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SANTA BARBARA • SANTA CRUZ

DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA
CENTER FOR HUMAN NUTRITION
1000 VETERAN AVENUE, A-650 REHAB. BUILDING
BOX 951742
LOS ANGELES, CALIFORNIA 90095-1742
PHONE: (310) 206-1987
FAX: (310) 206-5264

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PRS Reviewer

Clinicaltrials.gov

To whom it may concern

Thank you for your review of (NCT03676803, IRB# 17-000617, approved August 11, 2017) study titled “Effect of Spice Consumption on the Microbiome in Healthy Subjects: A Pilot Study”, per your request, I am submitting the statistical analysis plan.

If possible, we would like to keep this documentation confidential.

Sincerely,

Zhaoping Li, MD, PhD
Professor of Medicine
UCLA Geffen School of Medicine
Chief, UCLA Center for Human Nutrition

Statistical Analysis Plan (IRB#17-000617)

Sample Size Justification: In the absence of a spice study, to estimate whether the proposed sample size has sufficient power to detect differences between the spices and placebo intervention, we utilized data from a published intervention using red wine, which is also high in polyphenols (2). The study design was a cross-over intervention study with 10 healthy volunteers. The wine intervention was associated with an increase in *Bifidobacteria* from 7.1 ±2.3 $\log^{10}$ copies/g feces (control) to 9.9±1.8 $\log^{10}$ copies/g feces (red wine) providing an effect size of 1.35. Based on that data with a sample size of 13 subjects per treatment arm we will have >90% power to detect an expected an increase in *Bifidobacteria* with administration of a high polyphenol food. We assume that there will be a 10% drop out rate for this study so we will randomize 15 subjects per dose group to obtain the required final number of 13 per group.

Statistical Analysis: The Statistics Core Unit of the UCLA Clinical Nutrition Research Unit at the UCLA Center for Human Nutrition will be responsible for the statistical data analysis. Analysis of variance (ANOVA) will be applied as a two-period crossover design using software SAS version 9.2 (Statistical Analysis System, Cary, NC), followed by application of the Student-Newman-Keuls Test.