

Appendix D – Study Information Sheet for Focus Groups

**University of California, Irvine
Study Information Sheet**

***Socioeconomic, Cultural, and Political Facilitators and Barriers to Access,
Recruitment, and Retention in Orange County, California***

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Study Location(s): Orange County, California

Study Sponsor(s): 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

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0590). Do not return the completed form to this address.

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) the Children and Families Commission of Orange County, 3) the County of Orange Health Care Agency, and 4) Children's Hospital of Orange County.

- You are being asked to participate in a research study about the health and environment issues of concern to Orange County community members and factors that may play a role in their decisions to participate in the National Children's Study. The purpose of the National Children's Study is to help understand how the environment affects children's health, growth, and development. We are also interested in how the environment interacts with individual characteristics, such as genes, to prevent disease and promote health. The National Children's Study will observe child development from pre-conception through 21 years of age. We are currently conducting research on the concerns and unique characteristics of communities in Orange County, California to help us prepare for the National Children's Study.
- The research procedures involve participating in a 90-minute focus group. The group discussion will be audiorecorded and transcribed, although individuals will not be identified in the transcription.
- The only foreseeable discomfort associated with the study is the invasion of your privacy. There are no direct benefits from participation in the study. However, this study may explain what issues related to child health and development are of greatest concern to communities and what strategies might be used to engage communities in research. This could make the National Children's Study more successful, which would lead to numerous benefits to society and future generations of children.
- Participation in this study is voluntary. There is no cost to you for participating. You may refuse to participate or discontinue your involvement at any time without penalty. You may choose to skip a question or a study procedure.
- You will receive \$35 for participating in this research. We will also provide dinner and childcare during the focus group. Assistance is also available if you have transportation costs (travel to and from the group site) as a result of your participation.
- All research data collected will be stored securely and confidentially. Digital recordings will be stored on password-protected computers. We will not record your name on the forms you complete. We will use a unique number code to identify you. The stored data will only have these code numbers, not names, so that individuals cannot be identified. We will store information in a computer file

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protected by advanced security technology. Your data will be combined with data collected from all the people in the Study—more than 250 people. All the information we collect from you will be confidential and reported only as a group. Specific data about you personally, will never be reported in any Study publication.

- The research team, authorized UCI personnel, the study sponsor (if applicable), and regulatory entities such as the FDA, may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law.
- If you have any comments, concerns, or questions regarding the conduct of this research please contact the researchers listed at the top of this form.
- If you are unable to reach the researchers listed at the top of the form and have general questions, or you have concerns or complaints about the research, or questions about your rights as a research subject, please contact UCI's Office of Research Administration by phone, (949) 824-6662, by e-mail at IRB@rgs.uci.edu or at University Tower - 4199 Campus Drive, Suite 300, Irvine, CA 92697-7600.

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