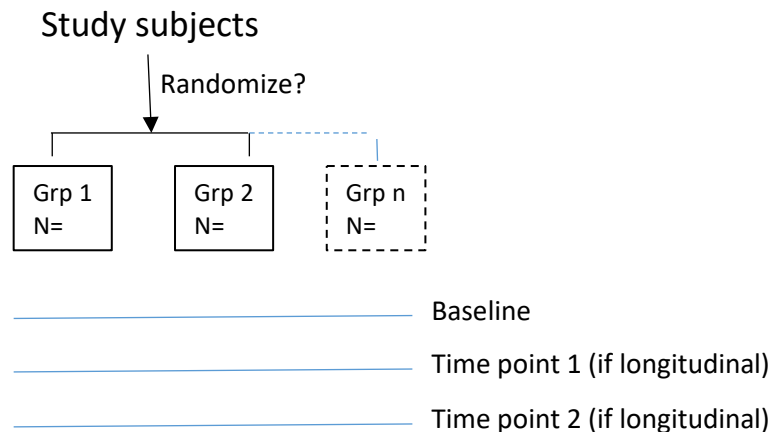


## For getting statistical help with mechanistic study grant

Please consider/prepare the elements below to facilitate the communication for statistical needs.

- 1) A simple study design diagram.



- 2) Make a list of all outcomes/measurements to be studied. Get an estimate of effect sizes (expected changes) and their associated standard deviations backed up either by preliminary data or literature.
  - a. Major outcome/measurement to be studied (one), for determining the sample size of the study.
  - b. Secondary outcomes/measurements to be studied. Not used for determining sample size but sometimes need estimated power given the sample size.
  - c. Exploratory outcome/measurements for preparing future studies (optional)
- 3) Hypothesis/comparisons
  - a. Primary comparison for the major outcome/measurement is for determining the sample size.
  - b. If you have more than one primary comparisons for the primary outcome/measurement, multiple testing is often considered, which reduces power or increases the sample size.
  - c. Comparisons for secondary outcomes/measurements are often in secondary analyses.
- 4) Covariates

List your covariates for each comparison, such as Age, sex, race, etc.

Special attention to:

- 1) Is there a maximum sample size you can realistically handle?
- 2) Is there a clinically significant effect size for your primary outcome?
- 3) Attrition rate.

- 4) Is the study a randomized intervention trial type of study? If yes, stratified randomization? If not randomized trial, will the arms be balanced regarding sample size and baseline characteristics?

(All need to be backed up by literature or preliminary results.)