

Published in final edited form as:

*J Asthma*. 2011 December ; 48(10): 1007–1014. doi:10.3109/02770903.2011.624235.

## The School Inner-City Asthma Study (SICAS): Design, Methods, and Lessons Learned

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### Abstract

**Background**—Children spend a significant amount of time in school. Little is known about the role of allergen exposure in school environments and asthma morbidity.

**Objectives**—The School Inner-City Asthma (SICAS) is an NIH funded prospective study evaluating the school/classroom specific risk factors and asthma morbidity among urban children

**Methods/Results**—This paper describes the design, methods, and important lessons learned from this extensive investigation. A single center is recruiting 500 elementary school aged children, all of whom attend inner-city, metropolitan schools. The primary hypothesis is that exposure to common indoor allergens in the classroom will increase the risk of asthma morbidity in children with asthma, even after controlling for home allergen exposures. The protocol includes screening surveys of entire schools and baseline eligibility assessments obtained in the spring prior to the academic year. Extensive baseline clinical visits are being conducted among eligible children with asthma during the summer prior to the academic school year. Environmental

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#### Declaration of Interest

All authors do not have any financial and personal relationships with other people or organizations that could influence (bias) their work. We have no disclosures of any affiliation with any organization with a financial interest, direct or indirect, in the subject matter or materials discussed in the manuscript (such as consultancies, employment, paid expert testimony, honoraria, speakers bureaus, retainers, stock options or ownership, patents or patent applications or travel grants) that may affect the conduct or reporting of the work submitted.

classroom/school assessments including settled dust and air sampling for allergen, mold, air pollution, and inspection data are collected twice during the academic school year and one home dust sample linked to the enrolled student. Clinical outcomes are measured every 3 months during the academic school year.

**Conclusion**—The overall goal of SICAS is to complete the first study of its kind to better understand school-specific urban environmental factors on childhood asthma morbidity. We also discuss the unique challenges related to school-based urban research and lessons being learned from recruiting such a cohort.

## INTRODUCTION

### Background and Rationale

Asthma is a disease that affects more than 12% of Americans under the age of 18 for over 14 million missed school days per year and is the number one cause of school absences in America[1]. Allergen exposure in the home environment is associated with asthma exacerbations and asthma morbidity[2], and the home environment has been a target for allergen avoidance interventions[2].

Elementary school children spend 6 to 10 hours a day in school, and most of that time is spent in one classroom. Although the school classroom environment may be as significant a source of allergen exposure and consequent asthma morbidity as allergen exposure in the home, [3–12] [13, 14] few studies have evaluated the relationship between allergen exposure in school classrooms and asthma morbidity. These studies have been mostly conducted in Europe. They are limited by their cross-sectional study design, lack of objective measures of allergen sensitization through allergen-specific skin test reactivity, and the absence of evaluation of the relative contribution of classroom and home allergen exposure to asthma morbidity. No large-scale longitudinal studies have ever been conducted relating allergen exposure in schools and asthma morbidity in the U.S., particularly in inner-city environments, known to have disproportionately higher levels of asthma morbidity[15].

The overall goal of this study is to perform a longitudinal study evaluating the role of indoor allergen and mold/fungal exposure, specific to the inner-city classroom environment, and asthma morbidity. Mold/fungi may be sources of both allergens and also of airway irritants. An understanding of exposure risk factors specific to the classroom is critical because the classroom environment could potentially be considered an effective target for interventions aimed at reducing inciting exposures to prevent asthma morbidity for many symptomatic children.

### Objectives of the Study

A missing link in the plethora of data suggesting the home environment is a significant source of asthma morbidity is the relative contribution of the school and classroom environment, in a population who suffers from significant asthma disease burden. Our hypothesis is that exposure to common indoor allergens in the classroom will increase the risk of asthma morbidity in inner-city children with asthma, even after controlling for home allergen exposures. To test these hypotheses, we are conducting a longitudinal study of 500 elementary school-aged children with asthma from multiple classrooms in 30 Boston inner-city schools, with the following main objective:

To evaluate whether elevated levels of allergens (e.g. mouse, cat, dog, cockroach) or mold/fungi in the classroom increase the risk of asthma morbidity (e.g., number of school days missed, number of unscheduled medical visits, days of wheezing, and number of

hospitalizations), over a 1 year period in inner-city children with asthma, even after controlling for allergen exposure in the home.

## METHODS

### Overview of the Study Design

Recruitment is ongoing over 5 years and started in spring 2008. Every spring prior to the academic year when follow-up is scheduled to occur, screening survey questionnaires are distributed to all the students in 7–10 elementary schools to determine eligible asthmatics that will be attending the same school in the subsequent fall. During the spring, eligibility assessments are obtained. The summer prior to the academic year, at a clinic visit, eligible subjects obtain a baseline assessment of their asthma symptoms, home and child-care characteristics, pulmonary function, and specific allergen sensitivities. These children are followed every 3 months throughout the school year with a final follow-up 12 months after baseline. Approximately 100 asthmatics from 7–10 schools are being enrolled per year, so that by the end of the 5 years, 500 students with asthma from 35 schools will be enrolled and complete follow-up (see Table 1 for schema).

This study is approved by the Children's Hospital, Boston and the Brigham and Women's Hospital, Investigational Review Board (IRB). It is also approved by the Research, Assessment, and Evaluation Division and Facilities Management Department of the Boston Public Schools.

## RESULTS

### Recruitment Protocol

**Recruiting Schools**—A unique and challenging feature of this study is collaboration and support from the schools and the community. Relationship development is ongoing over many years in order to obtain approvals and support from the officials, research, and facilities management of the schools. Principals are individually contacted and the details of the study are explained. Administrative and Nursing staff and Community advocates work to partner our staff with theirs in a collaborative effort that benefits everyone involved. Staff from Boston Connects, Facilities Management and other community groups are vital to the success of the outreach efforts. Boston Connects is an educational partnership between community colleges and other organizations and elementary schools with the overall goal to improve educational efforts in the city. We collaborated with school site coordinators conducting health education programs to connect with the school staff and students as part of their educational efforts. Furthermore, our years of collaboration and support from the school Facilities Management leaders helped us connect with school principals and staff to obtain buy-in from the schools. Involvement in community events, community advisory boards, and community outreach programs are also vital to obtain buy-in from the school, parent, and teacher community. Furthermore, many of the local high schools have programs that require student community educational and research involvement for graduation. Therefore, as much as possible, we engage high school students in the research efforts so they may learn from experience with our study. These multiple relationships have been critical in maintaining community support for our project.

Once the relationship is established, our main instrument used for recruitment is a one page screening survey (available in both Spanish and English) that is administered and distributed in the classrooms of participating schools with instructions for the students and their parents to fill out the questionnaire and return them to their teacher. Study staff arrange with the school a convenient time to provide a brief presentation to the students explaining the study

with instructions. A flyer is also distributed to all the school children after the questionnaires are distributed to encourage returning the questionnaires. The questionnaires are collected at the school by the study staff one week later. As a measure to encourage the return of completed surveys to the teacher, a small reward is given to the students for remembering. Initially, in year 1, a small toy was given as a token prize for return of surveys. In year 2, we learned that pizza parties were a more effective incentive. The classroom in each grade level that handed in the most surveys (by percentage) receives a pizza party for their efforts. The implementation of pizza party incentives raised survey return rates from 50–60% to 85–90%. We also learned that if there was an unforeseen low return rate of questionnaires, redistributing surveys is not as effective as approaching additional schools with multiple reminder flyers to encourage participation. We also work with the school on distributing flyers at approved school functions such as health fairs and Parent Teacher Organization meetings, because we find the face to face time is highly effective in improving recruitment rates.

The screening survey is voluntarily returned with contact information and is used to obtain information about the child's health including allergy and asthma symptoms for those children with asthma. Based on our inclusion criteria, children with asthma whose families indicate they are interested in the study are contacted, provided more information about the study, and are invited to come to Children's Hospital for a baseline clinic visit. This recruitment survey distributed to entire classrooms is also used to obtain basic demographic and home environment data. The questionnaire has a predetermined study ID for each student which is linked to the classroom where the questionnaire is distributed. This allows the investigator to know classroom data from each questionnaire.

After determining that a child is eligible, the recruiter contacts the family and describes the clinic and home visits, questionnaires, skin, pulmonary function, blood testing, and follow-up contact. The recruiter also explains to the family the school components of the study. Children with asthma who are interested in the study, are invited to participate in an evaluation at a baseline clinic visit at Boston Children's Hospital, to further characterize his/her asthma. Round-trip transportation is arranged and cab vouchers are provided to overcome transportation barriers to the clinic visit. Reminder packets with date and time of appointment, directions to Boston Children's Hospital, and medications to be avoided before appointment are sent 2 weeks prior to appointment. Reminder phone calls about clinic appointments are made one week and also two days prior to the visits.

Families are informed that they will be reimbursed for their time and expenses at \$50 to the parents for baseline visit and 2 movie tickets/gift cards to the children (value \$20), \$20 for each of the 4 follow-up assessments, and \$20 for returning the subject-collected home dust samples, and a movie ticket for the child after performing the fall and spring peak flow and pulmonary function test (value \$20) (\$190 total). A home telephone number and at least two alternate contact telephone numbers are obtained at recruitment and confirmed at baseline with the time of day preferred for receiving calls. The staff attempts to reschedule a no-show for baseline at least 2 times. Advisory support from other NIAID funded inner-city environment consortiums (Herman Mitchell, George O'Connor) is beneficial in providing additional support for these efforts.

## Population

The target population consists of children aged 5–15 years of English- or Spanish Speaking families who attend inner-city metropolitan schools.

## Definition of Asthma

Children who have a physician's diagnosis of asthma, which has been shown to correlate with indices of disease[16, 17], AND cough, wheezing, dyspnea, or whistling in the chest in the previous 12 months are considered as students with asthma and are eligible for the study (See inclusion criteria below, modeled from the National Inner-City Asthma Study (Table 2))[18].

## Baseline and Follow-up Clinical Assessments

Patients who fulfill inclusion/exclusion criteria at screening are invited for a baseline clinical assessment. During the extensive baseline visit, informed consent is obtained, and the caretaker and child are asked detailed questions regarding health symptoms, particularly asthma and allergy symptoms, and utilization of medical care, to further characterize the child's asthma. A baseline questionnaire also assesses home and child-care environmental characteristics, including tobacco smoke exposure and potential sources of allergens or respiratory irritants. These surveys are modeled after validated questionnaires from other inner-city studies[18]. The participants are asked to recall the child's asthma symptoms and functional status during the prior 2 weeks and are asked for a three-month recall of utilization and missed school days. Baseline allergen skin testing to 16 aeroallergens is tested in all subjects using a Multi Test device (Lincoln Diagnostics, Decatur, IL), in a site free of eczema, utilizing skin protocols used in the Inner-City Asthma Study and the National Cooperative Inner-City Asthma Study[18] [19, 20] for standardization and quality control. In addition to histamine (positive control) and saline solution (negative control), the following allergens tested are: house dust mite (*Dermatophagoides pteronyssinus* and *D. farinae*), German cockroach (*Blatella germanica*), cat, dog, mouse pelt, rat pelt, *Aspergillus*, *Alternaria tenuis*, *Penicillium*, *Cladosporium*, timothy grass pollen, oak tree pollen, and ragweed mix (Greer, Lenoir, North Carolina). A positive test reveals a wheal diameter at least 3 mm larger than the negative saline control read 15 minutes after placement. Allergy skin test results are immediately provided to the family with referral to primary care physicians and questions are answered by investigator physicians as needed.

An optional 5 ml blood sample is obtained for serum collection and DNA extraction. Saliva is collected for genetics analysis for those who do not provide consent for blood. Staff obtain follow-up clinical survey data at 3, 6, and 9, and 12 months after the baseline visit.

At the baseline clinic visit, pulmonary function testing (Koko spirometer, nSpire Health, inc., Longmont, CO, USA) and exhaled nitric oxide measurements are performed according to ATS guidelines.<sup>(53) (52)</sup> (NIOX TM System, Aerocrine, Sweden). Parents/children are also instructed how to operate a home electronic asthma monitor (KoKo Peak Pro 6 Meter, nSpire Health, inc., Longmont, CO, USA) that measures expiratory peak flows and FEV<sub>1</sub>. This home-based patient initiated data is obtained at baseline, 3, 6, 9, and 12 months follow up. In year 1, we learned that collecting home peak flow data was inefficient, requiring excessive staff/subject burden with poor return rates/compliance and excessive loss of these expensive monitors. In year 2, we approached the schools to obtain follow up staff-coached PFT data utilizing the same spirometer as the baseline visits, along with a peak flow/FEV<sub>1</sub> reading for comparison with year 1. By the spring of year 2, we are successfully obtaining follow-up lung function data in the school, twice during the academic year, linked to the fall/spring environmental sampling.

## Home Environmental Assessments

The home environment assessment is obtained by subject-collected dust samples from the bedrooms of those enrolled in the study, as utilized successfully in previous studies[21]. Detailed instructions and collectors (DACI lab, Johns Hopkins, Baltimore, MD) are

provided to the family at the enrollment visit, and subjects are loaned a portable vacuum cleaner, to standardize collection methods and ensure that all subjects have a working vacuum. Vacuum dust samples are returned to the clinical center or the school for pick up by study staff.

A follow-up home environment questionnaire is obtained at 3, 6, and 9, and 12 months after the baseline visit. In addition, time activity data for a typical week in the previous 3 months is collected at the same time.

### School Environmental Assessment

School and classroom environmental assessment data are obtained by inspection surveys completed at participating schools and classrooms. Settled dust samples (air and settled) are being collected from classrooms of 500 asthmatic children followed through the school year. Cafeteria and gym samples are collected from the schools of the study participants, allowing us to adjust for school exposures common to all children in the school while evaluating the health effects of specific classrooms (the primary unit of exposure is the classroom). School wide and classroom specific dust samples (air and settled) are collected in the same manner 6 months after the initial sample to capture exposure assessment in opposite seasons, linked to the enrolled child.

**School Environmental Dust Sampling Protocol**—An Oreck XL (model BB870-AD, Oreck, LLC, Nashville, Tennessee) vacuum is used fitted on the inlet hose with a dust collector filter (DACI lab, Johns Hopkins, Baltimore, MD) [18, 22]. Settled dust samples are collected in a standard fashion from desks, chairs and classroom floors of participating students. Schoolwide samples are also obtained from the cafeteria and gym linked to the participating students. Vacuum cleaning is performed for a total of 6 minutes per sample, 3 minutes on the floor and 3 minutes on other surfaces (desks, chairs), as in previous school studies[23]. Collected dust is sifted through a 40-mesh metal sieve (>425 micron particle exclusion), weighed, aliquoted and stored at  $-20^{\circ}\text{C}$  until extraction. A simple environmental assessment form/checklist is completed for each room sampled.

**School Airborne Allergen Sampling Protocol**—An air sampler is used to collect air dust samples that utilizes charged particles to measure airborne allergen and endotoxin concentration and is described by Platts-Mills' et al[24–26]. The air sampler is placed in a single classroom of each school for one week at least 2 feet away from any surface and during normal school operating hours. The dust is weighed, aliquoted, and extracted (50 mg/ml buffer) in borate buffered saline (as per the floor dust samples) and analyzed for selected indoor allergens. Methods established by Platts-Mills[26] are used to determine the flow rate by timing periods of each device. Using the sampling rate, total quantities of airborne concentrations are converted to airborne concentrations in cubic meters.

**School Fungal Spore Sampling and Analysis**—Fungal exposure assessments utilized Burkard Indoor Recording Air Samplers (Burkard Mfg. Co., Rickmansworth, Herts., U.K.) and direct microscopy [27]. After seven days exposure, tape is removed from the collection drum and timed segments corresponding to school daytime exposure are mounted onto glass micro-slides, covered with a gelatin mountant and cover glass, and spores are identified (generally to genus) and counted. Recoveries are reported as spores per cubic meter of air (spores/m<sup>3</sup>).

### Air Pollution Sampling

A small and unobtrusive passive air pollution sampler is placed in each classroom for the measurement of traffic pollutants (NO, NO<sub>2</sub>, Ozone). The monitor passively and noiselessly

collects a specimen for analysis during the same period that the other bioaerosol air allergen samples are already being collected. Ogawa (Ogawa & Co. Pompano Beach, Florida) tubes measure nitrogen dioxide (NO<sub>2</sub>) concentrations in air and have been widely used for indoor and outdoor air monitoring, and personal monitoring[28, 29]. These samplers are passive samplers (i.e., no air pumps required) with a relatively low limit of detection and good relative precision. Each sampler is approximately three inches in length made from acrylic plastic with two plastic end caps and has a diameter of one-half inch. Reference to EPA data on use of the sampler is at <http://www.ogawausa.com/passive.html>. Each sample is analyzed by ion chromatography for nitrite ion, which is quantitatively related to the integrated exposure to NO<sub>2</sub>.

**Measurements of Allergens and Endotoxin in Home and School/Classroom Dust Samples**—Dust collected is extracted in buffered saline and serially diluted for inclusion in Luminex microarray™ (Indoor Biotechnologies, Charlottesville, Virginia) assays that measure cockroach (*Bla g 2*), cat dander (*Fel d 1*), dog dander (*Can f 1*), and mouse (*Mus m 1*), dust mite (*Der p 1* and *Der f 1*), mite group 2, rat dander (*Rat n 1*), and Limulus amoebocyte lysate (LAL) assay (BioWhittaker Inc., Walkersville, MD) for endotoxin (Indoor Biotech, Charlottesville, Virginia). The lower limits of detection were 0.196 µg/g of dust for *Bla g 2*, 0.004 µg/g for *Fel d 1* and *Rat n 1*, and 0.012 µg/g for *Can f 1*, 0.002 µg/g of dust for *Mus m 1*, 0.12 µg/g of dust for *Der f 1* and *Der p 1*, 0.004 µg/g for mite group 2, and 500 endotoxin units (EU)/gm.

### Asthma Morbidity Outcomes

Asthma morbidity outcomes are determined by: clinical symptoms, use of health care services, activities of daily life, and effect on the parent or other caregiver. The assessment periods for the measures are two weeks, 4 weeks, or three months before the follow-up assessment. It is based on anticipated reliability of the recall information and modeled after previous inner-city asthma studies[18]. Primary outcome is health care services, particularly unscheduled doctor visit. Secondary outcome variables include the number of days with wheezing, nights lost sleep, number of school days missed, and changes in activity level. These variables are based upon previously well-standardized asthma morbidity studies[18, 30]

## STATISTICAL ANALYSES

### Data Analysis Plan

Measures of morbidity include respiratory symptoms and healthcare utilization (unscheduled medical visits and hospitalizations). Extensive univariate and multivariate analyses are planned to determine the relationship between these measures of morbidity and various demographic variables and risk factors. The study is designed to evaluate between classroom and between school differences, adjusting for home exposures. Multivariate analyses are planned using multi-level statistical methods that appropriately account for the clustering of children within classroom and within school. Standardized methods will compare distributions of allergen and environmental exposures and sensitization and other predictor variables with clinical outcomes, including non-parametric approaches with linear and nonlinear models considered[31]. Planned home exposure adjustment will be accounted for in all of these analyses.

**Power Assumptions**—The primary outcome is health care utilization, specifically unscheduled doctor visits. Power calculations were made under the assumption of two-sided tests at significance level 0.05 and utilizing effects found in other studies evaluating exposure and sensitization to indoor allergens and health care utilization[32]. To compute

power, we used an extension (unpublished) method of Liang and Zeger[33] which allows not only for correlation between outcomes measures on individuals within the same cluster (classroom/school) but also exposures. Our study will have power to detect various odds ratios as a function of the prevalence of the outcome in unexposed children. Our pilot data showed an intraclass correlation of 0.05 for mouse allergen exposure[34]. Assuming an intra-class correlation of 0.1 for exposure and 0.1 for outcome, we will have 80% power to detect odds ratios of 1.8 or higher with a prevalence rate of 0.2 or greater. Similarly, our power will improve if the prevalence of exposure is higher than 0.2.

We anticipate that we are well powered because our preliminary data suggests a high degree of within-school heterogeneity in exposure, and our initial data pilot data showed much higher prevalence rates of exposure, with 61% of samples having mouse allergen levels > 0.5 µg/g, which has shown clinical relevance in other studies[32, 34]. Furthermore, because there is significant variability between classrooms for the other exposures such as mold/fungi, cat and dog, we will also have similar power for the other allergens of interest. In addition, while recruitment is ongoing, our current pool of enrolled students comes from many more classrooms than originally anticipated, which will likely increase our level of variability and improve power.

**Data Management**—A computerized database management system is used to register patients, track data collection and study status, and enter study data. Dr. Phipatanakul oversees and manages the data management group (DMG), which consists of full-time staff with programming, data management and data analysis skills. The DMG builds and maintains recruitment tracking databases, utilizing well-established techniques and quality well-established in the Channing Laboratory/Brigham and Women's data management group.

### Quality Control

Principal investigator and project coordinator review study procedures and observe techniques for spirometry and skin testing. Throughout the course of the study, quality control is maintained by observing and monitoring study techniques. All staff have extensive training in standardized procedures and are certified for competence in performing the procedures prior to performing them on study patients. Data collection forms are subject to extensive and immediate edits and data checks distributed by the data management systems. Reports are double checked monthly.

## DISCUSSION and Lessons Learned

The School Inner-City Asthma Study (SICAS) represents one of the largest, most comprehensive evaluations of the school, classroom, and home environment's role in asthma morbidity among students in an urban environment in the United States. Our study is unique from other urban studies, which focused most of their environmental assessments in the home.

Barriers such as lack of insurance, transportation, and language barriers is assessed as well and modeled after previous childhood urban asthma studies[18]. We face many unique challenges that we continue to overcome. The greatest challenge was overcome years before the launch of the study. This was approval and engagement from the entire system to allow us to enter the schools. This requires ongoing approval and support from the Superintendent of schools, Facilities Management, to individual principals, teachers, and parents from each school and extensive community engagement. We include education and involvement of high school students utilizing their assistance in data collection to fulfill requirements for graduation.

We face several additional school-level challenges. One challenge is seasonal recruitment from the 7–10 schools approached each year and dependent on returned screening surveys distributed in the spring. Thus, we are limited to return rate and students attending particular schools. Furthermore, unanticipated language/cultural barriers from students whose parents' primary language is not English or Spanish are encountered. Successful steps that are implemented to overcome these challenges included: 1) Additional incentives to improve the return rate of screening surveys, such as class prize pizza parties for most returned surveys. This measure alone increased our survey return rate from 20% to over 60%, with many schools obtaining 85–90% return rate. This is essential to increase our pool of eligible students per school. Other successful measures utilized are: a) Doubling the number of schools attended each spring to further increase the screening survey return rate; b) Starting recruitment earlier in the spring to provide adequate time to go to additional schools if needed; c) Utilizing schools where English and Spanish are the primary language; d) Increasing efforts to engage schools staff (teachers, nurses, principals) in support of the study; e) Increasing community involvement and awareness of our study via venues such as advocacy groups, parent's nights, community asthma initiatives; f) Continuing External Advisory Board Meetings to get input from experts and staff with experience in overcoming the common challenges of Inner-City recruiting. This requires constant vigilance on the part of the investigators and staff to continue such a multifaceted effort to gain collaborative support.

Another unique challenge to our study is students moving schools between the spring screening period and the subsequent fall environmental sampling period. If the school is not one that we have permission to enter the subsequent fall, we are obligated to drop that student from the study for that year. While extra efforts are made to ascertain any potential moves, it is not always possible to anticipate. This is one of the unavoidable challenges in following enrolled students.

Another challenge was poor compliance with home electronic peak flow monitoring. We overcame this burden by obtaining spirometry in the schools. This measure actually improves compliance and engagement of the students and is an important lesson learned. Our follow up rate improved from 50% to 90% from this approach. Community buy-in and engagement from the school community is critical to the ongoing and continued success of this study. We also continue to have open dialogue with external advisors and investigators of other urban studies to learn any applicable inner-city recruitment and retention strategies[35, 36], but realize that our constraints to school and seasonal recruitment give us unique challenges.

## CONCLUSION

The extensive nature of the data collection, interviews and complete evaluation of the home and school/classroom environment makes this project unique. The requirement of total community involvement and the large numbers of dedicated and talented staff are critical to the ongoing and continued success of this project and cannot be underestimated. The next step may be consideration of further expansion of this project in the younger age group and identifying useful interventions to decrease important school/day-care environments that may help a community of children in the school environment. This study will help us understand exposure risk factors specific to the school classroom. This has important public health implications because the school environment could potentially be considered an effective target for an intervention to prevent inner-city asthma morbidity by reducing exposures to many symptomatic children.

## Acknowledgments

Supplies were generously donated or discounted by: Lincoln Diagnostics, Inc., Decatur, IL donated Multi-Test II devices; Greer Laboratories, Inc., Lenoir, NC donated allergenic extracts for skin testing.

Supported by grants R01 AI 073964 and R01 AI 073964-02S1 from the National Institutes of Health

This work was conducted with support from Harvard Catalyst | The Harvard Clinical and Translational Science Center (NIH Award #UL1 RR 025758 and financial contributions from Harvard University and its affiliated academic health care centers). The content is solely the responsibility of the authors and does not necessarily represent the official views of Harvard Catalyst, Harvard University and its affiliated academic health care centers, the National Center for Research Resources, or the National Institutes of Health.

## List of Abbreviations

|                |                                                       |
|----------------|-------------------------------------------------------|
| <b>CFU/gm</b>  | colony forming units per gram of dust                 |
| <b>DMG</b>     | Data Management Group                                 |
| <b>µg/g</b>    | microgram per gram                                    |
| <b>EU/gm</b>   | endotoxin units per gram                              |
| <b>SICAS</b>   | School Inner-City Asthma Study                        |
| <b>NIAID</b>   | National Institute of Allergy and Infectious Diseases |
| <b>NIH</b>     | National Institutes of Health                         |
| <b>Bla g 2</b> | blatella germanica 2, cockroach allergen              |
| <b>Fel d 1</b> | feline domesticus 1, cat allergen,                    |
| <b>Can f 1</b> | canis familiaris 1 dog allergen                       |
| <b>Mus m 1</b> | mus musculus m 1                                      |
| <b>Der p 1</b> | Dermataphagoides pteronyssinus 1                      |
| <b>Der f 1</b> | Dermataphagoides farina 1                             |
| <b>Rat n 1</b> | Rattus norvegicus1                                    |
| <b>LAL</b>     | Limulus amoebocyte lysate                             |
| <b>U/g</b>     | Units per gram                                        |

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Table 1

| SCHOOL INNER-CITY ASTHMA STUDY SCHEMA                                                |                                                                     |                               |                                                          |                               |                                                          |                                           |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------|----------------------------------------------------------|-------------------------------|----------------------------------------------------------|-------------------------------------------|
| Year 1                                                                               | Year 2                                                              |                               | Year 3                                                   |                               | Year 4                                                   |                                           |
| Spring-Summer<br>Group 1<br>- Screen<br>- Recruit<br>- Enroll                        | School Year<br>Group 1<br>-Follow- up                               | Summer<br>Group 1<br>complete | School Year<br>Group 2<br>-Follow-up<br>-Data collection | Summer<br>Group 2<br>complete | School Year<br>Group 3<br>-Follow-up<br>-Data Collection | Summer<br>Group 3<br>Complete             |
|                                                                                      | Group 2<br>-Screen<br>-Recruit                                      | Group 2<br>Enroll             | Group 3<br>-Screen<br>-Recruit                           | Group 3<br>-Enroll            | Group 4<br>-Screen<br>-Recruit                           | Group 4<br>Enroll                         |
| - Recruitment, Enrollment, 1 group per year (100 students each), and Data Collection |                                                                     |                               |                                                          |                               |                                                          |                                           |
|                                                                                      | - Dust Sample Analysis and Data Cleaning and Checking               |                               |                                                          |                               |                                                          |                                           |
|                                                                                      | - Data Checking and Cleaning, Data Analysis, Manuscript Preparation |                               |                                                          |                               |                                                          |                                           |
|                                                                                      |                                                                     |                               |                                                          |                               | School Year<br>Group 4<br>-Follow-up<br>-Data Collection | Summer<br>Group 4<br>Complete             |
|                                                                                      |                                                                     |                               |                                                          |                               | Group 5<br>-Screen<br>-Recruit                           | Group 5<br>Enroll                         |
|                                                                                      |                                                                     |                               |                                                          |                               |                                                          | Group 5<br>-Follow-up<br>-Data Collection |
|                                                                                      |                                                                     |                               |                                                          |                               |                                                          | DATA<br>Complete                          |

| Inclusion Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Exclusion Criteria                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Grades 1–8 the school year following spring recruitment (Ages 5–15 years)</li> <li>• Attend one of the schools in the fall where permission obtained for classroom sampling.</li> <li>• Able to provide assent if age appropriate and parent/guardian able to provide informed consent</li> <li>• Physician-Diagnosed asthma AND<br/>Wheezing in the previous 12 months<br/>OR</li> <li>• Physician-Diagnosed asthma AND<br/>Takes preventative or daily medicines for asthma<br/>OR</li> <li>• Physician-Diagnosed asthma AND<br/>Unscheduled physician or nurse visit for asthma in past year</li> </ul> | <ul style="list-style-type: none"> <li>• Significant pulmonary diseases other than asthma that might influence test results or pose risks (e.g., cystic fibrosis, sarcoidosis, bronchiectasis)</li> <li>• Cardiovascular disease that requires daily medication</li> <li>• Taking a beta blocker</li> <li>• Unable to follow through with study visit or complete study procedures</li> </ul> |