Protocol Summary Paragraph

Study Title: *Impact of Emergency Department Probiotic Treatment of Pediatric Gastroenteritis (Probiotics Study)*

Study Protocol Version: *v3.0, dated February 13, 2017*

ClinicalTrials.gov URL: https://clinicaltrials.gov/ct2/show/NCT01773967

Study Type: Interventional (IND)

Study Period: July 2014 – August 2018

Enrollment: 971

Consent: Yes

Purpose: This was a prospective, randomized, double-blind trial involving children 3 months to 4 years of age with acute gastroenteritis who presented to one of 10 U.S. pediatric emergency departments. The purpose of this study was to provide definitive evidence for, or against, using probiotic therapy for acute gastroenteritis. Participants were randomized to receive either probiotic therapy (Lactobacillus rhamnosus GG, ATCC 53103 (LGG)) or placebo. Participants were followed-up with by phone daily until symptoms resolved. A follow-up phone call also occurred once treatment had completed, on day 5. Additional follow-up by phone occurred on day 14 for outcome assessment, and at 1, 3, 6, 9 and 12 months for long-term safety outcomes. The hypotheses of this study were as follows:

1. In children with acute gastroenteritis, probiotic administration in the emergency department will be associated with a clinically-important decrease in the proportion of children suffering from moderate-severe disease, defined by a validated Modified Vesikari Score ≥ 9, compared to placebo.
2. In children with acute gastroenteritis, probiotic administration will not be associated with serious adverse events, and will have a similar rate of side effects (e.g. bloating, fever) as compared to placebo-treated children.

Patient enrollment took place between July 2014 and July 2017 with last follow up procedures completed in August 2018. This project was funded by NICHD.