Household ID # _____

Green Housing Study

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: The Green Housing Study

IRB Protocol number: CDC IRB # 5587

Sponsor: Centers for Disease Control and Prevention (CDC)

Principal Investigator: Ginger L. Chew, ScD (CDC)

1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand. Ask the study team to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Data collection is authorized under Section 301 of the Public Health Service Act

2. Why is this research being done?

Some apartment buildings in your community are undergoing renovations and some homes are not undergoing renovations. This research is being done to see:

(1) If levels of chemicals and other agents (such as mold or dust) are different among apartments in your community and among similar homes in other communities, and

(2) If these differences affect children's health.

Please note that the renovations are not part of this research study. They would take place whether the research is conducted or not.

How many people will be in this study? We expect to test samples from residents of over 800 apartments across the country. Families with children with asthma (ages 7-12 years) will be invited to enroll. One eligible child from each home can be enrolled in the study. To be eligible, the children (age 7-12 years) must have experienced asthma-related symptoms (wheezing, slow play or night awakening) during the past 6 months and must have been diagnosed with asthma by a doctor at some time in his/her life.

3. What will happen if you and your child join this study?

a. These are things that we will do in your home:

We will measure the air inside your home for chemicals, temperature, and humidity (see examples in the attached brochure). The machines will be put in your child's bedroom. The machines will run day and night for 5 days. When they run, they make no more noise than a pump in a fish tank. At the end of 5 days we will return to your home to remove the machines; we require that you or a designated adult be present during the pick-up. We will place small membrane badges in your child's bedroom which detect

additional chemicals in your air. We will also measure how air changes in your home. The air change measurement requires releasing a nontoxic chemical in your air and then measuring it with a detection membrane 5 days later. The relative humidity and temperature will be measured with small devices (see examples in the attached brochure) which will stay in your home for the same 5 days as the air change monitor. These devices are silent. We will also collect dust samples from the floor in your home and your bed, and your child's bed to test for agents in the dust which might affect your child's health.

All of these measurements will occur at the first visit before any renovation occurs in your apartment, the second visit after any renovation occurs (approximately 1 month after renovation), then 6 and 12 months (please see Table 1. for summary of data collection time points). If you are a control home, all of these measurements will occur at four visits which coincide with the time points for the renovated homes.

Table 1. Summary chart of environmental measurements in homes

Type of assessment	Start of study	1-month follow-up	6-Month follow-up	12-Month follow-up
Dust (for allergens and pesticides)	✓	✓	✓	✓
Air	✓	✓	✓	✓
Temperature	✓	✓	✓	✓
Relative humidity	✓	✓	✓	✓
Air change	✓	✓	✓	✓

* Dust sampling will occur in the children's beds as well as the bed of the mother/primary caregivers. Except for the pesticide measurements in the kitchen, all other measurements will be limited to the child's bedroom.

b. These are things we will ask you (the mother/primary caregiver of the child) to do:

Respond to Health and Home Surveys: During home visits, we will ask you questions about any breathing problems that your child may have. We will also ask questions about your child's lung health, breathing medication use, and home environmental characteristics.

In addition, we will contact you by telephone (at 3 and 9 months) assess changes in your child's breathing health. During the months when phone call or home visits are not scheduled, we will send you a series of brief text messages to ask about breathing problems that the child might have had in the past month.

Collect nose and throat swab samples from your child: You will be asked to collect nose and throat swabs from your child (see Figures A and B in the attached brochure) when your child experiences cold/flu symptoms. You will be given swabs and instructions how to collect and store the nose and throat swabs. You will also be asked to fill out a form about the symptoms and healthcare for each of the cold/ flu episodes that occur during the study. You will also be instructed about contacting study coordinator for specimen pick up.

c. These are things we will ask your child to do:

Provide height and weight measurements: We will measure height and weight which will be needed for input into the computer that does lung function tests. Please see Table 2. for summary of data collection points.

Give a blood sample: We will take about 2 teaspoons of blood from a vein in the arm. This will be stored in 2 tubes. The blood will be sent to a laboratory to determine if the study participant has allergies.

Perform breathing tests: We will ask your child to blow into machines that measures lung function and inflammation. In one test, your child will blow into a machine at least three times as hard as he/she can. In another test, your child will blow into a mouthpiece for about 6 to 10 seconds.

Give urine samples: We will ask your child to urinate in a cup at home. We will test the urine for chemicals (e.g., pesticides). We will not be testing for illegal drugs in the urine.

Have his/her nose and throat swabbed: When your child has cold/flu symptoms, his/her nose and throat will be swabbed by you (as described above). At the time when the nose and throat swabs are picked up from the home, the study technician will collect another nose swab and throat swab.

Table 2. Summary chart of clinical measurements

Factor	Child with asthma (Age 7-12)
Blood Start of study	✓
Urine Start of study 1-mo. follow-up 6-mo. follow-up 12-mo. follow-up	✓ ✓ ✓ ✓
Breathing tests Start of study 1-mo. follow-up 6-mo. follow-up 12-mo. follow-up	✓ ✓ ✓ ✓
Respiratory Symptoms Monthly	✓
Cold/ Flu assessment When the child experiences at least 3 of the following: feverish, stuffy/runny nose, cough, sore throat, body aches or tiredness, for more than 24 hours.	✓

* Blood will be used for assessment of allergy status
** Urine will be used for assessment of environmental chemical exposures

Reporting of Results:
All study results will be provided to you. We will also provide breathing test results within 3 months of when the tests are done. There are no government standards for residential levels for any of the environmental agents that we are measuring in your home. However, during your final home visit, we will: 1) give you the first environmental results that we collected from your home; 2) give you the first clinical results (blood and urine tests) that we collected from your child; 3) discuss the results with you; and 4) give you information (e.g. local health department phone numbers and a DVD and/or pamphlets) on how to lower environmental agents in your home. The rest of your results will be mailed to you within one year after you finish the study.

How long will you be in the study?
12 months if all study visits are completed on time.

4. What are the risks or discomforts of the study?

Blood collection: Taking blood may cause pain, bleeding or bruising where the needle is placed. In rare cases, it may result in fainting. There is a small risk of infection.

Breathing tests

- Your child may become dizzy.
- Occasionally minor chest soreness for several days after the testing.

Nose and throat swabs: Nose swabs quickly rub the back portion of the nose and may feel uncomfortable for a second. Rarely, nose swabs may cause a small amount of bleeding. Throat swabs may feel uncomfortable for a second.

The research team will comply with state and local law and will tell the local or state authorities if they suspect abuse or neglect of a child or dependent adult.

5. Are there benefits to being in the study?

From the blood test, you will learn about any allergies your child might have had at the time of the blood draw. You will also learn about your child's breathing function at the time that the breathing tests were administered, and this information should be shared with the child's healthcare provider to aid in the child's overall asthma management. All households will receive information about how to decrease their exposures to chemicals and other agents which can be associated with breathing problems during their last home visit.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your housing situation will not be affected. If your home has been scheduled to be renovated, it will still undergo the renovations.

7. Will it cost you anything to be in this study?

It will not cost you anything to be in the study. The costs of all of the measurements in the study are covered by the study.

8. What will you get if you join this study?

You will receive $50 for each of the home visits. You will be reimbursed $2 for each of the monthly text messages (month 1, 2, 4, 5, 7, 8, 10, and 11) and 3-month and 9-month phone calls (total = $20). If you complete all study activities, you will receive a total of up to $220.

9. Can you leave the study early?

You can agree to be in the study now and change your mind later. If you wish to stop, please tell us right away. Leaving this study early will not stop your child from getting regular medical care or affect your housing situation.

10. Why might we take you out of the study early?

You and your child may be taken out of the study:

- If it is in your or your child's best interest to be taken out of the study.
- If you fail to follow instructions.
- If the study is cancelled.
- There may be other reasons that we don't know at this time to take you out of the study.

11. How will your privacy be protected?

Information from the survey will be used for research purposes only. All answers you give will be kept private to the extent permitted by law. We do not plan to share your information with anyone other than CDC staff and its contractors. Data that identify you or where you live will not be included in any report. All information from the surveys will be kept in a locked file. Data will be stored separately from any personal identifiers.

The use of your information has no time limit. You can cancel your permission to use and disclose your information at any time by calling the Study Site Principal Investigator, Dr. _____ at tel# (_____) or by sending a letter to the Study Site Principal Investigator at the following address:

_____
Street address

_____
City State Zip code

If you cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

12. What treatment costs will be paid if you are injured in this study?

CDC does not have programs to pay you if your child is hurt or has other bad results from being in the study. The costs for any treatment or hospital care would be the responsibility of you or your insurance company.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?
The CDC IRB is generally made up of: Doctors, Nurses, Scientists, and Non-scientists

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The CDC Human Research Protection Office number is 1-800-584-8814.

b. What do you do if you have questions about the study?
Call the study site principal investigator, Dr. _____, at tel # _____ or the CDC principal investigator, Dr. Ginger Chew at 770-488-3992.

c. What should you do if you are injured or ill as a result of being in this study?
If you have an urgent medical problem you should call 911.

Call the study site principal investigator, Dr. _____at tel#_____ or the CDC principal investigator, Dr.Ginger Chew at 770-488-3992, if you think you are injured or ill because of this study.

d. What happens to data, blood, urine, and samples that are collected in the study?

Scientists at CDC work to find the causes and cures of disease. The data, urine, blood and samples collected during this study are important to both this study and to future research.

If you join this study:
- CDC and/or its outside partners in this research will own these collected data, blood, urine, and environmental samples.
- Scientists may study, test and use this material in future research only with your consent or with the approval of a special review board.

14. What does your signature on this consent form mean?

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Please initial here if it is okay for CDC to save the samples collected in this study for future research purposes related to public health. The samples may be kept indefinitely. These samples will not be identified by anyone's name. This means that I will not receive any results from any of those future studies.

Initials _____

_____

Signature of Participant (Printed Name) Date

_____

Signature of Person Obtaining Consent Date

_____

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT.**