

PREVAIL FAQs:

Will my baby be getting *new* vaccines?

This study is an observational study, so we will not be giving you or your baby any medications or vaccines for this study.

What if I don't want my baby to get any vaccines?

Since your baby will not be receiving any vaccines (shots) as part of this study, you should discuss your child's vaccines with his/her Pediatrician. Your child can still participate in this study even if you choose to not vaccinate your child.

What will happen if I forget to respond to a text? (Or, how often will I get text reminders?)

The text message for each week will be sent 3 times to remind you to complete the questionnaire. You will receive the text once a day for 3 days. If a questionnaire is not completed after the 3rd day, that week's questionnaire will no longer be available for completion.

What happens if the nurse is unable to collect my child's blood?

During this study, we would like to obtain a small amount (1 teaspoon) of your child's blood at various time points. Our nurses are well trained in infant and child blood draws and will make every effort to make you and your child comfortable during this process. If you are uncomfortable at any time, please let the nurses and study team know so we can discuss with you.

Will I have results of the study?

Once the study results have been analyzed and published, anyone will be able to find out the study results.

Will I receive results from samples collected?

Since the lab analyzing you and your child's biological samples is a research lab, not a clinical lab, you will not receive those results.

Can samples be picked up at a different residence sometimes?

Yes, as long as the different address is within 20 miles of University Hospital Medical Center. It is very important that you make sure you tell the courier you are in the PREVAIL study and give the correct place and address for pick up. We ask that the samples be collected by you or someone trained by the study team member and not by someone who has not been instructed on how to collect the samples.

What will happen at the Home study visits?

When your baby is around 2 weeks old, one of the study staff will visit your home. We will ask you questions about your baby & delivery. We will collect your baby's stool, a nasal swab and saliva.

When your child has a *fever and/or cough, study staff will call to ask you about your child's illness and may schedule a brief home visit to collect more information and nasal swabs.

*Fever: A thermometer reading of greater than 100.4 under the arm or greater than 98.6 taken rectally at any time during the previous week

Vomiting & diarrheal illness - 3 or more loose or watery stools and/or 1 or more vomiting episodes within 24 hours at any time in the previous week.

TIMEPOINT	WHEN & WHERE	WHAT WILL HAPPEN
ENROLLMENT	When you are at least 34 weeks pregnant with only one baby	Questionnaire, Maternal blood, saliva, and nasal swab
Birth	When you deliver your baby at the Hospital	Cord blood Meconium-your baby's first stool
Week 2 Home Visit	When your baby is 10-16-days old	Review study, Questionnaire, Breast milk, infant saliva, stool and nasal swab collections
Week 6 Clinic Visit	When your baby is 6 weeks old. At CCHMC research clinic	Questionnaire – Collection of breast milk and infant blood (1 teaspoon)
Month 4 Phone call	When your baby is 4 months old	Brief questionnaire – 5-10 minutes
Month 6 Clinic Visit	When your baby is 6 months old At CCHMC research clinic	Questionnaire and infant blood (1 teaspoon)
Month 9 Phone call	When your baby is 9 months old	Brief questionnaire – 5-10 minutes
Month 12 Clinic Visit	When your baby is one year old At CCHMC research clinic	Questionnaire and infant blood (1 teaspoon)
Month 15 Phone call	When your child is 15 months old	Brief questionnaire – 5-10 minutes
Month 18 Clinic Visit	When your child is 18 months old At CCHMC research clinic	Questionnaire and infant blood (1 teaspoon)
Month 21 Phone call	When your child is 21 months old	Brief questionnaire – 5-10 minutes
Month 24 Clinic Visit	When your child is two years old At CCHMC research clinic	Questionnaire and infant blood (1 teaspoon)
Weekly sample collections	Weekly – At your home	Nasal swab & stool sent to CCHMC by courier provided by study
Weekly texts	Sent to your phone The text will ask you to respond to the questions with a text	In the past week: Did your child have fever and/or cough? Did your child have vomiting and/or diarrhea?
When your child has fever and/or cough	Your home - Study coordinator calls to make a home visit to follow up	Questionnaire, nasal swab collection of your child and children ≤11 yrs. by study team
When your child has vomiting and/or diarrhea	Your home	Questionnaire & additional stool sent to CCHMC by courier service
Total participation is 2 years	PREVAIL	Compensation could be up to \$1555 for FULL participation

Clinic Visits at CCHMC Schubert Research Clinic

Home Visits – Scheduled at two weeks AND when your child has fever and/or cough

Weekly texts and sample collections