

TITLE OF PROJECT: PrEP, LUBE, AND THE RECTAL MUCOSA IN MSM AT RISK OF HIV
Emory IRB00077593
NCT02401230
PRINCIPAL INVESTIGATOR: Colleen F. Kelley, MD, MPH
19Jan2018

STATISTICAL ANALYSIS PLAN

Drug and dNTP concentrations were normalized to fmol/million cells and fmol/mg rectal tissue in blood and tissue, respectively. Detectable drug and dNTP concentrations as well as immune cell proportions were compared between the Truvada, Rectal Gel Lubricant and Rectal Gel Lubricant + Truvada study arms using a Wilcoxon Rank Sum Test. Left censoring was observed for drug concentration measurements below the limit of detection.