

SCHEMATIC OF STUDY DESIGN

*This section should include a diagram that provides a quick “snapshot” of the study and ideally be limited to 1 page. Below are examples of schematics that show the level of detail needed to convey an overview of study design. Depending on the nature of your study, one example may be more appropriate than another. Regardless, the examples included here are intended to guide the development of a schematic that is appropriate to the planned study design and will need to be customized for the protocol. If you utilize Example 1, complete the tables with study-specific information and adapt the table(s) to illustrate your study design. If you utilize Example 2, 3, or 4, revise with study-specific information and adapt the diagram to illustrate your study design (e.g., changing method of assignment to study group, adding study arms, visits, etc.). The time point(s) indicated in the schematic should correspond to the time point(s) in **Section 7.3, Study Schedule**, e.g., Visit 1, Day 0; Visit 2, Day 30 ± 7; etc.*

Example #1 provided as a guide, customize as needed: Table format (e.g., dose escalation)

Cohort A	ARM 1	Sample Size	Intervention 1
Cohort A	ARM 2	Sample Size	Intervention 2

Include instructions for progressing to next phase (if applicable):

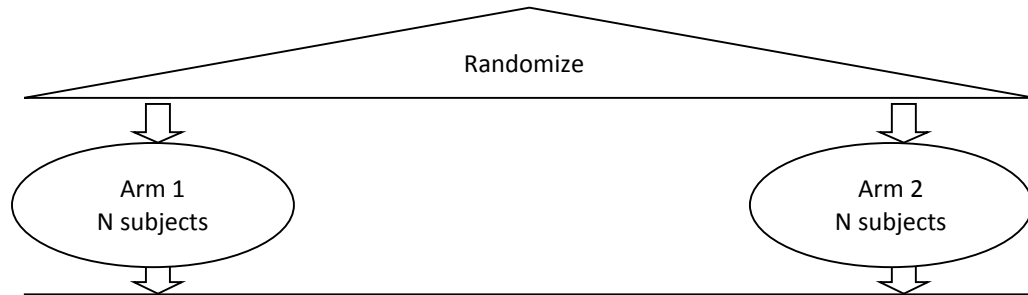
Interim Analysis

Cohort B	ARM 1	Sample Size	Intervention 1
Cohort B	ARM 2	Sample Size	Intervention 2

Example #2 provided as a guide, customize as needed: Flow diagram (e.g., randomized controlled trial)

Prior to Enrollment

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



Visit 1
Time Point

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 7.3.7, Schedule of Events Table**>
Administer initial study intervention.

Visit 2
Time Point

Repeat study intervention (*if applicable*).

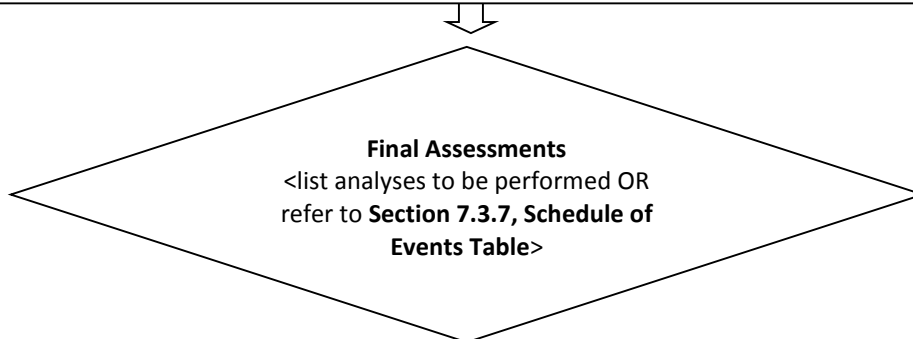
Visit 3
Time Point

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 7.3.7, Schedule of Events Table**>

Visit 4
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 7.3.7, Schedule of Events Table**>

Visit X
Time Point



Example #3 provided as a guide, customize as needed: Process diagram (e.g., randomized controlled trial)

Week/Day (Insert time) Screening

- Total n=x
- Obtain informed consent
- Screen potential subjects by inclusion and exclusion criteria
- Obtain history, document

Week/Day (Insert time) Randomization

- Treatment Group 1 (n=y)
- Placebo (n=z)

Week/Day (Insert time) Baseline assessments/ Study Intervention

- <List specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 7.3.7, Schedule of Events Table**>
- Administer initial study intervention

Week/Day (Insert time) 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 7.3.7, Schedule of Events Table**>

Week/Day (Insert time) 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 7.3.7, Schedule of Events Table**>

Week/Day (Insert time) End of Study Assessments

- <List specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 7.3.7, Schedule of Events Table**>

Week/Day (Insert time) Follow-up Telephone Call

- <List questionnaires to be completed OR refer to **Section 7.3.7, Schedule of Events Table**>

Example #4 provided as a guide, customize as needed: Timeline diagram (e.g., randomized controlled trial)

