

**PI:** Salvatore Scali

**Study Title:** Short-Term Dietary Protein Restriction  
Modulation of Skeletal Muscle Bioenergetics and  
Innate Immunity

**IRB number:** IRB20190098

**NCT#:** NCT03995979

Statistical Analysis Plan: This will be performed in a blinded fashion (no patient identifiers) by the UF Surgery Department Statistical Support Group.

**Primary Analysis:**

Functional Enrichment Analysis using Qiagen Ingenuity Pathways Analysis; Absolute LogF<sub>c</sub> cutoff =0.4 to describe regulation of genes; False Detection Rate (FRD)<0.1

Gene Comparison at Baseline, Day 2, Day 4, and Day 7

**Variable of Interest:**

- a) Characterization of MAIT transcription response to stDR
- b) Gut microbial changes to stDR

**Additional Quantitative Analysis:** Conical Pathways and Identification of Regulators

**Conical Pathways:**

Fischer Exact Test with FDR corrected p-value overlap threshold<0.05; Qiagen software calculations for significant pathway inhibition (negative z score) or activation (positive Z score) with |Z score|>2.0.

**Identification of Regulators:**

Fischer Exact Test with FDR corrected p-value overlap threshold<0.01 for curated gene regulators relationships; Qiagen software calculations for significant pathway inhibition (negative z score) or activation (positive Z score) with |Z score|>2.0.