Project’s title: Prenatal Lead Exposure, Early Child Growth and Physical Maturation

Principal Investigator: Dr. Karen E. Peterson.

Principal Site Investigator: Dr. Martha Ma. Téllez Rojo Solís.

Description of the study population: This study uses a subsample of the birth cohort to measure the sexual development of children, the etiology of childhood obesity and its association with lead exposure and other environmental contaminants.

About this letter of consent
This letter of consent will provide important information about our research project. A member of our research team will talk to you about your participation in this project. If you have any questions, please let us know. If you and your child decide to join this project, you must sign this form and your child must also agree to participate. Because you are a fundamental part of this study, your child may only participate if you also choose to do so. We will give you a copy of this letter of consent, which you should keep.

Purpose of this study
This research project is being carried out to determine whether exposure to lead during pregnancy and early childhood has an effect on growth and maturation in later childhood.

The University of Michigan in the United States with the National Institute of Public Health in Mexico are conducting this research, which is paid for by the National Institute of Sciences of Environmental Health Sciences and the Environmental Protection Agency of the United States.

You have already participated with us before when you were pregnant or when your child was small. We urge you to join us again so we can learn how your child is doing after a few years. We will study a total of 200 children who have participated with us in the past.
Study participation timeline
It will take approximately 3 years to complete this study. During this time, you and your child will be asked to pay one visit to the study site, which will last approximately 2 hours. When the time for the visit comes, we will pick you and your child up at your home, and we will take you both back home after the visit. Because we want to maintain a strict schedule, we ask that you do not go on your own to the Research Center. If you decide to participate, you agree to accept a ride to and from your home for the visit.

Description of your participation in this study
If you agree to participate in this study, you will be asked the following three things, which are listed below and we will explain each of them in detail:

We will ask your child to attend our Research Center to:

1. Allow a nurse to obtain a 20 mL (about 2 tablespoons) blood sample from the vein in the arm of your child and to provide a urine sample from your child of at least 20 mL.
2. Allow a trained physician or nurse to conduct a complete physical exam of your child to assess growth and development, which will include:
   a. Measuring height, weight, waist circumference, chest and arm circumference, and arm, back and abdomen skin fold thicknesses of your child.
   b. Measuring your child’s blood pressure from his/her arm.
   c. Conducting a physical examination of your child’s genital organ development.
3. Allow your child to fill out four questionnaires, including:
   a. questionnaire on food consumption frequency
   b. questionnaire about physical activity performed regularly
   c. questionnaire on the use of personal care products used daily
   d. questionnaire on physical maturation.

Risks and confidentiality of information
We do not expect any harm to you or your child by participating in this study. However, there is always a small possibility that outsiders may gain access to your personal information. We will take many safety measures to prevent this from happening. Furthermore, all data will be identified only by number, and will not contain your name, address or any other way that you or your child can be identified. Only the principal investigator and the project manager will have access to your personal information, which will be secured under password. If you or your child do not want to answer any questions you may stop responding.
Detailed explanation of each of the study actions

1. Collection and use of blood and urine samples

We will collect blood to determine the amount of developmental hormones in these samples, as well as to analyze the genetic material of your child. In addition, we are collecting a urine sample to determine the amount of pollutants to which you and your child have been exposed, such as phthalates and bisphenol A.

When we remove blood from the arm of your child, he/she could feel a slight sensation of pain. Some people find a bruise at the site of the needle prick and rarely, some faint, but without consequences for their health.

The blood and urine samples that we collect will be stored in Ann Arbor, Michigan, USA. You can decide how these samples will be used in the years after storage. Sometimes, there is new information indicating that other chemicals could also be toxic to children. These stored samples may be useful in future studies to determine if these environmental chemicals are actually toxic to children and women. We ask your permission to use these samples for non-genetic purposes.

Please check (✓) in one of the boxes below to indicate your decision.

☐ Yes, I allow you to obtain a blood sample from the arm of my child and a sample of his/her urine.

Please check (✓) in one of the boxes below to indicate your decision.

Researchers can use these samples:

☐ Only for this study.
☐ For this study and future studies

☐ No, I do not allow you to obtain a blood sample from the arm of my child or a sample of his/her urine.

Genes are very small units that carry information (known as DNA) about what is inherited from parents to children, including some diseases. Scientists can learn about the genes from a sample of DNA from blood by a test called genotyping. This analysis will be used only for research purposes. No genetic testing for other purposes will take place on your child’s DNA.

We assure you that if you decide not to allow your child’s genes to be analyzed, it will not affect their participation in the study.

Please check (✓) in one of the boxes below to indicate your decision.
Researchers can use my child’s DNA:

- I permit use of my child’s DNA, only for this study.
- I permit use of my child’s DNA, for this and future studies I do not permit analysis of my child’s DNA.

RESULTS OF DNA ANALYSIS
We will not send you the results from your child’s blood test about his/her genes, since at the moment we do not know that these genes cause any known disease. Therefore, this information won’t be useful to you or your physician.

2. Examination of Growth and Development

Growth and development can be important health determinants in life. Alterations in normal growth (weight and height) and at the stage of physical maturation may be a risk factor for cardiovascular disease, obesity, and later development. These health effects may be associated with complications in adult life such as type 2 diabetes and increased blood lipids.

We will ask your child if he/she will allow a qualified physician to perform a physical examination, including observation of their body to determine their stage of growth and development. The doctor and an attendant (a nurse) will be present during the examination. You may also be present if your child feels more comfortable having you there. We will also determine the height, weight, and fat distribution of your child and measure the blood pressure in his/her arm.

Many toxic chemicals change the way in which children develop sexually, either lengthening or shortening the time it takes to achieve development into adulthood. An important step in the development of your child to adulthood is puberty. During puberty in girls, breast development occurs and the growth of hair in the genital area. For boys, the penis develops and hair growth occurs in the genital area.

We will ask your child to allow a qualified physician to perform a physical examination including observation of their physical development. After your child’s weight, height, fat distribution, and blood pressure are measured, the doctor will perform a skilled physical examination, during which she will explain to your child what she will do during the exam. Before making the observations of the Tanner staging scale, the trained physician will explain the procedure to your child.

The visual examination of the breasts, pubic hair and genital development may make your child uncomfortable or embarrassed. Your child may skip any question or procedure that he/she does not want to answer or participate in. With the consent of your child, you may be present during the tests if that makes him/her more comfortable.
Please check (✓) in one of the boxes below to indicate if we have permission to take anthropometry and blood pressure measures of your child:

- Yes, I allow my child to be weighed and measured for height, circumference measures, and fat distribution (skinfolds) and to have blood pressure measures taken from his/her arm.
- No, I do not allow my child to be weighed and measured for height, circumference measures, and fat distribution (skinfolds) and to have blood pressure measures taken from his/her arm.

Please check (✓) in one of the boxes below to indicate if we have your permission to ask your child about having a physical examination performed.

- Yes, I allow a physical examination of my child’s physical development.
- No, I do not allow physical examination of my child’s physical development.

3. Completion of Questionnaires

The food a child eats and the amount of physical activity he/she usually completes in one week can also affect a child’s growth and the time of physical maturation. We will ask your child to complete a food frequency questionnaire, which consists of a list of foods where your child will tell us how many times a day, how many days a week, and the portion size that he/she eats for the specific food. We will also ask your child to fill out a questionnaire about physical activity performed and the amount of time spent doing physical activities on a specific day.

Some of the toxic chemicals that can affect how your child develops sexually are a group of man-made chemicals called phthalates. They are used in many products that your child may contact daily, such as plastic sheeting, vinyl floor and wall, perfumes, lotions, cosmetics, varnishes, lacquers, among others.

Let your child ask to fill out a questionnaire on the use of personal care products, so that we can assess the amount of products to which your child may be exposed to these chemicals. Your child will have the option to have you present in the room before they complete this questionnaire, since they may not know the answers to some questions about the elements present in the household.

Please check (✓) in one of the boxes below to indicate if we have your permission to ask your child to complete the questionnaires on food consumption, physical activity, and use of personal care products:

- Yes, I allow my child to complete the questionnaire on food consumption, physical activity, and use of personal care products.
- No, I do not allow my child to complete the questionnaire on food consumption, physical activity, and use of personal care products.
We also ask that your child fill out a self-assessment questionnaire on physical maturation (how their breasts are developing if female or penis development for a boy and hair growth for both genders). The interviewer shows the mother the questionnaire. We will ask your child if he/she prefers that you be present while they fill out the questionnaire.

Please check (✓) in one of the boxes below to indicate if we have your permission to ask your child to complete the self-assessment questionnaire.

- Yes, I allow my child to complete the self-assessment questionnaire on sexual maturation.
- No, I do not allow my child to complete the self-assessment questionnaire on sexual maturation.

Benefits of participating in this study
The physician will give you tips to protect your health and your child based on the results obtained and will notify you if it is determined that you or your child require medical care. Also, as part of this study your child will receive a free evaluation of their development and a general medical examination during the visit to the research center.

Remuneration for participating in this study
There will be no cash payment for participation in this study. Participation includes free transportation to the research clinic and a useful gift for your child.

Costs for participating in this study
There will be no cost to you for the procedures and tests that are performed on your child as part of this study. Research funds will cover these expenses.
Consequences of participating in this study
In the unlikely event of physical injury as a direct result of participation in the study, we will provide you and your child the care needed to treat the injuries. We reserve the right to charge you or others, if appropriate, for the care of the injury. We will try to pay these costs, but you may be responsible for some of them.

Providing care does not mean that participating institutions or investigators acted wrongly or are guilty. We do not condone that the participating institutions or investigators pay you or give any other form of compensation for the injury. However, the fact that you sign this consent form does not imply that you waive any of your legal rights.

If you think that you or your child have been injured or have suffered medical problem as a result of participating in this study, please tell the person responsible for the study as soon as possible. The investigator’s name and phone number are listed in the following section of this consent form.

Contact information for questions or concerns related to this study
You may call us ask questions or express any concerns. Our phone numbers are listed below. Feel free to contact us as much as you would like.

You can call the project leader, Dr. Martha Ma. Rojo-Tellez of the National Institute of Public Health at 01-777-329-3000 extension 3402, Monday through Friday 9:00 to 17:00.

If you have questions about visit scheduling or questions about your test results, you can contact Dr. Adriana Mercado, Research Coordinator, by phone at 52 30-80-00, extension 8903.

If you have general questions about your rights as a participant in a research study, you may contact the Chairperson of the Ethics Committee of the National Institute of Public Health, Dr. Julieta Ivone Castro, phone 01-777-329-3000, extension 7424, Monday through Friday 9:00 to 17:00. Or if you prefer, you can write to the following electronic mail address: etica@correo.insp.mx

Consent to participate in this research and permission to use or share your health information for research purposes.

Declaration of subject or person who gives the consent

- I have read this letter of consent.
- I have been informed of the purpose and procedures of the study.
- I have been informed of the risks, possible benefits, and other important things about this research study.
I have had the opportunity to ask questions, and all of my questions about the study have been answered satisfactorily.
If you understand the information that we have given you and would like to participate with your child in this research study and you also agree to allow their health information to be used as described above, then please sign below.

**Mother:**

___________________________________  ____________________________
Name and Signature  Date and time

**Witness 1:**

___________________________________  ____________________________
Name and Signature  Date and time
Relationship of to the Participant: ________________________________

**Witness 2:**

___________________________________  ____________________________
Name and Signature  Date and time
Relationship of to the Participant: ________________________________

Name and Signature of Investigator or Person who obtains the consent/assent  ________________ Date/Time: