrials.gov Database Requirements**

**Investigational Study Design Supplemental Questions**

**Study Design**

*Primary Purpose:* [Select one]

Treatment / Prevention / Diagnostic / Supportive Care / Screening / Health Services Research / Basic Science / Device Feasibility / Other

*Study Phase:* [Select one]

N/A / Early Phase 1 / Phase 1 / Phase 1 and 2 / Phase 2 / Phase 2 and 3 / Phase 3 / Phase 4

*Interventional Study Model:* [Select one]

Single Group / Parallel / Crossover / Factorial / Sequential

*Model Description:*

*Number of Arms:*

*Masking:* [Select all that apply]

Participant / Care Provider / Investigator / Outcomes Assessor / None (Open Label)

*Masking Description:*

*Allocation (select N/A for single-arm studies):* [Select one] N/A / Randomize / Non-Randomized

*Enrollment:* #\_\_\_ [Select one] Anticipated / Actual

**Arms and Interventions**

 *Arms:*

 *Arm Title:*

 *Arm Type:* [Select one]

Experimental / Active Comparator / Placebo Comparator / Sham Comparator / No intervention / Other

*Arm Description:*

*Add any additional arms by repeating the information above.*

 *Interventions*

 *Intervention Type:* [Select One]

Drug / Device / Biological/Vaccine / Procedure/Surgery / Radiation / Behavioral / Dietary Supplement / / Genetic / Combination Product / Diagnostic Test / Other

 *Intervention Name:*

 *Other Intervention Names (if any):*

 *Intervention Description:*

 *Add any additional arms by repeating the information above.*