

Scott & White Hospital & Clinics Clinical Research at Scott & White

Study Title: The Effect of a Probiotic Containing Infant Formula on Local Markers of Immunity and Gut Health

Project ID#: 71232

Department: Pediatric Clinic in Temple and Killeen

Sponsor: Nestlé Infant Nutrition

1. Provide a brief synopsis of the study (purpose of the study from abstract, consent form, or protocol using lay terminology):

Condition(s):	Treatment(s):
Healthy Infant	No treatment. Evaluating effects of formula containing probiotics on markers of the baby's immune system.

This study is to evaluate the effects of a starter infant formula that contains a probiotic
(cultures of bacteria like those found in yogurt) on the different markers (indicators) of the
baby's immune system. The markers for this study can be found in the baby's stool. Two
formulas will be used in this study, both are available in stores.

2. Who is eligible to participate in the study (basic qualifications such as age, gender, etc.)?

Age: Healthy infants 2-6 weeks old

Formula fed or breastfed

Male or female

3. What may be involved/required for subject participation (visits, tests, and/or logs, etc.)?

The infant will be in the study until he/she is 12 weeks old (3 months). There will be 4 clinic
Visits and 3 phone calls from the study staff. You will be required to collect 3 stool samples
From your baby and write in a daily record for 2 days before visits 1 and 2. Your baby must
Also receive his/her routine 2 month vaccinations.

4. Contact Information:

Coordinator(s): Debra Wilsterman, Temple / Angela Hodgkinson, Killeen

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