***Example #1 Flow Diagram*** *(e.g., randomized controlled trial)*

Total N: 120

Pre-screen potential participants by inclusion and exclusion criteria; schedule Visit 1.

Pre-Screening

<Time Point,

e.g., Day -30 to

Day 1>

Conduct informed consent process. Perform baseline assessments.

<list procedures, examinations or imaging or laboratory tests, or physical/cognitive assessments to be performed, questionnaires to be completed OR refer to **Section 1.3, Schedule of Activities**>

Visit 1

<Time Point,

e.g., Day 1>

Randomize

Visit 2

Administer study intervention Session 1

<Time Point,

e.g., Day 14 ± 7>

Visit 3

Administer study intervention Session 2 (*if applicable*)

<Time Point,

e.g., Day 28 ± 7>

Visit 4

Administer study intervention Session 3 (*if applicable*)

<Time Point,

e.g., Day 42 ± 7>

Post-Intervention assessments

Visit 5

<Time Point,

e.g., Day 56 ± 7>

**Final Assessments**

<list analyses to be performed OR refer to **Section 1.3, Schedule of Activities**>

Visit 6

<Time Point,

e.g., Day 365 ± 30>