(b) (4)

[redacted]

E. PROTECTION OF HUMAN SUBJECTS

SPECIAL POPULATIONS: Additional DHHS Protections for Pregnant Women, Fetuses, Neonates and Children Involved as Subjects in the Proposed Research.

We do not know of any potential risks to pregnant women, fetuses, neonates or children for procedures conducted as part of this study, including personal air monitoring, interviewing, blood drawing, psychological testing, and clinical examinations. All procedures are minimally invasive. Women are recruited during the third trimester of pregnancy. The research holds no prospect of direct benefit for the woman or fetus, since all monitoring and biological samples are taken or processed at the time of birth, so no prior intervention would be possible. The research holds minimal promise of direct benefit to the neonate or child except in the case that an exceptionally high toxic exposure level is found, the source of the exposure can be identified, and the source can be removed, as might be the case with hazardous pesticides, lead or mercury. All mothers provide informed consent in accord with the informed consent provisions of the OHSR. The consent form is a written document that embodies the elements of informed consent required by section 46.116, signed by the subject, who then receives a copy of the form. Each individual is fully informed regarding the reasonably foreseeable impact of the research on the fetus or the neonate. No inducements are offered to terminate a pregnancy. Individuals engaged in this research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy. Individuals engaged in this research will have no part in determining the viability of a neonate. If a neonate is not viable, there will be no additional research conducted involving the neonate. There will be no research involving, after delivery, the placenta, the dead fetus or fetal material. All research will be conducted in accord with sound ethical principles.

1. RISKS TO THE SUBJECTS

Human Subjects Involvement and Characteristics: The study will enroll and complete prenatal monitoring on 100 new pregnant African American and Latino (Dominican) women during pregnancy (for a total of 736 fully enrolled). This will allow us to follow 408 women and their 408 children through the child's 5th birthday through the funding period (12/08), 222 through the child's 7th birthday by 12/08 and 406 women and their 406 children through the child's 7th birthday after the funding period. We are currently funded to follow 292 children through age five. We are requesting follow-up of a remaining 116 subjects through age 5 and to follow all 408 (292 + 116) of these currently enrolled subjects beyond age 5 up to age 8 during the funding period. African American and Latino (Dominican) women will be included in approximately equal numbers. At the time of enrollment, the women will be 18-35 years of age and in good health (e.g., without pregnancy-related diabetes, hypertension or known HIV). Only women with a prenatal visit by the 20th week of pregnancy are eligible. Women who are smokers, use illicit drugs, who have not lived in the community for at least 1 year are ineligible. No collaborating site will have contact with human subjects. White (not Latino) women are not included because a central purpose of the research is to evaluate birth outcomes in a high risk, minority population. Following delivery, the mother and infant will be followed prospectively and contacted at regular intervals to collect research materials, specimens, records and other data (described below) until the end of the

funded period (12/08). Pregnant women and newborns are enrolled in order to evaluate risks to those likely to be most vulnerable to environmental toxicants.

Sources of Materials: All subjects in this study will be living. Questionnaires will be administered to the mother prenatally and every 3 months postnatally until the child's third birthday and every 6 months after that until the child's seventh birthday or the end of the study period. Medical record data will be extracted from the mothers' and infants' charts after delivery for all 100 newly-recruited subjects. All questionnaire data (environmental and health histories) and medical record data will be obtained by trained research staff for the purpose of this research. Two maternal urine samples will be collected from the mother during pregnancy and a maternal and umbilical cord blood sample and a newborn meconium sample will be collected at delivery. In addition, blood samples will be collected from the child at ages two, three, five and seven and a urine sample will be collected from the child at ages 3, 5 and 7. Additionally, the women will be asked to wear a small personal air monitoring for 48-hours during the 3rd trimester of pregnancy. We will also collect dust samples from homes of the study subjects during the 3rd trimester and again when the child is 1, 3 and 5 years old. At these time points, the home will be inspected for leaks, holes in the walls, or any other signs of physical damage.

Under the supervision of (b) (6) [redacted] developmental status of the infant, the home environment, and child behavior problems will be assessed at infant ages 6-, 12-, 24-, 36-, 48-, 60- and 84-months using standardized instruments. Under the supervision of (b) (6) [redacted] children who score in the upper 10% of the sample on a screening measure of behavior problems will be tested further by interview and clinical examination for behavior problems and diagnosis of ADHD at ages 5 and 7. Further screening and clinical evaluation of this subset of children will be conducted at (b) (6) [redacted] clinical research site at Columbia. Although we will not collect questionnaire data after age seven, we will collect public school performance data (test scores and special education placement) at age eight from all subjects.

Potential Risks: No physical risks beyond a possible bruising at the site of blood-drawing are likely. Because all possible measures will be taken to protect the women's confidentiality, we do not anticipate social or other risks to th individual.

2. ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent: Eligible women will be told of the study by a bilingual Research Worker. Each woman will be asked to sign a consent form approved by the IRB at CPMC and HH. The consent form (in English and Spanish) will clearly explain study goals and procedures as described in #2 above. The women will be fairly reimbursed for their participation: $50 during the 3rd trimester, $75 at delivery, $50 at the 6-month assessment, $75 at the 12-month assessment, $125 at the 24-month assessment, $125 at the 36-month assessment, $125 at the 48-month assessment, $125 at the 60-month assessment, and $125 at the 84-month assessment. As a further incentive, their travel costs to and from the clinics will be covered; and if necessary, subjects will be escorted to and from the clinics by research staff.

Protection Against Risk: All samples and data will be coded and kept in locked storage units to protect confidentiality of study subjects. Subject confidentiality will be protected at all stages of the study by elimination of names and other identifying information, including during data analysis. Data entry and analysis will be done only by approved research workers. All biological specimens, including DNA, will be coded and stored in locked facilities. No collaborators, including the NCI, will have access to personal identifier information. In the event of an adverse effect of blood drawing (fainting, bruising, etc.), medical intervention will be available. Children who are identified as having unacceptably high levels of lead or mercury in their blood will receive medical care. All children who score below the cut-point for developmental delay at any assessment will be referred to the New York State Early Intervention program. Follow-up phone call and a second referral will be made if the mother fails to follow through with the referral. All children who screen positive for ADHD or other diagnosable child psychiatric disorder will be referred to (b) (6) [redacted] for treatment and medical care will be made available. All guidelines recommended by the IRB for protecting confidentiality will be followed. All aspects of this study, including protocols for the assessment of genetic polymorphisms, have already been approved by the Columbia University IRB and we are in compliance with HIPAA.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

Potential benefits include the psychological benefit of contributing to knowledge that can prevent future adverse health effects in others. There may also be real benefits to participants and their children if research results lead to interventions to reduce harm from environmental exposures in this community. There is also the benefit of periodic monitoring of the child's health and development which may enable problems to be identified early and treated by referrals. The population included in the study is at high risk for air pollution exposures, social adversities, asthma and child developmental deficits. Information provided to subjects may help them use safer, less toxic pesticides, lower the pest populations in their homes, remove sources of lead and mercury toxicity, and improve knowledge about good child-rearing practices. In addition, there is a procedure in place to inform study subjects and community residents of research findings that reveal exposures that are potentially hazardous to health. Because this research study has a strong community participatory component, including a community advisory committee, all concerns on the part of subjects and community advisors are discussed regularly.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

The potential risks to subjects are reasonable given the benefits. This research study will add to the scientific knowledge base about environmental exposures that are hazardous to children and pregnant women. This research study and the team of investigators strongly supports the principles of community participatory research and environmental justice. A community outreach core will oversee all ethical issues regarding information sharing and confidentiality.

COLLABORATING SITES (NA for Growth and Development Study)

INCLUSION OF WOMEN

The study will enroll and complete prenatal monitoring on 100 new pregnant African American and Latino (Dominican) women during pregnancy. African American and Latino (Dominican) women will be included in approximately equal numbers. Women will be approached for participation at the hospital OB/GYN prenatal care clinics. At the time of enrollment, the women will be 18-35 years of age and in good health (e.g., without pregnancy-related diabetes, hypertension or known HIV). Only women with a prenatal visit by the 20th week of pregnancy are eligible. No special outreach programs will be used for recruiting women. Women who are smokers, use illicit drugs, who have not lived in the community for at least 1 year are ineligible. Following delivery, the mother and infant will be followed prospectively and contacted at regular intervals to collect research materials, specimens, records and other data until the end of the funded period (12/08). Pregnant women and newborns are enrolled in order to evaluate risks to those likely to be most vulnerable to environmental toxicants. The study will also extend follow-up contact for 408 current study participants whose children will reach the age of 5 years during the funding period. These mother-child pairs will be contacted regularly until the children reach 7 years of age, or until the end of the study period.

INCLUSION OF MINORITIES

The study will enroll and complete prenatal monitoring on 100 new pregnant African American and Latino (Dominican) women during pregnancy. African American and Latino (Dominican) women will be included in approximately equal numbers, based on self-identification. At the time of enrollment, the women will be 18-35 years of age and in good health (e.g., without pregnancy-related diabetes, hypertension or known HIV). Only women with a prenatal visit by the 20th week of pregnancy are eligible. Women who are smokers, use illicit drugs, who have not lived in the community for at least 1 year are ineligible. White (not Latino) women are not included because a central purpose of the research is to evaluate birth outcomes in a high risk, minority population. Following delivery, the mother and infant will be followed prospectively and contacted at regular intervals to collect research materials, specimens, records and other data until the end of the funded period (12/08). Pregnant women and newborns are enrolled in order to evaluate risks to those likely to be most vulnerable to environmental toxicants. The study will also extend follow-up contact for 408 current study participants whose children will reach the age of 5 years during the funding period. These mother-child pairs will be contacted regularly until the children reach 7 years of age, or until the end of the study period.

INCLUSION OF CHILDREN

The basic study design is to prospectively follow a birth cohort as written above. Newborns are enrolled in order to evaluate environmental risk factors that may be occurring at a particularly vulnerable time in life.

1. Proposed Dates of Enrollment

Enrollment of new study subjects will begin in December, 2003 and end on December, 2004.

2. 5/01 Targeted/Planned Enrollment

Table 4. Targeted/Planned Enrollment Table

Study Title: Identification and prevention of risks of neurodevelopmental impairment and childhood asthma from prenatal and postnatal exposure to urban pollutants

Total Planned Enrollment: 1,460 (including mothers and newborns)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	666	226	892
Not Hispanic or Latino	426	142	568
Ethnic Category Total of All Subjects	1,092	368	1,460
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	426	142	568
White	0	0	0
Unknown	666	226	892
Racial Categories: Total of All Subjects	1,092	368	1,460

(b) (4)

[redacted]

E. PROTECTION OF HUMAN SUBJECTS

Special populations: Additional DHHS Protections for Pregnant Women, Fetuses, Neonates and Children Involved as Subjects in the Proposed Research

We are unaware of any potential risks to pregnant women, fetuses, neonates or children for procedures conducted as part of this study, including personal air monitoring, interviewing, blood drawing, psychological testing, and clinical examinations. All procedures are minimally invasive. Women are recruited during the third trimester of pregnancy. The research holds no prospect of direct benefit for the woman or fetus, since all monitoring and biological samples are taken or processed at the time of birth, so no prior intervention would be possible. The research holds minimal promise of direct benefit to the neonate or child, except in the case that an exceptionally high toxic exposure level is found, the source of the exposure can be identified, and the source can be removed (e.g. hazardous pesticides, lead or mercury). All mothers provide informed consent in accord with the informed consent provisions of the OHSR. The consent form is a written document that embodies the elements of informed consent required by section 46.116, signed by the subject, who then receives a copy of the form. Each individual is fully informed regarding the reasonably foreseeable impact of the research on the fetus or the neonate. No inducements are offered to terminate a pregnancy. Individuals engaged in this research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy. Individuals engaged in this research will have no part in determining the viability of a neonate. If a neonate is not viable, there will be no additional research conducted involving the neonate. There will be no research involving, after delivery, the placenta, the dead fetus or fetal material. All research will be conducted in accord with sound ethical principles.

1. Risks to the subjects

Human subjects involvement and characteristics

The study will enroll and complete prenatal monitoring on 100 new pregnant African American and Latina (Dominican) mothers during pregnancy (for a total of 736 fully enrolled). This will allow us to follow 408 women and their 408 children through the child's 5th birthday through the funding period (12/08), 222 through the child's 7th birthday by 12/08 and 406 women and their 406 children through the child's 7th birthday after the funding period. African Americans and Dominicans will be included in approximately equal numbers. At enrollment, women will be 18-35 years of age and in good health (e.g., without diabetes, hypertension or known HIV). Only women with a prenatal visit by the 20th week of pregnancy are eligible. Women who are smokers, use illicit drugs, or have not lived in the community for at least 1 year are ineligible. No collaborating site will have contact with human subjects.

Sources of material

Questionnaires will be administered to the mother prenatally and every 3-6 months postnatally until the child's 3rd birthday, and every 6 months after that until the child's 7th birthday or the end of the study period. Medical record data will be extracted from the mothers' and infants' charts after delivery. All questionnaire and medical record data will be obtained by trained research staff for the purpose of this research only. Two maternal urine samples will be collected from the mother during pregnancy and a maternal and umbilical cord blood sample and a newborn meconium sample will be collected at delivery. In addition, blood samples will be collected from the child at ages 2, 3, 5 and 7 and urine sample will be collected from the child at ages 3 and 5. Additionally, the women will be asked to wear a small personal air monitoring for 48-hours during the 3rd trimester of pregnancy. We will also collect dust samples from homes of the study subjects during the 3rd trimester and again when the child is 1, 3 and 5 years old. At these time points, the home will be inspected for leaks, holes in the walls, or any other signs of physical damage. When the child is age 5 years, a lung function test will be performed under the supervision of (b) (6) [redacted] and an allergy skin test will be performed under the supervision of (b) (6) [redacted]

The National Cancer Institute of the NIH will have access to confidentially coded DNA only.

Potential risks

No physical risks beyond possible bruising at the site of blood-drawing are anticipated. Because all possible measures will be taken to protect the women's confidentiality, we do not anticipate social or other risks to the individual. Recent large studies, including one of 2471 children age 5-14 years [94] and another with 614 children age 5-8 years [95] reported no serious sequelae from epicutaneous testing. No risks will occur at any collaborating sites.

2. Adequacy of protection against risks

Recruitment and informed consent

Subjects will be recruited in prenatal clinics by investigators trained in Good Clinical Practice. Eligible women will be told of the study by a bilingual research worker. Each woman will be asked to sign a consent form approved by the IRB at CPMC and HH and a HIPAAA Clinical Research Authorization form. The forms (in English and Spanish) will explain study goals and procedures. The women will be fairly reimbursed for their participation: $50 during the 3rd trimester, $75 at delivery, $50 at the 6-month assessment, $75 at the 12-month assessment, $125 at the 24-month assessment, $125 at the 36-month assessment, $125 at the 48-month assessment, $125 at the 60-month assessments, and $125 at the 84 month assessment. As a further incentive, their travel costs to and from the clinics will be covered; and if necessary, subjects will be escorted to and from the clinics by research staff. Recruitment and consent will not occur at any collaborating sites.

Protection against risk
There are no physical risks beyond possible bruising at the site of blood-drawing or transient discomfort such as itching during the allergy skin tests. Large studies, including one of 2471 children age 5-14 years [94] and another with 614 children age 5-8 years [95] reported no serious sequelae from epicutaneous allergy testing, although there is a theoretical risk of a severe systemic allergic reaction. A physician will be present during all allergy skin testing. Because all possible measures will be taken to protect the women's and child's confidentiality, we do not anticipate social or other risks to the individual. In the event of an adverse effect, medical intervention will be available. All collected data will remain in locked storage units. Subject confidentiality will be protected at all stages of the study by elimination of names and other identifying information, including during data analysis. Data entry and analysis will be done only by approved research workers. All biological specimens, including DNA, will be coded and stored in locked facilities. No collaborators, including the NCI, will have access to personal identifier information. All guidelines recommended by the IRB for protecting confidentiality will be followed. All aspects of this study, including protocols for the assessment of genetic polymorphisms, have already been approved by the Columbia University IRB and we are in compliance with the HIPAA.

3. Potential benefits of the proposed research to the subjects and others

The potential risks to subjects are reasonable given the benefits. These include the psychological benefit of contributing to knowledge that can prevent future adverse health effects in others. There may also be real benefits to participants and their children if research results lead to interventions to reduce harm from environmental exposures in this community. There is also the benefit of periodic monitoring of the child's health which may enable problems to be identified early and treated by referrals. For example, participants and their primary care providers will be provided the results of the child's pulmonary function tests and allergy skin tests. In the case of allergy skin tests, age appropriate and culturally sensitive (under the guidance of community advisory board) educational materials will be given to the children and their guardians.

The population included in the study is at high risk for exposure to air pollution, social adversities, and asthma. There is a procedure in place to inform study subjects and community residents of research findings that reveal exposures that are potentially hazardous to health. Because this research study has a strong community participatory component, including a community advisory committee, all concerns on the part of subjects and community advisors are discussed regularly.

4. Importance of the knowledge to be gained
Information gained will lead to a better understanding of the causes of asthma and allergies, and ultimately could lead to better interventions against disease in the future. This research study and the team of investigators strongly support the principles of community participatory research and environmental justice. A community outreach core will oversee all ethical issues regarding information sharing and confidentiality.

Collaborating sites
The only research to be conducted at collaborating sites includes analysis of coded specimens. No collaborating site will have direct contact with human subjects.

Inclusion of women
The study will enroll and complete prenatal monitoring on 100 new pregnant African American and Latino (Dominican) women during pregnancy. African American and Latino (Dominican) women will be included in approximately equal numbers. Women will be approached for participation at the hospital OB/GYN prenatal care clinics. At the time of enrollment, the women will be 18-35 years of age and in good health (e.g., without pregnancy-related diabetes, hypertension or known HIV). Only women with a prenatal visit by the 20th week of pregnancy are eligible. No special outreach programs will be used for recruiting women. Women who are smokers, use illicit drugs, who have not lived in the community for at least 1 year are ineligible. Following delivery, the mother and infant will be followed prospectively and contacted at regular intervals to collect research materials, specimens, records and other data until the end of the funded period (12/08). Women who are pregnant are enrolled in order to evaluate risks to those likely to be most vulnerable to environmental toxicants.

Inclusion of minorities
Caucasian women are not included because a central purpose of the research is to evaluate birth outcomes in a high risk, minority population. All women enrolled will be African American or Latino.

Inclusion of children
The basic study design is to prospectively follow a birth cohort as written above. Newborns are enrolled in order to evaluate environmental risk factors that may be occurring at a particularly vulnerable time in life. The investigative team includes physicians board-certified in pediatrics (b) (6) [redacted] internal medicine (b) (6) [redacted]

(b) (6) [redacted] pediatric pulmonary, (b) (6) [redacted] adult pulmonary (b) (6) [redacted] and allergy/immunology (b) (6) [redacted] They are all experienced both in treating pediatric disease and performing clinical pulmonary research on children. A sufficient number of children will be enrolled to ensure sufficient power to address our research hypotheses.

Table 13: Targeted/Planned Enrollment Table

Study Title: Identification and prevention of risks of neurodevelopmental impairment and childhood asthma from prenatal and postnatal exposure to urban pollutants

Enrollment of new subjects will begin in December, 2003 and end in December, 2004.

Total Targeted Enrollment: 1,460 (including mothers and newborns)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	666	226	892
Not Hispanic or Latino	426	142	568
Ethnic Category Total of All Subjects	1,092	368	1,460
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	426	142	568
White	0	0	0
Unknown	666	226	892
Racial Categories: Total of All Subjects	1,092	368	1,460

(b) (4) [redacted]

E. PROTECTION OF HUMAN SUBJECTS

SPECIAL POPULATIONS: None. The study subjects will be a representative sample of adult residents of public housing in New York City. Although a few study subjects may be pregnant women, we know of no potential risks to them from procedures conducted as part of this study, including interviewing, collecting vacuumed dust samples from the floors and beds in their apartments, and setting sticky traps to measure the number of cockroaches in the apartment. All study participants provide informed consent in accord with the informed consent provisions of the OHSR. The consent form is a written document that embodies the elements of informed consent required by section 46.116, signed by the subject, who then receives a copy of the form. All research will be conducted in accord with sound ethical principles.

RISKS TO THE SUBJECTS

Human Subjects Involvement and Characteristics: In the Phase 1 study we will approach the approximately 240 public housing residents in East Harlem who are or will be taking part in our current study. We will ask for their consent to extend the study follow-up by a period of 6-12 months. Based on the 170 participants enrolled so far, this group is primarily female and of Latino ethnicity. At the time of enrollment, the eligibility requirements for participants were that they be the head-of-household, 18 years of age, and able to give informed consent. Ethnicity and gender were not criteria for eligibility. The current study follow both the intervention and control group families to six months post-intervention, at which point the control group receives the intervention. The Phase 1 extension will follow intervention group families for an additional six months to 12 months post-intervention, and the control group families for 12 months post-intervention.

In the Phase 2 study, an additional 200 residents who are heads-of-household in a public housing development in northern Manhattan will be enrolled in the study. The eligibility requirements are the same as in the Phase 1 study. The data collected will be the same, with the addition of questions about repairs made in the apartment, general perception of health, and housing-related quality of life. Data will be collected from participants at baseline, 3 months, and 12 months. All families will receive an annual inspection from the New York City Housing Authority to assess health-related housing conditions that need repair. Intervention group families will receive enhanced remediation services, while control families will receive remediation according to current practice. Enhanced remediation consists primarily of an accelerated schedule of normal repairs to leaky plumbing, broken windows, malfunctioning fire alarm, and infestations of cockroaches or mice. None of the remediation activities pose any health risk to families.

Sources of Materials: All subjects in this study will be living. In both Phase 1 and Phase 2, questionnaires will be administered to the head-of-household. Dust samples will be vacuumed from the kitchen floor and the beds of the respondent and any other family members with a history of asthma for analysis of the presence of cockroach and mouse allergen. Sticky traps will be placed and then collected after one week to measure the number of cockroaches in the apartment. Similarly, cornmeal bait blocks encased in a protective cover will be placed in each room to estimate the number of mice present based on the amount of cornmeal consumed. The cornmeal bait is harmless, and the protective cover makes the bait inaccessible to adults, children, and pets. All interviews will be conducted in the apartment with two research workers present.

Potential Risks: No physical risks are involved. Because all possible measures will be taken to protect the women's confidentiality, we do not anticipate social or other risks to the individual.

ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent: Eligible residents will be told of the study by a bilingual Research Worker. Each resident will be asked to sign a consent form approved by the IRB at CPMC and the New York City Department of Health. The consent form (in English and Spanish) will clearly explain study goals and procedures described above. The respondents will be fairly reimbursed for their participation: They will receive a $20 Metrocard for public transportation at the conclusion of each interview. This will total $20 for Phase 1 intervention group participants, $40

for Phase 1 control group participants, and $60 for all Phase 2 study participants. The Metrocards will be provided by the New York City Department of Health.

Protection Against Risk: All physical samples and data will be coded and kept in locked storage units to protect confidentiality of study subjects. Electronic databases will be kept in secure computers that are in locked offices with access only to research staff, and with file-specific password protection to provide additional protection against possible loss of confidentiality.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

Potential benefits include the psychological benefit of contributing to knowledge that can prevent future adverse health effects in others. There may also be real benefits to participants and their children if research results lead to interventions to reduce harm from environmental exposures in this community. The population included in the study is at high risk for air pollution exposures and asthma. Information provided to subjects may help them use safer, less toxic pesticides, and to lower the pest populations and mold levels in their homes. For study participants involved in the Phase 2 intervention, the benefits include possible reduction of pest populations, remediation of physical problems in their apartments, and reduction of other health-related housing conditions such as mold, malfunctioning smoke alarms, and broken window guards. Because this research study has a strong community participatory component, including a community advisory committee, all concerns on the part of subjects and community advisors are discussed regularly.

IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

The potential risks to subjects are reasonable given the benefits. This research study will add to the scientific knowledge base about how to reduce household pests in an effective way that minimizes the use of toxic pesticides that are hazardous to children and pregnant women. This research study and its team of investigators strongly support the principles of community participatory research and environmental justice. A community outreach core will oversee all ethical issues regarding information sharing and confidentiality.

COLLABORATING SITES

All work involving the recruitment and enrollment of human subjects will be performed at a single site: public housing administered by the New York City Housing Authority. The research team will include staff from Columbia University and the New York City Department of Health (see letter of support). All the information above applies to both sites. The Columbia University OHRP assurance number is M1356-01 and the Department of Health's OHRP assurance number is 1541.

INCLUSION OF WOMEN IN THE PHASE 1 STUDY

The Phase 1 study will enroll approximately 240 apartment residents in public housing who are enrolled in our current study, of which 230 are women. The eligibility and exclusion criteria cited above do not include any gender requirement.

INCLUSION OF MINORITIES IN THE PHASE 1 STUDY

The Phase 1 study will enroll approximately 240 apartment residents in public housing who are enrolled in our current study. The eligibility and exclusion criteria cited above do not include any selection based on race or ethnicity. Based on the residents currently enrolled, and the expectation that the remaining families enrolled will primarily be African-American, the expected target population is described in the table below.

INCLUSION OF CHILDREN IN THE PHASE 1 STUDY

Children will not be enrolled in the Phase 1 study because all participants in our current study, from which the Phase 1 study population will be drawn, were adults who were the head-of-household for the study apartment. The primary focus of the study is the condition of the apartment and the family's response to these conditions, and thus the head of household is best qualified to provide this information. The only involvement of children is through information provided by the study participants about the symptoms of children in their family who have asthma, and through dust samples that may be collected from children's beds. No children will be interviewed, nor will any data be collected directly from them.

Proposed Dates of Enrollment for Phase 1 study
Enrollment began in Phase 1 on March 1, 2003 and will continue through May 31, 2004.

1. 5/01 Targeted/Planned Enrollment Format Page for Phase 1

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Community-based Intervention Phase 1

Total Planned Enrollment: 240 (assuming we retain 80% of our current sample)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	128	32	160
Not Hispanic or Latino	64	16	80
Ethnic Category Total of All Subjects*	192	48	240
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	3	1	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	115	29	144
White	74	18	92
Racial Categories: Total of All Subjects *	192	48	240

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

INCLUSION OF WOMEN IN THE PHASE 2 STUDY

The Phase 2 study will enroll approximately 200 residents in a housing development located in northern Manhattan, of which we expect a similar proportion to be women. The eligibility and exclusion criteria are identical to Phase 1.

INCLUSION OF MINORITIES IN THE PHASE 2 STUDY

The Phase 2 study will enroll approximately 200 residents in a housing development located in northern Manhattan. The eligibility and exclusion criteria are the same as in Phase 1, and do not include any selection based on race or ethnicity. Anticipating that the housing development will be located in Central Harlem, we expect that the Majority

of families enrolled will be African-American. The expected target population is described in the table below.

INCLUSION OF CHILDREN IN THE PHASE 2 STUDY

Children will not be enrolled in the Phase 2 study because all participants must be adults who are the head-of-household for the study apartment. The primary focus of the study is the condition of the apartment and the family's response to these conditions, and thus the head-of-household is best qualified to provide this information. The only involvement of children is through information provided by the study participants about the symptoms of any children in their family who have asthma, and through dust samples that may be collected from children's beds. No children will be interviewed, nor will any data be collected directly from them.

Proposed Dates of Enrollment for Phase 2 study
Enrollment for phase 2 will begin in November, 2004 and will end in July 2005.

1. 5/01 Targeted/Planned Enrollment Format Page for Phase 1

Targeted/Planned Enrollment Table

Study Title: Community Based Intervention -- Phase 2

Total Planned Enrollment: 200

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	48	12	60
Not Hispanic or Latino	112	28	140
Ethnic Category Total of All Subjects*	160	40	200
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	2	2	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	121	29	150
White	37	9	46
Racial Categories: Total of All Subjects *	160	40	200

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

DATA AND SAFETY MONITORING PLAN

The Phase 1 and 2 studies involve housing maintenance interventions that have potential consequences for the health of study participants. Neither medical treatment nor disease-specific health education are involved in the research, and the only risk identified is the risk of loss of confidentiality. Because we are collecting information on resident perception of the health of themselves and their families, including asthma symptoms, we propose the following Data and Safety Monitoring Plan. The Principal Investigator for CCCEH, (b) (6) [redacted] holds biweekly staff meetings with CCCEH staff and staff from NYCHA and NYCDOHMH, our collaborating partners. At these meetings, he will regularly review staff reports involving illness or injury reported by study participants to the staff. When such reports occur, study staff will be asked to investigate whether the incident appears to have any relationship to the study intervention or evaluation activities, and what level of treatment was needed. Events that are serious enough to require hospitalization or a visit to the hospital emergency room for treatment will be reported to the Columbia University IRB and the NYCDOHMH IRB for further review.

(b) (4)

[redacted]