

GCO # 02-0584 (0001) 01 CM X \_\_\_\_\_

**PART I: RESEARCH PARTICIPANT INFORMATION SHEET**

**TITLE OF PROJECT:**

**Healthy Families Healthy Communities**

**A. PURPOSE OF THE STUDY:**

You and your child are being asked to participate in a research project. The purpose of this project is to demonstrate the effectiveness of control of factors in the home environment that contribute to asthma attacks. You and your child qualify to participate because your child has asthma, which may be triggered by something in your home environment.

**B. DESCRIPTION OF THE RESEARCH:**

You will be asked to attend educational group sessions every two months. In addition, our environmental specialist and/or Community Health Worker will come to your home to look at things in the home that could worsen asthma and provide education about how to control them. The environmental specialist and/or Community Health Worker will also provide home repairs of structural problems, do mold cleanup, provide some supplies as needed, e.g., air conditioners, hepa-vacuums air filters, allergy free mattress cover and pillow case; and assist you with any referrals related to these things that cause asthma to get worse and in any other steps to keep your child's asthma under control. Your home will be assessed as to its risk of lead exposure.

We will ask you to complete a questionnaire during our first visit and again at the last visit. This questionnaire will take about 30 minutes. We will revisit you at six and twelve months to assess your child's asthma and see how identified problems are resolving. We will ask you some questions in addition to assessing the home environment. These follow-up visits will be made by the Community Health Worker.

**C. COSTS/REIMBURSEMENTS:**

There will be no cost to you or your child for these services. You and your child will be asked to work with the team to try to control these allergens in your home by continuing the steps we take together.

**Subject/Surrogate Initials** \_\_\_\_\_

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**D. POTENTIAL RISKS AND DISCOMFORTS:**

There are no physical risks or discomfort associated with participation in this study.

**E. POTENTIAL BENEFITS:**

You and your child will receive the benefits of the environmental assessment, education, and home renovation and such supplies as may be necessary.

**F. ALTERNATIVES TO PARTICIPATION:**

You and your child have the option not to participate. There is no penalty to you or your child if you do not choose to participate.

**G. CONFIDENTIALITY:**

You and your child's identity as a participant in this research study will be kept confidential in any publication of the results of this study. The information obtained during this research (Research Record) will be kept confidential to the extent permitted by law. However, this Research Record and your personal Medical Record (if any and if relevant to the study) may be reviewed by government agencies (such as the Food and Drug Administration or the Department of Health and Human Services), the agency or company sponsoring this research, individuals who are involved in, or authorized to monitor or audit, the research, or the Institutional Review Board (the committee that oversees all research in humans at Mount Sinai School of Medicine) if required by applicable laws or regulations.

**H. COMPENSATION/TREATMENT:**

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Suzanne Gaynor at telephone number (212) 241-3185.

Subject/Surrogate Initials \_\_\_\_\_

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**I. VOLUNTARY PARTICIPATION:**

Participation in this study is voluntary. If you decide not to participate, this will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

**J. TERMINATION OF PARTICIPATION :**

Your participation will terminate after your eighteen-month follow-up visit. You may have the option of re-enrolling if problems persist. You may discontinue participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled.

**K. CONTACT PERSON(S):**

If you have any questions, at any time, about this research, or want to discuss any possible study-related injuries, please contact Dr. Suzanne Gaynor, at telephone number (212) 241-3185. If you still have questions regarding the study or your rights as a participant in the study you may discuss them with an administrator of the Institutional Review Board at Mount Sinai School of Medicine at telephone number (212) 659-8980.

**L. DISCLOSURE OF FINANCIAL INTERESTS:**

None

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From: \_\_\_\_\_ To: \_\_\_\_\_

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**AUTHORIZATION TO PARTICIPATE IN RESEARCH**

**The participant/surrogate and the investigator/delegate must each SIGN, DATE and TIME this two page authorization form.**

**Research Subject's Name (printed):** \_\_\_\_\_

1. I hereby volunteer to participate in a research program under the supervision of Dr. Suzanne Gaynor at (212) 241-3185 and her associates at Mount Sinai School of Medicine and/or its affiliated institution(s), the East Harlem Asthma Working Group, Inc.

2. I acknowledge that I have read, or had explained to me in a language understand, the attached consent document and that \_\_\_\_\_ has explained to me the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all of the questions I asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were in fact, properly completed before I signed this authorization.

Research Subject/Surrogate: \_\_\_\_\_  
Signature

Name: \_\_\_\_\_  
Print Name

Relationship: \_\_\_\_\_  
If signed by surrogate

**Subject/Surrogate Initials** \_\_\_\_\_

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**AUTHORIZATION TO PARTICIPATE IN RESEARCH (continued)**

*For subjects who are not able to read this consent document themselves, the following must be completed:*

I confirm that I have accurately translated and/or read the information to the subject:

Name: \_\_\_\_\_  
Signature

Name: \_\_\_\_\_  
Print Name

Address: \_\_\_\_\_  
Number and Street                      City                      State                      Zip Code

Date: \_\_\_\_\_                      Time: \_\_\_\_\_

I confirm that the consent document was translated and/or read to the subject:

Name of Witness: \_\_\_\_\_  
Signature

Name of Witness: \_\_\_\_\_  
Print Name

Date: \_\_\_\_\_                      Time: \_\_\_\_\_

I have fully explained to the above volunteer/patient/relative/guardian the nature and purpose of the foregoing drugs, devices or procedures, possible alternative methods of treatment which might be advantageous, the benefits reasonably to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the volunteer/patient/relative/guardian hereafter decides to discontinue such treatment. I believe that the above volunteer/patient/relative/guardian understands the nature, purposes, benefits, and risks of participation in this research. I have also offered to answer any questions the above volunteer/patient/relative/guardian might have with respect to such drugs, devices or procedures and have fully and completely answered all such questions.

**Subject/Surrogate Initials** \_\_\_\_\_

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From: \_\_\_\_\_ To: \_\_\_\_\_

**MOUNT SINAI SCHOOL OF MEDICINE  
CONSENT FOR RESEARCH**

**GCO # 02-0584 (0001) 01 CM X**

\_\_\_\_\_  
Signature of Principal Investigator/Delegate (person who obtained consent)

\_\_\_\_\_  
Print Name of person who obtained consent

\_\_\_\_\_  
Title

Date: \_\_\_\_\_

Time: \_\_\_\_\_

**Subject/Surrogate Initials** \_\_\_\_\_

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\_\_\_\_\_  
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From: \_\_\_\_\_ To: \_\_\_\_\_