

Extension
Information Collection Request
for

The Green Housing Study
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Supporting Statement
(Part B)

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

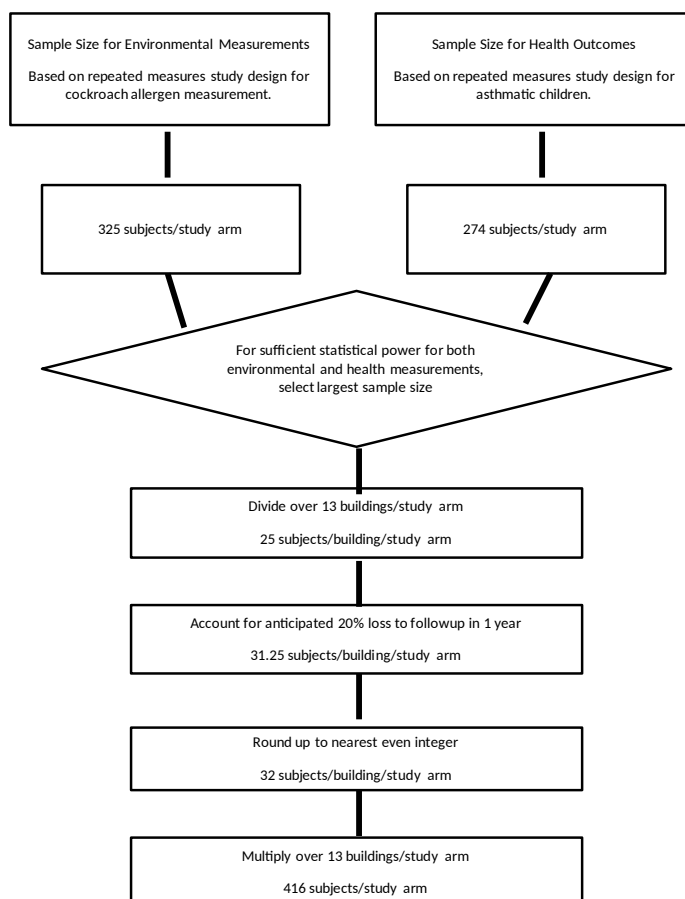
B.1. Respondent Universe and Sampling Methods

The purpose of this study is to provide insight into the potential implications of green renovations for the health of young asthmatics who live multifamily HUD-subsidized housing in the United States and US territories. According to HUD, 970,532 households live in public housing in the United States (HUD 2009). The number of M2M properties is in flux according to market forces and other factors such as landlord motivations for participation; however, it is estimated that since 1997, 1600 developments (with approximately 100 units each) have been renovated through the M2M Green Initiative

<http://www.hud.gov/offices/hsg/omhar/paes/greenini.cfm>.

Collecting data from asthmatic children in all housing units being renovated would be too burdensome, expensive, and logistically impractical. In total, we will include a targeted non-probability sample of 832 homes in 13 cities for this study methodology. HUD had selected housing developments for green renovations projects prior to the inception of this proposed study based upon specific requirements (e.g., use of low VOC materials, use of energy efficient appliances). Figure 1 illustrates the sampling process. Since the housing developments were already selected based on grant awards, random assignment of the green intervention was not possible for this study.

Figure 1. Summary of sample size



In the first two cities already completed under the first OMB approval period (Boston and Cincinnati), sampling occurred as follows:

- 1) We received information from HUD about green housing rehabilitations scheduled to occur within the next 5 years.
- 2) We approached landlords of housing complexes that had a large potential pool of participants (i.e., children) in order to get approval to invite their residents to participate in the Green Housing Study.
- 3) We used a multi-pronged approach to invite residents to participate in the Green Housing Study. Field study teams:
 - participated in housing community town hall meetings,
 - posted flyers throughout the housing complex, and
 - answered phone calls elicited from flyers.

This approach led to a convenience sample of children ages 7-12 years with asthma living in low-income, multi-family housing scheduled for green renovation in Boston and Cincinnati.

The selection of future cities are described in the study protocol (Appendix C – Methods, pages 12-3), and summarized. will be based upon the following:

1. The city must have one or more housing developments which are receiving a HUD-subsidized green-renovation.
 - a. These renovations must occur within the timeline of our next funding period (3 years). Thus, we are asking OMB for an extension prior to the expiration of the initial 3-year OMB approval.
 - b. Housing developments should have many apartments which will undergo the green renovations. Smaller housing developments would severely hamper recruitment of our targeted sample size in each city. However, we will consider cities which have several housing developments with a smaller number of apartments, given that the housing developments will undergo renovations within 6 months of each other.
 - c. Green renovations must meet inclusion criteria: Low VOC materials and Integrated Pest management (IPM).
2. The housing renovations within the city must occur in areas with high prevalence (i.e., greater than the national average, currently 9.1%) of childhood asthma, based upon National Health Interview Survey data (Akinbami et al. 2009). This is to enhance the potential pool of study participants. Areas of lower asthma prevalence would severely hamper recruitment of our targeted sample size in each city.
3. Cities are located in different regions of the country and/or represent different types of housing stock.

The study design allows us to provide insight into the societal benefits of green housing on low income families with asthmatic children. However, it is not generalizable to respondents or even geographically or demographically defined subgroups due to the fact that both the applicants of the HUD awards and the households themselves are self-selected. Specifically, the design does not allow generalizations based on city, type of locations (rural, suburban), climactic regions

(e.g., desert, arctic), or ethnicities. This study systematically excludes certain subsets of the population for logistical reasons:

- i. Public housing is comprised mostly of three main ethnicities: white, African-American, and Latino (HUD, 2009).
- ii. Our main health endpoint, asthma, is highest among Latinos and African-Americans. While several childhood asthma studies have focused on some minority populations in the United States (African American and Latino), only recently have investigators focused studies of Asian populations. In the Boston Chinatown neighborhood, researchers found a higher prevalence of asthma for children born in the US as compared to those who were foreign-born in an Asian population, enriched with recent Chinese immigrants (Brugge et al., 2007). These results confirm findings in a similar Asian population from the same community (Greenfield et al., 2005).
- iii. We do not have the capacity to translate into all languages. However, we determined that it would be beneficial to include Spanish and Chinese translations for the reasons mentioned above. In meetings with stakeholders at our first potential study site, Boston, we found that they have a substantial Chinese population (along with Latino and African-American). The tenants' organization asked if we would recruit the Chinese residents too and if we could translate all of our materials into Chinese. We believe that the tenants' organization's request is reasonable. Furthermore, in other potential study site locations (e.g., Los Angeles, New York, San Francisco), Chinese language translation might also be relevant. For details on why this study is not generalizable to all low-income children with asthma or to all green renovations in low-income multi-family housing (Appendix C).

Sample size: Our calculations estimate that 416 subjects per study arm (i.e., green vs. comparison homes) must be recruited in order to achieve sufficient power to statistically differentiate between the study arms (for details of power calculations, see Appendix C).

In order to have sufficient power to detect meaningful differences in both environmental measurements and health outcomes between the arms, we calculated sample sizes based on each of these measures (e.g., cockroach allergens, number of buildings, pesticides and VOCs, asthma morbidity outcomes, and number of children with asthma). We selected the larger of the two estimates—325 subjects per study arm—as the minimum sample size (see Figure 2). In addition, we augmented this number in order to account for an anticipated 20 percent loss to follow-up over a one-year period. In other words, we assumed an 80% participation rate for the eligible residents for the collection as a whole (as described in Section B.3). After rounding up where necessary, this increased the sample size to 416 subjects per study arm, comprising 32 subjects (one subject per apartment) in each of 13 buildings in each study arm. The total sample size for the study across both study arms is 832 subjects. For detailed calculations, see Appendix C. There are no other problems requiring specialized sampling procedures. The data collection plan requires only one series of data collection within a one-year follow-up period.

As can be calculated from data in Table 1, total site-specific response rates for the first two study sites were 78% (Cincinnati) and 86% (Boston).

Table 1. Description of the data in the existing information collection request (ICR) for the universe as a whole and for each of the sampling strata

	Universe	Sample size required (includes buffer for 20% loss-to-follow-up)	Enrolled	Completed follow-up	Response Rate
Overall Green Housing Study (original plan)					
Green homes	n= 500 (i.e. half of the 1000 total)	n=325 (i.e. 13 cities * 32 households in each city)	n/a (see individual data for current study sites below)	n/a (see individual data for current study sites below)	n/a (see individual data for current study sites below)
Control homes	n= 500 (i.e. half of the 1000 total)	n=325 (i.e. 13 cities * 32 households in each city)	n/a (see individual data for current study sites below)	n/a (see individual data for current study sites below)	n/a (see individual data for current study sites below)
Cincinnati Study site					
Green homes	n= 38 (i.e. 1000/13 cities * ½ (i.e. green))	n=32	n=24	n=20	83%
Control homes	n= 38 (i.e. 1000/13 cities * ½ (i.e. control))	n=32	n=21	n=15	71%
Boston Study site					
Green homes	n= 38 (i.e. 1000/13 cities * ½ (i.e. green))	n=32	n=26	n=21	81%
Control homes	n= 38 (i.e. 1000/13 cities * ½ (i.e. control))	n=32	n=25	n=23	92%

B.2. Procedures for the Collection of Information

The characteristics of study participants are: 1) Children age 7-12 years with asthma. The child must have been diagnosed with asthma by a physician and have had asthma-related symptoms (wheezing, slow play, or night awakening) during the past 6 months, and 2) mothers/ primary caregivers of enrolled children. Also, the mother/ primary caregiver must speak English, Spanish, or Chinese to be included in the study and the enrolled participants must live in the home (from which environmental samples will be collected) on average 7 days per week.

Briefly, information collection proceeds as follows: 1) trained study staff set up appointments for home visits; and 2) a team of two trained technicians collect questionnaire data and environmental samples at the study participant's home. For more details on the data collection procedures see the Overview of the Data Collection System (Section A.1.1) and Appendix C.

Grantees convene town meetings at each participating complex to describe the study to residents, answer questions, and invite their participation. Depending upon the number of residents who initially volunteer at the town hall, we convene additional town hall meetings to augment participation. Residents who express interest in the study can contact the site projector coordinator either at the town hall meetings or by telephone. Subsequently, the trained staff schedules a home visit with the residents. For quality control purposes, a team of two trained staff visits the home to collect questionnaire data via an in-person interview and perform environmental sampling. The environmental sampling technician reviews the questionnaire information that the other technician obtained during the interview with the study participant. Also, the database entry screen has validation checks (e.g., number of reported asthma symptoms cannot equal a negative number).

Matching: The study design is stratified by city. We frequency-match green intervention and comparison homes by HUD-subsidized housing development, age group of asthmatic children (7-12 years), and primary language spoken by mother/primary caregiver of the asthmatic child. We are not matching on ethnicity *per se*; however, much of the low-income housing in inner-city communities tends to be segregated to some extent, by race/ethnicity (Acevedo-Garcia and Lochner 2003). We record race/ethnicity in our questionnaire and adjust accordingly in our analysis. As mentioned earlier, this selection is limited by the availability of ongoing HUD renovation efforts. There are no other problems requiring specialized sampling procedures. The data collection plan requires only one series of data collection within a one-year follow-up period.

Statistical analysis: We are utilizing multiple statistical analysis techniques to meet the specific aims/address the statistical hypotheses of this study. In particular, we are conducting descriptive analyses and linear, logistic, and hierarchical regression modeling. The main independent variable of interest for the regression analyses is the type of home (green vs. comparison). A more detailed description of the statistical analysis plan is provided in Appendix C.

The two main hypotheses of the study are (Note: The hypotheses are abbreviated here for brevity. For complete wording see Appendix C):

Hypothesis 1: Green housing will lead to 1) lower levels of environmental contaminants compared with those of comparison housing, and 2) lower levels of related biomarkers in the residents of green vs. comparison housing.

Hypothesis 2: If irritants and allergens are lower in green vs. comparison housing, children with asthma (ages 7-12) living in green housing should experience fewer and less severe asthma exacerbations. (Note: Hypothesis is abbreviated here for brevity. For complete wording of hypothesis see Part A)

Preliminary descriptive analysis of the first two study sites (Boston and Cincinnati) has been conducted on demographic and baseline levels of clinical and environmental measurements using measures of central tendency, chi-square and t-tests. Further steps require data cleaning and will be followed by more complex statistical analysis, (e.g., mixed effects regression models for repeated measures, structural equation modeling, and principal components analysis).

Missing data: We anticipate the inevitable occurrence of missing data, including dropouts. First, if the missing data is sufficiently small and the associations of interest are sufficiently large, the simple device of imputing upper and lower bound data, if possible, will suffice. A more detailed description of the statistical analysis plan is provided in Appendix C.

Quality Control Procedures: Import programs with logic checking and verification have been written to import the data into tables of the database. Data-entry screens closely resemble the original paper questionnaire; this results in lower data-entry error rates. These logic checking codes preclude double-entry of data. Study participants will not be re-interviewed or re-contacted for data validation.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

In our first two study sites (Boston and Cincinnati), 96 eligible households (i.e., those households with children with asthma ages 7-12 years) replied to our flyers and voiced interest in the Green Housing Study during the town hall meetings. All 96 enrolled in the Green Housing Study and 79 completed all follow-up visits. Thus, overall we had an 82% response rate for completion of the 1-yr study. We anticipate that once enrolled into the Green Housing Study, participants in future study sites will have at least an 80% response rate for completion of the 1-yr follow-up.

We use two strategies to maximize response rates of the enrolled participants: 1) Study participants (mothers/ primary caregivers of children enrolled in study) receive tokens of appreciation for their participation as they complete the required study activities throughout the 1-year duration (see Section A.9 for details), and 2) we also give study results to the participants. Other investigators have found that study participants often wish to know their results (Brody et al. 2007). By offering an in-person discussion of their results during their last home visit, we maximize the chance for completion of their 1-yr follow-up.

We follow these steps to try to contact difficult-to-reach participants: 1) At least 10 attempts are made and documented in an effort to reach the participant; 2) Calls and visits to the participants are made at various times of days (mainly between 10 am-8 pm) and on different days of the week at a time convenient to the study participant; 3) When leaving a message, the trained technician leaves his/her name, the name of his/her institution, the reason for the call (i.e., housing study, and the call-back number; and 4) The technician will try calling “alternate contacts” to reach the study participants.

We employ a number of other strategies in an attempt to maximize response rates. These include having a trained technician (1) make multiple phone calls/visits at different times of day and on different days of the week; (2) leave detailed messages with call-back number; and (3) calling “alternate contacts” (see Appendix C for more details).

B.4. Tests of Procedures or Methods to be Undertaken

The Green Housing Study questionnaires are primarily based on questions from national health and housing surveys and different epidemiologic studies. The national surveys include the following:

1. The National Children’s Study (NCS)

2. The National Health and Nutrition Examination Survey (NHANES)
3. The National Health Interview Survey (NHIS)
4. The Behavioral Risk Factor Surveillance System (BRFSS)
5. The American Healthy Homes Survey (AHHS)
6. The American Housing Survey (AHS)

Results from the research studies have been extensively published in peer-reviewed environmental health journals that provide scientific basis for home-based asthma intervention studies (Wilson et al. 2009). Some questions were included verbatim; some were modified to fit our study framework; and some additional questions were added (Table 2). CDC epidemiologists modified some of the existing questions and developed new questions in consultation with academic peers and subject matter experts.

Table 2. Examples of questions used in the Green Housing Study and their provenance.

Questions	Questionnaire Type	Question	Name of the study	Reference article
Included verbatim	Baseline (Home Characteristics)	In the last 3 days: today or yesterday or the day before yesterday, have you either breathed fumes from <u>gasoline</u> or had it on your skin?	NHANES	n/a
	Baseline (Children with Asthma age 7-12)	Is [Child's name] currently covered by any kind of health insurance or some other health care plan?	NCS	n/a
	Illness checklist	Did you receive Tamiflu® or oseltamivir [<i>o sel TAM i veer</i>] or an inhaled medicine called Relenza® or zanamivir [<i>za NA mi veer</i>] to treat this illness?	BRFSS	n/a
Included with minor modifications	6 and 12-month Follow-up (Children with Asthma age 7-12) * note: the mother or primary caregiver answers this question, not the child.	<u>Green Housing Study version:</u> In the last 3 months, did [Child's name] receive Tamiflu® or oseltamivir [<i>o sel TAM i veer</i>] or an inhaled medicine called Relenza® or zanamivir [<i>za NA mi veer</i>] to treat this illness? <u>BRFSS version:</u> Last month, did you receive Tamiflu® or oseltamivir [<i>o sel TAM i veer</i>] or an inhaled medicine called Relenza® or zanamivir [<i>za</i>	BRFSS And also recent H1N1 flu pandemic surveillance	Cauchemez S, Donnelly CA, Reed C, Ghani AC, Fraser C, Kent CK, Finelli L, Ferguson NM. Household transmission of 2009 pandemic influenza A (H1N1) virus in the United States. N Engl J Med. 2009 Dec 31;361(27):2619-27.

		<i>NA mi veer]</i> to treat this illness?		
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Each of the questionnaires was pilot-tested at CDC on nine or fewer (in some cases not all 9 were available to participate) predominantly college-educated CDC employee-volunteers.

After development of an initial draft, the baseline questionnaire was distributed among CDC, NIH, EPA, and HUD colleagues and five non-federal academic peers (Drs. Gary Adamkiewicz, Brett Singer, Mark Mendell, Doug Brugge, and Tiina Reponen) for face and content validation. Based on repeated feedback received from peers, the questionnaire underwent multiple revisions before a final draft was prepared. Cognitive interviews with nine or fewer college-educated CDC colleagues were conducted in a controlled environment. The questionnaire underwent a final revision based on the responses from participants. Some of the results from this pilot testing are shown below.

Each of the questionnaires was originally pilot-tested at CDC on nine or fewer (in some cases not all 9 were available to participate) predominantly college-educated CDC employee-volunteers during non-work hours. The pilot tests were administered by two Green Housing Study researchers. The results of our pilot testing are shown in Table 3. Based upon pilot testing, the questionnaires were revised to increase ease of understanding and speed of response. We conservatively estimated the response times for our study participants (low-income mothers/primary caregivers living in multifamily, urban housing) based on the average response times recorded during our pilot tests. Data collected from the first two study sites indicated that the burden hours for each of the questionnaires was similar (less in some cases) to original estimates from the pilot study. The final column in this table reflects the actual data from the first two study sites. We believe that the differences between actual and the original estimated burden hours do not warrant changes in the burden table.

Table 3. Pilot test of each questionnaire and estimated response time for study participants

Form Name	Average response time (minutes)	Minimum response time (minutes)	Maximum response time (minutes)	Estimated response time for study participants (minutes)	Actual date from Boston and Cincinnati study sites (minutes)
Screening Questionnaire	4:52	2:16	7:57	10	5
Baseline Questionnaire (Home Characteristics)	6:03	4:37	7:15	15	10
Baseline (Part 2) Questionnaire (Home Characteristics)	2:56	2:26	3:31	5	5
Baseline Questionnaire (Demographics)	0:58	0:50	1:15	5	5

Baseline Questionnaire (Children 7-12 with Asthma)	6:38	6:20	6:50	15	15
3 and 9-month Follow-up Questionnaire (Children 7-12 with Asthma)	2:30	2:15	2:45	5	3
6 and 12-month Follow-up Questionnaire (Environment)	3:52	3:10	4:20	10	5
6 and 12-month Follow-up Questionnaire (Children 7-12 with Asthma)	3:07	3:00	3:15	10	10
Time/Activity Questionnaire (Children with Asthma 7-12 years)	0:40	0:35	0:50	5	2
Time/Activity Questionnaire (Mother/Primary Caregiver)	1:45	1:40	2:00	5	3
Illness Checklist	1:05	0:45	1:25	5	5
Text messages	not tested	not tested	not tested	1	2

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individuals Consulted on Statistical Aspects of the Design

Curtis Blanton, MS	CDC/NCEH	(770) 488-7114
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Grantees Responsible for Collecting Information for the Agency

Data will be collected by awardees to be determined.

Contractors Responsible for Analyzing Information for the Agency

Not applicable. CDC will analyze data.

REFERENCES

- Acevedo-Garcia, D. and K. A. Lochner (2003). Residential Segregation and Health. Neighborhoods and Health. I. Kawachi and L. F. Berkman. New York, NY, Oxford University Press: 265-287.
- Akinbami LJ, Moorman JE, Garbe PL, Sondik EJ. 2009. Status of childhood asthma in the United States, 1980-2007. *Pediatrics* 123 Suppl 3: S131-145.
- Brody, J. G., R. Morello-Frosch, et al. (2007). "Improving disclosure and consent: "Is it safe?": New ethics for reporting personal exposures to environmental chemicals." Am J Public Health 97(9): 1547-54.
- Brugge D, Lee AC, Woodin M, Rioux C. 2007. Native and foreign born as predictors of pediatric asthma in an Asian immigrant population: a cross sectional survey. *Environ Health* 6: 13.
- Cauchemez S, Donnelly CA, Reed C, Ghani AC, Fraser C, Kent CK, et al. 2009. Household transmission of 2009 pandemic influenza A (H1N1) virus in the United States. *The New England journal of medicine* 361(27): 2619-2627.
- Greenfield RO, Lee AC, Tang R, and D Brugge. (2005). Screening for asthma in Cantonese-speaking immigrant children. *BMC Public Health*. 5: 48.
- Wilson J, Dixon SL, Breyse P, Jacobs D, Adamkiewicz G, Chew GL, et al. 2009. Housing and allergens: a pooled analysis of nine US studies. *Environmental research* 110(2): 189-198.