UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Development of a Visit Assessment Tool to Address Birth Defects and Dysmorphology

You are being asked to provide consent for your child's participation in a research study. Participation in this study is voluntary. Please read the information below and then ask questions about anything that you do not understand before deciding if you want your child to participate. A researcher listed below will be available to answer your questions.

RESEARCH TEAM AND SPONSORS

Lead Researcher:
Feizal Waffarn, MD, MBA; Tel: (714) 456-8470
Professor, Pediatrics and Chair of UCI Department of Pediatrics

Other Researchers:
Carol Crichton, RN, M.Ed. (949)-824-3506
Carol Holliday, RN, MSN (949) 824-9249
Paula Voss, RN (949) 824-2119
Nancy Zehler, RN, M.Ed. (949) 824-9249

SPONSORS

The National Children's Study is a partnership between institutions in your community and four federal agencies: 1) The Eunice Kennedy Shriver National Institute of Child Health and Human Development; 2) the National Institute of Environmental Health Sciences; 3) the U.S. Environmental Protection Agency; and, 4) the Centers for Disease Control and Prevention. The Orange County Vanguard Center is composed of a team of community members, health professionals, and other individuals trained to carry out the national study in your area. The local partners include: 1) The University of California, Irvine, 2) Children's Hospital of Orange County, 3) the Children and Families Commission of Orange County, and 4) the County of Orange Health Care Agency.

PURPOSE OF STUDY

The purpose of this research study is to develop a method to document the various features of the face and body.

WHY IS THIS RESEARCH BEING CONDUCTED?

One of the main outcomes of the National Children's Study is to study the effects of prenatal environment and genetic background on children's health and development. Although many of the outcome measures require long term follow up, effects on the embryonic and fetal development could result in visible changes to external features that can be identified at birth and infancy. We are developing a system making standardized observations that can be used by both clinicians and research staff and may then be used in the National Children's Study.

Study Design
If you agree to your child's participation, your child will receive a physical assessment including a brief examination, photographs of his/her head, hands and feet, and a ten-second video of your child's face and diapered body.

SUBJECTS
Inclusion Requirements
Your child is eligible to take part in this study if he/she is a healthy newborn, a 6-month or 12-month old infant.

Exclusion Requirements
Your child is not eligible to participate in this study if he or she is not clinically stable at this time.

Number of Participants and Time Commitment
This study will include approximately 60 infants and will involve approximately 30 minutes of time. It is a single examination.

PROCEDURES
The following procedures will occur: The assessment will consist of one physical examination, similar to the one your pediatrician performs but it will include photographs of the head, hands and feet. We will measure some features. A ten-second video of your child's face and diapered body will be made. There will be two research nurses present at the time. Our goal is to capture the photographs when the infant is sleeping or quietly awake. After the assessment, as will ask you to complete a five-minute questionnaire about your experience.

RISKS & DISCOMFORTS
The possible risks and/or discomforts associated with the procedures described in this study include: We will unwrap the blanket but not completely disrobe the infant to obtain the pictures.

We are taking many steps to protect your information. There is always a chance that your information could be unintentionally disclosed. To protect your child's information we will keep his/her name or address separate from study data files accessed by researchers.

Participation in this study is voluntary. There is no cost to you or your child for participating. You may refuse to participate or discontinue your child's involvement at any time without penalty.

UNKNOWN RISKS
This is an observational study based on the physical assessment that is currently performed by medical professionals. At present, we do not believe any risks are associated with this procedure. There may be risks to being in this study that we do not know about now. Should any unforeseen risks be identified during the course of the study, you will be informed of these immediately.

BENEFITS
Subject Benefits
Your child will not directly benefit from participation in this study.

Benefits to Others or Society
Taking part in the National Children's Study may not benefit your child right now. But the Study may help us learn things about health that could benefit all of us- including your children and grandchildren- in the years to come.

ALTERNATIVES TO PARTICIPATION
The only alternative is not to participate in this study.

COMPENSATION, COSTS AND REIMBURSEMENT

Compensation for Participation
You will be paid $25 for your child's participation in this research. This is the only visit.
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Compensation for Injury
If your child is injured as a direct result of your participation in this study, the University of California will provide reasonable and necessary medical care to treat the injury at no cost to you or to your insurer/third party payer. The University of California does not routinely provide any other form of compensation for injury. It is important that you report any suspected study-related injury to the research team listed at the top of this form immediately.

Costs
There is no cost to you or your insurer or third party payer for participation in this study.

CONFIDENTIALITY
Research records will be stored in the following manner: All identifiable information about your child will be removed, with only a code to identify your child. The code that links your child's name to the data will be kept separate from the study data.

In addition to taking all these steps to protect your privacy, there's one more thing we have done. The National Children's Study has obtained a legal document from the U.S. Department of Health and Human Services (DHHS) that is designed to protect your privacy. The document is called a Certificate of Confidentiality. It will help protect your information from people who are not part of the Study.

With this Certificate, we cannot be forced, for example by court order or subpoena, to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. But if there is an audit or evaluation of the Study by staff of the DHHS, it may be necessary to disclose information to those staff. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this study. So if an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that in addition to our efforts, you and your family must also actively protect your own privacy.

Also, you should understand that we will take actions necessary under federal or local law, including reporting to authorities, to prevent serious harm to yourself, or others such as in cases of child abuse or neglect that we find out about or observe.

The Certificate of Confidentiality does not stop the reporting abuse or neglect of children, handicapped persons, or the elderly. In addition, parents or legal guardians have the right to information about a minor child unless an Institutional Review Board has approved the study with a waiver of parental permission.

Data Storage
This information will be protected and kept confidential in the following manner: All study data will be kept under lock and key and only authorized research team members will have access to it. Moreover, all data stored electronically will be stored on a secure network server.

Data Access
The research team, authorized UCI personnel, and the Office of Human Research Protections (OHRP), may have access to your child's study records to protect your safety and welfare. Any information derived from this research project that personally identifies you or your child will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you or your child. Publications and/or presentations that result from this study will not include identifiable information.

Data Retention
The researchers plan to maintain your child's identifiable research data until all data has been collected and analyzed. After that time, your child's identifiable data, such as names and addresses, will be securely destroyed.

NEW FINDINGS
If, during the course of this study, significant new information becomes available that may relate to your willingness to allow your child to continue to participate, this information will be provided to you by the research team listed at the top of the form.

OTHER CONSIDERATIONS

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES
You are free to withdraw your child from this study at any time. **If you decide to withdraw your child from this study you should notify the research team immediately**. The research team may also end your child's participation in this study if you do not follow instructions, your child's safety and welfare are at risk, or the study sponsor decides to stop the study.

Investigator Financial Conflict of Interest
No research personnel have reported disclosable financial interests.

IF YOU HAVE QUESTIONS

If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form. If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your child's rights as a research subject, please contact UCI's Office of Research Administration by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@rgs.uci.edu or in person at University Tower - 4199 Campus Drive, Suite 300, Irvine, CA 92697-7600.

VOLUNTARY PARTICIPATION STATEMENT

You should not sign this form unless you have read the attached "Experimental Subject's Bill of Rights" and have been given a copy of it and this consent form to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you or your child might otherwise be entitled. Your decision will not affect your future relationship with UCI or your child's quality of care at the UCI Medical Center. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

I agree to have my child participate in the study.

_____ _____

Subject Signature **Date**

_____

Printed Name of Subject

_____ _____

Researcher Signature **Date**

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Printed Name of Researcher

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections Program in the Office of Research Administration by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@rgs.uci.edu; or by writing us at University Tower - 4199 Campus Drive, Suite 300, Irvine, CA 92697-7600.