**Methods in Clinical Cancer Research**

**Homework III**

**Due Date: Apr 23**

**1. Read the clinical trial that I will have sent you via email (note that it should be considered confidential and not distributed. As such, I will not be posting it on the class website).**

**2. Provide a review with the following points:**

1. Are the research questions well defined, including objective outcome measures? Will the data collected provide information to answer the research question?
2. Is the design of the study appropriate? Have issues relating to patient drop-out, ineligibility or patient screening been addressed, if applicable? Is the design supported by the preliminary studies and data presented?
3. Will the proposed data and analyses answer the primary and secondary aims of the study?
4. Is there an appropriate justification of sample size? For power calculations, is the effect size to be detected reasonable?
5. Are there appropriate early stopping rules/interim analysis plans for safety, futility and/or efficacy?

3. As applied statisticians, we are often asked to help colleagues understand statistical reasoning or approaches without requiring our colleagues to have an in-depth understanding the statistical and probabilistic principles underlying. In the current trial, the statistical plan involves **sample size re-estimation** and interim calculation of **conditional power (see section 12.2)**. Imagine that, at the trial review (i.e. in the committee meeting), one of your colleagues asks you to explain to him **(a) what conditional power means (and why would it be calculated), and (2) how/why the sample size is re-estimated.** **Using ‘lay person’ language (i.e. non-statistical language, beyond what you would expect a clinical colleague to understand, use 1 paragraph to explain this in words.** (recall that this would be in conversation at a meeting, so there is no opportunity to use tables or graphics).

As an aside: as applied statisticians, we are also tasked **quite often** with learning about methods we have never heard of. So, if you do not know anything about conditional power or sample size re-estimation in the midst of a trial, consider this a great opportunity to hone your skills at finding out more about new statistical methods on your own.