FAQs

1. Who is conducting the study?

David Umbach, PhD, from the National Institute of Environmental Health Sciences (NIEHS), part of the National Institutes of Health (NIH), is the Principal Investigator on this study. **Natalie Shaw, MD,** works with Dr. Umbach as the Associate Investigator. The coordinating center for the study is Social & Scientific Systems, Inc. (SSS). Dr. Shaw can be reached at (919) 541-7798.

2. What is the purpose of the study?

The Infant Feeding & Early Development Follow-Up (IFED-2) Study is a continuation of the original IFED study carried out between 2010 and 2014, which studied early growth and development of infants who were fed one of three different ways:

- Fed with breast milk
- Fed with soy formula
- Fed with cow milk formula

The purpose of IFED-2 is to follow-up with the original IFED participants to collect more information about developmental changes in childhood and early adolescence.

3. Who is participating in the study?

About 283 mothers and their healthy babies completed the original study. Our goal is to enroll former IFED study participants to follow-up with their development since the initial study.

4. Who is eligible to participate?

All children who participated in the IFED Study between 2010 and 2014, which originally consisted of:

1. Healthy infants (not including twins or multiples)
2. Full term infants (defined as 37-41 weeks gestational age)
3. Infants weighing between 5.51 – 9.92 pounds (2,500 – 4,500 grams)

5. How long will my child's participation last?

At this time, we only want to know how many original cohort members would be interested in the follow-up study. The duration of the follow-up itself has not yet been determined, but we will contact you with pertinent information as soon as it becomes available, should you decide to participate in the study.

6. What will my child be asked to do in this study?

The study would include procedures and tests that you are already familiar with: body measurements, physical exams, blood and urine collections, and ultrasounds. You would be compensated for your time and travel.

7. Why do you need my address and phone number?

We would like to mail you a letter with details about the study as they become available. We would like your phone number so we can contact you for feedback, reminders, and questionnaires.

8. How will my child and I benefit from participating in this study?

You and your child may not directly benefit now or in the future from participating in this study. When the information we collect from your child is combined with the information from other participants, we will have more information about how different feeding methods affect growth and development in infants and children.

9. Will my child or I be paid for participating?

Compensation will be offered for your time, effort, and inconvenience.

10. What will it cost me to participate in this study?

There are no costs to you or your child other than the time for participating in the study.

11. Will anyone else access my information?

Your child's specimens and other data collected may be shared with researchers from other institutions. Any request for use of specimens or information will first be reviewed by appropriate scientific and institutional review boards, which are responsible for ensuring that the proposed research is of the highest quality and that your rights have been safeguarded. Your child's name will not be shared with other researchers. The data will only have a numeric code.

12. My child has friends similar in age, can they participate in this study?

No, this study is a follow-up of the original IFED study and its participants from 2010-2014. Unless the child was enrolled in the study during that time, they cannot participate in IFED-2.

13. What if I do not want to participate?

Taking part in this research study is completely voluntary. We hope that you and your child will participate in the entire study. However, you have the right to participate in part of the study and you have the right to withdraw your participation at any time. You will not be penalized, nor will you lose benefits (economic or otherwise) to which you may be entitled. Choosing not to participate will not affect your care at CHOP or any affiliated hospitals.

14. Who can I contact for more information?

You may contact the study coordinating center at 800-860-3474.