UCSF Clinical Trials Course (EPI 205) - Protocol Assignment #3

Please continue to revise the parts of your protocol from Section 2. Include the following sections of your protocol in this next assignment (max of 6-7 pages total, single spaced).

Reminder: email your protocol assignment to your assigned Section Leader **by 12 noon on Monday, March 6, 2017.**

Bring this protocol assignment to your third Section Meeting on Thursday, March 9, 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. Adverse event and side effect measures

11. Plans for interim monitoring

12. List one or two ethical issues related to your protocol and how you plan to manage them.

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