

UCSF Clinical Trials Course (EPI 205) - Protocol Assignment #2

Please continue to revise the parts of your protocol from Section I. Include the following sections of your protocol in this next assignment (max of 4 pages total, single spaced).

Reminder: email your protocol assignment to your assigned Section Leader **by 12 noon on Monday, February 13, 2017**.

Also bring this protocol assignment to your second Section Meeting on Thursday, February 16, 2017 from 8:45am to 10:15am. It is important to be on time. Notify your Section Leader in advance if you will miss a Section Meeting.

1. Study name

2. Research question(s)

- *Optional: background summary*

3. Type of randomized trial design

- Include, at minimum: (1) trial type (e.g., placebo-controlled, cross-over, factorial, etc.), (2) randomization type, (3) blinding, (4) length of follow-up, (5) timepoints of f/u study visits (e.g., randomization visit, month 1, month 3, etc.), and (6) single site or multicenter
- *Optional: # of sites and trial phase*

4. Subjects

- Include, at minimum: (1) target and accessible populations and (2) inclusion/exclusion criteria
- *Optional: sample size*

5. Outcome measures

- Include, at minimum: (1) primary efficacy/effectiveness objective(s) and primary safety objective(s) (as applicable) and (2) methods of data collection
- *Optional: methods and/or outline of the secondary/exploratory endpoints*

6. Control group(s)

- Clear definition and methods/details

7. Intervention group(s)

- Clear definition and methods/details

8. Methods for randomization and blinding

- Include, at minimum: (1) how randomization will be performed and (2) who will be blinded and how that will be done

9. Methods for maximizing adherence

- Include, at minimum: methods for maximizing adherence to the intervention(s) and control(s), as applicable
- *Optional: methods for maximizing study retention and study visit compliance (i.e., minimizing missed visits and lost to follow-up)*

10. *Optional: other details you think are important*