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

Prior to

Total N: Obtain informed consent. Screen potential participants by inclusion and exclusion criteria; obtain history, document.

Enrollment

Randomize

Perform baseline assessments.

<list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 1.3, Schedule of Activities**>

Administer initial study intervention.

Visit 1

Time Point

Repeat study intervention (*if applicable*).

Visit 2

Time Point

Follow-up assessments of study endpoints and safety

<list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 1.3, Schedule of Activities**>

Visit 3

Time Point

Follow-up assessments of study endpoints and safety

<list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 1.3, Schedule of Activities**>

Visit 4

Time Point

**Final Assessments**

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

Visit X

Time Point