

LA MUH Resident Survey- Child Health

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Resident- Child Health Questions Only

SMOKE-FREE MULTI-UNIT HOUSING POLICIES STUDY

Please read this consent form carefully and take time to ask the staff as many questions as you would like. Reading this form and talking to the study staff may help you decide whether or not to participate.

Purpose and Procedures:

The U.S. Centers for Disease Control and Prevention (CDC) is sponsoring a research study to learn how apartment complexes put into place rules about where people can or cannot smoke and how those rules affect residents' life and health.

You are being asked to be part of a research study of residents of apartment complexes in Los Angeles County. If you agree to be part of this research study, we will interview you now, and between six to nine (6-9) months later, at a time that is convenient for you. If you agree to participate, you will:

- Answer questions about the health of children in your household. If you do not want to answer a question, just say so, and the interviewer will move to the next one. You may also stop the interview at any time.
- Allow us to get a saliva sample from the child with the most recent birthday who is present today. This is painless. All you will have to do is ask your child to rinse his/her mouth with water 10 minutes before we do the test. Later, you will hold a cotton swab under his/her tongue for a short time, if the child cannot hold it him/herself. The testing will take around 10 minutes. The child may choose not to do this and your household can stay in the study.

The interview will last about 15 minutes. At the end of the interview, you will be given a \$10.00 Visa gift card. **If the child gives a saliva sample, we will give you another \$10.00 Visa gift card as a token of our appreciation. We will gift the same gift if you and your child complete these activities at the next visit in six to nine months as a token of our appreciation.**

Your Benefits and Risks from Participation in this Interview

You or your child will not receive any direct benefits from taking part in this study. If you wish, we can give you information on local stop smoking programs for which you or your family may qualify. We will not provide any medications or doctors' services as part of this project.

Attachment 8A-3(e)

Although you may not directly benefit from your involvement in this survey, by helping us test the survey questions, you can help increase understanding of how no-smoking rules can be applied in other communities.

We believe that you and your children's participation has few risks, the most significant being that you will be asked questions about personal issues during this study such your children's specific health conditions. These types of personal questions sometimes may make some people uncomfortable. You do not need to answer any question that makes you feel uncomfortable. If you do not wish to allow your child to give a saliva sample, you do not have to do so.

None of the information you share with us will be shared with the management of this apartment complex. Your rent or housing status will not be affected by your participation in this research.

Privacy

None of the information you share with us will be shared with the residents of this apartment complex or with your property's management. Your personal identifying information (name, address, phone number) will be kept separate from your questionnaire responses. All records will be stored in a locked file cabinet or a password-protected computer file, which only authorized project staff may access. Only those staff working on this study will know your name and data.

The saliva will be stored in low-temperature freezers at Los Angeles County Department of Public Health headquarters for up to three years (3) for possible later study. After three (3) years, the saliva samples will be disposed of using biohazard containers.

Being a study volunteer

Entering a research study is voluntary.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.

If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study staff decides to stop the study.
- You do not follow the study rules.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

NEW INFORMATION about the study

You will be told about any new information found during the study that may affect whether you want to continue to take part.

Who to Contact:

You may ask questions about the information on this form or about the study in general at any time. You may contact Carol Kawecki, Healthy Housing Solutions at 443-539-4183 or 877-312-3046, ext. 238.

If you have questions about your rights as a research participant, you may contact:

9. US Dept. of Health and Human Services Institutional Review Board:
10. Westat Institutional Review Board Administrator, Sharon Zack, at 800-937-8281, ext. 8828.
11. Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Toll-Free Telephone within the United States: (866) 447-4777
12. LACDPH Institutional Review Board Administrator:

J. Walton Senterfitt, PhD, RN, MPH
Chair, Administrator and Compliance Officer
Institutional Review Board
Los Angeles County Department of Public Health
313 N. Figueroa St., Room 127
Los Angeles, CA 90012
213-989-7075 or 213-250-8675

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

- THE NATURE AND PURPOSE OF THE STUDY.
- THE PROCEDURES IN THE STUDY AND ANY DRUG OR DEVICE TO BE USED.
- DISCOMFORTS AND RISKS TO BE EXPECTED FROM THE STUDY.
- BENEFITS TO BE EXPECTED FROM THE STUDY.
- ALTERNATIVE PROCEDURES, DRUGS OR DEVICES THAT MIGHT BE HELPFUL AND THEIR RISKS AND BENEFITS.
- AVAILABILITY OF MEDICAL TREATMENT SHOULD COMPLICATIONS OCCUR.
- THE OPPORTUNITY TO ASK QUESTIONS ABOUT THE STUDY OR THE PROCEDURE.
- THE OPPORTUNITY TO WITHDRAW AT ANY TIME WITHOUT AFFECTING YOUR FUTURE CARE AT THIS INSTITUTION.
- A COPY OF THE WRITTEN CONSENT FORM FOR THE STUDY.
- THE OPPORTUNITY TO CONSENT FREELY TO THE STUDY WITHOUT THE USE OF COERCION.
- STATEMENT REGARDING LIABILITY FOR PHYSICAL INJURY, IF APPLICABLE.

STATEMENT OF CONSENT

I have read the consent form. My questions have been answered. I consent voluntarily to participate in this research study. I give permission for my child between the ages of two (2) and seven (7) to provide a saliva sample, if that child is selected to provide a sample. I also give permission for project staff to review the saliva assent form with my older child, if he/she selected to provide a sample. I will receive a copy of this consent form for my records.

I am not giving up any legal rights by signing this form. Nothing in this is intended to change any applicable federal, state, or local laws.

Name of Participant (Print) Signature Date

Relationship to children in this household. (Please check all that apply).

- Parent
- Guardian
- Foster Parent
- Primary Caregiver During the Time the Child is in the Apartment

Name of Person Obtaining Signature Date

Consent

Form Valid For Enrollment From 05/16/2013 W 05/15/2014 Los Angeles County-Public Health Institutional Review Board
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Note: Below is the document whose language must be included in all informed consent documents in California, or that must be signed as a separate document and included in the study records.

HUMAN RIGHTS IN MEDICAL STUDIES

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. THE NATURE AND PURPOSE OF THE STUDY.
2. THE PROCEDURES IN THE STUDY AND ANY DRUG OR DEVICE TO BE USED.
3. DISCOMFORTS AND RISKS TO BE EXPECTED FROM THE STUDY.
4. BENEFITS TO BE EXPECTED FROM THE STUDY.
5. ALTERNATIVE PROCEDURES, DRUGS OR DEVICES THAT MIGHT BE HELPFUL AND THEIR RISKS AND BENEFITS.
6. AVAILABILITY OF MEDICAL TREATMENT SHOULD COMPLICATIONS OCCUR.
7. THE OPPORTUNITY TO ASK QUESTIONS ABOUT THE STUDY OR THE PROCEDURE.
8. THE OPPORTUNITY TO WITHDRAW AT ANY TIME WITHOUT AFFECTING YOUR FUTURE CARE AT THIS INSTITUTION.
9. A COPY OF THE WRITTEN CONSENT FORM FOR THE STUDY.
10. THE OPPORTUNITY TO CONSENT FREELY TO THE STUDY WITHOUT THE USE OF COERCION.
11. STATEMENT REGARDING LIABILITY FOR PHYSICAL INJURY, IF APPLICABLE.

IF YOU HAVE ANY QUESTIONS OR CONCERNS REGARDING THESE RIGHTS OR THE CHARACTER OF THE STUDY, PLEASE FEEL FREE TO DISCUSS THEM WITH THE PERSON(S) CONDUCTING THE STUDY, OR YOU MAY CONTACT THE RESEARCH COMMITTEE CHAIRMAN, LOS ANGELES COUNTY DEPARTMENT OF PUBLIC HEALTH, AT (213) 250-8675.

I HAVE READ AND UNDERSTOOD MY RIGHTS FOR PARTICIPATION IN THE STUDY.

SIGNATURE OF SUBJECT OR GUARDIAN
FIRMA DEL SUJETO O PERSONA RESPONSABLE

DATE
FECHA

DERECHOS HUMANOS EN ESTUDIOS MEDICOS

LA LEY DEL ESTADO DE CALIFORNIA REQUIERE QUE UD. TIENE QUE ESTAR INFORMADO SOBRE:

1. LA NATURALEZA Y EL PROPOSITO DEL ESTUDIO.
2. LOS PROCEDIMIENTOS DEL ESTUDIO Y CUALQUIER FARMACO, APARATO O DISPOSITIVO QUE SE VAYA A UTILIZAR.
3. LAS MOLESTIAS Y LOS RIESGOS QUE SE ANTICIPAN DEL ESTUDIO.
4. LOS BENEFICIOS QUE SE PUEDEN ESPERAR DEL ESTUDIO.
5. LOS PROCEDIMIENTOS ALTERNOS, FARMACOS O DISPOSITIVOS QUE PUEDEN SER UTILES Y LOS RIESGOS Y BENEFICIOS QUE ESTOS LLEVAN.
6. DISPONIBILIDAD DE TRATAMIENTO MEDICO EN CASO QUE OCURRAN COMPLICACIONES.
7. LA OPORTUNIDAD PARA HAGER CUALESQUEIRA PREGUNTAS SOBRE EL ESTUDIO O EL PROCEDIMIENTO.
8. LA OPORTUNIDAD PARA RETIRARSE DEL ESTUDIO EN CUALQUIER MOMENTO SIN AFECTAR SU ATENCION MEDICA FUTURA EN ESTA INSTITUCION.
9. UNA COPIA DE ESTE CONSENTIMIENTO FIRMADO PARA EL ESTUDIO.
10. LA OPORTUNIDAD PARA CONSENTIR LIBREMENTE AL ESTUDIO SIN EL USO DE COERCION.
11. DECLARACION ACERCA DE LA RESPONSABILIDAD POR DAÑOS FISICOS, SI ES APLICABLE.

SI UD. TIENE CUALESQUEIRA PREGUNTAS O PREOCUPACIONES ACERCA DE ESTOS DERECHOS O EL CARACTER DEL ESTUDIO, POR FAVOR SIENTASE LIBRE PARA DICUTIRLOS CON LA(S) PERSONA(S) LLEVANDO A CABO EL ESTUDIO, O UD. PUEDE PONERSE EN CONTACTO CON EL PRESIDENTE DEL COMITE INVESTIGATIVO DEL CONDADO DE LOS ANGELES SALUD PUBLICA, A (213) 250-8675.

YO HE LEIDO ESTE DOCUMENTO Y ENTIENDO MIS DERECHOS PARA MI PARTICIPACION EN EL ESTUDIO.

FormValidforEnrollmentFrom	
05/16/2013	05/15/2014
Los Angeles County-Public Health	

