

## Consent Form

TITLE: Asthma, Lead, and Injury Reduction by Home Remediation

### PURPOSE:

The purpose of this research project is to look for factors in the home which might increase the risk of childhood injuries, lead poisoning, or might make a child's asthma worse. Once these possible factors have been found, the study will recommend several changes you can make to your home such as repairs and renovations as well as different cleaning practices which should reduce these risk factors. By following up on the health of your child(ren), the study will be able to tell if home changes improve the health of children at risk for lead poisoning, asthma, and injuries. However, we do not know if following our recommendations will have any effect on the health of people in your home.

You were selected for this study because you volunteered to participate and you have at least 1 child in your home between the ages of 4 and 12 diagnosed with asthma by a health care provider. It is important for you to know that your participation in this study could affect other people who live in your home. By signing this consent form, you are saying that you have talked to other members of the household about the study, you have shown them the list of study activities which we mailed to you, and that they are aware of what is involved and agree to the study.

### CONFIDENTIALITY:

All responses you give on the questionnaire, information from medical records, and all data recorded will be kept strictly confidential and no one except project staff will have access to it. The data gathered will be used as summarized statistics (averages and percentages) without anything from which individual people or homes could be recognized. Anything we see or record (except evidence of child abuse or very dangerous situations like gas leaks) will be kept confidential. You can feel free to refuse to be in the project or stop the home assessment at any time. If the Home Assessment Team members do find something in your home which is not immediately dangerous but that could be a health problem, we will provide you with information to assist you, such as useful telephone numbers.

### PROCEDURES:

The study involves:

- Having a Home Assessment Team of 4 staff people come into your home to look in each room for possible asthma triggers, lead paint, and sources of childhood injury.
- They will test the air, using hand-held sampling meters, in every room of the home. They will need to spend about 10 minutes in each room. These meters will record the temperature, humidity, levels of dust in the air, levels of carbon dioxide, levels of

carbon monoxide, and levels of organic compounds, like formaldehyde, in the air of each room.

- They will collect dust samples from some of the rooms of your home.
- They will take pictures of any areas where they find large amounts of mold, mildew, or water damage. The pictures will be taken so that no one will be able to recognize your home from their content. They will only be labeled with the room and a site tracking number we use for our files.
- They will ask you some survey questions about your home, your neighborhood, your housekeeping practices, and your health and that of other members of the household.
- They will ask permission to check the medical records of each eligible child who agrees to participate. They will do this in order to count the number of visits the child had to a health care provider in the past six months and the reasons (asthma, lead, injury, other) for those visits. They will also need to do this again in six months and one year from the time of the first home visit.
- Each eligible child in the home who agrees to participate will be given a simple breathing test. This test uses a hand-held meter to measure the amount of air the child can breath out in a certain amount of time.
- Each eligible child in the home who agrees to participate will be asked to keep a diary of asthma symptoms, medication use, and visits to a health care provider.
- The team will leave 2 air sampling patches (one each for formaldehyde and nitrogen dioxide) taped to the wall in one of the rooms of your home. These patches must sit undisturbed for 24 hours until they are collected.
- One member of the Home Assessment Team will come back to your house the next day to pick up the air sampling patches.
- You will be mailed 2 copies of the report telling you what the Home Assessment Team found in your home and making recommendations for changes based on what they found.
- A member of the Home Assessment Team will call you about 10 days after the assessment report is mailed to you to make sure you got it and to answer any questions you may have about it.
- If you decide you want to make some of the recommended home renovations from the assessment report, members of the Home Assessment Team will be available to help you discuss these with your landlord, if needed. They will also help you to contact a renovation contractor who can do the recommended home repairs at a very low costs. They can even help you to arrange financing through the Boston Private Bank and Trust Company for large or expensive work such as deleading. **HOWEVER, THIS STUDY WILL NOT PAY FOR ANY OF THE RENOVATIONS YOU DECIDE TO MAKE, YOU WILL BE RESPONSIBLE FOR THOSE CHARGES YOURSELF.**

- The renovation contractor used by this study will be able to do the home repairs and other changes at a much lower cost than normal because he/she will have the help of volunteers from YouthBuild who are getting on-the-job training through this program. Any changes made to your home will be your decision; you can do as many or as few (even none) of the recommended changes as you like.
- Six months after the first home visit, you will be mailed a survey asking about the health of each child in the home. Once you have completed this survey, mail it back to the study staff along with each child's asthma diary. New diaries will be included with the survey.

One year after the first home visit, 2 members of the Home Assessment Team will call you and schedule a day for a home visit. At the home visit, they will ask you some survey questions, collect the children's asthma diaries, and give each child the same breathing test used in the first visit. They will also ask about changes you have made to your home in the last year and will ask to revisit some rooms to look for changes since the first visit. They will also ask your permission again at this time to look at each child's medical records to count the number of visits to health care providers in the last six months and the purposes (asthma, lead, injuries, other) of those visits.

The first home assessment visit should take about 2 hours of your time. This includes a 5 minute follow-up visit the next day to pick up the air samplers. **None of the tests performed will in any way disturb or damage your home and no chemicals will be released into your home from the testing equipment.** The final visit at the end of one year will last about 1 hour.

Your entire involvement in this study will take about 5 hours of your time. This time includes three home visits, a ten minute telephone call, and the time it will take you (about 30 minutes) to fill out and mail back a 6 month survey questionnaire as well as the time it will take you or each child to write down information in the asthma diary.

#### RISKS AND DISCOMFORTS:

At no time during your participation in this project will you be exposed to any physical harm or risk. However, you must be aware that as representatives of the Boston Public Health Commission, the project staff visiting your home have certain obligations. They must report any evidence they witness of child abuse or neglect while in your home. They must take appropriate action if they find a condition in your home which is very hazardous to your health and safety. This could include calling the fire department to evacuate the building if they find something like a gas leak or unsafe levels of carbon monoxide gas.

Also, it is possible that the home assessment will reveal conditions in your home which may be potential health risks and over which you have no power to make changes. This may cause you some amount of stress or anxiety. We will help you to discuss such issues with your landlord. There is the risk that you may need to move if your landlord will not fix a serious condition. It is also possible that you will wish to make some of the recommended changes to your home, but you cannot afford them and you cannot meet the Boston Private Bank and Trust Company's credit criteria. This may cause you some

amount of stress and discomfort. We will provide technical assistance or referral to other agencies at your request.

#### BENEFITS:

In return for your help and cooperation in completing this study, the Office of Environmental Health will be able to provide you with the following:

- Specific information on potential asthma triggers, lead paint hazards, and childhood injury risk factors found in your home and how to limit your child's exposure to those (although there may be no relationship between these factors and your child's health).
- Specific recommendations of things you can do in your own home to reduce your exposure to the identified risk factors. We can't make any changes within your home or pay for building repairs, but we can help you identify areas that should be changed and give you advice on how best to do it. We will also assist you by recommending a home renovation contractor who can do the work at a very low cost and helping you work with a bank (the Boston Private Bank and Trust Company) who can help you finance any large work projects.
- A report on our findings in your home which you can use to make changes at home and share with your health care provider to improve the quality of your medical care.
- Recommended changes which you decide to make may improve the value of your home.

In addition, you will be helping to build the scientific understanding of asthma, lead poisoning, and injury risks in the home and ways to deal with them. This information will help us to build a more permanent program for environmental home assessments and case management in the City of Boston.

#### ALTERNATIVES:

An assessment similar to the one provided by this program can be obtained from commercial consulting companies. You are free not to have these assessments done.

#### QUESTIONS:

If you have any questions about this project or your participation in it, please feel free to contact Dr. John Bernardo at the Boston Medical Center. He can be reached by telephone at (617)-638-5212.

#### COMPENSATION:

You will not be paid for your participation in this study. However, your participation in this study will give you the chance to have some home renovations done

at reduced costs. *Also, the project staff will bring you several items during their visit. These will include crayons and asthma coloring books for any children in the house as well as childhood safety supplies like outlet covers and cabinet locks. These incentives will have a total value of about \$20.00.*

**ADDITIONAL COSTS:**

It does not cost anything to be in this project. Your enrollment is voluntary and all services provided by this program are free of charge. However, your participation in this project may result in some costs to you if we find potential asthma triggers or other problems in your home which you decide to fix. How much this costs is entirely up to you as it is your decision as to what changes/repairs to make and what recommended changes not to make.

**RESEARCH RELATED INJURIES:**

If you are injured because you are in this study, medical treatment is available at Boston Medical Center. You may also get treatment at any other hospital or by any other doctor that you select. It is the policy of Boston Medical Center not to pay for this treatment or for any other losses. Either you or your insurance company will have to pay for any treatment. However, you do not give up any legal rights to seek payment for personal injury.

**MINOR’S STATEMENT OF ASSENT**

ASSENT: I agree to take part in this study. (for ages 8 to 17 years):

\_\_\_\_\_  
Patient/Subject’s Name

\_\_\_\_\_  
Age

\_\_\_\_\_  
Signature

**PARENT’S OR GUARDIAN’S STATEMENT OF CONSENT**

I have read the above description of this research study. I understand this statement of informed consent and the study risks. All of my questions have been answered to my satisfaction. I know that my child’s and my taking part in this research study is voluntary. I know that we may refuse to be in or quit this research study at any time. A copy of this form will be given to me.

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_  
Date

I have witnessed that the elements of the above informed consent have been adequately and appropriately explained to the subject.

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

I attest that I have fully and appropriately informed this subject of the nature of the above research study and have offered to answer any questions that he/she may have.

\_\_\_\_\_  
Signature of Principal or Designate

\_\_\_\_\_  
Date

**Human Studies Committee Statement**

Contact Dr. Susan Fish, (617/414-4318), Associate Chairperson of the Human Studies Committee (HSC), with any questions about your rights as a research subject or your taking part in this research study. The HSC was created to protect subjects taking part in research studies. Although the HSC has approved this as study # 98-093 on \_\_\_/\_\_\_/\_\_\_, your taking part is purely voluntary.