

# Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is “None”, please specify “None” as your response. “Not applicable” is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

1. **Grantee Institution:** Duquesne University
2. **Reporting Period (start and end date of grant award period):** 1/1/2009-6/30/2012
3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Julie H. Christy, B.S.
4. **Grant Contact Person’s Telephone Number:** 412-396-1886
5. **Grant SAP Number:** 4100047633
6. **Project Number and Title of Research Project:** 2 - Impact of Parental Smoking Cessation and Residential Hazard Reduction on Pediatric Respiratory Health: A Pilot Investigation of Effective Service Delivery
7. **Start and End Date of Research Project:** 1/1/2009-6/30/2012
8. **Name of Principal Investigator for the Research Project:** Stanley J. Kabala, Ph.D.; Michael J. Tobin, Ph.D.
9. **Research Project Expenses.**

9(A) Please provide the amount of health research grant funds spent on this project for the entire duration of the grant, including any interest earned that was spent:

\$ 47,207.40

9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project	Cost
Kabala	Principal Investigator	11	\$3,299.00
Tobin	Co-Principal Investigator, as Healthy Home Resources (HHR) Executive Director and as contractor to Duquesne University	3  46	\$1,302.00  \$20,000.00
Walsh	HHR staff	16	\$7,077.00
Trout	HHR staff	12	\$5,210.00
Latimore	HHR staff	12	\$5,210.00

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project
McKee	Graduate Assistant	2%
Snedden	Graduate Assistant	2%
McCalla	Paid intern	25%
Duffy	Paid intern	25%

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

For use on the project, HHR purchased two carbon monoxide monitors, a quantity of disposable mouthpieces, one tank of carbon monoxide calibration gas, and T-valves.

Type of Scientific Equipment	Value Derived	Cost
MicroCO monitor \$1095 Qty. 2	Essential to conduct the research	\$2190
PSA 1800 CO connector \$10 Qty. 2	Essential to conduct the research	\$20
3301 CO mouthpieces (bag 100) \$75 Qty. 2	Essential to conduct the research	\$150
MC10 20 ppm CO calibration gas \$85 Qty. 1	Essential to conduct the research	\$85
MC15 calibration kit \$165 Qty. 1	Essential to conduct the research	\$165

**10. Co-funding of Research Project during Health Research Grant Award Period.** Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please indicate the source and amount of other funds:

**11. Leveraging of Additional Funds**

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert “not funded” in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds to be awarded:
None	<input type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify: _____) <input type="checkbox"/> Nonfederal source (specify: __)		\$	\$

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes \_\_\_\_\_ No X \_\_\_\_\_

If yes, please describe your plans:

**12. Future of Research Project.** What are the future plans for this research project?

HHR had a unique combination of community access, ability to perform residential testing, devise targeted interventions, and provide education and outreach. This set of combined expertise was lost when the organization was forced to cease operation due to unforeseen funding losses. In the future, it is hoped that qualified partner(s) with the aforementioned skills can be identified so that funding for a collaborative effort to provide services to the community can be obtained.

**13. New Investigator Training and Development.** Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes  No

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male				
Female		2		
Unknown				
<b>Total</b>		<b>2</b>		

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic				
Unknown		2		
<b>Total</b>		<b>2</b>		

	Undergraduate	Masters	Pre-doc	Post-doc
White		2		
Black				
Asian				
Other				
Unknown				
<b>Total</b>		<b>2</b>		

**14. Recruitment of Out-of-State Researchers.** Did you bring researchers into Pennsylvania to carry out this research project?

Yes  No

If yes, please list the name and degree of each researcher and his/her previous affiliation:

**15. Impact on Research Capacity and Quality.** Did the health research project enhance the quality and/or capacity of research at your institution?

Yes  No

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

**16. Collaboration, business and community involvement.**

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes   X              No \_\_\_\_\_

If yes, please describe the collaborations:

The principal collaborator with the University was Healthy Home Resources (HHR). In support of HHR's Asthma Trigger Home Evaluation (*AT HOME*) program capitalized on the methodological expertise of local institutions such as the University of Pittsburgh Graduate School of Public Health, which provided guidance on privacy of participant information, safety of program participants, and HIPAA compliance; design of the Knowledge, Attitudes, and Beliefs (KAB) survey; and the use of SPSS evaluative database with which to analyze data, assess program progress, and determine whether program outcomes were achieved. The data gathered during provision of services was to have been analyzed at Duquesne University.

16(B) Did the research project result in commercial development of any research products?

Yes \_\_\_\_\_            No   X   \_\_\_\_\_

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes   X              No \_\_\_\_\_

If yes, please describe involvement with community groups that resulted from the research project:

The pilot project showed that the nature of the service delivery model and organizational nature are critical to the success of the interventions provided. The key element is multi-level and multi-sectoral partnerships. In a word, the factor in focus here is that of combining existing, overlapping skill sets that rarely exist in a single organization or institution, however large. The *AT HOME* Program engaged a wide range of institutions in its effort to enhance the quality of both its services and its operations. This practice was part of HHR's operations from its inception, when it served as a convening organization of Lead-Safe Pittsburgh, a consultative stakeholder body addressing residential lead exposure made up of researchers, service organizations, the County Health Department, residents, and landlords. This involvement led HHR to commission from the RAND Corporation the 2006 study *Improving Childhood Blood Lead Level Screening, Reporting, and Surveillance in Allegheny County, Pa.* This is illustrative of

HHR's practice of tapping major regional institutions for program-focused research. In the area of clean homes, HHR collaborated with the Housing Authority of the City of Pittsburgh to equip public housing tenants who failed housekeeping inspections and were at risk of eviction with the knowledge and tools to be able to live in a healthy home environment.

In terms of participant recruitment, HHR collaborated with the local chapter of the American Respiratory Alliance (ARA) to reach prospective participant families through such events as the Asthma Fair, Camp Huff-N-Puff, and Breathe E-Z. Children's Hospital of Pittsburgh played a similar role.

Most notably, HHR relied on ARA for development of *AT HOME*'s culturally sensitive educational curricula: a Community Worker curriculum, Participant Education curriculum, and Participant In-Home Education modules. The importance of culturally sensitive material for participants cannot be overstated. As noted elsewhere, in the case of the *AT HOME* Program, ARA tapped the expertise in this area of the University of Pittsburgh Center for Minority Health and the Greater Pittsburgh Literacy Council to ensure that curricula and associated print materials were culturally sensitive and at an appropriate educational level for the target audience.

Finally, both the pilot investigation and *AT HOME* Program relied directly on Tobacco-Free Allegheny, a regional partner in providing education and outreach for smoking cessation, for referrals of potential participating families and its well-regarded smoking cessation information package that was provided to smoking adults in participating families.

In summary, the collaborative relationships employed by the pilot project meant, in practice, having the staff of HHR use their skills in community and in-home intervention and education to carry out the tasks of pre- and post-intervention interviewing and surveying, home inspections, preparation of intervention plans, and counseling families in applying their intervention plans. Everything up to this point in the project was standard practice for HHR in its service delivery role. The research component began with gathering from participating families the survey and interview data that would be analyzed for indicators of the effectiveness of the service delivered to achieve the end-point goal of reducing the frequency and severity of respiratory impairment related to secondhand smoke.

## **17. Progress in Achieving Research Goals, Objectives and Aims.**

List the project goals, objectives and specific aims (as contained in the grant application's strategic plan). Summarize the progress made in achieving these goals, objectives and aims for the period that the project was funded (i.e., from project start date through end date). Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant

application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

**There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha ( $\alpha$ ) and beta ( $\beta$ ) should not print as boxes ( $\square$ ) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.**

### **Project Title and Purpose**

*Impact of Parental Smoking Cessation and Residential Hazard Reduction on Pediatric Respiratory Health: A Pilot Investigation of Effective Service Delivery*

This pilot project involved research-based residential assessments and interventions designed to directly and positively influence the respiratory health of children of smokers by reducing the ambient levels of tobacco smoke and other environmental triggers. A total of 50 families were to have participated over the course of the project. Triggers of primary concern were environmental tobacco smoke and combustion fumes, insect, rodent, pet, and dust mite allergens. Secondary triggers such as mold, dust, and household chemicals were also monitored. Based on the triggers identified in the initial assessment, a customized plan for parental education intervention with follow-up monitoring of participant respiratory health and ambient hazard levels was created for each family.

### **Project Overview**

The program model that this project sought to evaluate has two central characteristics, which may be called primary and secondary, based on their relative importance in defining the model.

The primary characteristic is that of using a non-profit, community-based organization to deliver health services. The second is the use of a research organization, in this case Duquesne University, to conduct research in the context of service delivery with the goal of assessing the end-point effectiveness of those services in order to refine and improve the delivery system. This division of labor tapped the primary expertise of the respective institutions. Healthy Home Resources (HHR), Pittsburgh-based nonprofit, as well as other organizations like it, are much more effective in delivering service at the home and community level than are universities, which, obviously, are not designed for that purpose. This effectiveness has to do not only with the quality of the delivery of service, but also with its relative cost, which is markedly lower in smaller non-profit organizations than in large institutions such as universities, and, it might be noted, hospitals as well. Contrariwise, the average community non-profit organization has neither the expertise nor the staff capacity in and of itself to either gather proper data or to analyze and interpret those data. Once the data have been interpreted, the non-profit and university together can apply the findings to modify or adjust the service delivery model.

The first objective of this pilot program investigation was to develop local, community-based partnerships among Duquesne University and HHR and the community. This program created the capacity to conduct housing and health assessments of the program participants; deliver in-home, community-based education on asthma and respiratory illnesses and allergen trigger control through a community services worker model. Also included were the provisions of standards-based remediation/trigger control protocols and follow-up housing and health assessments that are supported by an exemplary evaluation design. Participants were recruited from either HHR's Asthma Trigger HOME Evaluation (*AT HOME*) program, or by referral from Tobacco Free Allegheny, a local partner in providing education and outreach for smoking cessation. The principal eligibility requirements were that one or both parents or caregivers smoked, and that there were children under age 17 in residence. The proposed Environmental Assessment used in the program was based on American Industrial Hygiene Association and HUD vacuum dust sample collection protocols.

Residential sampling was to have taken place twice, consisting of an initial baseline and post-intervention measurements. The proposed Respiratory Health Assessment consisted of a carbon monoxide (CO) breath test for smoking parents and their children. In addition, a self-reporting respiratory illness survey monitoring days absent from school, emergency room visits, days with respiratory symptoms, and (for asthmatic children) frequency of rescue medication use. During the initial visit, staff provided the parents or care-givers a Knowledge, Attitudes, and Beliefs Survey (KAB). This tool, designed by colleagues at the University of Pittsburgh Graduate School of Public Health, modeled on the learning objectives in the American Respiratory Alliance (ARA) curriculum, was used to determine the effectiveness of the educational intervention by comparing the initial results to the follow-up KAB survey. Following the initial KAB survey, general educational materials developed by HHR and Tobacco Free Allegheny were given to the parent(s) or caregivers. The educational resources provided the parents with a general understanding of the risks of second-hand smoke to their children, as well as awareness of other residential triggers of respiratory illness or distress. Based on the initial Environmental and Respiratory Health Assessments, in conjunction with parent/caregiver KAB's, an intervention plan was to be developed for each participating family.

## **Project Background**

For two decades now, the federal government has identified asthma and associated respiratory illnesses as serious and growing pediatric health problems. In 1999, the President's Task Force on Environmental Health and Safety Risks to Children selected asthma as one of four targeted childhood diseases. According to the Centers for Disease Control, the prevalence of asthma has drastically increased since 1980. Of the 17 million people currently affected, an estimated 6.2 million are children under the age of 18, making asthma the most common chronic childhood disorder. (USEPA, 2005) Further research reported by the American Lung Association's July 2006 *Trends in Asthma Morbidity and Mortality Report* shows children between the ages of 5-17 having a significantly higher prevalence of asthma than any other age group, with approximately 140 in every 1,000 children having been diagnosed with asthma by a healthcare professional. On a regional level, the Pennsylvania Department of Public Health has noted that while asthma trends for the state generally those of the country as a whole, several Pennsylvania counties are particularly burdened by asthma and respiratory distress, with concentrations of increased prevalence, morbidity and mortality in the southeastern and southwestern parts of the state. As has been noted by the Asthma and Allergy Foundation of America (2006), Metropolitan Pittsburgh fits squarely within this area, ranking 16<sup>th</sup> among the most challenging places to live with asthma.

In 2005, the U.S. Environmental Protection Agency *Asthma Research Results Highlights* observed that people with lower socioeconomic status and families living in inner cities are more likely to be affected by respiratory distress due to higher exposures to environmental risk factors. (USEPA, 2005) Substandard housing coupled with the lack of knowledge and resources often underlie increased exposures to asthma triggers. Dr. Deborah Gentile, director of research at the Division of Allergy, Asthma, and Immunology at Allegheny General Hospital in Pittsburgh, has observed that "Over the last two decades, pediatric asthma admissions here at the hospital have more than doubled...and it disproportionately affects inner-city children. They are really the ones falling through the cracks." (Interview, *Pittsburgh Tribune-Review*, 2005) The American Lung Association reports that asthma occurs significantly more in African Americans than Caucasians (39%). African Americans also visit emergency rooms for asthma more than twice as often and are hospitalized for asthma more than three times as frequently. (USEPA, 2005)

A recent meta-analysis of 79 prospective studies conducted by Burke, et al (2012) estimated that pediatric exposure to passive smoke increases the incidence of wheezing and asthma by at least 20%. The authors conclude that preventing parental smoking is critically essential to the prevention of pediatric asthma. In addition to asthma and other respiratory problems, pediatric smoke exposure exacerbates the incidence and severity of chronic conditions later in life. These include dental decay, metabolic syndrome, atherosclerosis, and malignancies Winickoff, et al (2010). Treyster and Gitterman (2011) also urge that pediatricians aggressively pursue parental smoking cessation interventions that would lead to so many positive impacts on children's health.

## **Expected Research Outcomes and Benefits**

The goal of this pilot project was to improve child respiratory health in terms of morbidity and

severity. Specifically, it was hypothesized that enhanced educational outreach to smoking parent(s) and caregiver(s) would improve living conditions in the homes of 50 families in Allegheny County over a two-year period. Based on the results for the original *AT HOME* program, it was also expected that an increase in asthma and respiratory illness prevention knowledge by 30% or more (as evidenced by the initial and follow-up KAB surveys) will occur. Additionally, it was expected that the program would improve school attendance of participating children by 20% or more and decrease respiratory distress symptom days by an average of 6 days or more.

The envisioned outcomes of the research component of the project aimed at developing a two-pronged course of action on the efficacy of combining smoking cessation with residential hazard awareness to improve pediatric respiratory health. The purpose was and remains to craft recommendations for policy change at the local, state, and national levels and improved design and implementation of residential and community intervention and education projects.

### **Project Adjustment and Revision**

In late 2010, the project encountered a serious obstacle that came close to rendering it impossible to complete. Due to unanticipated losses of both federal and local funding, HHR ceased operation in August 2010. This was the result of its major funder, the U.S. Department of Housing and Urban Development (HUD) suspending a significant multi-year healthy homes grant in mid-course on the regrettable grounds that oversights on the part of municipal officials in Pittsburgh disqualified the grant award on technical grounds. Despite vigorous efforts by HHR to appeal the suspension, and agreement from HUD officials that HHR's work under that and previous grants was laudable and worthy of national replication, HUD reached the regrettable decision to terminate the grant. HHR exhaustively sought alternative sources of operational support that would allow the completion of the pilot project as well as its other service programs, but when it became clear that potential funding was either too small or its availability too far into the future, the HHR Board of Directors initiated the process of dissolution. In January 2011, HHR requested the termination of the Agreement by and between HHR and Duquesne University that had established HHR as the prime subcontractor for the project. At that time, the Principal and co-Principal Investigators planned to complete the original project by establishing subcontractor agreements with former HHR staff who had conducted the initial work. By spring 2011 it was clear that this was not possible because those individuals had found other full-time employment.

In June 2011, the Principal and Co-Principal Investigators initiated a no-cost extension request to the Pennsylvania Department of Health that entailed a revision of the original scope of work and revision of the project budget. This request was granted, extending the project term to June 30, 2012. The principal change under the revision was to make Co-Principal Investigator Dr. Michael J. Tobin the main project researcher, based on his specific expertise and his experience as Executive Director of HHR. This was done by placing him under contract with Duquesne University. Also, at that time, the investigators determined that archival records for both the pilot and *AT HOME* projects had been destroyed.

The actual cohort of thirty eligible participating families were recruited from HHR's *AT HOME* project that at the time was in its second round of four-year funding from HUD's Office of Healthy Homes. Other than the child and parent/caregiver carbon monoxide breath testing, the residential allergen sampling, the surveys, and the outcome measures such as child asthma symptom days and lost school days were identical to the *AT HOME* protocols. Most importantly, the original smoking cessation intervention protocols were enhanced by using the latest informational brochures from Tobacco Free Allegheny.

The revised project aimed to compare the heretofore unpublished *AT HOME* intervention outcomes, for which there were over 300 participant families, to published parental smoking cessation/pediatric asthma mitigation studies. As noted above, the smoking cessation interventions and outcomes for this pilot investigation are identical to the larger *AT HOME* cohort. Therefore, we feel that the pooled *AT HOME* outcomes will be representative of the pilot results, but with a higher degree of statistical power.

Under the revised scope of work proposed, the project consisted of three elements:

- a review of pertinent literature on relative significance of factors affecting asthma incidence and of in-home service delivery models;
- a meta-analysis performed to distinguish universally significant demographic and environmental exposure factors versus regional exposure factors relevant to the Metro Pittsburgh area that estimate the relative contribution to pediatric asthma incidence rates from indoor exposure factors, primarily passive smoke, to those outdoor factors associated with the unique topography of the Pittsburgh area;
- examination of the *AT HOME* model with an eye to identifying design elements that lend themselves to the crafting of a successful and effective service delivery system.

In brief, the service delivery model examined has three primary or structural and three secondary or procedural characteristics. The most important primary attribute is that of using a non-profit, community-based organization to deliver health service. That is joined by the use of a research organization to conduct research in the context of that service delivery with the goal of refining and improving the delivery system, and a thorough-going reliance on partnerships with other institutions to ensure the best expertise achieved cost-effectively. Secondary characteristics include appropriate personality and skill of the service delivery personnel, a carefully crafted protocol for both individual home visits and the overall process of visits, and careful attention to cultural sensitivity both in the design of program materials and on the part of personnel.

## **Objectives**

The pilot project as originally designed was intended to support the delivery of home-based social services in the area of asthma reduction as the vehicle for gathering unique data that would form the foundation for assessment of the effectiveness of the service model employed. On this basis the project was designed with five objectives. It sought to develop a local, community-based partnership among Duquesne University, HHR, and the community that could serve as a model for establishing similar programs. Based on standards-based remediation/trigger control protocols, this model would have the capacity to conduct housing and health assessments for

participant families and deliver in-home, community-based education on asthma and respiratory illnesses and allergen trigger control.

HHR's *At HOME* Program, from which the pilot investigation was developed, used a comprehensive 6-month regimen that provided in-home environmental testing, education, and over \$2,500 of asthma supplies and services to underprivileged children with asthma in Allegheny County and the city of Pittsburgh. *AT HOME* had several overlapping objectives. Its instrumental objective of increasing asthma-prevention knowledge on the part of participating families was intended to improve physical living conditions in order to reduce environmental trigger levels, thus creating "healthy homes" for children with asthma. In social terms, it was hoped that this would lead to improvement in school attendance of children with asthma. These aims were couched in the socio-economic framework of serving families living in low and moderate income Community Development Block Grant areas of Allegheny County and the city of Pittsburgh with the explicit aim of decreasing their asthma-related health care costs.

### **Pilot Project Design**

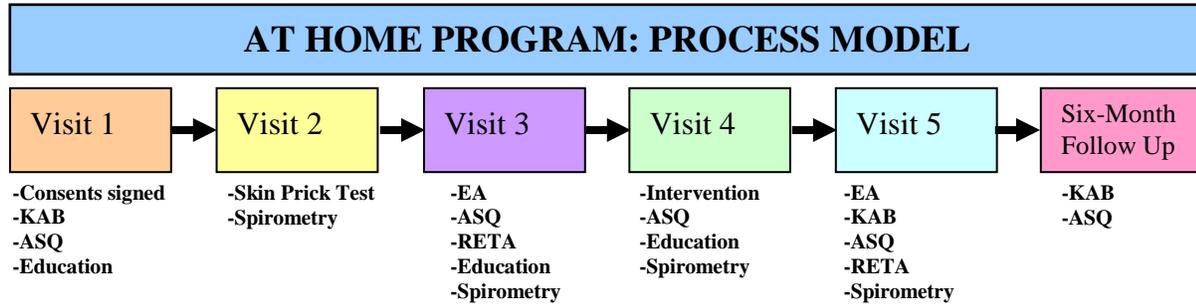
As noted earlier, the pilot investigation was a direct adaptation of the *AT HOME* program. In fact, as all participant families had completed the program, it is necessary to discuss the pilot project and its outcomes within the framework of the original *AT HOME* protocols and results.

HHR provided qualified participants with environmental interventions to reduce allergens in the home, thus alleviating the symptoms of children with asthma. During the five in-home visits spread over six months, HHR staff did a full inspection of the home and measured levels of environmental triggers that can cause asthmatic symptoms. These include allergens such as cockroach, rodent, pet, dust mites, pollens, and molds. HHR staff then prepared a plan to control the observed triggers so as to improve overall living conditions of the affected child and family. HHR staff also provided asthma education, demonstrated asthma-responsive cleaning techniques, and created an easy-to-follow "healthy home" strategy. In addition, participating families were given asthma-friendly cleaning supplies (HEPA vacuum cleaner, a dehumidifier, HEPA air purifier, professional dust mop & cloths) and, where appropriate, professional cleaning services (pest management, air duct cleaning, and carpet cleaning).

Qualitative and quantitative environmental assessments were repeated and compared throughout the sequence of visits. The Residential Environmental Trigger Assessment (RETA) was used to assess the qualitative aspects of the home environment through visual observation or interview the presence of environmental hazards or conditions leading to environmental hazards. A baseline RETA was delivered early in the program, a post-remediation RETA was delivered to assess the efficacy of the intervention plan on the home environment, and a final RETA was delivered at program conclusion to assess the sustainability of the intervention.

The KAB questionnaire survey was given to participants at specified intervals during the program. It served as a valuable part of the continuous improvement process by illuminating areas of concern in the management of asthma. In addition to the KAB, an ASQ was administered at intervals throughout the program in order to track asthma symptoms of the child, lost school days, emergency room visits, and rescue medication usage. Together, the information was used to evaluate tangible successes of the intervention and education programs.

The success of *At HOME* rested on several factors that are now evident: a well-established community network of providers, a professional staff well trained in the provision of in-home family health services, and a clear cut protocol for service provision. For example, each participating family proceeded through the *AT HOME* Program according to the process model shown here.



**VISIT 1** → Prior to scheduling any visits, a parent or guardian of the participant signed a consent form in order for the child to be enrolled in the program. During Visit 1, qualitative and quantitative assessments were done to determine the potential for the program to reduce environmental triggers and safety hazards. At this point HHR staff administered the KAB questionnaire, asked the participating child’s caretaker a series of questions about asthma, asthma triggers, and treatment; and the ASQ to gauge asthma severity in terms lost school days, emergency room visits, rescue medication usage, and asthma symptom days.

**VISIT 2** → For the second visit, participants had the option of going to a medical facility to have professional testing done at no cost to them. During this second visit, an allergy skin prick test was administered to determine the child’s specific sensitivities, and a spirometry test was done to measure the child’s breathing (in terms of forced expiratory volume).

**VISIT 3** → Activity during the third home visit comprised the EA, RETA, ASQ, and Spirometry test. At this point in the program, HHR staff provided the parent/caregivers education on recognizing and controlling asthma triggers. Cleaning services were arranged as needed after this visit. Services included Integrated Pest Management, air duct cleaning, and carpet cleaning, as warranted by the visual inspection.

**VISIT 4** → **Interventions** During this intensive, 2 hour visit each participating family was provided with a cost-effective, individualized intervention plan based on information gleaned during the preceding three visits. The plan was made up of the following components.

- An *Asthma-Friendly Cleaning Demonstration* showed caregivers how to do allergen-reduction cleaning and maintain a healthy home for the child with asthma and the entire family.
- Each family was provided at no cost an *Asthma-Friendly Cleaning Supplies* kit made up of a HEPA vacuum cleaner, a HEPA air cleaner, a dehumidifier, HVAC filters, microfiber cleaning clothes & mops, asthma-friendly cleaning products, allergen-control bed covers, and allergen control doormats.
- Families were provided with general information on asthma how to create nutrition and physical activity plans for an overall “healthy” home environment.

**VISIT 5** → The aim of this session was to gauge any changes in environmental triggers in the home and in the severity of the child’s asthma since entering the program. This was done by repeating the assessment conducted during the first and second visits: EA, KAB, ASQ, RETA, and spirometry test.

**FOLLOW UP** → A follow-up visit was done six months after Visit 5, during which the KAB and ASQ were once again administered.

## ***AT HOME* Outcomes**

Improving living conditions by reducing environmental trigger levels and creating “healthy homes” were evaluated through pre- and post-evaluations by comparing the RETA results from Visit 3 with those from Visit 5.

Increasing the asthma-prevention knowledge of the participants was determined by providing educational materials to participants and then testing their knowledge of asthma triggers. This was done by way of the KAB, with the results of the KAB taken at Visit 1 compared with those from Visit 5.

Tracking improvement in school attendance by participating children with asthma and decreasing asthma-related health care costs for participant families was measured by monitoring the participant’s asthma-related health indicators (lost school days, emergency room visits, rescue medication usage, and asthma symptom days) with the ASQ and spirometry tests showing levels of forced exhalation volume, comparing findings from Visits 2, 3, 4 and 5. A physician evaluated the results to determine if these indicators of pulmonary function changed over the duration of the program.

## **Methodology**

This pilot project, in effect follow-on based upon the proven *AT HOME* methodology, involved research-based residential assessments and interventions designed to directly and positively influence the respiratory health of children of smokers by reducing the ambient levels of tobacco smoke and other environmental triggers. An initial target of 50 participating families was established. Specific asthma triggers were environmental tobacco smoke and combustion fumes; and insect, rodent, pet, and dust mite allergens. Secondary triggers such as mold, dust, and household chemicals would also be monitored. The actual service deliverable, to be developed for each family on the basis of triggers identified in an initial home assessment, was a customized plan for parental educational intervention with follow-up monitoring of participant respiratory health and ambient hazard levels.

While *At Home* focused on a spectrum of asthma triggers, this investigation specifically singled out secondhand smoke as the factor of interest. The marker for exposure assessment was carbon monoxide (CO) breath levels of both parent/caregivers and children. This is highly potent indicator, given the fact that a 70 ppm mean CO breath level over an eight hour period is fatal. It is not uncommon to observe CO breath levels of 70 ppm after smoking only one cigarette. A specific factor of interest in this project was to assess the psychological motivational effect (Haltermann, et al, 2011; Farber, et al, 2008) on the parent/caregivers of seeing a child in their care possibly registering a CO breath level comparable to the adult smoker’s level.

Participating families in the pilot investigation were drawn from the ranks of families who had participated in the previous HUD-funded *AT HOME* program and had completed the full course of intervention. This investigation specifically recruited those participants who were still smoking after completing the previous *AT HOME* program. The principal eligibility requirement was that one or both parents or caregivers smoke, and that there were still children under age 17 in residence. Factors such as minority and economic status were also taken into consideration.

The rationale for recruiting families who had already completed the *AT HOME* program was three-fold. First, regardless of the overall efficacy of the individual *AT HOME* interventions, this cohort of parent/caregivers continued to smoke. Second, doing so provided HHR the opportunity for longer-term follow-up (1-2 years post-intervention) to observe whether participant families continued to follow the *AT HOME* intervention (housekeeping, HEPA vacuum use, room dehumidifiers, pet segregation from child bedroom, hypoallergenic bedding, etc.). This information would otherwise be unavailable. In addition, the families recruited for this pilot project already possessed the equipment and supplies at no cost to the project. Third, and most importantly, particular emphasis could be placed on the evident shortcoming of the smoking cessation component of the *AT HOME* intervention. Finally, the pilot design required only two visits instead of the five needed for the full intervention.

Trained HHR staff administered the Respiratory Health Assessment (RHA) comprised of the CO breath tests and re-administered versions of the KAB and Asthma Severity Questionnaire (ASQ) that focused on smoking, residential allergen tests were redone, and the family were then given the most recent smoking cessation information packet developed by Tobacco-Free Allegheny, a regional partner in providing education and outreach for smoking cessation.

We had proposed to compare initial and follow-up ambient environmental hazard levels, as well as the CO breath results. Standard statistical methods were to be employed to determine whether decreases in quantitative measurements correlate with improved respiratory health, as indicated by the initial and follow-up RHA survey results.

As the instrument of service delivery, HHR was the principal contact between project investigators and project participants. HHR operated in all its programs under standard policies that take great care to ensure the privacy of information and safety of program participants. For example, participants in the pilot investigation were tracked by way of individual identification numbers. No participant names were linked in any way to the data that was gathered. HHR complied with, as applicable, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) statutes. All documents, including consent forms, surveys, as well as HIPAA-compliant hard copy protection and retention, were reviewed and approved by Duquesne University Institutional Review Board.

## **Assessment Tools**

### ***Environmental Assessment***

The Environmental Assessment (EA) was based on American Industrial Hygiene Association and HUD vacuum dust sample collection protocols. Residential sampling was to have taken place twice, in an initial baseline, and in post-intervention measurement. Analytes included environmental tobacco smoke; insect, rodent, pet, and dust mite allergens; non-viable spore trap; total dust; and relative humidity/temperature. HHR staff performed the sampling and collected materials to be sent to a certified laboratory for analysis. Standard Quality Assurance protocols (i.e. duplicates, blanks, lab performance samples) were used to confirm the validity of all measurements.

### ***Respiratory Health Assessment***

The RHA consisted of a CO breath test for smoking parent/caregivers and their children. The hand-held *MicroCO*<sup>™</sup> monitor (CareFusion corp., San Diego, CA) was selected for ease of use, wide range (0-100 ppm), and minimal calibration requirements. Monitor accuracy was regularly verified using a 20 ppm CO calibration gas standard.

Used as well was a self-reporting respiratory illness survey that monitored days absent from school, emergency room visits, days with respiratory symptoms, and (for asthmatic children) frequency of rescue medication use. The CO breath test and respiratory illness survey were to have occurred twice, at the initial and post-intervention visits. The CO analyzer was periodically tested and re-calibrated.

### ***Knowledge, Attitudes, and Beliefs Questionnaire***

During the initial visit, HHR staff administered a Knowledge, Attitudes, and Beliefs (KAB) Survey with parents or care-givers. This tool, developed by HHR and the University of Pittsburgh Graduate School of Public Health, was modeled on the learning objectives contained in the American Respiratory Alliance (ARA) curriculum. It was used to determine the effectiveness of the educational intervention by comparing the results of the initial KAB survey with those of the follow-up KAB survey.

### ***Educational Materials***

Following the initial KAB survey, parent/caregivers were provided with general educational materials developed by HHR, ARA, and Tobacco Free Allegheny designed to provide them with a general understanding of the risks of secondhand smoke to their children, as well as to increase their awareness of other residential triggers of respiratory illness or distress. The expertise of the University of Pittsburgh Center for Minority Health and the Greater Pittsburgh Literacy Council was relied upon to ensure that curricula and associated print materials were culturally sensitive and at an educational level appropriate to the target audience.

### ***Interventions***

Based on the initial EAs and RHAs and the results of the initial parent/caregivers KAB survey, an intervention plan was crafted for each participating family. The plans aimed to reduce or eliminate specific environmental hazards that were identified in the home, especially smoking cessation, but also better housekeeping, keeping pets out of the child's bedroom, etc. In addition, further educational materials specific to assessment outcomes were provided to the parents.

## **Results and Discussion**

### **Summary statistics**

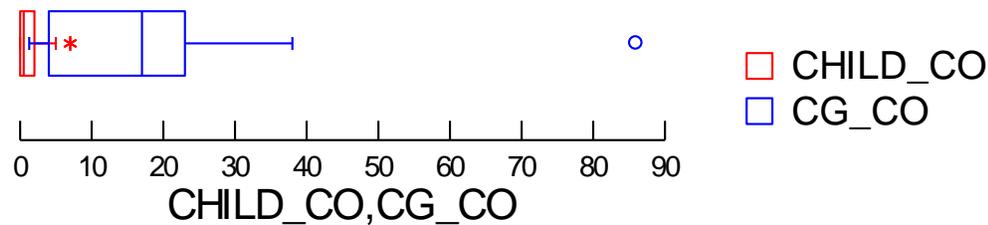
As of June 30, 2010, HHR had recruited 61 eligible participant families, of whom 30 had completed the initial baseline respiratory health assessment. In addition to measuring child and parent/caregiver CO breath levels, the number of days the child experienced respiratory distress

(symptom days), required rescue medication such as albuterol, missed school due to respiratory distress (lost school days), or required emergency room treatment in the preceding two weeks prior to the home visit were determined. Summary statistics are given in Table 1. Box plots comparing child and parent/caregivers CO breath levels are shown in Figure 1.

Table 1. Summary statistics for child CO, caregiver CO, symptom days (SYM), lost school days (LSD), days require rescue medication (RES), and emergency room visits (ERV).

	CHILD_CO	CG_CO	SYM	LSD	RES	ERV
N of Cases	30	30	30	30	30	30
Minimum	0.000	1.280	0.000	0.000	0.000	0.000
Maximum	7.000	86.000	14.000	2.000	14.000	1.000
Range	7.000	84.720	14.000	2.000	14.000	1.000
Interquartile Range	2.000	19.000	2.000	0.000	2.000	0.000
Median	0.500	17.000	0.000	0.000	0.000	0.000
Arithmetic Mean	1.267	17.411	1.633	0.233	1.600	0.067
Standard Deviation	1.982	16.462	2.942	0.568	3.587	0.254
Variance	3.926	270.984	8.654	0.323	12.869	0.064

Figure 1. Box plots of child and caregiver carbon monoxide concentration (ppm).



Qualitative information

The home inspection checklist for overall level of housekeeping included the cleanliness of floor dust swipes, evidence of pet fur, and evidence of indoor smoking. In addition, HHR staff noted whether participants continued to use the equipment (HEPA vacuum, room dehumidifier, etc.) provided over the course of the *AT HOME* program. Finally, staff debriefings revealed that 50 per cent of parent/caregivers expressed alarm upon learning their CO breath levels.

### AT HOME Program Evaluation

HHR contracted with the University of Pittsburgh for an independent analysis of the information collected over the course of the *AT HOME* program. This analysis showed HHR's asthma intervention protocols to be highly effective. Evaluation of asthma severity indicators (lost school days, rescue medication usage, symptom days) and parent/caregivers knowledge, attitudes, and beliefs showed statistically significant improvements post-intervention compared to pre-intervention values. For example, the reported number of days a child needed to use rescue medication over the preceding two weeks dropped 1.7 days compared to pre-intervention levels. This change is significant at  $p < 0.001$ . This is consistent with Coffman, et al (2008) who showed that providing pediatric asthma education significantly reduced the number of hospitalizations and emergency department visits. The statistical inferences and other information contained in this evaluation will be utilized in the ensuing discussion.

### Discussion: CO Breath Levels

One of the aims of this pilot study was to determine whether the CO breath level of parent/caregivers correlated with child CO breath level and respiratory health markers such as symptom days and frequency of rescue medication use in the two weeks prior to the assessment. While the final analysis was to consist of paired sample t-tests to measure efficacy of the smoking cessation and home environmental interventions, exploratory data analysis of the baseline results revealed several trends. There was no apparent association between child (1.27 +/- 1.98 range 0 – 7 ppm) and parent/caregivers (17.4 +/- 16.5 range 1.28 – 85 ppm) CO levels, as shown in Figure 1. The much broader range of parent/caregiver CO levels reflects both the self-reported number of cigarettes smoked per day (three to forty) and how recently the individual had smoked prior to the home visit. In addition, two children with a CO level of 7 ppm indicated that they regularly smoked. None of the remaining cohort of children smoked.

Likewise, there was no evident correlation between parent/caregiver CO level and reported symptom days, rescue medication use, emergency room visits, or lost school days. There was a modest correlation between child CO level and frequency of rescue medication use (Pearson R = 0.48), and a very weak correlation with symptom days (Pearson R = 0.11). No correlation was found between child CO level and emergency room visits or lost school days. It should be noted that for home visits conducted in the summer months, lost school days was replaced by 'lost camp days' whenever possible.

This investigation initially hypothesized that upon learning their children had measurable CO breath levels, parent/caregivers would be motivated to quit smoking. As noted earlier, non-smoking child CO levels were minimal. Instead, the motivating factor evidently effective on 50% of parent/caregivers was learning of their own excessive CO breath levels. Whether this 'wake-up call' by itself will provide lasting motivation to stop smoking (without support and follow-up) is doubtful. In any case, this finding does suggest that CO breath testing should be part of any future *AT HOME* smoking intervention package.

### Discussion: Behavioral Aspects

Home inspections for overall level of housekeeping were uniformly positive. Likewise, each participant family had continued to use the equipment (HEPA vacuum, room dehumidifier, etc.) provided over the course of the *AT HOME* program. This strongly suggests that parent/caregivers behavior in the home had changed as a result of the prior intervention.

One implicit element of information in this pilot project was that prior participation in the *AT HOME* program was not entirely successful because the parent/caregivers were still smoking. Recent research indicates that the success rate of smoking cessation programs solely based on behavioral intervention is very low. For example, Tobacco Free Allegheny's well-regarded programs achieve a permanent cessation rate of only 5%. The inability of the cohort to quit smoking in spite of the knowledge that smoking exacerbates their child's illness is consistent with Liem, et al (2007), Farber, et al (2008), and Halterman, et al (2010), who indicate that smoking parent/caregivers apparently do not grasp the association between their child's asthma severity and their habit. As a result, parent/caregivers who smoke clearly need ongoing support beyond what can be offered by service organizations like HHR.

The fact that (with the exception of child smokers), child CO breath levels were minimal indicates the original *AT HOME* smoking cessation education/outreach did motivate families to take steps to minimize child exposure to residential tobacco smoke, even though the parent/caregivers themselves were unable to quit. This is reinforced by their comments that after being educated about the presence and effects of secondhand smoke in the home, parent/caregivers were smoking less and/or smoking outside. The evident behavior modification (primarily smoking outdoors) found in this investigation contrasts with the conclusion of Liem, et al (2007) that parent/caregiver behavior did not change whether there was a family history of asthma, residential rural or urban location, or with socioeconomic status.

The conclusion to be drawn from these observations is that while the initial *AT HOME* intervention did not lead to smoking cessation, it did achieve behavior modification of a positive nature.

### Discussion: Indoor and Outdoor Air Quality and Pediatric Asthma Incidence Rate

Our desire to estimate the relative contribution to pediatric asthma incidence rates from indoor exposure factors to region-specific outdoor factors proved to be unsuccessful for the following reasons. First, the geographic distribution of participants was non-uniform, as families were primarily recruited from Community Development Block Grant locales. Second, in Metropolitan Pittsburgh, the areas with the highest poverty levels also tend to have the lowest outdoor air quality. In effect, these areas were oversampled by the *AT HOME* program. For example, Braddock Pa., an eastern suburb of Pittsburgh, has a median annual income of \$18,000, which is roughly half that of the Pittsburgh area. Braddock experiences heavy diesel truck emissions due to its proximity to the United States Steel Edgar Thompson works. Additional confounding factors include: a higher incidence of smoking in lower socioeconomic brackets and high utilization of emergency rooms for otherwise routine treatment. As a result there was no

way to correlate pediatric asthma incidence rate with outdoor air quality factors associated with the unique topography of the Pittsburgh area.

### **Service Delivery Model**

The service delivery model examined here has two central characteristics. The most important is that of using a non-profit, community-based organization to deliver health service, while the second is the use of a research organization to conduct research in the context of that service delivery with the goal of refining and improving the delivery system. This division of labor tapped the primary expertise of the respective institutions. HHR, as well as other organizations like it, are much more effective in delivering service at the home and community level than are universities, which, obviously, are not designed for that purpose. As noted, this effectiveness has to do not only with the quality of the delivery of service, but also with its relative cost, which is markedly lower in smaller non-profit organizations than in large institutions such as universities, and, it might be noted, hospitals as well. Contrariwise, the average community non-profit organization is subject to other constraints as well. First, it is most likely a provider of neither primary nor clinical care. Second, it has neither the expertise nor the staff capacity in and of itself to either gather proper data or to analyze and interpret those data. Once the data have been interpreted, the non-profit and university together can apply the findings to modify or adjust the service delivery model.

#### *Community Service Providers: Constraints on Range of Service*

One major constraint on service provider organizations like HHR is the inability to directly and ethically offer a pharmacological component to the smoking cessation strategy. A variety of treatment options, such as nicotine nasal spray, inhaler, or transdermal patches, and pharmaceuticals such as the antidepressant bupropion hydrochloride or varenicline, a nicotine antagonist, are available. (Frishman, 2010) Smith, et al (2009) reported that smoking cessation therapies combining counseling and pharmaceutical administration are up to 30% effective, a level significantly higher than typical behavior modification approaches. Given the potential adverse effects, clinical or preferably primary care provider supervision is necessary to ensure the appropriate use of these products.

Another limitation involves the implementation and coordination of community-level support groups for smokers trying to remain tobacco-free. Given the socioeconomic stressors of the target demographic, small focus groups consisting of neighbors and relatives (spouses/significant others, Murray, et al (1995) would likely be far more successful than anonymous counseling from a toll-free quit line (Gilchrist, 2007).

#### *Cost Effectiveness*

Within the acknowledged limited range of services that community service provider organizations can deliver, such organizations must be considered both efficient and cost-effective. This is illustrated by the case of HHR, which in 2010 conducted a literature review-based cost analysis of the *AT HOME* program for the U.S. Department of Housing and Urban Development that showed the value, in particular, of government support for residential asthma

intervention programs. Kleinman, et al (2009) evaluated direct and indirect health care costs for employees with asthmatic children compared to employees with children without asthma. They reported statistically significant annual cost differences for employee health care (\$154,  $p < 0.001$ ), prescriptions (\$95,  $p < 0.001$ ), sick leave (-\$41,  $p < 0.001$ ), short-term disability (-\$41,  $p < 0.008$ ), dependent health care (\$862,  $p < 0.001$ ), and prescriptions (\$534,  $p < 0.001$ ). They concluded that pediatric asthma is associated with significant additional health care and prescription costs for both employees and their dependents. On this basis, it is estimated that annual asthma-related healthcare costs per family without intervention were approximately \$2,290 at the time of the study.

Gendo, et al (2003) found that symptom days, i.e., the number of days that a child experiences asthma-related respiratory distress, are a direct predictor of healthcare costs. The *AT HOME* evaluation compared the number of symptom days for the two week period prior to intervention (mean = 5.3) and six months post-intervention (mean = 2.0), a 62.3 percent reduction.

The *AT HOME* evaluation included a total of 243 families. The average age of participant children was 9 years. Annual out-of-pocket (or insured) asthma-related expenses for 243 families without intervention equals \$556,470 (243 x \$2290) or \$5,008,230 for the average nine year period to age 18. Using the 62 per cent reduction in costs, the nine year total for 243 families with intervention drops to \$1,888,103, a net savings to family out-of-pocket/healthcare insurers of \$3,120,127. 45 of the 243 families, or 19%, were Medicaid recipients, consistent with the reported national average of 18%. The total asthma-related Medicaid costs to age 18 for 45 families without intervention are \$928,665. Using the 62 per cent reduction with intervention, the costs decrease to \$350,478, a net savings of \$578,187.

Median household income in the City of Pittsburgh in 2008 was \$36,709. Based on the number of symptom days before and after intervention, HHR figures used the assumption that 20% of symptom days (1 in 5) required a caregiver to take off work. Estimated annual lost wages per family with and without *AT HOME* intervention are calculated to be \$1049 and \$2774, respectively. Over a nine year period, the corresponding projected total lost wages for 243 families without intervention is \$6,078,538 versus \$3,784,498 for an equal number of participant families. It should be noted that employers could carry some of this loss if an employee were eligible for short-term disability or intermittent leave; however the total values are unchanged.

### *Personnel, Personality, and Training*

In addition to the nature of the service delivery organization is the nature of the personnel who deliver the service. Key to the effectiveness of the relationship between personnel and participants is the personality and skill of the personnel. It is said that generals are born not made. To some extent, the same is true of people who are effective at personalized service, particularly that taking place in a participant's home. It is quite possible that the right personality trumps training, and that even effective training cannot replacement the necessary caring demeanor. That said, even the most sympathetic of us cannot be expected to work properly without training in the proper "etiquette" of in-home service delivery. In line with the notion of the physicians bedside manner, we have come to term this invaluable attribute the appropriate "sofa-side manner".

Attention should be paid to two other considerations as well. The first of these factors has been noted, that of a carefully crafted protocol for both the individual home visits and the overall process of multiple visits. The second is the critical need for cultural sensitivity both in the design of program materials and on the part of personnel. Both can be achieved with requisite care. As noted in the discussion of partnerships in Section 16(c), in the case of *AT HOME*, HHR relied on the expertise of the University of Pittsburgh Center for Minority Health and the Greater Pittsburgh Literacy Council to ensure that curricula and associated print materials were appropriate in cultural terms to the target audience of low- and moderate-income participant families.

### Partnerships

While the foregoing shows that the nature of the service delivery organization is critical to the success of the interventions provided, there remains another element of the overall service delivery model that is central to its broader effectiveness. That element is multi-level and multi-sectoral partnerships. In a word, the factor in focus here is that of combining existing, overlapping skill sets that rarely exist in a single organization or institution, however large. The *AT HOME* Program engaged a wide range of institutions in its effort to enhance the quality of both its services and its operations. This practice was part of HHR's operations from its inception, when it serves as a convening organization of Lead-Safe Pittsburgh, a consultative stakeholder body addressing residential lead exposure made up of researchers, service organizations, the Allegheny County Health Department, residents, and landlords. This involvement led HHR to commission from the RAND Corporation the 2006 study *Improving Childhood Blood Lead Level Screening, Reporting, and Surveillance in Allegheny County, Pa.* The role of partnerships in this model is elaborated in Question 16(c) of this Final Progress Report.

As noted, the *AT HOME* service delivery model has much to recommend it, including appropriately trained staff, effective community partnerships, reliance on universities for procedural and research expertise, and cultural sensitivity, and cost effectiveness. Ironically, these strengths may be said to indicate the model's weaknesses, or, to put it differently, potential threats to its viability. In the area of participant recruitment, is its reliance, by necessity, first on partnerships with other non-profit organizations, a factor that is not under the control of the service delivery organization itself, in this case, HHR; and second, on extensive presence at neighborhood meetings, cultural activities, and other community events—something that requires considerable investment of staff time. Next, the very reliance of the model on partnerships with other organizations presupposes adequate funding of those entities. Both HHR and its community partners relied heavily on government and foundation support. The financial stability small non-profit organizations, tenuous in the best of times, became plainly perilous in a time of acute economic downturn such as that of the recession of 2007 – 2009. Funding resources diminished, and grant size markedly shrank. The closing over the past four years of small non-profits due to lack of funding took center stage in assessments of the non-profit and philanthropic sectors, viz the case in point of this project, HHR. In this context, the existence of both the direct service delivery organization, HHR, and its community partners, was gravely and sometimes fatally affected.

Non-profit organizations rely on four broad sources of financial support, in varying combinations: paying membership, fund raisers, philanthropic grant-making, and government grants and contracts. Small non-profits are almost exclusively dependent on the last two of these, largely existing from grant to grant, and devoting a large share of staff time to writing proposals for grants and contracts to keep the funding stream sufficiently full. HHR had been remarkably adept at diversifying its grant base, and was able to twice gain notably large federal grants for its work. However, when one large grant is halted without warning, as was the case of HHR's HUD grant, it is very difficult to replace it soon enough to allow the organization to maintain staff and operations. The villain of the piece is the nature of the U.S. non-profit sector, which for all practical purposes has no stream of steady, stable, designated funding on which to rely. If there is a conclusion to be drawn from this, it is to make the federal and state governments long-term support funders with the foundation sectors adding resources to that stable base on a project-by-project basis. That prospect does not appear to be likely in today's political and social climate.

## **Conclusions**

### *CO breath levels*

There were no correlations between parent/caregivers and child CO breath levels, symptom days, rescue medication use, emergency room visits, or lost school days.

There were modest-to-weak correlations between child CO breath levels and rescue medication use (Pearson  $R = 0.48$ ) and symptom days (Pearson  $R = 0.11$ ).

### *Behavioral Aspects*

Participant families continued to employ the equipment, supplies, and housekeeping principles from their initial *AT HOME* intervention. While the initial intervention did not lead to smoking cessation, there was clear evidence that parent/caregivers had taken steps to reduce child exposure to tobacco smoke, such as smoking less and smoking outdoors.

Half of the parent/caregivers expressed considerable concern over their own elevated CO breath levels, suggesting its utility as a motivational tool.

### *Nature of the Service Delivery Organization*

A major constraint on service provider organizations like Healthy Home Resources is the inability to directly and ethically offer a pharmacological component to the smoking cessation strategy to complement educational element to bring about behavioral changes. This calls for clinical or preferably primary care provider engagement in the program.

The socioeconomic stressors of the target demographic call for the use of community-level support groups (e.g., small focus groups consisting of spouses/significant others, neighbors and relatives) for smokers trying to remain tobacco-free.

The service provider model examined here is demonstrably cost effective, at two levels. First, it notably reduces medical care costs through intervention programming, achieving a roughly 62% cost reduction in asthma-related costs to the government, employers, insurers, and family out-of-pocket expenses such as lost wages and medical expenses. For a typical *AT HOME* service delivery objective of 300 participant families, this corresponds to an estimated net savings of 6 million dollars by the time the children reach adulthood. Second, it is cost-effective in administration because of the capability of community-based non-profit organizations to deliver in-home services at lower cost than larger institutions such as hospitals.

Two criteria are necessary in order to achieve effective service delivery in models of the type examined here. First are the personal characteristics and skill of the personnel providing the service. A combination of personality and suitable appropriate training is necessary to ensure appropriate “sofa-side manner” in the home setting. Second is the cultural sensitivity of the design of program materials and the personnel, both which can be achieved with requisite care.

### *Institutional Partnerships*

For such service delivery programs to be effective in both programmatic and cost terms, multi-level and multi-sectoral partnerships are critical in order to gain the value of overlapping skill sets that rarely exist in a single organization or institution. In the case of the *AT HOME* Program, these terrain of such partnerships included universities, hospitals, national healthcare organizations, regional single-focus health advocacy, community organizations, and local government.

### *Weaknesses of the Service Delivery Model*

The very strengths of the service delivery model examined here—appropriately trained staff, effective community partnerships, reliance on universities for procedural and research expertise, and cultural sensitivity, and cost effectiveness—indicate potential threats to its viability. These include the reliance on partner organizations and the need for extensive presence at events to recruit participants, the acute reliance of all or most partner organizations on government and foundation support, and the absence in social services of long-term support for small non-profits.

### **Recommendations**

Family CO breath monitoring should be performed at every home visit, five in the case of the *AT HOME* program model.

When a family with one or more parent/caregivers who smoke is recruited into an *AT HOME* style interventional pediatric asthma mitigation program, referral to established smoking cessation organizations such as Tobacco Free Allegheny should take place prior to starting the *AT HOME* program. Smokers would clearly benefit from more intensive and ongoing counseling and education, in effect, beyond the initial CO ‘wake-up call’. In addition, if at all possible, the family primary care physician (or clinician) should play a role in deciding whether pharmacological intervention(s) are appropriate. Partners for ongoing social support would also

help the smoking parent/caregivers, perhaps from Head Start or community church groups that provide a comfortable environment for behavior change.

Future funding efforts should budget for the cost of doctor visits and prescribed medication.

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## **Appendices**

- A. Recruitment Flyer
- B. Assent Form
- C. Consent Form
- D. Respiratory Survey
- E. Knowledge, Attitudes, and Beliefs Survey

### **Appendix A      Recruitment Flyer**

#### **Announcing the Respiratory Health Improvement Project!**

In partnership with Duquesne University Center for Environmental Research and Education, Healthy Home Resources is recruiting families for a study called the Respiratory Health Improvement Project. The project is open to families with children up to age 17 where one or both parents or caregivers smoke. This study is designed to improve the respiratory health of children of smokers by reducing the levels of tobacco smoke and other respiratory irritants (called triggers) in the home. Eliminating or reducing these irritants can mean a healthier life for you and your child.

There will be two home visits spaced about 3 months apart, and there will be a follow-up phone call made approximately 3 months after the last home visit. Each visit will take about two hours, where we will ask you some questions about smoking and your child's health and collect samples of air and dust to look for irritating triggers. You and your child will also breathe into a tube to check your breath for carbon monoxide.

Based on the triggers we find during the first visit to your home, we will create a plan for parental education and provide follow-up monitoring of respiratory health and trigger levels for your family.

Grocery and toy store gift cards are awarded for completing the two visits.

If you would like to see how Healthy Home Resources could help your child breathe easier, call us today at 412.965.8117.

**Appendix B            Assent Forms**

**ASSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY (6-9 YEARS)**

TITLE: Impact of parental smoking cessation and residential hazard reduction on pediatric respiratory health: A pilot investigation

SPONSORS: Pennsylvania Department of Health CURE Program, Healthy Home Resources, Duquesne University Center for Environmental Research and Education

PRINCIPAL INVESTIGATOR: Michael J. Tobin, PhD 412.431.4449 x 224  
Dr. Paul Richer, Chair, Duquesne University Institutional Review Board 412.396.6326

You are being asked to be in a test to see if we can make your breathing better. If you say yes, we will make two visits to your house. At these visits, we will ask some questions about your breathing. We will teach you and your family about asthma and breathing problems. We will also look around your house for things that may make your breathing worse. You will also do a breathing test by blowing into a tube.

You and your family will write down when you have trouble breathing.

We will make phone calls to your family to ask questions about your breathing.

We may write a paper on what we find out about your breathing but we will not use your name in it. You should talk to your family about this study before saying yes. Even if you say yes now, you can change your mind later and no one will get mad at you.

Writing your name on the line here means that you say yes to being in this test.

\_\_\_\_\_

Child's signature

\_\_\_\_\_

Date

\_\_\_\_\_

Witness signature

\_\_\_\_\_

Date

\_\_\_\_\_

Investigator signature

\_\_\_\_\_

Date

ASSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY (10-13 YEARS)

TITLE: Impact of parental smoking cessation and residential hazard reduction on pediatric respiratory health: A pilot investigation

SPONSORS: Pennsylvania Department of Health CURE Program, Healthy Home Resources, Duquesne University Center for Environmental Research and Education

PRINCIPAL INVESTIGATOR: Michael J. Tobin, PhD 412.431.4449 x 224  
Dr. Paul Richer, Chair, Duquesne University Institutional Review Board 412.396.6326

You are being asked to be in an experiment to see if we can make your breathing or asthma better by getting rid of things in your house that might cause allergies. If you say yes to being in the experiment, we will make two visits to your house. At each of these visits, four things will be done:

1. We will ask you and your family some questions about your breathing.
2. We will teach you and your family about your breathing and how to make it better.
3. We will look around your house for things that might cause allergies and make your breathing worse.
4. You will do a breathing experiment by blowing into a tube.

During the experiment, you and your family will write down on a calendar when you have trouble breathing. We will also make phone calls to your family to ask questions about your breathing.

This experiment might be good for you because your breathing may get better by getting rid of things in your house that cause allergies. You and your family can learn about getting rid of things that cause allergies without being in this experiment. This experiment will help us learn more about healthier breathing and this might help kids like you in the future.

We may write a paper on what we find out about your breathing but we will not use your name in it. You should talk to your family about this experiment before agreeing to be in it. Even if you agree to be in it now, you can change your mind later and no one will get angry with you.

Writing your name below means that you agree to be in this experiment.

\_\_\_\_\_  
Child's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator signature

\_\_\_\_\_  
Date

ASSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY (14-17 YEARS)

TITLE: Impact of parental smoking cessation and residential hazard reduction on pediatric respiratory health: A pilot investigation

SPONSORS: Pennsylvania Department of Health CURE Program, Healthy Home Resources, Duquesne University Center for Environmental Research and Education

PRINCIPAL INVESTIGATOR: Michael J. Tobin, PhD 412.431.4449 x 224  
Dr. Paul Richer, Chair, Duquesne University Institutional Review Board 412.396.6326

You are being asked to be in an experiment to see if we can make your breathing or asthma better by getting rid of things in your house that might cause allergies. If you say yes to being in the experiment, we will make two visits to your house. At each of these visits, four things will be done:

1. We will ask you and your family some questions about your breathing.
2. We will teach you and your family about your breathing and how to make it better.
3. We will look around your house for things that might cause allergies and make your breathing worse.
4. You will do a breathing experiment by blowing into a tube.

During the experiment, you and your family will write down on a calendar when you have trouble breathing. We will also make phone calls to your family to ask questions about your breathing.

This experiment might be good for you because your breathing may get better by getting rid of things in your house that cause allergies. You and your family can learn about getting rid of things that cause allergies without being in this experiment. This experiment will help us learn more about healthier breathing and this might help kids like you in the future.

We may write a paper on what we find out about your breathing but we will not use your name in it. You should talk to your family about this experiment before agreeing to be in it. Even if you agree to be in it now, you can change your mind later and no one will get angry with you.

Writing your name below means that you agree to be in this experiment.

\_\_\_\_\_

Child's signature

\_\_\_\_\_

Date

\_\_\_\_\_

Witness signature

\_\_\_\_\_

Date

\_\_\_\_\_

\_\_\_\_\_



## RESEARCH CONSENT AND PERMISSION FOR CHILD TO PARTICIPATE FORM

TITLE: Impact of parental smoking cessation and residential hazard reduction on pediatric respiratory health: A pilot investigation

SPONSORS: Pennsylvania Department of Health CURE Program, Healthy Home Resources, Duquesne University Center for Environmental Research and Education

PRINCIPAL INVESTIGATOR: Michael J. Tobin, PhD 412.431.4449 x 224  
Dr. Paul Richer, Chair, Duquesne University Institutional Review Board 412.396.6326

### **Research Consent and permission for child to participate in the Respiratory Health Improvement Project**

#### **DESCRIPTION**

Your child is being asked to participate in a program designed to improve the health of children with asthma or chronic breathing and respiratory problems by lowering in-home environmental trigger levels. This program is at no cost to you. Before you give your consent for your child to take part in this program, you should read this document and ask as many questions as necessary to be sure that you understand what is expected of you and your child as participants.

#### **BACKGROUND**

Asthma and other respiratory illnesses are the most common chronic health issues among children in the US and are a leading cause of children missing school. Asthma and other symptoms can be caused by environmental triggers such as secondhand tobacco smoke and allergies. Education and control of environmental triggers are important aspects to the treatment of breathing problems. This program will provide participating families with the education, skills, and tools needed to reduce or control environmental and safety hazards in the home. The environmental triggers of concern include cockroach, rodent, pet and dust mite allergies. Pollen, mold and moisture, and secondhand tobacco smoke will also be monitored as possible asthma triggers.

#### **PROGRAM DESCRIPTION**

Healthy Home Resources (HHR) designed this project to directly and positively influence the respiratory health of children of smokers by reducing the ambient levels of tobacco smoke and

other environmental triggers in the home. About 50 families in Allegheny County will participate in the project. Triggers of primary concern are environmental tobacco smoke and combustion fumes, insect, rodent, pet, and dust mite allergens. Secondary triggers such as mold, dust, and household chemicals will also be monitored. Based on the triggers identified in an initial assessment, a plan for parental education intervention with follow-up monitoring of participant respiratory health and ambient hazard levels will be created for each family. There will be two home visits spaced about 3 months apart, and there will be a follow-up phone call made approximately 3 months after the last home visit.

### VISIT 1

This visit will last about two hours. At this visit, you will complete two questionnaires. The first is called the Knowledge, Attitudes and Beliefs (KAB) Questionnaire and will help HHR to design a trigger management plan for your home. The second is called the Respiratory Illness Survey and will help HHR track the severity of your child's asthma or breathing problems. HHR staff will conduct an environmental assessment of your home during which they will ask questions about your home, inspect certain areas of your home, and collect samples of dust and air to test for levels of allergens, molds, and pollens. You and your child will be tested for Carbon Monoxide by blowing air into a tube. Finally, HHR staff will provide you with information to help you to reduce or stop smoking.

Once we receive the test results for your home, HHR will send you a report showing the environmental hazards that we found, and provide you with useful information you can use to reduce or eliminate these triggers. HHR staff will be able to provide advice by phone.

### VISIT 2

This visit will also last about two hours. You will complete a KAB Questionnaire and a Respiratory Illness Survey. You will be given a Program Evaluation Survey to complete after the visit. HHR personnel will conduct another environmental assessment of your home, and test you and your child for Carbon Monoxide. This will be the completion of the in-home portion of the program.

You will receive another report indicating whether the levels of environmental hazards in your home changed from the first visit, and additional advice as necessary.

### FOLLOW-UP PHONE CALL

This phone call will occur about 3 months after completion of the in-home portion of the program. HHR personnel will ask you to complete the Respiratory Illness Survey and the KAB Questionnaire.

### **POTENTIAL BENEFITS**

Direct benefits may include improvements in your child's respiratory health and improved housing conditions with respect to environmental triggers of asthma. However, your child is not guaranteed any benefit. Information that is obtained during this program may be useful scientifically and may benefit other children with asthma. It is hoped that by providing you with the education, skills, and tools needed to control the environmental triggers that exist in your home, you and your child will learn more about how to control breathing problems, and improve your child's health.

## POTENTIAL RISKS

Carbon Monoxide Breath Test. This test involves blowing air into a tube for a few seconds. As with any physical activity, there is a slight chance of minor respiratory distress such as a coughing or shortness of breath following this test.

## PAYMENTS

On the first visit you will receive a grocery store gift card and on the final visit your child will receive a gift card.

Participants will receive a gift card in the amount of \$10.00 for the first visit and your child will receive a \$15.00 gift card for the final visit. Participants may receive a \$25.00 gift card for the referral of an eligible family that enrolls in the Project.

## CONFIDENTIALITY

All personal information regarding you and your child's identity will be kept confidential. All data gathered in your home such as air monitoring will be assigned a confidential code number. In order to evaluate the success of the study, researchers will analyze the coded information. Your personal information will not be released.

## RIGHT TO WITHDRAW

Please understand that your participation in this program is voluntary. You have the right to withdraw your child from participation in this program at any time without penalty. **If you decide to withdraw your child from the program, please contact HHR personnel immediately.** In addition, HHR reserves the right to remove your child from the program for the following reasons:

- **Cancellation of any visit more than twice**
- **Failure to respond to phone calls made by HHR personnel**
- **Situations in which the health and safety of HHR personnel, our subcontractors, and/or partners may be jeopardized**
- **Situations where HHR personnel determines that the program will not be beneficial to your child**
- **Other situations based on HHR policies & procedures**

I acknowledge that I have read this consent and agree to full participation in the Respiratory Health Improvement Project and understand all of the terms and conditions described. I understand that should I have any further questions about my and my child's participation in this study, I may call Dr. Michael J. Tobin, Principal Investigator 412.431.4449 x224, and Dr. Paul Richer, Chair of the Duquesne University Institutional Review Board 412.396.6326.

\_\_\_\_\_  
Signature of Parent or Guardian

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

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

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

**Appendix D                      Respiratory Survey**

PIN: \_\_\_\_\_

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

Zip Code: \_\_\_\_\_

Interviewer: \_\_\_\_\_

The purpose of the Respiratory Illness Survey is to collect information about **child's** asthma symptoms or other breathing problems during the past two weeks.

**SYMPTOM DAYS**

1. In the past two weeks, about how many days did **child** have wheezing, tightness in the chest, coughing, or shortness of breath?

Number of days \_\_\_\_\_

**MISSED DAYS**

1. Does **child** usually attend school, daycare, preschool or camp?

Yes (specify which) \_\_\_\_\_ **\*If no (skip to question #6)**

2. In the past two weeks, was the **school, daycare, preschool, or camp** closed for any reason?

Number of days \_\_\_\_\_

3. In the past two weeks, how many days did **child** miss school, daycare, preschool, or camp because of asthma?

Number of days \_\_\_\_\_

5. How many days, in the past two weeks, did you miss work to take care of your child for his/her asthma? \_\_\_\_\_

**RESCUE MEDICATION USAGE**

6. In the past two weeks, how many days has **child** had to use their rescue medication?

Number of days \_\_\_\_\_

**EMERGENCY ROOM VISITS**

7. In the past two weeks, how many times has **child** had to go to the emergency room because of asthma?

Number of times \_\_\_\_\_

**MEDICAL COVERAGE**

1. What type of medical insurance do you have for your child?  
\_\_\_\_\_

2. What is the average monthly amount you spend on your child's medical costs (co-pays, medication, etc.) \_\_\_\_\_

**18. Extent of Clinical Activities Initiated and Completed.** Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be “No.”

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

\_\_\_\_\_ Yes  
\_\_\_X\_\_\_ No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

\_\_\_\_\_ Yes  
\_\_\_X\_\_\_ No

**If “Yes” to either 18(A) or 18(B), items 18(C) – (F) must also be completed.** (Do NOT complete 18(C-F) if 18(A) and 18(B) are both “No.”)

18(C) How many hospital and health care professionals were involved in the research project?

\_\_\_\_\_ Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

\_\_\_\_\_ Number of subjects originally targeted to be included in the study  
\_\_\_\_\_ Number of subjects enrolled in the study

**Note:** Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached, the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:

\_\_\_\_\_ Males  
\_\_\_\_\_ Females  
\_\_\_\_\_ Unknown

Ethnicity:

\_\_\_\_\_ Latinos or Hispanics  
\_\_\_\_\_ Not Latinos or Hispanics  
\_\_\_\_\_ Unknown

Race:

- American Indian or Alaska Native  
 Asian  
 Blacks or African American  
 Native Hawaiian or Other Pacific Islander  
 White  
 Other, specify: \_\_\_\_\_  
 Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

**19. Human Embryonic Stem Cell Research.** Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?

- Yes  
 No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

- Yes  
 No

19(C) Please describe how this project involved human embryonic stem cells:

**20. Articles Submitted to Peer-Reviewed Publications.**

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication or paper submitted for publication, listed in the table, in a PDF version 5.0.5 (or greater) format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, the number of the publication and an abbreviated research project title. For example, if you submit two publications for PI

Smith for the “Cognition and MRI in Older Adults” research project (Project 1), and two publications for PI Zhang for the “Lung Cancer” research project (Project 3), the filenames should be:

- Project 1 – Smith – Publication 1 – Cognition and MRI
- Project 1 – Smith – Publication 2 – Cognition and MRI
- Project 3 – Zhang – Publication 1 – Lung Cancer
- Project 3 – Zhang – Publication 2 – Lung Cancer

If the publication is not available electronically, provide 5 paper copies of the publication.

**Note:** The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
1. None				<input type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input type="checkbox"/> Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes   X   No \_\_\_\_\_

If yes, please describe your plans:

Journals to which the findings of this project would be of interest include *Addictive Behaviors; American Journal of Epidemiology; American Journal of Public Health; Annals of Allergy, Asthma, and Immunology; Environmental Health Perspectives; Health Education Research; Journal of the American Heart Association; Patient Education and Counseling; Journal of Epidemiological and Community Health; Pediatrics; Social Science and Medicine; and Tobacco Control.*

**21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project.**

Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. **DO NOT DELETE THESE INSTRUCTIONS.** There is no limit to the length of your response.

None.

**22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment.** Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. **DO NOT DELETE THESE INSTRUCTIONS.** There is no limit to the length of your response.

None

**23. Inventions, Patents and Commercial Development Opportunities.**

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes \_\_\_\_\_ No X \_\_\_\_\_

If "Yes" to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is "No.")

- a. Title of Invention:
- b. Name of Inventor(s):
- c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):
- d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?  
Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, indicate date patent was filed:

- e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?  
Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, indicate number of patent, title and date issued:  
Patent number:  
Title of patent:  
Date issued:
- f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes \_\_\_\_\_ No \_\_\_\_\_  
  
If yes, how many licenses were granted? \_\_\_\_\_
- g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes \_\_\_\_\_ No  X

If yes, please describe your plans:

**24. Key Investigator Qualifications.** Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages. *For Nonformula grants only – include information for only those key investigators whose biosketches were not included in the original grant application.*

#### **Principal Investigator**

Dr. Stanley J. Kabala is a member of the faculty of the Center for Environmental Research and Education at Duquesne University. Dr. Kabala's policy analysis interests in the field of environmental health focus on the health and developmental risks posed by lead in household paint and soil, mercury emissions from power plants, and endocrine disrupting chemicals used as plasticizers and pesticides. Dr. Kabala has been active in advancing community-based responses to these risks. Dr. Kabala initiated a cooperative project between HHR and the Duquesne University School of Nursing to address household child health hazards education in low-income residences in the city of Pittsburgh. Dr. Kabala also collaborates with the Investor Environmental Health Network, a national organization that works with corporations to reduce the health risks posed by chemicals in consumer products. His role in the project was to investigate policies and programs pertinent to the area of study, assess the design and outcomes of community-based intervention/education projects, and craft recommendations for policy changes at the local, state, and federal level and for enhanced community outreach and intervention programs.

## Co-Principal Investigator

Dr. Michael J. Tobin is an adjunct professor at the Center for Environmental Research and Education at Duquesne University. He holds a B.S. in Chemistry from the University of Pittsburgh and a Ph.D. in Chemistry from Carnegie Mellon University and has over twenty five years experience in both the private and public sectors. Tobin served on the HHR Board of Directors from 2003 to 2007, and was then Executive Director until its closure in 2011. He was the principal author of HHR's federal HUD grant projects on pediatric asthma reduction. Tobin's background in environmental epidemiology, risk assessment, and chemical hazard communication made him a natural choice to lead HHR. During his thirteen years on the faculty of the University of Pittsburgh Graduate School of Public Health, Dr. Tobin was a co-investigator on Dr. Herbert L. Needleman's Lead Exposure Study. His work on the behavioral effects of lead exposure can be seen in the publications listed below. Dr. Tobin's role in the project both during his tenure at HHR and afterward was as principal supervisor of service delivery, data gathering and analysis, and compliance assurance.

Morrow, L., Needleman, H.L., McFarland, C., Metheny, K., Tobin, M., *Past*  
"Occupational Exposure to Lead: Association Between Current Blood Lead and  
Bone Lead," *Archives of Environmental and Occupational Health*, 2007

Needleman, H.L., McFarland, C., Ness, R., Tobin, M., Greenhouse, J., "Bone  
Lead Levels in Adjudicated Delinquents: A Case-Control Study,"  
*Neurotoxicology and Teratology*, 2002

Campbell, T.F., Needleman, H.L., Riess, J.A., Tobin, M.J., "Bone Lead Levels  
and Language Processing Performance," *Developmental Neuropsychology*, 2000

Needleman, H.L., Riess, J.A., Tobin, M.J., Biesecker, G.E., Greenhouse, J.B.,  
"Bone Lead Levels and Delinquent Behavior," *Journal of the American Medical  
Association*, 1996