

**Children's Hospital Medical Center Consent to Participate in a Research Study
THE CINCINNATI ASTHMA PREVENTION STUDY**

Before agreeing that my child or I will participate in this study, it is important that I read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made about the results of the study. It is also understood that refusal to participate will not influence the availability of standard medical treatment.

I, _____
(Parent or Guardian Name)

residing at:

(Street Address)

_____, _____, _____
(City) (State) (Zip)

have been asked for my child:

(Child's Name)

aged _____ years old, to participate in a research study.

The purpose of this study is to determine whether children with asthma benefit from the placement of portable air cleaners in their homes, to see whether the air cleaners reduce indoor air pollution and are connected with a reduction in symptoms of asthma, unscheduled visits to see a doctor, or behavioral problems.

The study is a randomized trial, which means that half of the children and their families will receive "active" air cleaners to reduce their child's exposure to indoor air pollution, and the other half will receive "sham" air cleaners, which do not reduce a child's exposure to indoor air pollution. A random number table, like the flip of a coin, decides the selection of families who receive the "active" or "sham" inserts.

Procedures

I understand that my participation in this study will involve some temporary inconveniences.

I voluntarily agree to take part in the study and consent to having my child participate. My participation involves:

1. being visited in my home three times over a twelve month period, as follows:
 - at the beginning of the study, for 2 – 2 ½ hrs
 - in the middle of the study (at 6 months), for 1 hr
 - at the end of the study (at 12 months), for 2 – 2 ½ hrs;
2. having a few strands of hair cut from my child's head at each home visit;
3. having a urine specimen collected from my child at each home visit;
4. having about 2 teaspoons of blood obtained by a blood draw from my child at each home visit;
5. having my child exhale into a Mylar balloon (a shiny non-latex balloon) to measure lung function at each home visit;
6. assisting my child in using the electronic spirometer provided by the study, similar to what is used in a doctor's office, to measure lung function two times a day for the full year of the study;
7. having air samples taken from my home at the beginning and at the end of the study;
8. having dust samples taken from my home at the beginning and at the end of the study;

9. being interviewed over the telephone two times over a twelve month period;
10. answering questions about my child's asthma symptoms and any contacts with doctors every 3 months;
11. answering questions about the cigarette smoking patterns of everyone in my family every 3 months;
12. answering questions about my child's behavior at the beginning and the end of the study;
13. answering questions about myself and other members of my family at the beginning and the end of the study;
14. granting permission for my child's teacher to be contacted for completion of a questionnaire about my child's behavior at the beginning and end of the study;
15. approving the release of information from my child's medical chart and pharmaceutical records which apply to the year my child is in the study;
16. approving the storage of urine and blood from my child for lab tests which may be run anonymously in the future, such as tests of indicators of air pollution;
17. keeping two air cleaners running constantly in my home;
18. and notifying the study staff if my family is moving to a new home.

I understand that my child can stop any of the testing at any time, if either s/he or I feel uncomfortable about it.

I also understand that, for the purpose of the study, I will not be notified of the results of any tests until after the study is completed, and that the program staff will not know the results of these tests until the study is completed.

Potential Benefits

I understand that this study may benefit my child because it may reduce my child's exposure to indoor pollution, and possibly reduce my child's

symptoms of asthma, trips to the emergency department or physician's office, and behavior difficulties. I understand that my family has only a 50% chance (equivalent to the toss of a coin) of receiving the "active" air cleaners. I also understand that this study may benefit other children because it may help to identify ways to prevent exposure to indoor pollutants.

I understand that I will be able to keep the air cleaners after the study is finished. If I have received "sham" inserts, they will be activated at the end of the study period.

I understand that I will receive compensation for my participation in the study and to offset the cost of running the air cleaners continuously. This compensation will consist of gift certificates for groceries in the amounts of \$50 for each of the first two visits made to my house, and \$100 at the last visit, for a total of \$200 if my child participates in the entire study. If I run both air cleaners for the full year, I will also receive an additional \$187 to cover the cost of electricity.

Risks, Discomforts and Precautions

I understand that the air cleaners may make some noise which will require a short time to become accustomed to, and will take up some room on the floor. I understand that it may be awkward for my child to have urine, hair, and breath samples taken. I also understand that my child may experience slight discomfort when blood samples are being taken, but that the technician has a great deal of experience in working with children and will do his/her best to be gentle. My time will be needed for all visits in the home and for completing 2 telephone interviews. My child and I are being asked to use the hand-held electronic spirometer as a part of our daily routine: performing these tests every morning and evening for the full year. Finally, some of the questions during the interview may be sensitive in nature, but I am free to refuse to answer any questions I wish.

Alternatives

I understand that I may choose not to participate in this study, and this choice will in no way affect the treatment and service my child and I receive from staff at Children's Hospital Medical Center.

Confidentiality of Records

I understand that personal information will be kept in confidence by the study staff. I also understand that neither I, nor any member of my family, will be identified by name in any reports or publications from the study. Representatives of the Children's Hospital Medical Center Institutional Review Board and/or FDA might inspect the study records to ensure compliance with federal regulations.

Availability of Information

I understand that I can obtain additional information about this study and my rights by contacting:

Amy Kalkbrenner
Project Director
(513) 636-0151 or 1-877-421-4466

Cincinnati Asthma Prevention (CAP) Study
Children's Hospital Medical Center
TCHRF 6527
3333 Burnet Avenue
Cincinnati, OH 45229-3039

I understand that if I would like to request information about my rights or the rights of my child with regard to this research, I can contact the Chairman of the Institutional Review Board, Dr. Irwin Light, at 636-8039.

The Right to Withdraw

I understand that I have the right to not participate in this study. I also understand that I have the right to withdraw from the study at any time and that withdrawing from the study will not jeopardize my child's access to medical care. I also understand that any new findings at the study's completion will be provided to me.

Based on the information provided above and having had the opportunity to discuss any concerns with the investigator or designee, I voluntarily consent for my child to participate in the Cincinnati Asthma Prevention (CAP) Study.

Name of Legal Guardian (Printed)

_____/____/____
Signature of Legal Guardian indicating Consent Date

Name of Witness as to Voluntary Signature (Printed)

_____/____/____
Signature of Witness Date

Bruce P. Lanphear, MD MPH Principal Investigator

_____/____/____
Signature of Principal Investigator or Designee Date

The DHS and FDA policies on protection of human subjects list the basic elements of informed consent as follows:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subjects participation, a description of the procedures to be followed and identification of any experimental procedures.
2. A description of reasonably foreseeable risks and discomforts.
3. A description of any benefits to the subject or others that can reasonably be expected from the research.
4. Disclosures of appropriate alternative procedures or courses that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights and whom to contact in the event of a research-related injury to the subject.
7. A statement that participation is voluntary, that refusal to participate will not involve loss of benefits and that subjects may discontinue participation at any time without loss of benefits.

This study has been reviewed and approved by the Institutional Review Board of the Children's Hospital Medical Center (Chairman's office telephone number, 636-8039).