**Homework 3, CPH 675 Clinical Trials Spring 2015, Dr Melanie Bell**

**Due: 10 April 2015**

**Include only relevant code and output. Please do not show data manipulation code.**

1. [50pts] Read the CONSORT statement and the Henke paper. With two partners, go through the checklist, and briefly discuss how this paper did or did not comply with CONSORT reporting standards. Each group of 3 should turn in only one report. Failure to work with a group will result in a deduction of 25 points.

2. [8pts] Use the renal cancer dataset to investigate the whether the treatment effect (over time) on quality of life (as measured by the trial outcome index) depends on the baseline risk score (riskgrp; higher scores indicate greater risk). Use a mixed model, assuming a means model, random intercept and including the baseline TOI as an outcome. State your methods and your conclusion. You do *not* have to give an effect size and CI here.

3. [10pts] Use the renal dataset and appropriate contrasts to estimate the unadjusted treatment effect and 95% CI as measured by

a) the third time point. Compare to last homework’s estimates. Show the code for your model and contrast statement (estimate/lincom).

b) the average of the 3 post-baseline TOI assessments. SAS users may need to use the divisor option in the estimate statement.

4. [10pts] Use the renal cancer data to perform survival analysis. Note that the data is in long form, but for survival analysis it needs to be in wide form. Create a Kaplan-Meier survival graph and test whether the survival profiles are the same. Use months as your survival time unit and good graphing habits.

5. [4pts] Estimate the median survival time and 95% CI for each of the treatment groups.

6. [8pts] Use the Cox proportional hazards model to compare arms, while adjusting for risk group. Report results briefly, including an effect size for treatment and CI.

7. [10pts] Is there evidence of a difference in treatment on the survival effect based on risk group? Report the HRs and 95% CIs for treatment by risk group (based on one model).