Statistical Plan
Glucocorticoid Antagonist Treatment of Alcohol Use Disorder
From NIH Grant Application #AA023152
P.I. Barbara J Mason, Ph.D.
Submitted 2/7/2014

All analyses will be conducted in the intention-to-treat sample with $p<0.05$ for two-tailed tests of significance. Demographics and baseline measures will be examined for differences between treatment groups and tested individually for correlation with each outcome. Any baseline variable significantly associated with outcome or differing between treatment groups will be included in subsequent analyses as a covariate. Trend dose effects will be determined using single or multi parameter tests of Mixed Effect Model (MEM) effects, as required. All MEMs are repeated measures centered on the relevant time period. Time, treatment, and time x treatment will be evaluated as fixed effects in each model.

Mifepristone plasma concentration and baseline drinking levels were significant predictors of response in our Proof of Concept (POC) study and will be evaluated as predictors in the proposed study. Sex, age, age of onset and family history of alcoholism will be examined as covariates of response because of a potential association with cortisol in the case of the latter 3 variables and to assess differential treatment response for males and females, given mifepristone's antiprogesterone effects, and the trend for females to have better drinking outcome in our POC study. Motivation, e.g., to have abstinence as a treatment goal, will be examined as a non-specific predictor of treatment outcome. Potential pharmacogenetic predictors of response will be evaluated on an exploratory basis.